A Randomized Controlled Trial for the Intervention Effect of Early Exercise Therapy on Axial Pain after Cervical Laminoplasty

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Abstract:

Introduction: Cervical isometric muscle strengthening and cervical range of motion (ROM) training are recommended after laminoplasty (LP). However, their preventive effects on axial pain are unclear. We examined whether neck extension muscle strengthening and cervical ROM training from the early postoperative period effectively suppress postoperative axial pain.

Methods: Sixty-one patients undergoing a muscle-preserving LP attached to C2 and C7 for cervical spondylotic myelopathy or ossification of the posterior longitudinal ligament were randomly allocated to the cervical exercise (33 patients) or nonexercize (28 patients) groups. Postoperative cervical collars were not worn in any cases. The cervical exercise group underwent neck extension isometric muscle strengthening and cervical ROM exercises for 3 months starting on postoperative day 2. Changes in axial pain (visual analog scale [VAS]) from baseline at 2 weeks and 3 months after surgery were evaluated as the primary outcome. Cervical muscle strength, cervical ROM, and Japanese Orthopedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ) scores were evaluated as secondary outcomes.

Results: Axial pain was significantly exacerbated at 2 weeks after LP compared with before surgery, and then, a significant improvement was observed at 3 months after surgery. No significant interaction was observed between the intervention and nonintervention groups. There was no difference in secondary outcomes between groups. The change in the VAS of axial pain from before surgery to 3 months after surgery showed a greater decreased neck extension muscle strength resulting in severer axial pain.

Conclusions: Cervical muscle strengthening and cervical ROM exercise from the early postoperative period did not relieve axial pain at 2 weeks and 3 months after a muscle-preserving LP attached to C2 and C7. No significant difference in neck extension muscle and cervical movement was observed between the intervention and nonintervention groups. Therefore, a muscle-preserving LP attached to C2 and C7 is a good strategy to prevent axial pain in the early postoperative period.

Clinical Trials Registration Number: UMIN000040692

Keywords:

cervical laminoplasty, early exercise, axial pain, randomized controlled trial, intervention

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Introduction

Exacerbation of axial pain is a problem that can occur after cervical laminoplasty (LP)[1,2)]. Axial pain after LP has a significant adverse effect on health-related quality of life (QOL) and patient satisfaction[3)]. Factors for postoperative axial pain include muscle dysfunction due to paravertebral muscle damage and detachment of muscles attached to C2 and C7[4-8)], and external immobilization for a long period after surgery[9,10)].

Modification of the surgical technique and period of wearing a cervical collar have both been studied to prevent

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axial pain after LP, and their preventive effects have been confirmed[4,6,11,12]. Cervical isometric muscle strengthening and cervical range of motion (ROM) exercises from the early postoperative period have been recommended as therapy since the introduction of LP[13-18]. However, those studies did not include a formal analysis of the effect of early neck extension muscle strengthening and cervical ROM exercises on postoperative axial pain[19]. Thus, an appropriate treatment protocol after LP is not currently standardized.

This study aimed to examine whether neck extension muscle strengthening and cervical ROM exercise from the early postoperative period effectively suppress axial pain.

Materials and Methods

Study design and participants

This was a randomized, parallel-group, controlled trial based on the CONSORT 2010 guidelines[20]. The eligibility criteria were all patients undergoing LP for cervical spondylotic myelopathy (CSM) or ossification of the posterior longitudinal ligament (OPLL) diagnosed by spine specialists at the first author's institution between December 1, 2019, and December 31, 2020. The inclusion criteria were patients aged 40-89 years who underwent a muscle-preserving LP attached to C2 and C7. Patients with a history of cervical spine surgery, cerebrovascular disorders, or neurological diseases were excluded. Patients with severe postoperative axial or limb pain and hyperesthesia that makes activity difficult or deteriorating patients with limb paralysis were excluded as a cervical collar was prescribed. The sample size was calculated using power analysis software (G*Power 3.1.9.4). The effect size of the interaction of two factors, namely, group (intervention/control) and time (before surgery/2 weeks after surgery/3 months after surgery), in the primary outcome was moderate ($f=0.25$), and the required number of cases at a significance level of $\alpha=0.05$ and power of 0.8 was 44.

This study was approved by the Ethics Review Committee of the Graduate School of Health Sciences, Hirosaki University (2019-025). Eligible patients were given the explanatory document of the study protocol and received an explanation of the outline and objective of the study. All patients who received and understood the explanation agreed to participate in the study.

Prior to conducting this study, the patients were anonymized with due consideration for protecting personal information based on the Declaration of Helsinki.

Randomization and masking

The substitution block method was used for randomization, and the allocation task was performed by the clinical research management office to which the first author belonged, complying with the concealment. The allocation was performed prior to surgery, and the surgeon had no knowledge of the treatment group the patient had been allocated prior to surgery. The roles of the therapist and evaluator were fulfilled by a physiotherapist engaged in the treatment of spinal disorders who belonged to the same institution as the first author. Patients, therapists, and evaluators were not masked to the treatment group to which the patients had been allocated.

Surgery

The same surgeon performed surgery on all patients in this study using the same LP procedure (Kurokawa's method). The C7 semispinalis cervicis was not dissected. In some cases, C2 and C7 osteotomy was performed. Postoperative immobilization using a cervical collar was not performed in any patient. All patients received postoperative nonsteroidal anti-inflammatory drugs, weak opioids, pregabalin, acetaminophen, vitamin B12, or a combination of medications for 3 months.

Interventions

All patients were permitted to sit upright and walk starting the day after surgery. The epidural drain was removed 2 days postsurgery, followed by the initiation of the interventions. Patients were hospitalized at the author's institution for 2 weeks postsurgery. They were provided with a booklet describing the voluntary training method for each intervention at the time of discharge and encouraged to implement voluntary training and record its status daily. Patients who had implemented voluntary training were subsequently transferred to a recovery-phase rehabilitation hospital for approximately 2-3 weeks. Similar interventions were continued at the recovery-phase rehabilitation hospital. All patients were discharged home approximately 1 month postsurgery.

1) Cervical exercise group (group E)

i. Neck extension isometric muscle strengthening and cervical ROM exercises (Fig. 1a-d)

Starting on postoperative day 2, while lying in the supine position, patients performed the exercise of pushing and holding a pillow in the direction of neck extension for 5 s 10 times (3 sets).

The cervical ROM exercise was an active assisted exercise, in which patients performed active exercise in the supine position in the left-right rotation direction, assisted by a therapist in the same direction within manageable pain.

Patients capable of self-exercise were also instructed to perform an exercise for isometric muscle strengthening in the direction of neck extension while seated and cervical extension ROM exercise to standing.

ii. Stretching around the neck and shoulder girdle (Fig. 1e-h)

The cervical paraspinal, neck flexion, and trapezius muscles were manually stretched in the supine position. Patients were instructed to frequently move the scapula in each direction daily.

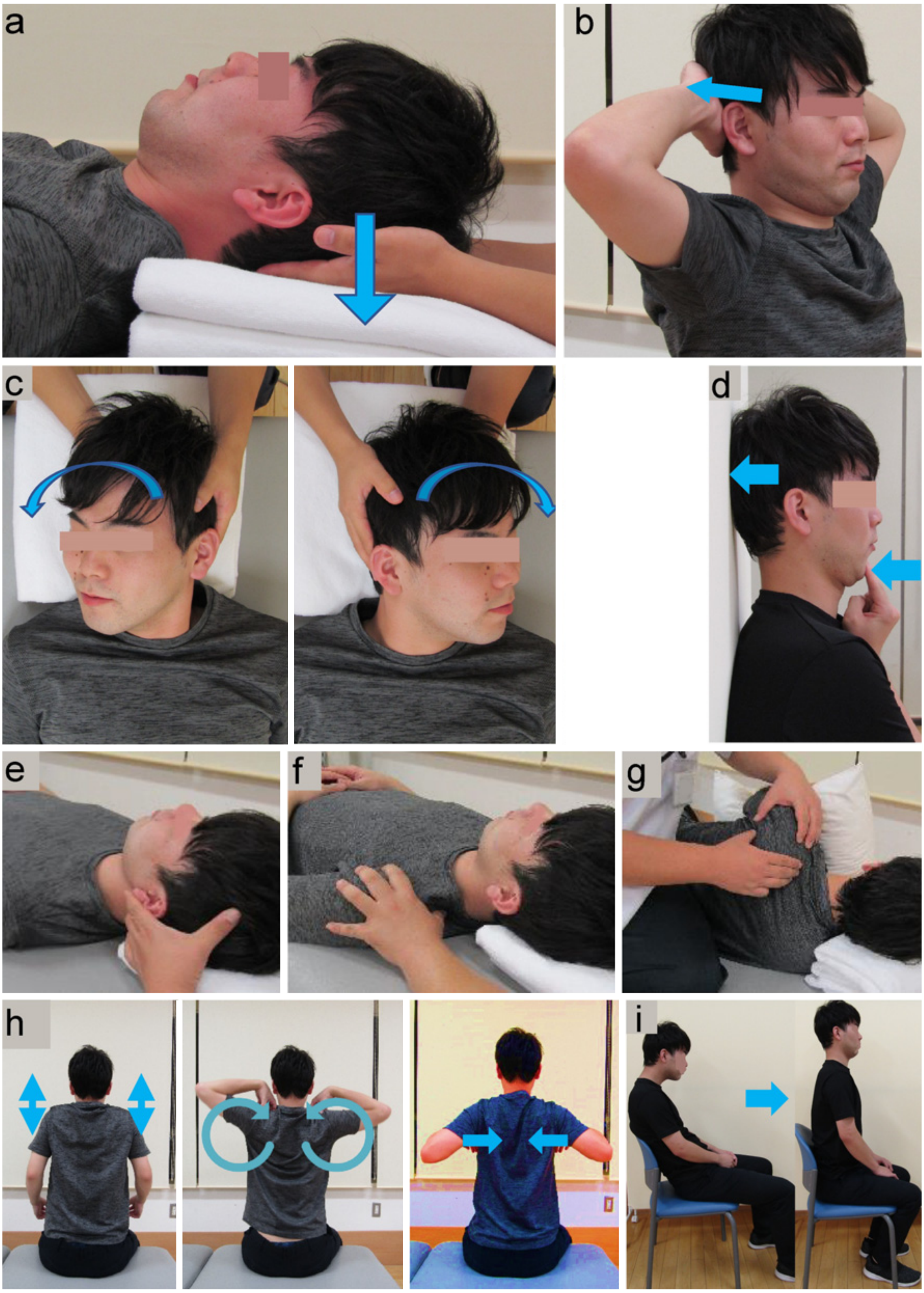

Figure 1. Cervical extensor isometric muscle strengthening and cervical range of motion exercise.
a, b; Cervical extensor isometric muscle strengthening. c; Active assistive range of motion exercises (cervical rotation). d; Active range of motion exercises (cervical extension). e, f, g; Manual stretching (sternomastoid muscle, scalene muscle, trapezius (upper), rhomboids, and levator scapula). h; Scapula exercises. i; Correction of the forward head posture. Written consent has been obtained for this figure.

2) Control group (group C)

No exercise was performed on the neck after postoperative day 2, and cervical movement was recommended as long as the pain did not increase. Instructions on stretching around the neck, shoulder girdle, and cervical posture were provided by a therapist.

3) Instruction on cervical posture (Fig. 1i)

For patients with a forward head posture (FHP) in the sitting and standing postures, the FHP was corrected by visual feedback using a mirror in both groups E and C.

As a precaution in daily life, they were instructed not to keep their gaze downward.

4) Instruction on self-exercise

When discharged from the first author's institution, patients in group E were provided with a booklet describing the methods of neck extension isometric muscle strengthening and cervical ROM exercises similar to those performed at the institution, and instructions on proper sitting posture and precautions in daily life.

Patients who performed self-exercise at least once daily after discharge were required to record it on a calendar and report at 3 months postsurgery.

At the time of final evaluation, the implementation rate of self-exercise (number of days performed/number of days from discharge to final evaluation date×100) was calculated for group E.

Patients in group C were provided with a booklet describing proper sitting posture and precautions in daily life. In addition, the patients were advised to lead a normal life and not perform any voluntary neck strengthening or ROM exercises.

Measurement items

1) Primary outcome

The endpoint of the primary outcome was axial pain, determined using the visual analog scale (VAS). Axial pain was evaluated before, 2 weeks after, and 3 months after surgery, and VAS [if you feel pain or stiffness in your neck or shoulders, mark the degree] of the Japanese Orthopedic Association Cervical Myelopathy Evaluation Questionnaire (JOACMEQ)[21] was used to evaluate axial pain.

2) Secondary outcome

The endpoints of the secondary outcomes were JOACMEQ, neck muscle strength, and cervical spine alignment. JOACMEQ and neck muscle strength were evaluated before, 2 weeks after, and 3 months after surgery, and cervical spine alignment was evaluated before and 3 months after surgery. JOACMEQ was used to determine the treatment effect before and after surgery. Patients with JOACMEQ scores ≥90 points before surgery and after treatment were excluded from the analysis.

Neck muscle strength was evaluated by measuring neck extension muscle strength and flexion muscle strength using a handheld dynamometer (HHD, Mobie MT-100, Sakai Medical Co.). Each measurement was performed twice in a sitting posture, and the average value was calculated. The measured values were divided by body weight for normalization.

To evaluate cervical spine alignment (Fig. 2), the 1: C2-7 lordosis angle, 2: C7 slope, and 3: C2-7 sagittal vertical axis were measured using plain radiography of the cervical spine from a standing side view and functional imaging (forward/backward bending)[22]. Measurements were performed by the same examiner. Each measurement was performed three times, and the average value was calculated. Cervical forward/backward ROM (forward/backward bending ROM) was calculated from the difference in C2-C7 lordosis angles at forward and backward bending. Left and right cervical bending and rotation ROM were measured in the sitting posture twice using a goniometer, and the average value was adopted.

Statistical analysis

The two sample t-test and the χ^2 test were used to compare the patient characteristics of each group before intervention. Analysis of variance (ANOVA) with a split plot design was used to examine the interaction of two factors: groups (group E/group C) and time (before/2 weeks after/3 months after surgery), and the effect size was calculated. Similarly, the interaction of two factors was examined for each item of neck muscle strength and cervical spine alignment, which were evaluated as secondary outcome endpoints, and the effect size was calculated.

An unpaired t-test was used to compare changes in the JOACMEQ values from before to 2 weeks postsurgery and those from before to 3 months postsurgery between the groups to examine the intervention effect. Stepwise multiple regression analysis was used to investigate changes in neck muscle strength and cervical spine alignment that affected changes in the VAS of axial pain.

R4.0.2 (CRAN, freeware) was used for statistical analysis, and the significance level was set at 5%. After all analyses, power was calculated from the effect size of the interaction of axial pain, which was evaluated as the primary outcome.

Results

Fig. 3 shows a flowchart of the randomized allocation procedure used in this study. A comparison of the participant attributes and baseline data is presented in Table 1. There was no significant difference in baseline demographics before surgery between the groups.

Intervention effect

Table 2 shows the results of ANOVA for determining the intervention effect. Axial pain was significantly exacerbated 2 weeks after compared to before LP and significantly improved from 2 weeks after to 3 months postsurgery. Post-hoc analysis revealed that the power (1-β) for the interaction of axial pain was low (0.12). Compared to before surgery, neck muscle strength decreased significantly 2 weeks after LP and then improved significantly at 3 months postsurgery. Improvement of extension and flexion muscle strengths to a

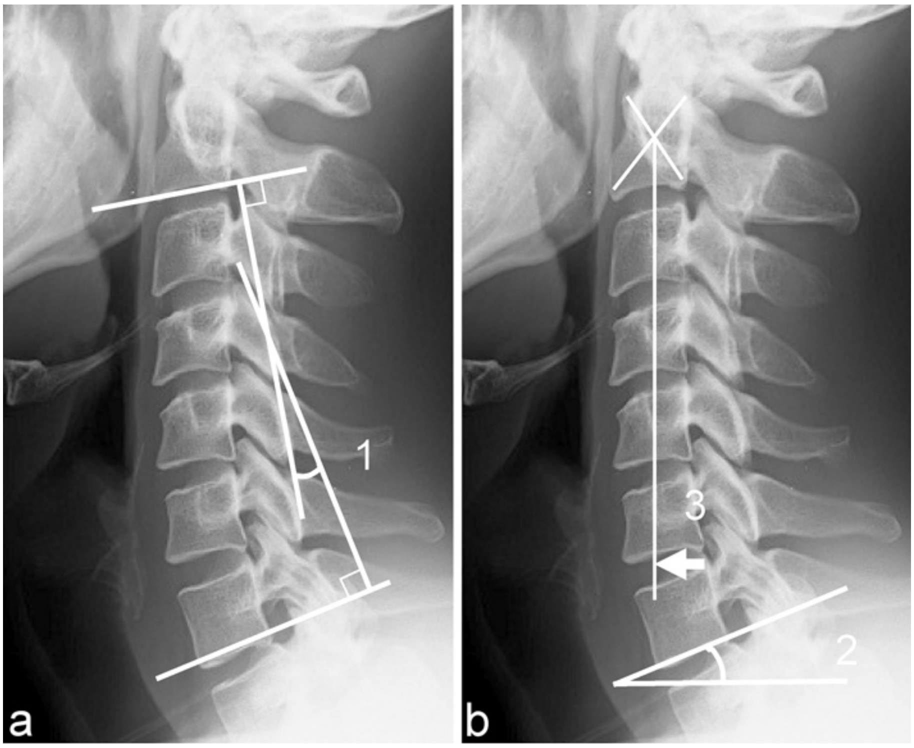

Figure 2. Radiographic evaluation.
a.1: C2–C7 lordosis [lordosis (degree)]; defined as the angle tangential to the lower endplate of the C2 vertebra and upper endplate of the C7 vertebra. b.2: C7 sagittal slope [C7 slope (degree)], defined as the angle tangential to the lower endplate of the C7 vertebra and horizontal line; range of motion of the cervical spine. 3: C2 sagittal vertical axis [C2 SVA (mm)], defined as the distance between the C2 plumb line and the superior-posterior aspect of the C7 vertebra.
・Range of motion of the cervical spine [ROM (degree)], defined as the residual C2–C7 lordosis angle during flexion and extension.

level comparable to or higher than that before surgery was observed at 3 months postsurgery.

No significant interaction with the intervention was observed in cervical spine alignment. For cervical spine alignment, there was no significant interaction between the interventions. In group E, the average implementation rate of self-exercise after discharge from the hospital was 70.2%±31.2%.

Table 3 shows the acquired JOACMEQ values. There was no significant difference in the JOACMEQ values of cervical spine function or other domains 2 weeks and 3 months postsurgery between the groups.

Changes in items affecting the changes in the VAS of axial pain

Table 4 shows changes in neck muscle strength and cervical spine alignment affecting changes in the VAS of axial pain before and 3 months postsurgery. Multiple regression analysis revealed that only changes in neck extension muscle strength significantly affected changes in axial pain at 3 months postsurgery (standard regression coefficient: −0.36). This indicates that lower neck extension muscle strength resulted in severer axial pain at 3 months postsurgery.

Discussion

This is the first randomized controlled trial (RCT) to examine whether cervical exercise therapies, recommended after LP, effectively prevent axial pain in the early postoperative period. Our study showed that neck extension muscle strengthening and cervical ROM exercise performed during the early postoperative period did not relieve axial pain 2 weeks and 3 months postsurgery. In addition, there was no significant difference in neck extension muscle, cervical spine alignment, and mobility between the groups with and without postoperative cervical exercise intervention.

Yoshida et al. emphasized that the paravertebral muscle plays an important role in preventing axial symptoms after LP[14]. Edwards et al. reported that early active ROM and cervical isometric exercises reduced the occurrence of axial symptoms and loss of movement[13]. Thus, neck extension muscle strengthening and cervical ROM exercises from the early postoperative period of LP have been established as standard treatments.

We initially predicted that axial symptoms would improve because of cervical stabilization by performing neck extension muscle strengthening from the early postoperative pe-

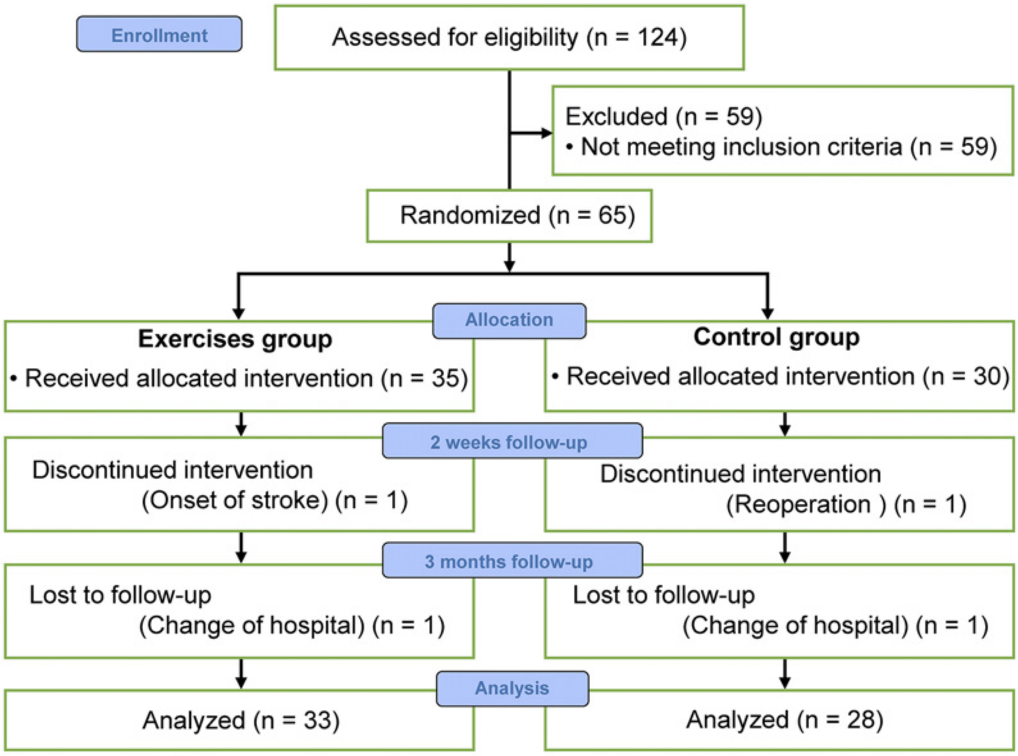

Figure 3. CONSORT flowchart of the randomized controlled trial.
Sixty-five patients were randomized into two groups. Two patients in each group dropped out by 3-month follow-up. Sixty-one patients were included in the analysis.

riod in response to the functional decline of the neck extension muscle caused by postoperative surgical invasion. In addition, we suspected that cervical mobility would be maintained by actively performing cervical ROM exercises from the early postoperative period to prevent contracture of the neck, contributing to the reduction of axial pain.

Although postoperative neck extension muscle strengthening has been recommended, there are no reports describing treatment details. One RCT found that an in-home program for isometric neck extension muscle strengthening in non-surgical patients with loss of cervical lordosis (18 to 45 years old, neck pain continues for more than 2 weeks with VAS of 40 mm or more), sitting upright, placing both hands on the back of the head, and pushing the head posteriorly while resisting posterior movements with the hands (3×30 seconds/day) for 3 months significantly improved the cervical lordosis angle in the exercise group ($P<0.001$) at the end of 3 months, and pain relief was approximately doubled in the exercise group compared to the control group[23]. In our study, a similar method was used in self-exercise. There were no serious drawbacks to the method or frequency of the cervical extension exercises performed in this study. We found that neck muscle strength was slightly higher in group E than in group C but recovered to baseline 3 months postsurgery with or without intervention.

Fujibayashi et al. showed an association between postoperative axial pain and muscle strength, reporting that neck extension muscle strength recovered to the preoperative baseline in the group with low axial pain at 3 months postsurgery[24]. In our study, all participants underwent a muscle-preserving LP to C2 and C7, which may have led to the absence of severe postoperative axial pain in all cases.

Ono et al.[7] showed that C3-6 LP, which maintains muscles attached to the C2 and C7 spinous processes, significantly reduces the incidence of postoperative axial neck pain. In this study, neck extension muscle strength recovered to baseline at 3 months postsurgery regardless of the method of postoperative intervention, indicating that postoperative extension muscle strength is expected to be maintained in muscle-preserving LP attached to C2 and C7. No effect of the exercise therapy intervention on cervical spine alignment and neck ROM was observed.

Our results also support the finding that a muscle-preserving LP attached to C2 and C7, which preserves the semispinalis cervicis attached to C7, maintains the function of the neck extension muscle and prevents axial symptoms by maintaining the function of the trapezius and rhomboid muscles[6]. Patients undergoing a muscle-preserving LP attached to C2 and C7 may not require active cervical exercise intervention because of the characteristics of the procedure. By contrast, the results of this study, in which changes in postoperative neck extension muscle strength affected those in postoperative axial pain, indicated the need for strengthening the neck extension muscles. Few studies have been conducted to determine the effectiveness and need for an active cervical exercise intervention in the early postoperative period, leaving scope for future research.

Table 1. Baseline Demographics and Comparison of Study Groups.

Preoperative Parameters	Exercise group (n=33)	Control group (n=28)	P value
Age (y)	71.6±10.5	71.1±10.7	0.83*
Sex (male:female)	23:10	20:8	0.81†
Body mass index (kg/m^2)	23.6±3.6	24.2±5.3	0.86*
Diagnosis (CSM:OPLL)	29:4	25:3	0.86†
Operation (Kurokawa type)			
muscle-preserving laminoplasty attached to C2 and C7	2	1	
+C2,C7-dome osteotomy	1	1	0.90†
+C7-dome osteotomy	30	26	
JOACMEQ (100-point system)			
Neck-P (0–100 mm)	27.1±26.6	23.1±22.7	0.65*
CSF	71.8±21.9	75.1±22.5	0.43*
UEF	82.4±14.7	82.9±15.5	0.77*
LEF	61.4±23.1	57.0±24.6	0.48§
BF	71.9±19.7	73.0±21.7	0.68*
QOL	45.0±12.7	50.3±16.4	0.17§
Neck Muscle Strength			
Flexion (N/kg)	1.3±0.3	1.4±0.3	0.09§
Extension (N/kg)	1.6±0.6	1.6±0.5	0.94§
Cervical spine alignment			
C2–7 Lordosis (deg.)	12.0±9.9	14.0±11.0	0.46§
C7 Slope (deg.)	27.7±8.6	25.4±7.7	0.35*
C2–7 SVA (mm)	29.3±17.8	21.7±14.8	0.08§
ROM (deg.)	41.7±10.9	41.0±12.8	0.80§
Right bending (deg.)	23.7±6.9	25.6±8.0	0.32§
Left bending (deg.)	23.9±8.0	22.7±8.0	0.63*
Right rotation (deg.)	56.8±13.0	55.7±9.8	0.45*
Left rotation (deg.)	56.7±12.7	56.6±10.0	0.98§

* Mann–Whitney U test.
†Pearson's chi-square test.
§Two sample t-test.
BF: bladder function, CSF: cervical spine function, CSM: cervical spondylotic myelopathy, JOACMEQ: Japanese Orthopedic Association Cervical Myelopathy Evaluation Questionnaire, LEF: lower extremity function, Neck-P: visual analog scale for degree of pain or stiffness in the neck or shoulders, OPLL: ossification of posterior longitudinal ligament, QOL: quality of life, ROM: range of motion, SVA: sagittal vertical axis, UEF: upper extremity function

Limitations

The number of cases in this study was small because of the low power (1-β) of the interaction of axial pain, evaluated as the primary outcome. In addition, because this study was limited to patients undergoing a muscle-preserving LP attached to C2 and C7, it did not examine the effect of cervical exercise intervention from the early postoperative period in patients undergoing procedures involving C2 and C7. Moreover, the evaluators of the outcomes could not be blinded. Exercise intervention from the early postoperative period to 3 months postsurgery had no effect on axial pain that occurred in the early postoperative period. However, its effect on long-term outcomes remains unknown and requires further study. It will further be necessary to focus on the cervical spine for postoperative exercise intervention and develop exercise therapy from a systemic perspective, such as at the level of the thoracic vertebra and lower extremity function.

Conflicts of Interest: The authors declare that there are no relevant conflicts of interest.

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Author Contributions: Toru Uehara: conceptualization or design of the work; or the acquisition, analysis, or interpretation of data for the work, drafting the work. Eiki

Table 2. Means of Neck-P, Muscle Strength, and Cervical Alignment; Exercise Group (n=33) Compared to Control Group (n=28).

Parameters	Preoperative	Post-2 weeks	Post-3 months	Groups		Time		Group×Time		Effect size
				F	p value	F	p value	F	p value	
Neck-P (0–100 mm)				0.259	0.613	18.328	0.000	0.476	0.623	0.004
E	27.1±26.6	42.8±24.0	25.3±23.1							
C	23.1±22.7	44.9±27.4	20.6±18.3							
Neck extension muscle strength (N/kg)				0.092	0.763	26.550	0.000	0.304	0.738	0.001
E	1.62±0.56	1.31±0.43	1.69±0.53							
C	1.61±0.47	1.30±0.39	1.61±0.47							
Neck flexion muscle strength (N/kg)				0.606	0.440	18.201	0.000	2.747	0.068	0.007
E	1.26±0.34	1.23±0.40	1.41±0.33							
C	1.41±0.33	1.25±0.36	1.44±0.36							
C2–7 lordosis (deg.)				0.301	0.586	12.085	0.001	0.224	0.638	0.004
E	12.0±9.9		8.7±13.1							
C	14.0±11.0		9.6±10.9							
C7 slope (deg.)				1.330	0.253	5.454	0.023	0.092	0.763	0.001
E	27.7±8.6		26.0±6.4							
C	25.4±7.7		24.1±8.6							
C2–7 SVA (mm)				3.645	0.061	0.494	0.485	0.004	0.949	0.000
E	29.3±17.8		30.3±18.5							
C	21.7±14.8		22.6±13.1							
ROM (deg.)				0.250	0.619	61.160	0.000	0.086	0.771	0.002
E	41.7±10.9		30.0±10.9							
C	41.0±12.8		28.3±9.8							
Right bending (deg.)				0.760	0.387	4.966	0.030	0.332	0.567	0.006
E	23.7±6.9		25.8±7.0							
C	25.6±8.0		26.9±7.0							
Left bending (deg.)				0.014	0.906	5.979	0.018	0.886	0.350	0.015
E	23.9±8.0		25.3±9.0							
C	22.7±8.0		26.0±7.6							
Right rotation (deg.)				0.244	0.623	6.777	0.012	0.000	0.996	0.000
E	56.8±13.0		60.0±8.1							
C	55.7±9.8		58.9±5.8							
Left rotation (deg.)				0.030	0.862	7.374	0.009	0.074	0.786	0.001
E	56.7±12.7		60.4±9.4							
C	56.6±10.0		59.6±7.5							

Mean±SD
ROM: range of motion, SVA: sagittal vertical axis
Split plot ANOVA, Effect size: Generalized η^2

Table 3. Comparison of JOACMEQ Effective Values 2 Weeks after Surgery and 3 Months after Surgery between Groups.

	Post 2 Weeks					Post 3 months				
	E-group	n	C-group	n	p	E-group	n	C-group	n	p
CSF	−19.2±30.8	31	−12.0±25.0	27	0.33	3.2±19.9	28	7.4±26.5	23	0.52
UEF	−1.1±11.5	24	1.5±17.0	21	0.55	6.4±11.5	23	5.8±15.0	20	0.87
LEF	1.7±16.3	32	7.1±20.2	26	0.25	9.2±21.6	30	11.9±19.4	25	0.63
BF	5.5±15.4	27	5.5±15.6	23	0.99	7.9±19.9	26	−1.3±17.6	24	0.09
QOL	3.5±14.6	33	3.2±17.9	28	0.93	10.2±21.2	33	5.5±19.1	28	0.82

There was no difference in the treatment effect between the two groups at 2 weeks and 3 months postoperatively.
CSF: cervical spine function, UEF: upper extremity function, LEF: lower extremity function, BF: bladder function, QOL: quality of life

Tsushima: conceptualization or design of the work, analysis, interpretation of data for the work. Shota Yamada, Shingo Kimura, Yuya Satsukawa, Akira Yoshihara: data collection. Atsushi Inada, Takashi Hayakawa: interpretation of data for the work. All of the authors were involved in drafting the work or revising it critically for important intellectual con-

Table 4. Factors Contributing to the Amount of Change in Axial Pain.

Parameter	Estimate	Std. Err.	DF	β	T-value	p value
Intercept	−1.247	3.437	59	0.000	−0.363	0.718
Δ Neck Muscle Strength: Extension	−26.065	8.746	59	−0.362	−2.980	0.004

Shown are the multiple linear regression coefficients. β: standardized coefficients, DF: degree of freedom
Model F-statistic=8.882, $p<0.01$. Adjusted $R^2=0.13$.

tent and provided final approval to publish the manuscript.

All of the authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Ethical Approval: This study was approved by the Ethics Review Committee of the Graduate School of Health Sciences, Hirosaki University (2019-025). Prior to conducting this study, the patients were anonymized with due consideration for the protection of personal information based on the Declaration of Helsinki.

Informed Consent: All patients who received and understood the explanation gave informed consent.

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