GEORGIAN MEDICAL NEWS


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Abstract.

Objectives: Highlighting the prospective evaluation of the surgical outcome of pedicle screw usage in the treatment of degenerative lumbar spine disease in fifty-five patients who were treated consecutively via a posterior surgical approach with pedicle screw fixation.

Methods: A total of 55 consecutive patients with degenerative lumbosacral spine disease were treated at AL Mosul Teaching Hospital. Patients were included if they were between the ages of 25 and 60 years, they were admitted to the hospital with chronic back pain and or radicular pain and had a pedicle anatomy (based on a preoperative X-ray) that could accommodate surgical stabilization with PS instrumentation and fusion. Posterior surgical stabilization of the degenerative lumbar spine disease with pedicular screws was done and before discharge, each patient underwent a postoperative X-ray of the lumbosacral spine.

Results: In this series 55 patients were operated on for pedicular screw fixation with connecting bar, all patients underwent decompression except 2 cases, 47 patients with 2-level fixation and 8 patients with 3-level fixation. All patients' pain disappeared or became less, as well as paraesthesia. 10 patients with lower limb neurological deficits improved. Only 5 of all patients are re-operated (three due to displacement, one due to a broken screw, and one due to a loose screw), 3 patients developed Dural tears and were treated by suturing with muscle patch, no vascular injury, no post-operative infection seen but one patient developed DVT post-operatively treated conservatively.

Conclusion: Pedicle screw fixation facilitates the bone-fusion process, and its use is associated with a relatively low complication rate. The application of pedicle screws can be technically demanding; a thorough working knowledge of spinal anatomy and the principles of pedicle screw insertion will greatly contribute to their safe and accurate placement. These devices should be used when there is any feature of instability or due to iatrogenic instability after wide bone removal or after the destruction of facet joints.

Key words. Pedicle, screw, fixation, degenerative lumbosacral spine.

Introduction.

Chronic back pain disables millions of people around the world every year. It is considered the most common cause of activity limitation. There are nearly 15 million physician office visits each year for low back pain of which 90% of patients improve within 1 month without treatment [1]. The cause of chronic low back pain includes various causes like Degenerated disc diseases, spondylosis, spondylolisthesis, spinal canal stenosis and osteophytes [2].

The clinical presentation differs from mild low back pain that occasionally radiates into the buttocks and posterior thighs, especially during high levels of activity. The patient with degenerative spondylolisthesis is typically older and presents with back pain, radiculopathy, neurogenic claudication, or a combination of these symptoms [3].

The treatment modalities of chronic back pain differ from simple medical treatment and physiotherapy to surgery and lumbar fixation. The goal of surgery is to decompress the neural elements and immobilize the unstable segment or segments of the spinal column. This is usually performed with the elimination of motion across the facet joint and the intervertebral disc through arthrodesis [4].

Some patients will improve after simple decompression, and others who will develop radiculopathy or back pain will benefit from posterolateral fusion. The use of instrumentation as an adjunct to lumbar fusion procedures has increased over the past two decades. Multiple techniques have been described for the surgical treatment of patients with chronic low-back pain [5]. Posterolateral fusion (PLIF) is one of the more widespread techniques and may be performed with or without the use of pedicle screw fixation to provide internal fixation as a surgical adjunct to the fusion procedure. The addition of instrumentation is associated with higher costs and higher complication rates [6].

Despite an increase in its popularity over the past decade, the role of spinal fusion in the management of degenerative conditions of the lumbar spine remains somewhat controversial. Improvements in diagnostic imaging, fusion technique and spinal instrumentation systems and accumulating evidence regarding the safety and efficacy of fusion procedures contribute to a more widespread belief that in selected cases, fusion may be superior to non-surgical therapy or decompression alone [7]. Posterolateral and interbody fusion have been used successfully either alone or in combination together. Highlighting the prospective evaluation of the surgical outcome of pedicle screw usage in the treatment of degenerative lumbar spine disease. To follow up on patients to detect response to treatment (clinically and radiologically) and compare our results with those of other studies [8-15].

Patients and Methods.

This study is a prospective descriptive case series study design adopted for the evaluation of patients with unstable degenerative lumbosacral spine disease treated with PSF. Instability, a controversial concept, is determined using a clinical and imaging evaluation along with the principles of the Meyerding Grading System.

Between 1.1.2011 and 30.12.2012, a consecutive series of 55 patients with unstable degenerative lumbosacral spine disease were studied in Mosul Teaching Hospital. No eligible patients refused participation. There were 10 male patients and 45 female
patients whose ages ranged from 25 to 60 years, with an average of 42.5 years. The neurological status of the patients spanned a broad spectrum. The presenting symptom was chronic low back pain in most patients, neurogenic intermittent claudication in 50 patients, and radicular pain in 40 patients. All patients were assessed radio logically by: 

**X-ray:** Plain X-ray of lumbosacral spine in anteroposterior view, lateral view, dynamic flexion, and extension radiograph.

**Magnetic resonance imaging (MRI) of lumbosacral spine:** A total of 30 patients were diagnosed pre-operatively as grade I spondylolisthesis, 15 patients grade II spondylolisthesis, 10 patients without pre-operative littestis, either multiple level need wide laminectomy (wide bone removal) or have previous operation in the same level because of iatrogenic instability.

Pedicle fixation and fusion of the lumbosacral spine is an extensive procedure that may frequently involve significant blood loss. Each patient’s medical status must be carefully assessed before surgery. The patient should be typed and cross-matched for at least 2 units of packed red blood cells. All aspirin products and non-steroidal anti-inflammatory medications are discontinued at least 1 to 2 weeks before surgery the effect of these medications on platelet function is well known. Substantial blood loss may occur perioperatively if these medications are not stopped. Cessation of smoking should be strongly encouraged before surgery because fusion failure is significantly greater in patients who smoke. Before surgery, each patient underwent a standardized clinical and imaging evaluation that included a detailed history and physical examination by the attending surgeon and a review of plain radiographs, dynamic study and Magnetic resonance imaging studies was performed to evaluate neurological deficits or stability, DEXA study (bone densitometry) done in some of them with a risk factor for osteoporosis. Before discharge, each patient underwent postoperative plain radiographs to assess the PS position. In addition, daily postoperative clinical evaluations were performed to identify systemic or local complications, including neurological, vascular, or visceral injuries that may have resulted from the initial injury or surgery.

**Treatment Protocol:** Surgical indications were based on: Individual patient factors: which include symptoms (pain, paresthesia, and sphincter control), job, weight, previous operation.

Neurological status: motor, sensory, reflexes.

Mechanical stability of the spine: by pre-operative x-ray Meyer grading Grading System to classify the degree of vertebral slippage and help guide treatment.

Preoperative plain radiographs were used to determine the PS starting point and pedicle diameter, length, and inclination in both sagittal and axial planes.

In the operating room patients were positioned prone. Spinal precautions were used while positioning the patients. Spinal cord monitoring is not standard practice for spinal fixation surgery at our hospital and was not used in these cases. Sandbags are placed under the hip and the chest of the patients, and a midline incision is performed, followed by a diathermic incision of the fascia. After sub-periosteal dissection of Para spinal muscles on both sides of spinous processes, the lamina exposed, and self-retaining retractors are usually used to keep the dissected Para spinal muscles out of the surgical field. The Para spinal muscles should be dissected to the lateral tip of the transverse processes then standard anatomical landmarks are identified for screw placement, but placement could vary slightly depending on preoperative imaging. The intersection of an axial plane through the centre of the transverse process and a sagittal plane through the superior articular facet is a relatively accurate method of localizing each pedicle. Metal pins (i.e., Stem Mann pins or K wires) can be inserted in each pedicle along a proposed screw trajectory by using fluoroscopic imaging. The fluoroscope is positioned to obtain a lateral image.

A pilot hole is created in the pedicle after an appropriate entry point and trajectory are chosen. A pedicle sound is inserted in the pilot hole to ensure that neither the cortical margins of the pedicle nor the anterior cortical margins of the vertebral body are perforated if a cortical perforation is identified, the surgeon must reexamine the anatomy of that pedicle and the imaging data used to select the screw entry point, sagittal trajectory, and axial trajectory. If feasible, the pilot hole is drilled, and its position is confirmed with the pedicle sound. Depending on the instrumentation system used, the pilot hole is either tapped before screw insertion or a self-tapping screw is inserted the major screw diameter should be 70 to 80% of the pedicle diameter. The sagittal angle of the pedicles is relatively horizontal from L1 – L4, at the L5 angle, becomes caudal at 18 o& S1 increases to 30. the axial pedicle angle increases with caudal progression from L1 through S1, increasing by about 5 o at each subjacent level to reach 25 – 30 o at S1.

The screw entry site is created by rongeuring the lateral cortical margin of the superior articular process. Before the screw is inserted the pedicle is probed and the position of the probe is verified by C-arm fluoroscopy then the screw is inserted, after placement of all screws two rods are used, one on the right and the other on the left, the rods are secured to the screws, the slandered method for fusion used in this study is inter transverse fusion by decorticating the transverse process and putting bone graft from small pieces of spinous process and cut lamina in addition to previous some time we need graft from iliac crest. In severely slipped vertebrae gentle distraction is done by distractor between adjacent segments to reduce the displacement and open the disc space. Then the wound is closed over a Radivac drain, all screws were MRI-compatible.

**Results.**

The patient’s age in the present study were from different age groups (25 – 60 years old). Out of 55 patients, only 3 patients were below 30 years old (5.5%) and 11 patients between 30 – 39 years old (20%). Patients between 40 – 49 years old represent the most common age group involving 23(41.8)% alongside 17 patients between 50 – 59 years old (30.9)%. Only 1 patient more than 60 years old (1.8)%.

About sex distribution as in other studies females (81%) were involved more than males (19%). Females affected 4 times more than males, this may be due to osteoporosis due to hormonal changes, also, pregnancy in females progresses the degenerative changes.

In this series 55 patients were operated on for pedicular screw fixation with connecting rode, all patients underwent...
decompression except 2 cases, where the pathology was only pars fracture. Regarding associated pathology, out of 55 patients, 31 of these patients were associated with stenosis, 22 were associated with disc prolapse, and only 2 of these patients were associated with pars fracture.

Patients were distributed according to the number of levels of fixation, 47 patients with 2-level fixation and 8 patients with 3-level fixation. However, according to common levels of fixation, 29 patients with level L4-L5 fixation (Figure 1), 16 patients with level L5-S1 fixation (Figure 2), 2 patients with level L3-L4 fixation, 7 patients with level L3-L4-L5 fixation, and only 1 patient with level L4-L5-S1 fixation (Figure 3 and Figure 4).

Fusion rate after one year from the operation: At follow-up period showed that in all of those operated patients who spent one year post-operatively, the fusion rate was 95% (38 out of 40 patients). 5% no fusion occurred but still there 15 patients not yet finish one year postoperatively. Fusion assessed by X-ray.

Clinical result: patients scored as having a good, fair, or poor clinical result. A positive outcome includes a good and fair clinical result. In our sample, 35 patients out of 55 were good results, 15 had fair and 5 had poor results.

Improvement of low back pain and leg pain: 40 patients out of 55 with pre-operative leg pain 38 of them improved or diminished. 50 patients with pre-operative low back pain 45 of them relieved according to (the Dennis Pain Scale).

Daily activities of life: about 20% of those patients were operatively disabilities after the operation only 1.8 % remain disabling.

Analgesic use: 46 patients out of 55 were using analgesics daily only 12 of them remained using analgesics post-operatively.

Reoperation: 5 patients needed re-operation from 55 patients, 3 of them due to malposition of screws, one due to a broken screw and one due to loosening of the screw (Table 1).
The glucose lowering effects induced by metformin was similar to those reported by Miller et al. [15], Diamanti-Kandarakis et al. [16]. These conflicting data on glucose lowering effects specially in PCOS women may be explained by the inhibition of hepatic glucose production encourage by metformin deposition in liver with subsequent signalling pathway.

Totally 236 pedicle screws were used all of them were polyaxial type made from titanium, their size was differ according to the level but ranged from 5 – 6 mm in diameter and 40 – 50 cm in length, diameter, and length smaller at S1 but larger at L3. All screw used was properly implanted under fluoroscopy and were fully contained within the pedicle wall, except 3 of which were implanted improperly, re-operated again, one re-operated due to loose screw & one due to screw fracture. 3 patients who developed dural tears were treated by suturing with a muscle patch. one developed fusion system failure and one screw breaking. Only one patient has a neural injury, while no vascular or visceral injuries. No postoperative infection was seen but one patient developed DVT postoperatively treated conservatively. Only 2 screws were broken from 236 screws and reoperated (Table 2).

**Discussion.**

The goals of the pedicle screw fixation in degenerative spine disease are correction of spinal deformity, fixation with rigid stabilization to prevent delayed neural injuries and maintenance of anatomic alignment .however specific approaches are to be used in the management of degenerative spine disease [8,9]. In addition to fusion, decompression is nearly always needed with fixation to expedite neurological recovery.

In other studies, the female ratio was 4 times more than male. This may be due to many factors like pregnancy aggravating the degenerative spine disease and hormonal changes that play a role in this situation like osteoporosis, and OA changes. Common age group affected were those between 40 – and 49 years old. Regarding the clinical results, however the patients come early, the prognosis is better. In our sample 35 patients out of 55 had good results, 15 had fair and 5 had poor results. 40 patients from 55 with pre-operative leg pain 38 of them improved or diminished. Of 50 patients with pre-operative low back pain 45 of them were relieved about 20% of those patients were preoperatively disabilities after the operation only 2% remain disabled 46 patients of 55 were using analgesics daily only 12 of them remain using analgesics postoperatively 5

**Figure 4.** Patients with the instability of (L4-L5)&(L5–S1) with 3 levels of fixation done.

**Table 1.** Demographic, clinical, and pathological characteristics of participants.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Types</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age groups (years)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;30</td>
<td>5.5</td>
<td></td>
</tr>
<tr>
<td>30-39</td>
<td>20</td>
<td></td>
</tr>
<tr>
<td>40-49</td>
<td>41.8</td>
<td></td>
</tr>
<tr>
<td>50-59</td>
<td>30.9</td>
<td></td>
</tr>
<tr>
<td>≥60</td>
<td>1.8</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>19</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>81</td>
<td></td>
</tr>
<tr>
<td>Decompression</td>
<td>Positive</td>
<td>96</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>4</td>
</tr>
<tr>
<td>Associated pathology</td>
<td>Stenosis</td>
<td>56</td>
</tr>
<tr>
<td></td>
<td>Disc prolapse</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>Pars fracture</td>
<td>4</td>
</tr>
<tr>
<td>Levels involved</td>
<td>Two levels fixation</td>
<td>85.5</td>
</tr>
<tr>
<td></td>
<td>Three levels fixation</td>
<td>14.5</td>
</tr>
<tr>
<td>Common levels involved</td>
<td>L4-L5</td>
<td>52.7</td>
</tr>
<tr>
<td></td>
<td>L5-S1</td>
<td>29.1</td>
</tr>
<tr>
<td></td>
<td>L3-L4</td>
<td>3.64</td>
</tr>
<tr>
<td></td>
<td>L3-L4-L5</td>
<td>12.7</td>
</tr>
<tr>
<td></td>
<td>L4-L5-S1</td>
<td>1.8</td>
</tr>
<tr>
<td>Fusion rate (1 year postop)</td>
<td>Complete fusion</td>
<td>95</td>
</tr>
<tr>
<td></td>
<td>No fusion</td>
<td>5</td>
</tr>
<tr>
<td>Clinical results</td>
<td>low back pain improvement</td>
<td>Pre-op</td>
</tr>
<tr>
<td></td>
<td>Post-op</td>
<td>0.1</td>
</tr>
<tr>
<td>Leg pain</td>
<td>Pre-op</td>
<td>2.7</td>
</tr>
<tr>
<td></td>
<td>Post-op</td>
<td>0.6</td>
</tr>
<tr>
<td>Disability</td>
<td>Pre-op</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Post-op</td>
<td>0.8</td>
</tr>
<tr>
<td>Daily Analgesic use</td>
<td>Pre-op</td>
<td>3.6</td>
</tr>
<tr>
<td></td>
<td>Post-op</td>
<td>0</td>
</tr>
</tbody>
</table>

**Table 2.** Complications of transpedicular screw fixation.

<table>
<thead>
<tr>
<th>Complications</th>
<th>N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intraoperative</td>
<td></td>
</tr>
<tr>
<td>Dual Tear</td>
<td>3(5.46)</td>
</tr>
<tr>
<td>Vascular injuries</td>
<td>0(0)</td>
</tr>
<tr>
<td>Neural injuries</td>
<td>1(1.81)</td>
</tr>
<tr>
<td>Malposition of screw</td>
<td>3(5.45)</td>
</tr>
<tr>
<td>Postoperative</td>
<td></td>
</tr>
<tr>
<td>Early postop</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>0(0)</td>
</tr>
<tr>
<td>Late postop</td>
<td></td>
</tr>
<tr>
<td>DVT</td>
<td>1(1.81)</td>
</tr>
<tr>
<td>Fusion system failure</td>
<td>0(0)</td>
</tr>
<tr>
<td>Device failure</td>
<td></td>
</tr>
<tr>
<td>Loose screw</td>
<td>1(1.81)</td>
</tr>
<tr>
<td>Broken Screw</td>
<td>1(1.81)</td>
</tr>
<tr>
<td>Rod or plate fracture</td>
<td>0(0)</td>
</tr>
<tr>
<td>Connector loosing</td>
<td>0(0)</td>
</tr>
</tbody>
</table>
patients needed reoperation from 55 patients, 3 of them due to malposition of screws, one due to broken screw and one due to loosening of screw regarding the Dural tear occurred in 3 cases all of them was operated on before. The malposition of screws happened in three cases they were obese, and the c-arm does not properly show the image. In our study, we used prophylactic antibiotic (ceftriaxone 1g) preoperatively and postoperatively same antibiotic + ampiclox iv was used. Fortunately, there was no infection in our study [10,11].

In the present study, the fusion rate was 95% (38 of 40 patients). Whereas a similar study was done by Fathy et. al in Egypt in 2010 [12]. It used transpedicular screw fixation with a cage, the fusion rate was 88% (44 from 50 patients) and the difference was not significant (p = 0.223). Trost and Kafas (1996) have reported nearly similar results [13]. Such techniques could potentially find application in degenerative lumbar diseases, acutely traumatized knee, and chondromalacia [14-16].

Conclusions.

Pedicle screw fixation facilitates the bone-fusion process. Its use is associated with a relatively low complication rate, however the working team had very good experience. The application of pedicle screws needs a thorough working knowledge of the pertinent spinal anatomy and the principles of pedicle screw insertion will greatly contribute to their safe and accurate placement. Pedicle screws should not be viewed as a substitute for meticulous bone-grafting techniques because the ultimate goal of the procedure is the attainment of a solid bony fusion. Patients with Pedicle screw fixation can start walking earlier than those with spinal instability without fixation & fusion.

REFERENCES