Safety and efficacy of three-dimensional printed patient-specific drilling templates for expansive open-door laminoplasty

Kang-Kang Huang¹, Xin Rong¹, Hao Liu¹, Bei-Yu Wang¹, Hua Chen¹, Ying Hong²

¹Department of Orthopedics, West China Hospital, Sichuan University, Chengdu, Sichuan 610041, China; ²Department of Operation Room, West China Hospital, Sichuan University, Chengdu, Sichuan 610041, China.

To the Editor: Expansive open-door laminoplasty (EOLP) is commonly performed for patients with multi-level cervical myelopathy of various causes. Nevertheless, there are still several complications. Among them, displaced complete fracture of the hinge side and lamina re-closure could result in neurological function deterioration. Chen et al.¹ reported that the use of the mini-plate could significantly reduce the incidence of lamina re-closure compared with the traditional suture technique. Nevertheless, the complete fracture rates were around 56.8% for both the mini-plate group and the suture suspension group. Accurately locating the trough position has been reported to lower the incidence of hinge side complete fractures.² In this study, three-dimensional (3D) printed patient-specific drilling templates were fabricated to guide the trough position in EOLP,³ to validate the safety and efficacy of the 3D printed templates.

This study was approved by the Ethics Committee of West China Hospital and all patients provided written informed consent. Between July 2016 and February 2018, a total of 22 patients underwent EOLP from C3 to C7 with the aid of the 3D printed patient-specific drilling templates in Department of Orthopedics, West China Hospital were retrospectively reviewed.

The patient’s pre-operative computed tomography (CT) scan was used for cervical spine reconstruction (Mimics 17.0, Materialize, Belgium). Two cutting paths were simulated at the junction between the lamina and the lateral mass. Next, part of the lamina surface was extracted to create the template body, which was then subtracted by the two cutting paths. Thereafter, the designed template was fabricated by a 3D printer in acrylate resin using stereolithography (Beijing AK Medical Co., Ltd., Beijing, China). Subsequently, the templates were thoroughly washed and vacuum dried. After sterilization with ethylene oxide, the 3D printed templates were stocked in plastic bags for later use [Supplementary Figure 1, http://links.lww.com/CM9/A101].

After the lamina was exposed, the template was firmly pressed to the lamina at each level. On the open side, the lamina was cut through along the cutting path. On the hinge side, the trough was created by sliding the bur along the path [Supplementary Figure 2, http://links.lww.com/CM9/A101]. Then, the lamina was opened carefully. The dural adhesions were carefully separated and the canal was decompressed properly. Then the Centerpiece mini-plate (Centerpiece™ Plate Fixation System; Medtronic Sofamor Danek, Memphis, Tennessee, USA) was anchored to the lamina and lateral mass.

Clinical evaluations were performed before surgery and at each follow-up of 1 week, 3, 6, and 12 months. The neurological function was assessed by the Japanese Orthopedic Association (JOA) score. The visual analog scale (VAS) score was used to evaluate neck pain intensity. The occurrence of complications, including wound infection, cerebrospinal fluid (CSF) leakage, axial symptoms, and C5 palsy, were recorded and dealt with accordingly. The anteroposterior diameter of the canal, the Pavlov ratio, the C2 to C7 Cobb angle, and the C2 to C7 range of motion (ROM) were all determined on X-ray films. The fracture type on the hinge side was assessed using the CT imagery 1 week after surgery. The occurrence of lamina re-closure was recorded, when a 10% decrease in the Pavlov ratio occurred.

Statistical analysis was performed using the SPSS software version 19.0 (SPSS Inc., Chicago, IL, USA). Continuous parameters were presented as mean ± standard deviation (SD). The paired Student’s t test was performed to test the difference before and after surgery. A value of P < 0.05 was considered statistically significant.

Access this article online

Quick Response Code: 10.1097/CM9.0000000000000476

Correspondence to: Dr. Hao Liu, Department of Orthopedics, West China Hospital, Sichuan University, 37# Guoxue Lane, Chengdu, Sichuan 610041, China. E-Mail: dr.liuhao6304@hotmail.com.
Finally, 22 patients (13 men and nine women) were included in this study, with median age of 57.1 years (range: 42.0–76.0 years). Laminoplasty was performed on a total of 110 levels. The mean operating time was 130.10 ± 11.83 min and mean blood loss was 225.40 ± 92.69 mL. Both the JOA and VAS scores improved significantly after surgery [Table 1]. Three patients experienced intensive neck and shoulder pain post-operatively. The axial symptoms were relieved after 1 month of physical therapy. One patient suffered from CSF leakage, and was treated with sustained drainage and recovered within 2 weeks. One patient developed transient symptoms of C5 palsy and spontaneously recovered within 1 month. No template-related complications were observed. The anteroposterior diameter and the Pavlov ratio increased significantly after surgery.

The C2 to C7 Cobb angle the C2 to C7 ROM decreased significantly after surgery.

A total of 110 hinge side troughs were analyzed. Based on the 1-week CT scans, 16 out of the 110 (14.5%) were completely fractured. The number of complete fractures between different levels was no significantly different (three for C3, two for C4, three for C5, four for C6, and four for C7, \( \chi^2 = 1.0239, P = 0.9061 \)). The fusion rates for the complete fracture at the hinge side at 3, 6, and 12 months were 81.3%, 93.8%, and 100.0%, respectively. No lamina re-closure was observed during the follow-ups [Supplementary Figure 3, http://links.lww.com/CM9/A101].

The complete fracture of the lamina on the hinge side which could compromise the stability of the lamina has been reported to range from 9% to 56.8%.[1,4,5] We previously reported the complete fracture rate as 56.8%, among which 3.68% of the lamina displaced into the canal.[1] Although no spinal disorders were detected in these patients during the follow-up, a longer observation time is still needed.

The hinge position was a risk factor for the complete fracture on the hinge side. According to the study conducted by Lee et al,[2] the medially located hinge gutter (over 1.9 mm from pedicle on outer cortex) seemed to be an important risk factor for the hinge fracture. The ideal position of the hinge-side trough was at the junction between the lamina and the lateral mass. In our study, the 3D printed templates were used to guide the position of the hinge-side trough. As a result, the hinge side complete fracture occurred in 16 laminae. Compared with the previous studies,[1] especially at the lower cervical level, the incidence of complete fracture was low in this study.

Table 1: Clinical and radiographic results of all patients in this study.

| Parameters                  | Values     | \( t \)  | \( P \) |
|-----------------------------|------------|----------|--------|
| JOA score                   |            |          |        |
| Pre-operation               | 8.55 ± 2.10| 6.00     | <0.0001|
| 3 months post-operation     | 11.9 ± 1.80| 14.38    | <0.0001|
| 6 months post-operation     | 13.05 ± 2.13| 9.85     | <0.0001|
| 12 months post-operation    | 14.32 ± 1.29| 11.41    | <0.0001|
| VAS score                   |            |          |        |
| Pre-operation               | 5.74 ± 1.08| 14.38    | <0.0001|
| 3 months post-operation     | 3.31 ± 0.80| 9.85     | <0.0001|
| 6 months post-operation     | 3.15 ± 1.13| 11.41    | <0.0001|
| 12 months post-operation    | 2.82 ± 0.79| 5.08     | <0.0001|
| C2-C7 Cobb (°)              |            |          |        |
| Pre-operation               | 19.21 ± 5.71| 5.08     | <0.0001|
| 3 months post-operation     | 16.37 ± 5.12| 5.61     | <0.0001|
| 6 months post-operation     | 15.98 ± 4.03| 2.67     | <0.0142|
| 12 months post-operation    | 14.88 ± 4.40|          |        |
| C2-C7 ROM (°)               |            |          |        |
| Pre-operation               | 48.48 ± 12.45| 4.59     | 0.0002 |
| 3 months post-operation     | 43.62 ± 8.79| 4.96     | <0.0001|
| 6 months post-operation     | 41.57 ± 11.03| 2.72    | 0.0129 |
| 12 months post-operation    | 39.86 ± 13.97|         |        |
| Anteroposterior diameter (mm) |          |          |        |
| Pre-operation               | 10.82 ± 2.50| 28.51    | <0.0001|
| 3 months post-operation     | 17.33 ± 3.01| 30.95    | <0.0001|
| 6 months post-operation     | 17.24 ± 2.89| 6.52     | <0.0001|
| 12 months post-operation    | 17.09 ± 3.07|          |        |
| Pavlov ratio                |            |          |        |
| Pre-operation               | 0.44 ± 0.11| 30.13    | <0.0001|
| 3 months post-operation     | 0.91 ± 0.17| 28.31    | <0.0001|
| 6 months post-operation     | 0.89 ± 0.12| 11.24    | <0.0001|
| 12 months post-operation    | 0.89 ± 0.15|          |        |

\(^*\) Compared with the pre-operative parameter. JOA: Japanese Orthopedic Association; VAS: Visual analog scale; ROM: Range of motion.
In conclusion, the use of 3D printed drilling templates was safe and effective in EOLP, which also seemed to be able to lower complete fracture rate on the hinge side.

**Funding**

This study was supported by grants from the Health Commission of Sichuan Province of China (No.17PJ202) and the Sichuan Province Science and Technology Program of China (No. 18ZDYF2182).

**Conflicts of interest**

None.

**References**

1. Chen H, Liu H, Zou L, Li T, Gong Q, Song YM, et al. Effect of mini-plate fixation on hinge fracture and bony fusion in unilateral open-door cervical expansive laminoplasty. Clin Spine Surg 2016;29:E288–E295. doi: 10.1097/BSD.0000000000000131.
2. Lee JH, Chough CK. Risk factors for hinge fracture associated with surgery following cervical open-door laminoplasty. Korean J Neurotrauma 2018;14:118–122. doi: 10.13004/kjnt.2018.14.2.118.
3. Rong X, Wang BY, Deng YX, Liu H. Three-dimensional printed patient-specific drilling templates for expansive open-door laminoplasty. Chin Med J 2016;129:2644–2646. doi: 10.4103/0366-6999.192786.
4. Park YK, Lee DY, Hur JW, Moon HJ. Delayed hinge fracture after plate-augmented, cervical open-door laminoplasty and its clinical significance. Spine J 2014;14:1205–1213. doi: 10.1016/j.spinee.2013.08.012.
5. Lee DH, Kim H, Lee CS, Hwang CJ, Cho JH, Cho SK. Clinical and radiographic outcomes following hinge fracture during open-door cervical laminoplasty. J Clin Neurosci 2017;43:72–76. doi: 10.1016/j.jocn.2017.04.037.

How to cite this article: Huang KK, Rong X, Liu H, Wang BY, Chen H, Hong Y. Safety and efficacy of three-dimensional printed patient-specific drilling templates for expansive open-door laminoplasty. Chin Med J 2019;132:2641–2643. doi: 10.1097/CM9.000000000000476