THE JOURNAL OF BONE & JOINT SURGERY

■ SPINE

The role of fusion in the management of burst fractures of the thoracolumbar spine treated by short segment pedicle screw fixation

A PROSPECTIVE RANDOMISED TRIAL

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The purpose of this study was to determine whether patients with a burst fracture of the thoracolumbar spine treated by short segment pedicle screw fixation fared better clinically and radiologically if the affected segment was fused at the same time. A total of 50 patients were enrolled in a prospective study and assigned to one of two groups. After the exclusion of three patients, there were 23 patients in the fusion group and 24 in the non-fusion group. Follow-up was at a mean of 23.9 months (18 to 30). Functional outcome was evaluated using the Greenough Low Back Outcome Score. Neurological function was graded using the American Spinal Injury Association Impairment Scale. Radiological outcome was assessed on the basis of the angle of kyphosis.

Peri-operative blood transfusion requirements and duration of surgery were significantly higher in the fusion group ($p = 0.029$ and $p < 0.001$, respectively). There were no clinical or radiological differences in outcome between the groups (all outcomes $p > 0.05$). The results of this study suggest that adjunctive fusion is unnecessary when managing patients with a burst fracture of the thoracolumbar spine with short segment pedicle screw fixation.

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doi:10.1302/0301-620X.94B8.28311 $2.00

J Bone Joint Surg Br 2012;94-B:1101–6.
Received 12 September 2011; Accepted after revision 27 March 2012

The ideal treatment for patients with a burst fracture of the thoracolumbar spine remains controversial.[1,2] The surgical management aims to realign the spine, maintain its stability and optimise the neurological outcome. Various methods of surgical treatment have achieved these objectives but are fraught with complications. Anterior corpectomy and fixation has given good results,[3,4] but the risk of morbidity and the technical expertise required precludes its routine use. Posterior fixation offers easy exposure and a less morbid approach, but with a high incidence of implant failure and recurrent kyphosis.[5] Among the many implants available for posterior fixation, pedicle screws have proved their superiority as it is possible with their use to engage all three columns of the spine and effect reduction with a short segment construct.[6-8]

Several techniques have been used to augment the stability of posterior implants, including spinal fusion. However, evidence of the need for posterior spinal fusion remains inconclusive. Several studies recommend posterior fusion,[9-12] but others have claimed that it affords no benefit.[13-17] The purpose of this study, therefore, was to compare short segment pedicle screw fixation alone with short segment fixation and posterior fusion for patients with a burst fracture of the thoracolumbar spine. We considered the relative duration of surgery, peri-operative blood loss, loss of correction and functional outcome of the two methods.

Patients and Methods

This was a single-blinded, randomised trial of patients with a burst fracture of the thoracolumbar spine who had been treated between January 2009 and January 2010. Patients with or without neurological deficit were included. Exclusion criteria comprised: a refusal to stop smoking for the period of the trial; if non-operative treatment could be attempted; psychosis of the patient or unlikely to comply with post-operative restriction of activity; if they had bedsores; or a follow-up of < 15 months. A detailed initial neurological examination used the American Spinal Injury Association Impairment Scale (AIS).[18] Radiological evaluation of the pattern and extent of the fracture was carried out using CT and assessment of the neural elements with MRI. The McCormack load sharing score[19] was calculated for the

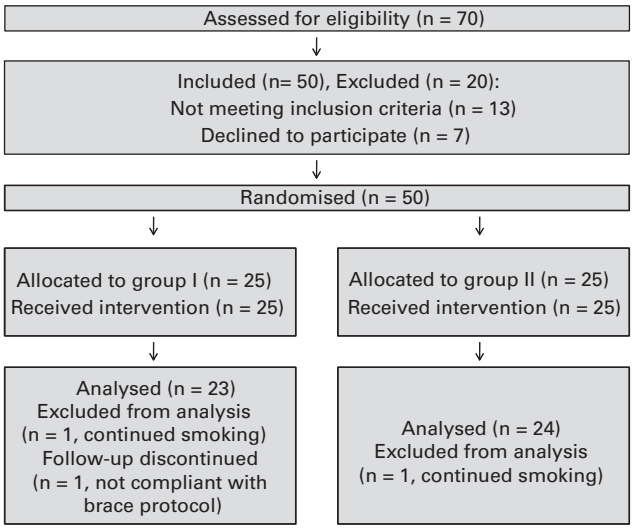


Fig. 1

Flow of participants in the trial.

fractured vertebral body for each case on the basis of pre-operative CT images. The score quantifies the comminution of the anterior column from 3 (least) to 9 (most), and predicts the success of posterior fixation in cases where the score is ≤ 6.

A total of 50 patients were assigned to one of two treatment groups by random computer generated sequence, with 25 patients in each group. Group 1 patients were treated by posterior short segment pedicle screw fixation and posterior fusion. Group 2 patients were treated by short segment pedicle screw fixation alone. Through a posterior midline exposure, screws were inserted freehand. Titanium top-loading screws (Pitkar Orthotools Pvt. Ltd, Pune, India), 6.5 mm and 5.5 mm in diameter, were used depending on the morphology of the pedicle. No patient underwent laminectomy and direct decompression. Posterior fusion was carried out after decortication of the posterior elements. Autologous bone graft was harvested from the posterior iliac crest and laid over the bleeding bone. In both groups meticulous haemostasis was achieved before closure: no drain was inserted in group 1. Post-operatively early mobilisation was encouraged and a thoracolumbar brace was worn for three months. Excessive strenuous work and forward bending were prohibited.

Radiological, neurological and functional evaluation was undertaken pre-operatively and at final review, with a minimum follow-up of 15 months. Radiologically, the angle of kyphosis was measured by Cobb's method using the superior endplate of the vertebra above and the inferior endplate of the vertebra below the fracture.[20,21] Two values were calculated: the absolute angle of kyphosis, and the deviation of the curvature in each case from the expected value in normal, asymptomatic subjects.[22] Both groups were compared in terms of duration of surgery and the need for peri-operative blood transfusion. Any complication in either group was recorded separately. Pain at the donor site in group 1 was evaluated on a visual analogue scale (VAS) of 0 to 10. Functional outcome was evaluated at final review using the Greenough Low Back Outcome Scale.[23]

Statistical analysis. The minimum sample size for this study was calculated on the basis of the angle of kyphosis. The minimum expected difference between the two groups was chosen to be 3° at final follow-up. Based on a p-value of 0.05 and power of 80%, we calculated that a minimal sample size of 44 was needed. Based on an anticipated dropout rate of 10%, 50 cases were enrolled in the study, with 25 in each group.

Qualitative baseline characteristics were compared in both groups using Fisher's exact test; continuous variables such as the angle of kyphosis, peri-operative transfusion requirements, duration of surgery and functional scores were compared using a two- tailed Wilcoxon–Mann-Whitney test. Paired analysis in each group was done using a two-tailed Wilcoxon's signed ranks test. Statistical analysis was carried out using SPSS version 19 (SPSS Inc., Chicago, Illinois); statistical significance was set with a p-value of 0.05.

Results

The flow of patients in the trial is depicted in Figure 1. All the patients were treated and appropriately assessed. Three patients were subsequently excluded at final analysis: two patients (one in each group) were unable to stop smoking and one in group 1 discarded their brace with implant failure two months post-operatively. This left a total of 47 patients at a mean final follow-up of 23.9 months (SD 3.59, 18 to 30).

The baseline demographics are shown in Table I. The two groups are comparable. The mean age was 29.4 years (15 to 55); they underwent surgery at a mean interval of 8.2 days (SD 6.0, 1 to 32) from the time of injury. The mean load-sharing McCormack score[19] was ≤ 6 (4 to 6) for all patients in the study.

The results are summarised in Table II. In group I the increase in the angle of kyphosis at final review was statistically significant ($p < 0.0001$, Wilcoxon's signed ranks test). There were two cases of implant failure at 11 and 15 months after surgery (Fig. 2). At the final follow-up the mean VAS pain score at the donor site was 1.56 (0 to 4). One patient had pain at the donor site that measured 6 on the VAS. He was given a local steroid injection on two occasions; at the time of final review at 28 months he reported a decrease in his pain to 4 on the VAS.

In group 2 both the decrease in angle of kyphosis post-operatively and the subsequent increase at final follow-up were statistically significant ($p < 0.0001$). In one patient the implant failed seven months post-operatively.

Patient age ($p = 0.966$), gender distribution ($p = 1.00$), interval between injury and surgery ($p = 0.089$) and load-sharing score ($p = 0.508$) were similar between the two groups. The mean operating time was significantly higher

Table I. Baseline demographic characteristics of the two groups; mean values are presented with standard deviation in parentheses

	Group 1	Group 2	Total
Patients (n)	23	24	47
Mean (SD) age (yrs)	29.6 (10.2)	29.3 (9.5)	29.4 (9.7)
Male:female	15:8	15:9	30:17
Mean (SD) load sharing score	5.5 (0.59)	5.6 (0.58)	5.5 (0.58)
Level of fracture (n, %)			
D11	1 (*4.3*)	1 (*4.2*)	2 (*4.3*)
D12	7 (*30.4*)	6 (*25.0*)	13 (*27.7*)
L1	12 (*52.2*)	12 (*50.0*)	24 (*51.1*)
L2	1 (*4.3*)	4 (*16.7*)	5 (*10.6*)
L3	1 (*4.3*)	1 (*4.2*)	2 (*4.3*)
L4	1 (*4.3*)	-	1 (*2.1*)
Neurological grade (AIS*) (n, %)			
A	8 (*34.8*)	10 (*41.7*)	18 (*38.3*)
B	1 (*4.3*)	2 (*8.3*)	3 (*6.4*)
C	8 (*34.8*)	6 (*25.0*)	14 (*29.8*)
D	3 (*13.0*)	2 (*8.3*)	5 (*10.6*)
E	3 (*13.0*)	4 (*16.7*)	7 (*14.9*)
Mean (SD) time to surgery (days)	7.7 (6.9)	8.8 (5.1)	8.2 (6.0)
Mean (SD) follow-up (mths)	24.2 (3.7)	23.6 (3.6)	23.9 (3.6)

* AIS, American Spinal Injury Association Impairment Scale

Table II. Comparison of variables between two groups

Parameter	Group 1	Group 2	p-value*
Mean (SD) age (yrs)	29.6 (10.2)	29.3 (9.5)	0.966
Male:female	15:8	15:9	1.00†
Mean (SD) time to surgery (days)	7.7 (6.9)	8.8 (5.1)	0.089
Mean (SD) load sharing score	5.5 (0.59)	5.6 (0.58)	0.508
Mean (SD) blood transfusion (ml)	486.5 (175)	378.0 (140)	0.029
Mean (SD) operating time (mins)	142.4 (27.8)	107.5 (11.1)	< 0.001
Mean (SD) absolute kyphotic angle (°)			
Pre-operative	18.46 (7.4)	16.98 (11.7)	0.242
Post-operative	5.03 (6.1)	4.93 (8.7)	0.924
Final follow-up	10.51 (6.9)	8.51 (9.4)	0.366
Loss of correction (°)	5.48 (5.0)	3.58 (3.9)	0.058
Mean (SD) kyphosis (deviation from normal, °)			
Pre-operative	17.86 (8.3)	16.39 (10.7)	0.283
Post-operative	4.42 (9.1)	4.38 (8.1)	0.840
Final follow-up	9.91 (8.9)	7.92 (9.7)	0.401
Mean (SD) Greenough Low Back Outcome score	33.35 (15.2)	34.92 (16.2)	0.741
Mean (SD) follow-up (mths)	24.22 (3.7)	23.63 (3.6)	0.586

* two-tailed Mann-Whitney test, unless otherwise stated
† two-tailed Fisher's exact test

in group 1 ($p < 0.001$), as were the peri-operative transfusion requirements ($p = 0.029$). There was no significant difference in outcome parameters or functional scores between the two groups at any stage (Fig. 3). The mean loss of correction in both groups was not statistically significant ($p = 0.058$). The neurological profiles of the patients before surgery and at final review were similar in both groups (Table III). There was no neurological deterioration in any patient in either group.

Discussion

Short segment pedicle screw fixation has emerged as the treatment of choice for patients with a burst fracture of the thoracolumbar spine.[8] Pedicle screws have a high pull-out and cut-out strength and can withstand high stresses without failure.[8] They can therefore achieve and maintain reduction of a short segment.

Despite these advantages, they are unable to prevent anterior collapse, especially in a highly comminuted fracture. Late

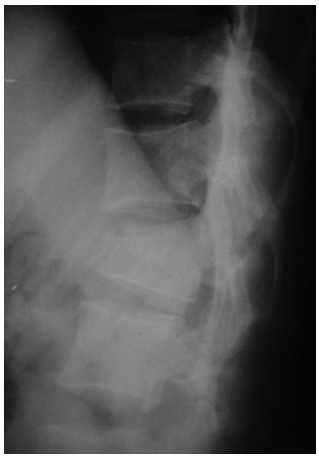
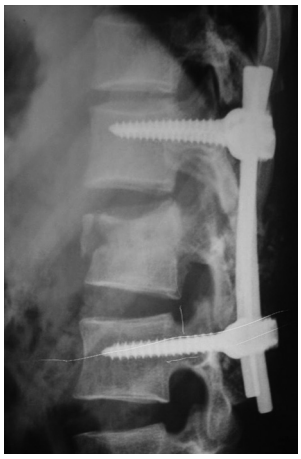


Fig. 2a

Fig. 2b



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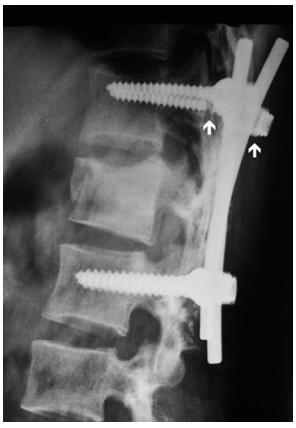

Fig. 2e

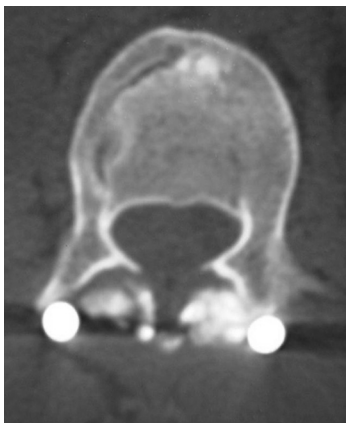

Fig. 2f

Fig. 2g

Fig. 2h

Imaging of a 24-year-old male patient with a burst fracture of the thoracolumbar spine treated by posterior short segment pedicle screw fixation and posterior fusion (group 1), with: pre-operative lateral radiograph (a) and axial CT cut (b), showing the amount of bursting and consequent retropulsion in the spinal canal; immediate post-operative lateral radiograph (c) showing restoration of vertebral height and CT (d) showing the effect of indirect decompression on the retropulsed bone; at 11 months post-operatively lateral radiograph (e) showing implant failure marked by arrows, and CT axial cut (f) showing restoration of spinal canal; g) CT coronal section showing pseudoarthrosis marked by arrow; and h) lateral radiograph after implant removal with minimal loss of correction.

complications such as implant failure with recurrent kyphosis can be troublesome. In an attempt to avoid such problems a number of modifications have been made to posterior constructs. These range from modifications of the system of fixation with the addition of a cross-connector or an extra screw at the fracture site, to procedures aimed at reducing the bone loss in the anterior column by transpedicular augmentation of the fractured vertebra, or kyphoplasty.

Opinion about the role of transpedicular augmentation of the fractured vertebra remains divided: Alanay et al[20] reported no benefit, whereas Liao et al[24,25] reported an improved outcome. Augmenting the anterior column by introducing cement has been shown to be of value in preventing collapse of the fractured vertebrae.[21,26] Shen et al[26] reported good results using vertebroplasty with calcium sulphate and short segment fixation. However, they excluded patients with a load-sharing score < 5, and hence included highly comminuted fractures that, according to conventional wisdom,[19] require anterior support.

A study conducted by Korovessis et al[27] compared the role of an anterior mesh cage with that of a simple posterior short segment fixation. They conceded that pain was improved only in the short segment group, and that the cage group needed a longer operating time, had greater blood loss and needed a longer hospital stay. Despite the lesser clinical benefit, an anterior cage maintained reduction better. The need for such a radical procedure for fractures with a load sharing score ≤ 6 remains debatable.

The mean intra-operative blood loss was much higher in the fusion group. The addition of a fusion increased the overall operating time by a third but did not affect the rate of recurrent kyphosis or the functional scores at final review. Patients in the fusion group reported some pain from the donor site.

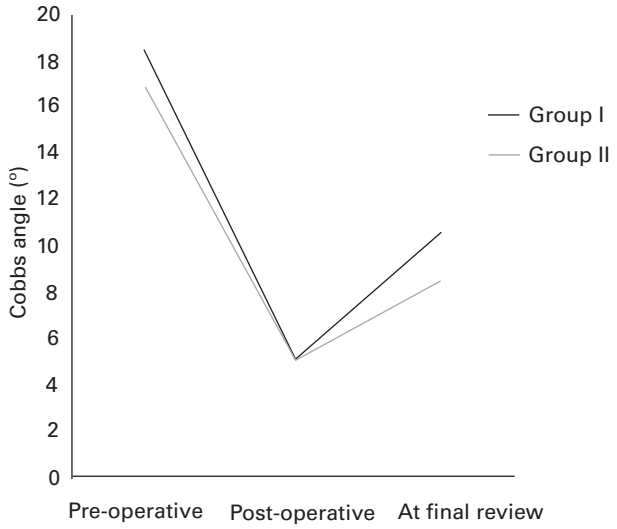

Fig. 3

Graph showing the mean kyphotic angle in both groups at various times during the study.

Table III. Neurological grading of the groups using the American Spinal Injury Association Impairment Scale (AIS)[18] pre-operatively and at final review

	Grade at final review				
Pre-operative grade	**AIS A**	**AIS B**	**AIS C**	**AIS D**	**AIS E**
Group 1					
AIS A (n = 8)	6	1	1	-	-
AIS B (n = 1)	-	-	1	-	-
AIS C (n = 8)	-	-	-	7	1
AIS D (n = 3)	-	-	-	1	2
AIS E (n = 3)	-	-	-	-	3
Group 2					
AIS A (n = 10)	7	1	2	-	-
AIS B (n = 2)	-	-	2	-	-
AIS C (n = 6)	-	-	1	5	-
AIS D (n = 2)	-	-	-	-	2
AIS E (n = 4)	-	-	-	-	4

The overall implant failure rate in our series was 6.4% (3 of 47); 8.7% (2 of 23) in the fusion group and 4.2% (1 of 24) in the non-fusion group.

The mean loss of correction in the fusion group was 5.5° compared to 3.6° in the non-fusion group. Although this difference was not statistically significant, it may be explained by the lack of posterior column support. Several authors[28,29] have shown that removal of the supraspinous and interspinous ligaments reduces the tension band effect of the posterior column. Sanderson et al[15] found that the loss of correction in their series of patients managed without fusion was less than that described in the literature with fusion. Similarly, Wang et al[14] attributed their apparently skewed results to the loss of soft tissue support caused by the increased exposure and tissue damage needed to perform a fusion. Laminectomy also potentially destabilises the spine[30]; the evidence supporting the need for decompression is lacking. A number of studies[31-33] have shown that there is no correlation between the canal clearance achieved and the subsequent clinical and neurological outcome.

The role of fusion is controversial. Qian et al[10] concluded that fusion significantly improves the clinical outcome and substantially reduces the incidence of recurrent kyphosis. A similar study by Wang et al[14] showed that the loss of vertebral body height correction, intra-operative blood loss and operating time were significantly greater in the fusion group than in the non-fusion group. Dai et al[13] found that posterior fixation without fusion yielded similar results to those of posterior fixation with fusion.

Uncontrolled series have shown that both procedures can give satisfactory results. Sanderson et al[15] fixed thoracolumbar fractures without fusion, with a mean loss of correction of 8° after a mean of 3.1 years. The results were reported to be satisfactory and comparable to those reported in the literature. Parker et al[9] reported successful results after treating all types of thoracolumbar spinal fracture with short segment fixation and fusion.

The mean follow-up in our study was 23.9 months. Although this may be perceived as short, published data[34,35] indicate that the first six months are the most critical, as this is the time when implant failure with recurrent kyphosis is most likely to occur. Consolidation of a fractured vertebra invariably occurs between six months and one year, thereby restoring the continuity of anterior column. Removal of the implants can then be carried out electively for cultural reasons,[14] as a part of a treatment protocol,[16] or because they have failed. Hardware may fail even after fusion has been achieved.[36] The only indication for implant removal in our series was its failure.

We acknowledge that patients in the non-fusion group will have symptoms after several years, even if these are slightly different from those of patients with fused spines. The capsule of the superior facet joint is directly violated in 30% of screw insertions.[37] This leads to altered mechanics of the motion segment immediately above the construct and contributes to degeneration of the facet, which may be seen after longer follow-up of these patients. As there is a paucity of literature about adjacent segment pathology in spines that have been instrumented but not fused, the closest clinical picture we can find is that of a fused spine with a pseudoarthrosis. A study conducted by Rahm and Hall[38] found that pseudoarthrosis protected against degeneration of the adjacent level, which suggests that the unfused spine may be similarly protected. It remains to be seen whether the function of the facet is preserved after the removal of implants from the unfused spine. Wang et al[14] removed implants in 32 of 58 patients within a year of surgery in both groups, but made no comment about the return of movement to the injured segment. Yang et al[16] removed the implants from 57 of 64 patients treated without fusion and reported an increase in segmental movement, though no

objective evidence was given. Non-elective implant removal in our series precludes deduction of any evidence regarding the incidence of degeneration and preservation of facetal function in fused and unfused spines.

We conclude that, for burst fractures of the thoracolumbar spine, the value of fusion in addition to short segment pedicle screw fixation is questionable. The outcome is similar whether or not fusion is undertaken.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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