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CERVICAL SPINOLAMINOPLASTY WITH NEWLY DESIGNED TITANIUM MINI-PLATES

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One of the complication of cervical laminoplasty is the restenosis of the opened laminae. Weakness of the screws placed on laminae may cause restenosis. Here, we describe a new technic 'spinolaminoplasty (Turkish Open-door laminoplasty)' with newly designed titanium mini plate that placed one side to lateral mass, and the other on spinous process to keep the laminae opened. Two different fixation materials were used for axial compression tests. One was Ultra high molecular weight polyethylene block with cervical vertebrae geometry and fresh ovine cervical vertebrae. In the first group, mini plates were fixed on laminae as in the conventional method described by Hirabayashi. In the second group, mini plates were fixed on spinous process to perform spinolaminoplasty with single and double screws. New fixation method with double screw provides 26% higher stiffness than the closest group, namely new fixation on polyethylene block. And new fixation method with double screw was exhibited significantly higher ($P < 0.005$) performance between the Ovine groups. As in the spinolaminoplasty technic fixing the mini plates to spinous process with longer screws instead of laminae, strengthens the system compared to the conventional method. This proves that rigidity of new construction model is more stable than the conventional method. Tight fixed laminae may prevent restenosis. Also applying the screw through spinous process instead of laminae may prevent the possible cord injuries.

Keywords: Laminoplasty; open-door; restenosis.

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1. Introduction

An ideal method for surgical decompression in patients with cervical spondylosis is still controversial. For many years, multi-level laminectomy has been the preferred method for cervical spondylosis.[1–5] In long-term follow-up examinations of this method, two complications often emerge, a kyphosis deformity and instability. Posterior cervical instrumentation was initially used in conjunction with a laminectomy due to the effects these complications have on a patient's quality of life.[6,7] As a result, after laminoplasty had applied, a laminectomy was developed as a new method to the prevent instability and the limited mobility. Laminoplasty was initially used for the treatment of multi-level cervical spinal stenosis during the early 1970s.[7–9] As a result of the protection provided to the posterior elements with a laminoplasty, spine stability is ensured and the membrane formation observed during the post-operative period is prevented. Several variations of the laminoplasty technique have been described.[2–5,7,8,10–14] In 1973, Oyama *et al.*[15] developed the Z-laminoplasty technique and later, in 1977, Hirabayashi *et al.*[7] developed the open-door laminoplasty technique. The intent of these two techniques was to increase the canal diameter by completely cutting the side of the lamina causing the spinal cord narrowing, and trimming the other side through the use of a high speed burr; thus, the lamina is overturned in a contralateral manner, like a door opening with a hinge.[7] Later, Kurokowa *et al.* defined the french door laminoplasty by separating the spinous process into two parts.[16] After separating the spinous process, a bone graft was placed in order to enlarge the canal.

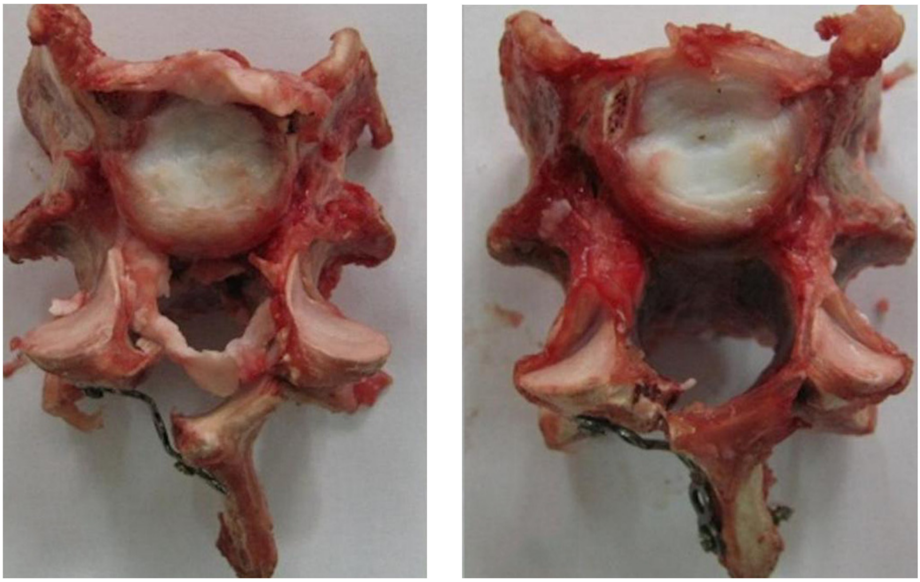
One drawback of laminoplasty is the problem of reclosure.[11] The aim of this study was to use an innovative design of mini-plates during laminoplasty to ensure the lamina remain open, and to compare the advantages and disadvantages of this system with previous techniques. Here, we describe a new titanium spacer that is inserted onto the spinous process that keeps the laminae opened and makes it easier to perform the classical method.[3]

2. Materials and Methods

In this study, two different fixation methods were tested with newly designed titanium miniplates (Ti6Al4V) being used for both methods.

The first method was the conventional method, previously described by Hirabayashi *et al.*[7] Briefly, the plate was fixed to the cervical vertebrae with two screws. One of the screws was placed on the lateral mass, and the other screw was placed on the lamina. A schematic view of the plate and fixation method can be seen in Fig. 1.

The second method was the new open-door laminoplasty technique. This technique was applied in two different methods. In the first method, two screws were used. One of the screws was placed on the lateral mass, and the other screw was placed on the spinous process. In the second method, three screws were used. One of them was placed on the spinous process, and the other screws were placed on the



(a) (b)

Fig. 1. Photographs of laminoplasty applied ovine cervical vertebrae. (a) Conventional method fixation and (b) Novel method fixation.

lateral mass. A schematic view of the plates and fixation methods can be seen in Fig. 1.

Both fixation methods were applied on the cervical vertebrae. Fresh frozen ovine vertebrae were used in tests. Fresh frozen cadavers were stored in a deepfreeze at -20°C. All samples were thawed at room temperature under laboratory conditions for 24 h before the tests. Saline was sprayed through the test samples during the tests to simulate *in vivo* conditions. Segments were randomly selected and a notch was opened on one side of the lamina, then, the lamina was cut from the opposite side. The lamina was opened until the opening was large enough to permit decompression. Then, plates were placed to conserve the space and fixed with appropriate screws. After that, a compression test was applied to both the polyethylene (PE) models (Fig. 2) and the ovine models (Fig. 3), as described in the figures. An axial compression force was applied with a constant cross head speed of 5 mm/min for all test protocols. Load and displacement plots were recorded with the 4 aid of an Instron 3300 testing machine and control system. The yield load was calculated with the 0.002 offset method. To the knowledge of authors, this is the first study on the mechanical loading of laminoplasty plates on site. There is no study in literature to evaluate the gap closing force on laminoplasty. However, on the flexion and rotation movements there is compression load on lamina and plate. Paraspinal muscles and other soft tissue cover the lamioplasty zone. That soft tissue is aligned longitudinally and attached to lower and upper

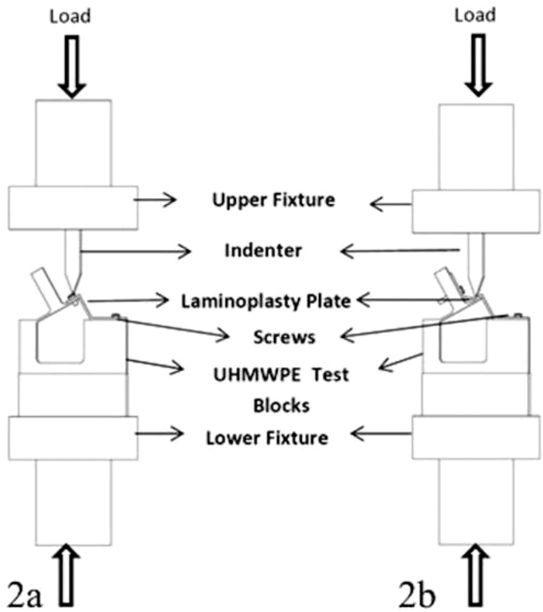


Fig. 2. Compression test setup for PE models. (a) Conventional method and (b) Novel method.

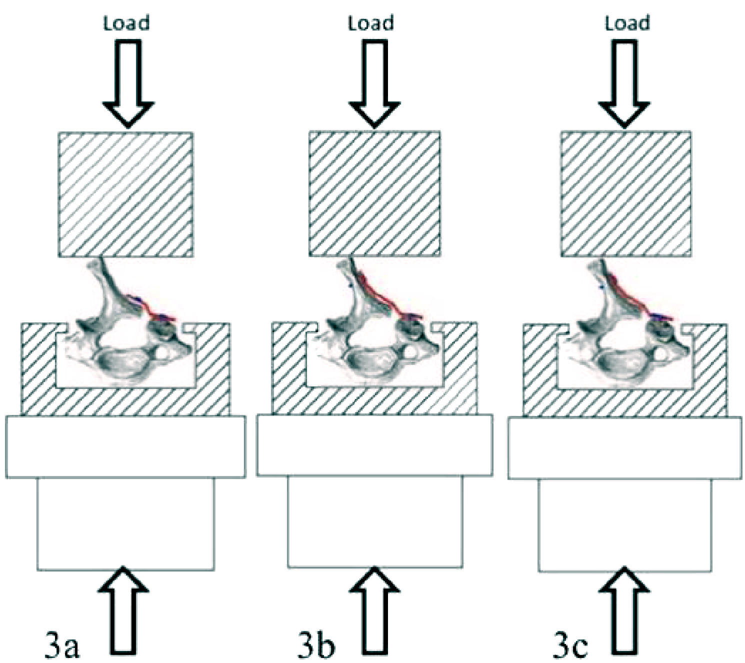


Fig. 3. Compression test setup for ovine models. (a) Conventional method, (b) Novel method (2 Screws) and (c) Novel method (3 Screws).

segments. This cause compression on plate during the flexion and rotation movements. With our method we have firstly described the required load value to close the gap.

Two different fixation materials were used for axial compression tests. One was an ultrahigh molecular weight polyethylene (UHMWPE) P1000 block with a cervical vertebrae geometry, and other was an ovine cervical vertebrae. The UHMWPE P1000 has a specific gravity of 0.930 g/cc, a hardness-shore D value of 60–70, the tensile strength at break was 40 MPa, the tensile strength at yield was 20 MPa, and the elasticity modulus was 0.6 GPa. Ovine bone was 2 years old and healthy. Bone mineral densities were measured by dual X-ray absorptiometry (DEXA). According to the T-Score values of tested samples, all tested samples were healthy with a T-Score of 2.3.

Displacement-controlled fatigue tests were also conducted on the plates. Laminoplasty plates were fixed to the synthetic testing blocks, made of UHMWPE P1000 that simulate cervical vertebrae of a healthy ovine, as shown in Fig. 4. These test blocks were mounted onto upper and lower fixtures of the test apparatus to apply fatigue tests at 10 Hz test frequency with a sinusoidal waveform. A 3 mm axial displacement was applied to all tested samples. Failure criteria for fatigue tests were

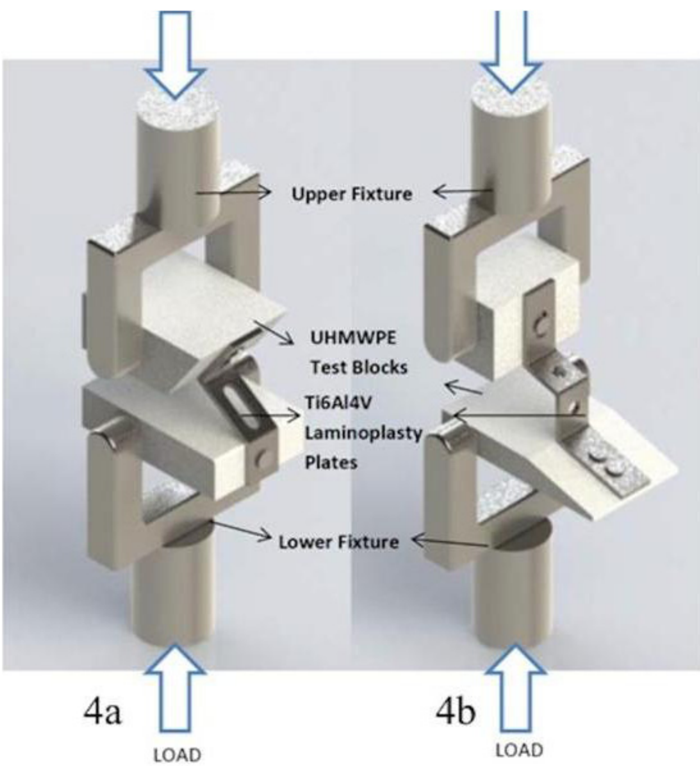


Fig. 4. Fatigue test setup. (a) Conventional method and (b) Novel method.

accepted as a plate, screw, or PE block failure. The specimens, which could endure 5,000,000 cycles, were successfully approved.

3. Experimental Results

3.1. *Statistical analysis*

t-test analyses were performed to determine whether the pullout dataset groups of tested samples were statistically similar or significantly different from each other.

According to the test results, there were no differences between fixation techniques when comparing the compression strengths on PE blocks. The upper yield loads were nearly equal. Similarly, stiffness differences between the two groups were less than 4%.

The ovine model with the conventional fixation method provided 47.1 N/mm stiffness, whereas this value was 53.1 N/mm and 93.4 N/mm for the new fixation method with single and double screws, respectively.

The highest upper yield load of 203.6 N was achieved by the ovine model with double screws through all tests. The lowest yield load of 76.7 N was again provided by the ovine model, but with a single screw. Additionally, the new fixation method with double screws provided 26% higher stiffness than the next closest group, the new fixation on the PE Block.

The stiffness difference between groups of fixation techniques tested on ovine vertebrae was possibly due to the bone section bias. C2–C7 vertebral segments were randomly used in the tests.

When comparing the new fixation technique on PE blocks, both groups exhibited similar ($p = 0.21$) performances. Alternatively, the new fixation method with double screws exhibited significantly higher ($p < 0.005$) performance between the ovine groups.

Mean upper yield values were similar ($p = 0.43$) for PE block tests. The maximum differences were seen between the new fixation with double screws and the new fixation with a single screw on ovine models, specifically, 126 N, a significant difference per t-test results.

Both fixation types completed fatigue tests without failure (Fig. 4).

4. Discussion

The controversy over whether a laminoplasty is superior to a laminectomy for the treatment of multiple cervical spondylosis remains unresolved. Cervical laminoplasty was developed as an alternative treatment to laminectomy for multilevel cervical stenosis.[14,17] It is possible to perform a laminoplasty on a straightened spine, but it is contraindicated in a kyphotic cervical spine. The development of post-surgical cervical kyphosis has been well described.[18,19] The risk has been shown to be reduced with lateral mass fixation. 20 Kyphosis developing as a result of a posterior cervical surgery is a major problem with these techniques. Studies indicate that the degree of kyphosis developing during a post-operative period is directly related to the neurological clinic.[9,20]

Various animals have been used in biomechanical studies for several reasons. There is some difficulty in obtaining *in vitro* models from human cadavers, they also come with high costs, and some variability. The reasons why we chose an *in vitro* animal model were because animal cadavers are easy to obtain, they are also inexpensive and have little variation. The reason we used sheep as an animal model was because sheep spines are similar to the human spine from a biomechanical viewpoint; this may be because sheeps tend to keep their heads in an upright position. Furthermore, studies suggest that the cervical spine in sheep is an appropriate model for humans in both anatomical and biomechanical aspects. Kandziora *et al.* compared the anatomic, radiographic, computerized tomographic, and biomechanical data of human and sheep cervical spines; their findings indicate a good comparability and encouraged the use of the sheep cervical vertebrae as a model for human cervical spine research.[21–33] The use of animal models also have some disadvantages including differences in anatomy, size, and kinematics compared with humans; however, animal models offer the advantages of good homogeneity (in terms of age, weight, and gender), availability, and similarities to humans. Additionally, the uncovertebral joints of the cervical spine in humans are not available in sheep. The function of this structure is not exactly known; however, it occurs at the outer edge of the endplate providing the unification of lower and upper vertebrae and is believed to provide a sliding back of the vertebrae and limited the lateral flexion.[1,9]

The aim of a laminoplasty is to enlarge the spinal canal and also preserves the stability of the cervical spine after decompression and prevents the development of post-laminectomy membrane.

One of the complications of cervical laminoplasty is the reclosure of the opened laminae. The incidence of reclosure of opened laminae is 1.5–10% in some studies.[4,7,14,31,34] Matsumoto *et al.* reported a rate of 34% for lamina closure in their patients. 15 Closure of the lamina are typically seen after one to three months following surgery.[5,25]

The original open-door laminoplasty was described by Hirabayashi *et al.*[7] In this technique, the supraspinous and interspinous ligaments are preserved during the exposure from C2 to C7.

Laminae are drilled down to the ligamentum flavum on the opened side and thinned on the closed side. Then, the laminae have to be opened carefully toward the closed side to avoid a spinal cord injury.

The inadequate fixation of an open laminae, or a fracture of the hardware, may cause restenosis. Strengthening the open lamina may prevent the reclosure until bone formation occurs.

In our study, we used longer screws that were placed on the spinous process to strengthen the hardware and prevent the closure of the opened laminae. As shown in Table 1, the new method had a stiffness that was 4% greater than the conventional

Table 1. Compression test results of tested fixation techniques.

			Upper yield (N)	Displacement at upper yield (mm)	Stiffness (N/mm)
Novel fixation method	PE Block	mean	110,64	1,43	69,4
		std	16,64	0,28	4,7
	Ovine vertebrae-single screw	mean	76,7	1,5	53,1
		std	10	0,5	5,6
	Ovine vertebrae-double screws	mean	203,6	2,7	93,4
		std	16,1	1,4	9,1
Conventional fixation method	PE Block	mean	110,87	1,68	65,94
		std	9,3	0,05	6,55
	Ovine vertebrae	mean	180,35	3,9	47,1
		std	14,2	0,4	6

method tested on PE blocks, but this difference was not statistically significant. The similarity may be due to the PE blocks simulating cortical bone of a healthy human. We also decided to test the fixtures on ovine cervical vertebrae. The ovine model test results showed that the new fixation method significantly increased the stiffness of the system under compression loads, especially when employed with a double screw. The highest upper yield load of 203.6 N was achieved by the ovine model with double screws through all tests. The lowest yield load of 76.7 N was also provided by the ovine model, but with a single screw. This strongly addresses the importance of the usage of the double screw with this new method. The stiffness difference between groups of fixation techniques tested on ovine vertebrae may be due to the bone section bias. C2–C7 vertebral segments were used randomly in tests. Overall, the new fixation method with double screws, among all the tested samples, exhibited the highest performance results on mechanical compression tests.

We suggest that restenosis, which is encountered in the technique of Hirabayashi *et al.*, and reported at a rate of 10–34%, will be significantly reduced with the new methods we have applied.[4,7,9,11,14,31,34] Meanwhile, the load resistance of the system may increase 2.5 fold due to the use of the longer screw system over that used by Hirabayashi *et al.*, this should improve the overall stability of the spine. Additionally, neural traumas, which may occur with the screw system used in the Hirabayashi *et al.* technique with the tube, are minimized with our screw system since our system does not have an association with the neural tube.

Neurological complications of laminoplasty are theoretically less than with a laminectomy.[14,26] During the removal of laminae, neurological deficits may occur through mechanical injury. It is well known that patients with severe cord compression by ossification of the posterior longitudinal ligament (OPLL) run a potential risk of spinal cord injury from minor trauma.[17] This new model may lead to preventing compression on the spinal cord during the procedure and decrease minor traumas to the spinal cord. In this model, screws are inserted on spinous processes instead of the laminae. Therefore, we think that another advantage of this model is that it may cause less neurological deficits compared to conventional laminoplasty. Further benefits may include decreases in overall surgery time and, during the surgery, protecting the spinal cord by putting a Penfield under the laminae is unnecessary.

5. Conclusion

Biomechanical studies of the newly designed titanium mini-plate tested on a PE model and on fresh ovine vertebrae showed that using longer screws applied to the spinous process strengthened the system and offered more resistance under heavy loads. The new fixation model, with double screws, has a stiffness of approximately twice the conventional model fixation's stiffness and 1.5 times the new fixation model single screw's stiffness. Tightly fixed laminae may prevent restenosis. Another advantage of this new technique is that by applying the screw through the spinous process, it may prevent possible spinal cord injuries.

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