



Retrospective analysis of the occurrence of radiologically detectable surgical error in cases of failed pedicle screw implants

Mohammed F. BUTT, Muneer FAROOQ, Shabir A. DHAR, Mohammed R. MIR, Bashir A. MIR, Khursheed A. KANGOO

From the Bone and Joint Hospital Barzallah Srinagar, India

Pedicle screw instrumentation is an important tool in an orthopaedic surgeon's armamentarium in the management of spinal fractures. Complications with this system have been studied extensively. Due to the exacting technique the possibility of surgical error exists while using this modality. We studied a series of 216 cases where pedicular screws had been used and isolated 34 cases of implant failure. Retrospective analyses of their radiographs showed that surgical error does contribute to the implant failure in a statistically significant manner.

Keywords : pedicular screws ; failure.

INTRODUCTION

The concept of transpedicular fixation in the spine was introduced in the mid 1950's (3). Roy-Camille *et al* (20), in 1963, first used pedicle screw plates for the stabilisation of spinal injuries. Dick *et al* (6), Steffee *et al* (22), and Louis (13) further popularised this concept. The technique has been widely used for various spinal disorders. The superiority of this fixation system in terms of biomechanical properties, fusion rates, early mobilisation and versatility has been shown conclusively (10). Presently, the pedicle screw system represents the so-called gold standard of spinal internal fixation (9). However the use of pedicle screws is technically demanding and is associated with complications. Implant failure remains one of the unsolved issues with this system.

The incidence of mechanical failure in pedicle screw systems due to either screw breakage or disengagement has been reported between 17 and 36.3% in patients who have short segment posterior instrumentation for thoracolumbar fractures (11, 23). The improvement in implant design, placement techniques and better understanding of biomechanical characteristics has led to decreased complication rates. The contribution of surgical error towards these failures has, however, been seldom evaluated. The present study analyses the contribution of these surgeon controlled factors in implant failure and highlights the importance of proper techniques in posterior spinal fixation of unstable spinal injuries.

MATERIAL AND METHODS

Between July 2000 and August 2003, 216 cases of unstable thoracolumbar fracture were stabilised by

-
- Mohammed Farooq Butt, MS, Senior Registrar.
 - Muneer Farooq, MS, Associate Professor.
 - Shabir Ahmed Dhar, MS, Senior Registrar.
 - Mohammed Ramzan Mir, MS, Professor.
 - Bashir A Mir, MS, Assistant Professor.
 - Khursheed A Kangoo, MS, Associate Professor.

Bone and Joint Hospital Barzallah, Srinagar, India.

Correspondence : Mohammed Farooq Butt, Bone and Joint Hospital Barzallah, Srinagar, 190005, India.

E-mail : mfbutt72@yahoo.co.in.

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transpedicular fixation and posterolateral fusion. Out of these, 40 patients developed implant failure besides other complications.

This study focussed on these very patients who developed implant failure.

In total there were nine women and twenty five men with an average age of 34.4 years (range : 19 to 47).

As per McAfee's system (14), 17 patients had unstable burst fractures, 9 flexion-distraction injuries and there were 8 cases of translational injury. Neurological status of patients was graded by Frankel's method (8). There were eighteen patients with neurological grade of E, nine with grade D, seven grade C, two grade B, and four patients with grade A. Only ambulatory patients were selected for this study in order to measure the effect of faulty instrumentation when the construct was under load. Therefore six patients with neurological grade of A and B were excluded from the study, leaving only 34 patients for final evaluation.

On admission to the hospital, the patients were clinically and neurologically assessed and a neurological grade was assigned. Plain radiographs and computerised tomography scans of the spine were analysed individually. Fractures were classified by McAfee's system, spinal canal encroachment was determined and decompression or otherwise was planned.

The operative technique involved a posterior approach to the spine. The pedicle was identified by local inspection and the level was confirmed by fluoroscopy. The junction of the transverse process and lateral articular facet was entered with a semi-blunt awl, which was used to develop a tract through the central portion of the pedicle. Subsequent steps of tapping and placement of screws followed, autologous cancellous bone was placed on transverse processes, lamina and facet joints. Plates of adequate length were placed after contouring to the sagittal curvature of the spine by using a template. On an average patients were discharged on the 5th day with an advise to use a thoracolumbosacral orthosis (TLSO) for 3 months.

To evaluate patients for complications and analysis of surgical inadequacies medical case sheets, operative notes, pre and postoperative radiographs and CT scans, and operative notes of repeat surgery were reviewed three months to one year after surgery. Only implant failure was considered in this review.

Pedicle screw breakage, bending, back-out and loosening were considered as implant failures.

Use of small diameter and /or short screws, misplacement or malplacement into the pedicle and inadequate contouring of plates were labelled as a surgical error.

A screw was considered to be of inadequate length when it did not cross 50% of the anterior-posterior length of the vertebral body (24). A screw accommodating less than 65% dimensions of the pedicle as measured in pre-operative computed tomography was considered to be of small diameter (2, 21). Screws with medial and lateral penetration of the pedicle on CT were considered screw misplacement (1). Screw loosening was defined by a continuous lucency at the screw bone interface 1 mm or more wide and surrounded by a thin sclerotic bone (19). Screw malplacement was determined by calculating the sagittal screw angle, transverse screw angle (15), plate screw angle and alignment of pedicle screws in the longitudinal axis (25). A spinal plate not conforming to the sagittal spinal curvature, as seen on lateral view, was considered to have been inadequately contoured.

RESULTS

The analysis of implant failures in 34 cases revealed two groups of patients : those who developed implant failures despite technically adequate fixation and others in which one or more surgical error was found in the instrumentation. We divided these patients into group I and group II respectively.

Group I comprised of 16 cases, 13 male and 3 females in the age group 19-46 years (average : 35 years). As for the fracture pattern there were eight cases of unstable burst fractures, three flexion distraction injuries, and five with translational injuries. All patients had a neurologic grade of C or above (2C, 4D, 10E). There were three cases wherein posterolateral decompression had been performed. Pedicle screws were placed in both pedicles of the vertebra above and below the fractured one. The instrumentation was technically perfect. Pedicle screws of 5.5 mm diameter or more were placed in the pedicle, crossed more than 50% antero-posterior vertebral body length, and did not in any case breach the pedicle walls. The relation of the pedicle screws to the plate was within 0-5 degrees from perpendicular. The sagittal screw angle and transverse screw angles were within ten degrees from neutral. The contouring of spinal plates was conforming to the sagittal spinal curvature. The pattern of complications in this group is depicted in table II.

Table I. — Patient variables, complications and assessment of surgical faults

Patient no	Age (years)	Gender	Neurological status (Frankel)	Level of injury	Type of injury	Complication	Surgical error	presentation	Secondary procedure
1	30	M	E	L2	UB	IR Screw break-age	Malplacement-40° caudal to pedicle axis	Asymptomatic	—
2	25	M	C	L2	UB	SR Breakage SL back out	Small diameter screw in L1, inadequate plate contouring	Painful subcutaneous implant	Removal of implant
3	37	M	E	L3	FD	SR bending SL Bending	Small diameter screws, inadequate plate contouring	Asymptomatic	—
4	39	F	E	D12	TRS	SL Breakage	Small dia. Screw	Asymptomatic	—
5*	40	M	C	L1	FD	IL Screw back out	Malplaced screw, medial wall breach	Painful subcutaneous implant	—
6*	33	F	D	L1	UB	Both proximal screw back out	Small diameter, short screws and inadequate contouring	Painful subcutaneous implant	Reoperation
7	43	M	E	L2	UB	IR screw back out	Malplacement, inadequate plate contouring,	Asymptomatic	—
8	26	M	D	L4	UB	Both inferior screw bending	inadequate plate contouring, malplacement of screw 45° cephalad to pedicle axis	Asymptomatic	—
9*	47	M	E	L2	TRS	SL screw back out	Malplaced screw on CT	Painful subcutaneous implant	Repositioning
10	34	F	C	L3	TRS	IL bending SL back out	Malplaced inf. Screw, small dia. Screw, inadequate plate contouring	Occasional pain	—
11*	35	F	D	D12	FD	SR back out	Short screw	Occasional pain	—
12	33	M	E	L1	FD	SR Back out SL Breakage	Small diameter proximal screws	Occasional pain	Removal
13	25	F	D	L2	FD	IL bending	Malplaced screw-40° caudal to pedicle axis	Asymptomatic	—
14	30	M	D	L1	UB	Loosening of SL, IL	Malplaced screws-SL medial breach, IL lateral breach	Subcutaneous hardware	— unilateral implant removal
15*	32	M	C	D12	UB	SL back out	Malplaced screw, directed towards disc space and into it (45° cephalad angulation)	Subcutaneous hardware	Didn't consent for surgery
16	43	F	C	L2	TRS	IL back out	Medially malplaced screws	Subcutaneous hardware	— Removal of screw
17	37	M	E	L3	UB	SL breakage IL loosening	Small diameter screw, inadequate plate contouring	Asymptomatic	—
18*	30	M	E	L2	UB	SR breakage, SL back out,	Small diameter screw, short screw, malplacement of screw	Painful subcutaneous implant	Queued for re-operation

M-male, F-female UB-unstable burst, TRS-translational injury, FD-flexion-distraction injury SR-superior Right, SL-superior left, IR-inferior right, IL-inferior left, * surgery carried out by senior residents.

Table II. — Type of implant failure

Type of implant failure	Group I Number	Group II Number
Screw loosening	01	03
Screw back-out	03	12
Screw breakage	11	06
Bent screw	02	07

In group II, there were 18 patients, 12 men and 6 women with ages ranging from 25 to 47 years (average : 34 years). The data on patient variables, complications, surgical inadequacies and reoperation are described in table I. The pattern of complication is also shown in table II. Eleven patients in this group were symptomatic because of the implant failure but only six were re-operated. One or more surgical error was found in all the cases. Malplacement of the screw into the pedicle was the most common surgical error, closely followed by use of small diameter screws and inadequate plate contouring. Inadequacy of contouring was determined by comparison with the other group for each level of fracture

The analysis of the complications in the two groups revealed interesting results which are described in some detail.

- 1) The demographic characters, fracture pattern, neurological grading, operative indications and follow-up were similar in both groups. Transpedicular decompression was done in three cases of group I, and two cases of group II.
- 2) The most common type of implant failure in group I was screw breakage as compared to screw back-out in the other group. Screw bending was also a common complication in the latter group.
- 3) Implant failure in most cases of group I was seen at the thoracolumbar junction, but in contrast 29% (8/28) complications were seen in lumbar pedicles of the third through fifth vertebrae in group II. Whereas, in group I all screw breakages occurred in the superior screws at the thoracolumbar junction, screw back out was the common pattern in the other group. All

screw bendings were seen in lumbar vertebrae, i.e. inferior screws in group II in contrast to bending of two upper screws in group one.

- 4) Complications in the first group were seen late as compared to the other group.
- 5) Most patients in group I were asymptomatic and implant breakage was an accidental finding on follow-up. In group II, however 60% of the patients reported symptoms arising from the failed implant, most commonly painful subcutaneous hardware.
- 6) Most surgeries in the former group were conducted by senior consultants in comparison to the other group where surgical procedures were also carried out by senior residents.

DISCUSSION

In this study the contribution of surgical errors towards implant failure in unstable thoracolumbar injuries stabilised by posterior transpedicular fixation were evaluated. The findings demonstrated that one or more surgical fault was related to the failure of instrumentation and subsequent loss of correction, a problem seldom discussed in literature. This suggests that proper methodology of instrumentation may reduce, if not eliminate, the rate of failure of constructs in unstable thoracolumbar injuries.

Proper placement of screws into the pedicles is of paramount importance as far as the stability of the construct and its early fatigue failure is concerned. The specific manner in which the screw is placed into the pedicle in relation to the often sagittally contoured spinal plates seems to be a factor which may contribute to screw failure. When the pedicle screws are placed at different angles, so that they are not in alignment with each other, the screws either have to be bent into alignment or forced into alignment by the plate during its application (25). This will certainly shorten the fatigue life of the screw. Matsuzaki *et al* (15) described the use of sagittal screw angle and transverse screw angle in as a method of determining the correct insertion point in non-traumatic disorders of the lumbar spine. We found this measurement an important tool in analysing the placement of the

screw in dorsal and upper lumbar pedicle as well. All pedicle screws with more than 15 degrees deviation in sagittal screw angle eventually failed. Likewise calculation of sagittal screw angle is helpful in calculating the medial angulation of the screws.

Use of a screw with a proper diameter could be a subjective criterion and it is debatable what a proper diameter screw is, but it has been established that a small diameter screw fails more often than a screw with a larger diameter. However, preoperative computed tomographic pedicle measurement could be obtained before instrumentation, and a screw of adequate diameter selected (2). Computed tomographic scan was done in all our cases, and we considered a screw to be of appropriate diameter if it filled 65-70% of the pedicle dimensions. Biomechanical study on pedicle screw resistance to axial pull-out strength and cyclical loading have revealed that larger diameter screws had the greatest pullout strength (24). In another study pull out strength and rotational stability was determined to be improved if the major screw diameter fills 70-80% of the pedicle diameter (18).

Fatigue life and rotational stability of a pedicle screw is stated to be improved when it is deeply inserted into the vertebral body (18). Zindrick *et al* (24) also expressed this view that a fully threaded screw deeply inserted to engage the anterior cortex results in most secure screw fixation. There was, however, no difference in resistance to pull out with a screw depth to 50% of antero-posterior length of the vertebral body and to depth extending to the anterior cortex. We observed that the screws that did not reach 50% antero-posterior dimensions of the vertebral showed fatigue failure, and it was manifest when one or more technical inadequacy was present. Clinical (1) as well as biomechanical studies (17) have also highlighted the importance of full depth insertion of the screw and use of longer screws and its relation to fatigue failure.

Misplacement of the pedicle screw breaching the medial or lateral pedicle wall is the most feared and commonly discussed complication, usually labelled as an outcome of poor surgical precision. Despite mounting evidence of medially perforating pedicle screws in the literature (21) no major neuro-

logical injuries have been reported in large series of thoracolumbar fractures treated by pedicle screw fixation (4, 12). Apart from the risk to neurological structures due to misplacement, such a screw is at a disadvantage because of presence of very little or no cuff of cortical or cancellous bone surrounding it nor is it embedded adequately in the vertebral body. If there is a decrease in the compliance of the sagittal cuff of cancellous bone surrounding the screw, a more concentrated moment and less of a distributed load results in a pedicle predisposing the screw to fatigue failure (16). McKinley *et al* (17) in their study on the effect of surgical technique on intravertebral and intrapedicular bending movements studied the effect of eccentric placement, apart from other variables, on the pedicle screw bending movements. They reported that eccentric placement of a screw was also an important factor that increased pedicle screw bending moments and even slight increase in these moments become clinically important because of the logarithmic relationship between bending moments and number of cycles to screw failure.

Accurate preoperative measurement of a desired spinal plate contouring in an injured spine is difficult, though not impossible, and determination of this factor retrospectively is even more cumbersome. It is desirable to prebend the plate to the sagittal curvature of the spine in a rigid construct. This is important to have a screw plate relationship as close as possible to 90° at each level, (though new versions of variable plate allow some freedom in this regard) ; variance from the latter may result in unidirectional torque of the screw against one wall of the pedicle, resulting in bending and breakage of screw. Moreover, to the extent that the angle of the screw varies from a perpendicular relationship to the portion of the plate to which it is affixed, this screw will be forced to either bend or seat in a position which generates constant torque, a bending movement will be generated and the screw will eventually fail (25).

All these factors in isolation or in combination place the pedicle screw in a precarious position under conditions of axial loading in an already unstable spine, resulting in early failure of implant, loss of correction of kyphotic deformity and often

a need for second surgery. Using four pairs of screws (two above and two below the affected level), as proposed by some surgeons (1) supposedly lengthens the lever arm of the posterior construct and would not only enhance the stability but also maintain effective reduction of the kyphotic deformity. It is also possible that surgical errors in such a construct are less likely to manifest early. To avoid screw bending failures, protection of pedicle screws by adding offset laminar hooks (5) or augmentation of posterior procedure with an anterior reconstruction have also been used (7). Although biomechanically sound, these methods increase morbidity and cost. We concur with McKinley *et al* (17) in that if attention to optimal screw placement can reduce bending moments and potential for screw failure without increasing morbidity, surgical risk, or operative time, then proper insertion technique in pedicle screw instrumentation assumes paramount importance.

The fact that implant failure was also seen in patients with near perfect fixation suggests that immunity against implant failures can still not be guaranteed by addressing the technical aspects only. Fracture characteristics are important, and anterior column reconstruction in selected fractures is highly desirable. Our experience with posterior only implants has been satisfactory but implant failure remains a problem (4). Another aspect of implant failure in this study was the timing, pattern and level of pedicles involved thereby suggesting that whereas they are mainly surgeon controlled in group II, this is not the case with group I where implant failure is on the pattern previously described in literature.

This study demonstrates the critical importance of accurate surgical technique for reducing the risk of pedicle screw and construct failure. The failure to insert adequate diameter screws, the use of relatively shorter screws, misplacement and malplacement of screws and inadequate prebending of plate, decrease the fatigue life and eventually result in the failure of pedicle screws. Therefore we are convinced that correct surgical procedure can avoid these complications and improve outcome. However failure of implants in group I suggests that anterior reconstruction needs to supplement posteri-

or fixation in unstable injuries with gross comminution of the vertebral body at the thoracolumbar junction, a transition zone with extremely unstable injuries and significant kyphotic deformity.

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