3D printed guiding device assisted bilateral crossing cervical microendoscopic laminoplasty for cervical spondylotic myelopathy: a study protocol for a randomized controlled trial

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Study protocol

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Abstract

Background Cervical microendoscopic laminoplasty (CMEL) is an important surgical method for the treatment of cervical spondylotic myelopathy (CSM). It has the advantages of minimal incision and quick recovery, meanwhile, it also has disadvantages, such as its tedious to install the implants and long operative time. This study proposes a new method of 3D printed guiding device assisted bilateral crossing cervical microendoscopic laminoplasty for CSM, which can further improve the accuracy and efficiency of surgery and shorten the operative time. **Methods/design** Patients who met the surgical criteria will be randomly divided into experimental group and control group. The experimental group will be treated with 3D printed guiding device assisted bilateral crossing cervical microendoscopic laminoplasty. The control group was treated with CMEL. The primary outcomes will be incision length, operative time, intraoperative blood loss and adverse events. The secondary outcomes will be the Japanese Orthopedic Association (JOA) score, the visual analogue scales (VAS) for neck and shoulder pain, cervical curvature index (CCI), range of motion (ROM), the sagittal diameter of the spinal canal, and the healing of the grooves. These parameters will be evaluated preoperatively, intraoperatively, 1 week postoperatively, as well as 3, 6, 12, 24 months postoperatively. **Discussion** This study was the first randomized controlled trial to compare 3D printed guiding device assisted bilateral crossing cervical microendoscopic laminoplasty with CMEL. The results of this study may facilitate the development of surgical treatment of cervical spondylotic myelopathy.

Background

Surgical treatment of CSM has been developed for decades [1]. Cervical laminoplasty is an important method for the treatment of CSM. The methods include open-door laminoplasty and bilateral open-door laminoplasty. Although laminoplasty had a satisfactory long-term effect, postoperative neck and shoulder pain, decrease in lordosis and ROM is observed in many patients [2-4].

In recent years, some minimally invasive surgical procedures for CSM had been reported [5-13], such as microendoscopic decompression, minimally invasive cervical microendoscopic laminectomy. In 2007, we developed a new minimally invasive procedure for multi-level CSM, namely cervical microendoscopic laminoplasty (CMEL) [5], the key points of CMEL are bilateral long groove-shaped decompression, the spinous process-ligament complex retroposition in the sagittal plane, and the fixation of titanium mini-plate. This surgical procedure represents a future development direction, which can significantly reduce trauma, meanwhile postoperative follow-up show that cervical disc may spontaneously be absorbed. However, there are still some difficulties in installing titanium mini-plate under the endoscope and achieving the retroposition of the spinous process-ligament complex: (a) Poor control accuracy: the retroposition of the spinous process-ligament complex relied on intraoperative manual lifting, which was inconvenient to precisely control; (b) Difficulty in operation: because the titanium mini-plate must be matched with the surface of lamina, the sliding grooves of the bilateral mini-plate cannot be parallel to the sagittal plane of the human body, which led to some troubles in the retroposition of the spinous process-ligament complex in this way; (c) The operation was cumbersome: because the mini-plate had a

certain length and was installed on the same side of the operation, which led to a larger incision. The structure of the spinous process was big on the top and small on the bottom, which led to twist screws on the spinous process side was difficult, and the operation was laborious and time-consuming; (d) Endoscopic operation was prone to skew: due to the anatomical markers cannot be used for positioning under direct vision, the long groove-shaped decompression was prone to skew, which may miscut the bone of the screw installation site, resulting in the difficulty in the installation of titanium mini-plate. These factors had seriously affected the promotion of this minimally invasive technology. Therefore, improving surgical precision, reducing surgical trauma, reducing the difficulty of the operation, and improving the efficiency of surgery have become important problems to be solved urgently.

To solve the above operational problems, we have developed a new surgical operating device for the bilateral crossing cervical microendoscopic laminoplasty (the patent application number is CN201910086277). Based on surface features of the lamina, a 3D printed guiding device is used for locating and navigating.

For all we know, there are no randomized controlled trials of 3D printed guiding device assisted bilateral crossing cervical microendoscopic laminoplasty versus CMEL for CSM. In this trial, we will conduct a randomized controlled trial (RCT) to compare 3D printed guiding device assisted bilateral crossing cervical microendoscopic laminoplasty with CMEL to demonstrate this new surgical method is safer, easier and more effective.

Methods/design

Study design

The study is a single-centre, prospective, randomized controlled trial, the objective of which is to evaluate the efficiency and safety of 3D printed guiding device assisted bilateral crossing cervical microendoscopic laminoplasty for CSM. A total of 256 patients will be randomly divided into experimental group and control group in a 1:1 ratio. The experimental group will be treated with 3D printed guiding device assisted bilateral crossing cervical microendoscopic laminoplasty. The control group was treated with CMEL. The flow chart of the study process is as follows in Fig. 1.

This trial is reported in accordance with the Standard Protocol Items: Recommendations for Intervention Trials (SPIRIT) guidelines [14] (Fig. 2, Additional file 1)

Ethical approval

The trial meets the requirements of the Helsinki Declaration formulated by the World Medical Association, and it has been reviewed and approved by the institutional ethics review board of the First Affiliated Hospital of Zhengzhou University (Approved number: KY-2019-LW-049). All participants will be required to sign an informed consent. The protocol had been registered in the Chinese Clinical Trial Registry

(ChiCTR). In 2007, ChiCTR was appointed to be the representative registry of China and joined the WHO ICTRP. The protocol number is ChiCTR1900023100.

Participants

The study is a RCT conducted at the First Affiliated Hospital of Zhengzhou University. Baseline characteristics of patients, such as age, gender, time of onset, symptoms of neck and limbs will be provided. Treatment decisions are made based on baseline characteristics. Surgical treatment is the best choice for patients with ineffective conservative treatment, aggravated pain, and even muscle paralysis.

Inclusion criteria

1. Age > 16 years old;
2. 2 to 5 levels of cervical degenerative disc disease or spinal canal stenosis at C3-C7;
3. Diagnosis of degenerative disc disease or spinal canal stenosis verified by medical history and physical examination;
4. MRI and CT showed that the canal/vertebral body sagittal ratio was less than 0.75, but no focal protrusion, fragment protrusion or nerve root compression;
5. Strict conservative treatment was ineffective for more than 3 months.

Exclusion criteria

1. Single-level spinal canal stenosis or degenerative disc disease;
2. Cervical spondylotic radiculopathy, radiological evidence of nerve root compression caused by disc herniation;
3. Severe osteoporosis;
4. Greater than grade 1 spondylolisthesis;
5. Unwilling to sign informed consent for the study.

Recruitment

The trial recruited the inpatients of the Department of Orthopaedics, the First Affiliated Hospital of Zhengzhou University, and distributed the research plan leaflets to the patients. After reading the leaflets, the patients and their families voluntarily decided whether to participate in the trial. Screening was conducted according to inclusion and exclusion criteria, patients could only be included in the study after signing the informed consent.

Randomisation and blinding

Patients will be randomly divided into an experimental group and a control group in a 1:1 ratio. It is impossible to blind the participants and surgeons, only the result evaluators are blinding, and these

evaluators are not involved in patient management. To prevent bias, the patient's randomization process will be performed by a third party.

Sample size calculation

We carried out a power analysis to evaluate the required sample size to show safety with a power ($1-\beta$) of 0.8 and α of 0.05. According to the relevant literature [5], the excellent and good rate of the control group was 84.4%. We hypothesise that the excellent and good rate of the experimental group could be 95%. We carried out a two independent samples t-tests using PASS (Power Analysis and Sample Size), and obtained a result of 128.

Surgical procedures

Experimental group

Before the operation, the patient underwent a CT scan of the cervical spine by 64 slice spiral CT (Siemens, Germany). After the scan, the original data was exported and stored in the standard STL format, and the STL format file was imported into E3D Medical Software for 3D reconstruction. The technique of 3D reconstruction which extracts the posterior surface features of the cervical spine, may help perform preoperative simulation on the obtained 3D model and determine some important information, such as the position of the decompression grooves, the entry point and depth of the lateral mass screws, the horizontal distance between the decompression groove and the entry point of the lateral mass screw on the same side, also the entry point and angle of the connecting rods pass through the root of the spinous process. A guiding device includes two guiding tubes, two guiding grooves and two aiming devices. The guiding tubes, the guiding grooves and the aiming devices were designed by using E3D Medical Software (Fig. 3), then printed by 3D printing technology, ensuring that the customized ends of the bilateral guiding tubes were perfectly matched with the bilateral lamina surface. Four indicators can be installed on the outside of the guiding tube. When customized ends of the bilateral guiding tubes were perfectly matched with the surface of lamina, the protruding height of the four indicators was identical.

After initiation of general anesthesia, the patient was placed in a prone position, the head was fixed. Under fluoroscopic guidance, the targeting level was confirmed. Two lateral incisions approximately 20mm in length were made at the targeting level. Then, the dilator was inserted into the bilateral incision in order, until it contacted the lamina. The dilator was removed after the guiding tube was inserted. The two guiding tubes were connected with the bilateral guiding grooves. The customized ends of the bilateral guiding tubes were perfectly matched with the surface of lamina by adjusting the guiding tubes, and then confirmed by the indicators (Fig. 4A). The guiding tube on the one side was removed, then the endoscope was inserted into the guiding tube on the contralateral side. Endoscopic partial laminotomy was initiated using a high-speed drill to roughen the conjunction of the lamina and the lateral mass, and the ventral cortex of the lamina was completely removed by using a 2mm Kerrison laminectomy rongeur. Then a groove of approximately 2 to 3mm wide was made at the junction (Fig. 4B). The guiding tube was removed towards the lateral side by a certain distance (this distance is the horizontal distance between

the decompression groove and the entry point of the lateral mass screw on the same side). Meanwhile, with the help of the working sleeve, the Magerl technique was used to fix the lateral mass screw at the lateral mass (Fig. 4C) [15]. The guiding groove was removed, the aiming device was installed on the guiding tube in the next, then the connecting rod passed through the root of the spinous process by using the aiming device and was fixed at the lateral mass screw in the last (Fig. 4D). Thereafter, the working sleeve was removed, the two guiding tubes were reconnected with the bilateral guiding grooves, and the same process was repeated on the contralateral side. Then two working sleeves were connected with the bilateral lateral mass screws. By adjusting the repositioning locking mechanism of the lateral mass screw to make the bilateral connecting rods reposition 1 to 3mm on the sagittal plane, therefore, the spinous process-ligament complex and the deep extensor muscle group also reposition 1 to 3mm on the sagittal plane (Fig. 4E,F).

After all of the above steps had been completed, the surgical cavity was flushed, the bleeding was tightly stopped, and a drainage tube was placed. Finally, the fascia layer and skin incision were closed by using standard techniques.

Control group

After initiation of general anesthesia, the patient was placed in a prone position, the head was fixed. Under fluoroscopic guidance, the targeting level was confirmed. Then, a midline skin incision approximately 20mm in length was made at the targeting level. Bilateral fascial layers were incised and a hole was drilled in each spinous process. Silk suture was used to thread through the hole, and prepared for suspension of the posterior column structure. Then, the dilator was inserted into the left/right side of the spinous process in order, until it contacted the lamina. The dilator was removed after the working sleeve of endoscope was placed on the surface of the lamina through it. Endoscopic partial laminotomy was initiated using a high-speed drill to roughen the junction of the lamina and the lateral mass, and the ventral cortex of the lamina was completely removed by using a 2mm Kerrison laminectomy rongeur. Thereafter, a groove of approximately 2 to 3mm wide was made at the junction. The working sleeve of endoscope could be swung cranially and caudally, and the small incision was long enough for three continuous levels simultaneously. The silk suture was pulled dorsally, then under its protection, the same process was repeated on the contralateral lamina. After decompression of the contralateral lamina was completed, the spinous process-ligament complex and the deep extensor muscle group reposition 1 to 3mm on the sagittal plane by pulling the silk suture. Thereafter, the medial side of the mini-plate was fixed at the root of the spinous process with a small screw, the lateral side of the mini-plate fixed at the lateral mass using the Magerl technique.

After all of the above steps had been completed, the surgical cavity was flushed, the bleeding was tightly stopped, and a drainage tube was placed. Finally, the fascia layer and skin incision were closed by using standard techniques.

Outcome measure

Primary outcomes

Incision length, operative time, intraoperative blood loss and adverse events.

Secondary outcomes

1. JOA
2. VAS
3. CCI
4. ROM
5. The sagittal diameter of the spinal canal.
6. The healing of the grooves.

The data will be collected preoperatively; intraoperatively; on 1 week postoperatively; as well as at 3, 6, 12, 24 months postoperatively.

Adverse event

Researchers should record the adverse events that occurred after cervical spine surgery and report them to the First Affiliated Hospital of Zhengzhou University for a time limit of 24 hours. Specific adverse events include neck and shoulder pain, incision infection, spinal cord injury, nerve root injury, the dural sac tear, major vascular injury, screws shedding and loosening, rods shedding and loosening. If these adverse events occur, the patient should be treated accordingly.

Assessment of outcome

The clinical outcome was measured by the visual analog scale(VAS) score (0=no pain, 10=worst imaginable pain) of axial neck pain (neck, neck or shoulder pains). The preoperative and postoperative neurological condition was evaluated by the Japanese Orthopaedic Association (JOA) score [16]. The excellent rate proposed by the method by Hirabayashi [17] was calculated using the following formula: Recovery rate (%)=[(postoperative JOA score-preoperative JOA score) / (17-preoperative JOA score)]×100. The criteria for efficacy grading are: excellent, recovery rate ≥ 75%; good, 50% to 74%; fair, 25% to 49%; poor, <25%. The incidence of adverse reactions was calculated and used to evaluate the safety of the procedure. The incidence of adverse reactions = the number of patients with adverse reactions / the total number of patients × 100%.

Radiographic evaluation

Outpatient follow-up was performed regularly at 3, 6, 12, 24, and 36 months after surgery. All patients underwent cervical spine radiographs at each follow-up (including lateral, neutral, flexion, and extension views). Cervical curvature index (CCI) and cervical range motion (ROM) were calculated. The CCI was calculated by measuring the angle between the upper edge of C3 and the lower edge of C7 on the lateral

radiograph of the cervical spine. The ROM was calculated by measuring the difference of included angle between C2 and C7 vertebral lower margin on lateral X-ray films of cervical hyperextension view and hyperflexion view. CT scan was used to evaluate the degree of spinal canal enlargement and bony unions of the grooves. MRI was used to evaluate the change of signal intensity and the decompression condition of the spinal cord.

Data management

Data were collected in the form of a Case Report Form (CRF) and summarized in a unified form. Specific data include the following aspects: demographic information, disease diagnosis, disease concomitant conditions and adverse reactions. These data are recorded and saved as electronic files by using Epidata data processing software. Research data of this clinical trial are kept by the First Affiliated Hospital of Zhengzhou University. Only researchers have the right to inquiry the documents of the database. The Independent Data Monitoring Committee (IDMC) supervises and manages data throughout the clinical research process. Professional statisticians will make a statistical analysis of the database files and get the statistical analysis results. The main researchers of the trial then write the research report based on the statistical results.

Statistical analysis

All statistical analyses are performed with SPSS V.21.0 statistical software (SPSS, Inc, Chicago, IL). All data are expressed as the mean $\pm$ standard deviation. The difference of incision length, operative time, and intraoperative blood loss between the two groups will be analyzed using a two independent samples t-tests ($\alpha = 0.05$). JOA score, VAS score, CCI, ROM and the sagittal diameter of the spinal canal of preoperatively, 1 week postoperatively, as well as 3, 6, 12, 24 months postoperatively will be analyzed using a repeated-measures analysis of variance. A value of $P < 0.05$ is considered statistically significant.

Discussion

3D printed guiding device assisted bilateral crossing cervical microendoscopic laminoplasty is a new minimally invasive spinal surgical technique. The innovations of this new surgical technique are as follows: (a) By using 3D printing technology, customized ends of the guiding tubes were perfectly matched with the surface of lamina for surgical locating, achieving the purpose of minimally invasive and precise surgery; (b) The guiding grooves can prevent long groove-shaped decompression of the lamina from deflecting; (c) The surgical operating device for the bilateral crossing cervical microendoscopic laminoplasty can achieve accurate decompression of the lamina, rapid fixation of lateral mass screws and precise reposition of the spinous process-ligament complex; (d) Through preoperative simulation, the position of the decompression grooves and the entry point of the lateral mass screws were determined to prevent complications.

This procedure can effectively enlarge the spinal canal while retaining most of the normal bone-ligament anatomical structure of the cervical spine. After full decompression, two lateral mass screws were

vertically twisted into the lateral mass on both sides. The connecting rod was twisted into the root of the spinous process through the aiming device and then fixed with the lateral mass screw. By adjusting the retroposition locking mechanism of the lateral mass screw to make the bilateral connecting rods retroposition 1 to 3mm on the sagittal plane, thereby the spinal canal was enlarged. With the help of the bilateral connecting rods, the spinous process-ligament complex and the lateral mass screws formed a stable triangular structure in posterior column of this level which further reducing the risk of postoperative spinal instability.

Indications of 3D printed guiding device assisted bilateral crossing cervical microendoscopic laminoplasty are as follows: (a) Congenital spinal canal stenosis; (b) Spinal canal stenosis caused by ossification of the posterior longitudinal ligament, hypertrophy of ligamentum flavum, and proliferation of articular process; (c) The dura mater is compressed by multi-level cervical disc herniation; (d) The anterior cervical operation cannot alleviate symptoms. Contraindications include patients with cervical kyphosis, cervical instability, cervical spondylolisthesis over 1 grade and severe osteoporosis.

This trial was the first randomized controlled trial to compare 3D printed guiding device assisted bilateral crossing cervical microendoscopic laminoplasty with CMEL. The purpose of the trial was to introduce a new minimally invasive laminoplasty technique and to demonstrate that this new surgical method is safer, easier and more effective.

Trial status

This trial was registered on 11 May 2019 (registration number ChiCTR1900023100). The trial is currently in the stage of recruiting patients. The trial began recruitment in 1 June 2019. Participants will be recruited until 1 June 2020.

Abbreviations

CMEL: Cervical microendoscopic laminoplasty; **CSM:** Cervical spondylotic myelopathy; **JOA:** Japanese Orthopedic Association scores; **VAS:** Visual analogue scales; **CCI:** Cervical curvature index; **ROM:** Range of motion; **RCT:** Randomized controlled trial; **ChiCTR:** Chinese Clinical Trial Registry; **WHO ICTRP:** World Health Organization International Clinical Trials Registry Platform; **MRI:** Magnetic Resonance Imaging; **CT:** Computed Tomography; **PASS:** Power Analysis and Sample Size; **CRF:** Case Report Form; **IDMC:** Independent Data Monitoring Committee; **SPSS:** Statistical Product and Service Solutions; **SPIRIT:**

Standard Protocol Items Recommendations for Intervention Trials

Declarations

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Availability of data and materials

Not applicable.

Authors' contributions

All authors are affiliated to the First Affiliated Hospital of Zhengzhou University, China. CLZ designed the study protocol. YF wrote the manuscript. CLZ and YX checked the manuscript. CLZ revised and finalized the study protocol. XY, TYY, CLS, LJS, YL, YYW and XZ are responsible for the recruitment and treatment of patients. All authors have read and approved the final manuscript.

Ethics approval and consent to participate

This trial meets the requirements of the Helsinki Declaration formulated by the World Medical Association, and it has been reviewed and approved by the Institutional Ethics Review Board of the First Affiliated Hospital of Zhengzhou University (Approved number: KY-2019-LW-049). All enrolled participants will be required to sign an informed consent. The protocol has been registered in Chinese Clinical Trial Registry (ChiCTR), assigned to be the representative registry of China to join WHO ICTRP in 2007, with the protocol number ChiCTR1900023100.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

Data sharing statement

The full data set will be made available when this trial is completed and published.

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Figures

Figure 1

flow chart of the trial.

TIMEPOINT	STUDY PERIOD							
	Enrolment	Allocation	Post-allocation					
	Baseline (prerandomization)	Randomization	Day of surgery	1 week post-surgery	3 months	6 months	12 months	24 months
ENROLMENT:								
Eligibility Screen	x							
Informed consent	x							
Allocation		x						
INTERVENTION:								
Experimental group			x					
Control group			x					
ASSESSMENTS:								
Incision length			x					
Operative time			x					
Blood loss			x					
JOA	x			x	x	x	x	x
VAS	x			x	x	x	x	x
CCI	x			x	x	x	x	x
ROM	x			x	x	x	x	x
The sagittal diameter of the spinal canal	x			x	x	x	x	x
The healing of the grooves				x	x	x	x	x
PARTICIPANTS SAFETY:								
Adverse events			x	x	x	x	x	x

Figure 2

Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) schedule of the trial.

Figure 3

The designed guiding tubes, guiding grooves and aiming device in E3D Medical Software.

Figure 4

Diagrammatic sketch of the 3D printed guiding device assisted bilateral crossing cervical microendoscopic laminoplasty. (A) The two guiding tubes were connected with the bilateral guiding grooves. After the two guiding tubes passed through the incisions on both sides, customized ends of the guiding tubes were perfectly matched with the surface of lamina by adjusting the guiding tube, and confirmed by the indicators. (B) The guiding tube on the one side was removed. Then the endoscope was inserted into the guiding tube on the contralateral side. Endoscopic partial laminotomy was initiated using a high-speed drill to roughen the conjunction of the lamina and the lateral mass, and the ventral cortex of the lamina was completely removed by using a 2mm Kerrison laminectomy rongeur. (C) The guiding tube was removed towards the lateral side by a certain distance, then the lateral mass screw was fixed at the lateral mass with the help of the working sleeve. (D) The aiming device was installed on the guiding tube, then the connecting rod was passed through the root of the spinous process by using the aiming device, and it was fixed at the lateral mass screw. (E) The same process was repeated on the contralateral side. Then two working sleeves were connected with the bilateral lateral mass screws. By adjusting the reposition locking mechanism of the lateral mass screw to make the bilateral connecting

rods reposition 1 to 3mm on the sagittal plane, therefore, the spinous process-ligament complex and the deep extensor muscle group also reposition 1 to 3mm on the sagittal plane. (F) With the help of the bilateral connecting rods, the spinous process-ligament complex and the lateral mass screws formed a stable triangular structure in posterior column of this level.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [SPIRIT.pdf](#)