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Indirect Spinal Canal Decompression Using Ligamentotaxis Compared With Direct Posterior Canal Decompression in Thoracolumbar Burst Fractures: A Prospective Randomized Study

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Abstract

Background: There is still no standard of care to manage thoracolumbar burst fractures. With all the recent advances, posterior approaches are still one of the mainstays of treatment. On the other hand, while spinal canal decompression in neurological impaired patients is an important goal of treatment, its technique remains controversial.
This study compared the effects of direct laminectomy decompression against ligamentotaxis/indirect canal decompression on neurological and radiographic improvements.

Methods: A prospective double-blind randomized clinical trial was conducted on 60 thoracolumbar burst-fracture patients meeting our inclusion and exclusion criteria. They were randomized into 2 treatment arms: (1) direct decompression using laminectomy and (2) indirect decompression using ligamentotaxis/distraction. Each patient was observed for 6 months, and their neurological and radiographical data were collected prospectively. Statistical analysis was done by the Student t test, Friedman test, Mann Whitney-U test, Wilcoxon ranked test, and 1-way analysis of variance.

Results: Among 60 patients enrolled in our study, each treatment arm had an improvement in Frankel scores but there was no difference between the groups at any given time. After 6 months of surgery, local sagittal kyphosis improved in both groups (from 32.2 to 7.43 and 29.93 to 8.77 for the indirect and direct groups, respectively), as well as anterior vertebral height ratio (from 57.73 to 70.7 and 62.17 to 66.27 for the indirect and direct group, respectively) and posterior vertebral height ratio (from 61.17 to 74.87 and 64 to 67.5 for the indirect and direct group, respectively). For between-group comparisons after 6 months, there was a significant difference only for posterior vertebral height ratio ($P = 0.040$).

Conclusion: Posterior approaches with ligamentotaxis have shown to be safe and may present the same outcome as direct decompression techniques using wide laminectomy.

Keywords: Ligamentotaxis, Burst fractures, Decompression, Indirect

Conflicts of Interest: *None declared*
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Introduction

Thoracolumbar spine fractures still have a great impact on health care systems worldwide. Near 90% of all spinal injuries are found in the thoracolumbar junction, of which 10% to 20% are burst-type fractures (1, 2). Burst fractures

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↑What is "already known" in this topic:
Thoracolumbar spine fractures still have a great impact on health care systems worldwide. Posterior approaches were developed in the past years and have been able to provide 3-column fixation and a significant amount of canal decompression.

→What this article adds:
There is significant controversy regarding the best treatment option. Few prospective clinical studies have been conducted to compare the effects of distraction movements on spinal alignment and canal decompression. This study aimed to compare the effect of ligamentotaxis/indirect canal decompression on neurological and radiographical improvements in burst fracture injuries.

result in vertebral height loss and spinal canal compression in terms of posterior displacement of bone fragments; therefore, these injuries are prone to neurological deficits and spine instability. Hence, the treatment goals in burst-fracture patients are canal decompression, spinal realignment, and stability.

There is significant controversy regarding the best treatment option. While some studies prefer anterior approaches, others prefer posterior fixation techniques (3-5). Posterior approaches were developed in the past years and have been able to provide 3-column fixation and a significant amount of canal decompression (4, 6). Using longitudinal distraction, Ligamentotaxis is a vital procedure for spinal alignment and canal indirect decompression, causing bone fragments from the posterior wall to be reintroduced into the vertebral body (7, 8). Few prospective clinical studies have been conducted to compare the effects of distraction movements on spinal alignment and canal decompression (9-11). On the other hand, research has shown that this method seems to be ineffective (12). This study aimed to compare the effect of ligamentotaxis/indirect canal decompression on neurological and radiographical improvements in burst fracture injuries.

Methods

The study was a randomized clinical trial held in a single tertiary trauma center (Imam Reza Hospital in Tabriz, Iran), from March 2016 to March 2018. The patients with thoracolumbar fracture who met our inclusion and exclusion criteria enrolled in our study and were randomized into 2 treatment arms: posterior spine instrumentation with and without distraction. Iranian Registry of Clinical Trials approval was obtained before initiating the study. (IRCT code: IRCT20120527009878N5). The study was also confirmed by the Biomedical Research Ethics Committee at Tabriz University of Medical Sciences (IR.TBZMED.REC.1397.596).

Patient Selection

The inclusion criteria were as follows: (1) Denis burst fracture, in which both the anterior and middle columns of the spine are disrupted (equivalent to AO type A3 and 4); (2) patients having a surgical indication; and (3) patients who have given their informed agreement to participate in the clinical trial. The exclusion criteria were as follows: (1) Patients with pathological fractures; (2) altered mental status; (3) any previous neurological impairment; (4) spinal injuries with vertebral dislocations; (5) concurrent cervical spine fracture; (6) fractures associated with dural tears that were revealed in surgery; and (7) patients in spinal shock (Figure 1).

Patients underwent computerized tomography (CT) scans to confirm the diagnosis. All patients underwent magnetic resonance imaging (MRI) to evaluate soft tissue, posterior ligamentous complex (PLC), and other possible pathologies. For each patient, the Thoracolumbar Injury Classification and Severity Score System (TLICS) score was calculated and was planned for surgery if the score was ≥4. Indication for surgery was evaluated by TLICS scoring. Based on this scoring, patients with the score of

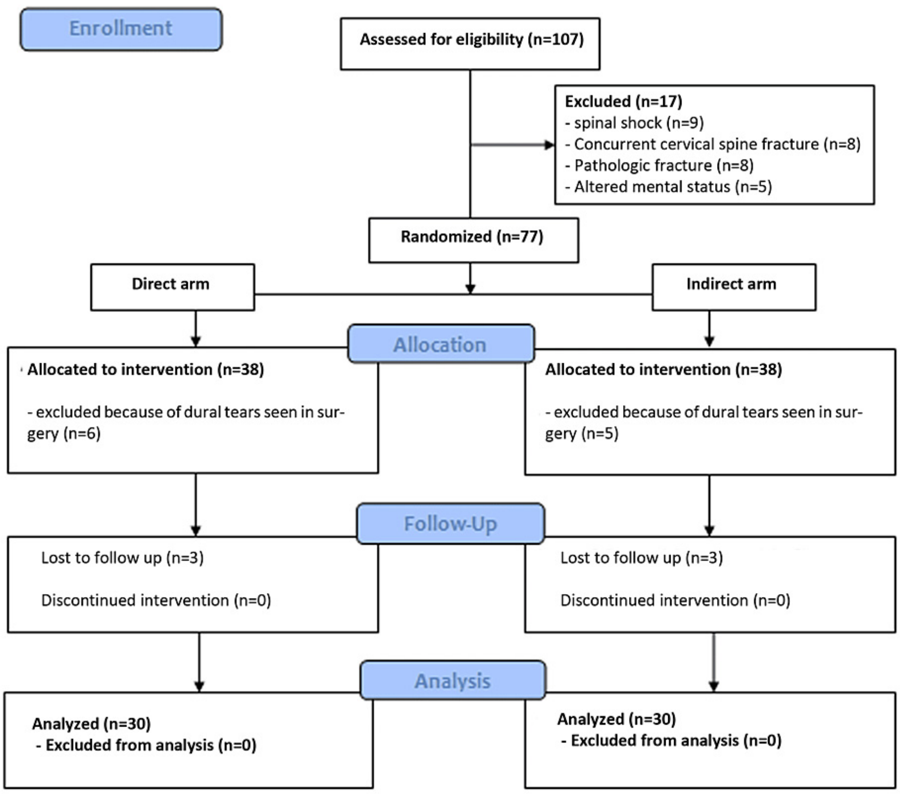

Figure 1. Flow diagram of patient selection

≥4 could be a candidate for surgery. Regarding a burst-fracture point in this classification (2 points), in case of any major neurological deficit or PLC disruption, the patient would be a candidate for surgery. However, there is some evidence that burst fractures without deficits could not be operated on (13). As a result, all patients with no deficiencies were given information regarding nonsurgical and surgical treatment alternatives and were included in the decision-making process. The Frankel impairment scale was used to classify the results of the motor and sensory examinations. These examinations were done by 2 examiners (junior and senior neurosurgery residents) immediately after admission to the emergency room and just before the operation. Absent bulbocavernosus reflex was interpreted as spinal shock and the patient was excluded from the study. Local sagittal kyphosis—defined by the angle between the superior endplate of the vertebra above the injured vertebra and the inferior endplate of the vertebra below the injured vertebra in the mid-sagittal plane—and anterior and posterior injured vertebral height ratio—based on the ratio between the injured level height and the average of the upper and lower noninjured height—were calculated and recorded.

Surgical Procedure

The 2 groups were taken into the operating room and positioned prone. A midline incision was performed; pedicular screws were placed in the upper and lower of the injured vertebra, no more than 2 vertebras beyond. In patients in direct decompression arm, laminectomy of the injured level was conducted, and bilateral foraminotomy was done. Then, the screws were fixed without any further screw distraction. The second group, on the other hand, received neither laminectomy nor foraminotomy and had the screws distracted before tightening. The surgeon calculated the amount of distraction based on the preoperative imaging. Both groups received allograft and autograft dorsolateral fusion. All patients received the same postoperative care, including antibiotics, analgesics, and hydration. Either group was mobilized only with thoracolumbar braces for 3 months.

Outcome Measures

Postoperative neurological evaluation and radiography were done 24 hours after surgery and at the 6-month follow-up. Surgical or medical complications (eg, wound infections, perioperative death, deep vein thrombosis/pulmonary embolism, adjacent segment disease, screw pullout, proximal junctional kyphosis [PJK], etc.) were included in the data as the secondary outcomes.

Randomization, Blinding, and Analysis

The statistical significance was set at $P < 0.05$, and the power was set to 80% ($\alpha = 0.05$ and $\beta = 0.2$). The student **t** test, Friedman test, Mann Whitney-U test, Wilcoxon ranked test, and 1-way analysis of variance (ANOVA) were used and all data analyses were done with SPSS 17.0. Using previous studies and the effect size of 0.4, the sample size was measured at 53, but for simplicity 60 were chosen. We used a blocked randomization technique using the R program and a double blinding strategy. Each patient was given a code using the blocked randomization technique mentioned earlier, and then was brought to the operation room and underwent surgery based on the code. The patients and the research team were not aware of the code meaning or the procedure performed.

Results

Preoperative Analysis

A total of 60 patients were enrolled in the study and were observed for 6 months after surgery in 2 equal groups (Figure 1). In general, the mean age of the patients was 27.13 ± 11.11 years, and only 12 (20%) patients were women. There was no difference between the 2 treatment arms in this manner ($P = 0.842$ and $P = 0.510$ for age and sex, respectively).

Also, 30% of all fractures occurred in T12 alone followed by more than 1 level (26.7%). The most common pattern in both groups was a multi-level fracture. There was no difference between the levels in the treatment arms ($P = 0.693$).

Regarding radiological and neurological parameters, the 2 treatment groups did not show any significant differences before surgery (Table 1).

Neurological Results

Of the patients, 71.7% had a Frankel D or E overall be-

Table 1. Reoperation data in treatment arms

Variable	Indirect Group		Direct Group		Mean Difference	P Value
Fracture level	T10	3 (10%)	T10	0 (5%)	-0.13	0.741
	T11	3 (10%)	T11	4 (11.7%)		
	T12	7 (23.3%)	T12	11 (30%)		
	L1	7 (23.3%)	L1	4 (18.3%)		
	L2	2 (6.7%)	L2	3 (8.3%)		
	multiple	8 (26.7%)	multiple	8 (26.7%)		
Frankel score	A	3 (10%)	A	1 (3.3%)	-0.6	0.070
	B	3 (10%)	B	2 (6.7%)		
	C	5 (16.7%)	C	3 (10%)		
	D	5 (16.7%)	D	2 (6.7%)		
	E	14(46.7%)	E	22(73.3%)		
Kyphosis	32.2 (SD=6.34)		29.93 (SD=6.03)		2.27	0.164
AVH	57.73 (SD=24.76)		62.17 (SD=22.60)		-4.43	0.470
PVH	61.17 (SD=17.95)		64 (SD=15.10)		-2.83	0.510

fore surgery (regardless of the treatment arm). There was no significant difference between neurological status measured before surgery in the 2 groups ($P = 0.070$).

For comparing the Frankel score within each treatment arm, we used the nonparametric Friedman test because of the violation of both sphericity and homogeneity of variances.

In the indirect decompression treatment arm, the Friedman test results showed a significant difference between Frankel scores in the patients measured before surgery, immediately after surgery, and after a 6-month follow-up ($P < 0.001$). The post hoc test using a Wilcoxon signed-ranked test, with a Bonferroni-adjusted alpha level of 0.017, showed that neurological improvements were significant between before surgery evaluations and after the 6-month follow-up ($P = 0.001$) and between immediately after surgery and the 6-month follow-up ($P = 0.004$). The analysis did not show any significant difference between Frankel scores before and immediately after surgery ($P = 0.046$).

In the direct decompression treatment arm, the Friedman test results showed a significant difference between Frankel scores in patients measured before surgery, immediately after surgery, and after a 6-month follow-up ($P = 0.002$). Post hoc test using a Wilcoxon signed-ranked test, with a Bonferroni-adjusted alpha level of 0.017, showed that neurological improvements were only significant between before-surgery evaluations and the 6-month follow-up ($P = 0.015$), and there was neither any difference between before-surgery and immediately after surgery ($P = 0.830$) nor between immediately after surgery and the 6-month follow-up ($P = 0.020$).

For between-group analysis, multiple independent t tests were used. The tests showed no significant differences between Frankel scores of the 2 treatment arms at any given time (before surgery, $P = 0.017$; immediately after surgery, P = 0.080; and 3 months after surgery, $P = 0.171$).

Radiographic Results

Local Sagittal Angle: A repeated measures ANOVA was conducted to compare the local sagittal angle of patients in 2 different treatment arms. The Levene test of equality showed that homogeneity was violated at the 6-month follow-up ($P = 0.040$). The Mauchly test indicated that the assumption of sphericity was met. There was a significant effect of time on the local sagittal kyphosis ($P < 0.001$; $\eta^2 = 0.953$). The analysis showed an interaction of time and group on local sagittal kyphosis ($P = 0.046$; $\eta^2 = 0.102$).

According to post hoc analyses, there was no difference between the 2 groups at either the baseline or 6 months after surgery ($P = 0.164$ and $P = 0.055$, respectively). However, there was a significant difference between the 2 groups immediately after surgery ($P = 0.009$) (Table 2 and Figure 2).

The pairwise comparison revealed that regardless of treatment arm, there was a significant difference between any given time ($P < 0.001$).

Table 2. Local sagittal angle changes in the 2 groups

Time	Indirect Group n = 30	Direct Group n = 30	Mean Difference	*P* Value
	Mean	Mean		
Before surgery	32.20	29.93	2.27	0.164
After surgery	3.04	4.87	-1.83	0.009*
6 months follow up	7.43	8.77	-1.34	0.055

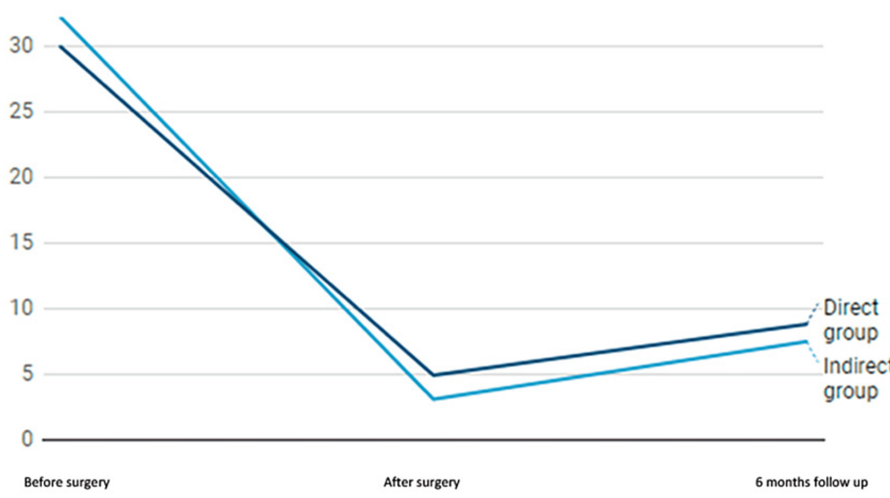

Figure 2. Local sagittal angle changes over time in two treatment groups

Anterior Vertebral Height Ratio

A repeated measures ANOVA was conducted to compare the anterior vertebral height ratio (AVHR) of the patients in the 2 different treatment arms. The Levene test of equality showed that homogeneity was not violated. The Mauchly test indicated that the assumption of sphericity had been violated; therefore, Huynh–Feldt corrected tests were reported. There was a significant effect of time on the AVHR ($P < 0.001$; η2 = 0.286). The analysis showed that there was an interaction of time and group on the AVHR ($P = 0.046$; η2 = 0.146).

Post hoc analyses revealed that there was no difference between the 2 groups at either the baseline or 6 months after surgery ($P = 0.470$ and $P = 0.351$, respectively). However, there was a significant difference between the 2 groups immediately after surgery ($P = 0.030$) (Table 3).

The pairwise comparison revealed that within the indirect decompression arm, there was a significant difference between the AVHR at any given time ($P < 0.010$). In contrast, in the direct decompression arm, there was no difference between the AVHR at any given time (before and immediately after surgery, $P = 0.251$; and immediately after surgery and the 6 months follow-up, $P = 0.080$) (Figure 3).

Posterior Vertebral Height Ratio

A repeated-measures ANOVA was conducted to compare the PVHR of patients in the 2 different treatment arms. The Levene test of equality showed that homogeneity was not violated. The Mauchly test indicated that the assumption of sphericity had not been violated. There was a significant effect of time on the PVHR ($P < 0.0001$; η2 = 0.618). The analysis showed an interaction of time and group on the PVHR ($P < 0.0001$; η2 = 0.322).

Post hoc comparisons indicated no difference between the 2 groups at baseline ($P = 0.510$). Nonetheless, a significant difference was observed between the 2 groups immediately after surgery ($P = 0.004$) and 6 months after surgery ($P = 0.043$) (Table 4).

The pairwise comparison revealed that within the indirect decompression group, there was a significant difference between the PVHRs at any given time ($P < 0.010$). While there was no change between the PVHRs before and just after surgery in the direct decompression arm ($P = 0.061$ and $P = 0.164$, respectively), there was a difference between the PVHRs before and right

after surgery and 6 months later ($P = 0.002$) in the indirect decompression arm (Figure 4).

Table 3. Anterior vertebral height changes in the 2 treatment groups

Time	Indirect Group n = 30	Direct Group n = 30	Mean Difference	P Value
	Mean	Mean		
Before surgery	57.73	62.17	-4.44	0.470
After surgery	75.8	65.54	10.267	0.030*
6 months follow up	70.7	66.27	4.44	0.351

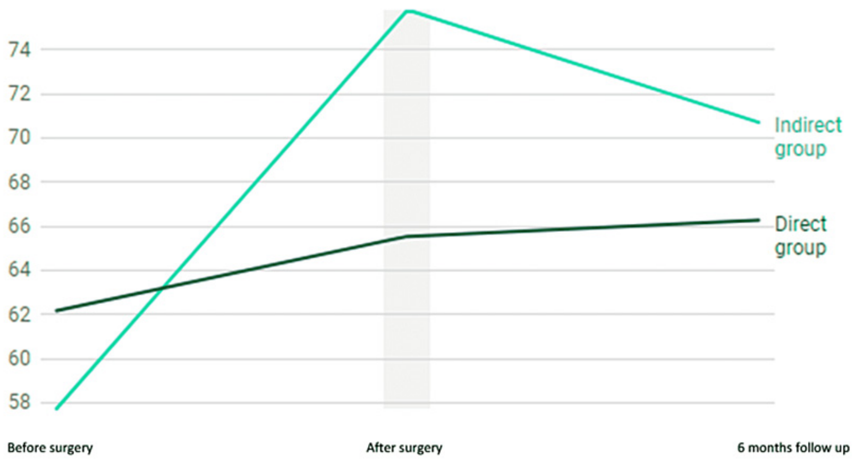

Figure 3. Anterior vertebral height changes over time in the 2 treatment groups

Table 4. Posterior vertebral height changes in the 2 groups

Time	Indirect group n = 30	Direct Group n = 30	Mean Difference	*P* Value
	Mean	Mean		
Before surgery	61.17	64	-2.83	0.510
After surgery	79.5	69.5	10	0.004
6 months follow up	74.87	67.5	7.37	0.043

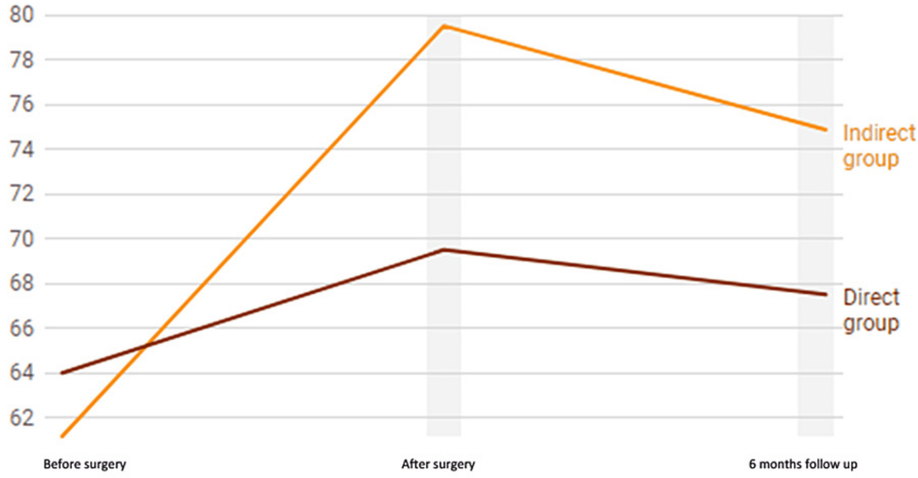

Figure 4. Posterior vertebral height changes over time in two treatment groups

Table 5. Intra and Postoperation Surgical Complications by Number of Patients

Complications	Indirect Group	Direct Group	*P* Value
PTE/DVT	3	2	0.580
Wound dehiscence	3	4	0.720
Wound infection	1	1	-
Proximal Junctional kyphosis (PJK)	0	0	-
Death	0	0	-

Complications

In general, each group encountered 7 surgical or postsurgical complications. No mortality or PJK was seen. One patient in each group experienced a wound infection that was superficial after MRI evaluation and was treated with oral antibiotics. In general, there was no significant difference in complications among groups (Table 5).

Discussion

The thoracolumbar junction is a critical biomechanical connection that may be damaged. Even in this day and age, burst fractures in this location remain a clinical concern. In the literature, several techniques for diagnosis, categorization, and treatment are studied and practiced. Although laminectomy for direct decompression of the spinal canal is very effective, it has disadvantages as well; it is time-consuming, increases blood loss, and can be complicated with dural injuries, resulting in further postoperative complications (CSF leak, wound dehiscence, etc). Although studies are showing no significant differences between surgical and nonsurgical treatments for stable and neurologically normal patients, surgery (either anterior, posterior, or a combined approach) is seen to be reasonable for unstable fractures or patients with neurological deficits (14, 15). In between there is an ongoing debate to treat burst fractures with no deficits. There is evidence that operative management of thoracolumbar burst fractures without neurologic deficit may improve residual kyphosis but does not appear to improve pain or function at an average of 4 years after injury and is associated with higher complication rates and costs (13).

While there is still no standard of care regarding an approach to thoracolumbar fractures, posterior approaches have shown promising results. Instrumentation and applying distraction have long been suggested for burst fractures, which showed different results. We aimed to study the effect of indirect canal decompression using distraction/ligamentotaxis—compared to direct canal decompression—on neurological function and radiographic outcomes. To our knowledge, only 1 clinical trial was conducted to assess and compare the effect of these 2 techniques in patients with neurological deficits (16).

The neurological outcome is the central goal of surgery in patients with deficits. In each group, there was a significant improvement in Frankel scores, although there was no difference in neurological status among the groups at any given time. This may found 2 important points. First, regardless of the technique used for spinal canal decompression, a good neurological outcome is expected. Second, these patients suffered mostly from spinal shock, which could last for months and this improvement in Frankel score could be associated with our measurement shortcomings and not the surgery. Similarly, Jaiswal et al in their randomized clinical trial showed that although there was a neurological improvement in patients' score at a 1-year follow-up, there was no in-between differences in the treatment arms (17). Likewise, in a 3-year case series, James J Yue et al showed a significant improvement in the neurological status of patients surgically treated with transpedicular screws (18).

Maintaining sagittal alignment in the long-term follow-up is another essential problem in burst-fracture procedures. Sagittal alignment was measured using 3 factors in our research. After 6 months, the current research found that either form of surgery corrects and maintains sagittal alignment. Although there was a clear advantage to using the distraction method for sagittal alignment correction just after surgery, surprisingly after 6 months, there were no significant differences among sagittal alignments in either treatment arm. This may show that preserving the sagittal alignment in a posterior approach only is not adequate, and combined approaches may be needed for extra kyphosis reduction.

There were limitations in our study. We had a short-term follow-up period and this could alter results. Adjacent segment disease and PKJ occur in the long-term and it may be the reason we did not see any in our study. Patients' body mass index, smoking status, pain scores, et cetera were not measured before and after treatment. MRI results were not included. Future studies should be conducted to study and compare ligamentotaxis related to anterior approaches as well in longer follow-ups.

Conclusion

Many surgical approaches are available for spinal canal decompression and stabilization in burst fractures, and there is still no consensus. Ligamentotaxis is safe and may provide the same results as direct decompression procedures using extensive laminectomy. Therefore, based on the individual assessment of the patient and fracture characteristics, both methods could be used. Longer follow-up periods and larger sample sizes are recommended for future studies.

Ethical Considerations

The study was approved by the Biomedical Research Ethics Committee at Tabriz University of Medical Sciences (IR.TBZMED.REC.1397.596).

Acknowledgments

None.

Authors Contribution

G.S. and P.J. Contributed to the design and implementation of the research. M.K.S performed the data analysis. A.I., M.K.S, and M.R.F contributed to writing the manuscript, M.A.B, S.T.M, and A. I. were involved in planning and supervision, and all authors discussed the results and commented on the manuscript.

Conflict of Interests

The authors declare that they have no competing interests.

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