Spine

SPINE Volume 42, Number 24, pp 1844–1850

Laminoplasty Does not Lead to Worsening Axial Neck Pain in the Properly Selected Patient With Cervical Myelopathy

A Comparison With Laminectomy and Fusion

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Study Design. Retrospective cohort study of prospectively collected data.

Objective. To determine if laminoplasty (LP) is associated with worsening axial neck pain in patients with multilevel cervical myelopathy, and to compare neck pain, clinical outcomes, and radiographic measures in a group undergoing laminectomy and fusion (LF).

Summary of Background Data. Postoperative new or worsening axial neck pain is commonly cited as a major disadvantage of laminoplasty. However, there remains a paucity of corroborative data from large series.

Methods. Following institutional review board approval, we reviewed the medical records, radiographs, and prospective clinical outcomes database of 85 patients undergoing LP and 52 patients undergoing LF for cervical myelopathy with minimum 1-year radiographic follow-up and average clinical follow-up of 18.5 months. LP was performed in those with neutral to lordotic C2–7 alignment and who did not complain of diffuse axial pain. Otherwise, LF was performed. Clinical outcomes included visual analogue score (VAS)-neck pain, VAS-total pain, neck disability index (NDI), short form 36, modified Japanese Orthopaedic Association (mJOA), and several radiographic parameters.

Results. VAS-neck did not worsen in LP (-0.2, $P=0.54$) and did improve in LF (-2.0, $P=0.0013$). VAS-total improved significantly in both groups (LF -1.04 ± 0.52, $P=0.05$; LP -1.4 ± 0.51, $P=0.008$). NDI improved in both groups, but was significant in only LP (LP decreased 6.79 ± 2.25, $P=0.0032$; LF decreased 4.01 ± 3.05, $P=0.19$). mJOA scores improved significantly in both groups (LP improved 2.89 ± 0.27, $P<0.0001$; LF improved 2.45 ± 0.33, $P<0.0001$). There was a small loss of cervical lordosis in both groups that was significant in LP (LP 2.92° loss, $P=0.0181$; LF 1.25° loss, $P=0.53$).

Conclusion. In a carefully selected group of myelopathic patients without significant diffuse axial pain preoperatively and appropriate sagittal alignment, laminoplasty did not lead to worsening axial neck pain, and it was associated with significant improvements in other clinical and myelopathy outcomes. Although laminoplasty is not indicated in every myelopathic patient, this study exemplifies its efficacy as a non-fusion operation in the appropriately selected patient and assuages concerns regarding worsening axial neck pain in such patients following surgery.

Key words: axial neck pain, cervical kyphosis, cervical laminectomy and fusion, cervical laminoplasty, cervical spondylotic myelopathy, laminectomy and fusion, laminoplasty, neck pain, open-door laminoplasty, postoperative neck pain.

Level of Evidence: 3

Spine 2017;42:1844–1850

Cervical open-door laminoplasty (LP) has become an increasingly popular surgical treatment option for the posterior decompression of patients with multilevel cervical myelopathy. Through the creation of an opening trough and a contralateral hinge, open-door laminoplasty increases the volumetric area available for the spinal cord while better maintaining cervical alignment when compared with multilevel laminectomy alone. Compared with posterior laminectomy and fusion (LF), laminoplasty avoids all fusion-related complications and offers potentially shorter operative time, less blood loss, faster recovery, lower implant costs, lower complications, and similar rates of neurologic recovery.[1–3]

Despite these advantages of laminoplasty, one commonly cited criticism is the potential development of either worsening or new onset axial neck pain postoperatively.[4–5] The

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Acknowledgment date: January 24, 2017. First revision date: April 22, 2017. Second revision date: May 22, 2017. Acceptance date: May 26, 2017.

The manuscript submitted does not contain information about medical device(s)/drug(s).

No funds were received in support of this work.

Relevant financial activities outside the submitted work: board membership, grants, stocks, travel/accommodations/meeting expenses.

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DOI: 10.1097/BRS.0000000000002308

literature demonstrates that patients reporting significant axial neck pain following laminoplasty have lower health-related quality of life scores.[4] Such concerns are often cited by surgeons who recommend alternative posterior approaches, such as LF over LP. However, it remains unclear from previous studies whether or not laminoplasty truly exacerbates axial symptoms, or whether those symptoms represent either a persistence or natural progression of spondylosis. In addition, proper patient selection is also an important consideration that has not been fully investigated in previous studies. Postoperative axial symptoms may be limited by avoiding laminoplasty in patients who have a substantial component of preoperative generalized axial pain, or in those who are likely to develop kyphosis. In addition, techniques to limit postoperative loss of lordosis—such as C3 and C7 laminectomy rather than laminoplasty,[6] avoidance of facet capsule disruption, meticulous repair of extensor muscles and fascia, and early postoperative extensor muscle rehabilitation protocols all likely play a role in prevention or limitation of neck pain following laminoplasty.[7]

In the present study, we sought to determine whether laminoplasty is associated with worsening or new axial pain in a properly selected cohort of myelopathic patients by comparing pain and other clinical outcomes to a cohort undergoing laminectomy and fusion.

MATERIALS AND METHODS

Following institutional review board approval, data were retrospectively reviewed from a list of consecutive patients treated by the senior author. Our inclusion criteria for this study were patients of at least 18 years of age on presentation, minimum of 1 year of clinical and radiographic follow up from date of surgery, and those patients receiving treatment between January 1, 2007 and March 18, 2015. Patients with history of trauma, fracture, infection, congenital abnormality, or tumor were excluded. Patients were selected as appropriate candidates for a posterior cervical decompression if the compressive pathology spanned $\geq$3 motion segments and the pattern of cord compression would allow for appropriate dorsal drift of the spinal cord after a posterior decompression (*i.e.*, K-line positive).[8] They were then further selected for cervical laminoplasty if they met two criteria: (1) diffuse or generalized axial neck pain was not a predominant or significant complaint—although unilateral radiating neck pain could be a complaint; and (2) upright lateral radiographs revealed a neutral to lordotic C2–7 sagittal angle. Those with a predominant complaint of diffuse or generalized axial pain, or those who demonstrated any amount of C2–7 kyphosis underwent laminectomy and fusion. In total, 85 patients were included in the laminoplasty group, and 52 patients were included in the laminectomy and fusion group. All laminoplasties were performed as plated, open-door operations. Laminectomy and fusions were performed with a combination of lateral mass, pars, or pedicle instrumentation as anatomically feasible based on preoperative imaging.

Data collected from retrospective chart review included the following: baseline demographic data, including age at time of surgery, sex, diagnoses of diseases, medical history, social history, previous surgical history, and surgical information including estimated blood loss (EBL), length of surgery (minutes), spinal levels, number of surgeries, previous surgeries, and length of hospital stay. Additional information gathered from clinical records included visual analogue score for neck pain (VAS neck), VAS for total pain (VAS total), neck disability index (NDI), short form 36 (SF-36) physical and mental component scores (SF-36 PCS, SF-36 MCS), and modified Japanese Orthopaedic Association (mJOA) scores. These measurements were collected preoperatively, and then at 6 weeks, 6 months, and 12 months postoperatively. mJOA was interpreted from the clinical notes by reviewers based on the standard mJOA questionnaire.

A radiographic analysis was conducted using measurements made from pre- and postoperative images at each available follow-up interval. Several measurements were made using sagittal radiographs, including C2 to C7 sagittal Cobb angle, T1 slope (the angle between a horizontal line and a line through the upper endplate of T1), C2–7 sagittal vertical axis (SVA) (the distance between a vertical plumbline dropped from the center of the C2 vertebral body and the posterior-superior corner of C7), and forward pitch (FP) (the distance between a vertical plumbline dropped from the center of the C2 vertebral body and the anterior-superior corner of C7). Although C2–7 SVA and FP are very similar,

Figure 1. Cervical forward pitch—a measurement from the anterior-superior corner of C7 to a plumbline dropped from the center of the C2 vertebral body.

TABLE 1. Baseline Characteristics of Patients Undergoing Laminoplasty (LP) and Laminectomy and Fusion (LF)

	LP (N = 85)	LF (N = 52)	*P*
Age at surgery, mean (SD)	61.48 (12.05)	62.04 (10.97)	0.78
Male, n (%)	37 (43.5%)	26 (50.0%)	0.46
Pre OP BMI, mean (SD)	29.97 (5.30)	30.21 (6.16)	0.81
Follow up (months), median	12.1	12.9	0.31
Pre OP mJOA, Mean (SD)	13 (3)	12 (3)	0.13
Pre OP NDI, mean (SD)	**35 (18)**	**43 (20)**	**0.03**
Pre OP SF PCS, mean (SD)	**36.48 (10.66)**	**30.80 (9.83)**	**0.008**
Pre OP SF MCS, mean (SD)	46.90 (10.10)	44.58 (11.78)	0.28
Pre OP VAS neck	**1.8 (2.8)**	**3.3 (3.6)**	**0.031**
Pre OP VAS total	**4.6 (0.39)**	**5.4 (0.52)**	**<0.001**
Pre OP Miyazaki, mean (SD)	18.30 (3.82)	18.36 (3.43)	0.94
Pre OP T1slope, mean (SD)	35.65 (9.92)	33.33 (11.15)	0.21
Pre OP C2–7 SVA, mean (SD)	31.15 (14.86)	36.04 (18.32)	0.09
Pre OP FP, mean (SD)	15.83 (17.49)	18.23 (19.31)	0.45
Pre OP axial spinal canal	6.0 (1.5)	6.1 (1.6)	0.41
Pre OP C2–7 angle, mean (SD)	**12.7 (1.12)**	**4.0 (1.84)**	**0.0001**

SD indicates standard deviation; BMI, body mass index; mJOA, modified Japanese Orthopaedic Association; NDI, neck disability index; PCS, physical component score; MCS, mental component score; SVA = sagittal vertical axis; VAS, visual analogue score; FP, forward pitch.
Bold indicates statistically significant P < .05.

we included FP because the anterior-superior corner of C7 is often more readily identifiable and less-often obscured than the posterior-superior corner (Figure 1).[9] The pre- and postoperative magnetic resonance imaging studies were also used to measure the axial canal diameter measured at most stenotic level (measured in millimeters) and the Miyazaki Spondylosis score, which has been shown to be a reproducible method of objectively quantifying cervical spondylosis.[10]

Statistical Analyses

Baseline and preoperative characteristics were compared between the study groups with a two-sided two-sample equal-variance *t* test or Wilcoxon rank-sum test for continuous variables and with the chi-square test or Fisher exact test for proportions. To compare longitudinal outcomes between LP and LF, repeated-measures analyses were performed with a means model via the SAS MIXED, Cary, NC Procedure (version 9.4) providing separate estimates of the means by time on study (baseline and 1-year) and study group (LP and LF). The adjusted model-based means are unbiased with unbalanced and missing data, so long as the missing data are non-informative (missing at random, MAR). All statistical tests were two-sided and unadjusted for multiple comparisons. VAS-neck pain data were available for a subset of LP and LF patients. Nonparametric methods were used to analyze this data to account for data distribution. Baseline pain scores (and pain at last follow-up) were compared between study groups by the Wilcoxon rank-sum test. Change over time within each study group was tested with the Wilcoxon signed-rank test.

RESULTS

Baseline Characteristics

Preoperatively, there were no significant differences in age, sex, body mass index (BMI), follow up duration, mJOA, and SF-36 mental component score. Pre and postoperative VAS total scores were available in all 137 patients, and VAS neck pain scores were available in a subset of 88 patients (53 LP patients and 35 LF patients), with the average clinical follow up of 18 months. There were significant differences in the

TABLE 2. Perioperative Data

	LP	LF	*P*
Operative levels	4.45 ± 0.748	5.73 ± 1.63	**<0.001**
Operative time (minutes)	122.3 ± 25.31	200.0 ± 71.3	**<0.001**
EBL (mL)	97.5 ± 73.8	177.0 ± 134.8	**<0.001**
Hospital stay (days)	2.62 ± 1.50	3.90 ± 2.03	**<0.001**
Deltoid Palsy	3	5	0.13

EBL = estimated blood loss.

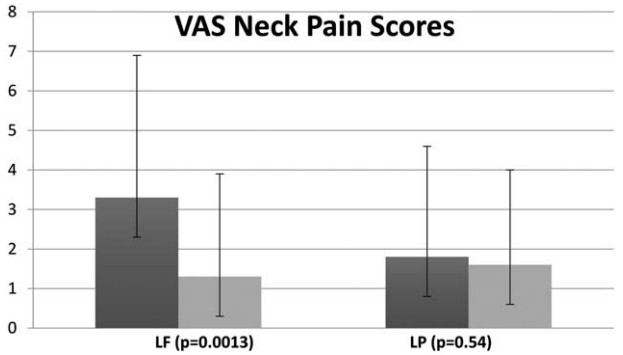

Figure 2. VAS neck pain scores decreased significantly in the LF group and remained low in the LP group. VAS indicates visual analogue score; LF, laminectomy and fusion; LP, laminoplasty.

preoperative NDI, SF-36 PCS, VAS neck, and VAS total with worse preoperative values in the LF group (Table 1). The LF group had a mean of 5.73 ± 1.63 levels fused, whereas the LP group had a mean of 4.45 ± 0.748 levels decompressed ($P < 0.001$; Table 2).

In terms of radiologic parameters, there were no significant differences in Miyazaki spondylosis score, T1 slope, C2–7 SVA, forward pitch, or AP spinal cord dimension (Table 1). The SVA had a trend towards a difference which was not significant (LP 31.54, LF 36.04, $P = 0.091$). There was a significant difference in preoperative C2–7 lordosis (LP $12.7^\circ \pm 1.12$; LF $4.0^\circ \pm 1.84$, $P < 0.0001$).

These results demonstrate that the LF group had worse baseline pain, disability, and overall physical function, as well as less cervical lordosis than the LP group, consistent with the fact that patients were not randomized but rather carefully selected to undergo either LP or LF based on preoperative criteria. However, the overall severity of myelopathy and radiologic evidence of spondylosis were no different between the two groups.

Pain

VAS neck (a measure of the amount of pain located in the neck only) significantly improved at 1 year in the LF group, from 3.3 to 1.3 (-2.0, $P = 0.0013$) (Figure 2). VAS neck was very slightly less at 1 year in the LP group, from 1.8 to 1.6, but the difference was not significant (-0.2, $P = 0.54$). Therefore, VAS-neck pain scores did not worsen in either group.

VAS total (a measure of total pain throughout the body), however, significantly improved in both groups (Figure 3). In the LF group, VAS total improved from 5.4 preoperatively to 4.3 postoperatively (LF -1.04 ± 0.52, $P = 0.05$). In the LP group, VAS total improved from 4.6 preoperatively to 3.2 postoperatively (LP -1.4 ± 0.51, $P = 0.008$). Therefore, both procedures resulted in significantly less total pain in this population. Approximately, 43% of patients (38/88 patients: 24/53 in the LP and 14/35 in the LF patients) reported a VAS total score of zero at both baseline and at final follow-up.

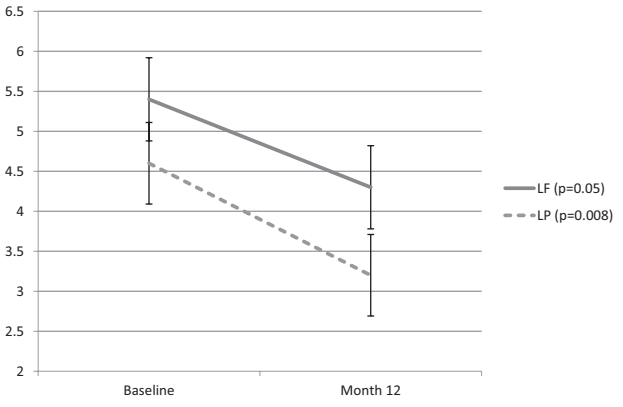

Figure 3. VAS total significantly improved in both groups (LP -1.4 ± 0.51, $P = 0.008$; LF -1.04 ± 0.52, $P = 0.05$). VAS indicates visual analogue score; LF, laminectomy and fusion; LP, laminoplasty.

Other Outcome Measures

NDI significantly improved for the LP group from baseline to 12 months (34.84 ± 2.05 *vs.* 28.04 ± 2.02, change of -6.79 ± 2.25, $P = 0.0032$). NDI also improved in LF but not in a statistically significant manner (42.91 ± 3.12 *vs.* 38.90 ± 2.91, change of -4.01 ± 3.05, $P = 0.19$) (Figure 4A–D). mJOA scores significantly improved in both groups from baseline to 12 months (LP 12.81 ± 0.28 *vs.* 15.69 ± 0.24, change of 2.89 ± 0.27, $P < 0.0001$; LF 12.10 ± 0.37 *vs.* 14.55 ± 0.38, change of 2.45 ± 0.33, $P < 0.0001$). In contrast, SF-36 PCS (LP 36.30 ± 1.24 *vs.* 36.46 ± 1.03, change of 0.16 ± 1.37, $P = 0.91$; LF 30.99 ± 1.50 *vs.* 33.33 ± 1.28, change of 2.34 ± 1.35, $P = 0.09$) and MCS (LP 46.90 ± 1.17 *vs.* 48.72 ± 1.15, change of 1.82 ± 1.40, $P = 0.20$; LF 44.69 ± 1.88 *vs.* 45.27 ± 1.47, change of 0.58 ± 2.33, $P = 0.80$) scores did not significantly improve in either group.

Radiologic Measures

Radiographically, there was a small but statistically significant loss of lordosis in the LP group (LP 12.7 ± 1.12 *vs.* 9.8 ± 1.23, change of -2.92°, $P = 0.0181$) (Figure 5). The LF group also lost a slight amount of lordosis, but this was not significant (LF 4.0 ± 1.84 *vs.* 2.7 ± 1.63, change of -1.25°, $P = 0.53$). The SVA increased significantly in the LP group (LP 31.5 ± 1.63 *vs.* 41.6 ± 2.09, change of 10.1, $P < 0.0001$) and decreased significantly in the LF group (LF 36.0 ± 2.52 *vs.* 27.9 ± 2.60, change of -8.09, $P < 0.0001$) (Table 3).

Perioperative Data

Operative statistics including operative time, EBL, and length of hospital stay differed between the two groups (Table 3). The LP group experienced shorter operative time (LP 122.3 ± 25.31 minutes, LF 200.0 ± 71.3 minutes, $P < 0.001$), less EBL (LP 97.5 ± 73.8 mL, LF 177.0 ± 134.8 mL, $P < 0.001$), and shorter hospital stays (LP 2.62 ± 1.50 days, LF 3.90 ± 2.03 days, $P < 0.001$).

Complications did not differ between the groups. Each group experienced one postoperative wound complication,

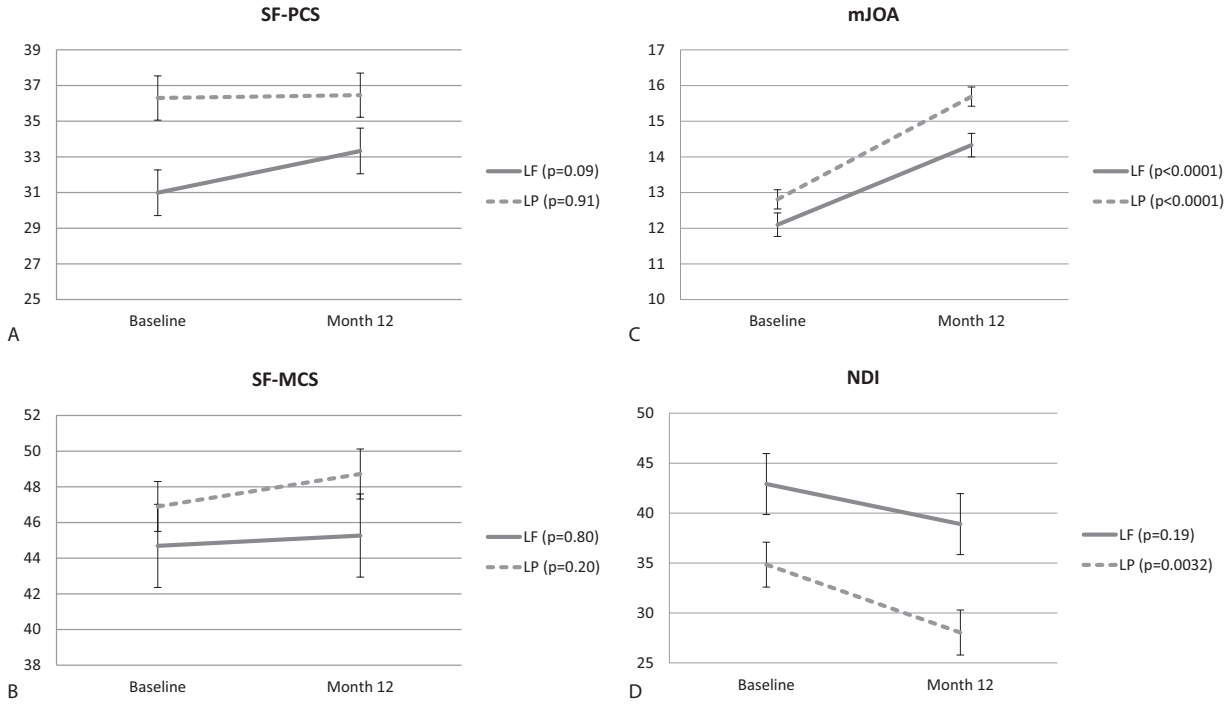

Figure 4. Line graphs showing the differences in SF PCS (**A**), SF MCS (**B**), mJOA (**C**), and NDI (**D**) betweeen preoperative and 1 year follow scores in LF (blue) and LP (red) groups. mJOA indicates modified Japanese Orthopaedic Association; NDI, neck disability index; LF, laminectomy and fusion; LP, laminoplasty; PCS, physical component scores; MCS, mental component scores.

both of which were wound infections that required repeat operation. The groups also did not differ with respect to postoperative deltoid weakness. Three patients in the LP group experienced postoperative deltoid weakness, while five patients in the LF group noted deltoid weakness ($P = 0.13$).

DISCUSSION

In the present study, we compared pain and other outcomes after laminoplasty *versus* laminectomy and fusion for cervical myelopathy. VAS neck pain scores actually *decreased* very slightly in the LP group at 1 year postoperative, although not significantly. VAS total pain did improve significantly. At the same time, important clinical outcomes such as mJOA and NDI scores also improved significantly with laminoplasty. LP was also associated with shorter operative times, less EBL, and shorter hospital stay, with no difference in the rate of perioperative complications such as infection or deltoid weakness. Because there were baseline differences between the LP and LF groups, and because patients were carefully selected to undergo a given operation based on criteria thought to make them better candidates for one procedure *versus* another, this study does not imply the superiority of one operation *versus* another in all myelopathy patients undergoing a posterior approach. However, we feel that in the appropriately selected and indicated patient—namely, those without a predominant complaint of generalized axial pain but who do demonstrate neutral to lordotic cervical alignment—laminoplasty improves clinical outcomes and, contrary to commonly cited concerns, does not worsen or exacerbate patient reported axial neck pain.

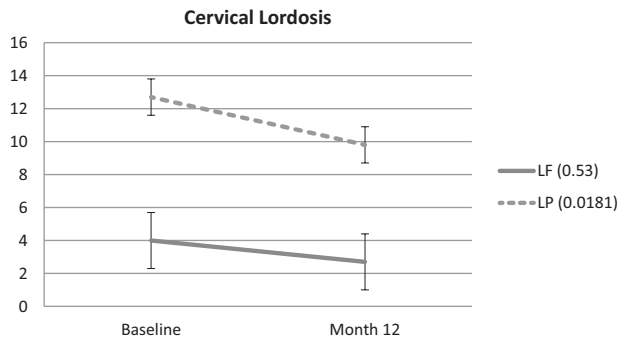

Figure 5. There was a small but statistically significant loss of lordosis in the LP group (LP −2.92°, $P = 0.0181$, LF −1.25°, $P = 0.53$). LF indicates laminectomy and fusion; LP, laminoplasty.

One impediment to wider acceptance of laminoplasty has been the concern that it exacerbates or creates axial neck pain. Previous literature has failed to resolve this issue. As with all of spine surgery, indications are paramount for maximizing outcomes, and we feel that our paper exemplifies the importance of reserving laminoplasty for patients without a chief complaint of diffuse or generalized axial neck pain, as well as appropriate upright neutral to lordotic alignment. Therefore, our finding that laminoplasty does not increase neck pain likely applies only to such an appropriately selected patient, and not necessarily to the general patient with myelopathy. However, in clinical practice, there are many myelopathic patients who do not have substantial axial pain and are otherwise suitable candidates

TABLE 3. Radiographic Data			
LP	**PRE OP**	**POST OP**	***P***
C2–7 angle	12.7 ± 1.12	9.8 ± 1.23	**0.0181**
C2–7 SVA	31.5 ± 1.63	41.6 ± 2.09	**<0.0001**
LF	**PRE OP**	**POST OP**	***P***
C2–7 Angle	4.0 ± 1.84	2.7 ± 1.63	0.53
C2–7 SVA	31.5 ± 1.63	41.6 ± 2.09	**<0.0001**

LP indicates laminoplasty; LF, laminectomy and fusion; SVA = sagittal vertical axis.

for laminoplasty. We feel that these patients are well served with a non-fusion operation like laminoplasty if a dorsal approach is deemed sufficient for neurologic decompression.

In this study, VAS neck pain scores demonstrated greater and significant improvement in the LF group *versus* LP. This finding reinforces the notion that fusion is more likely to improve spondylotic axial symptoms. Thus, in those myelopathic patients who present with significant axial pain, LF, or potentially an anterior operation, may be a better option than LP. However, even in the LF group, the improvement in VAS neck pain did not meet the quoted minimum clinically important difference (MCID) of 2.6.[11] It is always important when counseling patients that relief of axial symptoms after surgery for myelopathy may be unpredictable and incomplete, even with fusion-based operations. VAS-total did improve significantly in both groups (LP -1.4 ± 0.51, $P = 0.008$, LF -1.04 ± 0.52, $P = 0.05$), suggesting relief of neurogenic pain with spinal cord decompression.

Neck disability index, an instrument that exemplifies how neck pain and dysfunction affects a patient's quality of life, improved significantly for laminoplasty patients (-6.79 ± 2.25, $P = 0.0032$), but not for laminectomy and fusion patients (-4.01 ± 3.05, $P = 0.19$). However, NDI did improve by more than the quoted MCID of 3.5[12] in both groups. SF-36 mental and physical component scores, which are perhaps less specific to patients undergoing cervical spine surgery, did not significantly change in either group. With respect to neurologic recovery, both the laminoplasty and laminectomy and fusion groups demonstrated a significant improvement in mJOA scores (LP $+2.89 \pm 0.27$, $P < 0.0001$; LF $+2.45 \pm 0.33$, $P < 0.0001$). This result is coincident with findings from prior investigations.[13] Radiographically, there was a small, but statistically significant loss of lordosis in the laminoplasty group ($-2.92°$, $P = 0.0181$). However, it is important to consider that laminoplasty patients, as part of our selection criteria, had significantly more cervical lordosis preoperatively (*i.e.*, they had more to lordosis to lose). Potential loss of lordosis following laminoplasty is a definite concern that should be factored into decision-making when considering laminoplasty *versus* alternative operations in a given myelopathic patient. C2–7 SVA and forward pitch[9] are also important considerations in determining the suitability for laminoplasty in a given patient.

Notably, the amount of preoperative spondylosis, as measured by the Miyazaki score, did not differ between the laminoplasty *versus* laminectomy and fusion groups. This finding is consistent with the observation that the severity of radiographic spondylosis does not necessarily correlate with clinical complaints of axial neck pain. Therefore, the amount of radiographic spondylosis should not, in and of itself, be a contraindication to laminoplasty. Instead, we believe that appropriate criteria for laminoplasty should center on clinical complaints of significant axial pain and global (C2–7) sagittal plane alignment. This study did not, however, examine the impact of other factors, such as spondylolisthesis.[14]

While our study represents a large study comparing patients undergoing laminoplasty and laminectomy and fusion for cervical myelopathy, there are important limitations to consider. The retrospective nature of our study has inherent limitations, including selection bias and the possibility of differential loss to follow up. In this non-randomized series, patients were selected preoperatively by the treating surgeon to undergo either laminoplasty *versus* laminectomy and fusion based on a number of factors. These factors included the presence of substantial axial pain, as well as presence *versus* absence of lordosis. Thus, the LF patients had, for example, significantly less preoperative lordosis and worse axial neck pain scores preoperatively. Regardless, we do not feel that this limitation diminishes the primary finding of this study—namely, that laminoplasty does not lead to worsening of axial pain *in the properly selected patient*. Clearly, however, there are patients who by virtue of unfavorable alignment, severe generalized axial pain, or other factors, may be better suited to alternative, fusion-based operations.

CONCLUSION

In conclusion, the present study demonstrates the clinical efficacy of cervical laminoplasty in the appropriately selected myelopathy patient—namely, those without a predominant complaint of generalized axial neck pain and who demonstrate neutral to lordotic sagittal alignment. In this population, laminoplasty led to a slight, non-significant decrease in neck pain, and a significant decrease in total pain. Importantly, laminoplasty was not associated with a worsening of axial pain. Additionally, other clinical outcomes such as the NDI and mJOA scores improved significantly

after laminoplasty. Although laminoplasty is not indicated in every myelopathic patient, this study exemplifies its efficacy as a non-fusion operation in the appropriately selected patient and assuages concerns regarding worsening axial neck pain in such patients following surgery.

➢ Key Points

- ❑ In a cohort that did not have significant diffuse axial pain preoperatively and had neutral to lordotic alignment, axial neck pain scores (VAS-neck) did not significantly worsen following laminoplasty.
- ❑ Overall pain scores (VAS-total) improved significantly in patients undergoing both laminoplasty and laminectomy and fusion.
- ❑ Patients undergoing laminoplasty had significant improvement in neck disability index, whereas those patients undergoing laminectomy and fusion had improvement that was not statistically significant.
- ❑ There was a small amount of lost lordosis in both groups, which was statistically significant in patients undergoing laminoplasty.
- ❑ In the appropriately selected patient, cervical laminoplasty is a non-fusion operation that does not worsen axial neck pain and achieves improvement in myelopathy as well as other clinical outcomes.

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