Treatment of thoracolumbar burst fractures: extended follow-up of a randomized clinical trial comparing orthosis versus no orthosis

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OBJECTIVE A multicenter, prospective, randomized equivalence trial comparing a thoracolumbosacral orthosis (TLSO) to no orthosis (NO) in the treatment of acute AO Type A3 thoracolumbar burst fractures was recently conducted and demonstrated that the two treatments following an otherwise similar management protocol are equivalent at 3 months postinjury. The purpose of the present study was to determine whether there was a difference in long-term clinical and radiographic outcomes between the patients treated with and those treated without a TLSO. Here, the authors present the 5- to 10-year outcomes (mean follow-up 7.9 ± 1.1 years) of the patients at a single site from the original multicenter trial.

METHODS Between July 2002 and January 2009, a total of 96 subjects were enrolled in the primary trial and randomized to two groups: TLSO or NO. Subjects were enrolled if they had an AO Type A3 burst fracture between T-10 and L-3 within the previous 72 hours, kyphotic deformity $< 35^\circ$, no neurological deficit, and an age of 16–60 years old. The present study represents a subset of those patients: 16 in the TLSO group and 20 in the NO group. The primary outcome measure was the Roland Morris Disability Questionnaire (RMDQ) score at the last 5- to 10-year follow-up. Secondary outcome measures included kyphosis, satisfaction, the Numeric Rating Scale for back pain, and the 12-Item Short-Form Health Survey (SF-12) Mental and Physical Component Summary (MCS and PCS) scores. In the original study, outcome measures were administered at admission and 2 and 6 weeks, 3 and 6 months, and 1 and 2 years after injury; in the present extended follow-up study, the outcome measures were administered 5–10 years postinjury. Treatment comparison between patients in the TLSO group and those in the NO group was performed at the latest available follow-up, and the time-weighted average treatment effect was determined using a mixed-effects model of longitudinal regression for repeated measures averaged over all time periods. Missing data were assumed to be missing at random and were replaced with a set of plausible values derived using a multiple imputation procedure.

RESULTS The RMDQ score at 5–10 years postinjury was 3.6 ± 0.9 (mean $\pm$ SE) for the TLSO group and 4.8 ± 1.5 for the NO group ($p = 0.486$, 95% CI -2.3 to 4.8). Average kyphosis was $18.3^\circ \pm 2.2^\circ$ for the TLSO group and $18.6^\circ \pm 3.8^\circ$ for the NO group ($p = 0.934$, 95% CI -7.8 to 8.5). No differences were found between the NO and TLSO groups with time-weighted average treatment effects for RMDQ 1.9 (95% CI -1.5 to 5.2), for PCS -2.5 (95% CI -7.9 to 3.0), for MCS -1.2 (95% CI -6.7 to 4.2) and for average pain 0.9 (95% CI -0.5 to 2.2).

CONCLUSIONS Compared with patients treated with a TLSO, patients treated using early mobilization without orthosis maintain similar pain relief and improvement in function for 5–10 years.

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KEY WORDS thoracolumbar; burst fracture; thoracolumbosacral orthosis; spine; trauma

ABBREVIATIONS MCS = Mental Component Summary; NO = no orthosis; NRS = Numeric Rating Scale; PCS = Physical Component Summary; RMDQ = Roland Morris Disability Questionnaire; TLSO = thoracolumbosacral orthosis.

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THORACOLUMBAR burst fractures without neurological deficit result in a relatively stable injury because both the anterior and the middle columns of the spine fail under a compression load without associated distraction, shear, rotation, or translational injury.^{7,14} Treatment of the neurologically intact patient is controversial but is generally nonsurgical given that surgery has not demonstrated superiority over nonoperative treatment with respect to pain and functional outcomes or cost-effectiveness.^{1,2,9,21,25} Nonoperative treatment has evolved from long-term bed rest in the hospital to early mobilization in an adjustable thoracolumbosacral orthosis (TLSO).^{5,6,11,13,15,16,19,20,22,24} The inherent stability of the fracture and the limitations associated with the use of a brace, including accessibility, cost, resource utilization, and patient deconditioning, lead to the question of whether a brace is even necessary.⁴

In a recent multicenter prospective randomized trial, we compared the treatment of AO Type A3 burst fractures between T10 and L-3 with kyphotic deformity less than 35° either with or without a TLSO.^{3,4} The trial showed that treatment with a TLSO is equivalent to treatment without an orthosis out to 24 months postinjury according to our primary outcome measure, the Roland Morris Disability Questionnaire (RMDQ), as well as all other secondary outcome measures. Thus, in select patients with a thoracolumbar burst fracture, progressing to early ambulation with education and directed rehabilitation is both safe and equally effective with or without a brace.

Concerns about treatment without an orthosis include loss of spinal alignment, increased risk of neurological deterioration, and worse pain and functional outcome; no differences in these factors between patients with TLSO and those without were observed over the 2-year follow-up period in our study. No studies have reported on the long-term outcomes of early ambulation without orthosis. Therefore, to determine whether the 2-year outcomes would be sustained over time, we conducted a 5- to 10-year follow-up of patients at a single site from the original multicenter trial. We hypothesized that, on longer-term follow-up, patients treated without an orthosis would be functionally and radiographically similar to those treated with a conventional TLSO.

Methods

Study Design

The study design of the primary trial, which was registered with the ClinicalTrials.gov database (NCT01741168), has been described in detail elsewhere.^{3,4} Briefly, 110 patients were screened at three trial centers between July 2002 and January 2009. Patients were eligible for inclusion if they had an isolated AO Type A3 burst fracture between T-10 and L-3 within the previous 3 days, kyphotic deformity < 35°, no neurological deficit, and an age of 16–60 years old. The AO Type A3 fractures are considered relatively stable burst fractures that exclude the mechanism of flexion-distraction or rotation-shear (AO Type B and C fractures, respectively).^{14,18} As such, the posterior ligamentous complex is considered to be intact. Participants were randomly assigned by 1:1 allocation to the TLSO or no

orthosis (NO) treatment group based on a concealed, computer-generated, site-specific randomization list. Subjects were stratified based on workers' compensation status and severity of kyphotic deformity (< 20° vs ≥ 21°). Patients in the TLSO group were maintained on strict bed rest until fitted with a TLSO (Aspen Medical Products). Afterward, they were mobilized in the brace by a physiotherapist. All patients were instructed to wear the brace at all times, except when lying down, for a total of 10 weeks and to begin weaning from the brace at 8 weeks. Patients randomized to the NO group were mobilized immediately as tolerated by a physiotherapist with restrictions to limit bending and rotating through their trunk. They were encouraged to return to normal activities after 8 weeks.

Extended Follow-Up

The 36 subjects enrolled at one of the three study sites were contacted 5–10 years after their injury and were asked to participate in a posttrial follow-up study. Study approval was obtained from our institutional research ethics board.

Our primary outcome measure remained the RMDQ, which was administered at the last follow-up a minimum of 5 years postinjury. Secondary outcome measures included the 12-Item Short-Form Health Survey (SF-12) Mental Component Summary (MCS) and Physical Component Summary (PCS) scores (SF-36 in the original study), satisfaction, Numeric Rating Scale (NRS) for back pain, and posttraumatic kyphosis. In the original study, the outcome measures were administered at admission and 2 and 6 weeks, 3 and 6 months, and 1 and 2 years after injury; in the present extended follow-up study, outcome measures were administered 5–10 years postinjury.

The RMDQ evaluates 24 items to derive a score that varies between 0 (no disability) and 24 (severe disability).¹⁷ The SF-36 and SF-12 scores range from 0 to 100, with higher scores indicating less severe symptoms.¹⁰ The SF-36 was used during the initial 2-year follow-up period, and the SF-12 was administered at the 5- to 10-year follow-up. The SF-12 and SF-36 summary scores are highly correlated and directly comparable.^{12,23} The NRS for back pain ranged from 0 to 10, with lower scores indicating less severe symptoms. Satisfaction with treatment was assessed on a 7-point scale, with 7 indicating complete satisfaction. Kyphosis was measured based on the Cobb technique as the angle measured between the perpendicular to the superior and inferior endplate of the vertebral body above and below the fractured level, respectively.

Statistical Analysis

Data analysis was performed using PAWS Statistics version 23 (SPSS Inc.). Chi-square tests and unpaired t-tests were used to compare the present study participants to the cohort of patients from the primary trial not included in the present study (36 vs 60 patients), and to compare the present study participants with missing data at the final follow-up to those who had complete data (13 vs 23 patients). Missing data were assumed to be missing at random and were replaced with a set of plausible values derived using a multiple imputation procedure with 10 it-

erations, taking all time points into consideration. Treatment comparison between patients in the TLSO group and those in the NO group was performed at the latest available follow-up (5–10 years) using a Student t-test.

For the secondary analysis, the time-weighted average treatment effect was determined with complete cases analysis (that is, using the original data without imputed data) using a mixed-effects model of longitudinal regression for repeated measures averaged over all time periods (admission and 2 and 6 weeks, 3 and 6 months, and 1, 2, and 5–10 years postinjury). The main effects of time and treatment as well as time and treatment interactions were assessed, accounting for the correlation among the outcome scores in the same patient. Treatment (NO vs TLSO) and time (continuous) were included as fixed variables, and subject was included as a random variable. A comparative analysis was performed using the imputed full data set. A p value < 0.05 was considered statistically significant. No adjustments were made for multiple comparisons.

Results

All 36 patients from one of the sites participating in the original trial were enrolled in the long-term follow-up. Sixteen patients had been randomized to the TLSO group and 20 to the NO group. For the long-term follow-up, 23 patients had data, 8 were lost to follow-up, 2 declined to participate, 2 were out of the country, and 1 was deceased. There were no differences in baseline characteristics between the subjects who returned for a long-term follow-up (23 patients) and those who did not (13 patients). The average follow-up among those participating in the long-term study was 7.9 ± 1.1 (range 5.9–9.5 years). The proportion of enrollees who supplied data at each follow-up visit was 100% at admission and 2 weeks postinjury, 97% at 6 weeks and 3 months, 92% at 6 and 12 months, 86% at 2 years, and 64% at 5–10 years. Of the 23 patients who completed the long-term follow-up, 25% (3 of 12) in the NO group and 18.2% (2 of 11) in the TLSO group reported a change in their work status to modified, short-term disability, or long-term disability ($p = 0.692$). Regular medication for back pain was used by 8.3% (1 of 12) of patients in the NO group and 18.2% (2 of 11) of patients in the TLSO group ($p = 0.774$). Patients participating in the long-term follow-up were more likely to smoke, had more pain at baseline, and were less likely to receive compensation than the patient cohorts from the other primary trial sites not included in the present study. However, comparisons of patient-rated outcome measures at the 12-month follow-up visit were not different between the two groups (Table 1).

At the long-term follow-up, the RMDQ score was 3.6 ± 0.9 (mean $\pm$ standard error) for the TLSO group and 4.8 ± 1.5 for the NO group ($p = 0.486$, 95% CI -2.3 to 4.8). No differences in pain, PCS, and MCS scores were found between the TLSO and NO groups (Table 2). At the long-term follow-up, satisfaction in the TLSO group was comparable to that in the NO group ($p = 0.113$). Average kyphosis was similar between the two groups at 5–10 years postinjury ($18.3^\circ \pm 2.2^\circ$ for TLSO group and $18.6^\circ \pm 3.8^\circ$ for NO group, $p = 0.934$, 95% CI -7.8 to 8.5).

The overall RMDQ was not significantly different be-

TABLE 1. Comparison of baseline characteristics and outcomes for patients enrolled in the primary trial and included in the current study versus those not included in the current study

Parameter	Current Study Site	Sites Not Included in Current Study	p Value
No. of patients	36	60	
Mean age in yrs	40.8 ± 16.3	39.7 ± 14.2	0.740
No. of women (%)	14 (38.9)	15 (25.0)	0.151
Mean admission kyphosis in degrees	12.7 ± 5.1	14.9 ± 7.9	0.213
No. w/ kyphosis $\geq 20^\circ$ (%)	6 (16.7)	4 (6.7)	0.120
No. of smokers (%)	18 (50.0)	13 (21.7)	0.004
Level of fracture (no. [%])			
T-11	3 (8.3)	1 (1.7)	0.080
T-12	10 (27.8)	8 (13.3)	
L-1	18 (50.0)	32 (53.3)	
L-2	4 (11.1)	11 (18.3)	
L-3	1 (2.8)	8 (13.3)	
Compensation* (no. [%])	5 (13.9)	24 (40.0)	0.005
RMDQ at enrollment	18.6 ± 5.3	17.3 ± 5.3	0.243
SF-36 PCS at enrollment	28.0 ± 9.1	29.7 ± 10.9	0.431
SF-36 MCS at enrollment	49.5 ± 11.4	51.2 ± 12.8	0.523
Average pain at enrollment	6.5 ± 2.7	5.2 ± 2.2	0.018
Satisfaction at enrollment	6.3 ± 1.7	6.6 ± 1.4	0.470
RMDQ at 12-mo FU	5.0 ± 6.2	3.7 ± 4.6	0.276
SF-36 PCS at 12-mo FU	44.5 ± 11.8	45.8 ± 9.8	0.603
SF-36 MCS at 12-mo FU	53.0 ± 9.1	52.5 ± 8.5	0.806
Average pain at 12-mo FU	2.3 ± 2.3	1.6 ± 1.5	0.123
Satisfaction at 12-mo FU	6.3 ± 1.7	6.5 ± 1.3	0.609

FU = follow-up.

* Receiving workers' compensation, Insurance Corporation of British Columbia, or applications pending.

tween TLSO and NO from admission to 5–10 years postinjury ($p = 0.161$; Table 3 and Fig. 1A). Likewise, no difference was found between the time-weighted average treatment effects for all other secondary outcomes (Fig. 1B–E). Repeat analysis using multiple imputation for missing data showed no significant differences between the TLSO and NO groups. Treatment effect estimates for the multiple imputation analysis ranged from 2.0 to 2.6 for RMDQ, -3.8 to -1.4 for PCS, -2.7 to -0.3 for MCS, 0.9 to 0.7 for pain, and -1.1 to 0.3 for satisfaction. In both groups, RMDQ, PCS, MCS, and pain improved with time from admission for most time points until 6 months post injury (Fig. 1; $p < 0.01$ at all time points up to 6 months). Overall satisfaction with treatment did not change with time ($p = 0.930$).

Discussion

The longer-term follow-up results at one center from an original multicenter trial showed that, as compared with patients treated with a TLSO, those patients treated using early mobilization without orthosis maintain similar pain relief and functional improvement through 5–10 years after sustaining a stable AO Type A3 thoracolumbar burst

TABLE 2. Comparison of mean clinical and radiographic outcomes at the final follow-up at 5–10 years postinjury

Parameter	NO Group	TLSO Group	Treatment Effect	95% CI	p Value
RMDQ score*	4.8 ± 1.5	3.6 ± 0.9	1.3	–2.3 to 4.8	0.486
PCS score†	45.0 ± 3.8	46.5 ± 3.2	–1.5	–11.7 to 8.8	0.778
MCS score†	55.2 ± 2.4	55.8 ± 2.1	–0.6	–7.8 to 6.7	0.868
Average pain score*	2.9 ± 0.7	2.1 ± 0.6	0.9	–1.0 to 2.8	0.378
Satisfaction score	5.6 ± 0.5	6.5 ± 0.4	–0.9	–2.0 to 0.2	0.113
Kyphosis in degrees	18.6 ± 3.8	18.3 ± 2.2	0.4	–7.8 to 8.5	0.934

Values expressed as the mean ± standard error, unless indicated otherwise. Data are derived using multiple imputation and a Student t-test.

* Lower score indicates less severe symptoms.

† Mean summary scores are based on normative data and have a mean ± standard deviation of 50 ± 10.

fracture without neurological injury. Although many studies have shown that nonsurgical treatments such as body casting or bracing are safe and effective,^{5,11,19,20} the present study is the first to report on the long-term outcomes in treating these fractures without any external orthosis.

Our study revealed that patients treated with or without a TLSO can expect a significant improvement of symptoms in terms of RMDQ and pain over the first 6 months to 1 year, with little or no further change between 2 and 10 years after injury. The favorable clinical outcomes reported here are in agreement with those in previous studies of conservative treatment.^{9,11,25} In a randomized clinical trial by Wood et al.,²⁵ patients treated nonoperatively with a cast or brace were compared with those treated surgically at 4 and 20 years' follow-up. At 4 years after injury, the nonsurgically treated patients had residual disability (median RMDQ Score 2, range 0–24) and pain (median visual analog scale score 1.5 cm, range 0–9 cm) similar to that in our patients but a slight improvement in function according to the RMDQ score between the 4- and 20-year time points (median RMDQ Score 1, range 0–9). Furthermore, in the present study, at 5–10 years after injury, there was no deterioration in ability or increased pain in patients treated without orthosis compared to those treated with TLSO.

Consistent with the clinical outcome, patients treated with or without orthosis returned to work and required

minimal medications for back pain. Furthermore, regardless of the treatment modality, patients continued to be satisfied with their treatment at 5–10 years after injury.

Radiographic analysis revealed, regardless of treatment modality, an average progression of approximately 7° in the kyphosis angle from admission (NO 12° vs TLSO 13°) to 2 weeks after injury (NO 17° vs TLSO 18°) and little or no progression during the 5–10 years' follow-up (NO 19° vs TLSO 18°). Likewise, in a cohort study of 60 patients treated conservatively (brace), Jaffray et al.¹¹ reported an average increase in kyphotic deformity from 17° (range 5°–29°) to 20° (range 1°–28°) from admission to 3 months postinjury. The average kyphosis documented by Wood et al.²⁵ at 20 years after injury was 19° for conservatively treated patients. Our results are consistent with those of previous studies showing the natural history of thoracolumbar burst fractures more than 10 years after injury and confirm no increased loss of spinal alignment in patients treated with or without an external orthosis.

We acknowledge that this study has some limitations. First, our analysis included participants from one site of a larger trial (within-subgroup effect). Therefore, the number of patients was not prespecified, so ensuring adequate statistical power was not possible. However, to minimize the selection bias and baseline incomparability inherent in a subgroup analysis, end points were predefined and treatment assignment was based on a site-specific randomization list.⁸ Moreover, patients in the present study were more likely to smoke, had more pain at baseline, and were less likely to receive compensation than the cohort of patients from the primary trial that was not included in the present study. These potentially prognostic factors for this patient population were probably not influential as no difference between treatment groups emerged in the long-term follow-up. Additionally, post hoc comparison with the cohort from the other primary trial sites revealed no differences in 12-month outcome measures. Nonetheless, these behavioral traits should be considered when applying these findings to the general population. Second, we were unable to obtain all outcomes for all participants because of loss to follow-up. However, the longitudinal mixed-effects models used in the main analysis relied on the population average of all available data while accounting for missing values at random. In addition, analysis using a multiple imputation procedure yielded consistent results. Third, satisfaction was much higher than reported

TABLE 3. Overall means and treatment effects of secondary outcomes averaged across all follow-up time points during the 5–10 years of follow-up

Parameter	NO Group	TLSO Group	Treatment Effect (95% CI)
RMDQ score*	10.0 ± 1.1	8.1 ± 1.2	1.9 (–1.5 to 5.2)
PCS score†	37.1 ± 1.8	39.6 ± 1.9	–2.5 (–7.9 to 3.0)
MCS score†	51.3 ± 1.7	52.5 ± 2.0	–1.2 (–6.7 to 4.2)
Average pain score*	3.6 ± 0.4	2.8 ± 0.5	0.9 (–0.5 to 2.2)
Satisfaction score	6.2 ± 0.2	6.7 ± 0.2	–0.4 (–1.1 to 0.3)
Kyphosis in degrees	19.1 ± 1.9	17.8 ± 2.1	2.0 (–3.8 to 7.8)

Values expressed as the mean ± standard error, unless indicated otherwise. Overall mean, standard error, treatment effect, and 95% confidence interval are derived using mixed-effects model for repeated measures.

* Lower score indicates less severe symptoms.

† Mean summary scores are based on normative data and have a mean ± standard deviation of 50 ± 10.

FIG. 1. Outcomes at each follow-up visit through the long-term follow-up of 5–10 years: RMDQ (A), PCS (B), MCS (C), average pain (D), and satisfaction with symptoms (E). Error bars indicate the 95% confidence interval.

previously,⁶ probably because there was a ceiling effect, with the majority of patients reporting 6 out of a maximum score of 7 at baseline.

Conclusions

In summary, the results of this study reassure health care professionals that treating a thoracolumbar burst fracture patient with early ambulation is both safe and effective with or without a TLSO through 5–10 years postinjury.

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Disclosures

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Conception and design: C Bailey. Acquisition of data: C Bailey, Alrehaili, Rasoulinejad, Gurr, S Bailey. Analysis and interpretation of data: C Bailey, Urquhart. Drafting the article: C Bailey, Urquhart. Critically revising the article: C Bailey, Fisher, Rasoulinejad. Reviewed submitted version of manuscript: all authors. Approved the final version of the manuscript on behalf of all authors: C Bailey. Statistical analysis: Urquhart. Administrative/technical/material support: Urquhart, Alrehaili, Fleming. Study supervision: C Bailey.

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