Avoidable causes in pedicle instrumentation failure

Nasser M Sayed Ahmed¹, Hamed B Ibrahim¹, Alaa Farg², Ahmed Sleem²

Abstract

Objective: The authors reviewed factors related to the surgical techniques attributed to surgeon-errors which result in failures of the construct of the internal fixation of thoracolumbar fractures through transpedicular screws systems, and how these could be avoided.

Patients and methods: The authors reviewed 280 consecutive patients with traumatic thoracolumbar fractures who underwent spinal surgical fixation with short segment transpedicular screw instrumentation at two institutions, between January 1997 and June 2005. All patients in this series were victims of high-force trauma. Among this series, 30 patients had a construct failure attributed to surgeon-related errors. Clinical evaluation of the patients was performed on admission and at postoperative period using ASIA scale. All patients were radiologically investigated by plane x-rays and computerized tomographic scan spine on admission and occasionally MRI and 3D CT scan of the spine when required. We used McAfee classification of thoracolumbar injuries. Surgical treatment was indicated in cases of biomechanical instability of the spine and/or if a neurologic deficit was imminent or already present, the patients were followed-up as regard to clinical and radiological evidence of construct failure.

Results: Thirty patients out of 280 patients with post-traumatic thoracolumbar injuries had construct failures. Main clinical presentation of construct failure was severe pain and inability to walk at postoperative period. Radiologically there was progressive spinal deformity with and without implant failures. The locations of the fractures in order of frequency were as follows: L1 in 18 cases, L2 in 7 cases, T12 in 5 cases. The construct failure was in the form of screw binding in 6 patients, screw breakage in 12 patients, screw/rod dislodgement in 3 patients, progressive kyphosis in 5 patients, disengaged screw's cup in 2 patients, and broken rods in 2 patients.

Conclusion: Successful use of transpedicular screws in traumatic thoracolumbar fractures is predicated on understanding of biomechanical properties of both the spine and implants. Great attention must be directed to maintain the sagittal and coronal balances of the spine over the sacrum through reconstruction of comminuted anterior vertebral column and appropriate distraction of the construct. In spite of routine use of pedicle, screw has not been free of complications; the majority of construct failures is not actually device failures but instead is surgeon-related errors.

Key words: Pedicle instrumentation failure, traumatic thoracolumbar fractures and surgeon error.

Introduction

A traumatic fracture of the spine is a serious medical condition that can have a major impact on the patient’s quality of life. The management of traumatic fractures of the thoracic spine remains controversial. A large number of publications describe various surgical techniques for the reduction and fixation of spinal fractures without a consensus on the optimal treatment. In general, surgical treatment of thoracolumbar fractures is deemed necessary if the biomechanical stability of the spine is severely compromised and/or if a neurologic deficit is imminent or already present. Segmental fixation systems decrease the need for postoperative immobilization and bracing and facilitate early rehabilitation and ambulation.

Short-segment pedicle screw instrumentation is a well described technique to reduce and stabilize thoracolumbar fractures. It has been increasingly used over the past decade, with numerous reports of good clinical results. It is a relatively easy procedure but can indirectly reduce a fractured vertebral body, and the means of augmenting the...
injured vertebrae - was used for treatment of traumatic thoracolumbar fractures. Criteria for exclusion were:
1. Non-traumatic thoracolumbar fractures.
2. Patients who had evidence of osteoporosis.
3. Patients who did not apply thoracolumbar bracing postoperatively.
4. Patients who underwent an instrumentation procedure and then sustained to another insult of trauma.
5. Patients with follow-up period less than 6 months.

Out of the 280 patients, there were 190 males and 90 females with a mean age of 35.6 years (range 16 - 65 years). All patients in this series were victims of high-force trauma. The mechanism of injury was, 159 (56.8%) cases injured in automobile accidents, 84 (30%) cases fell from height, 28 (10%) cases pedestrians struck by a motor vehicle and 8 (2.8%) in motorcycle accidents. In our current group the order of mechanism of injury was the same.

At the time of admission, the initial neurological assessment was done according to ASIA scale, normal motor strength was demonstrated (type E) in 4 patients, mild motor weakness (type D) in 20, incomplete spinal cord or cauda equina injury with less than antigravity strength (type C) in one patient, and complete paraplegia (type A) in 5 patients (Table 1).

### Table 1 - Type of spinal fractures and construct failure.

<table>
<thead>
<tr>
<th>Fracture level</th>
<th>D10</th>
<th>D11</th>
<th>D12</th>
<th>L1</th>
<th>L2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of fracture</td>
<td>N</td>
<td>F</td>
<td>N</td>
<td>F</td>
<td>N</td>
</tr>
<tr>
<td>Wedge-compression</td>
<td>--</td>
<td>--</td>
<td>1</td>
<td>--</td>
<td>12</td>
</tr>
<tr>
<td>Stable burst</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Unstable burst</td>
<td>1</td>
<td>--</td>
<td>3</td>
<td>--</td>
<td>4</td>
</tr>
<tr>
<td>Chance</td>
<td>2</td>
<td>--</td>
<td>3</td>
<td>--</td>
<td>8</td>
</tr>
<tr>
<td>Flexion-distraction</td>
<td>4</td>
<td>--</td>
<td>4</td>
<td>--</td>
<td>25</td>
</tr>
<tr>
<td>Translational</td>
<td>4</td>
<td>--</td>
<td>6</td>
<td>--</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>11</td>
<td>---</td>
<td>17</td>
<td>---</td>
<td>51</td>
</tr>
</tbody>
</table>

Abbreviation: N = number of patients and F = failure of construct

The location of the fractures in the order of frequency was as follows: L1 level in 18 (60%) of the patients, L2 level in 7 (23.3%) of the patients, T12 level in 5 (16.7%) of the patients, (Table 2).

### Table 2 - Clinical presentation and construct failure.

<table>
<thead>
<tr>
<th>ASIA scale</th>
<th>Patients with construct failure</th>
<th>Total No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type A</td>
<td>5</td>
<td>80</td>
</tr>
<tr>
<td>Type B</td>
<td>--</td>
<td>10</td>
</tr>
<tr>
<td>Type C</td>
<td>1</td>
<td>27</td>
</tr>
<tr>
<td>Type D</td>
<td>20</td>
<td>108</td>
</tr>
<tr>
<td>Type E</td>
<td>4</td>
<td>55</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
<td>280</td>
</tr>
</tbody>
</table>
The distribution of patients included in this study during the specified time per year is demonstrated in Figure 1 and shows the relation between the numbers of failed construct with the numbers of operated patients by the same technique.

![Figure 1 - The number of patients with construct failure related to the total number of patients operated upon for pedicle instrumentation.](image)

**Radiological assessment**

Anteroposterior and lateral radiographs are performed in all patients. If one spinal fracture is detected, total spine x-ray was taken because noncontiguous spine fractures occur in 10 - 30% of patients.16

Computerised tomographic (CT) scan was done in all patients; CT has enhanced the understanding of mechanisms of neurologic injury and fracture morphology. The middle column and subtle posterior injuries can easily be diagnosed with CT. To allow accurate fracture classification and to help direct treatment, we recommended 3D CT examination.

Magnetic resonance imaging (MRI) is occasionally requested to demonstrate spinal cord pathology and the presence of neural compression, other soft tissue injuries and the state of the intervertebral disk can be identified. Magnetic resonance imaging can predict neurologic recovery in some cases based on T2-weighted images. Magnetic resonance imaging is indicated in patients with progressive neurologic deterioration, incongruous neurologic and skeletal injury, and unexplained neurologic deficit. Also, MRI can be used to assess the status of the posterior ligamentous complex.

**Classification of thoracolumbar fracture**

The McAfee system which identifies 6 fracture types based on CT scan findings is currently the best classification (Table 3).

**Indications for surgical treatment**

Indications for surgical treatment included: (1) Three column fractures or fracture/dislocations; with or without neurological deficits (2) Stable fractures with incomplete neurologic deficits, with spinal deformity or canal compromise.

**Table 3 - McAfee classification of thoracolumbar fractures and construct failure.**

<table>
<thead>
<tr>
<th>Type of fracture</th>
<th>Patients with construct failure</th>
<th>Total No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wedge-compression</td>
<td>5</td>
<td>75</td>
</tr>
<tr>
<td>Stable burst</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Unstable burst</td>
<td>21</td>
<td>135</td>
</tr>
<tr>
<td>Chance</td>
<td>--</td>
<td>16</td>
</tr>
<tr>
<td>Flexion-distraction</td>
<td>4</td>
<td>42</td>
</tr>
<tr>
<td>Translational</td>
<td>--</td>
<td>12</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>30</strong></td>
<td><strong>280</strong></td>
</tr>
</tbody>
</table>

**Timing of surgery**

Patients with incomplete or complete neurologic deficits which required surgical decompression were treated as soon as possible; (in the next scheduled morning surgical list). We did not operate any patient during night shift due to some technical difficulties. We preferred to operate on patients who were neurologically intact with compromised anterior vertebral column within the first two days to achieve optimum re-expansion of the collapsed vertebral body.

**Operative technique**

The patients were treated with short-segmental instrumentation consisting of pedicle screws applied immediately above and below the fractured level. All patients were operated upon in prone position laying on a transverse chest and pelvic rolls, which increase lordosis, to enhance reduction of the deformity. Decortication of the facet joint was performed (in some patients) to identify the proper entry point and make the surface of the joint flat. K-wire (Kirschner) was placed and lateral x-ray taken, AP view was not available in all the operative procedures either due to technical difficulties or unavailability of the C-arm machine. Spinal laminectomy opposite to the compromised neural canal was performed, when required for neural decompression and/or dural repair. No attempt was made to reduce the displaced or retropulsed fragment of the broken vertebra. No neurophysiological monitoring was conducted during the placement of instrumentation. Different transpedicular screw systems were used in this series of patients. Variable-angle (polyaxial) pedicle screws have been used and are preferred to overcome some limitations of the standard monoaxial screws. The posterior or posterolateral bone grafting was not used in any of our patients with short-segment transpedicular technique because intervertebral bone fusion was not approachable, especially in high mobility of the spinal region.
Follow-up studies
All patients were mobilized as soon as possible. Each patient wore an external orthosis (lumbosacral belt) for 6 - 8 weeks. Serial postoperative radiographs were obtained on follow-up; clinic visits at 2 weeks, 6 weeks, 3 months, 6 months and one year. Of the 280 patients, 150 (53%) patients were available for follow-up until the end of the study and 130 patients were followed-up for 6 months postoperatively.

Results
Thirty patients with construct failure were identified in 280 consecutive patients in whom short-segment transpedicular instrumentation was placed. The causes of failure were attributed to surgeon-related errors, in our opinion, resulting in an overall failure incidence of 10.7%. There were 25 men, and 5 women with the mean age of 25.6 years (range 18 - 40 years). On admission 4 (13.3%) patients were neurologically intact grade E according to ASIA scale, 20 (66.6%) patients had mild neurological deficits grade D, one (3.3%) patient with grade C, and 5 (16.6%) patients with complete no motor and sensory function grade A. All the patients with partial neurological deficits showed marked improvement postoperatively and ambulate independently without assistant (Table 3).

Five patients (16.6%) had wedge fracture, 21 (70%) patients with unstable burst fractures, and 4 (13.4%) patients with flexion-distraction spinal injury according to McAfee classification (Table 2). All patients in the current group showed some degree of spinal canal encroachment by retropulsed bony elements.

Surgical internal fixation was preformed at one level in 230 patients, and two levels in 50 patients. A total of 1350 screws were inserted in 280 patients. Fifty-five screws (4%) failed, either in the form of bending and malposition (24 screws) in 6 patients (Figs. 2 and 3), or broken (31 screws) in 12 patients (Fig. 4). The cups of screws disengaged from the head in 2 (6.6%) patients (Fig. 5), while we have 4 broken rods in 2 patients (Fig. 6), and rod dislodgement from the head of screws (Fig. 7) (Table 4).

Twenty-six (86.6%) patients underwent posterior decompression in the form of wide laminectomy and medial facetectomy in some cases. In 15 (50%) patients multiple levels were included. No intraoperative complications were noticed. All patients improved as regard to axial pain immediately postoperative, but as the construct failed the pain returned again and it was the main complaint. No patients in the current group showed postoperative deterioration for their neurological state, instead, all the patients with mild weakness improved postoperatively.

Discussion
The technique of posterior instrumentation for thoracolumbar fractures had been studied extensively. Various methods have been described for identifying the pedicle and placing the pedicle screws. Basic steps include: cleaning the soft tissues, exposing the cancellous bone of the pedicle by decortications at the intersection of the base of the facet and the middle of the transverse process, probing the pedicle, tapping the pedicle and placing the screw. In the lower thoracic levels, screw placement with a straight forward
direction may be safe. The incidence of pedicle wall violation was significantly reduced when screws were placed using open-lamina technique through partial laminectomy.\textsuperscript{3,14,23,31}

In the original technique described by Roy-Camille, the entrance point for screw insertion was situated in the intersection between a vertical line passing through the middle of the inferior facet and a transverse line passing through the middle of the transverse process.\textsuperscript{28} The direction of the screw was perpendicular to the posterior plane of the vertebra and straight forward. No information on pedicle wall violation was documented by Roy-Camille. Verlaan et al, were the first to evaluate the feasibility of Roy-Camille technique. They observed 41% penetration.\textsuperscript{33} A higher percentage of lateral (31.6%) and inferior (11.6%) wall perforation was also observed.

Routine use of pedicle screw has not been free of complications.\textsuperscript{26} The rate of screw misplacement has ranged from 10 - 25% and cortical violation up to 50% in some reports.\textsuperscript{3} The frequency of screw breakage ranged from 2.6 - 9%. Screw pull out and screw connector disengagements have been reported both in vitro testing and in vivo. The variable-angle screws are most useful in multilevel constructs in which several screw/rod connections are necessary. In this regard, there is a greater "margin of safety" in both the mediolateral and sagittal dimensions. The need for rod contouring is lessened and each screw may be placed on an axis parallel to the superior endplate, reducing the chance of construct failures.\textsuperscript{30}

Anterior column support is often insufficient in burst fractures of the vertebral body and should be restored because a recurrent kyphosis, even neurological deficit, could otherwise develop. With balloon vertebroplasty, fractured endplates can be reduced directly and the intravertebral defect can be filled with methyl methacrylate.\textsuperscript{34} In combination with pedicle-screw instrumentation, used for anatomical alignment and indirect reduction, fracture stabilization and anterior column augmentation can be achieved with a posterior approach only. It was concluded that both methyl methacrylate, and calcium phosphate cement can safely be used as bone void fillers but the latter is preferred in young patients due to its superior biocompatibility.\textsuperscript{24,25}

Complications in this patient study group occurred early in our experience and were due to errors in surgical techniques such as: error in probing the pedicle to verify the 4 walls of the pedicle, and not using 2-plane image guides to make sure correct placement of screws. Handling of the implants was very important to reduce the incidence of screw/rod disengagement, and loose screw's cup. While negligence of

the competent of the anterior vertebral column especially in cases of burst and severe wedge fractures leading to progressive spinal deformity and failure of constructs. In our most recent cases we commenced using transpedicular vertebroplasty with methyl methacrylate to restore and support the anterior column with promising results.

In a clinical trial with 20 patients suffering from traumatic thoracolumbar burst fractures, the balloon vertebroplasty procedure (additional to a pedicle screw construct) proved to be a feasible and safe technique.\textsuperscript{34}

In our series, 2 patients had broken rods with the explanation of marked torsional stiffness of the implants due to use of multiple transverse connectors. Wood et al, demonstrated that the pedicle screws increased torsional stiffness when placed at the distal end of the constructs implanted for deformity correction.\textsuperscript{37}

Edwards et al, found excellent maintenance of alignment in terms of kyphosis, vertebral body height and translation in their review of 122 patients.\textsuperscript{9} The spinal canal area was improved by 32% (from 55% patency to 87%) if the rod-sleeve construct was inserted within 2 days of injury. Between 3 and 14 days, they found a 23% improvement in canal deviance (range, 53 - 76%). Little improvement was found with surgery after 14 days. In our study we advised early surgical correction of spinal deformity; our patients were operated within the first two days post-trauma with good results as regard to re-expansion of the collapsed vertebral body and angle of kyphosis. Short-segment fixation using Cotrel-Du-bousset (CD) instrumentation has had poor outcome, as reported by McLain et al. They reviewed 19 patients and found vertebral collapse, vertebral translation or hardware failure in 10 patients.\textsuperscript{22} The primary cause for failure was attributed to the fixation device. Good outcome studies used a hybrid system using pedicular screws, rods and laminar hooks.\textsuperscript{2,6,29}

**Conclusion**

Short-segment pedicle screw fixation is a common and relatively simple method for treating thoracolumbar fracture. However, the posterior approach has some limitations, so training on the other alternative approaches is a must; especially with comminuted anterior vertebral column with anterior encroachment on the neural canal. It must also be preformed within the first two days of trauma to achieve optimum re-expansion of the collapsed vertebral body.

Therefore, great attention must be directed to maintain the coronal and sagittal balance of the fractured spine by the proper distraction of the implant, and early reconstruction of the comminuted anterior column. However, failure to
support the anterior spinal column after posterior correction and instrumentation is the main factor in construct failure.

Transpedicular vertebroplasty may solve the problem of progressive deformity and construct failure in cases with compromised anterior vertebral column but it still needs a further simplification of the injected material and technique.

Proper insertion of transpedicular screws does not depend only on the experience of the surgeon but also on the availability of suitable image monitoring to avoid malposition of the screws.

Proper application of the rods over the screw head in a straight perpendicular angle and application of the screw's cup in the correct mechanical manner is necessary.

The use of variable-angle (polyaxial) screws minimize the need for rod contouring, avoids pre-stress load applied on the construct and reduces early construct failure.

Additional instrumentations such as transverse connectors provide more rigidity and redistribute the loading weight over the implants.

Spinal implant failures can be caused not only by device-failure but also by surgeon-related errors, so a learning curve must be expected for spinal surgeons.

References
30. Steffee AD, Brantigan JW: The variable screw placement


