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Effects of Bracing on Clinical and Radiographic Outcomes Following Thoracolumbar Burst Fractures in Neurologically Intact Patients

A Meta-Analysis of Randomized Controlled Trials

Nicholas Wallace, MD

Michael McHugh, MD

Rakesh Patel, MD

Ilyas S. Aleem, MD, MSc, FRCSC

Investigation performed at the Division of Spine Surgery, Department of Orthopaedic Surgery, University of Michigan, Ann Arbor, Michigan

Abstract

Background: We conducted a meta-analysis of randomized trials to determine the effect of the use of an orthosis (as compared with no orthosis) on clinical and radiographic outcomes in neurologically intact patients with thoracolumbar burst fractures. Optimal nonoperative treatment of thoracolumbar burst fractures in neurologically intact patients remains inconclusive. Conventional care prescribes spine precautions and a thoracolumbar orthosis. Recent studies have suggested that patients with stable burst fractures can obtain comparable outcomes with or without bracing.

Methods: We performed a comprehensive search of the literature with use of OVID MEDLINE, Embase, and the Cochrane Library. Two independent reviewers assessed the eligibility of studies and the risk of bias of included trials. We analyzed several outcomes: the Roland Morris Disability Questionnaire (RMDQ) score, Oswestry Disability Index (ODI), Short Form-36 Physical and Mental Component Summary (SF-36 PCS and MCS) scores, pain, length of stay, treatment failure, and kyphotic angle. We used weighted mean differences and standardized mean differences in a random-effects model.

Results: We included 3 studies with a total of 59 patients who were managed with use of a brace and 60 patients who were managed without a brace. There was no significant difference between groups treated with or without an orthosis in terms of SF-36 PCS, SF-36 MCS, RMDQ/ODI, pain, length of stay, failure rates, or kyphosis angle at baseline or 6-month follow-up. Similar outcomes were seen at long-term follow-up of ≥5 years.

Conclusions: This meta-analysis suggests that neurologically intact patients with thoracolumbar burst fractures obtain similar clinical and radiographic outcomes with or without bracing at both short and long-term follow-up. Routine use of orthoses following these fractures may incur substantial costs and patient morbidity without clinical benefit.

Level of Evidence: Therapeutic Level I. See Instructions for Authors for a complete description of levels of evidence.

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Thoracolumbar burst fractures account for nearly two-thirds of all thoracolumbar fractures, most commonly occurring in young males after high-energy trauma[1,2]. The thoracolumbar junction accounts for the vast majority of thoracolumbar injuries, in part because of the stress concentration that is formed as axial forces transfer through the rigid, kyphotic thoracic spine. A fulcrum is created as the force transitions to the relatively flexible, lordotic lumbar spine and stresses concentrate within these vertebral bodies at the thoracolumbar junction[3]. Approximately 50% of all thoracolumbar burst fractures occur between T11 and L1, whereas 30% occur between L2 and L5[2,4,5].

Despite how common these fractures are, treatment remains controversial. Many attempts have been made to classify thoracolumbar burst fractures to guide management[6-10]. Treatment courses are primarily divided into surgical and conservative interventions, both of which aim to provide mechanical and neurological stability, early mobilization, pain control, and avoidance of complications[11,12]. In the narrowest terms, thoracolumbar spinal trauma cases can be simplified into those in patients who are neurologically intact and those in patients who are not neurologically intact. The former type is often a stable injury, whereas the latter is unstable, requiring decompression and surgical stabilization. Historically, thoracolumbar burst fractures have been aggressively treated with surgical fixation, but in recent years, treatment has shifted toward more conservative methods[13-17]. Gnanenthiran et al. found that bracing was more beneficial than surgical intervention for the treatment of burst fractures in neurologically intact patients as indicated by the achievement of similar outcomes but with lower complication rates and costs[18]. By convention, neurologically intact patients with a thoracolumbar injury are fitted with a thoracolumbosacral orthosis to maintain mechanical stability, reduce pain, or promote mobility before ambulation and therapy are initiated[19-21].

Recently, however, this convention has been challenged. Thoracolumbosacral orthoses carry their own morbidity and costs. Agabegi et al. identified several disadvantages of spinal orthoses: pressure-induced ulcers, skin maceration, deconditioning of paraspinal muscles and trunk stabilizers, poor patient compliance, and disuse osteopenia[22]. In recent years, several investigators have tested the need for such bracing by comparing burst fractures that were treated with or without orthoses in randomized controlled trials and have found no difference between groups[23-29]. The results of those trials call into question the necessity of bracing for stable thoracolumbar burst fractures. We therefore performed a systematic review and meta-analysis to determine the effect of orthosis use (as compared with no orthosis use) on clinical and radiographic outcomes following thoracolumbar burst fractures in neurologically intact patients.

Materials and Methods

Literature Search Strategy

A literature search of Embase, Ovid, and the Cochrane Library was performed on December 31, 2018, to identify relevant studies. The following MeSH terms and their combinations were used for title/abstract searches: *spine, vertebral body, burst or compression fracture, A3, thoracolumbosacral orthosis, orthosis, or brace.* A manual search of reference lists was also performed. A detailed description of search strategies is included in the Appendix.

Inclusion and Exclusion Criteria

The titles and abstracts were screened to identify studies that met the following inclusion criteria: (1) prospective randomized controlled trials comparing the treatment of thoracolumbar burst fractures (levels T11 to L3) in neurologically intact adult patients with or without an orthosis, (2) a minimum duration of follow-up of 6 months, and (3) evaluation of clinical or radiographic outcomes following conservative treatment. The exclusion criteria included (1) retrospective comparative studies (case-control, cohort), (2) studies comparing surgical versus nonsurgical treatments, and (3) studies on osteoporotic vertebral compression fractures. Editorials, review articles, case reports, and animal studies were also excluded. Levels of evidence were assigned to the studies according to the criteria described in *Clinical Orthopaedics and Related Research,* which are adapted from the Oxford Centre for Evidence-based Medicine levels of evidence[30,31]. Level-I studies were included in the meta-analysis.

Search Result Screening

Two of the authors independently reviewed all titles and/or abstracts, with the senior author being available to resolve a dispute if a consensus agreement was not reached after discussion. All irrelevant titles were excluded, and full-text papers were obtained when titles were deemed relevant or when eligibility was unclear. Two of the authors independently assessed these full-text manuscripts, and disagreement was resolved with consensus agreement after discussion with the senior author as needed. A record of reasons for excluding studies was maintained for reference.

Data Extraction

Outcome data and study characteristics were extracted in duplicate. Two of the authors independently extracted data from the eligible studies, and disputes were resolved by consensus agreement, with the senior author being available as needed. Missing information on the methods and missing statistics (such as the number of patients, means, and standard deviations) were encountered during data extraction. These missing data were collected by contacting the study authors or by using Plot Digitizer software (version 2.6.8; SourceForge Project) to extract numerical values from figures and graphs.

The following data were extracted from eligible studies: (1) study identifiers (authors, publication year, title); (2) study characteristics (design, region, sample sizes, sex, age, smoking status, level of injury); (3) clinical outcomes (Roland Morris Disability Questionnaire [RMDQ], Short-Form-36 Physical

Component and Mental Component Summary scores [SF-36 PCS, SF-36 MCS], pain, satisfaction, Oswestry Disability Index [ODI]) at baseline, 6 months, 2 years, and latest follow-up; (4) radiographic outcomes (kyphosis angle) at the same time intervals; (5) average length of hospital stay; and (6) complications or failure of treatment leading to surgery. Of note, the kyphosis angle was measured between the superior end plate of the upper and the inferior end plate of the lower non-injured vertebrae, as per the Cobb method.

Quality Assessment

A systematic assessment of bias in the randomized controlled trials was performed with use of the Cochrane criteria[32]. The items used for the assessment of each study were divided into the following sources of bias: selection (randomized sequence and allocation concealment), blinding, detection, attrition and management of drop-out, selective outcome reporting, and other potential sources of bias. Two of the authors reviewed included studies and independently assessed risk of bias.

Statistical Analysis

All meta-analyses were performed with use of Review Manager 5.3 (RevMan 5.3; The Nordic Cochrane Centre, The Cochrane Collaboration, 2014) and STATA 15.1 (Stata Statistical Software, Release 15.1; StataCorp, 2017) software. The weighted mean difference and standardized mean difference with 95% confidence intervals (CIs) in a random effects model were used to compare continuous variables. A probability of $p < 0.05$ was considered to be significant. An I^2 test was used to calculate statistical heterogeneity, with a value of >50% representing substantial heterogeneity.

Results

Search Results

The flow diagram of the search strategy is summarized in Figure 1. A total of 1,540 articles were initially identified with use of the search strategy. An additional 65 records were identified with use of reference lists. Three hundred and eight articles were excluded because of duplication. After screening of the titles and abstracts, 1,287 articles were excluded (Cohen kappa value for interrater reliability = 0.94, very good strength of agreement). The remaining 10 studies underwent a comprehensive full-text evaluation. Finally, 3 studies with a total of 119 patients (59 managed with an orthosis and 60 managed without) met the inclusion criteria and were included in this meta-analysis.

Study Characteristics and Quality Assessment

Among the 3 included studies, there were 2 randomized controlled trials and 1 subgroup analysis of a randomized controlled trial with extended follow-up at 5 to 10 years (Table I)[24,26,28]. Of note, all 3 studies were performed in Canada. Bailey et al. included patients who met the following criteria: an AO-A3 burst fracture between T10 and L3, a kyphotic deformity of <35°, intact neurological function, an age of 16 to 60 years, and admission within 3 days after the injury[24]. Urquhart et al.[26] performed a subgroup analysis of all patients who presented to 1 of the 3 level-I trauma centers in the study by Bailey et al[24]. Shamji et al. included patients with a burst fracture from T10 to L4 who were neurologically intact. Both randomized controlled trials excluded patients with prior spinal surgery or an inability to wear a brace. The study by Shamji et al. also excluded patients with an age of <18 years, associated head injury, or radiographic evidence of instability resulting from posterior element injury or focal kyphosis (without a maximum kyphotic angle cited)[28]. In

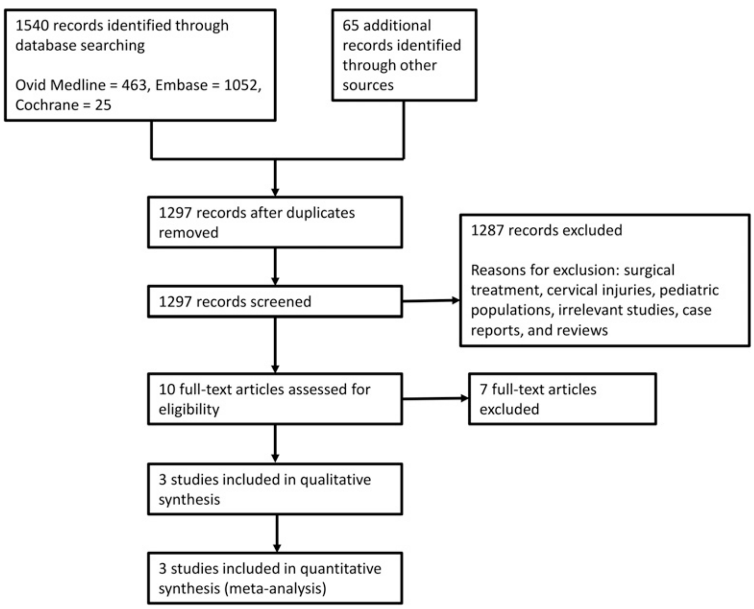

Fig. 1
Flow diagram of study selection process.

TABLE I Characteristics of Included Studies*

Study	Region	No. of Centers	Design	Level of Evidence	Age† *(yr)*	Sample Size *(no. of patients)*		
						Total‡	Orthosis	No Orthosis
Bailey et al.[24] (2014)	Canada	3	RCT	I	40.1 (40.5, 39.8)	96 (67:29)	47	49
Shamji et al.[28] (2014)	Canada	2	RCT	I	40.1 (37, 43)	23 (14:9)	12	11
Urquhart et al.[26] (2017)	Canada	1	RCT	II	40.8 (NA)	23 (NA)	11	12

*NA = data not available and RCT = randomized controlled trial. †The values are given as the mean for the entire study, with the mean values for the orthosis and no-orthosis groups in parentheses. ‡The male:female ratio is given in parentheses.

randomized controlled trials, AO-A3 burst fractures were classified according to the AO/OTA system, wherein only a single end plate (superior or inferior) is fractured under compressive load (Fig. 2)[1]. Patients were deemed "neurologically intact" (i.e., no findings consistent with spinal cord or nerve root injury) after physical examination by a fellowship-trained spine surgeon. The 3 included studies were assessed with use of the Cochrane risk-of-bias tool. All 3 studies demonstrated adequate random sequence generation, allocation concealment, blinding of outcome assessment and data analysis, low attrition, and low risk of reporting bias. There was a high risk of bias

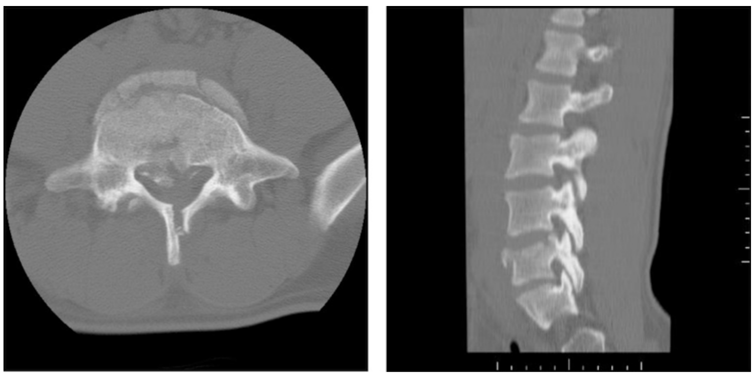

Fig. 2

Axial and sagittal CT reconstructions of an AO-A3 burst fracture, showing failure of the anterior and posterior aspects of the superior end plate of L5.

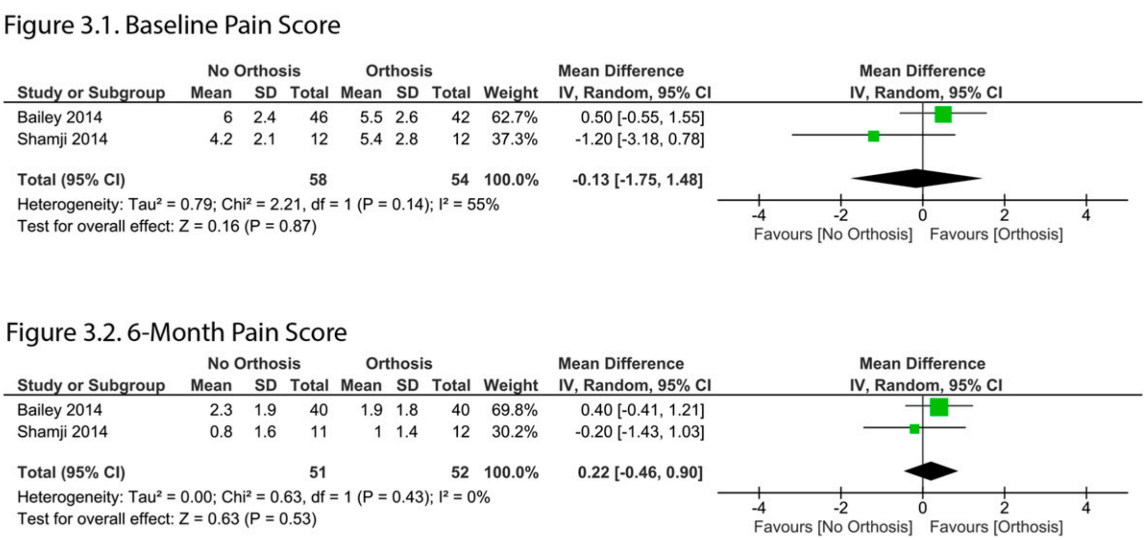

Fig. 3

Forest plots for the weighted mean difference in the baseline pain score at the time of injury and the 6-month follow-up between the orthosis and no-orthosis groups. SD = standard deviation, IV = inverse variance, and df = degrees of freedom.

TABLE I (continued)

Smokers		Level of Injury									
		Orthosis					No Orthosis				
Orthosis	No Orthosis	T11	T12	L1	L2	L3	T11	T12	L1	L2	L3
16 (34%)	15 (31%)	2	9	21	12	3	2	9	29	3	6
7 (58%)	4 (36%)	3	7	2	0	0	2	8	1	0	0
NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA

resulting from poor participant and personnel blinding because of the obvious difficulties of blinding which patients were managed with an orthosis and which were managed without an orthosis.

Clinical Outcomes Measures

Shamji et al. and Bailey et al. reported pain values on a 10-point scale at the time of injury and 6 months following treatment[24,28]. A total of 112 patients (54 in the orthosis group, 58 in the no-orthosis group) were included in the comparison of the pain level (Fig. 3). The weighted mean difference between patients managed with or without an orthosis did not show a statistical difference at baseline (−0.13; 95% CI = −1.75 to 1.48) or 6 months (0.22; 95% CI = −0.46 to 0.90). At the 6-month follow-up, the SF-PCS, SF-MCS, and RMDQ or ODI data were collected in both randomized controlled trials. There was no significant difference between the orthosis group and no-orthosis group for all 4 outcome measures at 6 months (Fig. 4). No statistically significant heterogeneity was seen in the meta-analysis of clinical outcomes, although the baseline pain comparison did show substantial heterogeneity ($I^2 = 55\%$).

Radiographic Assessment

Both Bailey et al. and Shamji et al. recorded the kyphotic angle at baseline and at 6 months of follow-up[24,28]. There was no significant difference in the weighted mean difference between the 2 groups at baseline (−1.04; 95% CI = −3.91 to 1.82) or 6 months (−1.99; 95% CI = −5.97 to 1.99). The mean difference slightly favored an increased kyphotic angle in the no-orthosis group at 6 months, but this trend was similar

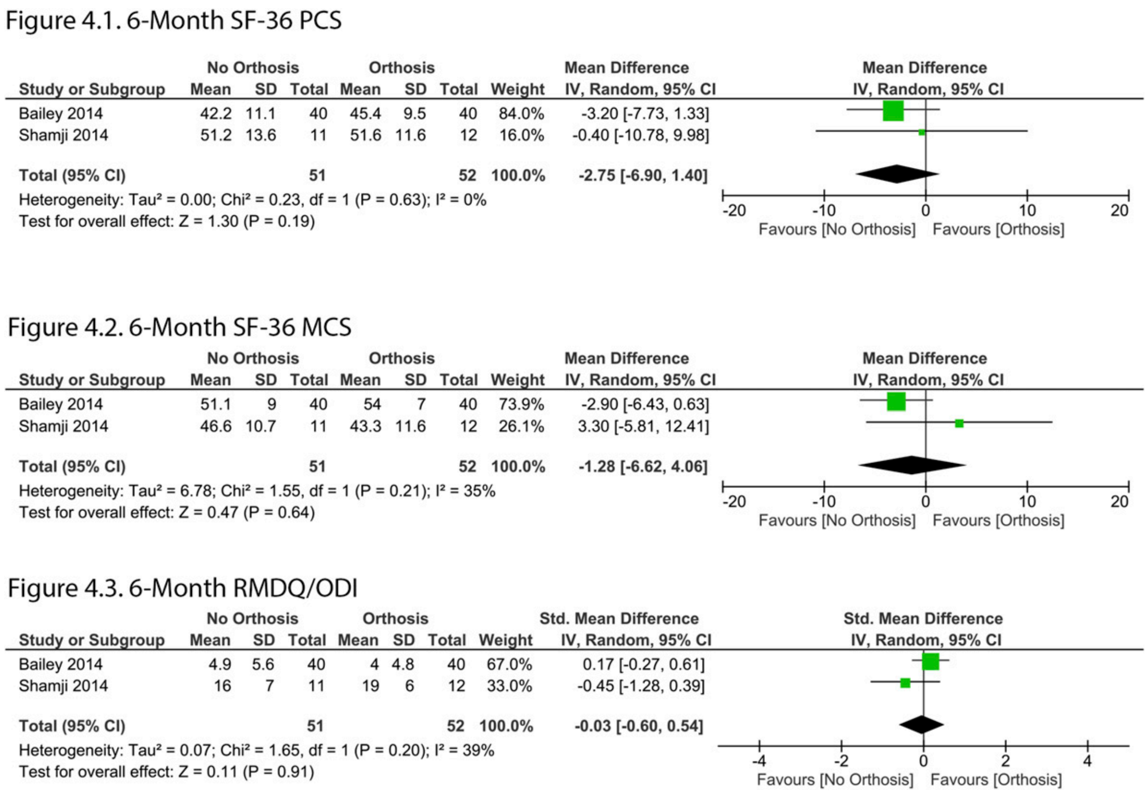

Fig. 4

Forest plots for the mean difference in the SF-36 MCS, SF-36 PCS, and RMDQ/ODI scores at the 6-month follow-up between the orthosis and no-orthosis groups. SD = standard deviation, IV = inverse variance, and df = degrees of freedom.

Figure 5.1. Baseline Kyphosis

Study or Subgroup	No Orthosis Mean	No Orthosis SD	No Orthosis Total	Orthosis Mean	Orthosis SD	Orthosis Total	Weight	Mean Difference IV, Random, 95% CI
Bailey 2014	14	6	46	15	8	42	92.7%	-1.00 [-3.98, 1.98]
Shamji 2014	9.4	6.6	11	11	17.4	12	7.3%	-1.60 [-12.19, 8.99]
Total (95% CI)			**57**			**54**	**100.0%**	**-1.04 [-3.91, 1.82]**

Heterogeneity: Tau² = 0.00; Chi² = 0.01, df = 1 (P = 0.91); I² = 0%
Test for overall effect: Z = 0.71 (P = 0.48)

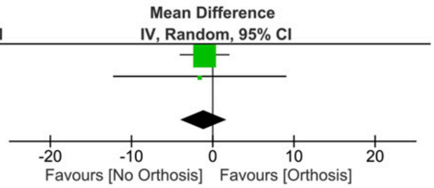

Figure 5.2. 6-Month Kyphosis

Study or Subgroup	No Orthosis Mean	No Orthosis SD	No Orthosis Total	Orthosis Mean	Orthosis SD	Orthosis Total	Weight	Mean Difference IV, Random, 95% CI
Bailey 2014	20	11	40	22	7	40	96.9%	-2.00 [-6.04, 2.04]
Shamji 2014	14.6	24.8	11	16.3	30.1	12	3.1%	-1.70 [-24.17, 20.77]
Total (95% CI)			**51**			**52**	**100.0%**	**-1.99 [-5.97, 1.99]**

Heterogeneity: Tau² = 0.00; Chi² = 0.00, df = 1 (P = 0.98); I² = 0%
Test for overall effect: Z = 0.98 (P = 0.33)

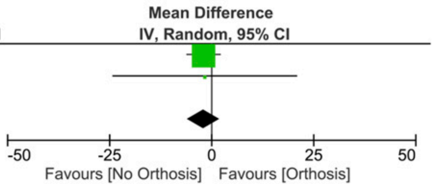

Fig. 5

Forest plots for the mean difference in kyphosis angle at the time of injury and 6-month follow-up between the orthosis and no orthosis groups. SD = standard deviation, IV = inverse variance, and df = degrees of freedom.

to differences in the kyphotic angle at baseline and was statistically insignificant at both time points (Fig. 5). No significant heterogeneity was seen in the comparison of kyphosis.

Length of Hospital Stay

Pooling the data on the length of hospital stay from the 2 randomized controlled trials indicated there was no difference between treatment groups (weighted mean difference, −1.64; 95% CI = −5.16 to 1.89). However, there was a high level of heterogeneity in the comparison (I^2 = 92%). Bailey et al. found no significant difference between groups in terms of the length of hospital stay[24], whereas Shamji et al. showed a significantly longer hospital stay in the orthosis group (mean difference, 3.5 days; 95% CI = 1.27 to 5.73 days)[28].

Complications Leading to Surgical Intervention

In the study by Bailey et al., 12 of 96 enrolled patients (including 6 in the orthosis group and 6 in the no-orthosis group) required surgical intervention at some point during the trial[24]. Six patients (4 in the orthosis group and 2 in the no-orthosis group) required surgical intervention after they had provided consent and treatment had been initiated, but the causes were not described. Five additional patients required surgery before hospital discharge. Of those 5 patients, 2 (1 from each treatment group) developed severe radicular pain with initial mobilization that was not present when supine, requiring decompression and stabilization. The other 3 patients had severe mechanical back pain that necessitated surgical stabilization to facilitate ambulation. Finally, 1 patient in the thoracolumbosacral orthosis group required an osteotomy 8 months after the fracture. Shamji et al. reported no complications requiring surgery within either group during the 6-month span of the trial[28]. The pooled data for required surgical intervention showed no difference in the weighted risk difference between groups treated with or without an orthosis.

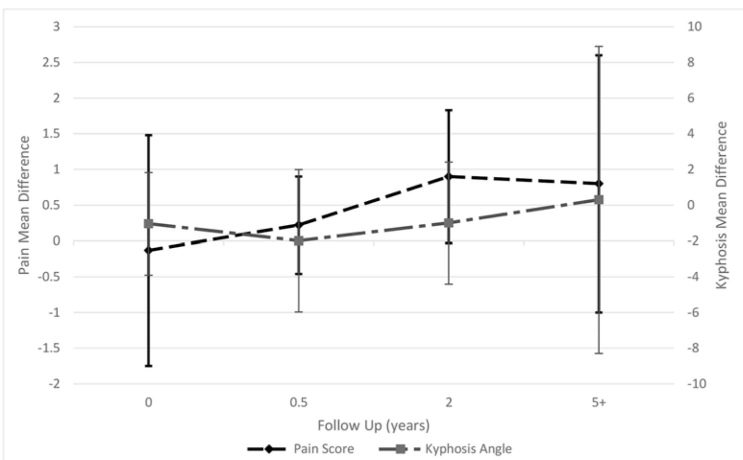

Fig. 6

Line graph showing the mean difference in the pain scores and kyphosis angle at baseline and 0.5 year (pooled data), 2 years (Bailey et al.[24]), and ≥5 years (Urquhart et al.[26]). The error bars signify the 95% confidence interval. Positive values favor orthosis use.

Long-Term Follow-up

Urquhart et al.[26] collected longer-term data (at 5 to 10 years after the initial presentation) from the patients who had been managed at 1 of the level-I trauma centers originally included in the study by Bailey et al.[24]. To our knowledge, those data represent the longest-term data from a randomized controlled trial that have been published to date. When compared with the 2-year follow-up data from the study by Bailey et al. and the pooled meta-analysis data of the present study, the kyphosis angle and pain scores consistently showed no difference between groups at all time points. The mean differences for both kyphosis and pain at baseline and 6 months (pooled data), 2 years (Bailey et al.[24]), and ≥5 years (Urquhart et al.[26]) are illustrated in Figure 6.

Publication Bias and Subgroup Analysis

Because of the limited number of included studies, no formal assessment of publication bias was performed. No details could be obtained on patient hospital course or discharge, and as such no subgroup analysis could be performed for the high heterogeneity found within the length of hospital stay.

Discussion

The treatment of thoracolumbar burst fractures generally has shifted to a more conservative approach over the past several decades. By convention, a stable, isolated burst fracture in a neurologically intact patient has been treated with a thoracolumbosacral orthosis or plaster cast before the initiation of mobilization and therapy because of concerns regarding the inherent mechanical instability of the injury or poor pain control[19,20]. In the present meta-analysis involving 119 patients with thoracolumbar burst fractures, we compared the safety and efficacy of treatment with or without an orthosis and found that both groups achieved equivalent and satisfactory clinical and radiographic outcomes. Specifically, no difference was found at 6 months following treatment with or without an orthosis in terms of the kyphotic angle or the SF-PCS, SF-MCS, RMDQ/ODI, or pain scores. In addition, long-term follow-up at 1, 2, and 5 to 10 years showed similarly equivalent findings between groups. In both included randomized controlled trials, patients showed substantial improvements in all outcome measures over time, but there was no significant difference between the treatment and control groups. We conclude that treatment with or without an orthosis can achieve similar and satisfactory functional results for neurologically intact patients with isolated thoracolumbar burst fractures.

The kyphotic angle demonstrated no difference between treatment groups at all time points, but it progressively increased over time in both groups. The utility of this outcome is questionable and it has been shown to be a poor marker for effective treatment[33,34]. Even if initial kyphotic deformity is corrected either surgically or with bracing, some loss of correction is expected on long-term follow-up[33,34]. Radiographic outcomes such as the focal kyphosis angle, vertebral body height loss, and canal compromise have not been found to be associated with long-term functional outcomes[14,15,34]. However, kyphosis of >30° traditionally is believed to be a better radiographic predictor of long-term back pain[2].

The length of hospital stay was found to be equivalent between groups, although Shamji et al. showed a significant difference between patients managed with and without an orthosis[28]. This finding created substantial heterogeneity when pooling the data for length of hospital stay. In both trials, the described protocol was similar with respect to immediate patient mobilization and therapy once a patient was randomized to the no-orthosis group. However, Bailey et al. did not describe the time requirement needed to fit and apply the orthosis[24], whereas the treatment protocol in the study by Shamji et al. required that a customized thoracolumbosacral orthosis be fitted by an orthotist within 24 hours after group assignment. Differences between the centers in terms of the access to orthotists and bracing supplies may partially account for differences in length of stay. Additionally, no data were reported on final disposition (home versus subacute rehabilitation versus inpatient rehabilitation), which can substantially affect the length of stay. If those data become available, a subgroup analysis based on final disposition may shed light on the heterogeneity between studies.

Nonoperative treatment of burst fractures in neurologically intact patients has many benefits compared with operative treatment, including decreased costs and complications and improved functional outcomes[16,17,21,35]. Furthermore, treatment without an orthosis has the potential to amplify the cost-effectiveness of conservative management. Custom-fitting and production of a thoracolumbosacral orthosis requires 1 to 2 days in addition to the time and expertise of several trained professionals. Shamji et al. did not record specific costs associated with thoracolumbosacral orthosis treatment but did note several added costs of care specific to the orthosis group, including the cost of the thoracolumbosacral orthosis (~$1,000), hourly fees for customized fitting of the thoracolumbosacral orthosis by a certified orthotist, hourly fees for instructions on correct utilization of the thoracolumbosacral orthosis by a certified physical therapist, and the cost of care before fitting of the thoracolumbosacral orthosis. Furthermore, thoracolumbosacral orthoses incur patient morbidity (e.g., decubitus ulcers and skin breakdown) and the need for additional help at home. Treating specific burst fractures without an orthosis would avoid these added costs and may lead to overall decreased cost of care.

The present meta-analysis had several limitations. First, the number of included studies was limited by the number of high-quality randomized controlled studies that have been published to date. Several retrospective observational studies comparing conservative treatments have been published[15,36-38]; however, they were excluded from the present meta-analysis in an attempt to maintain a high level of evidence. Second, the small sample size of included patients limits the power to detect a true difference in treatments and thus creates a higher risk of type-II error. Last, all included studies were performed in the Canadian heath system, which is a publicly funded, single-payer system that highly incentivizes cost-effective, accessible, scalable treatment options. Similar trials reproduced in other regions outside of Canada would improve the generalizability of these findings.

Conclusions

The present meta-analysis demonstrated that neurologically intact patients with thoracolumbar burst fractures had similar clinical and radiographic outcomes with or without bracing at both short and long-term follow-up. No difference was seen with regard to the hospital length of stay or the rate of treatment failure after data were pooled. Future trials with larger numbers of patients and focusing on longer-term outcomes to identify appropriate indications and ideal patient selection are warranted.

Appendix

Supporting material provided by the authors is posted with the online version of this article as a data supplement at jbjs.org (http://links.lww.com/JBJSREV/A507).

Nicholas Wallace, MD[1],
Michael McHugh, MD[1],
Rakesh Patel, MD[1],
Ilyas S. Aleem, MD, MSc, FRCSC[1]

[1]Division of Spine Surgery, Department of Orthopaedic Surgery, University of Michigan, Ann Arbor, Michigan

E-mail address for I.S. Aleem: ialeem@med.umich.edu

ORCID iD for N. Wallace: 0000-0002-0614-377X
ORCID iD for M. McHugh: 0000-0001-6549-4070
ORCID iD for R. Patel: 0000-0003-2726-181X
ORCID iD for I.S. Aleem: 0000-0003-4818-8578

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