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Comparing Single Versus Double Screw-Rod Anterior Instrumentation for Treating Thoracolumbar Burst Fractures with Incomplete Neurological Deficit: A Prospective, Randomized Controlled Trial

Authors' Contribution:

Study Design A
Data Collection B
Statistical Analysis C
Data Interpretation D
Manuscript Preparation E
Literature Search F
Funds Collection G

AEG 1 **Yu Yu**
BF 2 **Juan Wang**
BF 1 **Gaohai Shao**
CD 1 **Qunbo Wang**
A 1 **Bo Li**

1 Department of Orthopedics, Yongchuan Hospital of Chongqing Medical University, Chongqing, P.R. China
2 Department of Neurology, Yongchuan Hospital of Chongqing Medical University, Chongqing, P.R. China

Corresponding Author: Bo Li, e-mail: cqeylibo@163.com

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Background: Following a thoracolumbar burst fracture (TCBF), anterior screw-rods apply pressure upon the graft site. However, there is limited evidence comparing single screw-rod anterior instrumentation (SSRAI) to double screw-rod anterior instrumentation (DSRAI) for TCBFs. Our objective was to compare SSRAI versus DSRAI for TCBFs with incomplete neurological deficit.





Material/Methods: A total of 51 participants with T11-L2 TCBFs (AO classification: A3) were randomly assigned to receive SSRAI or DSRAI. Key preoperative, perioperative, and postoperative data were collected. Statistical analysis was conducted to determine the independent factors associated with inferior clinical outcomes, as well as the comparative efficacy of SSRAI and DSRAI.

Results: There were no significant differences in the key demographic and clinical characteristics between the two groups (all $p > 0.05$). Smoking status was significantly associated with inferior three-month and six-month Denis pain scores (Wald statistic=4.246, $p = 0.039$). Both SSRAI and DSRAI were significantly effective in improving three-month and six-month postoperative degree of kyphosis, three-month and six-month postoperative ASIA impairment scale scores, three-month and six-month postoperative Denis pain score, and three-month and six-month postoperative Denis work score (all $p < 0.001$). Although there were no significant differences between DSRAI and SSRAI with respect to all outcomes (all $p > 0.05$), DSRAI displayed significantly longer operating times, as well as significantly larger operative blood losses (both $p < 0.001$).

Conclusions: SSRAI may be preferable over DSRAI for TCBFs with incomplete neurological deficit due to its lower operating time and amount of operative blood loss.

MeSH Keywords: **Bone Screws • Spine • Surgical Instruments**

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Background

Thoracolumbar burst fractures (TCBFs) can result in vertebral endplate disruption and retropulsion of the posterior vertebral body wall into the spinal canal [1,2]. Various therapeutic approaches have been developed to address such vertebral fractures, including conservative bed rest, vertebroplasty, kyphoplasty, and open reduction-internal fixation [3,4]. In cases of extensive comminution of the vertebral body accompanied by a load sharing classification (LSC) of greater than six, the recommended approach is anterior surgical decompression followed by vertebral body reconstruction with instrumentation [5]. To accomplish this task, anterior screw-rod constructs are commercially available and can adequately apply compressive pressure across the graft site [5]. Relative to single screw-rod anterior instrumentation (SSRAI), double screw-rod anterior instrumentation (DSRAI) may better stabilize the graft site for early mobilization [6]. However, DSRAI has limited efficacy with smaller vertebral bodies and can yield greater risk of harm to great vessels [5]. Moreover, there is evidence that spinal surgery patients that receive more extensive instrumentation experience higher levels of soft tissue disruption, greater degrees of dissection, greater blood loss, longer operative durations, greater rates of implant-related complications, and higher implant costs [7–9].

Unfortunately, there is limited clinical evidence that directly compares SSRAI to DSRAI for TCBFs. For example, Sharma et al. found evidence that SSRAI was effective for the treatment of TCBFs, but did not directly compare SSRAI to DSRAI [5]. Therefore, the objective of this prospective, randomized controlled trial was to compare the outcomes of SSRAI to DSRAI for TCBFs with incomplete neurological deficit.

Material and Methods

Ethics statement

This study was approved by the Ethics Committee (IRB) of Yongchuan Hospital of Chongqing Medical University (Chongqing, China). All subjects recruited for this study provided written informed consent prior to participation.

Patient selection

Adult patients (aged 18 years and older) with TCBFs were screened at the Department of Orthopedics at Yongchuan Hospital of Chongqing Medical University. We only included candidates with T11-L2 burst fractures with an AO classification of A3. We excluded candidates with (i) an 'A' score on the ASIA impairment scale; (ii) an LSC score of less than six; (iii) posterior ligament complex (PLC) disruption by magnetic

resonance imaging (MRI); (iv) severe co-morbidities that precluded anterior surgery (such as pulmonary tuberculosis or ischemic heart disease); and/or (v) patients failing to follow up after the initial screening. As a result, a total of 51 participants (35 males and 16 females, aged 19–52) were consecutively recruited into this study.

Experimental group construction and preoperative data collection

The 51 participants were randomly and blindly assigned to receive either SSRAI (SSRAI group) or DSRAI (DSRAI group). Prior to surgery, the following preoperative clinical data were collected for each participant: patient ID number, age (years), sex, BMI, smoking status, diabetes status, history of previous vertebral surgery, cause of current vertebral injury (e.g., car accident, fall), vertebrae involved (T11-L2), preoperative LSC score (from CT scans), preoperative American Spinal Injury Association (ASIA) impairment scale score (A-E), preoperative kyphosis (°), preoperative Denis pain score, preoperative Denis work score, and vertebral body dimensions (length x width x height). Vertebral body dimensions were measured through sagittal and coronal CT scans with 3-mm cuts, as previously described by Sharma et al. [5].

Operative methods and perioperative data collection

For each participant in the study, the following perioperative clinical data were collected: patient ID number, time from injury to surgery (hours), operating time (minutes), and estimated operative blood loss (mL). The trans-diaphragmatic procedure was applied for T11/T12/L1 fractures, while the anterior retroperitoneal procedure was employed for L2 fractures, as previously described by Sharma et al. [5]. For the trans-diaphragmatic approach, one-lung ventilation was performed by endotracheal tubing; otherwise, all the following procedures were used for both approaches. Patients were positioned laterally, a sub-axillary roll was placed, and the fracture site was appropriately positioned. The surgery was performed on the left-hand side in order to prevent liver retraction and inferior vena caval injury. A partial corpectomy was performed, and the pedicle was removed. The whole vertebral body was excised with a thin bone shell preserved anteriorly and laterally to reduce vascular injury risk. The surgeon extended decompression to the contralateral pedicle. The posterior longitudinal ligament (PLL) was left intact with adequate decompression being achieved when the PLL anteriorly bulged. End plates were fashioned by excising cartilage until blood was sighted. Caution was exercised in removing a minimal amount of bony end plate. The patient's anterior iliac crest was used to harvest tricortical grafts in order to reconstruct the middle and anterior columns. Graft length was calculated by adding 6 mm to the distance between the two endplates in order to allow 2–3 mm

Table 1. Baseline preoperative demographic and clinical characteristics of the participants.

Characteristic	DSRAI group (n=26)	SSRAI group (n=25)	p-value
Age (yrs)	34.5±7.5	36.0±7.7	>0.05
Gender (male/female)	17/9	18/7	>0.05
BMI	22.0±3.6	22.2±3.6	>0.05
Smoker	9 (35%)	9 (36%)	>0.05
Diabetic	1 (4%)	1 (4%)	>0.05
Previous surgery on the injured vertebrae	0 (0%)	0 (0%)	>0.05
Cause of injury			
Fall	10 (38%)	12 (48%)	>0.05
Motor vehicle accident (MVA)	12 (46%)	11 (44%)	
Other	4 (15%)	2 (8%)	
Vertebrae involved			
T11	2 (8%)	2 (8%)	>0.05
T12	6 (23%)	7 (28%)	
L1	14 (54%)	13 (52%)	
L2	3 (12%)	2 (8%)	
Vertebral body height	61.4±7.0	60.9±5.6	>0.05
Preoperative LSC score			
7	7 (27%)	8 (32%)	>0.05
8	18 (69%)	15 (60%)	
9	1 (4%)	2 (8%)	
Preoperative kyphosis (°)*	21.5±4.3	21.9±4.4	>0.05
Preoperative ASIA impairment scale**			
A	0 (0%)	0 (0%)	>0.05
B	4 (15%)	2 (8%)	
C	17 (65%)	17 (68%)	
D	5 (19%)	6 (24%)	
E	0 (0%)	0 (0%)	
Preoperative Denis pain score			
3	4 (15%)	7 (28%)	>0.05
4	19 (73%)	16 (64%)	
5	3 (12%)	2 (8%)	
Preoperative Denis work score			
3	2 (8%)	6 (24%)	>0.05
4	21 (81%)	17 (68%)	
5	3 (12%)	2 (8%)	

* Kyphosis was measured on lateral radiographs using the Cobb method; ** American Spinal Injury Association (ASIA) impairment scale: A = No motor or sensory function is preserved in the sacral segments S4–S5; B = Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4–S5; C = Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade of less than 3; D = Motor function is preserved below the neurological level, and at least half of the key muscles below the neurological level have a muscle grade of 3 or more; and E = Motor and sensory function are normal.

Table 2. Risk factors associated with inferior clinical outcomes.

Variable	Six-month kyphosis			Six-month ASIA impairment scores			Six-month Denis pain scores			Six-month Denis work scores		
	<7	≥7	p-value	A-D	E	p-value	<2	≥2	p-value	≤2	>2	p-value
Age (yrs)	37.0 ±8.2	34.0 ±7.0	>0.05	35.2 ±7.7	35.4 ±7.6	>0.05	33.5 ±7.1	36.6 ±7.8	>0.05	35.6 ±7.7	34.4 ±7.6	>0.05
Gender												
Male	14	21	>0.05	25	10	>0.05	15	20	>0.05	21	14	>0.05
Female	7	9		12	4		7	9		13	3	
BMI												
<18.5	3	5	>0.05	7	1	>0.05	4	4	>0.05	5	3	>0.05
18.5–23.9	8	18		18	8		12	14		17	9	
≥24	10	7		12	5		6	11		12	5	
Smoker (yes/no)	6/15	12/18	>0.05	13/24	5/9	>0.05	4/18	14/15	0.026*	14/20	4/13	>0.05
Injury-to-surgery time (hours)	4.4 ±1.0	4.9 ±1.5	>0.05	4.5 ±1.4	5.1 ±1.0	>0.05	4.6 ±1.2	4.8 ±1.4	>0.05	4.8 ±1.3	4.5 ±1.3	>0.05
Operating time (min)	289.9 ±37.2	291.9 ±36.5	>0.05	291.2 ±36.4	290.5 ±37.8	>0.05	284.5 ±36.0	296.0 ±36.5	>0.05	293.0 ±38.2	287.1 ±33.4	>0.05
Estimated operative Blood loss (ml)	423.0 ±55.7	429.3 ±57.7	>0.05	430.8 ±55.3	415.8 ±59.9	>0.05	416.6 ±51.2	434.3 ±59.9	>0.05	424.7 ±56.2	430.8 ±58.5	>0.05

* Statistically significant (p<0.05).

to be sunk into the vertebral body. The table was flexed to distract the corpectomy site. After grafting, the surgeon decreased flexion to enable a snug fit for the graft. Tricortical grafting was supplemented with resected rib as well as vertebral autografts positioned between the anterior shell and the graft.

Then, depending on the experimental group, SSRAI or DSRAI (7-mm or 8-mm, Universal Spine System (USS), Synthes) was positioned immediately below and above the corpectomy site. Through digital palpation and imaging guidance, caution was taken to avoid leaving the screw's tip extending out of the vertebral body. Pressure was applied with a connecting rod (6-mm) across the graft before completing the construct. A suction drain was placed prior to surgical closure.

Postoperative care and follow-up data collection

Postoperatively, physiotherapy as well as incentive spirometry were initiated on postoperative day (POD) one. The suction drain was removed when the preceding day's output fell below 50 mL (usually on POD two). Self-catheterization was taught to patients with bladder complications. A thoracolumbar sacral orthosis (TLSO) was applied until solid fusion was confirmed by radiography (usually at month three). For each participant in the study, the following postoperative clinical

data were collected at three and six months post-operation: postoperative complications and treatment (if any), three-month and six-month postoperative degree of kyphosis (°), three-month and six-month postoperative ASIA impairment scale (A–E), three-month and six-month postoperative Denis pain score, and three-month and six-month postoperative Denis work score.

Statistical analysis

All statistical analysis was conducted using SPSS (IBM). Statistical significance was set at a p value of less than 0.05. For all variables, the means and standard deviations (SD) were calculated for the SSRAI group and the DSRAI group. First, we checked for any significant differences in the key demographic and clinical characteristics between the two experimental groups. Next, we determined the factors associated with inferior clinical outcomes using a univariate analysis. The Student's t-test was applied for symmetrically distributed variables; otherwise, the non-parametric Wilcoxon test was applied. Based on the univariate findings, we conducted a stepwise logistic regression analysis of selected variables to identify independent factors associated with inferior clinical outcomes. Next, we determined which experimental groups were associated with positive outcomes. A paired t-test was used to compare

Table 3. Comparison of preoperative and postoperative variables.

Variable	DSRAI group	p-value (compared with preoperative)	SSRAI group	p-value (compared with preoperative)
Kyphosis*				
Preoperative	21.5±4.3		21.9±4.4	
Three-month postoperative	3.3±0.9	<0.001	3.3±0.7	<0.001
Six-month postoperative	6.9±1.0	<0.001	6.7±0.9	<0.001
ASIA impairment scale**				
Preoperative	4(B), 17(C), 5(D)		2(B), 17(C), 6(D)	
Three-month postoperative	3(C), 19(D), 4(E)	<0.001	3(C), 19(D), 3(E)	<0.001
Six-month postoperative	1(C), 18(D), 7(E)	<0.001	1(C), 17(D), 7(E)	<0.001
Denis pain score				
Preoperative	4(P3), 19(P4), 3(P5)		7(P3), 16(P4), 2(P5)	
Three-month postoperative	12(P2), 14(P3)	<0.001	14(P2), 11(P3)	<0.001
Six-month postoperative	9(P1), 16(P2), 1(P3)	<0.001	13(P1), 11(P2), 1(P3)	<0.001
Denis work score				
Preoperative	2(W3), 21(W4), 3(W5)		6(W3), 17(W4), 2(W5)	
Three-month postoperative	1(W2), 20(W3), 5(W4)	<0.001	1(W2), 18(W3), 6(W4)	<0.001
Six-month postoperative	17(W2), 8(W3), 1(W4)	<0.001	17(W2), 8(W3)	<0.001

* Kyphosis was measured on lateral radiographs using the Cobb method; ** American Spinal Injury Association (ASIA) impairment scale: A = No motor or sensory function is preserved in the sacral segments S4-S5; B = Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5; C = Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade of less than 3; D = Motor function is preserved below the neurological level, and at least half of the key muscles below the neurological level have a muscle grade of 3 or more; and E = Motor and sensory function are normal.

mean preoperative and postoperative scores for the clinical outcomes in each experimental group. Finally, we compared the efficacy of SSRAI versus DSRAI. A Student's *t*-test was used to compare the clinical outcomes in the SSRAI and DSRAI groups.

Results

A total of 51 participants (35 males and 16 females, aged 19–52) were recruited into this study and were randomly segregated to receive either SSRAI (n=25) or DSRAI (n=26). The key demographic and clinical characteristics of these two experimental groups are detailed in Table 1. There were no significant differences in these key demographic and clinical characteristics between the two experimental groups (all *p*>0.05; Table 1).

Next, applying a univariate analysis, we assessed the factors associated with inferior clinical outcomes (Table 2). Of all the

factors investigated, smoking status was significantly associated with an elevated (≥ 2) six-month Denis pain score (*p*<0.05; Table 2). Based on this finding in smokers, we conducted a stepwise logistic regression analysis to identify independent factors associated with inferior clinical outcomes. This analysis revealed that smoking status was significantly associated with inferior three-month and six-month Denis pain scores (Wald statistic=4.246, *p*=0.039).

Next, we determined which experimental groups were associated with positive outcomes through comparing mean preoperative and postoperative scores for the clinical outcomes in each experimental group (Table 3). We found that both SSRAI and DSRAI were significantly effective in improving all clinical outcomes under investigation, including three-month and six-month postoperative degree of kyphosis, three-month and six-month postoperative ASIA impairment scale scores, three-month and six-month postoperative Denis pain score, and

Table 4. Comparative efficacy of single versus double screw-rod instrumentation.

Variable	DSRAI group (n=26)	SSRAI group (n=25)	p-value
Operating time (min)	317.8±21.0	263.2±26.9	<0.001
Estimated operative blood loss (mL)	475.3±26.8	376.1±25.6	<0.001
Kyphosis			
Three-month postoperative	3.3±0.9	3.3±0.7	>0.05
Six-month postoperative	6.9±1.0	6.7±0.9	>0.05
ASIA impairment scales			
Three-month postoperative	3(C), 19(D), 4(E)	3(C), 19(D), 3(E)	>0.05
Six-month postoperative	1(C), 18(D), 7(E)	1(C), 17(D), 7(E)	>0.05
Denis pain scores			
Three-month postoperative	12(P2), 14(P3)	14(P2), 11(P3)	>0.05
Six-month postoperative	9(P1), 16(P2), 1(P3)	13(P1), 11(P2), 1(P3)	>0.05
Denis work scores			
Three-month postoperative	1(W2), 20(W3), 5(W4)	1(W2), 18(W3), 6(W4)	>0.05
Six-month postoperative	17(W2), 8(W3), 1(W4)	17(W2), 8(W3)	>0.05

three-month and six-month postoperative Denis work score (all $p < 0.001$; Table 3).

Finally, we compared the efficacy of SSRAI versus DSRAI (Table 4). DSRAI displayed significantly longer operating times as well as significantly larger operative blood losses (both $p < 0.001$; Table 4). However, there were no significant differences between SSRAI and DSRAI with respect to all clinical outcomes under investigation, including three-month and six-month postoperative degree of kyphosis, three-month and six-month postoperative ASIA impairment scale scores, three-month and six-month postoperative Denis pain scores, and three-month and six-month postoperative Denis work scores (all $p > 0.05$; Table 4).

Discussion

The aim of this trial was to compare the outcomes of SSRAI versus DSRAI for TCBFs with incomplete neurological deficit. We found that both SSRAI and DSRAI were significantly effective in improving degree of kyphosis, ASIA impairment scale scores, Denis pain scores, and Denis work scores. Although DSRAI displayed significantly longer operating times as well as significantly larger operative blood losses, there were no significant differences between the two constructs with respect to the aforementioned clinical outcomes. We also found that smoking status was significantly associated with inferior three-month and six-month Denis pain scores in these patients. These findings suggest that SSRAI may be preferable

to DSRAI due to its lower operating time and amount of operative blood loss.

The thoracolumbar junction is recognized as the most common location of injury to the axial skeleton, since the biomechanical forces along the kyphotic thoracic spine abruptly transition onto the lordotic lumbar spine at this junction [10]. Consequently, the most common thoracolumbar junction injury occurs around the T12 or L1 level, which previous studies have estimated to constitute about 80–82% of TCBFs [10,11]. Consistent with these previous findings, we found that T12 and L1 fractures constituted 78% of TCBFs observed here. The leading etiology of thoracolumbar junction injury in developed regions is motor vehicle accident (MVA), while falls are the leading etiology in developing regions [10,11]. Accordingly, we found that MVA (45%) and falls (43%) were the two leading causes of TCBFs observed here.

TCBFs are the most common type of thoracolumbar junction injury and are estimated to constitute about 68–83% of thoracolumbar junction injuries [11,12]. TCBFs result in the anterior and middle columns failing in compression, which can lead to spinal deformity and neural compromise [10]. Therefore, the primary objectives of TCBF surgery are to (i) establish early stabilization; (ii) achieve neural decompression; and (iii) gain prompt spinal mobilization in order to prevent the development of complications [10]. In particular, both posterior and anterior screw-rod stabilization following TCBF have been demonstrated to produce improvements in kyphosis as well as ASIA scale scores [10,13,14]. As posterior screw-rod stabilization is the

more frequently used approach, the anterior approach is not as well-known to surgeons in the field [15]. Therefore, there has been little research that has comparatively assessed SSRAI and DSRAI for TCBFs. Our current findings showed no significant differences in efficacy between the two types of anterior instrumentation, suggesting that SSRAI may be preferable to DSRAI for TCBFs with incomplete neurological deficit due to its lower operating time and amount of operative blood loss.

There are several limitations to this study. First, with two arms consisting of 25 and 26 participants, the sample size of this study was rather limited. Second, as the spinal surgeons conducting this study were experienced in the installation of screw-rod anterior instrumentation, the applicability of our findings may not extend to surgeons who lack sufficient expertise with such devices. Such experience is critical, as there is heterogeneity in spinal anatomy across patients, and improper screw-rod installation can produce serious complications, such as nerve root damage or vessel injury [16]. Third, as different models of screw-rod instrumentation may affect

functional outcomes, our findings should be limited to the USS Synthes instrumentation used in this trial.

Conclusions

This study showed no significant differences in efficacy between SSRAI and DSRAI for TCBFs with incomplete neurological deficit, suggesting that SSRAI may be preferable to DSRAI due to its lower operating time and amount of operative blood loss.

Statement

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

Conflicts of interest

None.

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