



# Effects of Lumbar Fusion Instrumentation Removal in Patients Who Experienced Continued Pain After Lumbar Spinal Fusion Surgery for Lumbar Degenerative Disease

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## ABSTRACT

**AIM:** To investigate the visual analogue scale (VAS) and Oswestry Disability Index (ODI) scores after the removal of the instrumentation system in patients who underwent lumbar instrumentation for lumbar degenerative disease (LDD).

**MATERIAL and METHODS:** This study included 30 patients (19 female, 11 male) who had undergone posterior lumbar instrumentation for LDD in whom postoperative continuous or recurrent pain led to the removal of the implant system in our clinic between December 2013 and December 2019. The patients had continuous or recurrent low back pain that did not respond to medical treatment, physical therapy, or any type of lumbar block. Nine patients had continuous low back pain in the surgical area, while twenty-one had recurrent low back pain.

**RESULTS:** There was a significant reduction in the number of admissions to the hospital ( $p<0.001$ ), and the daily number of analgesics used ( $p<0.001$ ) in six months after surgery compared to six months before surgery. There were significant decreases in VAS scores, both at the one-month ( $p<0.001$ ) and six-month ( $p<0.001$ ) postoperative assessments compared to preoperative measurements. ODI scores were significantly lower than the preoperative scores at both one-month ( $p<0.001$ ) and six-month ( $p<0.001$ ) postoperative score.

**CONCLUSION:** Our study showed that the instrumentation system removal after fusion for patients with LDD may be beneficial since it alleviates pain and analgesic usage.

**KEYWORDS:** Lumbar fusion, Removal, Instrumentation, Degenerative disease

## INTRODUCTION

Elective lumbar spinal fusion surgery as a treatment for lumbar degenerative disease (LDD) is a common general neurosurgical practice. In the United States alone, over 300,000 lumbar spinal fusion surgeries are performed annually (1,11). Despite this, patients may experience persistent lumbar pain after surgery. Failed degenerative lumbar spine surgery does not indicate that surgery has failed. It can be more accurately described as new and/or increasing low back and leg complaints due to lumbar degeneration changing the counter to natural progression, the natural progression of the degeneration disease, or a combination of these factors

(5). Postoperative low back pain can be a result of infection, adjacent segment disease, pseudoarthrosis or a sensitized disc. Pain caused by the instrumentation itself is included in the differential diagnosis of such pains. Depending on the instrumentation system, the surgery is repeated in up to 15% of patients due to persisting back pain and/or increased back pain after fusion surgery (9).

As treatment for LDD, especially for lumbar stenosis type, decompression alone, decompression and fusion, or fusion alone is performed on the vertebrae. Naturally, these different surgical methods may produce different responses in different patients. When the disease is treated surgically, the patient may

develop a new symptom related to the surgery, independent of the symptoms of lumbar degeneration (5). To treat these new symptoms, patients often start using more non-steroidal anti-inflammatory or opioid medications and may have to cope with new symptoms related to the use of these drugs, such as kidney, heart, liver or psychiatric problems (6). Due to the increasing number of surgeries performed related to the treatment of diseases of the lumbar region, the number of patients requiring repeat surgeries is also gradually increasing (5).

Removal of the implants and exploration of the fusion area could be an appropriate treatment approach for the small number of patients for which a specific cause of pain, other than recurrent low back pain, has not been identified (6,10). Although the removal of instrumentation is rarely performed, this surgical procedure may be required for selected patients. The purpose of this study was to evaluate the effect and safety of removing the multi-level instrumentation system applied for LDD in selected patients with continuous low back pain.

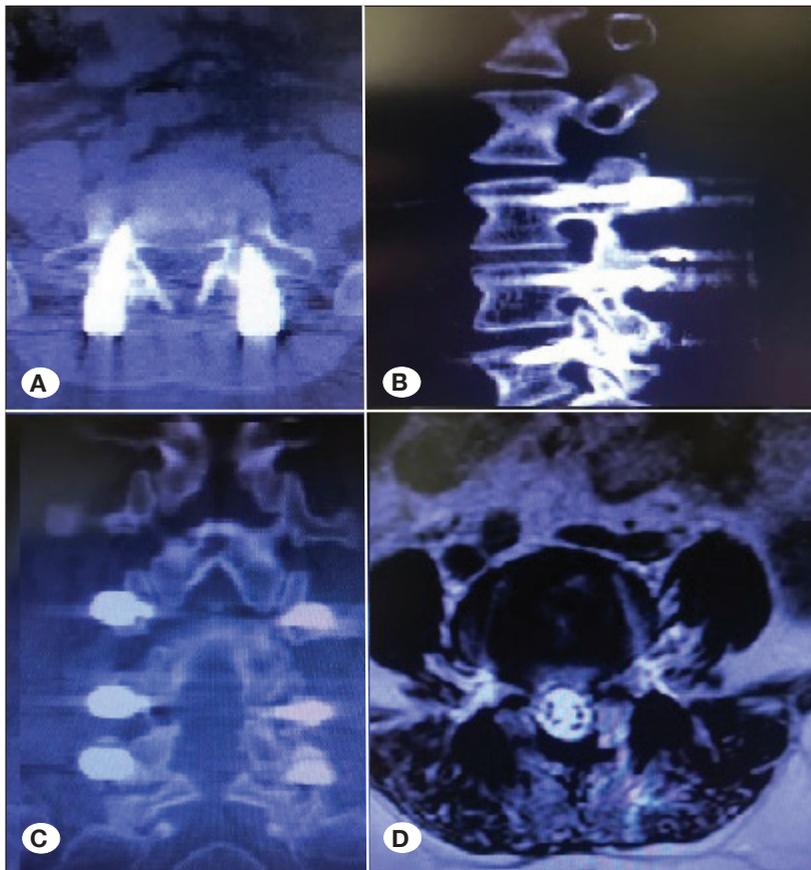
## ■ MATERIAL and METHODS

This study was a retrospective study; it included 30 patients who had undergone posterior standard L1-5 vertebral instrumentations at different levels including short segment instrumentation, decompression, and fusion for lumbar spinal stenosis in which postoperative continuous or recurrent

pain led to the removal of the implant system in our clinic between December 2013 and December 2019 (Table I) (Ethics Committee of Adiyaman University Faculty of Medicine; No: 2019/5-3, Date: 20.12.2019).

All patients had continuous or recurrent low back pain that did not respond to medical treatment, physical therapy or any type of lumbar nerve root block. While 9 patients had continuous low back pain in the surgical region, 21 had recurrent low back pain. All patients were evaluated by radiographs, computed tomography (CT), and magnetic resonance imaging (MRI) scans, and other causes of pain such as adjacent segment degeneration, coronal imbalances, flatback deformity, and pseudoarthrosis were excluded (Figure 1A-D). Lateral plane X-rays were obtained to evaluate the sagittal plane angulation in all patients before surgery and at the six-month postoperative follow-up.

The patients' fusion level number, the implant type and the "halo sign," which is the finding of transpedicular screw loosening, were evaluated by X-ray. A halo sign thicker than 2 mm was considered screw loosening and patients with this finding were excluded from the study. Patients with screw/rod breakage or loosening in the implant were also excluded from the study. To avoid the introduction of additional variables, patients who had undergone procedures for deformity, trauma, or kyphoplasty-vertebroplasty were also excluded from the study. Patients with a history of lumbar disk development,



**Figure 1:** Axial (A), sagittal (B) and coronal (C) computed tomography, and axial T2-weighted magnetic resonance imaging (D) scans show the radiographic evaluations that were included in the study.

corpus fracture, or lumbar spondylodiscitis-trauma, as determined by CT or magnetic resonance imaging (MRI), were also excluded from the study.

Patients with high C-reactive protein (CRP), sedimentation, and other inflammatory markers were excluded from the study. The implants were sent to microbial analysis as a standard procedure after their removal; patients whose implants were positive for microbial analysis were excluded from the study.

The visual analog scale (VAS) and the Oswestry Disability Index (ODI) were used to evaluate the preoperative and postoperative pain. The patient scores were determined preoperatively, and at one and six months postoperatively. In this retrospective evaluation, patients whose ODI and VAS evaluations were not assessed or were not assessed at the one- and six-month routine follow-ups were excluded from the study.

Data regarding analgesic use and hospital admission history were obtained from the hospital data processor. Among these, admissions and medication use related to lumbar complaints were screened and evaluated.

### Statistical Analysis

Statistical analyses were performed using SPSS version 20 statistical program (IBM Corp. in Armonk, NY). The Shapiro-

**Table I:** The Number of Patients Undergoing Instrumentation Removal and Their Levels

	Number of Patients
L3-4-5	12
L2-3-4-5	9
L2-3-4	4
L1-2-3	3
L4-5	2

**Table II:** Comparison of 6<sup>th</sup> Month Preoperative and Postoperative Number of Admissions to the Hospital and Daily Analgesic Usage

Variables (n=30)		For 6 months before surgery	For 6 months after surgery	p*
Number of admissions to the hospital	Median (IQR)	5.00 (3.75–3.00)	3.00 (2.00–4.00)	<0.001
Daily analgesic usage (pill/day)	Median (IQR)	3.00 (2.00–5.00)	2.00 (1.00–2.00)	<0.001

*IQR:* Interquartile range; *\*Related-Samples Wilcoxon Signed Rank Test was used.*

**Table III:** Comparison of 1<sup>st</sup> Month Preoperative and Postoperative and 6<sup>th</sup> Month Postoperative VAS and ODI Scores

Variables (n=30)		Preoperative	Postoperative 1 <sup>st</sup> month	p*	Postoperative 6 <sup>th</sup> month	p*
VAS score	Median (IQR)	7.00 (7.00–8.00)	4.00 (1.75–5.00)	<0.001	1.50 (1.00–2.00)	<0.001
ODI score	Median (IQR)	65.00 (62.00–74.00)	19.00 (10.00–20.00)	<0.001	20.00 (11.50–30.00)	<0.001

*VAS:* Visual Analogue Score, *ODI:* Oswestry Disability Index, *IQR:* Interquartile range.

*\*Related-Samples Wilcoxon Signed Rank Test was used to compare with preoperative measurements.*

Wilk and Kolmogorov–Smirnov tests were used to evaluate the distribution of the numerical data. The descriptive data were presented as median with interquartile range for non-normally distributed numerical variables. The Related-Samples Wilcoxon Signed Rank Test was used for comparing the preoperative and postoperative data. A p level of <0.05 was considered statistically significant.

## RESULTS

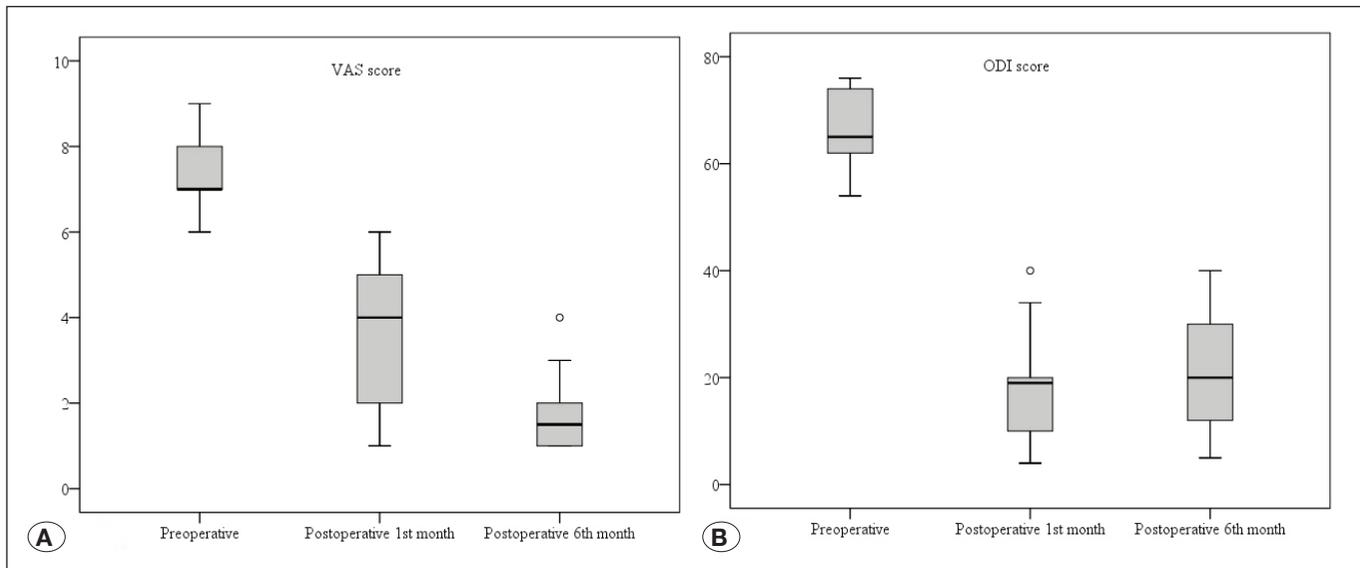
The 30 patients [19 female (63.3%), 11 male (36.7%)] included in this study underwent lumbar spinal fusion instrumentation removal between December 2013 and December 2019. The median age of the patients was 64.0 (60.0–68.0: median interquartile range) years. The mean time between the first operation for fusion and the removal of implant was 19.4 months.

There was a significant reduction in the number of admissions to the hospital ( $p<0.001$ ) and the daily number of analgesics used ( $p<0.001$ ) in the six months after surgery compared to the period of six months before surgery (Table II).

The median preoperative VAS score was 7.00, the one month postoperative VAS score was 4.00, and the six months postoperative VAS score was 1.50. There were significant decreases in VAS scores, both at the one month ( $p<0.001$ ) and six months ( $p<0.001$ ) postoperative assessments compared to preoperative measurements. Similarly, the median preoperative ODI score was 65.00, the one month postoperative ODI score was 19.00, and the six months postoperative ODI score was 20.00. The ODI scores were significantly lower compared to the preoperative scores at both one month ( $p<0.001$ ) and six months ( $p<0.001$ ) postoperative (Table III and Figure 2A, B). There was no wound infection or any other complication in any patient after surgery.

## DISCUSSION

Lumbar degenerative disease patients who experienced



**Figure 2:** Comparison of preoperative and one month and six months postoperative **A)** visual analog scores (VAS), and **B)** Oswestry disability index (ODI) scores of patients who underwent instrumentation removal surgery after lumbar spinal fusion.

continuous low back pain after a lumbar spinal fusion underwent a procedure to remove the lumbar instrumentation system. Patients' VAS and ODI scores significantly improved in the one month and six months postoperative assessments compared to the preoperative scores. Although spinal fusion instrumentation removal is an uncommon procedure, our study results demonstrate that it can successfully treat continuous or recurrent low back pain in patients who found no relief from other therapies. Thus, for select patients, instrumentation removal provides effective, alternative, and inexpensive treatment with a relatively short operation and hospitalization duration.

At present, spinal fusion with lumbar instrumentation is a common treatment for LDD (8). Despite various imaging and injection methods, it is rather difficult to identify problems resulting from the placement of instrumentation (10). It is difficult to inspect the results of a spinal fusion through means such as x-ray films, bone evaluations, CT and MRI (2,10). Spinal fusion performed with pedicular screw fixation is typically successful but in some patients, low back pain may persist, increase, or recur (7). The most common causes of recurrent low back pain after fusion are pseudoarthrosis, flatback deformation, adjacent segment failure and painful disc due to posterolateral fusion (5). Among these, pseudoarthrosis as a result of implant loosening or breakage is a common presentation of painful implants (7).

Some patients experience pain at the fusion site, despite the absence of pathology such as pseudoarthrosis; removal of the implants in such patients is a matter of debate. The effect of the implant on symptoms and pain that persist after spinal fusion is not well established in the literature. Likewise, the indications and results of implant removal due to pain are generally unclear in previous reports. Despite these uncertainties, in the practice of neurosurgery, implant removal is considered a safe and practical surgical procedure

for reducing patient pain (6). The results of this study are an important contribution to the literature, as the positive effects of implant removal surgery have been reported.

In a previous study, five (56%) of the nine patients experienced either temporary or no improvement in pain complaints following the removal of solidly fused implants (3). In another study, 30 patients who had undergone implant removal were evaluated retrospectively and pseudoarthrosis was detected in 10 patients (6). The study reported that implant removal provided significant improvements in 45 patients who did not have pseudoarthrosis and that the pain particularly decreased in patients with loosened pedicular screws (10). In this study, we identified that in cases where the source of pain could not be identified in patients with successful fusion of lumbar instrumentation, removal of the implant can lead to a significant improvement in quality of life, as quantified by a reduction in painkiller use and hospital admissions, as well as VAS and ODI scores.

A previous study evaluated the prevalence of pain related to the instrumentation system used in lumbar spinal fusion surgery (4). Patients with neural blockages or who received local anesthetic injections were excluded. The study identified that the most common localization of low back pain after instrumentation was in the sacroiliac joint, likely due to stress transfer distribution (4). Besides the distribution of mechanical forces, immune reactions in response to the metal instrumentation system can also play a role in the development of pain (11). However, the effect of the load on lumbar degeneration and instrumentation is likely the main source of pain generation; there is little evidence to support the hypothesis that immune system sensitivity to metal occurs leading to the subsequent development of severe pain. Spinal fusion implant pain may develop as a result of infection-induced inflammation or non-infectious causes such as metallic corrosion, debris, and local irritation (7). In this study,

we excluded patients with high inflammatory parameters, such as CRP, sedimentation and with radiologically and microbiologically positive results of explants materials for infectious or non-infectious inflammation from the study. In this respect, our study evaluated a homogeneous group.

We hypothesize that unexplained pain could be attributed to micro-traumas of the implants that cannot be detected on radiological images, causing patients to experience pain in sensitive bone structures and other tissues surrounding the instrumentation. We observed statistically positive effects of implant removal as a treatment for patients who experience unexplained pain after lumbar spinal fusion.

## ■ CONCLUSION

In patients who have undergone implant removal, the VAS and ODI scores, the number of hospital admissions, and analgesic use have improved significantly. We suggest that implant removal in lumbar degenerative disease patients with unexplained low back pain should be considered as a treatment method for patients who found no relief from other therapies.

## ■ ACKNOWLEDGEMENTS

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