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Comparison of thoracolumbosacral orthosis and no orthosis for the treatment of thoracolumbar burst fractures: interim analysis of a multicenter randomized clinical equivalence trial

Clinical article

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Object. The authors compared the outcome of patients with thoracolumbar burst fractures treated with and without a thoracolumbosacral orthosis (TLSO).

Methods. As of June 2002, all consecutive patients satisfying the following inclusion criteria were considered eligible for this study: 1) the presence of an AO Classification Type A3 burst fractures between T-11 and L-3, 2) skeletal maturity and age < 60 years, 3) admission within 72 hours of injury, 4) initial kyphotic deformity < 35°, and 5) no neurological deficit. The study was designed as a multicenter prospective randomized clinical equivalence trial. The primary outcome measure was the score based on the Roland-Morris Disability Questionnaire assessed at 3 months postinjury. Secondary outcomes are assessed until 2 years of follow-up have been reached, and these domains included pain, functional outcome and generic health-related quality of life, sagittal alignment, length of hospital stay, and complications. Patients in whom no orthotic was used were encouraged to ambulate immediately following randomization, maintaining "neutral spinal alignment" for 8 weeks. The patients in the TLSO group began being weaned from the brace at 8 weeks over a 2-week period.

Results. Sixty-nine patients were followed to the primary outcome time point, and 47 were followed for up to 1 year. No significant difference was found between treatment groups for any outcome measure at any stage in the follow-up period. There were 4 failures requiring surgical intervention, 3 in the TLSO group and 1 in the non-TLSO group.

Conclusions. This interim analysis found equivalence between treatment with a TLSO and no orthosis for thoracolumbar AO Type A3 burst fractures. The influence of a brace on early pain control and function and on long-term 1- and 2-year outcomes remains to be determined. However, the authors contend that a thoracolumbar burst fracture, in exclusion of an associated posterior ligamentous complex injury, is inherently a very stable injury and may not require a brace. *(DOI: 10.3171/2009.3.SPINE08312)*

Key Words • thoracolumbar spine • burst fracture • no orthosis • prospective randomized clinical trial

The treatment of thoracolumbar burst fractures remains controversial.[42,44,49,50] A variety of treatment options are available and effective, but none has been definitively shown to be superior.[44] There are several reasons for clinical equipoise in management. The majority revolve around retrospective research involving heterogeneous populations and difficulties in defining burst fractures and their inherent stability.[44,50]

Historically, conservative treatment with prolonged bed rest and postural reduction has been the management strategy of choice.[5,14] More recently, investigators have demonstrated good results treating burst

Abbreviations used in this paper: AP = anteroposterior; RMDQ = Roland-Morris Disability Questionnaire; TLSO = thoracolumbosacral orthosis; SF-36 = 36-Item Short Form Health Survey; VAS = visual analog scale; VB = vertebral body; WCB = Workers' Compensation Board.

This article contains some figures that are displayed in color online but in black and white in the print edition.

fractures with an orthotic and varying protocols for ambulation.[1,2,8–10,18,22–24,28,31,36,40,41,45,47,49] Recumbence periods ranging from 3 months of bed rest to "early ambulation as tolerated" with various types of orthoses have led to favorable results irrespective of how restrictive were the treatment protocols.[2,8–10,41,47] Shen and Shen[41] reported a retrospective, 4-year follow-up study of 38 patients treated with immediate ambulation. Jewett braces were used in 9 patients, and no brace therapy was used in the remainder. There was no difference in outcome between those who wore a brace and those who did not. We contend this does not suggest that a TLSO does not effectively stabilize a thoracolumbar burst fracture, but rather that a thoracolumbar burst fracture, in exclusion of an associated posterior ligamentous complex injury, is inherently a very stable injury and may not require a brace at all.

In the thoracolumbar spine, orthoses reduce gross spinal motion to varying degrees depending on their design.[4,6,13,16,25,29,32] Overall, the body cast is most effective in limiting motion in all planes of the thoracolumbar and lumbar spine.[13,32] The Jewett hyperextension brace is effective in limiting instability in flexion but not in rotation or lateral bending.[32,35] The custom-molded TLSO provides protection in all 3 planes.[3,25]

In theory braces provide stability to the fracture, thereby reducing pain, maintaining alignment, facilitating hospital discharge, and providing the patient with a good functional outcome. Braces, however, are not without potential theoretical disadvantages including muscular atrophy, deconditioning, skin irritation, cost, and delays in reactivation while awaiting the brace. Off-the-shelf ready-fit braces partially eliminate this last problem.

There appears to be equipoise as to whether an orthosis or no brace would be more effective in the management of thoracolumbar burst fractures. With that in mind, we undertook this study to compare the functional outcome at 3 months postinjury in patients with an AO Classification Type A3 burst fractures[27] treated with a TLSO or no orthosis. The alternative hypothesis is that no difference will be proven, and therefore, this is an equivalence trial. Secondary outcomes included pain, functional outcome, and generic health-related quality of life for 2 years postinjury; sagittal alignment; length of hospital stay; and complications. We present the preliminary findings of an ongoing multicenter study.

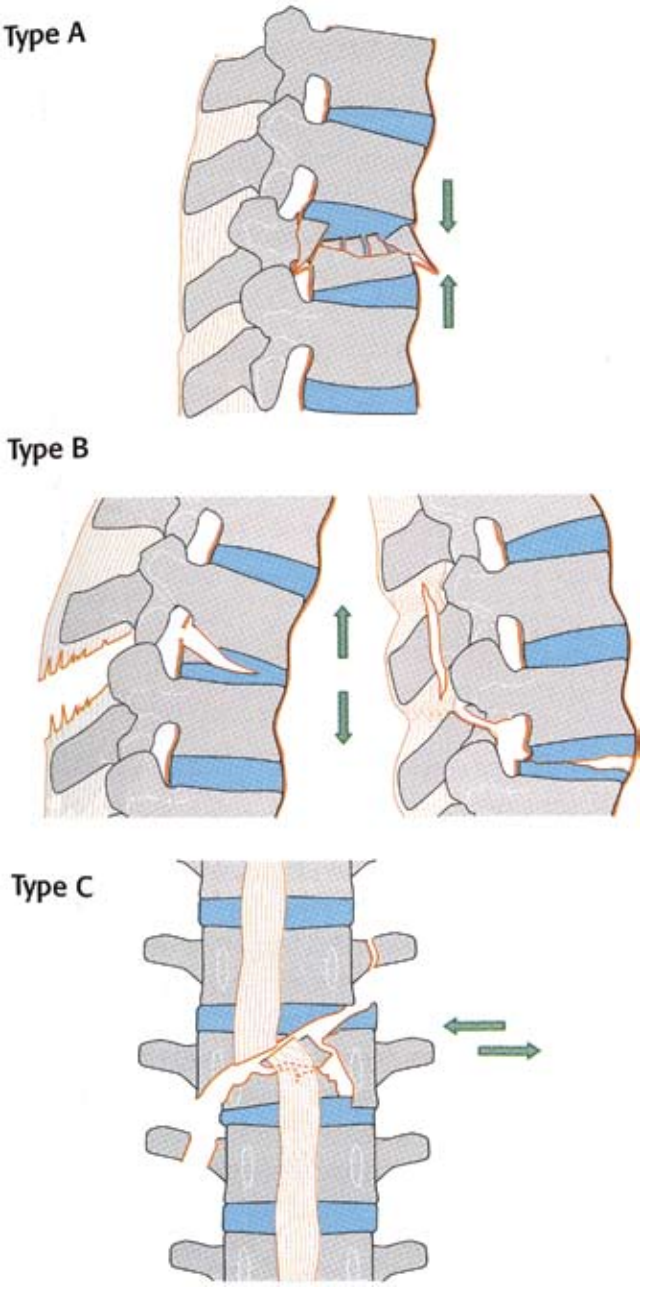

Fig. 1. Schematics showing the classification of AO Type A VB compression, Type B distraction injury, Type C rotational fractures.

Methods

Study Design

We conducted a multicenter prospective randomized clinical equivalence trial initiated at Vancouver General Hospital, a tertiary care spine center, in June 2002. The trial became multicenter in June of 2004 with the addition of the Calgary Health Network and London Health Sciences Centre in July 2005. All consecutive patients with thoracolumbar burst fractures underwent clinical assessment and imaging (radiography, CT, and MR imaging) performed by a fellowship-trained spine surgeon who determined eligibility for the study. All patients who met the following inclusion criteria were invited to participate: 1) Type AO Type A3 burst fractures between T-11 and L-3 (Fig. 1),[27] 2) skeletally mature and < 60 years of age, 3) admitted within 72 hours of injury, 4) initial kyphotic deformity < 35°, and 5) neurologically intact or with a single nerve root motor/sensory deficit. Exclusion criteria included the following: 1) pathological fracture, 2) open fracture, 3) associated injury significant enough to disrupt the treatment protocol (that is, change in weight-bearing status or an inability to wear a brace), 4) pregnancy, 5) body mass index > 40, 6) previous injury to or surgery in the thoracolumbar region, 7) unable to read or comprehend the outcome instruments, and 8) al-

cohol or drug abuse. Patients agreeing to participate were given consent by the treating surgeon and randomized using a computer-generated random number program. The sequence was concealed from the treating surgeon until the study site coordinator assigned the patient to a group. Prior to randomization, patients were stratified by study site, WCB status, and kyphosis angle < 20° or ≥ 20°. All patients who declined participation in the study were recorded in a rejection log and were recommended for TLSO treatment.

Outcome Assessment

Follow-up evaluations were performed by a site-specific independent blinded evaluator at discharge, 2 and 6 weeks, 3 and 6 months, and 1 and 2 years. The primary outcome measure was the RMDQ, which evaluates 24 items to produce a score that ranges from 0 (no disability) to 24 (severe disability). The questionnaire evaluates disability due to low-back pain and is short, simple to administer, sensitive, and reliable.[30,37,38] The primary outcome was measured at the 3-month follow-up, the time at which we expect significant functional recovery and readiness to resume most normal activities.

Secondary outcomes included the SF-36, a 10-point VAS evaluating the patient's average subjective pain during the previous 7 days,[17,46] and a VAS satisfaction score. The SF-36 is a 36-item measure of general health, which assesses 8 health dimensions. A physical and mental component can be derived. The dimensions of physical health can be computed into a Physical Component Summary score, which weighs physical function, physical role, bodily pain, and vitality into a single score. It has been shown to be valid when applied to the spine patient.[15,33] Overall satisfaction with treatment was assessed on a 7-point scale, using the sentence, "All things considered, how satisfied are you with the results of your recent treatment for your spine fracture?" This is a recommended tool for assessing global satisfaction.[19]

Time to hospital "discharge status" represented the number of days it took for the patient to meet all discharge criteria following his/her randomization. The day the patient was randomized represented the 1st hospital day. Discharge criteria included a safe and independent ambulatory status as assessed by the physiotherapist, the ability to don the brace and perform necessary tasks of daily living as assessed by the occupational and/or physiotherapist, adequate pain control with oral analgesics, and a satisfactory alignment on a standing AP and lateral radiographs. The number of patients able to return to work/school was recorded. All complications arising from the fracture or treatment were recorded. The local kyphosis angle was measured initially and at all follow-up points using the Cobb technique.[11]

Treatment Protocol

Patients were admitted to the spine unit, and all spine-related precautions were taken. Patients in the TLSO group were kept on bed rest until they were fitted with a prefabricated TLSO (Aspen Medical Products). The TLSO was provided at no charge to the participating patients. The orthosis was required to be worn at all times except when lying flat in bed. Compliance in wearing the brace was self-reported by the patient at all relevant follow-up periods. While in hospital, the patient received instruction from an occupational therapist on how to properly don the brace and perform self-care techniques. Under the supervision of the physiotherapist, the patient ambulated as tolerated once the brace was fitted. We enforced 90° hip flexion restrictions for the first 8 weeks. At the 8-week mark, the patient began weaning the brace over a 2-week period.

Patients who did not receive the TLSO were encouraged to ambulate immediately following randomization under the supervision of the physiotherapist. Walking tolerance progressed as tolerated. Truncal bending or twisting and 90° hip flexion restrictions were enforced for the first 8 weeks.

The graded functional rehabilitation program designed specifically for this study was encouraged throughout the first 3 months for both treatment arms. At centers external to the tertiary care facility, certified physiotherapists administered rehabilitation. At 4 weeks, isometric spine-stabilization exercises commenced and progressed to isotonic exercises at 8 weeks. At 9 weeks, all patients had occupation-specific rehabilitation incorporated into their program. Physiotherapy was not financially supported by the study.

Sample Size and Statistical Analysis

Seventy-four patients per group are required to ensure an adequate power. This sample size was determined using an α of 0.05, an SD of 5.2 for the RDMQ,[7,23,26,43] and a clinical difference of 2.5.[7,37] As an equivalence trial, a β of 10% was chosen to reduce the risk of a Type II error. Additionally, because a range is recommended for the responsiveness or minimal important change, we erred on the low side of the range until better evidence is available. The study protocol was approved by the ethics review board at all participating hospitals. A data safety monitoring board was assigned to ensure that there were no protocol violations. An interim analysis was performed once 50% of participants had reached the primary outcome to ensure that neither adverse outcomes occurred, nor that a superior effectiveness of one therapy was demonstrated. It is the interim analysis, performed in March 2007, that we present in this paper.

An unpaired, double-tailed Student t-test was used to analyze all continuous outcome measures. Patients in the non-TLSO group, who required the use of an orthosis, crossed over to the TLSO group and were analyzed in the TLSO group to bias against equivalence. Otherwise, patients who dropped out or for whom treatment was contaminated were analyzed following the principle of "intent to treat." Only patients who refused to continue under observation were withdrawn from the trial. Contamination included the need for surgery for mechanical or neurological instability or a prolonged period of brace treatment. To protect against bias, any deviation from the treatment protocol had to be agreed upon by the treating physician and another investigating surgeon. Mean values are presented ± SD.

Results

Seventy-two of 86 eligible patients were recruited into the study and have been followed to the primary outcome time point. Thirty-six were randomized to the TLSO treatment group and 36 to non-TLSO treatment group. Of the 14 eligible patients not recruited for the study, 3 resided outside the country, 8 refused participation, and 3 had not given consent prior to independent ambulation. At the Vancouver and London sites, a complete rejection log was accurately maintained. No patient meeting the inclusion/exclusion criteria was withheld from involvement by a participating surgeon. Table 1 provides a summary of the demographic and stratification data for the 2 treatment arms. At the time of this interim analysis, the Vancouver site had recruited 44 patients, the Calgary site 9, and the London site 19.

Three patients, 2 randomized to the non-TLSO treatment group, were lost to follow-up by the primary outcome timeframe of 3 months. By 6 months a total of 3 individuals in the non-TLSO group and 1 in the TLSO group were lost to follow-up. Four patients required surgery prior to their initial hospital discharge (average 5 days postadmission) after they had given consent and treatment initiated. Two patients (1 from each treatment group) developed severe radicular pain, not present when supine, once they initiated mobilization. Retropulsed bone–induced nerve impingement in the lateral recess was the cause, and it required decompression to facilitate mobilization. In 2 other cases randomized to the TLSO treatment group, the patients had severe mechanical back pain necessitating surgical stabilization to allow ambulation. The demographic information for each of these 4 patients is listed in Table 2. At 2 weeks, 5 patients (14%) admitted to not wearing the brace 100% of the time when upright, and this number increased to 11 patients (31%) at 6 weeks. On average, at 2 and 6 weeks, patients in the TLSO treatment group wore the brace 90 and 83% of the time when upright, respectively.

No significant difference was found in the primary outcome. The mean RMDQ scores were 7 ± 6 and 6 ± 5 for the non-TLSO treatment group and TLSO treatment group, respectively, at 3 months ($\alpha = 0.33$). There was no significant intergroup difference for any of the secondary outcome measures at any of the follow-up intervals, including the RMDQ, SF-36, VAS for pain, and patient satisfaction (Tables 3 and 4). The RMDQ demonstrated that functional disability improved to the 6-month mark, whereas pain and physical health continued to improve to the 1-year point. The VAS pain score seemed to favor the TLSO treatment group without statistical significance ($\alpha = 0.08$) at 2 weeks and then mirrored the no-orthosis treatment group thereafter (Table 4). By defining "minimal pain" as a VAS score ≤ 3, ~ 80% (range 76–82%) of patients complained of minimal to no pain at 3 months and thereafter, with no intergroup difference. Overall, patients were equally satisfied with the treatment they received as depicted by the high scores recorded in Table 4.

Time required to meet the discharge criteria once randomized to a treatment was 3.4 and 3.0 days for the non-TLSO and the TLSO treatment groups, respectively ($\alpha = 0.92$). Six patients in the non-TLSO group and 9 in the TLSO group had yet to return to work.

TABLE 1: Demographic data and stratification information

Variable	No. of Patients/Value (%)	
	No Orthosis	TLSO
participants present		
recruited	36	36
at 6 wks	35	35
at 3 mos	34	35
at 6 mos*	27	33
at 1 yr*	23	24
age (yrs)	39	39
sex		
female	8 (22)	9 (25)
male	28 (78)	27 (75)
WCB support		
no, <20° kyphosis	25 (69)	27 (75)
yes, <20° kyphosis	8 (22)	5 (14)
no, ≥20° kyphosis	1 (3)	3 (8)
yes, ≥20° kyphosis	2 (6)	1 (3)
thoracic		
T-11	1 (3) =	1 (3)
T-12	6 (17)	5 (14)
lumbar		
L-1	21 (58)	16 (44)
L-2	3 (8)	11 (31)
L-3	5 (14)	3 (8)
smoker	5 (14)	7 (19)

* Number of patients for which outcome was available. Those lost to follow-up and those enrolled who have not yet reached the evaluation time point are not included.

TABLE 2: Summary of conservative treatment failures requiring surgery

Case No.	Level	Admission Kyphosis Angle (°)	Age (yrs)	Sex	Receiving WCB Support	Treatment Group	Op Indication
1	L-1	14	30	male	no	no orthosis	radicular leg pain
2	L-1	19	19	female	yes	TLSO	radicular leg pain
3	L-2	0	59	female	no	TLSO	mechanical back pain
4	L-2	21	22	male	no	TLSO	mechanical back pain

TABLE 3: Summary of RMDQ scores*

Follow-Up Interval	RMDQ Score		α Value
	No Orthosis	TLSO	
discharge	18 ± 5	17 ± 5	0.31
2 wks	16 ± 6	16 ± 6	0.62
6 wks	12 ± 6	10 ± 5	0.19
3 mos	7 ± 6	6 ± 5	0.33
6 mos	5 ± 6	3 ± 4	0.17
1 yr	5 ± 5	3 ± 6	0.23

* Scores are presented as the mean ± SD.

The mean kyphosis at time of randomization was 11.8 ± 9.5 in the non-TLSO group and 10 ± 6.7 in the TLSO group, which is not a statistically significant difference ($\alpha = 0.46$). The mean kyphosis values are reported in Table 5. Figures 2 and 3 show imaging studies in 2 patients with kyphosis. No difference at any follow-up point was found between groups. However, the largest discrepancy is seen at discharge ($\alpha = 0.10$), which equalizes over the ensuing follow-up periods.

Discussion

Despite the large volume of literature published on the management of thoracolumbar burst fractures, the optimum treatment of this injury continues to be debated.[44] We believe that the thoracolumbar burst fracture, as defined by our inclusion and exclusion criteria, is an inherently stable injury and therefore can be treated by having the patient become immediately ambulatory, as tolerated, and does not require a TLSO to achieve a good clinical outcome. It has been shown that there is no correlation between the duration of bed rest and degree of kyphotic progression following mobilization during conservative treatment.[21,48] Early mobilization is now generally accepted as the recommended approach for these fractures.[8–10,40,41] To our knowledge, there has been no randomized clinical trial, and few retrospective studies, to evaluate patients with a stable thoracolumbar burst fracture who undergo conservative treatment with or without a TLSO. Shen and Shen,[41] reporting on a 29 patient cohort that was treated without an orthosis, had similar results to those obtained with a Jewett brace. Kinoshita et al.[21] found that the radiographic postural reduction that occurs when an individual is supine cannot be maintained in an orthotic devic once the patient is mobilized, demonstrating an average collapse to near-injury kyphosis. The orthosis may facilitate earlier hospital discharge and improve initial function by providing spinal stability and thereby controlling pain. However, disadvantages could include truncal deconditioning leading to delayed functional recovery, skin irritation, and financial cost. Our randomized clinical trial was designed to demonstrate that no difference in functional outcome exists between treatment with a prefabricated TLSO and treatment without an orthosis for the "stable" burst fracture.

Good results have been well demonstrated treating "stable" thoracolumbar burst fractures conservatively.[1,2,8–10,18,22–24,28,31,36,40,41,45,47,49] These studies have excluded patients with unstable fractures using various criteria. Biomechanical studies have identified the integrity of the posterior column as a predictor of mechanical stability.[20,34] In the literature, clinical guidelines have reflected this, defining posterior-column compromise by a range of radiographic parameters: kyphosis > 15–35°, loss of > 40–60% of the anterior VB height, and fracture/dislocation of the posterior elements.[8,10,12,24,36,39–41] In our study only fractures that were classified as AO Type A3 were included; by definition this excluded unstable posterior-column injuries—in other words, all fractures associated with a flexion/distraction (Type B) or rotatory fracture/dislocation (Type C) injury pattern (Fig. 1).[27] We did not consider the severity of VB comminution or loss of VB height in our inclusion/exclusion criteria because fracture morphology has not been shown to predict clinical outcome following nonoperative treatment of thoracolumbar burst fractures.[8,10,31] Recognizing the percentage of anterior VB collapse is frequently considered as an indirect measure of posterior-column stability; this study relied on the direct kyphosis measurement. Based on the reports of Shen and Shen[41] and Reid et al.[36] who included fractures with a kyphosis up to 35°, we excluded a burst fracture for which ≥ 35° of kyphosis was demonstrated on the supine lateral radiograph. In our practice patients with unstable

TABLE 4: Summary of outcome scores*

Follow-Up	SF-36 PCS Score		VAS Pain Score		Patient Satisfaction Score	
	No Orthosis	TLSO	No Orthosis	TLSO	No Orthosis	TLSO
discharge	30	28	5.9	5.2	5.7	6.4
2 wks	25	29	4.8	3.7	6.1	6.4
6 wks	31	34	3.4	3.1	6.4	6.2
3 mos	37	39	2.8	2.6	6.4	6.3
6 mos	40	43	2.4	2.1	6.0	6.6
1 yr	44	45	2.1	1.8	5.8	6.7

* The SF-36 Physical Component Summary (PCS) scores range from 0 to 70, with 50 being the average physical health of a normal population; VAS scores range from 0 to 10, with 0 equal to no pain and 10 most severe pain; and patient satisfaction ranges from 0 to 7, with 7 representing most satisfied.

TABLE 5: Summary of radiographic measurements of kyphosis

Follow-Up	Kyphotic Angle (°)		α Value
	No Orthosis	TLSO	
admission	11.8 ± 9.5	10 ± 6.7	0.46
discharge	15.8 ± 9.3	11.1 ± 8.1	0.10
2 wks	15.3 ± 9.8	13.5 ± 6.1	0.49
6 wks	17.7 ± 10.4	15.2 ± 7.5	0.38
3 mos	16.1 ± 10.0	15.7 ± 6.3	0.89
6 mos	18.1 ± 8.9	17.3 ± 6.3	0.80
1 yr	17.0 ± 10.3	16.2 ± 6.4	0.82

* Kyphotic values are presented as the mean ± SD in degrees.

fractures, based on the aforementioned radiographic exclusion criteria, are treated surgically. Patients with a neurological deficit (spinal cord, conus medullaris, or cauda equina injury) are also considered surgical candidates and therefore not included in this study. Interestingly, 4 patients required surgery to facilitate mobilization despite the presence of "stable" radiographic criteria; 2 due to severe lumbar radicular pain; and 2 due to severe low-back pain. The mean time from attempted mobilization to surgery was 4 days (range 3–9 days). It then required on average another 7 days to facilitate a patient's discharge from the hospital. The failures in this study illustrate our final indication for surgery, which is a failure to mobilize with conservative treatment, whether that is due to pain (as was the case in this study) or multiple trauma.

With regard to both our primary and secondary outcome measures, no statistical or clinical significant difference has yet been shown between treatment with and without the TLSO for thoracolumbar burst fractures. Our primary outcome, the RMDQ, is a spine-specific functional outcome measure that assesses pain-related disability. Three months was selected as the period in which most patients start to experience a significant functional improvement, and we hypothesized that a delay in recovery of 1 treatment modality compared with the other at this point would be detected. At 3 months, patients in both treatment arms have exhibited a clinically significant improvement in average function, from an initially profound disability of 18 and 17 to 7 and 6, for no-orthosis and TLSO groups, respectively (Table 3). However, the RMDQ showed further mean functional improvement by 6 months with no further improvement thereafter. This RMDQ-documented low level of disability is consistent with the findings of other retrospective studies that have reviewed the conservative treatment of patients with thoracolumbar burst fractures.[23,31,47]

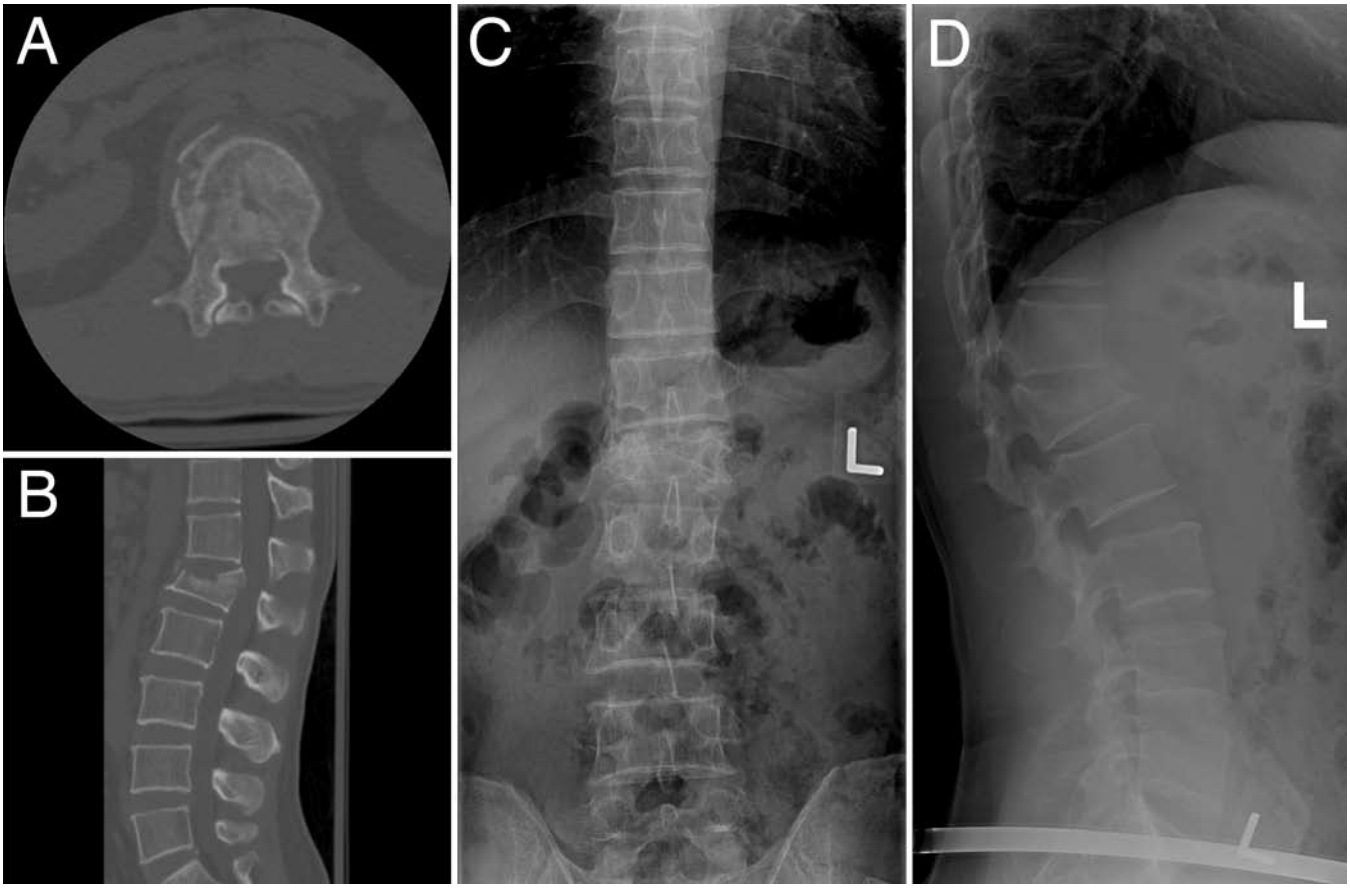

FIG. 2. Representative imaging studies in a 42-year-old woman: axial (A) and midsagittal (B) CT scans acquired at the time of injury, and AP (C) and lateral (D) radiographs obtained at 3 months follow-up. At admission, kyphosis was 21° in the supine position and 29° in the standing position at 3 months follow-up.

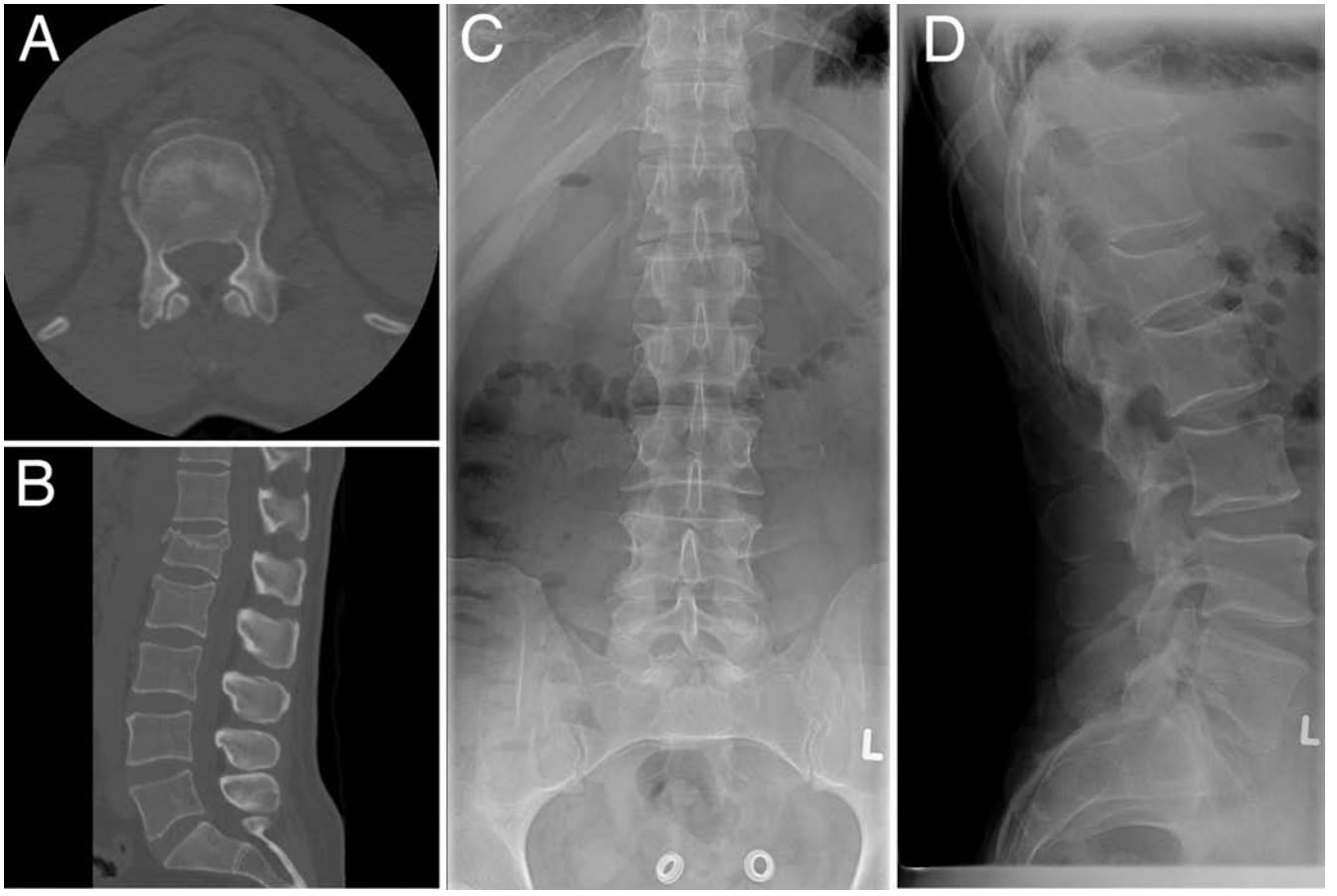

Fig. 3. Representative imaging studies in a 48-year-old man: axial (A) and midsagittal (B) CT scans obtained at the time of injury and AP (C) and lateral (D) radiographs acquired at 6 weeks follow-up. Kyphosis was 3° at 6 weeks postinjury measured laterally in a standing position.

The 4 physical component scales of the SF-36, Physical Component Summary scores, and VAS pain scores mirrored the improvement seen in the RMDQ scores in the 3-month period. The mean VAS pain score was reduced by half the initial score at 3 months in both treatment arms. Approximately 80% of patients complained of minimal to no pain by this follow-up visit, reflecting the findings of other case series in the literature.[2,8–10,41] The SF-36 Physical Component Summary scores improved progressively at each follow-up period. At 1 year, the Physical Component Summary score suggested that the mean physical health of both treatment groups is still below the average for a healthy population, represented by a score of 50. Interestingly, the mean 2-week VAS pain score and the 2- and 6-week Physical Component Summary scores highlight a larger disparity between treatment groups than occurred at all other follow-up points, favoring the TLSO treatment group (not a statistically significant difference). Although a similar finding is not seen on the RMDQ, it is possible that these findings may illustrate an advantage of wearing a prefabricated TLSO early in the treatment course in terms of pain control and physical health. With the enrollment of more patients, it will be important to follow this trend in our secondary outcome measures to see if they become significantly different. Certainly, at 3 months and thereafter, there has been no suggestion that a difference between treatment groups exists in any of the study's outcome measures. Thus far we have not found any advantage of a prefabricated TLSO in improving pain and function initially or decreasing the time to discharge, but it will be important to report on intervals up to the 2-year follow-up point after completed enrollment.

There was no difference in the mean kyphotic deformity between treatment groups at any follow-up point. However, at discharge the difference did approach statistical significance (15.8 ± 9.3° of kyphosis for the no-treatment group and 11.1 ± 8.1° of kyphosis for the TLSO group, $\alpha = 0.10$). By 3 months, the values were all but equal, suggesting initial stabilizing influences of the TLSO. The progression in kyphotic deformity over the first 6 weeks is expected and comparable with case series reporting an average progression between 3 and 7°.[8,10,31,36,40–42,48,49] It has been well documented that no correlation exists between kyphosis and clinical outcome, a point consistent with the findings of this interim analysis.[44]

There were 4 failures, 3 in the TLSO group and 1 in the non-TLSO group. All required surgical intervention. There were no other adverse events. These preliminary results suggest that immediately mobilizing a patient with

an AO Type A3 burst fracture without a brace is probably safe.

Because we are reporting the interim analysis performed at the 50% recruitment mark, the sample size is too small to provide adequate power. This is particularly pertinent in light of the nonsignificant difference in secondary outcome measures (VAS pain and Physical Component Summary scores, as well as kyphosis) demonstrated at the earlier follow-up time points. Although it is likely that when this trial is complete we will observe equivalence in the primary outcome measure, it is possible that, once appropriately powered, a significant finding may be shown in these secondary outcome measures. Therefore, although we do not expect a clinical difference in final outcome between the 2 groups, the TLSO may be shown to facilitate pain control and function during the initial weeks of treatment. The preliminary results in the 3- and 6-month follow-up periods suggest that ultimately abstaining from brace treatment is safe and equivalent to brace therapy. Despite being underpowered, we believe this study provides valuable information for physicians treating patients who cannot undergo brace therapy for various reasons (body habitus, comorbidities, financial constraint, or compliance issues) as these patients now have an alternative early mobilization treatment option. Because there has been no randomized clinical trial to date addressing this issue of brace/no brace treatment, these interim results provide evidence that such patients do not have to undergo surgery or prolonged bed rest, with its associated morbidity and cost.

It is reasonable to suggest that maintaining compliance in the TLSO treatment is influenced by the patients' knowing they could have been randomized to the no-brace treatment group. It is for this reason that we carefully monitored compliance. At 2 weeks, 86% of the patients indicated they wore the TLSO 100% of the time when upright, which decreased to 69% at 6 weeks. On average patients in the TLSO treatment group wore the brace the majority of the time when upright, an average of 90% of the time at 2 weeks and 83% at 6 weeks. We believe that the compliance is indicative of the effectiveness of the treatment as opposed to the efficacy and therefore makes the study more generalizable.

Conclusions

This interim analysis of a multicenter prospective randomized clinical trial has found equivalence between treatment with a prefabricated TLSO and no orthosis in patients with thoracolumbar AO Type A3 burst fractures. This finding provides early support for the notion that the thoracolumbar burst fracture, as defined by our inclusion and exclusion criteria, is a relatively stable injury and can be safely mobilized early with no brace. The results of this study are preliminary and the final outcome remains to be determined.

Disclosure

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References

1. Agus H, Kayali C, Arslantas M: Nonoperative treatment of burst-type thoracolumbar vertebra fractures: clinical and radiological results of 29 patients. **Eur Spine J 14:**536–540, 2005
2. Aligizakis A, Katonis P, Stergiopoulos K, Galanakis I, Karabekios S, Hadjipavlou A: Functional outcome of burst fractures of the thoracolumbar spine managed non-operatively, with early ambulation, evaluated using the load sharing classification. **Acta Orthop Belg 68:**279–287, 2002
3. Anderson PA: Nonsurgical treatment of patients with thoracolumbar fractures. **Instr Course Lect 44:**57–65, 1995
4. Axelsson P, Johnsson R, Stromqvist B: Effect of lumbar orthosis on intervertebral mobility. A roentgen stereophotogrammetric analysis. **Spine 17:**678–681, 1992
5. Bedbrook GM: Treatment of thoracolumbar dislocation and fractures with paraplegia. **Clin Orthop Relat Res 112:**27–43, 1975
6. Benzel EC, Larson SJ: Postoperative stabilization of the posttraumatic thoracic and lumbar spine: a review of concepts and orthotic techniques. **J Spinal Disord 2:**47–51, 1989
7. Beurskens AJ, de Vet HC, Koke AJ: Responsiveness of functional status in low back pain: a comparison of different instruments. **Pain 65:**71–76, 1996
8. Cantor JB, Lebwohl NH, Garvey T, Eismont FJ: Nonoperative management of stable thoracolumbar burst fractures with early ambulation and bracing. **Spine 18:**971–976, 1993
9. Chan DP, Seng NK, Kaan KT: Nonoperative treatment in burst fractures of the lumbar spine (L2-L5) without neurologic deficits. **Spine 18:**320–325, 1993
10. Chow GH, Nelson BJ, Gebhard JS, Brugman JL, Brown CW, Donaldson DH: Functional outcome of thoracolumbar burst fractures managed with hyperextension casting or bracing and early mobilization. **Spine 21:**2170–2175, 1996
11. Cobb JR: Outline for the study of scoliosis, in JW Edwards (ed): **Instructional Course Lectures,** Ann Arbor: American Academy of Orthopaedic Surgeons, 1948, Vol 5, pp 261–275
12. Danisa OA, Shaffrey CI, Jane JA, Whitehill R, Wang GJ, Szabo TA, et al: Surgical approaches for the correction of unstable thoracolumbar burst fractures: a retrospective analysis of treatment outcomes. **J Neurosurg 83:**977–983, 1995
13. Fidler MW, Plasmans CM: The effect of four types of support on the segmental mobility of the lumbosacral spine. **J Bone Joint Surg Am 65:**943–947, 1983
14. Frankel HL, Hancock DO, Hyslop G, Melzak J, Michaelis LS, Ungar GH, et al: The value of postural reduction in the initial management of closed injuries of the spine with paraplegia and tetraplegia. I. **Paraplegia 7:**179–192, 1969
15. Grevitt M, Khazim R, Webb J, Mulholland R, Shepperd J: The short form-36 health survey questionnaire in spine surgery. **J Bone Joint Surg Br 79:**48–52, 1997
16. Grew ND, Deane G: The physical effect of lumbar spinal supports. **Prosthet Orthot Int 6:**79–87, 1982
17. Haefeli M, Elfering A: Pain assessment. **Eur Spine J 15 (Suppl 1):**S17–S24, 2006
18. Hitchon PW, Torner JC, Haddad SF, Follett KA: Management options in thoracolumbar burst fractures. **Surg Neurol 49:** 619–626, 1998
19. Hudak PL, Wright JG: The characteristics of patient satisfaction measures. **Spine 25:**3167–3177, 2000
20. James KS, Wenger KH, Schlegel JD, Dunn HK: Biomechanical evaluation of the stability of thoracolumbar burst fractures. **Spine 19:**1731–1740, 1994
21. Kinoshita H, Nagata Y, Ueda H, Kishi K: Conservative treatment of burst fractures of the thoracolumbar and lumbar spine. **Paraplegia 31:**58–67, 1993
22. Knight RQ, Stornelli DP, Chan DP, Devanny JR, Jackson KV: Comparison of operative versus nonoperative treatment of

lumbar burst fractures. **Clin Orthop Relat Res 293:**112–121, 1993
23. Kraemer WJ, Schemitsch EH, Lever J, McBroom RJ, McKee MD, Waddell JP: Functional outcome of thoracolumbar burst fractures without neurological deficit. **J Orthop Trauma 10:**541–544, 1996
24. Krompinger WJ, Fredrickson BE, Mino DE, Yuan HA: Conservative treatment of fractures of the thoracic and lumbar spine. **Orthop Clin North Am 17:**161–170, 1986
25. Lantz SA, Schultz AB: Lumbar spine orthosis wearing. I. Restriction of gross body motions. **Spine 11:**834–837, 1986
26. Leclaire R, Blier F, Fortin L, Proulx R: A cross-sectional study comparing the Oswestry and Roland-Morris Functional Disability scales in two populations of patients with low back pain of different levels of severity. **Spine 22:**68–71, 1997
27. Magerl F, Aebi M: A comprehensive classification of thoracic and lumbar injuries, in Aebi M, Thalgott JS, Webb JK (eds): **AO ASIF Principles in Spine Surgery.** Springer, 1998, pp 20–41
28. Mcevoy RD, Bradford DS: The management of burst fractures of the thoracic and lumbar spine. Experience in 53 patients. **Spine 10:**631–637, 1985
29. Miller RA, Hardcastle P, Renwick SE: Lower spinal mobility and external immobilization in the normal and pathologic condition. **Orthop Rev 21:**753–757, 1992
30. Muller U, Roder C, Greenough CG: Back related outcome assessment instruments. **Eur Spine J 15 (Suppl 1):**S25–S31, 2006
31. Mumford J, Weinstein JN, Spratt KF, Goel VK: Thoracolumbar burst fractures. The clinical efficacy and outcome of nonoperative management. **Spine 18:**955–970, 1993
32. Nagel DA, Koogle TA, Piziali RL, Perkash I: Stability of the upper lumbar spine following progressive disruptions and the application of individual internal and external fixation devices. **J Bone Joint Surg Am 63:**62–70, 1981
33. Nemeth G: Health related quality of life outcome instruments. **Eur Spine J 15 (Suppl 1):**S44–S51, 2006
34. Oxland TR, Panjabi MM, Southern EP, Duranceau JS: An anatomic basis for spinal instability: a porcine trauma model. **J Orthop Res 9:**452–462, 1991
35. Patwardhan AG, Li SP, Gavin T, Lorenz M, Meade KP, Zindrick M: Orthotic stabilization of thoracolumbar injuries. A biomechanical analysis of the Jewett hyperextension orthosis. **Spine 15:**654–661, 1990
36. Reid DC, Hu R, Davis LA, Saboe LA: The nonoperative treatment of burst fractures of the thoracolumbar junction. **J Trauma 28:**1188–1194, 1988
37. Roland M, Fairbank J: The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. **Spine 25:**3115–3124, 2000
38. Roland M, Morris R: A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. **Spine 8:**141–144, 1983
39. Schnee CL, Ansell LV: Selection criteria and outcome of operative approaches for thoracolumbar burst fractures with and without neurological deficit. **J Neurosurg 86:**48–55, 1997
40. Shen WJ, Liu TJ, Shen YS: Nonoperative treatment versus posterior fixation for thoracolumbar junction burst fractures without neurologic deficit. **Spine 26:**1038–1045, 2001
41. Shen WJ, Shen YS: Nonsurgical treatment of three-column thoracolumbar junction burst fractures without neurologic deficit. **Spine 24:**412–415, 1999
42. Siebenga J, Leferink VJ, Segers MJ, Elzinga MJ, Bakker FC, Haarman HJ, et al: Treatment of traumatic thoracolumbar spine fractures: a multicenter prospective randomized study of operative versus nonsurgical treatment. **Spine 31:**2881–2890, 2006
43. Stratford PW, Binkley JM, Riddle DL, Guyatt GH: Sensitivity to change of the Roland-Morris Back Pain Questionnaire: part 1. **Phys Ther 78:**1186–1196, 1998
44. Thomas KC, Bailey CS, Dvorak MF, Kwon B, Fisher C: Comparison of operative and nonoperative treatment for thoracolumbar burst fractures in patients without neurological deficit: a systematic review. **J Neurosurg Spine 4:**351–358, 2006
45. Tropiano P, Huang RC, Louis CA, Poitout DG, Louis RP: Functional and radiographic outcome of thoracolumbar and lumbar burst fractures managed by closed orthopaedic reduction and casting. **Spine 28:**2459–2465, 2003
46. Von Korff M, Jensen MP, Karoly P: Assessing global pain severity by self-report in clinical and health services research. **Spine 25:**3140–3151, 2000
47. Weinstein JN, Collalto P, Lehmann TR: Thoracolumbar "burst" fractures treated conservatively: a long-term follow-up. **Spine 13:**33–38, 1988
48. Willen J, Anderson J, Toomoka K, Singer K: The natural history of burst fractures at the thoracolumbar junction. **J Spinal Disord 3:**39–46, 1990
49. Wood K, Butterman G, Mehbod A, Garvey T, Jhanjee R, Sechriest V: Operative compared with nonoperative treatment of a thoracolumbar burst fracture without neurological deficit: a prospective, randomized study. **J Bone Joint Surg Am 85:** 773–781, 2003
50. Yi L, Jingping B, Gele J, Baoleri X, Taixiang W: Operative versus non-operative treatment for thoracolumbar burst fractures without neurological deficit. **Cochrane Database Syst Rev:**CD005079, 2006

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