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Research article

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Is it a requirement or a preference to use cross-links in lumbar instrumentation?

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Ethics Committee approval was taken from the Tekirdağ Namık Kemal University Ethics Committee. (date: May 31, 2022 number: 2022.87.05.13).
All procedures in this study involving human participants were performed in accordance with the 1964 Helsinki Declaration and its later amendments.

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Abstract

Background/Aim: The use of cross-links (CL) is controversial due to reasons such as cost increases and instrument redundancy. While there are many biomechanical studies, the clinical data is limited. The aim of this study is to present the clinical effects of CL by putting forward postoperative clinical outcomes and long-term results of patients with (CL+) and without (CL-) CL augmentation.

Methods: In this retrospective cohort study, patients who underwent lumbar posterior instrumentation with CL+ (n = 164) and without CL- (n = 111) augmentation were evaluated. Demographic data, surgical results, preoperative and postoperative visual analogue scale (VAS), the Oswestry Disability Index (ODI) differences, and pseudoarthrosis and adjacent segment disease (ASD)-related recurrence for more than three years of follow-up were determined. Data of CL+ and CL- groups were compared.

Results: CL+ and CL- groups were similar in terms of age and gender (P = 0.319 and P = 0.777, respectively) There was no difference between the two groups in terms of bleeding amount, duration of surgery, and duration of hospitalization (P = 0.931, P = 0.669 and P = 0.518, respectively). Groups were similar in terms of VAS and ODI differences (P = 0.915 and P = 0.983, respectively), yet there was one case of infection in the CL+ group and two cases of infection detected in the CL- group. There were 13 ASDs in the CL+ group, and eight ASDs in the CL- group. Pseudoarthrosis was seen seven times in the CL+ group, while it was four in the CL- group.

Conclusion: It was observed that adding CL in patients who underwent lumbar instrumentation did not change the early period surgical results. The prevalence of complications was compatible with the scientific literature. In our study, there was no preventive advantage in terms of clinical or postoperative complications found in the use of CL.

Keywords: Internal fixators, Pedicle screws, Pseudoarthrosis, Lumbar vertebrae

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Introduction

Lumbar spinal stenosis is a gradually increasing disease in aging societies, which usually occurs due to degenerative spondylolisthesis. This disease impacts the lifestyle of middle aged and older patients, and the solution is usually surgical [1, 2]. There are limited non-surgical options, such as medication, injections, or physiotherapy; however, surgery is performed for most symptomatic patients [3]. This is always elective surgery even in severely symptomatic patients. The aim of surgery is to decompress the nerve root and spinal cord compression.

Traditional laminectomy, bilateral laminectomies, bilateral decompression through unilateral laminotomy, and different forms of laminoplasty are applied with the aim of decompression [4]. Spinal arthrodesis for spinal fusion is used in cases of spinal stenosis associated with degenerative spondylolisthesis, recurrent stenosis after previous decompression, instability, or scoliosis [5].

Dorsal instrumentation is the most frequently used arthrodesis method, and the aim is to increase the fusion rate by creating a rigid stabilization [6]. Many devices, such as plates, hooks, cerclages, CLs and interbody cages are used for the increase of rigidity. CL is a system, which is applied on contralateral rod or screw head. There are many biomechanical studies about it in scientific literature; yet, there are few clinical studies on the long-term results in the lumbar region [7]. The biomechanical advantages are controversial due to disadvantages, such as wide exposure, increase of implant load, and increase in cost and surgical period. CL, which is nowadays a method used by many surgeons, is a personal preference rather than a necessity.

We aimed in this study to present the clinical effects, patient outcomes, and long-term results of the CL use on patients with posterior instrumentation (augmentation) in the lumbar region.

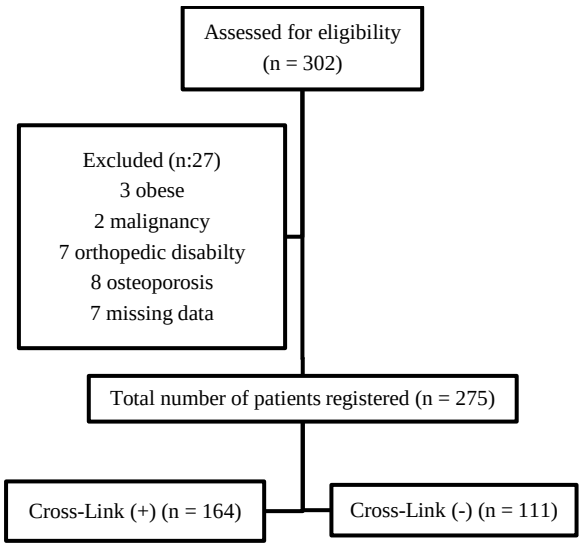
Materials and methods

Patient files and radiological images of decompression and dorsal instrumentation applied to 275 patients with degenerative lumbar spinal stenosis, ranging from 40 to 81 years of age between December 2014 and June 2019 were analyzed by the same surgeon at Tekirdağ Namık Kemal University, Neurosurgery Clinic (Figure 1). The approval for this study was granted by the Tekirdağ Namık Kemal University Ethics Committee (date: May 31, 2022 number: 2022.87.05.13).

Surgical indication criteria consisted of low back and/or radicular pain despite medical treatments. Other inclusion criteria were patients who described neurogenic claudication below 100 mt, those with a canal anterior-posterior diameter of 11.5mm in their lumbar MR images, those with a canal section area below 1.45cm², and need stabilization due to concomitant degenerative spondylolisthesis, instability, or scoliosis.

Patients with severe osteoporosis history, malignancy, advanced gonarthrosis, coxarthrosis, those with a BMI above 30, and those who had undergone interbody arthrodesis were excluded from the study.

Figure 1: Flowchart of the study



Patients were divided into two groups, one of which consisted of patients with CL use (CL+ group), and the other who had not had CL augmentation (CL- group) in their surgery. Data of the patients, such as age, gender, follow-up periods, and a three-month-period record of preoperative and postoperative visual analogue scale (VAS), and Oswestry Disability Index (ODI) were recorded. The preoperative and postoperative differences of VAS and ODI of patients were taken. ODI differences were categorically classified as very poor if below 5, poor between 6-10, fair between 5-11, good between 16-20, and excellent if above 20.

CL+ and CL- groups were analyzed in terms of infection, pseudoarthrosis, adjacent segment development, and ODI differences.

Statistical analysis

Data were analyzed by using the Statistical Package for the Social Sciences (SPSS) 24.0 (SPSS Inc., Chicago, IL, USA) statistical computer program. The Chi-square test for categorical variables was used to compare the groups with or without CL augmentation. For the comparison of continuous variables, the independent sample t-test was used. Cases in which the *P*-value was below 0.05 and the type 1 error level was below 5%, were interpreted as statistically significant.

Results

A total of 275 patients was included in the study. It was determined that 109 (66.4%) of 164 patients in CL+ were women, and 55 (33.5%) were men, while 74 (66.6%) out of 111 patients in the CL- group were women, and 37 (33.3%) were men. There was no difference between the two groups in terms of gender (P = 0.777). While the average age was 61.6 (10.6) years in the CL+ group, it was 60.2 (11.4) years in the CL- group, and both groups were similar in terms of the distribution of age (P = 0.319). Demographic characteristics of patients and surgical results are summarized in Table 1.

While the bleeding amount in the CL+ group was 285.4 (110.4) cc, it was 285.9 (109.7) cc in the CL- group, and no difference was determined between the two groups (P = 0.931). When the average surgical duration was analyzed, it was found to be 160.4 (41.8) minutes in the CL+ group, whereas it was 157.0 (38.2) minutes in the CL- group. Both groups were similar in terms of duration of surgery (P = 0.669). The duration of

hospitalization in the CL+ group was 5.4 (4.1) days, whereas it was 4.8 (2.2) days for the CL- group. Both groups were similar in terms of the duration of hospitalization (P = 0.518). When VAS differences were analyzed, it was found to be 6.81 (0.7) for the CL+ group, while it was 6.89 (0.8) for the CL- group, and the difference was insignificant (P = 0.915). ODI differences for the CL+ group were very poor for 4 patients, poor for 36 patients, fair for 89 patients, good for 30 patients, and excellent for 5 patients. ODI differences for the CL- group was very poor for 2 patients, poor for 20 patients, fair for 64 patients, good for 21 patients, and excellent for 4 patients (Figure 2). Both groups were similar in terms of ODI differences (P = 0.983). Postoperative spondylodiscitis developed in two (1.2%) patients in the CL+ group while it developed in one (0.9%) patient in the CL- group. ASD was seen in 13 (7.9%) patients in the CL+ group, while it was seen in 8 (7.2%) patients in the CL- group. When the number of pseudoarthrosis was calculated, it was determined to be seven (4.2%) for the CL+ group while it was four (3.6%) in the CL- group (Figure 3). There were no implant failures in our series.

Table 1: Demographic features and surgical outcomes of patients with and without cross-link use.

		CL + Mean (SD) / n	CL - Mean (SD) / n	*P*-value
Age		61.6 (0.6)	60.2 (11.4)	0.319
Gender	female	109	74	0.777
	male	55	37	
Bleeding amount (cc)		285.4 (110.4)	285.9 (109.7)	0.931
Duration of surgery (min)		160.4 (41.8)	157.0 (38.2)	0.669
Duration of hospitalization (day)		5.4 (4.1)	4.8 (2.2)	0.518
VAS difference		6.81 (0.7)	6.89 (0.8)	0.915

SD: Standard deviation, CL: Cross-link, ODI: Oswestry Disability Index, VAS: Visual analogue scale

Figure 2: Distribution of ODI differences between groups.

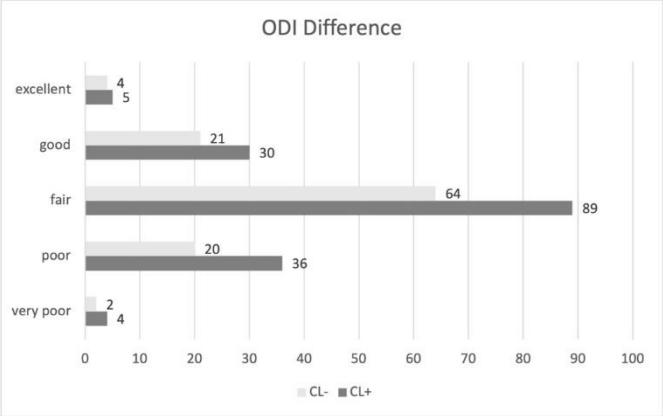
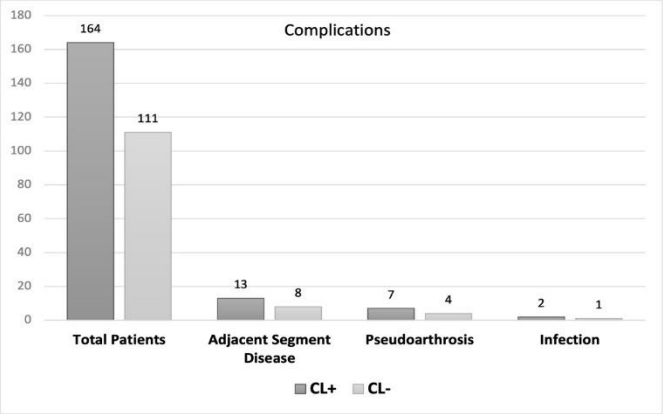


Figure 3: Distribution of adjacent segment disease, pseudoarthrosis, and infection between groups.



Discussion

Our study determined that there was no significant difference between the patients with or without CL augmentation, in terms of bleeding amount during surgery or length of postoperative hospitalization. Furthermore, there was no significant difference in the VAS and ODI, which evaluate the preoperative and postoperative functional recovery of patients. Postoperative infection, as well as ASD and pseudoarthrosis, which are late term complications in both groups, were found to be compatible with the scientific literature.

Although there have been several publications about CL augmentation for many years for patients who plan fusion surgery to increase stability, its use is still controversial [7, 8]. Most studies related to CL augmentation, which increases the instrument cost, are about biomechanical studies on synthetic materials and animal or cadaver backbones; yet, there are only few studies on clinical results [9, 10]. Most of these studies assert that CL augmentation has primarily had significant impact on axial rotation, whereas it affects lateral bending and particularly flexion extension slightly [7]. Lehman et al. [11] stated in their cadaveric study that CL augmentation in spinal fusion surgery performed between C1-C2 decreased the range of motion (ROM) at axial rotation 57%. It was also stated that this percentage decreased more between the C3-6 lower cervical area, yet the CL augmentation in the cervicothoracic region led to a decrease of 27% in the axial ROM [12, 13]. It was further argued that in the thoracic area, which already has a limited axial ROM due to the rib cage, flexion extension and lateral bending did not contribute to CL [14]. Other studies indicate that axial rotation is hindered (21%) in the lumbar region, yet it was not effective on flexion extension and lateral bending [15]. As a result, all these biomechanical studies may suggest that CL augmentation in upper cervical and cervicothoracic junction areas will accelerate fusion by preventing axial rotation; however, the advantage of CL augmentation in terms of cost-effectiveness in lumbar and thoracic areas is controversial.

Kulkarni et al. [16], in their study about CL with 208 patients and 707 fused segments excluding the cervical area, asserted that biomechanical studies did not have a clinical advantage and that the use of CL was unnecessary. In addition, Garg et al. [17] stated that CL augmentation in adolescent idiopathic scoliosis did not improve clinical or radiological outcomes. Similar findings were determined in our study for the lumbar region. When VAS and ODI scores of patients were analyzed, it was found out that CL augmentation did not provide any clinical advantage.

Following spinal fusion surgery, the reoperation percentage within five years due to infection, instrument failure, pseudoarthrosis, insufficient decompression, and adjacent segment disease is 20% [18, 19]. Of these reoperations, 51% are due to ASD, and the annual incidence for the lumbar area varies from 2% to 4% [20]. In our series within a three-year follow-up, reoperation rate due to ASD in the CL+ group was 7.9%, and it was 7.2% in the CL- group. This rate is within tolerable limits for both groups.

The prevalence of spondylodiscitis after any kind of spinal surgery varies between 0.21% and 3.6% [21, 22]. The infection ratio in the CL+ group was 1.2%, and was determined

as 0.9% in the CL- group. Looking back, it was discovered that three patients were diabetic. Although there are many publications arguing that the increased number of instruments lead to an increase in the susceptibility of infection, it is not possible to assert such an association in our study.

Pseudoarthrosis is defined as non-union in spinal surgery. It reveals itself as lack of fusion, rod breakage, or as a halo-shaped hypodense area around screws in CT images [23]. The most common reason for revision surgery in adult scoliosis is adjacent segment degeneration. This is followed by pseudoarthrosis, which is seen in 25% of all cases [24]. A pseudoarthrosis development incident in adult spine deformities is stated to be between 5% and 27% [25]. In various reviews, in which patients who underwent surgery due to deformity were analyzed, the incidence of pseudoarthrosis development was found to be between 0 and 41% [26]. In our study, the rate was 4.2% in the CL+ group, while it was determined as 3.6% in the CL- group. The development of infection, ASD, and pseudoarthrosis being within tolerable limits in both groups, indicates that the use of CL material, which leads to both additional cost and instrumental burden, should be questioned. It is obvious that CL affects the axial ROM the most. In lumbar region surgeries where the surgical aim is fusion, the contribution of preventing axial rotation, which is already low, to fusion is controversial. There are no available guidelines regarding the use of CL augmentation in recent surgical practice. It is just implemented as the choice of the surgeons. Even if some surgeons use multiple CL in order to enhance the rigidity of instruments, the economic burden of CL, the possible cause to complications such as corrosion, infection, and instrument failure should be kept in mind [16]. There are many publications indicating that the use of multiple CL leads to a decrease in the fusion area by causing instrument crowding [26].

Our clinical experience suggests that it is wrong to perform CL augmentation in cases where laminectomy is not performed, in other words, in cases where the posterior tension band has not been impaired. In such cases, it is necessary to perform osteotomies to back elements in order to be able to use CL augmentation. It should be used only in cases where wide osteotomy or facetectomy is performed, as a preference of the surgeon in order to prevent axial rotation and increase instrument rigidity. Nevertheless, in our opinion, the routine use of CL is unjustified, and should be restricted in order to avoid instrument crowding and potential risks.

Limitations

In our study, the percentage of infection, ASD, and pseudoarthrosis was lower in the CL- group; however, the scarcity of complications in this series led to an unreliable statistical comparison. This is the most important limitation in our study. We think that particularly these rare complications should be evaluated via meta-analyses.

Conclusion

While there are plenty of biomechanical studies related to CL, there are quite few clinical studies. CL, which has become habitual, and is routinely used by surgeons, is an instrument the use of which is unclear in terms of clinical benefits, yet it is certain to increase the hospital costs. According to the results of our study, in patients where fusion is aimed in the lumbar area, there are no advantages or disadvantages in CL augmentation in early or late surgical periods.

We think that particularly in surgeries where posterior elements are preserved, and in cases with no severe instability, CL augmentation should be abandoned in order to decrease both the number of instruments and the surgical costs.

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