



Comparison of clinical outcomes of modified laminoplasty with preservation of muscle group inserted into C2 and C7 spinous processes versus conventional C3–C7 laminoplasty: a prospective, randomized, controlled, noninferiority trial

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Background: The efficacy and noninferior of performing modified double-door laminoplasty (MDDL) (C4–C6 laminoplasty plus C3 laminectomy, alongside a dome-like resection of the inferior part of the C2 lamina and the superior part of the C7 lamina) in patients with multilevel cervical spondylotic myelopathy (MCSM) is equivocal. A randomized, controlled trial is warranted.

Objective: The objective was to evaluate the clinical efficacy and noninferior of MDDL compared with traditional C3–C7 double-door laminoplasty.

Study design: A single-blind, randomized, controlled trial.

Methods: A single-blind, randomized, controlled trial was conducted in which patients who with MCSM with greater than or equal to 3 levels of spinal cord compression from the C3 to the C7 vertebral levels were enrolled and assigned to undergo either MDDL group or conventional double-door laminoplasty (CDDL) group in a 1:1 ratio. The primary outcome was the change in the Japanese Orthopedic Association score from baseline to 2-year follow-up. The secondary outcomes included changes in the Neck Disability Index (NDI) score, the Visual Analog Scale (VAS) for neck pain, and imaging parameters. Operative complications were also collected and reported. The outcome measures were compared between the groups at 3 months, 1 year, or 2 years after surgery.

Results: A total of 96 patients (mean age 67 years, 39.8% women) underwent randomization. Of these patients, 93 completed 3-month follow-up, 79 completed 1-year follow-up, and 66 completed 2-year follow-up. The changes in the Japanese Orthopedic Association score did not differ significantly between the study groups at the three time points after surgery. With respect to amelioration of neck pain and disability related to neck pain, patients in the MDDL group had a significantly greater decrease in the VAS and NDI component summary score than did those in the CDDL group at 1-year (VAS: -2.5 vs. -3.2 , difference -0.7 , 95% *CI* -1.1 to -0.2 , $P=0.0035$; NDI: -13.6 vs. -19.3 , difference -5.7 , 95% *CI* -10.3 to -1.1 , $P=0.0159$) and 2-years (VAS: -2.1 vs. -2.9 , difference -0.8 , 95% *CI* -1.4 to -0.2 , $P=0.0109$; NDI: -9.3 vs. -16.0 , difference -6.7 , 95% *CI* -11.9 to -1.5 , $P=0.0127$). The changes in the range of motion (ROM), the C2–C7 Cobb angle, and the cervical sagittal vertical axis in the MDDL group were significantly less than those in the CDDL group (ROM: -9.2 ± 6.4 vs. -5.0 ± 6.0 , $P=0.0079$; C2–C7 Cobb angle: -7.9 ± 7.8 vs. -4.1 ± 6.2 , $P=0.0345$; cervical sagittal vertical axis: 0.6 ± 0.9 vs. 0.2 ± 0.6 , $P=0.0233$). The MDDL group had less blood loss (428.1 vs. 349.1 , $P=0.0175$) and a lower rate of axial symptoms (27.3 vs. 6.1% , $P=0.0475$) than the CDDL group.

Conclusions: Among patients with MCSM, the MDDL produced similar cervical cord decompression compared with the conventional C3–C7 double-door laminoplasty. The modified laminoplasty was associated with meaningful improvement in amelioration of neck discomfort, maintaining a better cervical ROM and sagittal alignment, decreasing blood loss, and reducing the incidence of axial symptoms.

Keywords: axial symptoms, cervical spondylotic myelopathy, Japanese Orthopedic Association score, modified laminoplasty, neck disability index, RCT study, visual analog scale

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Introduction

Cervical spondylotic myelopathy (CSM) is an age-related degenerative disease that is the most common cause of neurological dysfunction of the spinal cord worldwide^[1]. CSM is characterized by compression of the spinal cord, which presents a series of clinical symptoms and signs such as neck pain or stiffness, bladder dysfunction, gait instability, fine finger motor difficulties, hyperreflexia, weakness, and alteration in proprioception. A clinical practice guideline^[2] recommended surgical intervention for patients with moderate or severe CSM. For patients with mild CSM who pursue initial non-operative management, operative intervention is recommended if neurological function fails to improve or deteriorates.

Double-door laminoplasty (DDL) has been an effective posterior cervical decompression method for treating multilevel cervical spondylotic myelopathy (MCSM) since Kurokawa described this operation^[3,4]. Clinical follow-up results indicate that DDL achieves positive clinical outcomes with effective decompression and stable neurologic improvement^[5,6]. In conventional C3–C7 DDL, it is necessary to cut the semispinalis cervicis (SSC) muscle from the C2 spinous process while opening the C3 lamina. In addition, the C3–C7 spinous processes are resected, which will lead to structural damage of the posterior cervical tension band and muscles, resulting in muscle atrophy and cervical sagittal imbalance. Consequently, there are several postoperative complications, such as loss of lordotic curvature, decrease in the neck range of motion (ROM), postoperative kyphotic deformity, and axial symptoms (AS)^[7–11]. To prevent perioperative complications and to improve quality of life, many researchers have modified the traditional surgical techniques by focusing on a minimally invasive surgical approach to preserve the nuchae muscular attachments to the spinous processes. According to previous reports, modified DDL that preserves the SSC insertion into C2 and/or preserves nuchal muscle insertion into C7 can achieve similar decompression. This approach can also maintain a better cervical lordosis curve, reduce ROM loss, and decrease the incidence of postoperative complications including axial neck pain compared with the conventional C3–C7 DDL^[12–18].

Nevertheless, the importance of preserving the muscle group inserted into the C2 or/and C7 spinous process is equivocal^[19]. To date, there is no class I evidence that modified laminoplasty is not inferior to conventional laminoplasty for the treatment of MCSM. This lack of evidence complicates the effort to develop guidelines and to standardize surgical practice, so a randomized, controlled trial is warranted. In this randomized controlled trial, we modified the posterior surgical approach: we preserved muscular insertion into the C2 and C7 spinous processes. We aimed to investigate whether this modified DDL with a minimally invasive surgical approach is noninferior to conventional DDL in the treatment of CSM. The clinical outcomes were reported here.

Methods

Study design and oversight

We conducted a single-blind, randomized controlled trial at ** Hospital. The trial followed the requirements of the Declaration of Helsinki and was registered as a Chinese domestic clinical trial (ChiCTR**) at Chict.org. In this trial, patients who with MCSM

HIGHLIGHTS

- The modified laminoplasty with preservation of muscle insertions into the C2 and C7 spinous process achieved similar cervical cord decompression and neurological recovery as the conventional C3–C7 laminoplasty and showed obvious advantages in alleviating postoperative neck discomfort.
- The modified laminoplasty showed obvious advantages in maintaining the sagittal alignment and reducing postoperative axial symptoms.
- The modified laminoplasty was less invasive, which could reduce intraoperative bleeding and shorten postoperative hospital stay.

with greater than or equal to 3 levels of spinal cord compression from the C3 to the C7 vertebral levels were randomly assigned, in a 1:1 ratio, to undergo either modified double-door laminoplasty (MDDL) group or traditional C3–C7 double-door laminoplasty group. The institutional ethics review board approved the trial, and all patients provided written informed consent. The data were managed by an investigator who was not involved in the randomization process and surgery. The trial has been reported in line with Consolidated Standards of Reporting Trials (CONSORT) Guidelines^[20]. All of the authors vouch for the completeness and accuracy of the data and for the trial's fidelity to the protocol.

Patients

Patients were assessed for MCSM before they underwent randomization. The inclusion criteria for screening and enrollment were age 40–80 years; cervical myelopathy, defined as having two or more of the following typical signs or symptoms of spinal cord compression: fine finger motor difficulties, gait disturbance, hyperreflexia, the Babinski sign, bladder dysfunction, or ankle clonus; three or more levels of spinal cord compression from C3 to C7, confirmed by MRI or computed tomography myelography; and nonoperative treatment with no effect. The exclusion criteria included C2–C7 kyphosis greater than 5° (measured on standing cervical lateral radiographs); cervical instability; previous cervical spinal surgery; cervical spinal cord compression above C3 or below C7; or a significant health-related comorbidity such as cancer, severe cardiovascular diseases, and other critical diseases. A panel of five expert spine surgeons was formed to review a brief clinical vignette plus standardized radiographic and MRI for each patient to assess suitability for randomization. Baseline data were obtained during the perioperative period, and follow-up data were obtained during outpatient follow-up through medical records, imaging examinations, and questionnaires.

Randomization and blinding

Patients were randomly assigned, in a 1:1 ratio, to undergo either MDDL group or conventional double-door laminoplasty (CDDL) group. Randomization was performed with the use of a random number table method and opaque envelopes, which enabled random treatment assignment. Random numbers were selected and concealed in the envelopes. The patients submitted to MDDL or CDDL were determined by odd or even numbers in the

envelopes. In this trial, patients, data collectors, and statistical analysts were blinded to the treatment, but surgeons were aware of the treatment.

Interventions

For patients assigned to undergo CDDL, the SSC insertion into the C2 spinous process was detached during posterior cervical muscle dissection, and C3–C7 laminoplasty was performed without preservation of the muscle and ligament complex of the C7 spinous process. In the event of upper C3 involvement, a C2 dome-shaped laminectomy was performed. For patients who were assigned to undergo MDDL, C4–C6 laminoplasty plus C3 laminectomy was used, and a dome-like resection of the inferior part of the C2 lamina and the superior part of the C7 lamina were added after a total laminectomy of C3, in which the muscle and ligament complex insertions into the C2 and C7 spinous processes were preserved (Fig. 1). In both groups, the laminoplasty procedure was adopted for spinous process splitting using a thread-wire saw, and hydroxyapatite spinous process spacers were placed between the split spinous processes to fix them in place. All the trial surgeons were senior consultants and were highly experienced in performing the two trial interventions. All patients had cervical collar fixation for 2 weeks, got out of bed 1 week after surgery, and began neck and shoulder functional exercise 2 weeks after surgery.

Outcomes

The primary outcome was the change in the Japanese Orthopedic Association (JOA) score from baseline to 2-year follow-up. This questionnaire comprises six questions with a total score ranging from 0 to 17, where lower scores indicate greater impairment

related to spinal cord compression. It has been used and validated to assess treatment outcomes in patients with CSM. The minimal clinically important difference, which was determined based on previous studies, was prespecified to be 2.5 points^[21,22].

The change in the Neck Disability Index (NDI) score (range 0–100, with higher scores indicating greater disability related to back pain) and the Visual Analog Scale (VAS), (range 0–10, with higher scores indicating a greater degree of neck pain) from baseline to 2-year follow-up were secondary outcome measures. Other secondary outcomes included the change in the imaging parameters to assess cervical alignment and sagittal balance, including ROM, C2–C7 Cobb angle, T1 slope (T1S), thoracic inlet angle (TIA), and cervical sagittal vertical axis (CSVA) 2 years after surgery (shown in Fig. 2).

Additional outcome measures were operative complications recorded at 30 days and 2 years after surgery. Complications included those associated with laminoplasty like AS and C5 palsy, and other common complications in spinal operation that occurred within 1 month after surgery, such as spinal cord injury, cerebrospinal fluid fistula, rebleeding, hematoma, fever (unknown source), surgical incision infection, delayed wound healing, venous thromboembolism, urethritis, ileus, spinal cord injury, and reoperation. The length of the procedure, blood loss, the length of stay after surgery, and the quantity of postoperative drainage were also collected and reported.

Statistical analysis

The sample size was estimated based on previous nonrandom prospective or retrospective studies^[16–18]. We reviewed these studies and calculated that the total SD of the postoperative JOA score for all patients involved in the three studies was 2.9. On the conservative assumption of a mean SD of 3 points during the

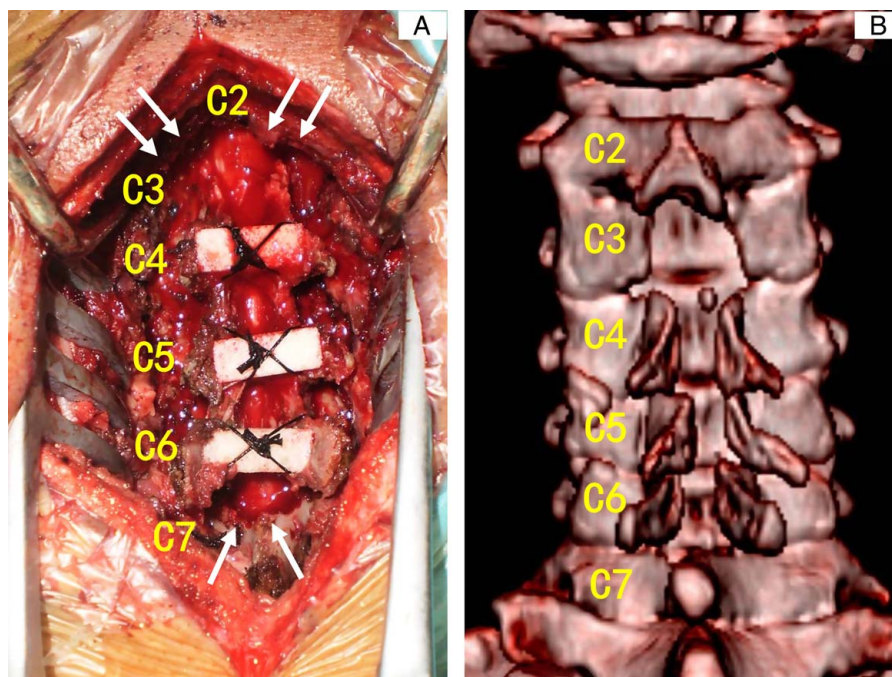


Figure 1. Schematic diagram of the modified double-door laminoplasty. (A) intraoperative image, arrows indicate dome-like resection of the inferior part of the C2 lamina and the superior part of the C7 lamina; (B) postoperative three-dimensional computed tomographic reconstruction.

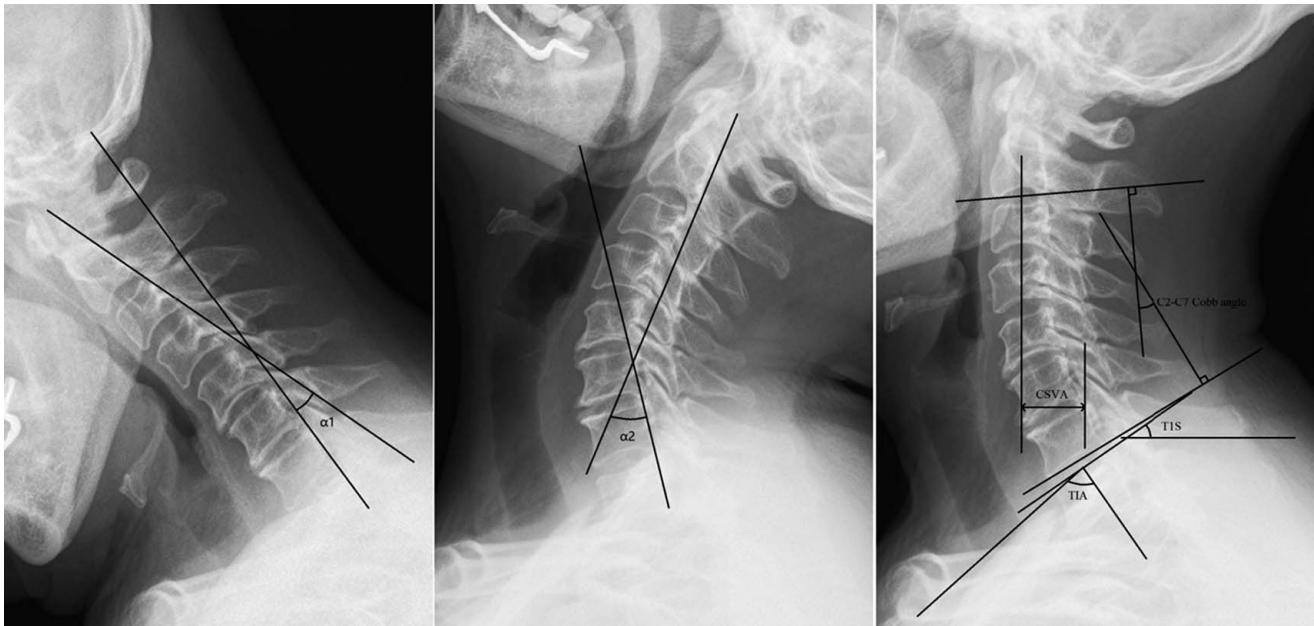


Figure 2. Diagram of the imaging measurement. Range of motion, the angle between the posterior edge of the C2 and C7 vertebral body was measured as α_1 in the full flexion and as α_2 in the full extension radiographs, Range of motion = $\alpha_1 + \alpha_2$; C2–C7 Cobb angle, the angle between the inferior endplate of C2 and the inferior endplate of C7; T1 slope (T1S), the angle between the T1 superior endplate and the horizontal plane; thoracic inlet angle, the angle between the vertical line of the T1 superior endplate and the line an angle formed by a line perpendicular to the superior endplate of T1 and a line connecting the center of the T1 upper end plate and the upper end of the sternum; cervical sagittal vertical axis, the distance between a plumb line dropped from the center of C2 and the superior posterior aspect of C7. CSVA, cervical sagittal vertical axis; TIA, thoracic inlet angle.

second year, we calculated that a sample of 31 patients per treatment group would be required to provide statistical power of 0.90 with a one-tailed significance level of 0.025 to detect non-inferiority of MDDL to CDDL with a 2.5 noninferiority margin (the minimal clinically important difference of the JOA). To account for a possible dropout rate of 20%, 40 patients were required in each group.

The primary analysis included the patients who could be evaluated in the per-protocol population (i.e. patients who had completed at least one follow-up). We used mixed-effects models for repeated measures for the between-group comparisons of changes in the JOA, VAS, and NDI scores from baseline. We included fixed effects for the treatment (CDDL vs. MDDL), time (3 months, 1 year, and 2 years after randomization), and the time \times treatment interaction and calculated least-squares means and 95% CI. We computed the robust standard errors and test statistics involving the fixed effects by using the PROC MIXED procedure (SAS Institute). We compared least-squares means between the treatment groups at each time point and between time points within each treatment group by using appropriate contrasts within the mixed-effects models for repeated measures. For other analyses, we performed independent-sample *t*-tests for continuous variables, which are presented as means and SDs, and the χ^2 -test or Fisher's exact test for categorical variables, which are presented as numbers and percentages.

Results

Patient characteristics

Figure 3 shows the enrollment, randomization, and follow-up for the trial. From July 2015 to December 2018, we screened 257

patients, 134 of whom were eligible. Of these patients, 38 declined to participate in the trial 96 consented to be assigned randomly to one of the two groups. Of the randomized patients, 93 completed at least the 3-month follow-up and were included in this analysis. In addition, 79 patients completed a 1-year follow-up, and 66 completed a 2-year follow-up. The final follow-up date was December 2020. All baseline characteristics were comparable between the two groups (Table 1).

Primary outcome

Partial data loss can be allowed in mixed-effects models, so patients who had completed at least one follow-up (93 patients, 47 in the CDDL group and 46 in the MDDL group) were included in the primary outcome analysis. After surgery, patients in both groups had an increased JOA score compared with baseline. As shown in Table 2, there was no significant difference in the least-squares means of the change in the JOA score between the groups at 3 months (3.5 vs. 3.3 points, difference -0.2 , 95% CI -0.8 to 0.4 , $P = 0.5415$), 1 year (4.1 vs. 3.7 difference -0.4 , 95% CI -1.0 to 0.3 , $P = 0.2681$), and 2 years (3.6 vs. 3.4, difference -0.2 , 95% CI -0.8 to 0.6 , $P = 0.7417$). The difference in the JOA score change between the two groups was the smallest at the last follow-up.

Secondary outcomes

The amelioration of neck pain and disability related to neck pain were measured by the change in the VAS and NDI scores at 3 months, 1 year, and 2 years. Neck pain showed the greatest relief at 3 months after surgery, followed by a slow increase at the 1-year and 2-year follow-ups. As shown in Table 2, there was no significant difference in the change in the

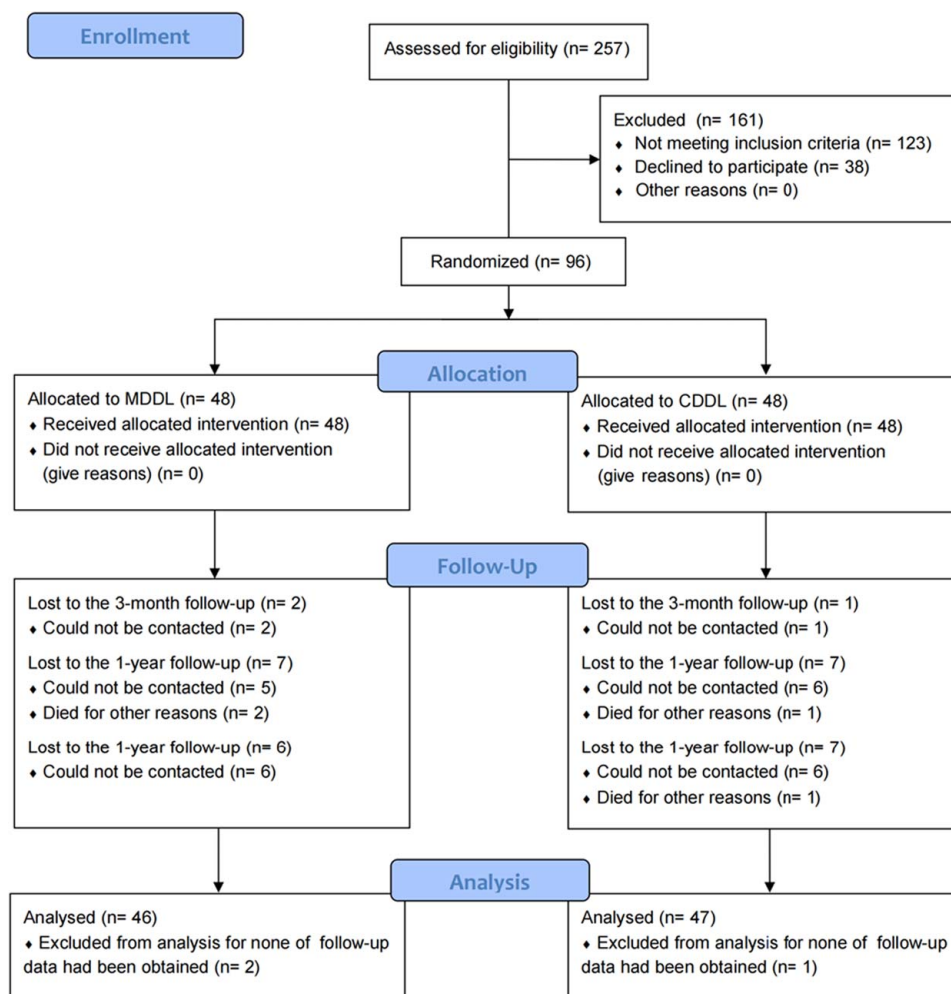


Figure 3. Consort diagram of participants flow. CDDL, conventional double-door laminoplasty; MDDL, modified double-door laminoplasty.

VAS and NDI scores between the two groups; however, patients in the MDDL group had a significantly greater decrease in the VAS score and the NDI component summary score than did those in the CDDL group at 1 year (VAS: -2.5 vs. -3.2 , difference -0.7 , 95% CI -1.1 to -0.2 , $P=0.0035$; NDI: -13.6 vs. -19.3 , difference -5.7 , 95% CI -10.3 to -1.1 , $P=0.0159$) and 2 years (VAS: -2.1 vs. -2.9 , difference -0.8 , 95% CI -1.4 to -0.2 , $P=0.0109$; NDI: -9.3 vs. -16.0 , difference -6.7 , 95% CI -11.9 to -1.5 , $P=0.0127$). We further analyzed the changes in the imaging parameters of the patients. At the 2-year follow-up, the changes in ROM, the C2–C7 Cobb angle, and CSVA in the MDDL group were significantly less than in the CDDL group (ROM: -9.2 ± 6.4 vs. -5.0 ± 6.0 , $P=0.0079$; C2–C7 Cobb angle: -7.9 ± 7.8 vs. -4.1 ± 6.2 , $P=0.0345$; CSVA: 0.6 ± 0.9 vs. 0.2 ± 0.6 , $P=0.0233$), and there were marginal, nonsignificant differences in the change in TIA between the two groups (2.6 ± 4.8 vs. 0.2 ± 5.0 , $P=0.0584$) (Table 3). Blood loss was significantly less in the MDDL group than in the CDDL group (428.1 vs. 349.1 , $P=0.0175$). There was a trend for a shorter length of stay in the MDDL group (12.8 vs. 10.9 , $P=0.0846$). The MDDL group had a lower rate of AS than the CDDL group (27.3% vs. 6.1% , $P=0.0475$) (Table 4).

Discussion

In this trial, we evaluated whether modified laminoplasty with preservation of muscle and ligament complex insertion into C2 and C7 was noninferior to conventional C3–C7 laminoplasty. The primary outcome measures—the change in cervical spinal cord neurological dysfunction after 2 years, as measured by the JOA score—was not different between the groups. This finding suggests that modified laminoplasty can achieve similar decompression results as conventional laminoplasty. The between-group differences in the decreases in the NDI and VAS scores were clinically meaningful, which were the secondary outcome measures of disability related to neck pain. Hence, MDDL had significant advantages over CDDL in ameliorating postoperative neck discomfort. By reviewing the patients' imaging data, we found that the modified laminoplasty reduced postoperative cervical ROM loss and helped maintain cervical curvature and sagittal balance. In addition, the modified procedure resulted in less intraoperative bleeding and a shorter postoperative hospital stay because of the smaller surgical approach; more importantly, it also reduced the incidence of postoperative AS.

At present, laminoplasty is the preferred treatment for MCSM in China. However, after surgery, patients are prone to the loss of

Table 1
Baseline characteristics of the patients

Characteristic	CDDL group		P
	(n=47)	(n=46)	
Age—years	60.0±10.9	59.5±10.0	0.8342
Female — No/total (%)	17/47(36.2)	20/46(43.5)	0.4716
BMI	25.6 ±4.8	25.8±3.4	0.7575
Smoking — No/total (%)	22/47(46.8)	20/46(43.5)	0.7470
Underlying diseases			
Hypertension — No/total (%)	21/47(44.7)	20/46(43.5)	0.9070
Diabetes — No/total (%)	9/37(19.1)	10/46(21.7)	0.7568
Cardio-cerebro-vascular diseases — No/total (%)	14/47(29.8)	12/46(26.1)	0.6910
Respiratory diseases — No/total (%)	1/47(2.1)	2/46(4.3)	0.9849
Urinary system diseases — No/total (%)	1/47(2.1)	1/46(2.2)	1.0000
Kyphosis line — No(negative)/total (%)	1/47(2.13)	0	1.0000
JOA score	10.3±1.9	10.2±2.5	0.8627
VAS score	4.9±1.4	4.8±1.4	0.5831
NDI score	33.7±13.3	33.9±16.1	0.9451
ROM — degree	41.1±10.4	43.2±9.3	0.3958
C2–C7 Cobb angle — degree	18.1±12.1	20.2±11.1	0.4637
T1S at baseline — degree	25.3±7.2	25.9±6.3	0.7320
TIA at baseline — degree	79.8±9.1	81.0±7.8	0.5532
CSVA at baseline — cm	1.9±1.5	1.8±1.4	0.8489

CDDL, conventional double-door laminoplasty; CSVA, cervical sagittal vertical axis; JOA, Japanese Orthopaedic Association; MDDL, modified double-door laminoplasty; NDI, Neck Disability Index; ROM, range of motion; T1S, T1 slope; TIA, thoracic inlet angle; VAS, Visual Analog Scale.

physiological neck curvature, reduced mobility, and pain, which may be related to the cervical mechanical imbalance caused by the destruction of the neck extensor muscle group during the operation. Neck balancing consists of static and dynamic equilibria. Muscles and ligaments around the neck are considered the components of dynamic stabilizers^[23,24]. It is generally agreed that posterior cervical deep extensors, especially the SSC, act as the primary dynamic stabilizers, maintaining lordosis and alignment of the cervical vertebrae^[25–27]. Thirty-seven percent of the extension moment-generating capacity comes from SSC at the neutral position^[25]. The C7 spinous process also plays an important role in the biomechanics of the cervical posterior extensor muscle. The height of this spinous process increases the moment arm of the extensor muscle complex^[19]. Muscles that attach to the C7—the rhomboideus minor, serratus posterior superior, and splenius capitis—provide a large portion of the extension moment-generating capacity^[25,28].

Given the anatomical importance of muscle attachments to the C2 and C7 spinous processes, many studies have focused on re-suturing or preserving the C2 and C7 spinous processes and their muscle attachments during laminoplasty. Kurokawa^[29] modified DDL by preserving the spinous process as long as possible as an anterior support and re-sutured the SSC that had been detached earlier from the C2 spinous process before closure. However, reconstruction possibly failed due to considerable individual variations in the morphologic features of the C2 spinous process and the C2 insertion of the SSC^[30]. Therefore, many researchers have modified laminoplasty (unilateral or double open door) to preserve muscle attachments. Shiraishi *et al.*^[31] developed a new surgical technique named skip laminectomy, which preserves the attachments of the SSC and multifidus muscles on the cervical spinous processes and limits the damage to the attachments of the interspinous and rotator muscles. Takeuchi *et al.*^[12] presented a modified surgical technique to preserve the SSC insertion into C2

Table 2
Changes in the Japanese Orthopaedic Association (JOA), Visual Analog Scale (VAS), and Neck Disability Index (NDI) scores from baseline

Outcomes	Change from Baseline			P
	CDDL group (n=46)	MDDL group (n=47)	Difference in Change (95%CI)	
JOA score				
Baseline*	10.3	10.2	NA	NA
3months	3.5	3.3	−0.2 (−0.8 to 0.4)	0.5415
1year	4.1	3.7	−0.4 (−1.0 to 0.3)	0.2681
2 years	3.6	3.4	−0.2 (−0.8 to 0.6)	0.7417
VAS score				
Baseline*	4.9	4.8	NA	NA
3months	−3.3	−3.3	0.0 (−0.5 to 0.5)	0.8820
1year	−2.5	−3.2	−0.7 (−1.1 to −0.2)	0.0035
2 years	−2.1	−2.9	−0.8 (−1.4 to −0.2)	0.0109
NDI score				
Baseline*	33.7	33.9	NA	NA
3months	−21.2	−22.5	−1.3 (−6.4 to 3.9)	0.6346
1year	−13.6	−19.3	−5.7 (−10.3 to −1.1)	0.0159
2 years	−9.3	−16.0	−6.7 (−11.9 to −1.5)	0.0127

*The baseline scores shown are the mean values in group.

CDDL, conventional double-door laminoplasty; JOA, Japanese Orthopaedic Association; MDDL, modified double-door laminoplasty; NA, not applicable; NDI, Neck Disability Index; VAS, visual analog scale.

by C4–C7 laminoplasty with C3 laminectomy. The results showed that this modified procedure could reduce the incidence of AS and improve alignment, which are similar to the results we reported in this trial. Kihara *et al.*^[13] developed a modified technique, namely C3–C6 laminoplasty plus resection of the superior one third of the C7 lamina to preserve the architecture of the C7 vertebra and attached the nuchal ligament while decompressing the C6–C7 area. Similarly, it has been reported that preserving the C7 spinous process and its muscle attachments can improve postoperative neck discomfort and reduce the incidence of AS^[15]. A meta-analysis^[32] reported that laminoplasty with C3 laminectomy and C7 spinous process conservation produced a lower incidence of AS than only C3 laminectomy or only C7 spinous process conservation. In the same way, the modified unilateral

Table 3
Changes in imaging parameters from baseline

Outcomes	CDDL group	MDDL group	P
ROM at baseline — degree	41.1±10.4	43.2±9.3	0.3958
Changes in ROM from baseline to postoperative 2 years — degree	−9.2±6.4	−5.0±6.0	0.0079
C2–C7 Cobb angle at baseline — degree	18.1±12.1	20.2±11.1	0.4637
Changes in C2–C7 Cobb angle from baseline to 2 years — degree	−7.9±7.8	−4.1±6.2	0.0345
T1S at baseline — degree	25.3±7.2	25.9±6.3	0.7320
Changes in T1S from baseline to 2 years — degree	2.6±6.3	0.8±4.3	0.1782
TIA at baseline — degree	79.8±9.1	81.0±7.8	0.5532
Changes in TIA from baseline to 2 years — degree	2.6±4.8	0.2±5.0	0.0584
CSVA at baseline — cm	1.9±1.5	1.8±1.4	0.8489
Changes in CSVA from baseline to 2 years — cm	0.6±0.9	0.2±0.6	0.0233

CDDL, conventional double-door laminoplasty; CSVA, cervical sagittal vertical axis; MDDL, modified double-door laminoplasty; ROM, range of motion; T1S, T1 slope; TIA, thoracic inlet angle.

Table 4
Surgical complications

Complications	CDDL group	MDDL group	P
Length of procedure — min	135.1±23.8	138.7±24.5	0.4749
Blood loss — ml	428.1±145.4	349.1±129.2	0.0175
Quantity of postoperative drainage — ml	308.5±159.3	264.8±131.6	0.1491
Length of stay after operation — days	12.8±6.3	10.9±4.2	0.0846
AS — No/total (%)	9/33 (27.3)	2/33 (6.1)	0.0475
C5 palsy — No/total (%)	1/33 (3.0)	1/33 (3.0)	1.0000
Rebleeding — No/total (%)	1/47 (2.1)	1/46 (2.2)	1.0000
Fever (unknown source) — No/total (%)	1/47 (2.1)	1/46 (2.2)	1.0000
Surgical incision infection — No/total (%)	1/47 (2.1)	0	1.0000
Delayed wound healing — No/total (%)	1/47 (2.1)	0	1.0000
Urethritis — No/total (%)	0	1/46 (2.2)	1.0000

AS, axial symptoms; CDDL, conventional double-door laminoplasty; MDDL, modified double-door laminoplasty.

laminoplasty technique, which preserved muscle attachments to the C2 and C7 spinous process, ensured very good neurological status and ROM after 2 years and was associated with low incidences of axial neck pain and serious complications^[33].

As mentioned above, muscles that attach to the C2 and C7 spinous processes provide a large part of the posterior extension moment. CDDL damages the muscle attachment to the C2 and C7 spinous processes, which dramatically weakens the mechanical role of the posterior extensor muscle group in maintaining the cervical curvature and sagittal alignment, resulting in the loss of cervical curvature and ROM and sagittal imbalance. We conclude that destroying the posterior extensor muscle group attached to the C2 and C7 spinous processes reduces the neck's torque and range of posterior extension, thereby reducing the neck ROM. At the same time, with strong relative antagonism of neck flexion, cervical lordosis is hard to maintain, and the head shows a downward trend. For maintaining the head in a neutral position, the undamaged extensor will contract greater, and the curvature of segments without laminoplasty will be compensatory increased. The above changes are shown by a decrease in the C2–C7 Cobb angle and an increase in the T1S, T1A, and CSA on X-ray film. Prolonged contraction and stretching of muscles lead to pain, stiffness, and even spasm in the neck and shoulders, which may cause AS. The MDDL preserved more posterior neck extensor muscles, which may explain less neck discomfort and a lower incidence of AS after surgery.

Randomized controlled trials provide a high level of clinical evidence and are the gold standard for clinical effect evaluation. However, there are still some limitations to this study. First, this study only considered patients from a single center. Second, more than 30% of the patients were lost to follow-up at 2 years after randomization. Although we recruited additional patients with the approval of the ethics committee to meet the requirements of the minimum sample size, the limitation was still inevitable. Third, the follow-up period was only 2 years, so it was not possible to obtain a long-term efficacy evaluation. In addition, due to the low incidence of complications such as AS and C5 palsy, a large number of samples are needed to compare accurately between the groups, so the comparison of complications in this study may be biased. Finally, the contribution of a single structure to the efficacy could not be determined because muscle attachments to C2 and C7 spinous processes were preserved simultaneously. In future studies, it is necessary to increase the sample size, extend

the follow-up time, and design a single structure preservation control group to address these limitations.

Conclusions

In this study, we conducted a prospective randomized controlled trial and found that MDDL with preservation of muscle insertions into the C2 and C7 spinous process achieves similar cervical cord decompression and neurological recovery as conventional C3–C7 DDL. MDDL also maintains a better cervical ROM and sagittal alignment, alleviates postoperative neck pain, and reduces the incidence of AS.

Ethical approval

This research was approved by the institutional ethics committee of Beijing Shijitan Hospital (sjtkyll-lx-2017(37)).

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Author contribution

W.L., J.S., and L.D. were involved in study concept and design; W.L. and J.S. drafted the manuscript; S.Y. and Y.Z. recruited and randomized the patients; M. Y. and M. Y. collected and managed the data; Y.F. and Z.L. analyzed the data; L.D. supervised the study.

Conflicts of interest disclosure

The authors declare no conflicts of interest associated with this manuscript.

Research registration unique identifying number (UIN)

1. Name of the registry: Chinese Clinical Trial Registry
2. Unique Identifying number or registration ID: ChiCTR1800016810
3. Hyperlink to your specific registration (must be publicly accessible and will be checked): <http://www.chictr.org.cn/showproj.aspx?proj=16644>

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Data availability statement

No additional data are available.

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