

Original Article

Evaluation of postoperative bracing on unstable traumatic lumbar fractures after pedicle screw fixation

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Abstract: Background: Fractures of the thoracolumbar and lumbar regions are very important. There is still debate on the use of braces after surgical operations. The current study aims to evaluate and report the outcomes of postoperative bracing following pedicle screw fixation in patients with thoracolumbar and lumbar fractures in Iran. Methods: This is a clinical trial performed from 2012 to 2022 on 144 patients diagnosed with lumbar and thoracolumbar fractures. Demographic data of patients including age and gender were obtained. Patients' fractures were classified as Frankel (A to E) in terms of clinical and neurological manifestations. Patient's quality of life (QOL) was measured using the 36-Item Short Form Survey (SF-36). All patients underwent surgical fixation of the fracture. Patients were then randomized into two groups using Random Allocation Software. The first group received post-operation bracing and the second group did not receive braces. Thus, radiographic and clinical evaluation data of 1, 3, and 12 months after surgery were used to determine bone fusion. Results: The most common mechanisms of trauma included falling from a height in 99 patients (68.7%), vehicle accidents in 39 patients (27.1%), and the most common fracture sites were the L1 vertebrae in 73 patients (50.7%), 111 patients (77.1%) had burst fractures, and 105 patients (72.3%) had no neurological defects (Frankel E). At the beginning of the study, there were no significant differences between the two groups regarding the mentioned data, patients' QOL, and pain severity. All patients (100%) had early mobilization. Most patients (85.4%) did not report persistent back pain 12 months after surgeries. 90.2% returned to their daily activities and all patients (100%) had full fusion based on radiologic data. The QOL and pain severity of patients improved significantly compared to baseline ($P < 0.001$ for both). Conclusion: The use or non-use of braces did not affect the treatment results. As a result, patients who have received pedicle screw fixation for unstable thoracolumbar fractures do not require braces in the postoperative period.

Keywords: Thoracolumbar fractures, braces, surgery, trauma

Introduction

Fractures of the thoracolumbar and lumbar regions are among the most common spinal injuries [1]. Thoracolumbar traumatic injuries are most frequently caused by falls from heights, motor vehicle accidents, recreational injuries, and work-related injuries [2, 3]. The type of fracture varies depending on the patient's age, the severity of the trauma, seat belt use, and the body condition at the time of the accident. These fractures are divided into stable and unstable groups [4, 5]. The types of vertebral fractures are based on Denis' three-column

model and include burst, compression, fracture-dislocation, and flexion-distraction fractures [6].

According to these classifications, some unstable fractures require surgery for fixation, and for many years, conventional postoperative bracing surgery has been used to help repair and fix the spine [5]. Bracing for a few hours a day has been shown to help reduce pain and provide spinal stability in adults by stabilizing the sagittal and coronal planes [7, 8].

Since the 1980s, spinal surgeons have widely used pedicle screw fixation of the thoracolum-

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bar spine, which has been in clinical use since the 1960s [9]. Pedicle screw fixation has been used extensively to stabilize the thoracolumbar spine following trauma, correct deformity, and provide rigidity to motion segments undergoing arthrodesis, with the latter being the most common indication [10, 11]. An increase in the rate of effective arthrodesis and the clinical result is thought to be the purpose of enhanced rigidity [12].

The presence of a neurological deficit with bone compression on imaging and/or a fracture pattern that results in instability are used to guide the treatment of thoracolumbar fractures. Several grading measures have been established to assist clinicians in making surgical decisions. Conservative treatment, such as thoracic, lumbar, or thoracolumbar bracing, is a feasible alternative to surgery [13]. The primary purpose of the Thoracic Lumbar Sacral Orthosis (TLSO) brace is to limit the range of motion to optimize fracture healing, promote stability, prevent progressive kyphotic deformity, and reduce pain so that early mobilization can occur, though there is considerable debate in the literature about the role of bracing stable fractures in the absence of neurological deficits [14, 15].

The additional stability provided by postoperative bracing, particularly in patients undergoing pedicle screw fixation, is even less understood in surgical stabilization patients [16]. While a recent survey of spine surgeons determined that postoperative bracing is unnecessary, actual practice varies significantly by institution and surgeon [17, 18].

Epidemiologic data have indicated a vast range of success rates in different populations. So far, various studies have evaluated the results of postoperative bracing following pedicle screw fixation in different patients. Still, to the best of our knowledge, very few studies have investigated these results in our country. The current study aims to evaluate and report the outcomes of postoperative bracing following pedicle screw fixation in patients with thoracolumbar and lumbar fractures.

Material and method

Study design

This is a clinical trial that was performed from 2012 to 2022 in Mellat and Babaie orthopedic

clinics in Tehan, Iran. The study population consisted of all patients diagnosed with lumbar and thoracolumbar fractures from 2012 to 2022. The study protocol was approved by the Research Committee of Tehran University of Medical Sciences and the Ethics committee has confirmed it (Ethics code: IR.TUMS.MEDICINE.REC.1391.237, Iranian Registry of Clinical Trials (IRCT) code: IRCT2017010920258N25).

Inclusion and exclusion criteria

Inclusion criteria were age more than 18 years, diagnosis of lumbar and thoracolumbar fractures from T11 to L5, diagnosis based on radiologic findings by orthopedic surgeons, admission in our clinics in 2012-2021 and signing the written informed consent to participate in this study. The unstable thoracolumbar fracture was defined as the following: anterior and middle column fail in compression, the posterior column is also disrupted due to compression, lateral flexion or rotation. The exclusion criteria were surgical history of the level adjacent to the injured vertebra and patients with severe osteoporosis, vertebral tuberculosis, a spinal tumor, or other suspected pathological fractures, and lack of consent.

Study population and assessments

All patients that met the inclusion criteria entered the study using the census method. The study population was considered 150 patients based on the sample size calculation formula. Demographic data of patients including age and gender were obtained. Causes of fractures were noted and types of fractures were classified as burst fracture, wedge fracture, or facet fracture-dislocation.

Patients' fractures were classified as Frankel (A to E) in terms of clinical and neurological manifestations [19].

The Frankel Grade classification provides an assessment of spinal cord function and is used as a tool in spinal cord injury, as follows:

Grade A: Complete neurological injury - No motor or sensory function detected below the level of lesion.

Grade B: Preserved sensation only - No motor function detected below the level of lesion,

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some sensory function below the level of lesion preserved.

Grade C: Preserved motor, nonfunctional - Some voluntary motor function preserved below the level of lesion but too weak to serve any useful purpose; sensation may or may not be preserved.

Grade D: Preserved motor, functional - Functionally useful voluntary motor function below the level of injury is preserved.

Grade E: Normal motor function - Normal motor and sensory function below the level of lesion, abnormal reflexes may persist.

We assessed the patient's quality of life (QOL) using 36-Item Short Form Survey Instrument (SF-36). The pain of the patients was evaluated using the Visual Analogue Scale (VAS).

Questionnaires and scoring systems

The QOL was measured using the 36-Item Short Form Survey (SF-36). SF-36 is a set of generic, coherent, and easily administered quality-of-life measures covering eight domains of health [20]. Each scale is directly transformed into a 0-100 scale, assuming that each question carries equal weight. Rand and colleagues first developed this questionnaire. These measures rely upon patient self-reporting and are now widely utilized by managed care organizations and Medicare to monitor and assess care outcomes in adult patients. The VAS also measures pain and each patient expresses his/her pain on a Likert scale from 0 (no pain) to 10 (most severe pain) [21]. Return to previous activities and work was also considered as being present in the workplace for more than 80% of weekdays [22].

Randomization and grouping

All patients underwent surgical fixation of the fracture by pedicle screw fixation by one experienced surgeon using an autologous bone graft from the iliac crest for posterior, lateral, and lateral fusion. Patients were then randomized into two groups using Random Allocation Software. The first group received post-operation bracing and the second group did not receive TLSO braces. In this investigation, we used TLSO

braces for support. A two-piece clamshell design is typical of a TLSO. It could also be a single piece with a front opening. A Turtle Brace is another name for it. From just below the collarbones to the pelvis, a TLSO exists. It is used to enhance healing and reduce discomfort by stabilizing the spine following surgery or in the event of a spinal fracture.

The two groups of patients were matched in terms of demographic data, including mechanism of injury, fracture level, neurological grade, and interfering variables in bone fusion such as age, early mobilization, osteoporosis, nutritional and hormonal status, underlying diseases, and smoking.

Postoperative follow-up

The follow-up period was at least 12 months. Thus, radiographic and clinical evaluation data of one, 3, and 12 months after surgery were used to determine bone fusion. The radiographic examination consisted of standing antero-posterior and lateral flexion-extension lumbosacral radiographs.

To be considered fused; a level had to have bridging trabeculae and no lucency or motion in either plane. If there was motion in either plane, a level was considered definitely not fused, and equivocal if there was no motion but positive lucency or negative bridging trabeculae.

During the postoperative follow-up examination, the quality of clinical results was evaluated according to the patient's pain, return to work, and regular activities. Patient's QOL and pain severity were assessed at the end of follow-ups.

Statistical analysis

After collecting the study data, they were entered into SPSS software (version 25, IBM Corporation, Armonk, NY) and analyzed. Chi-square and Fisher's exact tests were used to analyze the therapeutic effect in both groups. Quantitative variables had a normal distribution and a standard deviation was presented. Independent T-test was used to compare data. In all tests, values of $P < 0.05$ were considered a significant level.

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Table 1. Demographic variables of study population

Variables		Braced (n = 72)	Non-braced (n = 72)	P-value*
Age (year) (mean ± SD)		33.5 ± 7.2	34.3 ± 6.3	0.16
Gender (%)	Male	50 (69.4)	48 (66.6)	0.39
	Female	22 (30.6)	24 (33.4)	
Mechanism of injury (n (%))	Falling	48 (66.6)	51 (70.8)	0.63
	Car accident	21 (29.2)	18 (25)	
	Dropping heavy object	3 (4.2)	3 (4.2)	
Fracture type	Burst	54 (75)	57 (79.1)	0.66
	Wedge	12 (16.7)	3 (4.2)	
	Fracture-dislocation	6 (8.3)	12 (16.7)	
Frankel grading	A	9 (12.5)	18 (25)	0.28
	B	3	-	
	C	6 (8.3)	3 (4.2)	
	D	-	-	
	E	54 (75)	51 (70.8)	
SF-36		53.6 ± 7.20	54.9 ± 9.41	0.33
Pain (VAS)		8.14 ± 2.07	8.12 ± 1.93	0.09

*using Independent T-test.

Result

Study population

During the study period, 168 patients underwent surgery for unstable fractures of the thoracolumbar and lumbar regions. Among them, 144 patients that underwent pedicle screw fixation were included in the study. Patients included 98 men and 46 women with a mean age of 33.8 ± 6.3 years. None of the patients had comorbidities and was not malnourished.

Fracture data

The most common mechanisms of trauma included falling from a height in 99 patients (68.7%), vehicle accidents in 39 patients (27.1%), and a heavy object dropping on the back in 6 patients (4.2%). The most common fracture sites were the L1 vertebrae in 73 patients (50.7%) and other fracture sites included L2 in 33 patients (22.9%), T12 in 24 patients (16.7%), L4 in 5 patients (3.4%), T11 and L3 in 6 patients (4.1%), and L5 fracture in 3 patients (2.2%). In terms of fracture type, 111 patients (77.1%) had burst fractures, 15 patients (10.4%) had wedge fractures, and 18 patients (12.5%) had facet fracture-dislocation. 105 patients (72.3%) had no neurological defects (Frankel E). 27 patients (18.7%) had

complete anomalies (Frankel A), 9 patients (6.3%) had unusable mobility (Frankel C), and 3 patients were classified as Frankel B (2.7%). At the beginning of the study, there were no significant differences between the two groups regarding the mentioned data, patients' QOL, and pain severity. These data are presented in **Table 1**.

Intervention outcomes

The effect of using or not using TLSO braces is presented in **Table 2** and shows that residual back pain in patients with postoperative bracing was absent in 63 patients (87.5%) and was mild in 6 patients and moderate in 3 patients. In the mild type, NSAIDs and moderate type, narcotics were used to control pain. Also, in this group, return to work at the level of previous activities was observed in 88.8% of patients. Three months and one year after surgery, the fusion rate was 60% and 100%, respectively.

In patients without postoperative bracing, residual back pain was absent in 83.3% of patients and was mild in 6 patients and moderate in 6 patients. In this group, 91.6% of patients return to their previous activity level. Three months and one year after surgery, the fusion rate was 58% and 100%, respectively.

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Table 2. The effect of surgery in patients with unstable fractures in terms of group therapy

Surgical efficacy		Braced	Non-braced	P-value*
Early mobilization (N (%))		72 (100)	72 (100)	> 0.99
Remaining back pain (N (%))	None	63 (87.5)	60 (83.3)	0.67
	Low	6 (8.3)	6 (8.3)	
	Medium	3 (4.2)	6 (8.3)	
Return to previous activities		64 (88.8)	66 (91.6)	0.27
Fusion after one year		72 (100)	72 (100)	> 0.99
QOL (mean ± SD)		84.31 ± 11.55	86.47 ± 10.44	0.08
Pain (mean ± SD)		2.93 ± 1.57	3.04 ± 1.22	0.41

*using Independent T-test.

Mobilization and pain assessments

All patients (100%) had early mobilization based on our data. Most patients (85.4%) did not report persistent back pain 12 months after surgeries. 90.2% returned to their daily activities and all patients (100%) had complete fusion based on radiologic data. The QOL and pain severity of patients improved significantly compared to baseline ($P < 0.001$ for both).

Further assessments indicated no significant differences between the two groups based on Chi-square and Fisher's exact test regarding early mobilization ($P > 0.99$), remaining back pain ($P = 0.67$), return to previous activities ($P = 0.27$), fusion after one year ($P > 0.99$), QOL ($P = 0.08$) and pain severity ($P = 0.41$). These data are shown in **Table 2**.

Discussion

Our study was performed on 144 patients who underwent pedicle screw fixation. The most common fracture mechanism was falling from a height, the most common site of vertebral fracture was L1 and the most common type of fracture was burst fracture. The rate of fusion after three months in the group receiving braces was 60%, and in patients without braces was 58%, and this rate was 100% after one year in both groups. Overall, our study showed that the use or non-use of braces has no therapeutic effect on unstable lumbar fractures after pedicle screw fixation. However, there is no general agreement on using TLSO braces in patients after surgery.

Bailey and colleagues conducted a prospective study in which 96 patients were random-

ized and assigned to receive TLSO or no brace with early ambulation for thoracolumbar burst fractures with no neurologic injury. This study recommended using TLSO brace during the postoperative period in patients. However, a postoperative brace remains routine due to the lack of clinical research demonstrating or disproving the additional advantage following surgical stabilization of thoracolumbar fractures [22].

Yee and colleagues conducted a prospective randomized trial in which 72 patients underwent one to three levels of posterolateral instrumented lumbar fusion for degenerative lumbar disease. In a two-year follow-up, wearing a brace after surgery did not affect complication rates, re-operation rates, or quality of life as those who didn't wear a brace [23].

In 2017, Piazza and others conducted a study to determine the utility of bracing following pedicle screw fixation for thoracic and lumbar burst fractures. A total of 2081 patients were enrolled in the study, 1328 braced. The re-operation rate for non-union or clinically significant hardware failure was significantly lower in braced patients. Overall, this study concluded that postoperative bracing following pedicle screw fixation for thoracolumbar burst fractures did not improve stability substantially or increase wound complications. Furthermore, these findings indicate that postoperative bracing may not be a cost-effective intervention [24]. This study is in line with our research.

In 2016, Skoch and colleagues reported a systematic review to evaluate the bracing after surgical stabilization of thoracolumbar fractures. Postoperative bracing was used in 62 studies, with a median duration of 13.3 weeks. There

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were no significant differences between the postoperative bracing and non-postoperative bracing groups in terms of pain, return to work, Frankel score improvement, or instrumentation failure. The postoperative bracing group experienced a slightly more significant loss of surgical kyphotic reduction. The overall complication rate was also higher in the postoperative bracing group. However, the pseudoarthrosis rate was lower in the braced group [25].

Considering the treatment of lumbar and thoracolumbar fractures, the best results are obtained by correcting and stabilizing the spine's alignment and immobilizing unstable segments [26]. Instrumentation and fixation of these fractures with a pedicle screw system are increasingly used. Features such as better deformity correction and higher fusion rate are well known [27]. Most researchers agree that surgical treatment of unstable burst fractures and fracture-dislocation of thoracolumbar and lumbar regions with fusion and instrumentation will cause immediate spinal stabilization, deformity correction, faster patient initiation, and better long-term practical results.

Due to the almost complete fusion in the group without braces and the satisfaction of surgery in patients and return to their previous working level, and also because there is no statistically significant difference in terms of residual back pain in both groups and the disadvantages of using braces such as weakness of the back and lumbar muscles, soft tissue contracture, and psychological dependence in the patient following the use of braces, it seems that the use of braces after surgery has no advantage over not using them. Therefore, there is no need to use TLSO braces in the postoperative period of thoracolumbar and lumbar fractures that have been fixed by the pedicle screw method.

The shortcomings of this study were restricted study population and conducting this study on thoracolumbar fractures in T11 to L5. We believe that further studies on more comprehensive fracture ranges could reveal additional data.

Conclusion

According to the existing evidence, the use or non-use of TLSO braces does not affect the

treatment results. As a result, patients who have received pedicle screw fixation for unstable thoracolumbar fractures do not require TLSO braces in the postoperative period.

Disclosure of conflict of interest

None.

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