A Novel Method of Making Hinges Using a Newly Designed Sharp Rongeur to Enhance Radiological and Clinical Outcomes in French-Door Cervical Expansive Laminoplasty

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Objective: Although the lamina open angle of making hinges is closely related to the outcomes of French-door laminoplasty (FDL) for treatment of cervical spondylosis, there have been no methods to predict the lamina open angle preoperatively as yet. The aim of this study was to investigate the accuracy of predicting the laminal open angle using our newly designed sharp rongeur, and to compare the postoperative outcomes and complications between the methods of making hinges using the newly designed sharp rongeur and the traditional high-speed micro-drill during the FDL.

Methods: This was a single-center retrospective study. Following the approval of the institutional ethics committee, a total of 39 patients (Male: 28; Female: 11) diagnosed with cervical spondylos who underwent FDL in our institution between January 2018 and May 2019 were enrolled. Patients were divided into two groups based on the method of making hinges (sharp rongeur: 22 cases; high-speed micro-drill: 17 cases). The average age at surgery was 59.1 years (range: 16–85 years). The radiological parameters, clinical outcomes, modified Japanese Orthopaedic Association (mJOA) scale score, and the recovery rate of mJOA were recorded and compared between the groups, respectively. The radiological parameters and clinical measurements at pre- and post-operation stages were compared using the paired-sample t-test, the Wilcoxon signed-rank test, and the Friedman's test, and variables in the two groups were analyzed using an unpaired Student’s t-test or a Mann-Whitney U test.

Results: The average follow-up period was 20.4 months (range: 14.0–25.9 months), the postoperative open angle was 60.13° ± 3.69° in the rongeur group with 22.78° ± 4.34° of angular enlargement, which was significantly lower than that of 68.96° ± 1.00° in the micro-drill group with 32.75° ± 4.22° of angular enlargement (U = 19.000, p < 0.001). The rongeur group showed a higher fusion rate (34.1% vs 14.7%, χ² = 11.340, p = 0.001), and a lower fracture rate of the lamina (7.8% vs 25.5%, χ² = 14.185, p < 0.001) at 1-month post-surgery, compared to the micro-drill group. There were no significant differences in the clinical outcomes and postoperative complications between the two groups (p > 0.05), except in the recovery rate of mJOA scores (0.836 ± 0.138 vs 0.724 ± 0.180, U = 115.000, p = 0.042) and neck disability index (NDI) at the final follow-up (7.55 ± 10.65 vs 14.71 ± 8.72, U = 94.000, p = 0.008).

Conclusions: The special sharp rongeur with a tip angle of 20° could be a preferred method to make hinges during FDL, which can predict the laminal open angle accurately and enlarge it to about 23°, thus reducing the fracture rate and accelerating the bony fusion of hinges compared with the outcomes of the traditional micro-drill method.

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**Introduction**

French-door laminoplasty (FDL) is widely used to treat cervical spondylosis. In this process, the lamina is sagitally split in a double door manner to produce sufficient canal expansion for better surgical outcomes. However, there are some postoperative complications associated with FDL that may affect the clinical outcomes, such as C5 nerve root palsy, a decrease in the cervical dynamic range of motion, laminar fracture, spinal cord injury, and cerebrospinal fluid (CSF) leakage. Among these, axial neck pain (ANP) and C5 nerve root palsy (C5-NRP) are reportedly the most common complications, with an incidence rate of 45–80% and 4.7%, respectively. Clinical investigations have suggested that the pathogenesis of both ANP and C5-NRP could be linked to the post-surgical posterior spinal cord movement. However, the exact reason remains unknown. Uematsu et al. has reported that the excessive open angle may increase the rates of ANP and C5-NRP incidences. Lee et al. has shown that the laminar fracture rate could be as high as 20.7% while performing FDL for the treatment of cervical spondylosis. The reason for this secondary complication might be the excessive depth of hinges or laminar opening angle during surgery.

Currently, the high-speed micro-drill has been routinely used in clinical practices to make hinges during the cervical expansive laminoplasty. However, controlling the hinge depth or laminar open angle width is difficult during the surgery, which may potentially increase the risk of laminar fracture. In Uematsu’s opinion, an optimum opening angle should be kept within 60°, which could prevent postoperative radiculopathy. Notably, it has been found that laminar fracture could also induce ANP onset. Technically, fluctuations in the optimal gutter depth and laminar open angle width largely depend on the operator’s experience. Currently, the open angle measurement, which cannot be predicted before surgery, is usually estimated using postoperative computed tomography (CT) scan. Prediction of the hinge-gutter depth exceedingly depends on the operator’s experiences, resulting in either excessive canal expansion or insufficient open-door laminoplasty in most cases, leading to unsatisfactory clinical outcomes. Thus, it is of vital importance to precisely predict the measurements of laminar open angle and gutter-depth and to find out an innovative and effective surgical technique to create accurate hinges during the FDL.

To do so, we specially designed a sharp rongeur with a tip angle of 20°, the technique of making hinges using rongeur has been successfully applied in the FDL procedure based on our previous experiences. However, the clinical outcomes and postoperative complications in making hinges using the newly designed sharp rongeur remained indefinite. Moreover, to the best of our knowledge, there have been few studies reporting the construction of an innovative surgical technique to make hinges using the newly designed sharp rongeur during FDL.

Therefore, the major aims of this study were: (i) to evaluate the accuracy of predicting the laminar open angle using this newly designed sharp rongeur during FDL; (ii) to determine if there would be any differences in the radiological outcomes, the clinical outcomes, and the postoperative complications in making hinges using this sharp rongeur, as compared with the traditional high-speed micro-drill used in FDL; and (iii) to establish an innovative and effective surgical technique to create precise hinges using this sharp rongeur.

**Methods**

**Patients**

This study was approved by the Institutional Review Board (the research and experimental animal ethics committee of the seventh affiliated hospital of Sun Yat-sen university, certificate No.2018SYSUSH-002). Between January 2018 and May 2019, 39 patients with cervical spondylosis accepted FDL, performed by the same chief surgeon in the study hospital. Patients voluntarily agreed to participate in this study and signed the approval for required surgeries. We used the STROBE cross-sectional reporting guidelines.

Patients were included based on the criteria as follows: (i) with the diagnosis of multi-segmental cervical spondylosis (≥3 segments) caused by cervical spinal stenosis (developmental or degenerative), based on patients’ clinical manifestations and concordant imaging examination; (ii) with complete medical records and follow-up (1, 3, and 12 months after surgery, and the final follow-up); and (iii) without neurological symptoms resulting from spinal cord compression of thoracic or lumbar spine. The exclusion criteria: (i) with musculoskeletal trauma, infections, tumors, surgery, or other neurological disorders; (ii) without complete clinical data; and (iii) those followed up less than 1 year.

Based on the method applied for hinge formation during the FDL, patients were divided into two groups: the sharp rongeur group (n = 22, 15 males and 7 females) and the high-speed micro-drill group (n = 17, 13 males and four females). The average age at surgery was 59.1 years (range: 16–85 years), and the average follow-up period was 20.4 months (range: 14.0–25.9 months).

**Sharp Rongeur**

We specially designed a sharp stainless steel rongeur with a tip angle of 20° (Figure 1, the patent application has been...
registered for the rongeur design, Qing Niu Company, Suzhou, China). This specially designed angular sharp rongeur could create hinges of “V” shape to ensure that the two sides of the hinge touch each other closely after expansive laminoplasty, ideally enlarging the laminar open angle about 20°.

**Surgical Procedures**

The FDL was performed following Kurokawa’s method with slight modifications.12 Bilateral hinges were made with the 20° sharp rongeur or the high-speed micro-drill at the border of the laminae and facets based on the group classification (Figure 2(A)). Subsequently, the spinal canal enlargement was achieved by opening the split lamina bilaterally with a spreader, and a sizeable hydroxyapatite spacer was tied to bridge the bilateral edges of the laminae and fixed with wires (Figure 2(B)).

Patients could sit up with a soft neck collar and walk at 24 hours post-surgery. Removal of the soft collar was allowed 1 week after the surgery. All patients were then encouraged to start range of motion and isometric muscle strengthening exercises of the neck as early as possible.

**Clinical and Radiological Analysis**

The operative time and amount of blood loss using this procedure were recorded. At the time of pre-operation, at 1, 3, and 12 months after surgery, and the final follow-up, the neurological status, and clinical outcomes were evaluated using the visual analog scale (VAS), Neck Disability Index (NDI),14 and modified Japanese Orthopaedic Association (mJOA) scale.15,16 The recovery rates using mJOA scores were calculated according to the previous study.16 Routine anteroposterior, lateral, and dynamic X-ray and CT scans were performed before and immediately after the surgery, at 1, 3, and 12 months and the final follow-up (except the dynamic X-ray at 1 month). The laminar open angle was determined by measuring the angle between the lamina and the coronal plane in the CT scans, and this postoperative angle was defined as the open angle (Figure 3). Angles of bilateral sides were then averaged. The C2-7 Cobb angle and the cervical dynamic range of motion (ROM) were also assessed and compared based on our previous study (See supplementary data Figure 1).12 The bony fusion time and the fracture rate of the hinges were also recorded and compared. The criteria of fusion followed the guidelines described by Rhee et al.,17 which was defined as the disappearance of hinge lines, and both the ventral and dorsal cortices were bridged with bone without any distinct visible line on the CT images. All images were assessed by two researchers independently and repeated three times. Concordance Correlation Coefficients (CCC) were used to assess the concordance between the two researchers, and the CCCs of all the measured variables were more than 0.75, which indicated satisfactory concordance.
Statistical Analysis
The SPSS (version 25.0, IBM Corporation, Armonk, NY) was used for the statistical analysis. Quantitative data are presented as the mean ± standard deviation (SD). The data including age at surgery, mJOA score, recovery rates of JOA, NDI, Cobb angle, ROM between the two groups were compared by the unpaired Student’s t-test. The mJOA score, recovery rate of mJOA, VAS, NDI, Cobb angle, ROM, preoperative angle of surgical segment, postoperative angle of surgical segment, enlargement of open angle, operative time, blood loss between the two groups were compared by the Mann–Whitney U test. The laminar fusion rate, laminar fracture rate between the two groups were compared by the chi-squared (χ²) test. The gender, complications between the two groups were compared by the Fisher’s exact test. The VAS and NDI of drill group were compared between preoperative and final follow-up by a paired-sample t-test. The VAS and NDI of rongeur group and open angle of each group were compared between preoperative and final follow-up by a Wilcoxon signed-rank test. The JOA, NDI, and VAS of each group were compared between preoperative and final follow-up by a Wilcoxon signed-rank test. p value <0.05 indicated a significant difference.

Results

Patients’ Demographics
No significant differences were observed between these two groups concerning age, sex, mJOA score, VAS score, NDI, Cobb angle, and the cervical dynamic ROM before surgery (Table 1). There were also no significant differences in the operative time and perioperative blood loss between the groups (Table 2).

Clinical Outcomes
Both groups showed significant improvements in scores of NDI (the rongeur group: 19.23 ± 10.12 vs 7.55 ± 10.65, Z = -3.801, p < 0.001, the drill group: 18.59 ± 7.27 vs 14.71 ± 8.72, t = 2.125, p = 0.049) and VAS (the rongeur group: 3.84 ± 3.68 vs 0.932 ± 1.48, Z = -3.415, p = 0.001, the drill group: 4.82 ± 3.459 vs 1.029 ± 1.700, t = 4.820, p < 0.001) at the final follow-up (p < 0.001, Table 3). No significant differences were also observed in the mJOA and VAS scores at any given time point between the groups. However, much lower NDI scores (7.55 ± 10.65 vs 14.71 ± 8.72, U = 94.000, p = 0.008) were detected in the rongeur group compared to that of the drill group at the final follow-up (Table 3 and Figure 4). There were no significant differences in the recovery rates based on mJOA scores between the groups at 1, 3, and 12 months post-operation. The rongeur group showed a higher recovery rate in mJOA scores compared to that of the drill group at the final follow-up (0.84 ± 0.14 vs 0.72 ± 0.18, U = 115.000, p = 0.042, Figure 4).

Radiological Outcomes
As shown in Table 4, there were no significant differences in the laminar open angles between the groups preoperatively. After the operation, open angles in the rongeur and drill groups were significantly increased by 22.78° ± 4.34° and 32.75° ± 4.22°, respectively, compared to those before operation (rongeur group: Z = -4.107, p < 0.001; drill group: Z = -3.621, p < 0.001). The

| TABLE 1 Patient demographics |
|-----------------------------|
| Groups | Age at surgery (years) | Gender (male:female) | Preoperative mJOA score | Preoperative VAS score | Preoperative NDI | Preoperative Cobb angle (°) | Cervical ROM before surgery (°) |
|-------|---------------------|------------------|------------------------|--------------------|-----------------|----------------------|-------------------------------|
| Rongeur (n = 22) | 59.32 ± 11.33 | 15:07 | 10.46 ± 3.47 | 3.84 ± 3.37 | 19.23 ± 10.12 | 11.89 ± 17.06 | 38.91 ± 10.73 |
| Drill (n = 17) | 58.88 ± 16.68 | 13:04 | 10.71 ± 2.49 | 4.82 ± 3.46 | 18.59 ± 7.27 | 11.82 ± 13.09 | 39.88 ± 13.93 |
| t or U | 0.097 | / | 185,000 | 165,000 | 185,000 | 184,500 | 186,500 |
| p value | 0.923 | 0.725 | 0.967 | 0.547 | 0.967 | 0.944 | 0.989 |

Abbreviations: mJOA, modified Japanese Orthopaedic Association; NDI, neck disability index; ROM, range of motion; VAS, visual analog scale.

| TABLE 2 Comparison of surgical parameters |
|------------------------------------------|
| Groups | Operative time (min) | Blood loss (mL) |
|-------|---------------------|----------------|
| Rongeur (n = 22) | 171.1 ± 36.9 | 111.4 ± 48.6 |
| Drill (n = 17) | 156.8 ± 47.8 | 126.5 ± 98.2 |
| t or U | 130,500 | 182,500 |
| p value | 0.110 | 0.900 |

FIGURE 3 The radiological measurement of lamina open angle. The laminar open angle was defined as the angle between the line along the lamina and the line drawn parallel to the posterior border of the vertebral body in the exact axial section. (A) The lamina open angle before operation; (B) The lamina open angle after operation.
predictive enlargement of the laminar open angle was about 20° using the sharp rongeur, however, the actual enlargement was 22.78° ± 4.34° on average, which showed significant differences compared to the drill group (32.75° ± 4.22°, U = 19,000, p < 0.001).

Based on the criteria of bony fusion at 1-month postsurgery, 45 out of 132 hinges were fused in the rongeur group (Figure 5), and the fusion rate was 34.1%. While, in the drill group, only 15 out of 102 hinges were fused, and the fusion rate was only 14.7%, which was significantly lower compared with that of the rongeur group ($\chi^2 = 11.340, p = 0.001$).

At 3 months post-surgery, fusion rates in the rongeur and drill groups were 89.4% and 82.4%, respectively, and all hinges were fused within 12 months. There were no significant differences in the fusion rates between the groups at 3 ($\chi^2 = 2.416, p = 0.120$) and 12 ($\chi^2 = 0, p = 1.000$) months after surgery. The representative CT imaging of hinges in the rongeur and drill groups are shown in Figures 6 and 7, respectively.
In the rongeur group, 10 out of 132 laminas were found fractured in the first CT scan after surgery, with the laminar fracture rate of 7.8%, while in the drill group, 26 of 102 laminas were fractured, having a fracture rate of 25.5%. There was a statistical difference between the groups ($\chi^2 = 14.185$, $p < 0.001$).

There were no significant differences in Cobb angles and cervical dynamic ROMs between the groups at each time point pre- and postoperatively, as shown in Figure 8 and Table 5.

**Surgery-Related Complications**

In terms of ANP, only one patient in the rongeur group complained about mild axial pain, and three of 17 patients in the drill group also showed similar symptoms but without significant differences between the groups (Fisher’s exact test, $p = 0.300$). One patient was suffering from the superficial infection in the drill group, and another patient from superficial fat liquefaction in the rongeur group. Both were cured after medications and dressing changes. The other common complications, such as C5-NRP and lamina closure, were not detected in both groups.

**Discussion**

In this current study, we demonstrated a novel method of making hinges using a newly designed sharp rongeur to enhance radiological and clinical outcomes in French-door cervical expansive laminoplasty compared with the outcomes of the traditional micro-drill method.
The Newly Designed Sharp Rongeur Enhances the Accuracy of the Prediction of the Open angle and Hinge Creation

The laminal open angle in the cervical laminoplasty is closely related to the prognosis, suggesting that the open angle should be less than 60°.6 The excessive open angle may cause posterior spinal cord movement increasing the rates of postoperative ANP and C5-NRP.7,18 In this study, the postoperative open angle in the rongeur group was significantly less than that in the drill group. In agreement with previous suggestions that the open angle should be no more than 60°, owing to the preoperative laminar angle of about 36°–37°, we designed the sharp rongeur with a tip angle of 20° to make hinges during the FDL. Ideally, the rongeur was able to limit the shape and depth of the hinges and enlarge the laminal open angle at about 20°. The open angle enlargement was 22.78° on average using this sharp rongeur, which was greater than 20°. That might be due to the repeated manipulation of biting during the operation. Indeed, it was difficult to predict the open angle precisely before the operation. However, we could estimate the approximate enlargement of the laminar open angle preoperatively using this sharp rongeur, which was helpful for surgeons controlling the angle.

In our opinion, the use of the high-speed micro-drill to make hinges during the cervical laminoplasty could be more vulnerable to removing excessive bone fragments along the hinge line. Consequently, this caused the excessive open angle and an increased rate of postoperative laminar fracture, which was significantly different from the preoperative estimations.9,19 Here, results showed that the fracture rate of the lamina in the rongeur group was significantly lower than that in the drill group. This demonstrated that it was much safer to make hinges using our newly designed sharp rongeur during FDL.

The Designed Sharp Rongeur Enhances more Satisfactory Radiological and Clinical Outcomes for FDL, Compared to the Traditional High-Speed Micro-Drill

Considering the thermal effect, the application of high-speed micro-drills can stop excessive blood loss due to a localized increase of temperature during the surgery.20 However, our study detected that there was no statistical difference in terms of intra-operative blood loss between the groups. As concerned, skilled operators and tamping hemostatic materials can effectively reduce the intra-operative bleeding using this sharp rongeur.

The reduction of cervical ROM is one of the major complications of cervical laminoplasty.21 The cervical ROM decreases by 30%–70% after laminoplasty, depending on the surgical method, the number of vertebrae involved in surgery, the open angle, functional exercise, and the wearing time of the neck collar.22 Several studies have reported that the destruction of the C7 structure may lead to the missing of the cervical ROM.23–25 There was no significant difference in the cervical ROM between the groups in our study, indicating that the use of sharp rongeur to make hinges did not cause a further reduction in the cervical ROM compared...
with the high-speed micro-drill procedure. Consequently, the occurrence rate of axial symptoms, which were positively related to the reduction of the cervical ROM, also showed no significant difference between the groups. Of note, there was no occurrence of CS-NRP in both groups, which might be due to the relatively small sample size in this study.

It is noteworthy that the NDI and recovery rate of the mJOA score in the rongeur group showed significant improvement at the final follow-up compared to that of the drill group, although there were no significant differences between the groups in the early period. We speculated that the use of this sharp rongeur could reduce the manipulation-related destruction of the facet joints compared to the high-speed micro-drill technique and thus could delay the degenerative processes of the cervical spine, which could help in improving clinical symptoms.

An Innovative and Effective Surgical Technique to Create Precise Hinges Using this Sharp Rongeur during FDL

Lamina closure is also a common complication of postoperative cervical laminoplasty. The percentage of postoperative re-closure has been reported to be 34%. The major reasons include the weak fixation and the delayed union or non-union of the gutters. The bone structure at the cervical lamina consists of the dorsal, ventral, and cortical bones, as well as the cancellous bone between these two parts. During the laminoplasty, a fracture could form on one or both sides of the lamina. Ideally, the ventral-cortical bone at the lamina should be partially intact after surgery, forming an incomplete fracture. Fracture healing gradually arises at the hinges postoperatively. However, if the ventral cortex ruptures, the healing could be inevitably prolonged. Studies have reported that the excessive removal of the cancellous bone can lead to delayed union or non-union of bones, and bone healing is better if the lamina is thicker. In our study, a specially designed sharp rongeur was used to safely make hinges avoiding the rupture of ventral-cortical bone and maintaining the hinges in “V” shapes. This method would allow the two sides of the hinge to touch each other closely, which was demonstrated to accelerate the fusion time and reduce the laminar fracture rate. Functional mechanisms of the sharp rongeur could be postulated as: first, the enormous heat generated during the use of the high-speed drill may induce bone cell apoptosis, loss of local blood supply, and enhancement of local osteoclast activity, resulting in the delayed union, in agreement with the previous study that irreversible apoptosis of the bone cells could be induced by heating at 47 °C for 60 s or at 55 °C for 30 seconds, the shape of the hinge gutter made by sharp rongeur was similar to a triangle, compared to the gutter made by bone drilling, which could make the inner walls of the gutters closer and be beneficial to the bony fusion, and finally, the inner walls of gutters made by rongeur were relatively rough, which was conducive to the migration and crawling of osteocytes.

Limitations and Strengths

The current study has several limitations. This was a retrospective study, and the sample size might be insufficient. Besides, we did not evaluate the long-term efficacy of the FDL using the newly designed sharp rongeur. Further study would be needed to expand the sample size, extend the follow-up time, and clarify the association of long-term outcomes with the instrument types being used for making hinges. Nonetheless, we controlled all our measurements as these data were measured by three independently experienced clinical spine surgeons. Despite the relatively small size, and inadequate follow-up time, the results of our study also provide certain important information for future high-quality study. Moreover, the specific mechanism of sharp rongeur to promote the healing of the hinges is being conducted.

Conclusion

Use of the special sharp rongeur with a tip angle of 20° could be a preferred method to make hinges during FDL, which can predict the laminal open angle accurately and enlarge it to about 23°, thus reducing the fracture rate and accelerating the bony fusion of hinges compared with the outcomes of the traditional micro-drill method.

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Ethics Statement

All authors listed meet the authorship criteria according to the latest guidelines of the International Committee of Medical Journal Editors, and all authors are in agreement with the manuscript.

Author Contributions

Conceptualization: Fuxin Wei and Shaoyu Liu. Data collection: Lanze Yu, Xizhe Liu, and Guoliang Chen. Formal analysis: Xuenong Zou, Dacheng He and Yanrun Li. Data analysis: Jiaming Yang, Shangbin Cui, and Le Wang. Writing—original draft: Ningning Chen and Lanze Yu. Writing—review and editing: Fuxin Wei.

Conflict of Interest

There are no conflicts of interest to disclose.

Supporting Information

Additional Supporting Information may be found in the online version of this article on the publisher’s web-site:

Supplementary Data: Supporting Information.
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