Removal versus Retention of Posterior Spinal Implants in Patients with Healed Thoracolumbar Fractures: Analysis of Clinical and Radiographic Outcomes—A Randomized Controlled Trial

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Abstract:

Introduction: There is ongoing debate over whether to remove or retain posterior spinal implants following the successful union of thoracolumbar fractures. This study aimed to compare clinical and radiographic outcomes following removal versus retention of posterior spinal implants in patients with healed thoracolumbar fractures.

Methods: All patients who underwent posterior short segment fixation for thoracolumbar (T11-L2) fractures and presented to the outpatient clinic of our institution (level I trauma center) from October 2020 to October 2022 were enrolled in the study. The participants were randomly assigned to one of the two groups. The EQ-5D-5L was the primary outcome of the study. The secondary outcomes were the Oswestry Disability Index (ODI), loss of correction, and incidence of complications.

Results: A total of 52 patients were included in the final analysis with 26 patients in each group. During the 6-month and 1-year follow-up visits, the implant removal group had a statistically significant improvement in the EQ-Index, EQ-VAS, and ODI, while there were no significant differences in these parameters in the implant retention group. There was no significant difference between the two groups regarding loss of correction (P=0.109).

Conclusions: In patients who have undergone posterior instrumentation for thoracolumbar fractures, the removal of implants following fracture consolidation demonstrates enhanced clinical outcomes when compared to retaining the implants. Although loss of correction is marginally higher in the implant removal group than in the retention group, this disparity did not attain statistical significance, nor did it correlate with inferior clinical outcomes. Furthermore, the incidence of complications following implant removal remained minimal. These findings emphasize the favorable efficacy and safety profile of implant removal procedures within this patient population.

Keywords:

Thoracolumbar fracture, Implant removal, Loss of correction, EQ-5D-5L

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Introduction

The increased utilization of internal fixation for fracture treatment has sparked interest in implant removal surgeries. Implant removal following successful bone union is a common practice in orthopedic surgeries, including spinal procedures[1)]. General indications for spinal implant removal include infection, nonunion, symptomatic misplacement, implant breakage or loosening, local irritation, or growth disturbance[2)]. However, there is controversy regarding the benefits and indications for routine spinal implant removal in asymptomatic patients with successful unions. Advocates of implant removal argue that it can address concerns associated with retained implants, such as adjacent segment degeneration, limited mobility, facet arthritis, metal fretting, allergic reactions, micromotion, and stress shielding-induced osteopenia[3-6)]. Nonetheless, this secondary surgical procedure carries inherent risks, such as surgical site infections, neurovascular injury, loss of correction, or even refracture[6-8)]. Previous studies have attempted to address this controversy of

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implant removal versus retention following posterior instrumentation for thoracolumbar fractures[2,6,9-11]. However, the current level of evidence is weak due to several inherent limitations in these studies. These limitations include the heterogeneous nature of patient demographics and surgical procedures across published studies, retrospective study designs, short-term follow-up durations, and the absence of direct comparison and non-randomized designs[12-14]. To our knowledge, this study represents the first randomized controlled trial aimed at comparing clinical and radiographic outcomes following implant removal versus retention in patients with healed thoracolumbar fractures.

Materials and Methods

Study design

This prospective randomized controlled trial was approved by our institutional review board. The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines. Written informed consent was obtained from all participants before enrollment in the study. This study was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Participant selection

From October 2020 to October 2022, all patients who underwent posterior short segment fixation for thoracolumbar (T11-L2) fractures and presented to the outpatient clinic of our institution (level I trauma center) were enrolled in the study. The inclusion criteria were as follows: (1) single level, type A or B fracture according to AO spine classification, (2) at least 1 year after the index surgery, (3) the index surgery that was performed at our institution with retrievable complete medical reports, (4) complete fracture consolidation as detected by CT, and (5) patient's informed consent including the limited evidence of the benefit for pedicle screw removal. The exclusion criteria were as follows: patients with type C fractures, lower lumbar fractures (below L2), multi-level fractures, pathological fractures, neurological deficit, long segment fixation, metal failure, or deep implant infection and those who underwent posterior direct decompression, anterior reconstruction, or supplementary posterior fusion. The final follow-up of the last patient was completed in October 2023.

Sample size

Sample size calculation was conducted using Statulator (a web-based statistical calculator). The minimal clinically important difference for the EQ-VAS is typically considered to be 7.5 points, with a standard deviation of approximately 9.07[15]. Accordingly, in a (clinically important) superiority study design aiming for 80% power at a significance level of $P<0.05$, 46 participants are required to detect such a difference in EQ-VAS. Estimating a loss of follow-up of 20%, we would need a sample size of 56 patients (28 in each group).

Randomization and blinding

The participants were randomly assigned to one of the two groups using a computer-generated randomization sequence, with an allocation ratio of 1:1 in fixed blocks of 2. Allocation concealment was ascertained using sequentially numbered, opaque, sealed envelopes. After assessing the eligibility and obtaining the required consent, the outpatient clinic nurse opened the envelope and informed the investigators with patient's assigned group. To minimize bias in assessing clinical and radiographic outcomes, measures were taken to ensure that surgeons were not involved in outcome assessment. Although it was unfeasible for the assessors to remain blinded to the type of intervention visible in radiological images, they were entirely detached from the treatment process. This deliberate separation of roles greatly reduces the likelihood of bias in evaluating patient outcomes.

Surgical procedure

Implant removal was conducted under general anesthesia with the patient positioned prone, using the primary incision line from the initial operation. Prophylactic antibiotics were administered during implant removal, and wound drains were retained until output ceased and then subsequently removed. Following the procedure, patients were encouraged to mobilize as tolerated. Any perioperative complications were diligently documented. Patients were followed up for at least 12 months.

Outcome measures

This study focuses on the EQ-5D-5L as the primary outcome. This involved comparing differences within the groups and between the groups. The secondary outcomes were the ODI, loss of correction, and incidence of complications.

EQ-5D-5L and ODI questionnaires were completed by the patients at recruitment (baseline) and at 1 year. The EQ-5D-5L is a widely used generic health status measure comprising two components. The first component, known as the descriptive system, evaluates health across five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension offers five response levels ranging from "no problems" to "extreme problems/unable to." These responses can be converted into a single numeric value representing health status, ranging from 11111 (best health) to 55555 (worst health). Moreover, this value can be further transformed into a summary index value, EQ-Index, from 0 (indicating death) to 1 (indicating best health) using a predetermined value set derived from national or regional values. The EQ-VAS, the second component of the questionnaire, involves a visual analog scale where patients rate their health state on a scale from 0 (worst) to 100 (best)[16].

Loss of correction was evaluated by the change in Cobb angle[17] measured on lateral spine radiographs at different

time points: before primary surgery, after primary surgery, at recruitment (baseline), and at final follow-up. Radiographic images were also used to measure the disc heights of injured discs, which were identified as intervertebral discs with traumatic endplates. The disc height was reported as a percentage, representing the measured disc height relative to the presumed disc height. The presumed disc height was calculated by averaging the heights of the adjacent cranial and caudal normal discs[18]. This can be represented by the following equation:

$$\textit{Presumed Disc Height} = \frac{(\textit{Height of Cranial Adjacent Disc} + \textit{Height of Caudal Adjacent Disc})}{2}$$

$$\textit{Disc Height} = \left(\frac{\textit{Measured Disc Height}}{\textit{Presumed Disc Height}}\right) \times 100\%$$

Disc height was measured for the anterior, middle, and posterior thirds at different time points: before primary surgery, after primary surgery, at recruitment (baseline), and at final follow-up.

All radiographic measurements were performed using Surgimap Spine, a dedicated and validated software (Nemaris, Inc., New York, NY, USA)[19]. After undergoing two training sessions on how to perform the measurements, two trained investigators independently conducted the measurements, and the average of the two measurements was adopted. Analyzing the average values helped reduce potential errors in the measurements.

Statistical analysis

Statistical analyses were performed using GraphPad Prism for macOS version 9.5.0 (GraphPad Software, San Diego, CA, USA). Continuous and nominal data were expressed as mean±SD and frequency (percentage), respectively. Chi-squared test was used to compare the nominal data of different groups in the study, whereas unpaired t-test was used to compare the means of the two groups. Paired t-test was used to compare the preoperative and follow-up assessments of the same group. Pearson correlation was used to determine the correlation between loss of correction and clinical outcomes. The level of confidence was kept at 95%; hence, a *P* value of <0.05 was considered statistically significant.

Results

Throughout the 2-year study period, 75 patients were assessed for eligibility. However, 19 patients were subsequently excluded. At the 1-year follow-up, four participants were lost to follow-up, rendering their data unavailable for analysis. A total of 52 patients were included in the final analysis with 26 patients in each group (Fig. 1). Fig. 2 and 3 show representative cases.

Table 1 shows a summary of the baseline demographics of the study participants. There were no significant differences between the two groups regarding age, sex distribution, fracture level, or fracture classification (Table 1). In addition, at recruitment (baseline), there was no significant difference between the two groups in terms of clinical or radiographic parameters, indicating similar characteristics between the groups at the start of the study (Table 2, 3, 4).

During the follow-up period, the implant removal group had a statistically significant improvement in the EQ-Index, EQ-VAS, and ODI scores, while there were no significant differences in these parameters in the implant retention group. Consequently, at the 6-month and 1-year follow-ups (after recruitment), the EQ-Index, EQ-VAS, and ODI scores of the implant removal group were significantly better than those of the implant retention group (Table 2 and Fig. 4).

In the implant removal group, there was a statistically significant improvement in all domains of the EQ-5D-5L between baseline and final follow-up. Conversely, in the implant retention group, there were no statistically significant changes in any domain of the EQ-5D-5L between baseline and final follow-up (Table 3).

Compared with the general Egyptian population scores on the EQ-5D-5L[20], the implant removal group did not exhibit a higher frequency of problems across all domains during the final follow-up assessment. In contrast, the implant retention group reported a significantly higher frequency of problems across all domains, with the exception of self-care, at the final follow-up evaluation (Table 3 and Fig. 5).

Comparison of Cobb angle measurements showed no significant differences between the implant removal and implant retention groups at various time points (P>0.05 for all comparisons). In addition, the total loss of correction and loss of correction after recruitment did not significantly differ between the groups (P>0.05 for all comparisons).

Regarding the changes in Cobb angle within each group, both groups exhibited improvement in Cobb angle from before to after primary surgery, with a substantial decrease in Cobb angle. However, over time, both groups started to experience a loss of correction. This loss of correction was evident before recruitment and continued afterward. Notably, the total loss of correction (final follow-up minus after primary surgery) was significant (P2<0.0001 and P2=0.0003 for the implant removal and implant retention groups, respectively). However, the loss of correction after recruitment (final follow-up minus recruitment) was not significant (P3> 0.05 for both groups) (Table 4 and Fig. 6). Subgroup analysis for loss of correction in the implant removal group showed no significant correlation with clinical outcome scores.

Analysis of injured disc height at different thirds, i.e., anterior, middle, and posterior, showed comparable measurements between the implant removal and implant retention groups across all time points (P>0.05 for all comparisons). In addition, there were no significant differences in the total loss of correction and loss of correction after recruitment in injured disc height between both groups (P>0.05 for all comparisons).

The changes in injured disc height within each group over time were significant for the anterior and middle thirds.

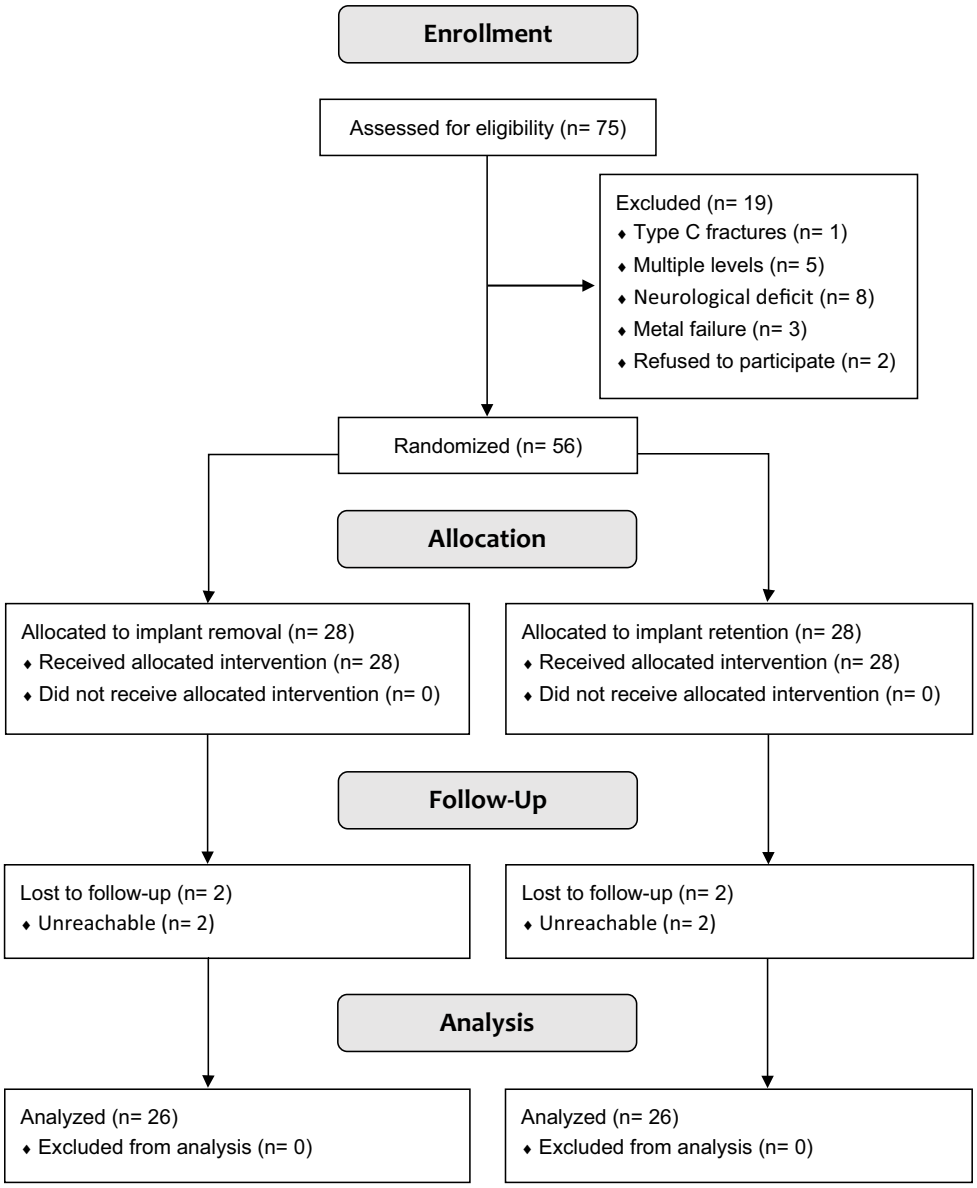


Figure 1. Flow diagram of the study according to the CONsolidated Standards of Reporting Trials (CONSORT).

Both groups showed improvement in injured disc height from before to after primary surgery. However, there was a subsequent loss of correction over time, which was significant between the measurements taken after primary surgery and at final follow-up (total loss of correction) (P2=0.0001 and P2=0.0036 for the anterior third and P2=0.0003 and P2 =0.0080 for the middle third in the implant removal and implant retention groups, respectively). Nevertheless, there were no significant differences in the loss of correction between recruitment and final follow-up (loss of correction after recruitment) (P3>0.05 for both groups in the anterior and middle thirds). The changes within each group over time were not significant at any interval for the posterior third (P >0.05) (Table 4 and Fig. 6).

There were two (7.69%) complications in the implant removal group. One patient experienced a hematoma and required re-admission, drainage, and drain placement for treatment, and another patient developed superficial infection, which was managed with oral antibiotics and daily dressing.

Discussion

The ongoing debate surrounding the removal or retention of implants in patients with healed thoracolumbar fractures has been the subject of previous studies[2,6,9-11]. However, the heterogeneity in patient characteristics, surgical techniques, and follow-up protocols, along with the lack of direct comparison and randomization in these studies, have resulted in conflicting findings and hindered the establishment of evidence-based guidelines[14]. In this study, researchers aimed to address these limitations by using a randomized controlled trial design, ensuring comparability between the two treatment arms, minimizing bias, and providing high-quality evidence to guide clinical decision-making.

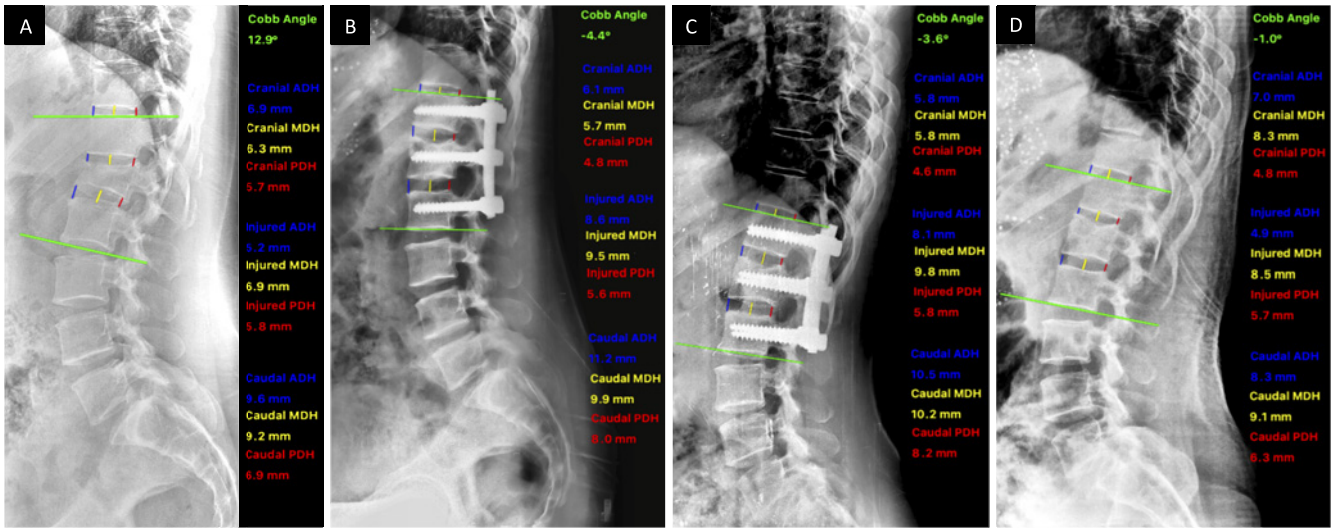


Figure 2. A 25-year-old female with fracture L1 (A3). (A) Preoperative lateral radiograph. (B) Immediate postoperative lateral radiograph after short segment fixation. (C) Lateral radiograph at recruitment (1-year post-fixation). (D) Lateral radiograph at the latest follow-up after metal removal. ADH, anterior disc height; MDH, middle disc height; PDH, posterior disc height

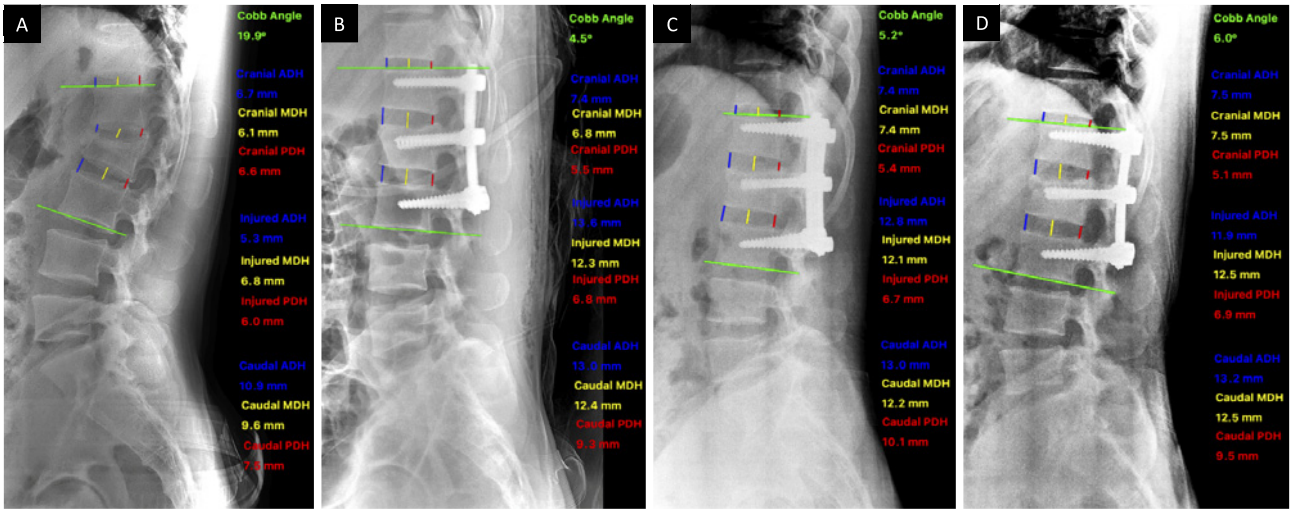


Figure 3. A 32-year-old male with fracture L2 (A3). (A) Preoperative lateral radiograph. (B) Immediate postoperative lateral radiograph after short segment fixation. (C) Lateral radiograph at recruitment (1-year post-fixation). (D) Lateral radiograph at the latest follow-up with retained metal. ADH, anterior disc height; MDH, middle disc height; PDH, posterior disc height

Previous studies primarily focused on pain assessment using the VAS, indicating less pain after implant removal compared with before removal[9,21,22]. Other studies have used back specific outcome measures such as the ODI. However, there are conflicting findings regarding the ODI. One study reported significantly better mean ODI scores at both the 1- and 2-year follow-ups in the implant removal group compared with the control group[6]. Conversely, another study found that although the mean ODI score at follow-up was lower in the implant removal group than in the implant retention group, the difference was not statistically significant. They argued that implant-related disability might impact the ability to return to work and baseline activities, aspects that may not be fully captured by the ODI or pain scores[13]. Therefore, in this study, we incorporated the EQ-5D questionnaire to assess quality of life. Once again, the implant removal group demonstrated significantly superior clinical outcomes (EQ-Index, EQ-VAS, and ODI) than the implant retention group. This significant difference was more evident in the EQ-Index and EQ-VAS than in the ODI. This could be explained by the fact that the EQ-5D-5L is more sensitive than the ODI in detecting minor changes in health status. This discrepancy can be explained by the fact that the psychological aspects measured by the EQ-5D, particularly in the anxiety/depression domain, account for a large percentage of the improvement in the total EQ-Index. These psychological aspects are not fully captured by the ODI, which could explain why the ODI did not exhibit the same dramatic improvement observed in the EQ-5D.

Nevertheless, the exact mechanism underlying this ob-

served clinical improvement remains unclear. Factors implicated in implant-related pain, such as micromotion, metal fretting, allergic reactions, low-grade infections, and potential stress concentration at adjacent segments, have been cited in the literature[2,3,5,20]. In this study, although all domains of the EQ-5D-5L exhibited significant improvement following implant removal, it is noteworthy that the domains of anxiety/depression and mobility demonstrated the most pronounced enhancements. This might be elucidated by the hypothesis that implant removal mitigates anxiety associated with retained implants and facilitates the restoration of spinal mobility[9,23].

Table 1. Demographic Data of Both Groups.

	Implant removal (n=26)	Implant retention (n=26)	*P* value
Age	33.03±13.62	35.25±12.33	0.536
Gender			0.473
Male	15 (57.69%)	17 (65.38%)	
Female	11 (42.30%)	9 (34.61%)	
Fracture level			0.617
D11	3 (11.54%)	2 (7.69%)	
D12	6 (23.08%)	8 (30.77%)	
L1	14 (53.84%)	12 (46.15%)	
L2	3 (11.54%)	4 (15.38%)	
AO spine classification			0.17
A	15 (57.69%)	14 (53.84%)	
B	11 (42.31%)	12 (46.15%)	

Data expressed as mean (SD), frequency (percentage).

Regarding the Cobb angle, within each group, a progressive significant loss of correction occurred from after primary surgery to final follow-up (total loss of correction). This loss of correction began before recruitment and continued afterward, regardless of whether the implant was removed or retained. Therefore, implant removal did adversely affect the attained correction. This is supported by two observations: There was no statistically significant difference in loss of correction after recruitment between the implant removal and implant retention groups (P=0.1090) and there was no statistically significant loss of correction after recruitment within the implant removal group (P=0.0862). Moreover, this loss of correction did not demonstrate a significant correlation with clinical outcomes.

These findings are consistent with those reported in previous studies[6,18,22,24]. Chou et al.[18] and Jeon et al.[6] conducted retrospective studies comparing an implant removal group to an implant retention control group. They reported that there was no statistically significant loss of correction between the time of implant removal and the final follow-up. In addition, Lorente et al.[22] and Oh et al.[24] found that there was no statistically significant loss of correction after implant removal in patients with thoracolumbar fractures who underwent percutaneous fixation. This was further supported by Ko et al.[25], who reported that there was no significant difference in Cobb angle between the time of implant removal and the final follow-up in their study with at least a 10-year follow-up.

In contrast, other studies reported a significant loss of correction following implant removal; however, this did not adversely affect the clinical outcomes, which continued to show significant improvement[11,21,26-28]. Therefore, it can be ar-

Table 2. Changes in Clinical Parameters.

	Implant removal (n=26)	Implant retention (n=26)	*P*1 value
ODI			
At recruitment (baseline)	14.19±3.75	14.23±2.61	0.9646
At 6-month after recruitment	11.31±2.88	13.27±3.19	0.0241*
At 1-year (final) follow-up	10.42±1.45	13.25±4.90	0.0068*
***P*2 value**	<0.0001*	0.3724	
EQ-VAS score			
At recruitment (baseline)	66.53±13.83	67.59±13.10	0.7778
At 6-month after recruitment	78.00±11.61	67.27±14.02	<0.0001*
At 1-year (final) follow-up	84.28±9.97	68.63±13.80	<0.0001*
***P*2 value**	<0.0001*	0.7816	
EQ-Index score			
At recruitment (baseline)	0.526±0.359	0.532±0.407	0.9523
At 6-month after recruitment	0.871±0.104	0.518±0.403	<0.0001*
At 1-year (final) follow-up	0.899±0.048	0.556±0.428	<0.0001*
***P*2 value**	<0.0001*	0.8367	

Data expressed as mean (SD). *P*1 value compares both groups, whereas *P*2 value compares at recruitment (baseline) and at 1-year (final) follow-up measurements in the same group. ODI, Oswestry Disability Index. *Statistically significant.

Table 3. Distribution of EQ-5D-5L Domain Responses.

	Implant removal (n=26)		*P*1	Implant retention (n=26)		*P*2	*Egyptian population*	*P*3	*P*4
	Baseline	Follow-up		Baseline	Follow-up				
Mobility									
No problems	42	65	0.0011*	38	35	0.6595	69	0.5475	<0.0001*
Problems	58	35		62	65		31		
Self-care									
No problems	85	96	0.0080*	89	92	0.4694	94	0.5164	0.5794
Problems	15	4		11	8		6		
Usual activities									
No problems	50	65	0.0319*	58	54	0.5688	69	0.5475	0.0293*
Problems	50	35		42	46		31		
Pain/discomfort									
No problems	35	50	0.0319*	31	23	0.2026	40	0.1552	0.0097*
Problems	65	50		69	77		60		
Anxiety/depression									
No problems	15	38	0.0002*	12	20	0.1228	36	0.7696	0.0117*
Problems	85	62		88	80		64		

Data expressed as frequency (percentage). *P*1 value compares baseline and follow-up measurements in the implant removal group, whereas *P*2 value compares baseline and follow-up measurements in the implant retention group. *P*3 value compares follow-up measurements of the implant removal group and standardized scores weighted for the Egyptian population. *P*4 value compares follow-up measurements of the implant retention group and standardized scores weighted for the Egyptian population. *Statistically significant.

gued that concerns on potential loss of correction do not provide sufficient justification against the practice of implant removal.

Several studies have investigated the factors contributing to the loss of correction after surgical fixation of thoracolumbar fractures. These investigations have consistently identified disc degeneration and the resulting decrease in disc height as primary etiological factors[11,18,29,30]. Moreover, Chou et al.[18] reported that progressive loss of disc height at the anterior third of the injured disc occurred over time, regardless of whether the implant was removed or retained. In this study, we observed that there was significant loss of injured disc height at the anterior and middle thirds from the period following the primary surgery to the final follow-up. This loss of disc height began before implant removal and continued afterward, irrespective of whether the implant was removed. This pattern of disc height loss mirrored the pattern of correction loss in the Cobb angle.

However, the observed phenomenon in which the loss of correction did not significantly differ between the implant removal and implant retention groups warrants further exploration. We posit that the loss of correction is attributable to the reduction in disc height, stemming from disc degeneration induced by traumatic endplate fractures, which disrupt the blood supply to the disc. This degenerative process initiates post-injury and persists over time. Although it would be anticipated that the implant should mitigate the adverse impact of disc height loss on the corrected Cobb angle, this was not observed in this study. A plausible explanation for this could be the intraoperative observation of loosened screws during implant removal surgery. Therefore, even with an intact implant and complete fracture consolidation, the loss of disc height can occur and lead to a loss of Cobb angle correction, due to the loosening of the screws.

Previous studies have reported a low rate of complications following implant removal. Reported complications included wound infection, hematoma formation, screw breakage during the removal procedure, and instability after removal[11,13]. In this study, the complication rate in the implant removal group was 7%, with one case of superficial infection and one case of hematoma. Notably, all complications were effectively managed with no long-term sequelae. Given this favorable safety profile characterized by a low incidence of significant complications, implant removal procedures are generally considered as safe[13].

Limitations

This study has some limitations. We recruited patients who had thoracolumbar fractures and had already undergone transpedicular screw fixation. The baseline for this study was set at least 1 year after the primary surgery. Consequently, we had to retrieve some of the patients' data from hospital records, such as fracture classification, neurological status, whether the patient underwent decompression, and whether fusion was performed. Some may argue that recruitment should have commenced before the primary surgery to enhance reliability. However, this approach would have prolonged the study duration and subsequently increased the rate of dropout. Furthermore, patients with broken metal im-

Table 4. Changes in Radiographic Parameters.

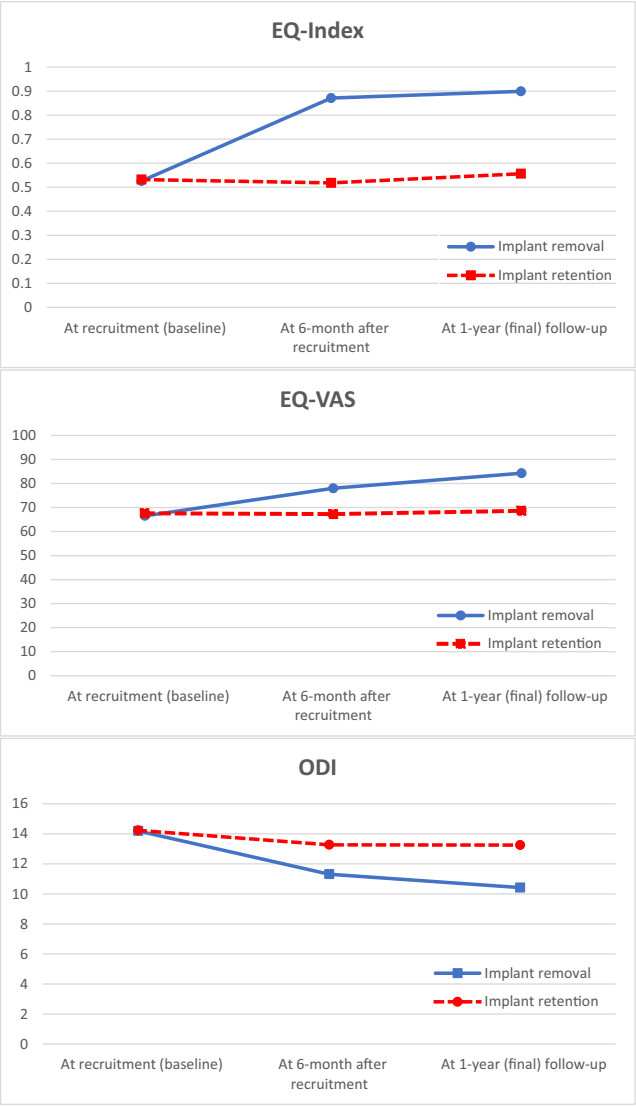
	Implant removal (n=26)	Implant retention (n=26)	*P*1 value
Cobb angle			
Before primary surgery	19.45±4.75	20.10±4.65	0.6202
After primary surgery	5.02±1.35	5.25±1.45	0.5565
At recruitment (baseline)	7.02±4.73	7.38±3.76	0.7625
At final follow-up	9.12±3.88	8.41±3.90	0.5135
Total loss of correction (final follow-up − after primary surgery)	4.10±4.11	3.16±4.15	0.4158
Loss of correction after recruitment (final follow-up − baseline)	2.01±2.54	1.03±1.71	0.1090
***P*2 value**	<0.0001*	0.0003*	
***P*3 value**	0.0862	0.3370	
Injured disc height at anterior third (%)			
Before primary surgery	69.50±5.42	67.05±5.28	0.1041
After primary surgery	83.64±2.81	84.04±2.85	0.6126
At recruitment (baseline)	81.55±4.48	82.16±3.14	0.5722
At final follow-up	79.41±4.35	80.80±4.59	0.2677
Total loss of correction (after primary surgery − final follow-up)	4.23±2.41	3.24±2.78	0.1762
Loss of correction after recruitment (baseline − final follow-up)	2.14±2.17	1.36±1.91	0.1750
***P*2 value**	0.0001*	0.0036*	
***P*3 value**	0.0867	0.2182	
Injured disc height at middle third (%)			
Before primary surgery	75.17±4.66	73.75±3.61	0.2251
After primary surgery	86.99±1.91	86.29±1.97	0.1993
At recruitment (baseline)	85.67±3.72	85.38±2.98	0.7577
At final follow-up	84.05±3.40	84.29±3.12	0.7919
Total loss of correction (after primary surgery − final follow-up)	2.94±2.55	1.99±1.41	0.1027
Loss of correction after recruitment (baseline − final follow-up)	1.62±1.39	1.08±0.89	0.1015
***P*2 value**	0.0003*	0.0080*	
***P*3 value**	0.1075	0.2036	
Injured disc height at posterior third (%)			
Before primary surgery	82.12±3.16	83.32±2.13	0.1147
After primary surgery	87.36±1.14	87.22±1.11	0.6556
At recruitment (baseline)	86.47±2.38	86.37±2.31	0.8784
At final follow-up	86.34±3.39	86.13±3.36	0.8234
Total loss of correction (after primary surgery − final follow-up)	1.03±1.94	1.09±1.89	0.9105
Loss of correction after recruitment (baseline − final follow-up)	0.13±2.06	0.24±1.98	0.8452
***P*2 value**	0.1521	0.1226	
***P*3 value**	0.8735	0.7653	

Data expressed as mean (SD). *P*1 value compares both groups, *P*2 value compares after primary surgery and final follow-up measurements in the same group, and *P*3 value compares at recruitment (baseline) and final follow-up measurements in the same group. *Statistically significant.

plants were excluded, which may introduce selection bias. The exclusion is based on the likelihood that these patients would not consent to being randomized into the metal retention group, coupled with the standard practice at our institution of removing implants in such cases.

Another limitation is the absence of MRI evaluation for disc degeneration, which was not used due to the associated costs. To address this, we assessed disc degeneration by measuring the loss of disc height at the anterior, middle, and posterior thirds using standard radiographs. In addition, this study lacks an economic analysis comparing the costs associated with the implant removal procedure against the financial benefits of improved quality of life and return to work after implant removal. Moreover, we did not evaluate the mental or psychological backgrounds that could have affected clinical outcomes. Further studies are needed to address these limitations.

Despite these limitations, this study possesses distinctive strengths. It represents the first randomized controlled trial to compare clinical and radiographic parameters following implant removal versus retention in patients with thoracolumbar fractures.



ODI, Oswestry Disability Index

Figure 4. Clinical outcome measures of both groups.

Conclusions

In patients with posterior instrumentation for thoracolumbar fractures, implant removal after fracture consolidation leads to better clinical outcomes compared with implant retention. Although the loss of correction was higher in the implant removal group than in the implant retention group, this difference was not statistically significant and was not associated with worse clinical outcomes. Furthermore, the complication rate after implant removal was low, with only minor complications and no long-term sequelae. These findings support the favorable efficacy and safety profile of implant removal procedures in this patient population.

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Author Contributions: A.S.A. and M.F.I. conceived and designed the study. K.M.H. and M.S.M. performed the surgeries. M.F.I., A.S.A., and M.E. conducted the measurements, collected, and analyzed the data. All authors reviewed the paper. M.F.I. and M.E. drafted the paper and designed the figures and tables.

Ethical Approval: The study was conducted in accordance with the Declaration of Helsinki and Good Clinical Practice guidelines and was approved by the institutional review board of our institution (IRB No.: 17100676).

Informed Consent: Informed consent for publication was obtained from all participants in this study.

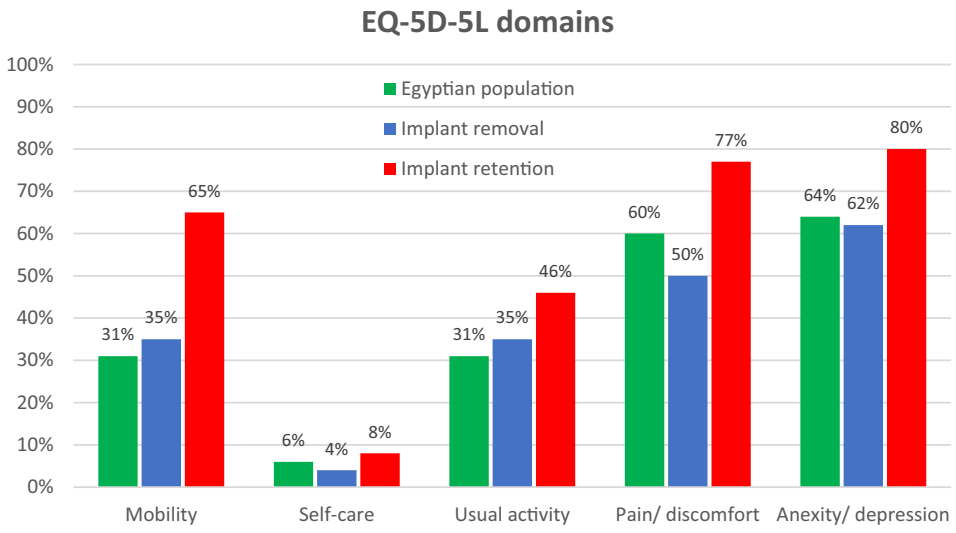

Figure 5. Percentage of patients that reported problems on the different EQ-5D-5L domains compared with the Egyptian population.

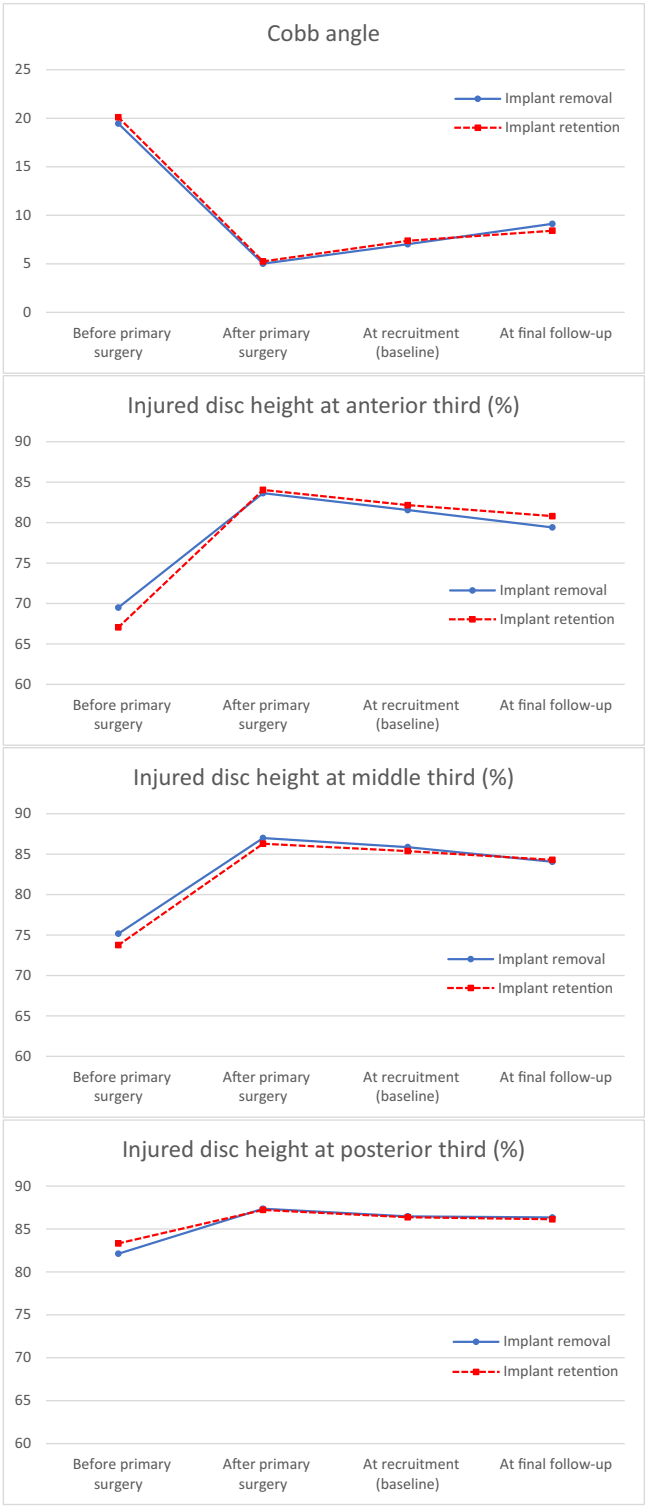

Figure 6. Radiographic outcome measures of both groups.

Trial Registration: ClinicalTrials.gov on October 15, 2020 (identifier: NCT04597567)

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