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

A Prospective Randomized Study with Follow-up at Sixteen to Twenty-Two Years\*

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**Background:** Studies comparing operative with nonoperative treatment of a stable burst fracture of the thoracolumbar junction in neurologically intact patients have not shown a meaningful difference at early follow-up. To our knowledge, longer-term outcome data have not before been presented.

**Methods:** From 1992 to 1998, forty-seven consecutive patients with a stable thoracolumbar burst fracture and no neurological deficit were evaluated and randomized to one of two treatment groups: operative treatment (posterior or anterior arthrodesis) or nonoperative treatment (a body cast or orthosis). We previously reported the results of follow-up at an average of forty-four months. The current study presents the results of long-term follow-up, at an average of eighteen years (range, sixteen to twenty-two years). As in the earlier study, patients at long-term follow-up indicated the degree of pain on a visual analog scale and completed the Roland and Morris disability questionnaire, the Oswestry Disability Index (ODI) questionnaire, and the Short Form-36 (SF-36) health survey. Work and health status were obtained, and patients were evaluated radiographically.

**Results:** Of the original operatively treated group of twenty-four patients, follow-up data were obtained for nineteen; one patient had died, and four could not be located. Of the original nonoperatively treated group of twenty-three patients, data were obtained for eighteen; two patients had died, and three could not be located. The average kyphosis was not significantly different between the two groups ( $13^{\circ}$  for those who received operative treatment compared with  $19^{\circ}$  for those treated nonoperatively). Median scores for pain (4 cm for the operative group and 1.5 cm for the nonoperative group; p = 0.003), ODI scores (20 for the operative group and 2 for the nonoperative group; p <0.001) and Roland and Morris

continued

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scores (7 for the operative group and 1 for the nonoperative group; p = 0.001) were all significantly better in the group treated nonoperatively. Seven of eight SF-36 scores also favored nonoperative treatment.

**Conclusions:** While early analysis (four years) revealed few significant differences between the two groups, at long-term follow-up (sixteen to twenty-two years), those with a stable burst fracture who were treated nonoperatively reported less pain and better function compared with those who were treated surgically.

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

burst fracture of the thoracolumbar junction is a common phenomenon, comprising up to 20% of all thoracolumbar injuries<sup>1-4</sup>. Despite a substantial body of literature focusing on this specific injury, there remain contrasting opinions regarding the ideal management of the neurologically intact patient, as both operative and nonoperative approaches have been recommended<sup>2,3,5-15</sup>. Operative management has been proposed to offer immediate stability, correction of the deformity, earlier ambulation, and less reliance on orthotic containment. Nonoperative care offers the avoidance of surgical intervention with its attendant risks and morbidity.

In 2003, we presented the results of a prospective randomized study comparing operative and nonoperative treatment of a stable thoracolumbar burst fracture in patients with no neurological deficit—the first such study, to our knowledge<sup>16</sup>. Forty-seven consecutive patients were randomized to treatment with either a body cast/orthosis or open reduction, internal fixation, and fusion. At an average of forty-four months of follow-up, we found no significant differences between the two groups with respect to return to work, pain, and functional disability as measured with use of the Short Form-36 (SF-36) health survey, the Roland and Morris disability questionnaire, and the Oswestry Disability Index. The principal differences found were the cost of the hospitalization, including the surgical treatment, and the more frequent complications seen in those treated with surgery.

Since then, there have been numerous systematic reviews of the literature as well as other institutional publications that have confirmed these findings of favorable results when utilizing nonoperative care<sup>17-24</sup>. Other authors have advocated for surgery and consider it to be the preferred treatment<sup>25-29</sup>. In 1984, in a retrospective comparison of operative and nonoperative treatment of fifty-two cases of burst fractures without a neurological deficit, Denis et al. found that all patients treated surgically had no unrelated disability and all returned to fulltime work, while 25% of those treated nonoperatively were unable to return to work full time8. In addition, 17% of those treated nonsurgically were reported to have developed neurological problems. Siebenga et al., in a multicenter prospective randomized trial, compared sixteen patients treated nonoperatively with eighteen patients who received surgery for thoracolumbar Type-A fractures without neurological deficit at four years<sup>25</sup>. They reported that all functional outcome scores were significantly better in the operative group and that the percentage of patients who returned to their original jobs was

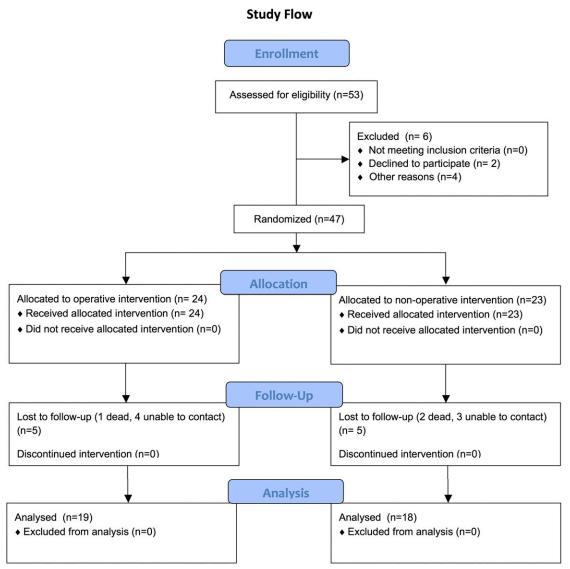
also higher in that group. In a subsequent article, Siebenga et al. also concluded that not only were clinical outcomes superior when treating patients surgically but, compared with nonoperative care, surgical treatment was also more cost-effective<sup>29</sup>.

Reviewing these conflicting positions, it is apparent that there may be principal differences among the many reports because of, in part, variances in follow-up duration—some studies with as little as one year, and many comparative studies with only five to six years of follow-up, at most. At the time of this writing, the longest retrospective review of a single treatment method, to our knowledge, is from eight to thirteen years<sup>22,28</sup>.

To determine whether our earlier results regarding the apparent lack of superiority of surgery to nonoperative care for a

TABLE I Patient Demographic	TABLE I Patient Demographic Data		
	Operative	Nonoperative	
No. of patients	19	18	
Male	13	15	
Female	6	3	
Median age (yr)	62	62.5	
Age range (yr)	38-84	39-80	
Level of fracture			
T12	4	5	
L1	12	10	
L2	3	3	
Cause of injury			
Motor vehicle accident	11	6	
Fall	4	9	
Work	2	0	
Sledding	1	1	
Dirt bike accident	0	1	
Snowmobile accident	0	1	
Other	1	0	
Treatment			
Anterior spine fusion	2	0	
Posterior spine fusion	17	0	
Brace	0	8	
Cast	0	10	
Median follow-up (mo)	216	229.5	
Follow-up range (mo)	204-242	205-268	

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CONSORT diagram detailing the study flow from enrollment through analysis. Forty-seven patients were randomized to one of two groups: operative treatment (twenty-four patients) and nonoperative treatment (twenty-three patients). Five were lost to follow-up in each group, resulting in the final analysis of thirty-seven patients (nineteen in the operative group and eighteen in the nonoperative group).

thoracolumbar burst fracture would hold up over a much longer period, we sought to conduct a fifteen to twenty-year follow-up study of the original patients. Our hypothesis was that, at longerterm follow-up, the original findings would be upheld: neurologically intact patients treated with nonoperative management of a stable thoracolumbar burst fracture would be, at a minimum, functioning at least as well as those who were treated with surgery.

### **Materials and Methods**

From 1992 to 1998, following institutional review board approval, forty-seven patients agreed to practice. seven patients agreed to participate in the original study and were randomized to receive either nonoperative care (treatment with a cast or brace) for three months or surgical treatment. We used a computer-generated randomization process. Treating physicians consulted administrative assistants to receive blinded treatment assignments after potential subjects were made aware of all treatment options and agreed to participate in a prospective randomized study. It was the treating physician (surgeon) who enrolled the participants and informed the patients of the treatment group to which they were assigned. From this point forward, it became an unblinded study (Fig. 1, CONSORT [Consolidated Standards of Reporting Trials] diagram).

Eligibility criteria included all of the following: (1) an isolated burst fracture within the thoracolumbar region (T10 to L2) as seen on anteroposterior and lateral radiographs; (2) computed tomography (CT) revealing a burst-type compression fracture with retropulsion of vertebral body bone posteriorly into the spinal canal; (3) no new neurological abnormality of the lower extremities or abnormality of bowel and bladder function; (4) presentation within three weeks of the time of injury; (5) an age between eighteen and sixty-six years; (6) no medical illnesses that would preclude operative intervention; (7) no ongoing cancer, infection, bleeding disorder, or skin disease; and (8) an understanding of the English language. Other concomitant stable compression (not burst) fractures elsewhere in the spine were permitted if they did not need treatment.

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		Operative			Nonoperative	
Measure	4 Years	20 Years	P Value	4 Years	20 Years	P Value
VAS (cm)	3 (0-8)	4 (1-7)	0.078	1.5 (0-9)	1.5 (0-6)	0.36
ODI	20 (0-48)	20 (0-48)	0.43	4 (0-52)	2 (0-22)	0.21
RM	6 (0-19)	7 (0-19)	0.96	2 (0-24)	1 (0-9)	0.03

<sup>\*</sup>Values are presented as the median with the range in parentheses. VAS = visual analog scale, ODI = Oswestry Disability Index, and RM = Roland and Morris.

Participants were initially managed with one to five days of bed rest, followed by either the surgical procedure or the cast/thoracolumbosacral orthosis. The patients who were treated nonoperatively (twenty-three patients) wore a cast for eight weeks, and then an orthosis for the final four weeks. For some patients, treatment was managed with orthosis alone for twelve weeks, with removal allowed for upright bathing. Patients who received operative intervention (twenty-four patients) were managed with either a short-segment (two to four-level) posterolateral arthrodesis with pedicle screw-hook instrumentation and autologous bone-grafting, or an anterior two-level fibular and rib-strut construct arthrodesis with local autogenous bone-grafting and lateral instrumentation.

At final follow-up, patients were evaluated both clinically and radiographically. Local kyphosis, loss of anterior height of the vertebral bodies, adjacent-segment degenerative processes, and sagittal balance were all calculated from upright full-spine radiographs. We also gathered information as to the patient's work status, medication use, and whether there had been other subsequent orthopaedic or spine-related issues. At the time of admission and at two years, four years, and at the most recent follow-up (sixteen to twenty-two years), patients indicated the degree of pain on a 10-cm visual analog scale, and completed the Roland and Morris questionnaire on spine disability, the SF-36, and the Oswestry questionnaire 30-32.

All entrance data (outcome instruments, radiographic studies, etc.) were collected at the time of hospitalization.

Statistical analysis included the use of the Student two-tailed paired t test, the Wilcoxon signed-rank test, Shapiro-Wilk normality testing, and the Mann-Whitney rank-sum test. The level of significance was set at p < 0.05. No specific power analysis was conducted before commencing the study.

### Source of Funding

Funding for this study was obtained from departmental research funds. The funding source played no role in this investigation.

### **Results**

Between January 2012 and June 2013, we were able to contact and obtain long-term follow-up data for nineteen (79%) of the twenty-four patients treated operatively and eighteen (78%) of the twenty-three patients treated nonoperatively (Table I). The average duration of follow-up was 223 months (18.6 years) (range, 204 to 268 months). Of the group treated operatively, one patient had died and four could not be contacted. Of the group treated nonoperatively, two had died and three could not be contacted. The final operative group comprised six women and thirteen men; three women and fifteen men made up the nonoperative group. At the time of follow-up, the median age of those treated operatively was 62 years (range, 38 to 84 years), and the median age of those treated nonoperatively was 62.5 years (range, 39 to 80 years). The patients lost to follow-up and the patients who were successfully contacted did not differ signifi-

cantly in terms of demographics and patient-related outcomes at baseline and at the four-year analysis.

The most common etiology of the fractures was a motor-vehicle accident (43%) followed by a fall (34%), a work-related injury (13%), and recreational trauma (9%).

### Radiographic Results

The average amount of kyphosis in the group treated operatively was  $10^{\circ}$  on admission and  $5^{\circ}$  at the time of discharge. At the four-year follow-up, an average of  $8^{\circ}$  of correction had been lost, for an average kyphosis of  $13^{\circ}$  (range,  $-3^{\circ}$  to  $42^{\circ}$ )<sup>16</sup>. At long-term follow-up, the amount of kyphosis remained at  $13^{\circ}$  (range,  $5^{\circ}$  to  $42^{\circ}$ ). As in the intermediate-term study, no correlation was found between the final amount of kyphosis and degree of pain reported, or disability according to the Roland and Morris questionnaire (r = 0.05; p = 0.6) or the Oswestry questionnaire (r = 0.45; p = 0.1).

Of those treated nonoperatively, the average amount of kyphosis on presentation was  $11.3^{\circ}$  (range,  $-12^{\circ}$  to  $30^{\circ}$ ) and  $9^{\circ}$  at discharge. At the intermediate follow-up at four years, the initial correction had been lost and the average kyphosis was  $14^{\circ}$  (range,  $-3^{\circ}$  to  $28^{\circ}$ ). At an average of 18.6 years of follow-up, the average kyphosis was  $19^{\circ}$  (range,  $10^{\circ}$  to  $29^{\circ}$ ). As in the group treated surgically, no correlation was found between the final kyphosis and pain reported (r = 0.32; p = 0.2) or disability (r = 0.3; p = 0.39).

Disc-space narrowing, spur formation, kyphotic angulation, listhesis, or combinations of the above at the segment immediately caudad to the area treated with an instrumented fusion was seen in 64% of those treated sixteen to twenty-two years

TABLE III Com	parison of Outco	omes at 20 Years*	
Measure	Operative	Nonoperative	P Value
VAS (cm)	4 (1-7)	1.5 (0-6)	0.003
ODI	20 (0-48)	2 (0-22)	<0.001
RM	7 (0-19)	1 (0-9)	0.001

<sup>\*</sup>Values are presented as the median with the range in parentheses. VAS = visual analog scale, ODI = Oswestry Disability Index, and RM = Roland and Morris.

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Domain	Operative	Nonoperative	P Value
Physical function	70 (30-100)	89.5 (65-100)	0.01
Role-physical	75 (0-100)	100 (25-100)	0.005
Role-emotional	100 (0-100)	100 (57-100)	0.163
Energy fatigue	56 (10-90)	75 (50-100)	0.02
Mental health	72 (24-100)	89 (60-100)	0.128
Social function	75 (37-100)	100 (50-100)	0.003
Pain	50 (13-87)	87 (35-100)	<0.001
General health	70 (20-95)	95 (55-100)	0.002

previously. Degeneration of the most caudad lumbar spine, L3 to S1, was also seen on radiograph in 75% of the patients who were treated with surgery. Of the group treated with a cast or brace, immediate subjacent-segment degeneration was also seen in 70% of individuals, but only 55% had radiographic evidence of more caudad lumbar degeneration. This difference between the two groups was significant (p = 0.02).

In terms of sagittal balance, although there were varying degrees of local kyphosis related to the fracture and treatment, all patients maintained balance, with the C7 sagittal vertical axis falling within 5 cm of the posterior corner of S1.

### Clinical Results

At an average of 18.6 years, the median pain score as measured on a 10-cm visual analog scale was 4 cm (range, 1 to 7 cm) for those treated surgically and 1.5 cm (range, 0 to 6 cm) for those treated with a cast or brace. Within each group, the change over the years did not reach significant levels; however, at long-term follow-up, the difference in pain scores between those treated nonoperatively and those treated operatively was significant (p = 0.003) (Tables II and III).

The median Roland and Morris functional disability score<sup>30</sup> for those treated operatively was 7 (range, 0 to 19) on a scale of 25 (with 0 representing no disability and 25 indicating complete disability). The median score for those treated non-operatively was 1 (range, 0 to 9). This difference was significant (p=0.001). Although, within the group treated surgically, there was very little change in the median score over the years, there was a significant improvement in this function score within the group treated nonoperatively (p=0.03).

The median score on the Oswestry questionnaire  $^{32}$  at the long-term follow-up evaluation was 20 (range, 0 to 48) for those treated operatively and 2 (range, 0 to 22) for those treated nonoperatively (a score of 0 to 20 represents minimal disability, and 21 to 40 represents moderate disability). This difference between the groups was also significant (p < 0.001). As with the visual analog pain scores, within each treatment group, there was little overall change in the median score over the interval years.

Six of the eight scores on the SF-36 favored nonoperative management to a significant degree (Table IV). Only the scores for role-emotional and mental health did not differ significantly between those treated operatively compared with those treated nonoperatively.

There were no new neurological deficits or symptoms in either group related to the fracture.

At the four-year point, 58% of those treated surgically were found to have returned to a regular work status by twenty-four months. At final follow-up, nine of nineteen (47%) were still regularly employed. Six had voluntarily retired, and four had lost employment. Of those treated nonoperatively, at the intermediate stage, 83% were able to return to a full work schedule. At final follow-up, thirteen of eighteen (72%) were still working. Three had retired, and two had lost employment.

Regarding medications taken, three of the patients treated operatively took regular narcotic medications for pain, while none of those treated nonoperatively took anything more than occasional nonsteroidal anti-inflammatory medications.

### **Discussion**

This investigation is, to our knowledge, the first prospective randomized study to compare operative and nonoperative treatment of neurologically intact patients with a burst fracture of the thoracolumbar junction (T10 to L2) with a substantial long-term follow-up (sixteen to twenty-two years).

Radiographic examination revealed insignificant differences between the two cohorts, with little change demonstrated between the intermediate and long-term follow-up. The sagittal profile of both groups remained relatively stable, although the group treated nonoperatively continued to lose a few more degrees of correction than those treated with surgery over the sixteen to twenty-two-year period. This difference, however, did not reach significance, nor was any radiographic finding associated with clinical symptoms.

Of note, the frequency of immediate adjacent-segment degeneration evidenced radiographically was similar between the two groups over time, which was somewhat unexpected, given the lack of fusion or instrumentation in one of the cohorts. In THE JOURNAL OF BONE & JOINT SURGERY · JBJS.ORG VOLUME 97-A · NUMBER 1 · JANUARY 7, 2015 OPERATIVE VERSUS NONOPERATIVE TREATMENT OF A
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the case of most fractures treated nonoperatively, we found that bone bridged anteriorly along the adjacent vertebrae, resulting in a more rigid segment, not unlike in those treated with open reduction and internal fixation. This, then, could have conceivably put additional strain on adjacent segments, hastening their degeneration. Caudally, however, in the lower lumbar spine, there was significantly less disc-space narrowing and degeneration seen in the group treated nonoperatively.

Regarding pain and function-related outcomes, our findings suggest that surgery compromises these results compared with nonoperative management. Those treated nonoperatively reported a greater degree of comfort and were more functional as measured by the pain scale, the Oswestry questionnaire, the Roland and Morris questionnaire, and the SF-36, with all strongly favoring nonoperative treatment.

The ability of patients with a nonoperatively treated thoracolumbar burst fracture to return to vigorous work has been previously demonstrated, most recently by Gnanenthiran et al. in a study with up to 118 months of follow-up<sup>12,15,24,25</sup>. Our results are in keeping with these authors and, in fact, show that at a much later date, more patients who were treated nonoperatively were engaged in full-time occupations ranging from the sedentary (office) to the vigorous (farming and construction) compared with those who were treated operatively.

At sixteen to twenty-two years post-injury, our study's nonoperatively treated group was taking fewer narcotic pain medications, and if anything, tended to principally use occasional nonsteroidal anti-inflammatory medications only.

There remain limitations to our study. Obtaining followup data for patients in a transient population is always difficult, and we were unable to contact all of our original patients. However, we were able to reach 78% of the patients who received nonoperative treatment and 79% of the patients who were treated with surgery, which represents an acceptable percentage of return, especially at such a late date.

Also, in a study group of this size, it is still difficult to interpret substantial and significant differences between the groups, especially with such wide ranges of data points. A properly designed prospective study would require a power analysis, which would certainly detail the hundreds of patients needed to demonstrate meaningful clinical differences in areas such as pain and disability.

In conclusion, we now believe that nonoperative treatment is the optimal management of the neurologically intact patient with a stable thoracolumbar burst fracture. Patients treated nonoperatively may well be more functional and have less pain symptoms at a time period of up to twenty-two years. In an ongoing study, we seek to determine if demographic and social factors relate to outcomes, as has been reported for patients who have undergone lumbar fusion who had other indications for their surgery.

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