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Postoperative rigid cervical collar leads to less axial neck pain in the early stage after open-door laminoplasty – a single-blinded randomized controlled trial

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1

2 **Abstract**

3 **Background:** Cervical collars are used after laminoplasty to protect the hinge opening, reduce  
4 risks of hinge fractures and avoid spring-back phenomena. However, their use may lead to  
5 reduced range of motion and worse neck pain.

6 **Objective:** We aim to investigate the clinical, radiological and functional outcomes of patients  
7 undergoing single-door laminoplasty with or without collar immobilization.

8 **Methods:** This was a prospective, parallel, single-blinded randomized controlled trial. Patients  
9 underwent standardized single-door laminoplasty with mini-plates for cervical myelopathy and  
10 were randomly allocated into two groups based on the use of collar postoperatively. Clinical  
11 assessments included cervical range of motion, axial neck pain (VAS), and objective scores (SF-  
12 36, NDI, mJOA). All assessments were performed preoperatively and at postoperative 1-week,  
13 2-weeks, 3-weeks, 6-weeks, 3-months, 6-months and 12-months. Comparative analysis was  
14 performed via analysis of variance adjusted by baseline scores, sex and age as covariates.

15 **Results:** 35 patients were recruited and randomized to collar use (n=16) and without (n=19).  
16 There were no dropouts or complications. There were no differences between groups at baseline.  
17 Subjects had comparable objective scores and range of motion at postoperative timepoints.  
18 Patients without collar use had higher VAS at postoperative 1-week (5.4 vs 3.5; p=0.038) and 2-  
19 weeks (3.5 vs 1.5; p=0.028) but subsequently follow-up revealed no differences between the two  
20 groups.

21 **Conclusions:** The use of a rigid collar after laminoplasty leads to less axial neck pain in the first  
22 two weeks after surgery. However, there is no additional benefit with regards to range of motion,  
23 quality of life, and complication risk.

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2 **Level of Evidence:** 1

3 **Running title:** Less pain with collars in single-door laminoplasty

4 **Key Words:** Cervical myelopathy; neck collar; randomized controlled trial; open-door  
5 laminoplasty; plates

6

## 1 Introduction

2 The hugely popularized “open-door” technique, originally reported by Hirabayashi *et al*<sup>1</sup>,  
3 is commonly used for cervical myelopathy treatment. The opening created by this technique is  
4 historically held open by sutures but this carries risk of “spring-back” phenomenon where the  
5 lamina opening closes leading to recurrence of symptoms.<sup>2</sup> Recent trends in cervical  
6 laminoplasty are for the adoption of more rigid devices like mini-plates to maintain the laminar  
7 opening.<sup>3-7</sup> These stronger fixation methods may avoid complications such as loss of fixation,  
8 hinge fracture and spring-back deformity. Titanium plates for fixation has long lasting patency  
9 with biological healing of the laminar arch without much complications.<sup>7</sup>

10 There is still no consensus regarding the use of rigid cervical collar immobilization in the  
11 early postoperative period. Collars are commonly used by surgeons especially after anterior  
12 cervical surgery to avoid instrumentation complications and to improve fusion rates despite  
13 limited evidence.<sup>8,9</sup> For laminoplasty, its use may be helpful to protect the hinge, reduce risks of  
14 hinge fractures and avoid springback phenomena. However, certain complications have been  
15 reported with rigid neck collars. Its use has been shown to reduce cervical range of motion on  
16 average by 62.9%.<sup>10</sup> To perform the usual functional activities of daily living one requires less  
17 than half of the normal cervical range of motion,<sup>11</sup> but with 5 days of rigid collar use, there is a  
18 decreased velocity of voluntary eye movement and subtle deterioration in anterior-posterior body  
19 sway induced by vibration of calf muscles.<sup>12</sup> Prolonged cervical movement restriction may have  
20 a detrimental effect on static postural control and balance during dynamic movement.<sup>12</sup>  
21 Although, the duration of neck collar use has also been attributed to postoperative axial neck  
22 pain<sup>13-15</sup>, Hida *et al*<sup>16</sup> suggested that there were no differences in pain and outcomes with 2-  
23 weeks postoperative use of rigid neck collars after double-door laminoplasty. However, results  
24 should be interpreted with caution due to unknown sensitivity of secondary outcomes (range of  
25 motion, lordotic angle or functional scores) with a high dropout rate.

26 With the trend towards more rigid fixation for maintaining hinge opening, plates may  
27 preclude the need for cervical collars. This may allow for earlier mobilization, less neck stiffness  
28 and axial neck pain while reducing the cost for manufacturing neck collars, daily fitting and  
29 maintenance. Ultimately, this may improve patient-reported outcomes. Hence, we aim to conduct  
30 a randomized controlled trial to investigate the clinical, radiological and functional outcomes of

1 patients undergoing open-door laminoplasty with or without cervical neck collar for  
2 postoperative immobilization.

3

#### 4 **Methods**

##### 5 *Study design and participants*

6 The study was a prospective, parallel single-blinded randomized controlled trial  
7 conducted during the study period from April 2015 to February 2018. Patient recruitment was  
8 performed at two tertiary referral centers by the attending spine specialist. Inclusion criteria was  
9 any male or female patient aged over 18 years, clinical and radiological signs compatible with  
10 cervical myelopathy undergoing open-door laminoplasty for one or more spinal compression  
11 levels. Patients were required to be literate and able to comprehend the study to be enrolled.  
12 Exclusion criteria included all patients with previous cervical spine surgery, congenital  
13 deformities, spine infection or inflammation, tumor, previous spinal fusion surgery, non-Chinese  
14 ethnicity, undergoing workman's compensation and unable or refuse to follow the standardized  
15 rehabilitation protocol. All patients were given information sheets regarding the study protocol  
16 and both verbal and written informed consents were obtained at the time of recruitment. Patients  
17 were consented for a study comparing the clinical, radiological and functional parameters with or  
18 without rigid neck collar use after single-door laminoplasty. Details regarding each study  
19 parameter were not divulged to the study participants. Ethics approval was obtained from the  
20 local institutional review board. There were no changes to the methods after trial  
21 commencement.

22

##### 23 *Randomization and masking*

24 Patients who fulfilled the inclusion and exclusion criteria and agreed for participation in  
25 the study were consecutively recruited and randomized at the time of surgery to either receive a  
26 Philadelphia collar for 3 weeks postoperatively or to be allowed free mobilization without any  
27 collar immobilization. Random allocation was performed using a computer program with a block  
28 size of 10. One independent investigator generated the random allocation sequence, enrolled

1 participants and assigned participants to interventions. It was not possible for patients and  
2 operating surgeons to be blinded to the group allocation. All assessors of clinical, radiological  
3 and objective scores were blinded to patient details. All patients randomized to the neck collar  
4 group had the collar removed prior to assessments to maintain blinding.

5

#### 6 *Sample size calculation*

7 Due to lack of previous available data comparing patients with collar immobilization  
8 after open-door laminoplasty, we performed a pilot study and periodically assessed the  
9 difference in axial neck pain (primary outcome) between the two groups measured by the visual  
10 analogue scale (VAS). Based on the 2 weeks postoperative data for the first 20 subjects  
11 recruited, we found that a sample size of 16 patients in each group could achieve a power of  
12 >80% with a significance level of 0.05 to detect a minimal VAS difference of 1.5 as reported as  
13 the minimal clinically important difference (MCID).<sup>17-20</sup> Hence, based on this, we included a  
14 total of 35 patients assuming a 10% attrition rate.

15

#### 16 *Treatment procedure*

17 Operative techniques were standardized and performed by four surgeons from the same  
18 institute. After exposure of the bony posterior elements, a full-thickness trough was drilled on the  
19 side of the laminae with a high-speed burr. The side chosen was based on the side with more  
20 significant clinical symptoms. On the contralateral side, a partial-thickness trough was created at  
21 the junction of the lamina and the lateral mass using the same burr. The lamina was opened  
22 toward the side with the partial-thickness trough as a hinge. The spinal canal was thus expanded  
23 and maintained open by titanium mini-plates at all levels. After fixation was completed, the  
24 wound was closed over a deep drain which was kept until the 24-hour blood loss was less than  
25 50ml. For patients allocated to the collar group, they were allowed to remove the collar  
26 temporarily whilst resting in bed. All patients were prescribed pregabalin 75mg twice daily for  
27 the first week after surgery and allowed paracetamol 500mg 4 times daily as needed  
28 postoperatively. For the postoperative rehabilitation protocol, all patients were allowed

1 respiratory and circulatory exercises, transfer and walking training as well as other activities of  
2 daily living. Patients were allowed discharge to home once independent living or carer was  
3 arranged. General home training program included exercises, postural training and walking. Both  
4 groups were restricted from contact sports, heavy lifting or outer-range cervical spine  
5 movements within 3 months of operation.

6

### 7 *Study parameters and outcome measures*

8 All primary and secondary outcome measures were recorded immediately preoperatively  
9 (day before surgery), at 1, 2, 3 and 6 weeks postoperatively, and at 3, 6 and 12 months  
10 postoperatively. This was standardized and followed without any changes during the trial. A 1-  
11 year follow-up was deemed adequate as collar use was only an early postoperative intervention  
12 with unlikely long-term influences. The primary outcome measure was reported axial neck pain  
13 by VAS. Secondary outcome measures were divided into clinical, radiological and objective  
14 scores, namely short-form 36-item questionnaire (SF-36) and neck disability index (NDI).

15 Clinical assessments included the cervical spine range of motion measured in a  
16 standardized order: active extension, flexion, lateral flexion (right then left) and rotation (right  
17 then left). The range of motion was measured by a fluid goniometer (MIE Medical Research  
18 Ltd., Leeds, UK). The modified Japanese Orthopaedic Association (mJOA) score was measured  
19 for functional outcomes. Recovery rate was measured by the Hirabayashi method<sup>21</sup>: Recovery  
20 rate (%) = (postoperative JOA – preoperative JOA)/(17 [full score] – preoperative JOA) x 100.  
21 All clinical assessments were performed by an independent investigator who maintained  
22 blinding.

23 Lateral cervical spine radiographs were obtained at each time-point. The anteroposterior  
24 canal diameter was measured using Wolf's method,<sup>2, 22, 23</sup> from the middle of the posterior border  
25 of the vertebral body to the anterior border of the lamina. Cervical sagittal alignment was  
26 measured at C2-7 from the lower endplate of C2 to the lower endplate of C7. All lateral  
27 radiographs were obtained with the patient erect, standing against a board with set shoulder  
28 position. Patients were advised to have a horizontal gaze during the imaging. The focus film  
29 distance was set as 180cm while centering at the angle of the mandible. The exposure was 62-

1 peak-kilovoltage and 8-10 milliamperage-seconds of x-ray energy. All images were assessed by  
2 three independent readers who maintained blinding. When the difference in measurements was  
3 less than 1mm or 5 degrees, the mean of the three measurements were recorded. If there was a  
4 discrepancy of more than 1mm or 5 degrees, a joint concluded value for reporting was decided  
5 based on consensus between the readers. Inter- and intrarater reliability analyses were performed  
6 for the radiographic measurements via intraclass correlation coefficient (ICC). The 2<sup>nd</sup> round of  
7 reliability measurements were performed 1 month after the 1<sup>st</sup> round of measurements.

8 Any complications including perioperative events, surgical site infections, post-  
9 laminoplasty C5 palsy and reoperations were recorded. Radiographs were assessed for fracture  
10 or loosening of implants, and spring-back as determined by >1mm loss of initial anteroposterior  
11 canal diameter expansion.<sup>22</sup>

12  
13 *Statistical analysis*

14 Due to the multiple covariates and time-points, one-way analysis of covariance  
15 (ANCOVA) was conducted for assessing whether the collar and without-collar groups were  
16 statistically different having adjusted for covariates. Data were presented by mean scores ±  
17 standard deviation unless stated otherwise. Statistical significance was tested at 5% level for all  
18 tests. Intention to treat principle was used for continuous and discrete data. As alluded to in the  
19 sample size calculation, post-hoc analysis was performed with G\*Power (version 3.0.10,  
20 Heinrich Heine University, Dusseldorf, Germany) to determine whether difference in axial VAS  
21 between groups achieved adequate power of >80%. 95% confidence intervals (95% CIs) were  
22 reported when appropriate. Post-hoc power analysis (Cohen effect size) was used to assess the  
23 sensitivity for secondary parameters.

24  
25 **Results**

26 A total of 35 patients with mean age of 64.9±11.4 years at surgery were consecutively  
27 recruited and randomized to collar use (n=16) and without collar immobilization (n=19). **Figure**  
28 **1** shows the flow diagram of patient enrollment and follow-up. The first patient was enrolled on

1 April 2015 and the last 1-year follow-up assessment was performed on February 2018. There  
2 were no dropouts nor complications. All subjects were analyzed by all primary and secondary  
3 outcomes. Preoperatively, both groups (**Table 1**) were comparable with no differences in age,  
4 VAS, range of motion, cervical spine alignment, canal diameter and outcome scores. The inter-  
5 and intrarater reliability were good (**Table 2**). Sensitivities for outcome parameters are listed in  
6 **table 3**.

7 The mean absolute and change in VAS are listed in **Table 4**. There was statistically  
8 significantly lower mean VAS for the collar group at postoperative 1 ( $3.5 \pm 2.0$  versus  $5.4 \pm 2.5$ ,  
9  $p=0.038$ ), 2 ( $1.5 \pm 1.4$  versus  $3.5 \pm 2.4$ ,  $p=0.028$ ) and 3 ( $1.3 \pm 1.0$  versus  $2.8 \pm 1.9$ ,  $p=0.031$ ) weeks  
10 (**Figure 2**). Significant reductions in postoperative VAS compared to preoperative VAS were  
11 observed only at postoperative 1 ( $0.8 \pm 2.4$  versus  $3.8 \pm 3.5$ ,  $p=0.016$ ) and 2 ( $-0.9 \pm 3.4$  versus  
12  $1.8 \pm 3.2$ ,  $p=0.004$ ) weeks for the collar group. There were no differences at postoperative 3  
13 weeks to 12 months follow-up assessments.

14 Regarding the outcome measures, subjects had comparable NDI scores (**Table 5**)  
15 between groups. Patients with collar use appeared to have fewer limitations and bodily pain  
16 subscores ( $p=0.032$ ) of SF-36 (**Table 6**) than those without collar use. However, these  
17 differences were only in the immediate postoperative period, and did not affect the overall  
18 physical and mental component summaries. There were overall gradual improvements in mJOA  
19 (**Table 7**) from preoperative to postoperative 12 months follow-up. Similar findings were  
20 observed for the recovery rate (**Figure 3**).

21 From the one-way ANCOVA analysis, there were no differences in the adjusted mean  
22 spinal canal diameter between the two groups (**Table 8**). Based on the absolute canal widening at  
23 postoperative 1 week, there were also no significant losses in canal expansion suggesting no  
24 spring-back phenomena. The cervical alignment was preserved in both groups and was  
25 consistent throughout follow-up.

26 Both groups recorded similar cervical range of motion (**Table 9**) at all follow-up  
27 assessments, except for the larger range of rotation at right side for the without-collar group at  
28 postoperative 3-weeks ( $p=0.046$ ). Limitations of extension, flexion, lateral flexion and rotation



1 were observed within the first two weeks postoperatively for both groups. There were gradual  
2 improvements observed up till postoperative 6 weeks and were consistent beyond that.

3

#### 4 **Discussion**

5 This study assessed whether rigid cervical collar immobilization in the early  
6 postoperative period for open-door laminoplasty is necessary. Previously, there was no evidence  
7 to support the use of neck collars after open-door laminoplasty. Establishing all the benefits of  
8 collar use is necessary to improve our postoperative recovery protocols. Results from our study  
9 suggest that collar immobilization reduces the severity of early postoperative axial neck pain.  
10 However, due to limited differences in overall patient-reported outcomes and no reduced  
11 complication rate, the authors suggest that postoperative collar use should only be recommended  
12 for patients for concerns of postoperative axial neck pain, and not be strictly enforced.

13 Based on the VAS assessments, benefits of postoperative rigid cervical neck collar use  
14 are limited to reduced axial neck pain within the initial 2 weeks after surgery. Beyond 2 weeks,  
15 the VAS between both groups were similar. Although the VAS was also significantly lower for  
16 the collar group at postoperative week 3, the difference did not reach MCID and was considered  
17 not clinically relevant.<sup>17-20</sup> There was a 2-3-point lower VAS on average with collar  
18 immobilization consistent until postoperative week 2. From postoperative week 3 to 1 year, there  
19 were no differences between the two groups. It is likely that the use of postoperative collars may  
20 help patients cope with the initial postoperative pain and disability. Furthermore, resisting  
21 excessive neck mobilization may aid with wound pain, which typically recovers by the end of  
22 postoperative week 2.

23 Although there were observed differences in axial neck pain VAS and bodily pain (SF-36  
24 subscale) between the two study groups, this did not translate into detectable differences in  
25 patient-perceived outcomes via NDI and SF-36 (both physical and mental component summary  
26 scores). The bodily pain component scores were superior in the neck collar group in the first 3  
27 postoperative weeks and were only balanced at the postoperative 6 weeks reading. The absence  
28 of such impact on the overall physical and mental component summaries suggest that pain was  
29 not the predominant clinical symptom driving satisfaction after surgery. Perhaps the

1 improvements in myelopathy were far more impactful to their health perception. This is a  
2 drawback of utilizing general health questionnaires as compared to disease specific  
3 questionnaires.

4 It was crucial to determine if there were any differences in clinical and radiological  
5 outcomes for efficacy and safety concerns. Both groups observed gradual improvements  
6 postoperatively from 1 week to 1 year in mJOA (mean 3.8) and recovery rate (54%), which is  
7 similar to previous reports.<sup>24-26</sup> This is to be expected as collar use should not impact the rate of  
8 improvement in myelopathic symptoms and hence despite a small effect size, it should not be an  
9 important secondary outcome to consider for differentiating the two groups. Despite having no  
10 patients requiring reoperation, spring-back is a concern for patients undergoing laminoplasty due  
11 to the re-narrowing of the spinal canal and diminished symptomatic relief. Traditionally, spring-  
12 back has a reported rate of 10% if stay sutures are used to hold open the laminae.<sup>2</sup> By  
13 comparison, mini-plates provide more rigid fixation<sup>27, 28</sup> and our measured canal sizes suggest  
14 that spring-back does not occur in plated levels even without postoperative immobilization. In  
15 addition, no differences in cervical alignment suggests that collar use does not aid maintenance  
16 of lordotic posture.

17 One of the advantages of not immobilizing the cervical spine postoperatively is to allow  
18 for early range of motion exercises. Furthermore, the use of rigid cervical neck collars has been  
19 shown to reduce the usual cervical range of motion by 62.9%.<sup>10</sup> Yet, both study groups had  
20 comparably reduced extension, flexion, lateral flexion and rotation in the early postoperative  
21 period before returning to near normal range at postoperative 3 weeks. Although right rotation  
22 for the without-collar group appeared to normalize quicker at postoperative 3 weeks, there was  
23 lack of early or late follow-up differences seen in the two study groups. This suggests that a  
24 period of immobilization does not restrict overall range of motion. Rather, early restrictions may  
25 be a result of postoperative pain and adjustments to disability. Having a collar may not assist  
26 recovery of the posterior musculature that is injured as part of the laminoplasty surgery.<sup>29</sup>  
27 Nevertheless, our effect size for range of motion was small and thus may need to be addressed in  
28 a larger study.

29 An important limitation of this study is the placebo effect undoubtedly present due to the  
30 study design. Since patients were informed that this was a study comparing the outcomes with or

1 without neck collar use, study subjects using collars may experience a placebo effect. In contrast,  
2 patients not using collars may feel insecure with a perceived unstable cervical spine. Despite not  
3 disclosing the exact outcome parameters under study, patient reported measures may very well  
4 be affected by such perceptions. An ideal study design would comprise of blinding patients to the  
5 reason for this study. Different durations of postoperative immobilization may have additional  
6 influences on outcome scores. For this study, we avoided introducing another confounding  
7 element by utilizing a standardized 3-week immobilization protocol. Further trials comparing  
8 shorter or longer duration immobilization should be performed to study these effects. Although  
9 multiple objective scores were utilized in this study, the Japanese Orthopaedic Association  
10 Cervical Myelopathy Evaluation Questionnaire (JOACMEQ) is an important patient-perceived  
11 health-related quality of life score that should be applied in these outcome comparisons as it  
12 includes not only domains of the original JOA score but also patient-perceived health status.<sup>30-32</sup>  
13 It is also a disease-specific questionnaire that may identify subtle changes in targeted treatment  
14 groups. Regarding the canal measurements, while a well-established radiological method was  
15 utilized in this study to identify spring-back complications, the lateral cervical radiographs may  
16 not be as sensitive as computed tomography (CT). Nevertheless, we found no differences using a  
17 randomized study design and radiographs are much more readily available and with significantly  
18 less radiation exposure as compared with CT.

19 This randomized controlled trial provided level I evidence for the benefits of early  
20 postoperative axial neck pain reduction with rigid neck collar use after single-door laminoplasty.  
21 These findings should be generalizable with standardized treatment protocols and objective  
22 assessments. Our study was adequately powered for this primary outcome with sensitivity tested  
23 to be sufficient for canal diameter measurements and NDI, both of which are key secondary  
24 outcomes of safety and efficacy, respectively. In this modern age with an increasingly conscious  
25 society to health economics, any management must also be balanced in terms of healthcare cost.  
26 It is our duty to select the best and most cost-effective treatment option for patients. Despite  
27 better reported axial neck pain with collar use, limited benefits are observed in other parameters  
28 both in the early postoperative period and at longer follow-up. Hence, surgeons must consider  
29 carefully whether the additional costs of a neck collar after surgery is worth the small clinical  
30 benefits.

1

2 **Conclusion**

3           Many postoperative management protocols consider the use of rigid cervical neck collars  
4 after laminoplasty to avoid implant failure, loss of correction and recurrence of neurological  
5 deficit due to perceived risk of spring-back. With modern rigid plating fixation, the risk of such  
6 complications is low. Via a randomized controlled trial, we determined that postoperative collar  
7 use in the first two weeks after surgery leads to reduced axial neck pain. However, this difference  
8 in pain response does not impact the overall quality of life of patients. Hence, the authors  
9 recommend a temporary two-week use of rigid neck collars postoperatively to patients for better  
10 pain relief but strict adherence is not necessary as limited benefits are observed elsewhere with  
11 no difference in long-term outcomes.

12

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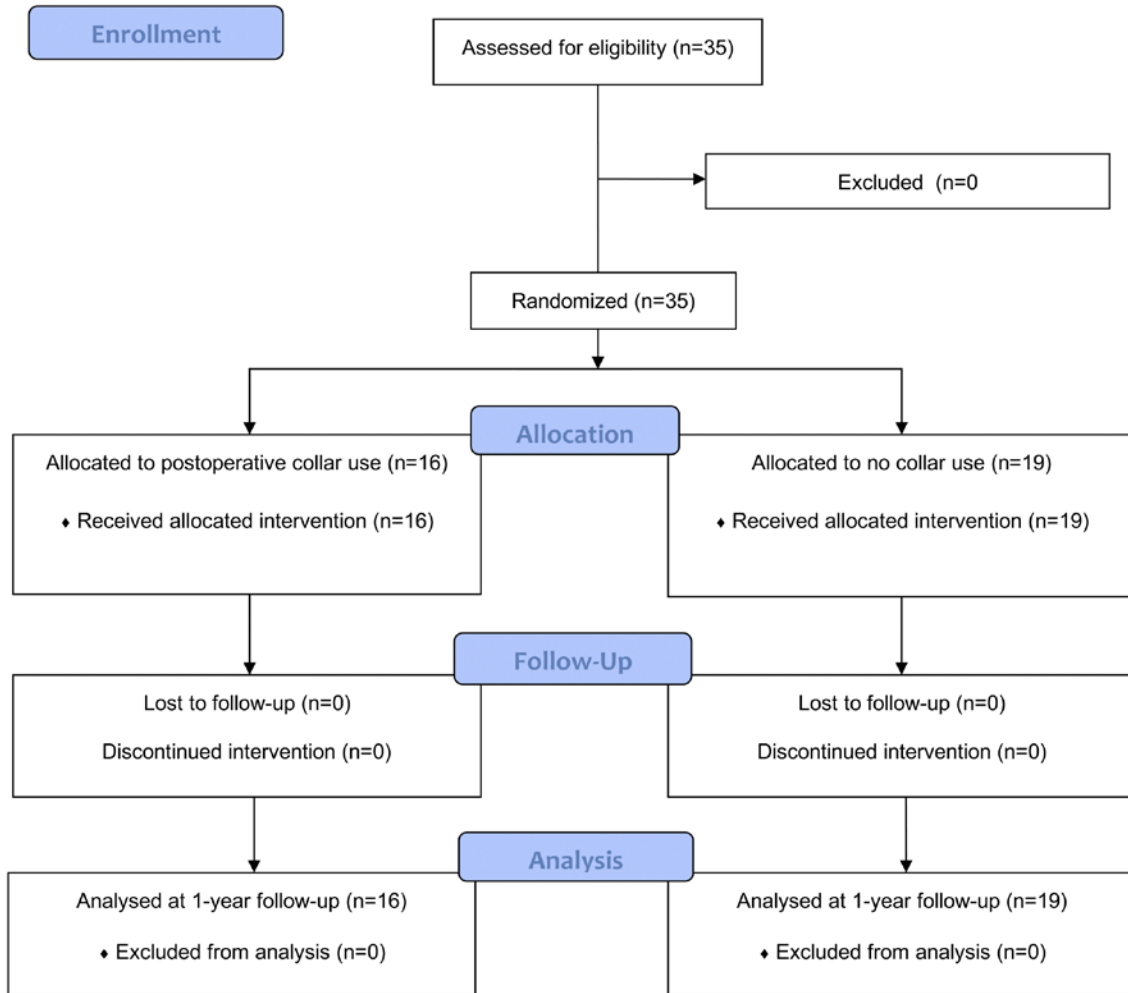
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29

1 **Figure Legends**

2

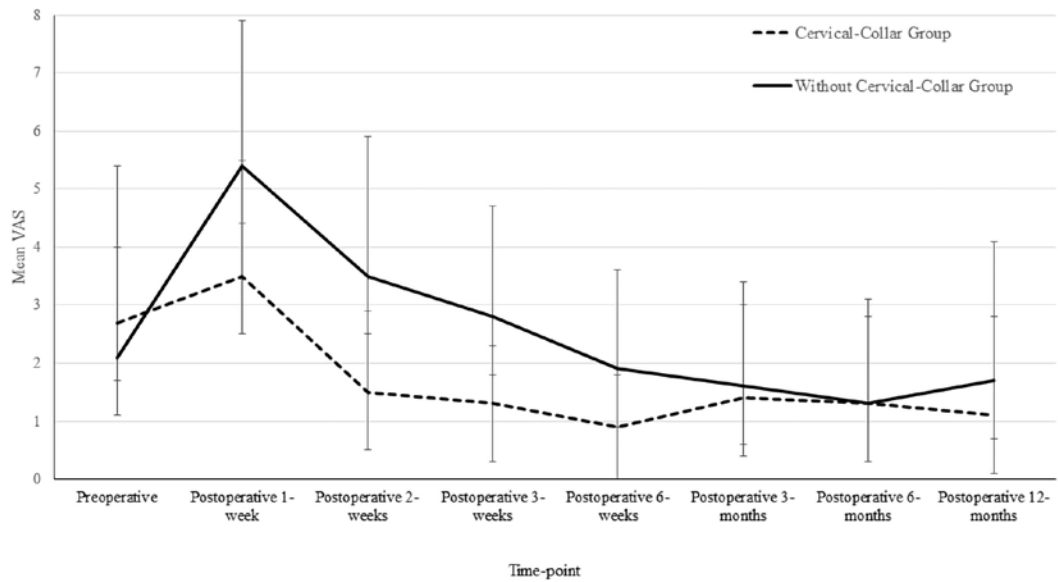


3

4 **Figure 1:** CONSORT Flowchart of the randomized controlled trial. 35 patients were randomized  
5 into two groups and all patients reached 1-year follow-up without dropout.

6

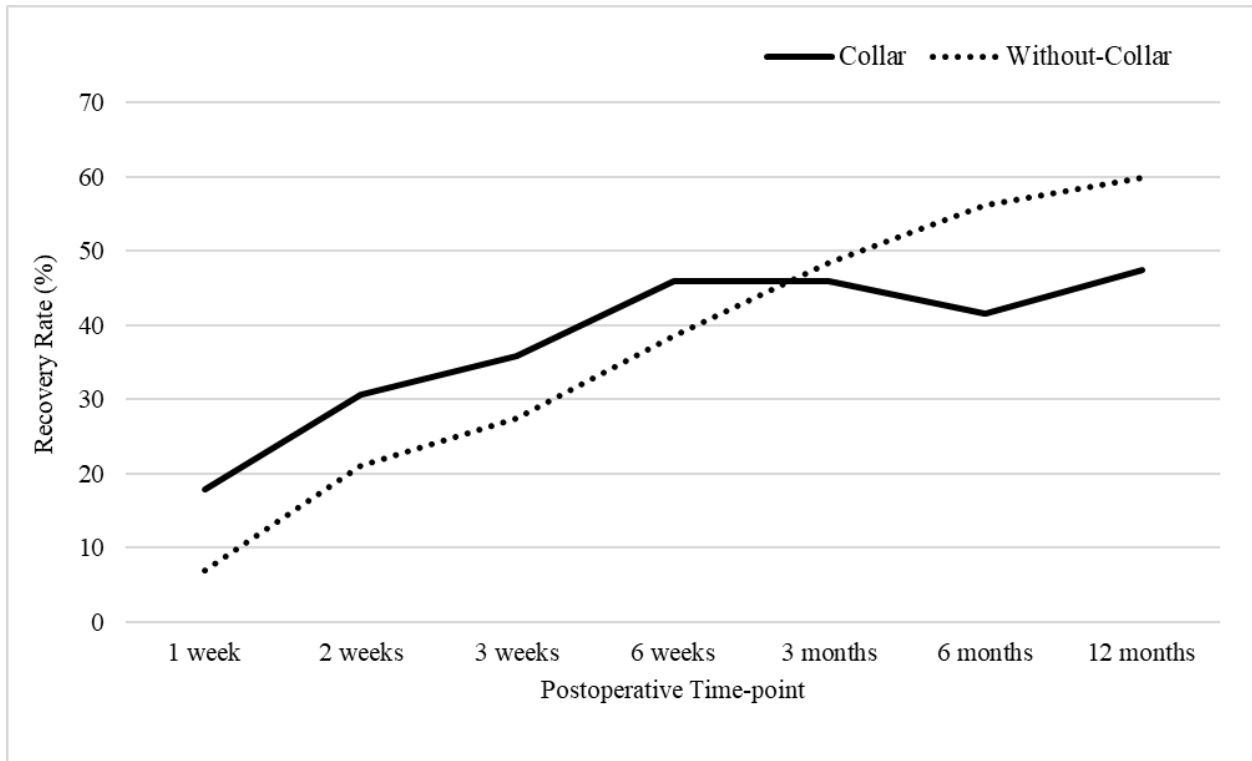




1

2 **Figure 2:** Mean VAS with standard deviation bars at each follow-up. There was less axial neck  
 3 pain for the cervical collar group as compared to no collar group at early postoperative period.

4



1

2 **Figure 3:** Postoperative recovery rates (%) at each follow-up. The recovery rates were  
 3 comparable from postoperative 1 week to postoperative 12 months.

Table 1: Baseline demographics and comparison of study groups

Parameters	Whole Study Population	Cervical-Collar Group	Without Cervical-Collar Group	p-value
Number (n, %)	35	16 (45.7)	19 (54.3)	-
Male:Female	20:15	10:5	10:10	-
Age at Surgery (years, $\pm$ SD)	64.9 $\pm$ 11.4	61.7 $\pm$ 14.3	67.2 $\pm$ 8.4	0.199
<b>Clinical Parameters</b>				
Axial Neck Pain VAS (0-10)	2.3 $\pm$ 2.2	2.9 $\pm$ 0.7	2.6 $\pm$ 2.6	0.298
<b>Cervical Range of Motion (degrees, <math>\pm</math>SD)</b>				
Extension	47.8 $\pm$ 13.8	44.1 $\pm$ 14.1	50.6 $\pm$ 13.2	0.172
Flexion	55.0 $\pm$ 15.3	55.5 $\pm$ 12.1	54.6 $\pm$ 17.6	0.871
Lateral - Right	36.3 $\pm$ 11.1	35.4 $\pm$ 8.0	37.1 $\pm$ 13.0	0.669
- Left	35.4 $\pm$ 12.7	34.9 $\pm$ 11.3	35.9 $\pm$ 13.9	0.824
Rotation - Right	59.1 $\pm$ 14.9	59.1 $\pm$ 15.9	59.1 $\pm$ 14.6	0.995
- Left	57.1 $\pm$ 14.4	54.7 $\pm$ 14.8	58.9 $\pm$ 14.1	0.410
<b>Radiological Parameters</b>				
Cervical spine alignment - Cobb angle (degree, mean $\pm$ SD)	10.2 $\pm$ 11.4	8.0 $\pm$ 11.8	12.1 $\pm$ 11	0.299
<b>Spinal Canal diameter (mm, mean <math>\pm</math> SD)</b>				
C3	13.6 $\pm$ 2.1	13.3 $\pm$ 1.6	13.9 $\pm$ 2.6	0.458
C4	12.5 $\pm$ 2.2	12.1 $\pm$ 1.7	11.8 $\pm$ 3.6	0.729
C5	12.0 $\pm$ 2.0	11.5 $\pm$ 1.5	12.5 $\pm$ 2.3	0.159
C6	11.5 $\pm$ 2.4	11.3 $\pm$ 2.0	11.8 $\pm$ 2.8	0.586
C7	10.7 $\pm$ 2.7	11.0 $\pm$ 2.9	10.6 $\pm$ 2.6	0.701

SD: standard deviation; VAS: Visual Analogue Scale

Table 2: Overall inter- and intrarater reliability

Interrater reliability	95% confidence interval	Intrarater reliability		95% confidence interval
0.89	0.79-0.94	Rater 1	0.96	0.95-0.98
		Rater 2	0.82	0.75-0.88
		Rater 3	0.80	0.70-0.86

Table 3: Sensitivities for outcome parameters

Primary outcome	Cohen's D Effect size (d), 95% CI	Secondary outcomes	Cohen's D Effect size (d), 95% CI
VAS	1.02, 0.72-1.32	Canal diameter	1.43, 1.01-1.85
		NDI	0.99, 0.70-1.28
		Spinal alignment	0.66, 0.47-0.85
		mJOA	0.15, 0.11-0.19
		SF-36 PCS	0.47, 0.33-0.61
		SF-36 MCS	0.19, 0.13-0.25
		ROM	0.28, 0.20-0.36

Values based on the power of 82% obtained for visual analogue scale

Cohen's D: large effect size (d=0.8), medium effect size (d=0.5), small effect size (d=0.2)

VAS: Visual Analogue Scale for axial neck pain; NDI: Neck Disability Index; mJOA: modified Japanese Orthopaedic Association score; SF-36 PCS: Short-form 36-item questionnaire physical component summary; SF-36 MCS: Short-form 36-item questionnaire mental component summary; ROM: cervical range of motion

Table 4: Comparison of postoperative axial neck pain

Time-point	VAS (mean $\pm$ SD)		p-value
	Cervical-Collar Group	Without Cervical-Collar Group	
Preoperative	2.7 $\pm$ 2.7	2.1 $\pm$ 1.9	0.659
Postoperative 1-week	3.5 $\pm$ 2.0	5.4 $\pm$ 2.5	0.038*
Postoperative 2-weeks	1.5 $\pm$ 1.4	3.5 $\pm$ 2.4	0.028*
Postoperative 3-weeks	1.3 $\pm$ 1.0	2.8 $\pm$ 1.9	0.031*
Postoperative 6-weeks	0.9 $\pm$ 0.9	1.9 $\pm$ 1.7	0.139
Postoperative 3-months	1.4 $\pm$ 1.6	1.6 $\pm$ 1.8	0.873
Postoperative 6-months	1.3 $\pm$ 1.8	1.3 $\pm$ 1.5	0.811
Postoperative 12-months	1.1 $\pm$ 1.7	1.7 $\pm$ 2.4	0.607
	Change of VAS score with preoperative VAS as reference		
Postoperative 1-week	0.8 $\pm$ 2.4	3.8 $\pm$ 3.5	0.023*
Postoperative 2-weeks	-0.9 $\pm$ 3.4	1.8 $\pm$ 3.2	0.046*
Postoperative 3-weeks	-1.2 $\pm$ 2.8	1.1 $\pm$ 2.6	0.148
Postoperative 6-weeks	-2.0 $\pm$ 2.9	-0.5 $\pm$ 2.6	0.125
Postoperative 3-months	-1.1 $\pm$ 2.5	-0.5 $\pm$ 2.4	0.630
Postoperative 6-months	-1.5 $\pm$ 3.0	-0.8 $\pm$ 2.3	0.918
Postoperative 12 -months	-1.8 $\pm$ 3.2	-0.5 $\pm$ 3.1	0.430

VAS: Visual Analogue Scale; SD: standard deviation

\*denotes statistical significance (p<0.05)

Table 5: Comparison of Neck Disability Index scores

Time-point	NDI (expressed as %, mean $\pm$ SD)		p-value
	Cervical-Collar Group	Without Cervical-Collar Group	
Preoperative	31.8 $\pm$ 16.9	31.0 $\pm$ 11.0	0.931
Postoperative 1-week	34.2 $\pm$ 17.7	44.5 $\pm$ 11.2	0.252
Postoperative 2-weeks	32.0 $\pm$ 15.9	47.0 $\pm$ 14.4	0.094
Postoperative 3-weeks	28.4 $\pm$ 19.5	33.1 $\pm$ 14.0	0.573
Postoperative 6-weeks	24.8 $\pm$ 10.0	34.0 $\pm$ 9.5	0.147
Postoperative 3-months	22.5 $\pm$ 18.1	22.8 $\pm$ 7.7	0.796
Postoperative 6-months	22.4 $\pm$ 18.3	23.1 $\pm$ 12.5	0.608
Postoperative 12 months	20.8 $\pm$ 18.0	22.9 $\pm$ 10.7	0.695

NDI: Neck Disability Index; SD: standard deviation

Table 6: Comparison of Short Form 36-item Questionnaire scores

Time-point	Preoperative		Postop 1-week		Postop 2-weeks		Postop 3-weeks		Postop 6-weeks		Postop 3-months		Postop 6-months		Postop 12-months	
	Collar	No collar	Collar	No collar	Collar	No collar	Collar	No collar	Collar	No collar	Collar	No collar	Collar	No collar	Collar	No collar
<b>Subscale</b>																
Physical functioning	32.7 ±21.8	43.3 ±32.4	26.3 ±26.5	28.8 ±22.7	37.5 ±33.4	32.6 ±23.7	41.1 ±32.9	44.7 ±25.0	53.6 ±28.3	47.2 ±26.3	51.7 ±26.7	47.4 ±27.4	54.5 ±30.0	54.1 ±25.1	64.6* ±18.4	50.6* ±25.4
Role limitations due to physical health	6.8 ±16.2	12.5 ±31.1	13.3 ±28.1	13.2 ±33.2	16.1 ±31.9	7.4 ±24.6	25.0 ±40.8	6.9 ±24.0	23.2 ±38.6	11.1 ±28.7	25.0 ±40.1	7.4 ±24.6	22.7 ±28.4	25.0 ±35.4	25.0 ±40.8	32.4 ±41.2
Role limitations due to emotional problems	36.4 ±45.8	47.2 ±50.2	26.7 ±38.2	27.5 ±41.2	31.0 ±40.2	27.5 ±31.7	35.9 ±46.1	29.6 ±41.0	42.9 ±47.9	33.3 ±44.3	40.0 ±40.2	33.3 ±45.6	21.2 ±37.3	43.1 ±46.8	43.6 ±45.9	52.9 ±47.2
Vitality	39.5 ±21.7	38.3 ±24.2	48.7 ±16.6	44.1 ±15.0	56.8 ±23.7	43.5 ±16.5	51.5 ±19.5	48.1 ±17.9	50.0 ±22.2	53.1 ±16.1	50.0 ±21.2	52.1 ±22.1	44.5 ±25.6	55.3 ±22.7	49.2 ±27.5	56.2 ±16.3
Mental health	54.5 ±28.7	67.7 ±20.7	58.7 ±14.5	57.2 ±18.4	67.1 ±25.3	62.8 ±16.5	67.1 ±22.0	67.7 ±20.7	65.1 ±25.1	68.9 ±12.8	64.0 ±20.8	65.2 ±14.9	62.9 ±20.3	71.5 ±10.6	74.8 ±20.7	70.8 ±16.5
Social functioning	40.9 ±30.2	52.1 ±26.0	50.0 ±32.0	47.8 ±30.1	51.8 ±33.9	46.3 ±26.4	51.0 ±32.9	50.0 ±23.9	62.5 ±29.4	57.6 ±27.5	55.0 ±25.4	63.2 ±26.3	52.3 ±26.1	69.9 ±23.4	76.9 ±19.7	66.9 ±26.1
Bodily pain	42.2 ±26.2	47.1 ±22.1	44.9 ±17.2	34.9 ±19.0	54.9* ±26.9	34.5* ±23.3	52.5 ±23.6	43.1 ±16.4	52.0 ±21.0	51.7 ±17.7	54.1 ±28.4	60.3 ±25.4	54.1 ±26.5	56.6 ±20.5	61.4 ±32.9	62.8 ±24.5
General health perception	39.6 ±16.4	43.3 ±20.8	48.1 ±18.6	43.6 ±16.3	53.9 ±22.3	47.8 ±14.2	48.8 ±20.2	51.9 ±16.3	47.8 ±18.9	55.0 ±19.2	47.2 ±21.0	54.0 ±24.4	44.6 ±25.5	53.4 ±21.4	50.9 ±25.4	53.0 ±17.9
<b>Physical Component Summary</b>	28.8 ±5.8	30.4 ±9.5	29.6 ±7.9	28.3 ±6.4	32.6 ±12.3	27.8 ±7.8	33.2 ±12.9	31.4 ±6.8	35.2 ±10.8	33.2 ±7.8	35.5 ±10.2	34.5 ±7.7	36.3 ±9.8	36.0 ±9.0	39.0 ±9.8	36.7 ±9.2
<b>Mental Component Summary</b>	41.7 ±11.7	46.1 ±11.4	43.4 ±8.4	42.9 ±8.7	45.7 ±10.0	43.9 ±8.7	45.4 ±9.7	43.8 ±9.1	45.8 ±11.5	46.1 ±9.7	44.5 ±8.3	45.2 ±9.8	41.0* ±10.0	48.3* ±8.4	48.3 ±11.2	48.9 ±9.0



Data represented as mean  $\pm$  standard deviation

\*denotes statistical significance ( $p < 0.05$ )

Table 7: Comparison of modified Japanese Orthopaedic Association scores

Time-point	mJOA (mean $\pm$ SD)		p-value
	Cervical-Collar Group	Without Cervical-Collar Group	
Preoperative	9.8 $\pm$ 4.0	10.7 $\pm$ 3.0	0.610
Postoperative 1-week	11.7 $\pm$ 2.6	12.1 $\pm$ 2.9	0.706
Postoperative 2-weeks	11.9 $\pm$ 3.2	12.3 $\pm$ 2.2	0.970
Postoperative 3-weeks	12.5 $\pm$ 2.7	12.5 $\pm$ 2.2	0.794
Postoperative 6-weeks	13.8 $\pm$ 1.5	13.3 $\pm$ 1.9	0.613
Postoperative 3-months	14.0 $\pm$ 1.4	13.8 $\pm$ 1.6	0.798
Postoperative 6-months	13.8 $\pm$ 1.3	14.0 $\pm$ 2.0	1.000
Postoperative 12 months	14.1 $\pm$ 1.4	14.5 $\pm$ 1.8	0.636

mJOA: modified Japanese Orthopaedic Association; SD: standard deviation

Table 8: Comparison of adjusted means of spinal canal diameter measurements

Level	Adjusted means of spinal canal diameter $\pm$ SE (mm)		p-value
	Cervical-Collar Group	Without Cervical-Collar Group	
Postoperative 1-week			
C3	18.9 $\pm$ 0.5	19.5 $\pm$ 0.5	0.272
C4	17.6 $\pm$ 0.5	18.6 $\pm$ 0.4	0.138
C5	18.2 $\pm$ 0.6	18.2 $\pm$ 0.6	0.998
C6	17.1 $\pm$ 0.6	17.8 $\pm$ 0.4	0.321
C7	13.1 $\pm$ 0.9	13.7 $\pm$ 0.8	0.580
Postoperative 2-weeks			
C3	18.8 $\pm$ 0.3	19.1 $\pm$ 0.3	0.457
C4	18.2 $\pm$ 0.2	17.8 $\pm$ 0.2	0.198
C5	17.8 $\pm$ 0.3	18.3 $\pm$ 0.2	0.177
C6	16.9 $\pm$ 0.3	17.3 $\pm$ 0.3	0.392
C7	12.8 $\pm$ 0.5	12.4 $\pm$ 0.4	0.542
Postoperative 3-weeks			
C3	19.2 $\pm$ 0.4	19.0 $\pm$ 0.3	0.730
C4	17.8 $\pm$ 0.3	17.6 $\pm$ 0.3	0.726
C5	17.3 $\pm$ 0.4	18.0 $\pm$ 0.4	0.212
C6	16.3 $\pm$ 0.5	17.0 $\pm$ 0.5	0.303
C7	11.3 $\pm$ 0.6	11.6 $\pm$ 0.5	0.661
Postoperative 6-weeks			
C3	19.2 $\pm$ 0.3	18.7 $\pm$ 0.2	0.182
C4	18.1 $\pm$ 0.3	17.4 $\pm$ 0.3	0.159
C5	17.3 $\pm$ 0.5	18.1 $\pm$ 0.5	0.265
C6	16.5 $\pm$ 0.5	17.1 $\pm$ 0.5	0.439
C7	12.8 $\pm$ 0.7	13.1 $\pm$ 0.7	0.771
Postoperative 3-months			
C3	18.8 $\pm$ 0.3	19.2 $\pm$ 0.3	0.387
C4	17.6 $\pm$ 0.3	17.8 $\pm$ 0.3	0.753
C5	16.8 $\pm$ 0.4	18.0 $\pm$ 0.4	0.061
C6	16.6 $\pm$ 0.4	17.0 $\pm$ 0.4	0.472
C7	12.8 $\pm$ 0.6	13.0 $\pm$ 0.5	0.852
Postoperative 6-months			
C3	18.6 $\pm$ 0.3	18.4 $\pm$ 0.3	0.656
C4	17.8 $\pm$ 0.3	16.8 $\pm$ 0.3	0.038
C5	17.4 $\pm$ 0.5	16.9 $\pm$ 0.4	0.465
C6	16.6 $\pm$ 0.6	16.0 $\pm$ 0.5	0.459
C7	12.7 $\pm$ 0.5	12.5 $\pm$ 0.4	0.765
Postoperative 12-months			
C3	17.9 $\pm$ 0.4	18.0 $\pm$ 0.3	0.844
C4	17.3 $\pm$ 0.3	16.9 $\pm$ 0.3	0.444
C5	16.7 $\pm$ 0.5	17.4 $\pm$ 0.4	0.273
C6	16.6 $\pm$ 0.5	16.1 $\pm$ 0.4	0.487
C7	13.0 $\pm$ 0.6	13.5 $\pm$ 0.5	0.520

SE: standard error

Table 9: Comparison of cervical range of motion

	Cervical range of motion (degrees, mean $\pm$ SD)		p-value
	Cervical-Collar Group	Without Cervical-Collar Group	
<b>Preoperative</b>			
Extension	43.9 $\pm$ 13.6	51.0 $\pm$ 54.5	0.095
Flexion	55.5 $\pm$ 11.7	54.5 $\pm$ 18.0	0.909
Lateral - Right	35.4 $\pm$ 7.8	37.2 $\pm$ 13.4	0.883
- Left	34.9 $\pm$ 10.9	35.9 $\pm$ 14.3	0.832
Rotation - Right	58.9 $\pm$ 15.4	59.3 $\pm$ 14.9	0.909
- Left	54.1 $\pm$ 14.5	59.6 $\pm$ 14.1	0.271
<b>Postop 1-week</b>			
Extension	34.4 $\pm$ 14.8	32.9 $\pm$ 15.9	0.832
Flexion	24.5 $\pm$ 10.0	26.3 $\pm$ 14.1	0.909
Lateral - Right	26.8 $\pm$ 10.8	26.4 $\pm$ 11.6	0.806
- Left	22.7 $\pm$ 9.1	25.9 $\pm$ 13.3	0.481
Rotation - Right	41.8 $\pm$ 14.0	45.1 $\pm$ 17.7	0.523
- Left	42.9 $\pm$ 15.7	46.9 $\pm$ 18.0	0.403
<b>Postop 2-weeks</b>			
Extension	43.1 $\pm$ 15.3	42.3 $\pm$ 15.2	0.987
Flexion	29.1 $\pm$ 9.4	34.8 $\pm$ 12.9	0.161
Lateral - Right	29.8 $\pm$ 7.5	28.6 $\pm$ 8.0	0.806
- Left	27.5 $\pm$ 8.7	28.0 $\pm$ 9.5	0.883
Rotation - Right	48.9 $\pm$ 10.8	49.7 $\pm$ 12.9	0.731
- Left	51.0 $\pm$ 16.2	52.6 $\pm$ 16.7	0.731
<b>Postop 3-weeks</b>			
Extension	47.3 $\pm$ 14.4	48.6 $\pm$ 11.8	0.528
Flexion	42.0 $\pm$ 10.5	44.5 $\pm$ 12.4	0.484
Lateral - Right	38.4 $\pm$ 7.5	34.8 $\pm$ 6.0	0.073
- Left	33.1 $\pm$ 10.1	32.8 $\pm$ 12.0	0.851
Rotation - Right	50.9 $\pm$ 10.2	56.0 $\pm$ 14.6	0.046*
- Left	56.2 $\pm$ 12.5	59.4 $\pm$ 16.2	0.443
<b>Postop 6-weeks</b>			

Extension	54.4 ± 13.4	50.4 ± 12.3	0.403
Flexion	51.6 ± 7.9	51.8 ± 12.8	0.707
Lateral - Right	40.9 ± 10.2	35.4 ± 9.9	0.088
- Left	35.3 ± 11.5	36.2 ± 10.8	0.422
Rotation - Right	59.4 ± 12.2	61.6 ± 11.2	0.621
- Left	63.7 ± 13.6	64.8 ± 13.2	0.806
<b>Postop 3-months</b>			
Extension	52.5 ± 19.5	55.1 ± 12.9	0.973
Flexion	48.9 ± 10.8	50.1 ± 12.2	0.679
Lateral - Right	40.2 ± 8.8	38.2 ± 7.8	0.529
- Left	39.1 ± 8.5	36.2 ± 9.3	0.397
Rotation - Right	61.4 ± 10.0	63.0 ± 9.2	0.553
- Left	63.4 ± 10.6	62.8 ± 13.5	0.788
<b>Postop 6-months</b>			
Extension	58.5 ± 18.4	58.8 ± 15.4	0.707
Flexion	47.7 ± 16.0	53.3 ± 8.6	0.502
Lateral - Right	40.3 ± 9.8	39.1 ± 11.5	0.864
- Left	36.3 ± 10.2	39.7 ± 11.2	0.430
Rotation - Right	59.7 ± 8.4	63.3 ± 10.3	0.319
- Left	61.0 ± 8.1	65.2 ± 8.9	0.202
<b>Postop 12-months</b>			
Extension	59.6 ± 12.7	57.7 ± 14.8	0.683
Flexion	49.1 ± 11.3	51.9 ± 7.0	0.367
Lateral - Right	37.2 ± 9.3	39.8 ± 9.3	0.286
- Left	34.0 ± 9.4	38.4 ± 9.7	0.193
Rotation - Right	59.4 ± 11.2	61.6 ± 11.6	0.781
- Left	64.4 ± 9.9	66.2 ± 10.8	0.545

SD: standard deviation

\*denotes statistical significance (p<0.05)