Operative Compared with Nonoperative Treatment of a Thoracolumbar Burst Fracture without Neurological Deficit

A Prospective, Randomized Study

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Background: To our knowledge, a prospective, randomized study comparing operative and nonoperative treatment of a thoracolumbar burst fracture in patients without a neurological deficit has never been performed. Our hypothesis was that operative treatment would lead to superior long-term clinical outcomes.

Methods: From 1994 to 1998, forty-seven consecutive patients (thirty-two men and fifteen women) with a stable thoracolumbar burst fracture and no neurological deficit were randomized to one of two treatment groups: operative (posterior or anterior arthrodesis and instrumentation) or nonoperative treatment (application of a body cast or orthosis). Radiographs and computed tomography scans were analyzed for sagittal alignment and canal compromise. All patients completed a questionnaire to assess any disability they may have had before the injury, and they indicated the degree of pain at the time of presentation with use of a visual analog scale. The average duration of follow-up was forty-four months (minimum, twenty-four months). After treatment, patients indicated the degree of pain with use of the visual analog scale and they completed the Roland and Morris disability questionnaire, the Oswestry back-pain questionnaire, and the Short Form-36 (SF-36) health survey.

Results: In the operative group (twenty-four patients), the average fracture kyphosis was 10.1° at the time of admission and 13° at the final follow-up evaluation. The average canal compromise was 39% on admission, and it improved to 22% at the final follow-up examination. In the nonoperative group (twenty-three patients), the average kyphosis was 11.3° at the time of admission and 13.8° at the final follow-up examination after treatment. The average canal compromise was 34% at the time of admission and improved to 19% at the final follow-up examination. On the basis of the numbers available, no significant difference was found between the two groups with respect to return to work. The average pain scores at the time of the latest follow-up were similar for both groups. The preinjury scores were similar for both groups; however, at the time of the final follow-up, those who were treated nonoperatively reported less disability. Final scores on the SF-36 and Oswestry questionnaires were similar for the two groups, although certain trends favored those treated without surgery. Complications were more frequent in the operative group.

Conclusion: We found that operative treatment of patients with a stable thoracolumbar burst fracture and normal findings on the neurological examination provided no major long-term advantage compared with nonoperative treatment.

Level of Evidence: Therapeutic study, Level II-2 (poor-quality randomized controlled trial [e.g., <80% follow-up]). See Instructions to Authors for a complete description of levels of evidence.

Ninety percent of all spinal fractures occur in the thoracolumbar region, and burst fractures comprise approximately 10% to 20% of such injuries[1-4] (fifty-nine [14%] of 412 thoracolumbar fractures in one series[3] and 25,000 [15%] of 162,000 fractures in another[1]). Despite the fact that it is such a common fracture, there are various opinions regarding the ideal management, especially in patients without an associated neurological deficit.

Researchers have advocated both an operative[2,3,5-19] and a nonoperative approach[20-32]. Open reduction, arthrodesis, and

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internal fixation offers the possibilities of immediate stability, correction of deformity, early walking, reduced reliance on orthotic containment, and the theoretical protection against spinal malalignment or neurological injury when the patient is upright[5,11,18,19,33,34]. Nonoperative care, in the form of either a body cast or a brace, offers the avoidance of a surgical intervention with its attendant morbidity.

We are unaware of a prospective, randomized study comparing the two treatment options with respect to the evaluation of not only the radiographic and surgical results but also the patient-reported outcomes regarding pain, daily function, and return to work after long-term follow-up[1,7,21-23,27].

The purpose of this study was to test the hypothesis that neurologically intact patients with a thoracolumbar burst fracture who were managed with surgical intervention and rigid fixation over a minimum number of levels would have an improved outcome and higher satisfaction than would those who were managed with a nonoperative approach.

Materials and Methods

From 1992 through 1997, sixty-five individuals who were seen with a single burst-type fracture of the thoracolumbar junction (T10 to L2) without a neurological deficit were identified and evaluated for participation in a prospective, randomized study comparing operative and nonoperative treatment. The patients were enrolled from three associated level-I trauma facilities by two surgeons (K.W. and G.B.). Institutional review board approval was obtained at each institution before the study was initiated. The patients who met the inclusion criteria were invited to participate in a blind, computer-generated randomization process. Fifty-five patients met the inclusion criteria, and fifty-three of them agreed to participate. Twenty-seven individuals were randomized to receive nonoperative care, and twenty-six were randomized to surgical treatment.

Entrance criteria included all of the following: (a) an isolated burst fracture within the thoracolumbar region demonstrated on anteroposterior and lateral radiographs (Figs. 1-A through 1-E); (b) a computed tomography scan revealing a burst-type fracture with retropulsion of vertebral body bone posteriorly into the spinal canal; (c) no new neurological abnormality of the lower extremities or abnormality of bowel or bladder function; (d) presentation less than three weeks after the time of the injury; (e) an age between eighteen and sixty-six years; (f) no medical illnesses that would preclude an operative intervention; (g) no ongoing cancer, infection, bleeding disorder, or skin disease; and (h) an understanding of the English language. Concomitant stable compression fractures elsewhere in the spine were permitted if they did not require specific treatment.

Exclusionary criteria included (a) a closed-head injury (a score of <14 points on the Glasgow coma scale[35] on admission); (b) an open vertebral fracture; (c) a neurological deficit related to the fracture; (d) a loss of structural integrity within the posterior osteoligamentous complex (such as facet fracture-dislocation or flexion-distraction ligament disruption); and (e) a senile, osteopenic, or insufficiency fracture. A laminar fracture was neither an exclusionary criterion nor a contraindication for nonoperative treatment. No absolute degree of kyphosis, canal encroachment by bone, or anterior loss of height was a criterion for exclusion.

On admission to the randomization protocol, all participants indicated the degree of pain, with use of a 10-cm visual-analog scale[36], before they received treatment. The patients also completed a modification of the twenty-five-item questionnaire on spinal disability described by Roland and Morris[37] to assess any thoracolumbar dysfunction that they may have had before the injury.

Figs. 1-A through 1-E Case 5. Radiographs of the spine of a forty-nine-year-old man who was managed with only a thoracolumbosacral orthosis after sustaining a burst fracture of L1 following a fall at work. **Fig. 1-A** Anteroposterior radiograph made before treatment. **Fig. 1-B** Lateral radiograph made before treatment, showing 25° of kyphosis.

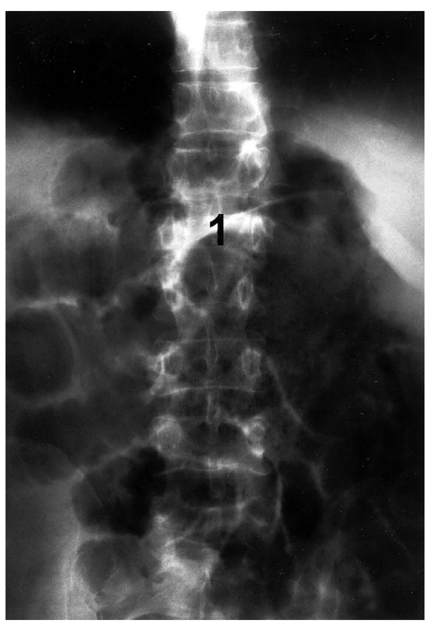

Fig. 1-A

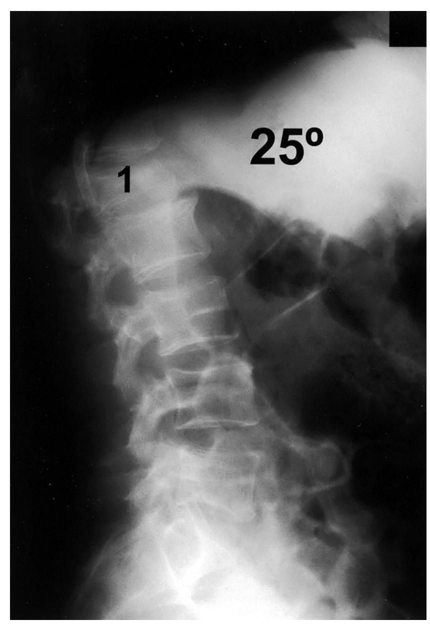

Fig. 1-B

Those participating in the study were initially managed with bed rest for two to five days until either the operation was performed or the cast or thoracolumbosacral orthosis was applied.

The patients who were managed with a body cast were placed in the supine position on a Risser-like cast table with a canvas belt temporarily wrapped around the waist of the cast. An anterior force was applied to reduce the fracture kyphosis. The patients who were managed with a thoracolumbosacral orthosis were placed with the spine in hyperextension to reduce the kyphosis and were fitted with a molded plaster cast that was then converted to an encompassing plastic jacket. No thigh extensions or shoulder straps were used. Patients wore the brace for twenty-four hours a day; however, they were allowed to remove it to take a shower with no bending or twisting. Casts were worn for eight to twelve weeks, depending on fracture-healing and patient comfort, and then the patient was managed with a thoracolumbosacral orthosis for an additional four to eight weeks. The patients who were treated with a thoracolumbosacral orthosis alone wore it for twelve to sixteen weeks (Figs. 1-A through 1-E).

The patients who were randomized to receive operative intervention were managed with either a short-segment (two to five-level) posterolateral spinal arthrodesis with pedicle screw-hook instrumentation and autologous iliac crest bone-grafting (Figs. 2-A through 2-E) or an anterior two-level fibular and rib-strut construct arthrodesis with local autogenous bone-grafting and instrumentation (Figs. 3-A through 3-D). A normal sagittal contour was obtained primarily by positioning on the operating table. The surgical approach was dictated solely by the preference of the surgeon. Regardless of the degree of osseous retropulsion, no formal attempt was made to decompress the neural canal.

The patients were followed clinically and radiographically at two, four, six, twelve, and twenty-four months, and then every twelve months thereafter. Kyphosis and loss of the anterior height of the vertebral body were calculated according to the method of Atlas et al.[38]. The computed tomography scan was repeated at two years, and the degree of canal compromise was calculated by dividing the available anteroposterior diameter of the canal space at the injured level by the average of the diameter of the canal space at the two uninjured vertebrae cephalad and caudad to the injured level. The presence of pseudarthrosis was assessed on plain radiographs and computed tomography scans.

At the time of the latest follow-up, the patients indicated the degree of pain on a 10-cm visual-analog scale[36] and completed the modified Roland and Morris disability questionnaire[37], the Oswestry back-pain questionnaire[39] (a measure of any longstanding or chronic spinal disability), and the Short Form-36 (SF-36) health survey[40].

Hospital and outpatient records were analyzed for patient demographics, comorbidity variables, method and type of injury, associated injuries, length of hospitalization, and any treatment-associated complications. We also compared the cost of treatment (the charges billed to insurance carriers, Workers' Compensation, or medical assistance) for the two groups by isolating the expenses related solely to the spinal fracture and its attendant care. We did not include the individuals who received care for other injuries as it was frequently

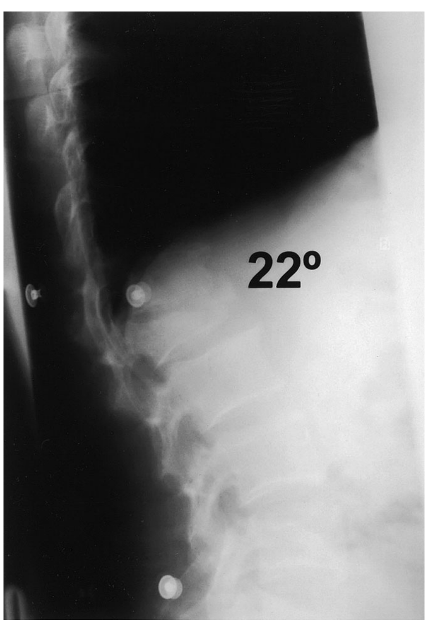

Fig. 1-C

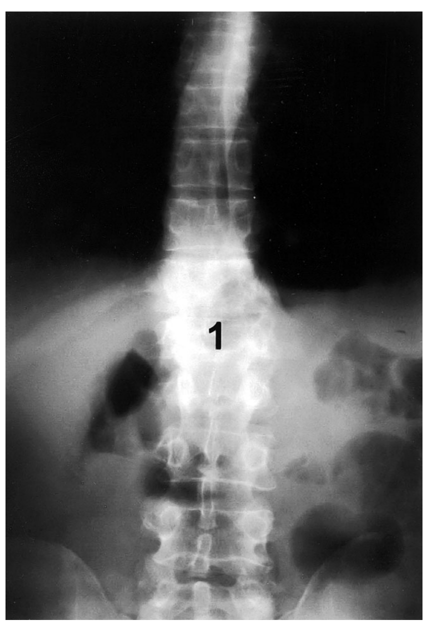

Fig. 1-D

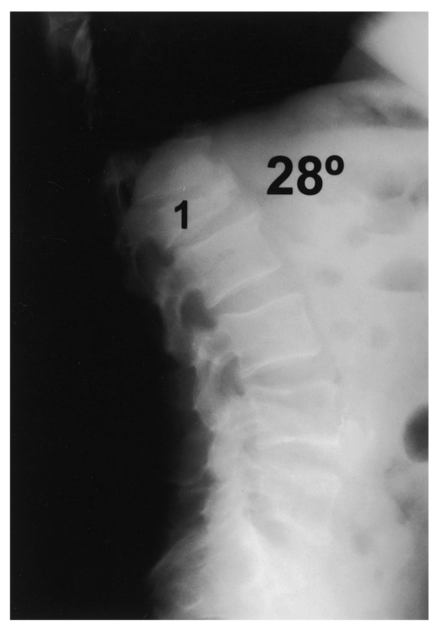

Fig. 1-E

Fig. 1-C Lateral radiograph of the spine, made with the patient in a thoracolumbosacral orthosis at the time of discharge from the hospital, demonstrating 22° of residual kyphosis. **Figs. 1-D and 1-E** Anteroposterior and lateral radiographs, made thirty-six months after the injury, showing 28° of local kyphosis. The patient-reported scores were 1 cm (of a possible 10 cm) on the visual-analog pain scale, 2 points on the Roland and Morris questionnaire, and 4 points on the Oswestry index.

Figs. 2-A through 2-E Case 6. A forty-two-year old man who was managed operatively after he sustained a burst fracture of L1 after a fall from a height at work. **Fig. 2-A** Anteroposterior radiograph made preoperatively. **Fig. 2-B** Lateral radiograph made preoperatively showing 11° of kyphosis.

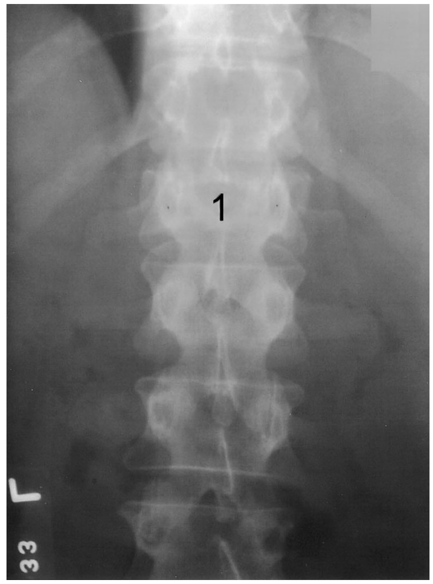

Fig. 2-A

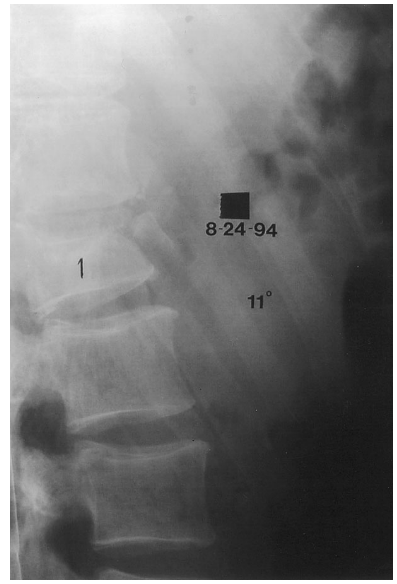

Fig. 2-B

impossible to apportion the charges.

Statistical evaluation included the use of the Student t test, Wilcoxon signed-rank test, Pearson correlation coefficient, and chi-square analysis. The Cochran-Mantel-Haenszel test and analysis of covariance were applied to control for covariates. The level of significance was set at $p < 0.05$. No adjustment for multiple testing was used.

Results

Of the fifty-three individuals (twenty-six who were treated operatively and twenty-seven who were managed nonoperatively) who agreed to participate, four (two from each group) were lost to follow-up as they could not be contacted. Two additional individuals, who were both in the nonoperative group, died from unrelated causes before the final follow-up examination could be performed. Both deceased individuals had been followed clinically for more than two years, and their radiographic data are included; however, the final results with respect to pain and function and the Oswestry and SF-36 questionnaires were not obtained. Thus, forty-seven patients (89%) were followed clinically and radiographically for a minimum of two years (average, forty-four months) (see Appendix). There were thirty-two men and fifteen women, and they were first seen between 1994 and 1998.

One individual with Parkinson disease who was assigned to treatment with a cast but was subsequently treated surgically because of an inability to tolerate the cast was thus excluded.

The most common etiology of the fractures was a motor-vehicle accident (twenty patients; 43%) followed by a fall (sixteen; 34%), a work-related injury (six; 13%), recreational trauma (four; 9%), and a sports injury (one; 2%). These types of injuries were evenly divided between the two treatment groups.

Twenty (43%) of the forty-seven patients were smokers at the time of the injury. They included sixteen (67%) of the twenty-four patients in the operative group and four (17%) of the twenty-three patients in the nonoperative group; the difference was significant ($p < 0.01$).

The mean duration of hospitalization was 7.9 days (range, two to seventeen days) in the group treated nonoperatively and 10.7 days (range, six to twenty-seven days) in the group treated operatively. The duration of hospitalization did not appear to be related to age, gender, or comorbidities.

Fig. 2-C

Axial computed tomography scan made preoperatively demonstrating approximately 40% canal compromise from the retropulsed fragment.

Radiographic Results

The average amount of kyphosis for the group treated operatively was 10.1° (range, –10° to 32°) on admission and 5° (range, –10° to 25°) at the time of discharge from the hospital; the difference was significant (p = 0.003) (see Appendix). However, during the follow-up period, this group lost an average of 8° (range, –4° to 22°), resulting in an average kyphosis at the time of the final follow-up examination of 13° (range, –3° to 42°) (p = 0.0001). No correlation was found between the final amount of kyphosis and the degree of pain reported (r = 0.05; p = 0.8) or disability according to the Roland and Morris questionnaire (r = 0.05; p = 0.8) or the Oswestry questionnaire (r = 0.3; p = 0.14).

In the group treated nonoperatively, the average amount of kyphosis was 11.3° (range, –12° to 30°) on admission, 8.8° (range, –5.5° to 22°) on discharge from the hospital (p = 0.013), and 13.8° (range, –3° to 28°) at the final follow-up examination (see Appendix). As in the other group, no correlation was found between the final amount of kyphosis and the pain reported (r = 0.22; p = 0.29) or disability according to the Roland and Morris questionnaire (r = 0.19; p = 0.39) or the Oswestry questionnaire (r = 0.25; p = 0.27).

At the final follow-up examination, no significant difference was found between the two treatment groups with respect to the sagittal plane measurements (p = 0.6).

Two participants in each group had not had a computed tomography scan made at the final follow-up examination, so data were available for forty-three patients (twenty-two in the operative group and twenty-one in the nonoperative group). In the group treated operatively, the average midsagittal diameter of the spinal canal at the level of the fracture was initially 39% (range, 13% to 63%) less than normal (canal compromise), which improved to 22% (range, 0% to 58%) at the final follow-up examination (p = 0.0001). In the group treated nonoperatively, the average degree of anteroposterior canal compromise on presentation was 34% (range, 5% to 75%), which also improved significantly to an average of 19% (range, 0% to 46%) at the last follow-up examination (p < 0.0001) (Figs. 4-A and 4-B).

Clinical Results (see Appendix)

The average pain score before treatment of the injury, as measured on the visual analog scale, was 6 cm (range, 3 to 9 cm) for the operative group and 5.8 cm (range, 0 to 9 cm) for the group treated nonoperatively. At the last follow-up examination, the average pain scores were 3.3 cm (range, 0 to 7.5 cm) and 1.9 cm (range, 0 to 9 cm), respectively. While the change within each group was significant (p = 0.0001), no significant difference in pain reduction between the two treatment groups was found, with the numbers available (p = 0.18).

The Roland and Morris[37] preinjury functional disability scores, which were estimated on presentation, were also very similar for the two treatment groups, with an average score of 1.88 points (range, 0 to 9 points) for the operative group and 0.7 point (range, 0 to 7 points) for the nonoperative group. As a score of 0 points indicates no disability and 25 points indicates complete disability, the results suggest that both groups had a low level of back disability before the traumatic injury. At the last follow-up examination, the average score was 8.16 points (range, 0 to 19 points) for the group treated operatively and 3.9 points (range, 0 to 24 points) for the group treated nonoperatively. Those treated nonoperatively were found to have significantly

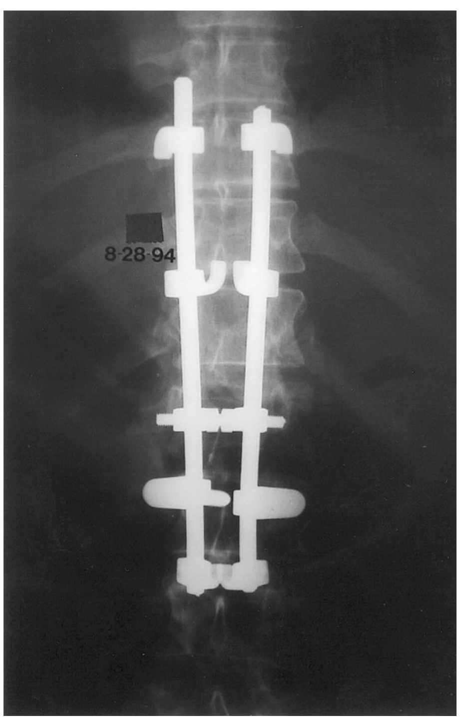

Fig. 2-D

Fig. 2-E

Figs. 2-D and 2-E Anteroposterior and lateral radiographs showing posterolateral spinal arthrodesis with instrumentation and restoration of normal sagittal contour.

lower pain scores than those treated operatively (p = 0.02).

The average score on the Oswestry[39] questionnaire at the final follow-up evaluation was 20.75 points (range, 0 to 48 points) for the group treated operatively and 10.7 points (range, 0 to 52 points) for the group treated nonoperatively. A score of 0 to 20 points indicates minimal disability; 20 to 40 points, moderate disability; and 40 to 60 points, severe disability.

The scores on the SF-36 (see Appendix) varied in both groups, with significant differences between the groups only with respect to physical function (p = 0.002) and role (physical) (p = 0.003).

The rates at which the patients returned to work were not found to be significantly different between the groups. Ten (42%) of the twenty-four patients who were treated surgically returned to work within six months after discharge, and four others returned to work between six and twenty-four months postoperatively. Eight of them returned to a similar job, and seven worked at a less physically demanding occupation (this includes one patient who returned to work more than twenty-four months postoperatively). Of the twenty-three patients who were treated nonoperatively, seventeen (74%) were able to resume work within six months and two returned between six and twenty-four months postoperatively. Fifteen of them returned to a similar job, and four returned to a less strenuous job.

Cost

Fifteen of the twenty-four patients who were treated operatively and seventeen of those who were treated nonoperatively had an isolated thoracolumbar burst fracture without other substantial trauma requiring specific treatment during the initial hospitalization. With these caveats, a comparison of the hospital charges for similar average lengths of stay demonstrated that the average charge per injury for the group treated surgically was approximately $49,063 (range, $26,517 to $102,583). The average charge for hospitalization and cast or brace treatment for those managed nonoperatively was $11,264 (range, $4686 to $20,891). The difference in charges between the two treatment groups was highly significant (p < 0.01).

Complications

The prevalence of complications between the two groups was also distinctly different (see Appendix). Nineteen complications occurred in sixteen of the twenty-four individuals who were treated operatively compared with two complications in three of the twenty-three patients treated nonoperatively. There were no impairments of neurological function regardless of treatment approach, and all patients had normal findings on a neurological examination performed at the time of the final follow-up.

Discussion

The present investigation is the first prospective, randomized study, as far as we know, to compare operative and nonoperative treatment of neurologically intact patients with a burst fracture of the thoracolumbar junction (T10 to L2).

Radiographic examination demonstrated no significant differences between the two groups with respect to the fracture kyphosis on admission, after treatment, or after long-term follow-up. Both groups initially showed improvement in the kyphosis with treatment; however, much of the correction was subsequently lost—albeit without symptoms in most patients—over the duration of the follow-up period. Yet, despite these radiographic findings, there appears to be little association between the degree of kyphosis at the time of the final follow-up or the percentage of correction lost and any clinical symptoms. As most loss of correction appeared to occur during the first year, we believe that it probably represented a

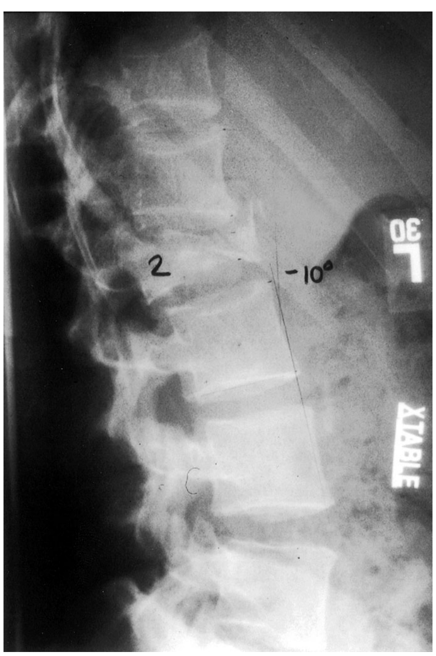

Fig. 3-A

Fig. 3-B

Figs. 3-A through 3-D Case 17. A thirty-six-year-old woman who had operative treatment after she sustained a burst fracture of L2 when she fell from a roof at work. **Fig. 3-A** Lateral radiograph made preoperatively showing –10° of kyphosis. **Fig. 3-B** Axial computed tomography scan made preoperatively, demonstrating >60% canal compromise from the retropulsed fragment.

combination of fracture-settling combined with subsequent intervertebral disc-narrowing.

The degree of compromise of the canal seen on midsagittal computed tomography scans at the time of presentation was similar in both groups (34% to 39%), and both groups had an average improvement to <22% at the final follow-up examination. This degree of canal remodeling has been reported by advocates of both the operative and the nonoperative approach[2,21-23,27,28,41-43]. As other authors have reported, there was no association between the degree of canal compromise and any clinical outcomes[12,18,25,27,31]. Some investigators[44,45] have advocated decompression of the spinal canal, even if there is no neurological deficit, but we believe that the risks of neurogenic injury, nonunion, and other surgical complications need to be carefully weighed. In our opinion, in the setting of a detailed neurological examination with normal findings, no degree of canal compromise would, by itself, serve as an indication for operative intervention and decompression in this fracture.

As for pain and function-related outcomes, no significant differences were found, with the numbers available, between the two treatment groups with respect to pain either at the time of presentation or at the final follow-up examination. The average level of discomfort, according to the visual-analog pain scale, for both groups at the final follow-up evaluation was relatively low although the range was high (0 to 9 cm). Our failure to demonstrate any association between reported pain and radiographic parameters, such as the kyphotic fracture angle, is in agreement with the findings in many previous studies[1,10,21,22,24-28,32,46,47].

The ability of patients with a nonoperatively treated burst fracture to return successfully to vigorous work has been reported often[21,23,25-27,48]. Mumford et al.[23] reported that 81% (twenty-six) of thirty-two patients who were treated with a brace were able to return to work and >60% (seventeen) of them returned to jobs at the same level of activity. Knight et al.[48] reported that patients who were treated nonoperatively returned to work in half of the time needed by the patients who were treated operatively. Shen and Shen[27] reported that twenty-nine of thirty-eight patients returned to full-time work at the same level that they had sustained before the injury.

A noteworthy finding was that, although no significant difference between the two groups was found with respect to the average length of hospitalization, the average charges related to hospitalization and treatment in the operative group were more than four times greater than those in the nonoperative group.

The complication rate is in agreement with those reported in numerous other studies on both operative[3,29,49,50] and nonoperative treatment[8,9,21,23,48,51]. Our experience, especially with the operatively treated group, may have been influenced, in some cases, by the high rate of smokers in the group (67% compared with 17% of those treated nonoperatively). However, while nine of the sixteen smokers in the operative group reported complications, seven of the eight nonsmokers also reported some form of complication.

There are limitations in our study. Obtaining follow-up data on patients in a transient population is always difficult, and we were not able to contact six (11%) of the fifty-three individuals initially enrolled. However, their demographic characteristics, treatment protocols, and early data obtained after treatment did not appear to be notably different from those of the rest of the study population as a whole.

In a study group of this size, it became apparent that there were few if any substantial and significant differences between the two groups, especially in the presence of such wide ranges in data points and large standard deviations. A power study is essential when performing prospective studies of this

Figs. 3-C and 3-D Anteroposterior and lateral radiographs, made at the final follow-up examination, demonstrating anterior spinal arthrodesis with instrumentation and realignment of normal sagittal profile.

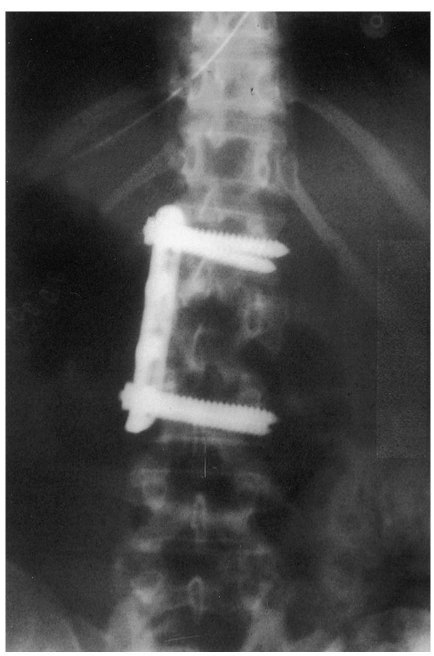

Fig. 3-C

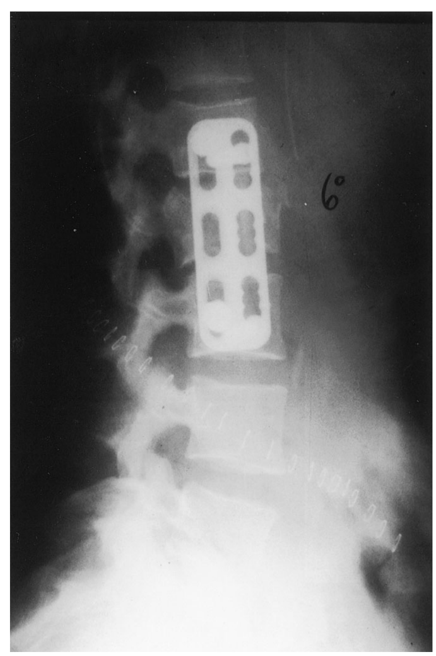

Fig. 3-D

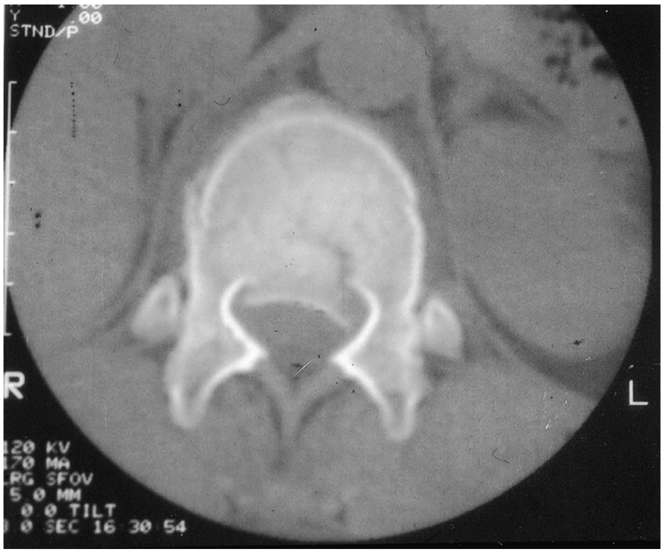

Fig. 4-A

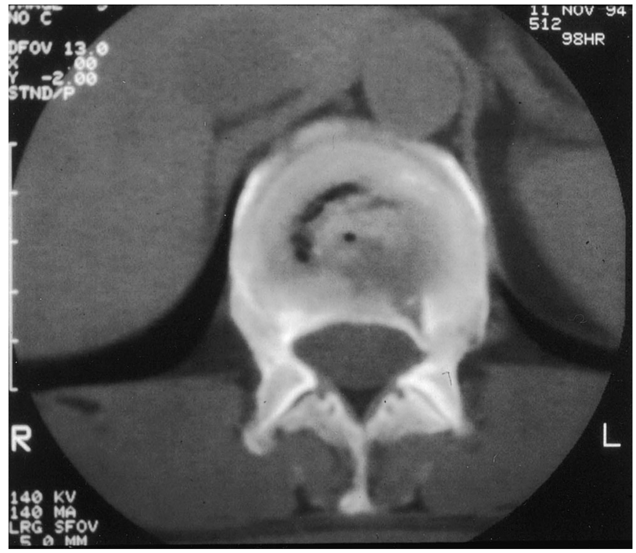

Fig. 4-B

Figs. 4-A and 4-B Case 9. A thirty-eight-year-old man who was managed nonoperatively after he sustained a burst fracture of T12 while snowmobiling. **Fig. 4-A** Axial computed tomography scan made at the time of presentation, showing 37% canal compromise from the retropulsed fragment. **Fig. 4-B** Axial computed tomography image, made three years after the injury, demonstrating >50% resolution of the canal compromise.

nature so as to be certain that subtle and nonsubtle differences can be properly assessed.

Some questions remain unanswered, particularly for the group treated surgically. Because of the relatively small numbers involved, we could not determine whether there was any difference between those treated from an anterior or a posterior approach. We also could not determine whether anterior realignment clears the canal of bone better than posterior realignment, as the computed tomography scans were performed at least two years after the procedure and not immediately postoperatively.

For those treated nonoperatively, we could not determine whether management with a cast was superior to the use of a brace or ascertain the length of time that each should be worn. We believe, however, that cast application with use of a Risser-like cast table allows the spine to be realigned more than is possible with simply applying an off-the-shelf manufactured brace. Also, compliance may well be inherently better with a cast than with a removable orthosis. Thus, our current recommendation is to manage the patient with immobilization in a cast during the most critical initial four to eight weeks during early fracture consolidation and then convert the cast to a removable brace when radiographic and clinical symptoms allow.

In conclusion, we believe, on the basis of the results in the present study, that operative treatment of patients who have a stable thoracolumbar burst fracture and are neurologically intact provides no substantial benefit compared with nonoperative treatment with a cast and/or brace.

Appendix

eA Tables showing demographic and radiographic data, and patient-reported outcomes and complications are available with the electronic versions of this article, on our web site at www.jbjs.org (go to the article citation and click on “Supplementary Material”) and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM). ■

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The authors did not receive grants or outside funding in support of their research or preparation of this manuscript. They did not receive payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, educational institution, or other charitable or nonprofit organization with which the authors are affiliated or associated.

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