Outcomes in Thoracolumbar and Lumbar Traumatic Fractures: Does Restoration of Unfused Segmental Mobility Correlated to Implant Removal Time—a retrospective study

Jian Wu

Daping hospital of Army Medical University

Jun Zhu

Daping hospital of Army Medical University

Zhong Wang

Daping hospital of Army Medical University

Huaijian Jin

Daping hospital of Army Medical University

Yingbo Wang

Daping hospital of Army Medical University

Baiyi Liu

Daping hospital of Army Medical University

Xiang Yin

Daping hospital of Army Medical University

Longbin Du

Daping hospital of Army Medical University

Yu Wang

Daping hospital of Army Medical University

Mingyong Liu

Daping hospital of Army Medical University

Peng Liu (✉ liupengd@163.com)

Army Medical University <https://orcid.org/0000-0002-6678-2266>

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Abstract

Background

Posterior fixation without fusion can treat thoracolumbar and lumbar traumatic fractures effectively. However, whether patients benefit from implant removal, as well as the correlation between the range of motion (ROM) of the involved segments and the removal time, has not been determined.

Methods

Fifty consecutive cases with thoracolumbar traumatic fractures that had undergone implant removal at different times were enrolled. We found 17 patients (Group A), 21 patients (Group B), and 12 patients (Group C) underwent implant removal following the index surgery within 12 months, between 12 to 24 months, and over 24 months, respectively. Clinical and radiological outcomes, including visual analog scale (VAS) for back pain, patient satisfaction, the Oswestry disability index (ODI) and EuroQol five dimensions questionnaire (EQ-5D) for quality of life and segmental ROM were analyzed.

Results

The average follow-up time was 9.1 ± 5.7 months after implant removal. There were no significant differences in VAS and patient satisfaction among the three groups at the same observation time points. Patients of group A gained the lowest ODI and highest EQ-5D scores after removal and at final follow-up than those in group B and C. The best ROM was obtained in Group A followed by Group B and C ($11.5 \pm 6.2^\circ$, $5.5 \pm 1.6^\circ$ and $2.4 \pm 0.6^\circ$, respectively).

Conclusions

Immobilization of the involved segments over 24 months may lead to ankylosis. Regained segmental ROM is correlated negatively with implant removal time. Patients have implant removal within 12 months can gain a better quality of life.

Background

The increasing incidence of traumatic fractures in the thoracolumbar and lumbar region, especially among the young and middle-aged populations, has become a major cause of hospitalization and disability. Surgical treatment is the most frequently employed method in such patients for providing greater initial stability and for regaining normal sagittal alignment¹.

In recent decades, posterior pedicle screw fixation without fusion was proven to be as effective as fusion surgery^{2,3}. Theoretically, such nonfusion surgery may preserve the normal spine structure after implant

removal compared to fixation with intersegmental fusion. In addition, given the possibility of implant failure attributed to long term fretting wear of nonfusion segments, all implants should be removed if fusion is not conducted. Previous studies mainly focused on the necessity of implant removal because of the potential hazards, such as symptomatic misplacement, implant breakage or loosening⁴. Several studies concentrated on improving clinical outcomes, such as back pain and quality of life⁴⁻⁶. Other cohort retrospective studies with limited samples described that the range of motion (ROM) of the fixed segments could be regained after implant removal⁶. Nevertheless, to our knowledge, no consensus has been reached on the correlation between outcomes and implant removal time.

The present study aimed to evaluate the clinical and radiological outcomes of patients following implant removal at different times and to identify the proper removal time that benefits patients most.

Material And Methods

The study was approved by the ethics committee of the Army Medical Center of PLA (IRB approval number: 2019120) and was conducted according to the principles of the Declaration of Helsinki. In addition, it was registered in the Clinical Trial Registry (ChiCTR) with no. ChiCTR1900028097.

Study subjects

From January 2018 to October 2020, 50 consecutive patients who underwent implant removal following successful posterior fixation without fusion for thoracolumbar and lumbar traumatic fractures in our institute were enrolled in this study. All surgeries were performed by experienced senior surgeons at our institute.

Inclusion criteria: (1) patients underwent implant removal following posterior fixation surgery without fusion; and (2) bony healing of the fractured vertebrae was assessed by a computed tomographic (CT) scan before removal; and (3) complete clinical and radiological data were available. Exclusion criteria: (1) involving fractures above T10; or (2) complicating with other dysfunctions that affected spine mobility and clinical outcomes, such as ankylosing spondylitis, untreated severe osteoporosis and so on; or (3) a deep surgical site infection; or (4) a neurological deficit.

Fifty patients were divided into three groups based on the removal time after index surgery. The removal time was defined as the time interval between the fixation and the removal surgery. Patients who underwent implant removal within 12 months (mean: 10.6 months, range: 8.8 to 11.9 months) were enrolled into Group A (n=17), patients between 12 and 24 months (mean: 17.9 months, range: 13.0 to 23.6 months) were enrolled into Group B (n=21), and patients with removal after 24 months (mean: 32.8 months, range: 24.1 to 67.1 months) were enrolled into Group C (n=12).

Patients' data collected at the time before removal surgery, including age, sex, body mass index (BMI), smoking status, injury and operation related information were obtained from medical documents and through interviews.

Clinical outcomes assessment

The clinical outcomes were assessed by a visual analog scale (VAS)⁷ for back pain, the Oswestry disability index (ODI)⁸ and EuroQol five dimensions questionnaire (EQ-5D) for quality of life and patient satisfaction⁹ were compared among the three groups at the timepoints of preresection, postresection and final follow-up. The EQ-5D questionnaire focused on patients' opinion concerning experienced benefit and satisfaction gained at the final follow-up. These were answered on a three-level scale (a lot, some or none), and the first two answers were seemed as problem while the last as no problem.

Radiological Findings Assessment

From lateral standing radiographs, the Cobb angle of the fixed segments was defined as the angle between the superior end plate of the upper instrumented vertebra and the inferior endplate of the lower instrumented vertebra⁴. Specifically, total ROM of the fixed segments was identified on flexion-extension radiographs at final follow-up¹⁰ (Fig. 1), and ROM per level was calculated through the total ROM divided by the number of fixed levels. In addition, the percentage of regained ROM per level to the normal one was calculated. The normal ROM from T10 to S1 was 9°, 12°, 12°, 12°, 14°, 15°, 17° and 20° respectively¹¹. All measures were conducted three times one week apart by three independent researchers who were unaware of the implant removal time, and their inter- and intraobserver correlation coefficients were calculated. The average of the values was used as the final one.

Statistical Analysis

All statistical analysis was performed using SPSS software version 21.0 (IBM Corp., Armonk, NY). Categorical data are presented by frequencies (percentages) and analyzed by the Pearson chi-square test and Fisher exact probability test among the three groups. Continuous data were presented as the mean±standard deviation (SD) and analyzed by one-way analysis and the least significant difference (LSD) test was used for pairwise comparisons. The intra- and interclass correlation coefficient (ICC) statistics were used to evaluate the consistency of the Cobb angles measured among the three surgeons. The repeated measures analysis of variance test was used to explore whether the VAS, ODI and Cobb angle had changed with time. Differences were deemed statistically significant when *P* values were less than 0.05.

Results

Patients' general information

All patients underwent implant removal successfully, and no severe operation-related complications occurred. Minor complications included screw breakage in two patients of group B, and poor incision healing in two of group B and one of group C, but all of these patients eventually healed without sequelae. The demographics, injury and surgery-related information of three groups are shown in Table 1.

There was no significant difference in any of the baseline data among the three groups (all $P > 0.05$). The mean follow-up time was 9.1 ± 5.7 months.

Clinical outcomes

The mean VAS for back pain was decreased significantly after implant removal (all $P < 0.05$) and maintained at the final follow-up, but with no significant differences among the three groups at the same time points (all $P > 0.05$). Patient satisfaction among the three groups showed no significant difference ($P > 0.05$). The mean ODI declined significantly after removal (all $P < 0.05$) and was maintained until the final follow-up in all three groups. Furthermore, the ODI of group A was lower than that of group C ($P < 0.05$), but similar to group B ($P > 0.05$) after removal and at final follow-up. The mean EQ-5D scores increased significantly after removal (all $P < 0.05$) and was maintained until the final follow-up in group A and B (both $P < .0001$), but remained almost unchanged in group C ($P > 0.05$). Furthermore, the ODI of group A was lower than that of group C ($P < 0.05$), and EQ-5D scores of group A was higher than that of group B and C after removal and at final follow-up (both $P < 0.05$) (Table 2). Among the EQ-5D questionnaire, patients of group A showed the lowest proportion of problems in all dimensions except for self-care (Fig. 2).

Radiological findings

A reliability analysis showed that the interobserver consistency among the observers in measuring the Cobb angle of these 50 patients was very good, with an ICC value of at least 0.970. After removal of the implants, the Cobb angle increased by 5.0° to 8.6° on average at final follow-up, but the difference between postfixation and the final follow-up of the three groups showed no significant difference (group A, $5.0 \pm 2.4^\circ$, group B, $8.5 \pm 7.1^\circ$, group C, $8.6 \pm 4.2^\circ$, $P > 0.05$). Both total segmental ROM and ROM per level in group A were significantly greater than that of group B and C ($P < 0.05$), while those in group B were greater than in group C ($P < 0.05$) (Table 3).

Discussion

The result of the present study suggest implant removal is beneficial to clinical and radiological outcomes for patients treated successfully for thoracolumbar traumatic fractures, and the outcomes were negatively correlated with the time of removal. Patients subjected to implant removal within 12 months could obtain better clinical outcomes, especially in ODI and EQ-5D, and patients subjected to implant removal within 12 months could also regain greater ROM of the fixed segments.

Posterior short-segment fixation surgery with pedicle screws has become the most widely used method to repair traumatic spine fractures since it was first introduced in the 1980s¹². Kim *et al.*¹³ has suggested that a nonfusion method appears to also be effective in achieving favorable sagittal alignment with a shorter operative time and less blood loss. This unfused method has also been confirmed by prospective studies¹⁴ and meta-analyses and systematic reviews in recent years^{15, 16}.

Considering the disadvantages of leaving the implants in situ, such as back pain, functional impairments and implant-induced injury to the spine^{17–19}, implant removal following nonfusion surgery seems beneficial. Although implant removal surgery has been widely used especially among nonfused patients in recent years, the literature has reported conflicting results following implant removal because of heterogeneity in the patients' demographics and surgical objectives.

Jeon *et al.*¹⁰ reported 45 patients with implant removal and 45 age- and gender-matched patients with implant retainment after being successfully treated for thoracolumbar (T11-L2) burst fractures. Both the mean VAS for back pain and the mean ODI in the implant removal group were significantly lower than those in the control group at the 1-year and 2-year follow-up. In addition, the segmental ROM of the implant removal group increased significantly at the 1-year follow-up, but no obvious difference was found in the control group.

As for clinical outcomes, similar to Jeon, the present study showed that implant removal had high patient satisfaction and benefited patients in regard to VAS, ODI and EQ-5D regardless of removal time. The exact mechanism is still unclear but may involve the local microenvironments, metallic properties, surgical site infections or allergic reactions that can cause implant-related pain^{20–22}. It was certain that the back pain caused by the irritation of the internal fixation can be relieved through removing the implant, and the quality of life is consequently improved.

It might be an interesting observation in this work that different removal times had little impact on patients' back pain, but they did on ODI. Patients who underwent implant removal after 24 months showed undesired recovery of ODI and EQ-5D compared to those with an earlier removal. We analyzed the reason for the high ODI level further, and found such patients generally exhibited easy muscle fatigue.

Recurrent kyphosis after implant removal has always been a major concern for surgeons. In a study by Lindsey *et al.*²³, 80 patients with thoracolumbar fracture were analyzed, and a mean postoperative kyphosis of 6° became a kyphosis of 9.5° one year after surgery. Kanazaki²⁴ also reported the median local kyphosis angle correction loss was 9° and concluded that the kyphosis changes occurred mainly at the intervertebral disc level, rather than at the site of the vertebral body. Similar to these papers, our study showed a recurrent kyphosis of the involved segmental as well (range from 5.0° to 8.6° on average), but no obvious correlation between increased kyphosis and implant removal time was seen.

As for ROM of the fixed vertebral segments, studies^{10, 17, 18} have shown that implant removal could regain it. Ko *et al.* observed 60 patients who received posterior fixation without fusion for thoracolumbar and lumbar fractures (T11-L3), and then they underwent implant removal at a mean time of 12.2 months. They concluded that, based on 38 months of follow-up after implant removal, the total mean ROM was 9.12°²⁵. In addition, Jeon *et al.*¹⁰ studied 45 cases with thoracolumbar fractures (T11-L2) treated by long-segment instrumentation (4.4 levels on average) with short-segment fusion (1.2 levels on average). The time from index fracture surgery to implant removal was 18.3 months on average. They found that the

mean segmental motion angle was 1.6° at the time of removal, which increased to 5.8° at the 1-year follow-up and was maintained until the 2-year follow-up.

Based on our study covering the whole course of treatment, we concluded that patients with thoracolumbar fractures (T11-L3) in group A can achieve a functional segmental ROM 11.5° on average and restore 41.6% of the normal value, which is in accordance with Ko's findings. Meanwhile, the average ROM in group B was close to Jeon's findings and did little to improve spinal mobility. In addition, our results demonstrated that the ROM in group C was significantly smaller, which was equivalent immobility. We concluded that the restored segmental ROM correlated with removal time and that prolonged fixation leads ROM to be unrecoverable, but this might not be caused by intervertebral fusion. Gardener and Armstrong²⁶ found spontaneous fusion in only two of 75 facet joints after instrumentation without fusion. They also reported that 33.3% of nonfused temporarily fixed lumbar facet joints became sclerotic when implants were removed at 18.3 months after surgery on average. Meanwhile, no spontaneous fusion of facet joints and no bony bridge formation between vertebrae in this study were seen under CT before removal. Therefore, we speculate the reduced segmental ROM was caused by spontaneous stiffness of the facet joints resulting from prolonged immobilization of the fixed segments.

Limitations

Several limitations of the present study should be considered: (1) This study was a retrospective cohort with a relative low evidence level; (2) Patients in this study were grouped by year. As we know, there are four bone remodeling cycles per year. An optimal removal time shorter than 12 months may exist. A prospective study is necessary to identify whether a shorter time interval than 12 months would address this issue.

Conclusions

For patients treated successfully for thoracolumbar traumatic fractures, implant removal following vertebral fracture healing can preserve the injured segmental ROM, and it is negatively related to the removal time. Implant removal performed within 12 months could achieve better functional spinal mobility and favorable quality of life, and for patients with instrumentation retained for 24 months or more, implant removal provides fewer benefits.

Abbreviations

ROM: range of motion; VAS: visual analog scale; ODI: Oswestry disability index; EQ-5D: EuroQol five dimensions questionnaire; BMI: body mass index

Declarations

Acknowledgements

Not applicable

Authors' contributions

PL and ML designed the study and performed the surgery; JW, JZ, and ZW performed the study and interpretation; HJ, YW, and BL contributed in writing the manuscript; XY, LD and YW assisted with the statistical analysis. All authors read and approved the final manuscript.

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Availability of data and materials

The data and materials might be obtained from the corresponding author upon request.

Ethics approval and consent to participate

The study was approved by the ethics committee of the Army Medical Center of PLA, Chongqing, China (ethical review number: 2019120) and was registered in the Clinical Trial Registry (ChiCTR) with no. ChiCTR1900028097.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Tables

Table 1. Demographics, Injury and Surgery Related Information

Variable	Group A (n=17)	Group B (n=21)	Group C (n=12)	P
Age (y, mean±SD)	42.7±10.6	45.6±10.1	38.8±10.7	NS
Male (n, %)	10 (58.82)	14 (66.67)	5 (41.67)	NS
BMI (Kg/m ² , mean±SD)	22.2±3.2	23.6±2.8	24.5±3.5	NS
Current smoker (n, %)	3 (17.65)	5 (23.81)	0	NS
Injury mechanism (n, %)				NS
Fall from height	15 (88.24)	18 (85.71)	6 (50.00)	
Traffic accident	2 (11.76)	2 (9.53)	3 (25.00)	
Others	0	1 (4.76)	3 (25.00)	
Number of fractured vertebral bodies (n, %)				NS
single	17 (100)	16 (76.19)	11 (91.67)	
multiple	0	5 (23.81)	1 (8.33)	
Fractured vertebra (n, %)				NS
T10-L2	16 (94.12)	13 (61.90)	9 (75.00)	
L3-L5	1 (5.88)	8 (36.10)	3 (25.00)	
Number of fixation segments (n, %)				NS
2	17 (100)	15 (71.43)	11 (91.67)	
3	0	5 (23.81)	0	
4	0	1 (4.76)	1 (8.33)	
mean	2.00	2.38	2.17	
Surgery time (days after injury, mean±SD)	4.1±2.7	5.0±2.4	6.4±2.8	NS

P were calculated using a combination of chi-square and one-way ANOVA appropriately.

NS no significant difference

Table 2. VAS scores for back pain, patient satisfaction, ODI and EQ-5D scores for life quality

Variable	Group A (n=17)	Group B (n=21)	Group C (n=12)	<i>P</i> *
VAS for back pain (score, mean±SD)				
Pre-removal	1.94±1.52	1.38±1.24	2.50±1.09	NS
Post-removal	1.24±1.03 ^a	0.81±1.24 ^a	1.58±1.24 ^a	NS
Final follow-up	0.47±0.80 ^{ab}	0.57±1.40 ^{ab}	0.83±0.94 ^{ab}	NS
<i>P</i> #	※	※	※	
Patient satisfaction (score, mean±SD)	7.53±1.12	7.38±1.16	7.67±0.98	NS
ODI (% , mean±SD)				
Pre-removal	18.30±11.51	17.25±8.95	23.33±7.06	NS
Post-removal	11.50±4.99 ^a	11.21±7.49 ^a	17.04±7.42 ^a	※ C > A, B
Final follow-up	9.40±3.83 ^{ab}	10.68±6.91 ^{ab}	15.37±4.69 ^{ab}	※ C > A, B
<i>P</i> #	※	※	※	
EQ-5D				
Pre-removal	53.95±8.75	53.96±4.89	58.57±6.90 ^b	NS
Post-removal	64.21±7.69 ^a	59.17±7.32 ^a	55.00±2.89	※ A > B, C
Final follow-up	82.11±6.52 ^a	63.75±6.63 ^a	56.43±2.44 ^b	※ A > B > C
<i>P</i> #	※	※	NS	

*P** were calculated using one-way ANOVA among three groups and LSD between groups.

P# were calculated using repeated analysis among three groups.

Compared to “Pre-removal”, ^a*P* < 0.05; Compared to “Post-removal”, ^b*P* > 0.05.

※, *P* < 0.05.

Table 3. ROM of Involved Segments at Final Follow-up

Variable	Group A (n=17)	Group B (n=21)	Group C (n=12)	<i>P</i>
Total (°)	11.5±6.2 (5.4 to 32.3)	5.5±1.6 (2.7 to 8.6)	2.4±0.6 (1.8 to 4.1)	※ A > B > C
Per segment (°)	5.8±3.1 (2.7 to 16.1)	2.5±0.9 (0.7 to 4.3)	1.2±0.4 (0.6 to 2.0)	※ A > B > C
% of normal values	41.6±13.0 (25.6 to 65.3)	18.4±5.9 (7.1 to 29.6)	8.8±3.3 (5.2 to 17.0)	※ A > B > C

P were calculated using one-way ANOVA among three groups and LSD between groups.

※, *P* < 0.05.

Figures

Figure 1

Patients with thoracolumbar and lumbar fractures underwent implant removal at different times following posterior fixation surgery without fusion. A. A 45-year-old male had a burst fracture at L2 with implant removal after 9 months. (A1) Anteroposterior radiograph obtained at 1 week after fixation surgery; (A2, A3) Flexion-extension lateral radiograph obtained at 3 months after implant removal, Cobb angle were -30° and 2° , segmental ROM was 32° . B. A 41-year-old male had a burst fracture at L3 with

implant removal after 13.5 months. (B1) Anteroposterior radiograph obtained at 1 week after fixation surgery; (B2, B3) Flexion-extension lateral radiograph obtained at 3 months after implant removal, Cobb angle were -22.3° and -16.0°, segmental ROM was 6.3°. C. A 43-year-old female had a burst fracture at L2 with implant removal after 24.1 months. (C1) Anteroposterior radiograph obtained at 1 week after fixation surgery; (C2, C3) Flexion-extension lateral radiograph obtained at 2 months after implant removal, Cobb angle were 3.6° and 1.8°, segmental ROM was 1.8°.

Figure 2

Proportions of patients that reported problems on the different EQ-5D domains among three groups at final follow-up. Group A showed the lowest proportion of patients that reported problems in all domains except for self-care. Compared to group B and C, *P < 0.05; Compared to group C, #P < 0.05.