

Outcome Evaluation of Modified Uninstrumented Open-door Cervical Laminoplasty for Ossified Posterior Longitudinal Ligament with Cervical Myelopathy

Abstract

Study Design: This was a retrospective study. **Purpose:** To evaluate the short term outcomes of a novel self-developed technique of performing uninstrumented open-door cervical laminoplasty (ODCL) in patients with cervical myelopathy secondary to ossified posterior longitudinal ligament (OPLL). **Review of Literature:** Published literature on cervical laminoplasties largely focuses on the outcomes of instrumented variants. **Materials and Methods:** Retrospective data were collected from 54 patients who underwent uninstrumented ODCL for cervical OPLL at a single institution from January 2010 to February 2017. The preoperative and postoperative modified Japanese Orthopaedic Association score (mJOA) and Nurick grading were documented. Cervical lordotic angle at C2–C7 and range of motion (ROM) were obtained from the preoperative and postoperative lateral cervical radiographs in neutral and flexion extension views, respectively. Descriptive and analytical statistics were generated by SAS 9.4 University Edition (SAS Institute, Cary, North Carolina, USA). **Results:** The average age was 58.6 ± 7.8 years. The average time of presentation from the onset of symptoms was 7.6 ± 3 months. Of the 54 patients who were included in the study, majority (48.14%) had segmental type of OPLL while C3–C6 was the most commonly operated level (66.67%). The mean operating time was 115 ± 31 min with a mean blood loss of 165.9 ± 75 ml. There was a significant improvement in the mJOA scores (9.2 ± 1.1 – 13.7 ± 0.9 , $P < 0.0001$) and Nurick grading (3.4 ± 0.8 – 1.6 ± 0.5 , $P < 0.0001$) at 24-month followup. Preoperative C2–C7 angle had an average decrease of 4.5° at 24-month followup (19.3 ± 7.2 – 14.8 ± 8.8 , $P < 0.0001$). There was a mean reduction of $4.3^\circ \pm 3.78^\circ$ noted in the C2–C7 ROM between the preoperative and final followup. **Conclusion:** Uninstrumented ODCL is an easily reproducible and economical alternative to the standard instrumented laminoplasty with equivalent short term outcomes. This technique is a valuable option in the treatment of cervical OPLL, especially in regions with scarce resources.

Keywords: Cervical myelopathy, open-door cervical laminoplasty, ossified posterior longitudinal ligament

Introduction

The standard surgical algorithm for treating cervical myelopathy caused by ossification of posterior longitudinal ligament (OPLL) is controversial.¹ Options include anterior cervical corpectomy and fusion, open-door cervical laminoplasty (ODCL), and cervical laminectomy and fusion.² The literature has reported significant complication rates associated with anterior corpectomy and fusion which has increasingly led to the popularity of posterior-based procedures.³ ODCL was developed to widen the spinal canal dimensions without permanently removing the dorsal elements of the cervical spine. The rationale behind ODCL

is indirect decompression achieved by posterior shift of the spinal cord caused by realignment of the laminae.⁴

ODCL, due to the conservation of the posterior cervical tension band, seems to decrease the incidence of cervical instability and postsurgical kyphosis.^{5,6} It also prevents epidural scarring and preserves neck range of motion (ROM) as compared to laminectomy and posterior fusion.⁷

Numerous techniques of ODCL have been described in literature. Most of the studies focus on instrumented laminoplasties. The implants and instrumentation for laminoplasties are expensive and not readily available in developing countries. Therefore, this study proposes a novel,

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affordable uninstrumented technique to maintain the laminotomy side open, using a polyester suture as a suspension bridge to prevent restenosis due to fallback of the laminae.

Objectives

We have developed a unique modification of the ODCL procedure to keep the laminae expanded, with the aim of preventing reclosure of the vertebral arch without using any implants or expensive tools. Our aim is to study the effectiveness of the modified ODCL technique developed at our institution by evaluating the surgical and radiological outcomes.

Materials and Methods

A total of 64 patients underwent ODCL over a 7-year period from January 2010 to February 2017 for OPLL of the cervical spine. All procedures were performed by a single surgeon with a minimum followup of 2 years. The patients were included on the basis of the following inclusion and exclusion criteria.

Inclusion criteria

Patients with symptomatic cervical myelopathy secondary to OPLL who had failed to respond to conservative treatment at least for 3 months were included in the study.

Exclusion criteria

Patients who underwent additional anterior surgery, those who had inadvertent laminectomy while flipping the laminae, revision cases, and those who were lost to followup were excluded from the study.

Of a total of 64 patients, 8 patients underwent additional procedures apart from ODCL and 2 patients were lost to followup and hence were excluded. The remaining 54 patients were included in the study.

All patients underwent detailed clinical examination and their modified Japanese Orthopaedic Association (mJOA) score and Nurick grading were documented preoperatively on outpatient basis. The presence of OPLL was confirmed with the help of lateral view of cervical radiograph, computed tomography, and magnetic resonance imaging. All patients underwent a minimum of 3 months of conservative management. The patients who did not improve after 3 months of conservative management or those who deteriorated during this period were advised ODCL surgery.

All preoperative patients underwent cervical spine lateral radiograph and flexion extension radiograph to obtain cervical lordotic angle and ROM, respectively. Lordotic angle at C2–C7 was derived from the posterior tangents of the odontoid process and the C7 vertebral body in lateral radiographs of the cervical spine [Figure 1]. It was expressed as positive values for lordosis and negative values for kyphosis. ROM was obtained by difference

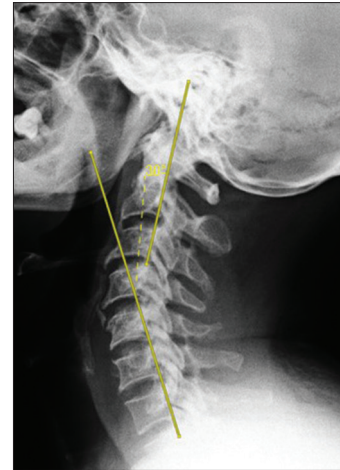


Figure 1: Radiograph showing measurement of C2–C7 cervical angle (+30°)

between the angles created by tangential lines to inferior aspect of the C2 and C7 body on the flexion and extension radiographs [Figure 2].^{8,9} These measurements were performed by the operating surgeon and a spine fellow to reduce the interobserver bias. All measurements were made using a picture-archiving and communication system.

All routine blood investigations, electrocardiogram, two-dimensional echo, and radiographs of the chest were done as a routine protocol for preanesthesia workup. Once fit, the patient was advised admission a day before surgery.

Surgical procedure

All patients underwent fiberoptic intubation for general anesthesia (GA). Mayfield frame was applied after GA, and the patient was gently rolled into prone position using a neck immobilizer. For majority of patients, the most severely compromised levels were between C3 and C6. If the patient had radicular symptoms, the hinge was positioned on the side contralateral to intended foraminotomies. In patients without radicular symptoms, right-sided hinge was preferred.

Approach and exposure

With sterile preparation, a midline incision is performed from the external occipital protuberance to the C7 spinous process. Subperiosteal dissection of the paraspinal musculature is done along the median raphe. Adequate exposure is obtained from the inferior edge of C2 to the superior edge of C7 lamina.

Laminotomy and greenstick fracture

The spinous processes of C3–C6 are removed from their base using the Liston spinous cutting forceps. The bleeding bone edges are waxed to achieve hemostasis. A 5-mm burr (Aesculap round fluted) is used to make a unicortical groove in between the laminae and the lateral masses on both the sides until cancellous bone is seen. On the side of the hinge, the inner cortex is thinned with

a 2-mm burr (Aesculap round fluted), whereas on the opposite side (free door), the inner part of the cortex is excised using a 2-mm burr (Aesculap diamond tip) aided with a 1-mm Kerrison rongeur to complete laminotomy in the longitudinal axis along with the resection of the ligamentum flavum, in between the laminae [Figure 3].

The use of 5-mm burr for superficial decortication followed by 2-mm burr for deep cortex thinning creates a conical defect on the hinge side facilitating the posterior greenstick fracture, such as the walls of the groove created do not impinge during the elevation of the laminae. This allows for adequate opening of the laminotomy defect and hence optimum expansion of the spinal canal. Special interest should be paid to this side of the laminoplasty during the drilling of the upper and lower edges of each lamina because they are the areas with the densest concentration of cortical bone. Suboptimal burring could make the elevation of the laminae difficult. Then, a 2-mm Kerrison is used to section the ligamentum flavum transversally at the C2–C3 and C6–C7 interlaminar space. This maneuver creates free laminar edges that correspond with the upper and lower limits of the laminoplasty.

Laminae are lifted upward with a Cobb's periosteal elevator levering on the longitudinal free edge of the laminoplasty pushing toward the opposite side to create greenstick fracture of the hinge. Due care is rendered during this maneuver to ascertain that the fracture is not complete and inadvertent laminectomy is prevented. In addition, care must be taken so that the free laminar edge does not slip and produce potential cord damage. Hemostatic agents (Ethicon Surgiflo Hemostatic Matrix – Flowable gelatin matrix) and bipolar coagulation can be utilized to stop the bleeding from the epidural vessels.

The modification

In our modified ODCL procedure, a #2 polyester suture (#2 Ethicon-Ethibond Excel, Johnson and Johnson Pvt. Ltd.) is anchored at the C2 and C7 spinous processes and is used as a suspension bridge to support the laminae over the decompressed levels [Figure 4].

To achieve this, a 1-mm burr (Aesculap round fluted) is used to make a transverse fenestration in C2 and C7 spinous processes. Fenestrations are then made near the free edge of the C3 and C6 laminae while protecting the cord using a Cobb's elevator or Penfield dissector.

A #2 polyester suture is then passed through the fenestration in C2 spinous process, doubled on itself, and anchored with a knot. The two free ends of the suture are passed through an eye of a curved needle. The tip of the needle is chopped off to have blunt advancing end, to avoid unintended injury to the dura. The suture is then passed through the C3 lamina from dorsal to ventral aspect. The suture then traverses distally, ventral to C4 and C5 laminae before it escapes dorsally through a fenestration in C6 lamina.

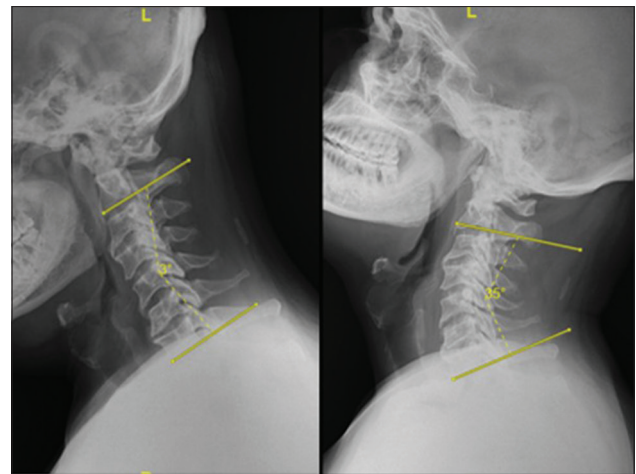


Figure 2: Radiographs showing measurement of range of motion (35° in extension – 3° in flexion = 32°) in flexion and extension views

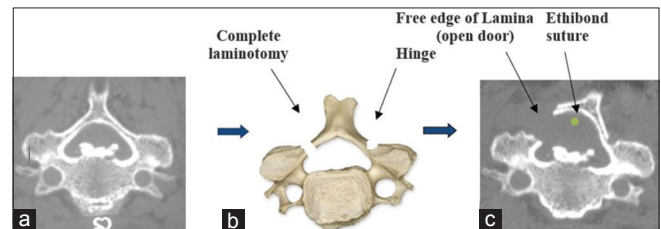


Figure 3: Stages in uninstrumented open-door cervical laminoplasty; (a) intact lamina, (b) creation of hinge and laminotomy defect, and (c) elevated lamina with Ethibond suture as a suspension bridge to decompress spinal canal

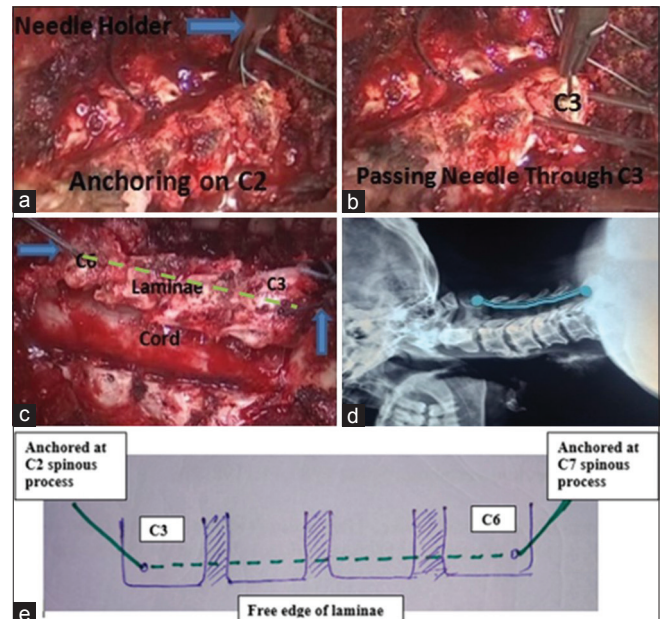


Figure 4: (a) Anchoring of Ethibond suture on C2 spinous process; (b) the needle is then passed from dorsal to ventral aspect of C3 lamina; (c) Ethibond suture is ventral to C3, C4, C5, and C6 laminae acting as a suspension bridge to keep laminoplasty defect open; (d) illustrative radiograph showing an Ethibond suture as a suspension bridge; and (e) illustrative hand drawn diagram showing Ethibond suture as suspension bridge

Finally, the suture is passed through the C7 spinous process and is anchored with adequate tension to suspend the free

end of the lamina and maintain them in open position. Care is taken to ascertain that the laminar opening is adequate. After thorough hemostasis, gelfoam (AbGel-Absorbable gelatin sponge USP, Sri Gopal Krishna Labs Pvt. Ltd.) is

applied on the open side for additional protection of the cord. Wound is closed in layers with drain *in situ*.

The case example is depicted in Figure 5.

Clinical outcome measures

All patients underwent serial followup at 6 weeks, 3 months, 6 months, 1 year, and 2 years after surgery. Subsequently, yearly followup was done. Myelopathic symptoms were assessed using the mJOA score [Table 1],¹⁰ its recovery rate, and Nurick grading scale [Table 2].¹¹

The recovery rate is calculated using the preoperative mJOA score and the postoperative mJOA score as per the following formula:

Recovery rate = (postoperative mJOA score – preoperative mJOA score)/(18 – preoperative mJOA score) × 100 (%).¹²

The presence or absence of axial pain and postoperative C5 palsy was also evaluated. We used Hironobu criteria [Table 3],¹³ to define neck pain and its severity. Postoperative axial neck pain was defined as posterior neck and/or periscapular pain that developed or became aggravated after surgery.¹³ Severe or moderate grades on Hironobu criteria were considered to have significant pain.

Radiological outcome measures

The C2–C7 cervical lordotic angle and cervical ROM were obtained preoperatively. These measurements were also done at 3, 6, 12, and 24 months of followup visits. In addition, the change between the preoperative and postoperative C2–C7 angle was expressed as the Δ C2–C7 angle. The Δ C2–C7 angle was considered positive for a postoperative increase of C2–C7 angle and negative for a postoperative decrease of C2–C7 angle.



Figure 5: (a and b) T2- and T1-weighted midsagittal magnetic resonance imaging showing segmental type of ossified posterior longitudinal ligament with cord signal changes at the C3–C4 level; (c) preoperative axial computed tomography scan at the C5 level; and (d) immediate postoperative axial computed tomography scan showing open-door cervical laminoplasty at the C5 level

Table 1: Modified Japanese Orthopaedic Association scoring system (cervical spondylotic myelopathy functional assessment scale) (Benzel *et al.*¹⁰)

Score and its definition	
Motor dysfunction	Lower extremities (maximum score 7)
Upper extremities (maximum score 5)	0: Complete loss of motor and sensory function
0: Unable to move hands	1: Sensory preservation without ability to move legs
1: Unable to eat with a spoon but able to move hands	2: Able to move legs but unable to walk
2: Unable to button shirt but able to eat with a spoon	3: Able to walk on flat floor with a walking aid (cane or crutch)
3: Able to button shirt with great difficulty	4: Able to walk up- and/or downstairs w/aid of a handrail
4: Able to button shirt with slight difficulty	5: Moderate-to-significant lack of stability but able to walk up- and/or downstairs without handrail
5: No dysfunction	6: Mild lack of stability but able to walk unaided with smooth reciprocation
Sensory dysfunction	7: No dysfunction
Upper extremities (maximum score 3)	Sphincter dysfunction (maximum score 3)
0: Complete loss of hand sensation	0: Unable to micturate voluntarily
1: Severe sensory loss or pain	1: Marked difficulty in micturition
2: Mild sensory loss	2: Mild-to-moderate difficulty in micturition
3: No sensory loss	3: Normal micturition

Statistical analysis

Descriptive and analytical statistics were generated by SAS 9.4 University Edition (SAS Institute, Cary, North Carolina, USA). The comparison of means was done using the paired sample *t*-tests. ANOVA was used to assess the mean difference of mJOA score at serial followups. Pearson's correlation coefficient was utilized to assess colinearity.

Table 2: Nurick grades for neurological deficit in spastic paraplegia (Nurick¹¹)

0: Signs or symptoms of root involvement but without evidence of spinal cord disease
1: Signs of spinal cord disease but no difficulty in walking
2: Slight difficulty in walking which did not prevent full-time employment
3: Difficulty in walking which prevented full-time employment or the ability to do all housework, but which was not so severe as to require someone else's help to walk
4: Able to walk only with someone else's help or with the aid of a frame
5: Chair bound or bedridden

Table 3: Hironobu criteria for the assessment of postoperative axial neck pain severity (Sakaura *et al.*¹³)

Grade	Criteria
Severe	Painkillers or local injection needed regularly
Moderate	Physiotherapy needed regularly
Mild	No treatment needed

Results

A total of 54 patients were included in the study. The average age was 58.6 ± 7.8 years. Majority of the patients were in the 5th and 6th decades of life (85.18%; $n = 46$) comparable to the demography in the published literature.^{14,15} The average duration of symptoms at the time of presentation was 7.6 ± 3 months [Table 4].

Majority of cases had segmental type of OPLL (48.14%) [Table 5]. Most commonly, the operated levels were C3–C6 (66.67%) [Table 6]. The mean operating time was 115 ± 31 min with a mean blood loss of 165.9 ± 75 ml [Table 4]. In a systematic review by Kohno *et al.*, they reported an average operative time of 137.4 min with a mean blood loss of 299.6 ml.¹⁶

Clinical and radiological results

There was a significant improvement in the mJOA scores (9.2 ± 1.1 – 13.7 ± 0.9 , $P < 0.0001$) and Nurick grading (3.4 ± 0.8 – 1.6 ± 0.5 , $P < 0.0001$) at 24-month followup. Preoperative C2–C7 angle had an average decrease of 4.5° at 24-month followup (19.3 ± 7.2 vs. 14.8 ± 8.8 , $P < 0.0001$). In C2–C7 ROM, an average reduction of $4.3^\circ \pm 3.78^\circ$ was noted between preoperative and final followup (35 vs. 30.7, $P = 0.004$) [Table 7].

There was a significant negative correlation between duration of symptoms at presentation and mJOA scores at presentation and final followup [Table 8].

One patient had a transient worsening of myelopathy after surgery which recovered over a period of 6 months. Two patients had early postoperative superficial surgical

Table 4: Demography, clinical, and radiological parameters

Variables	Mean	SD	Minimum	Maximum
Age (years)	58.6	7.8	45.0	78.0
Symptom duration (months)	7.6	3.0	3.0	15.0
Intraoperative blood loss (ml)	165.9	75.0	50.0	600.0
Duration of procedure (min)	115.0	31.0	75.0	200.0
Preoperative mJOA score	9.2	1.1	8.0	11.0
Preoperative Nurick grade	3.4	0.8	2.0	5.0
Postoperative mJOA score	13.7	0.9	12.0	15.0
mJOA score - 6 months	13.9	0.9	12.0	16.0
mJOA score - 12 months	14.1	1.0	12.0	16.0
mJOA score - 24 months	14.1	1.0	12.0	16.0
Postoperative Nurick grade	2.0	0.0	2.0	2.0
Nurick grade - 6 months	1.8	0.4	1.0	2.0
Nurick grade - 12 months	1.6	0.5	1.0	2.0
Nurick grade - 24 months	1.6	0.5	1.0	2.0
C2-C7 angle ($^\circ$) - preoperative	19.3	7.2	-1.0	43.0
C2-C7 angle ($^\circ$) - at 24-month followup	14.8	8.8	-7.0	37.0
Δ C2-C7 angle ($^\circ$) - difference between preoperative and at 24-month followup	4.5	3.6	-2.0	16.0
C2-C7 range of motion ($^\circ$) - preoperative	35.0	12.3	8.0	59.0
C2-C7 range of motion ($^\circ$) - at 24-month followup	30.7	8.5	14.0	48.0
Final followup (months)	46.7	13.2	24.0	64.0

SD=Standard deviation, mJOA=modified Japanese Orthopaedic Association

site infection which was managed with repeated wound debridements. No other major complications were noted.

Discussion

The compressed cervical spinal cord in OPLL can be decompressed using an anterior approach, a posterior approach, or through a combined strategy. Most surgeons prefer the posterior approach, if the involvement is at several levels (3 or more), provided cervical lordosis is maintained.¹⁷ Nearly half of the patients in our series had segmental type of OPLL which is similar to the incidence reported in the literature.¹⁸ Cervical laminoplasty was developed to overcome the disadvantages shown by the conventional laminectomy and fusion, with the objective of achieving an adequate decompression of the spinal cord while preserving functional mobility of the cervical column. In recent years, diverse clinical studies have shown that the cervical laminoplasty offers better clinical results than conventional laminectomy and fusion.¹⁹⁻²¹

In 1981, Hirabayashi described the expansive uninstrumented single open-door laminoplasty technique, in which the door is kept open by placing suture through the facet capsule on the closed side anchored to the spinous processes.¹² However, failure in the attachment system of the open side or a complete fracture of the laminae in the hinged side may lead to spring-back phenomenon of laminae placing the cord at risk of compression. Subsequently, other authors have described diverse strategies to keep the laminae in decompressed

position using an array of spacers and instrumentation. Most of the current literature is reported on experience with instrumented laminoplasties.²²⁻²⁴ Our technique is a variation of the Hirabayashi's method with addition of polyester suture acting as a suspension bridge. To keep laminoplasty open, this is an inexpensive, technically easy, and reproducible method.

A significant advantage of ODCL over fusion is the relative preservation of neck movements. Loss of cervical ROM after ODCL has been reported to be around 17%–50% of preoperative range with an average loss of approximately 50%.⁷ We obtained a mean decrease of 4.3° of ROM at the end of 24-month followup from an average preoperative ROM of 35°, a 12.28% loss. The comparative preservation of motion in our series could be attributed to limited muscular dissection and capsular preservation.

There are very few long term studies reporting neurological recovery after cervical laminoplasty. Among them, Mizayaki *et al.* reported that neurological improvement was maintained for a median of 12 years after the intervention.²⁵ In our series, the neurological and functional improvement was consistent at 2 years of followup.

Recent literature on the natural course of cervical myelopathy has improved our understanding of its progressive nature and reinforced the need of early intervention to prevent further neurological deterioration. In our study, we found that patients who presented late had significantly poor mJOA scores at presentation and also at the final followup. Various authors, in their laminoplasty series, have reported the recovery rate of approximately 60% in the mJOA score.^{26,27} We had an improvement of 55.31% in the mJOA scores at 24 months.

A review of literature reports that cervical laminoplasty seems to present less global rate of complications than the conventional laminectomy and fusion.¹⁹⁻²¹ It has been reported that the incidence of neurological deterioration due to postoperative hematoma is less probable in the laminoplasty against the laminectomy with posterior instrumentation due to the natural protection by laminae.^{9,15} In contrast, Lao *et al.* in their comparison between instrumented laminoplasty and laminectomy and fusion found no statistically significant differences between the techniques with regard to wound complications, the incidence of postoperative kyphosis, or paresis of the C5 nerve root.²⁸ In our series, two patients had wound infection which was managed by debridement and secondary

Table 5: Type of ossified posterior longitudinal ligament

OPLL	Frequency (%)
Segmental	26 (48.14)
Continuous	16 (29.62)
Mixed	12 (22.22)

OPLL=Ossified posterior longitudinal ligament

Table 6: Surgical levels of decompression

The Underwent procedure	Frequency (%)
ODCL C2-5 dome C2	3 (5.55)
ODCL C2-6 dome C2	1 (1.85)
ODCL C3-6	34 (66.67)
ODCL C3-6 dome C2	9 (16.67)
ODCL C3-6 dome C7	3 (5.56)
ODCL C4-6	2 (3.70)

ODCL=Open-door cervical laminoplasty

Table 7: Statistical analysis of radiological and clinical outcomes

	Preoperative	Postoperative at 24 months	Mean difference	t-score	P
mJOA score	9.2	13.7	4.5	48.7	<0.0001
Nurick grade	3.4	1.6	1.8	13.8	<0.0001
C2-C7 angle (°)	19.3	14.8	4.5	9.13	<0.0001
C2-C7 ROM (°)	35.0	30.7	4.3	3.78	0.0004

mJOA=modified Japanese Orthopaedic Association, ROM=Range of motion

Table 8: Duration of symptoms and its correlation with preoperative and postoperative modified Japanese Orthopaedic Association scores

Duration of symptoms (in months) in correlation with presentation	Pearson's coefficient	P
Preoperative mJOA score	-0.75	<0.0001
Postoperative mJOA score - 24 months	-0.63	<0.0001

mJOA=modified Japanese Orthopaedic Association

suturing, and one patient had neurological deterioration who went on to a full recovery at the end of 6 months. There was no case of postoperative hematoma formation or kyphosis.

Postoperative C5 palsy is thought to be caused by trauma induced by the surgical technique, displacement of the lamina on the hinge side, a tethering effect induced by an excessive posterior shift of the spinal cord after decompression, traction stress on the nerve root, or damage to the gray matter of the spinal cord. However, the precise mechanism responsible for C5 palsy remains unclear.^{29,30} The reported incidence of C5 palsy is about 5%.³¹ In this series, none of the patients developed C5 palsy. This may be explained by the small mean opening angle of the vertebral arch in this procedure, which may prevent the clinical condition caused by traction on C5 root.

A frequently reported drawback with laminoplasty is the postoperative axial neck pain.^{14,15} However, significant neck pain has also been reported after laminectomy and fusion.^{20,21} Pain is usually maximal during immediate postoperative period. Postoperative muscular stiffness leads to chronic axial neck pain which can be satisfactorily resolved during the 1st year with judicious use of physical therapy.³² We prescribe soft cervical collar for the 1st postoperative month and encourage the patients to do neck ROM exercises subsequently. In our series, eight patients had neck stiffness and moderate pain which resolved gradually by final followup.

Limitations

Our study had a few limitations. While we had a reasonably good number of cases, larger series of patients would substantiate the equivalence of this economic procedure. A longer followup duration would have shed more light on the long term outcomes compared to literature reporting on instrumented ODCL. Finally, experience with this technique is currently limited to only our institute, and multicentric trials are desirable to validate our observations on large scale.

Conclusion

In our experience, uninstrumented ODCL is a viable alternative to instrumented ODCL achieving similar outcomes and postoperative improvement at lesser cost, especially in Third World countries. It is easily

reproducible and has added advantage of avoiding potential complications associated with instrumentation, bone grafts, or implants. Uninstrumented ODCL can be considered as a procedure of choice whenever and wherever the resources are scarce.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given his consent for his images and other clinical information to be reported in the journal. The patient understands that name and initials will not be published and due efforts will be made to conceal identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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