Pedicle-Screw Fixation in the Lumbar Spine

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Abstract

This article provides a perspective on the development of pedicle-screw fixation in the lumbar spine, the biomechanics of its application, the possible complications, and the scientific evidence that supports specific applications in selected disorders. The overall goal is to objectify the debate currently surrounding the use of these devices. Lumbar-pedicle fixation devices are currently considered class III medical devices. According to the Food and Drug Administration, such devices are investigational or experimental, have not been proved safe and effective, and may potentially pose a risk to patients.

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A variety of degenerative, traumatic, and neoplastic disorders may destabilize the lumbar spine or cause significant cauda equina and nerve-root compression manifested as unrelenting pain, progressive deformities, and neurologic dysfunction unresponsive to nonoperative treatment. The surgical removal of posterior elements (i.e., laminae, articular facets, and pars interarticularis) may also contribute to significant current or future instability.

Historically, lumbar or lumbosacral fusion has been an accepted way to deal with these disorders and other mechanical causes of low back pain, such as spondylolisthesis. The commonly accepted indications for lumbar fusion include the following: (1) unstable thoracolumbar or lumbar fracture; (2) primary or metastatic tumors with significant vertebral body involvement, causing or increasing the risk of instability and/or neurologic compromise; (3) isthmic spondylolisthesis associated with unrelenting back pain and/or leg pain; (4) spondylolisthesis (isthmic or degenerative) that leads to leg pain for which a laminectomy is performed; (5) progressive scoliosis with back or leg pain; (6) symptomatic degenerative lumbar stenosis requiring significant removal of posterior elements, leading to potential instability; (7) iatrogenic symptomatic lumbar instability; and (8) symptomatic lumbar pseudarthrosis.

History and Role of Internal Fixation

The role of internal fixation is to increase the rate and rapidity of spinal fusion, correct deformities, and provide early stabilization. The devices should significantly decrease the pseudarthrosis rate. If these goals can be achieved with limited risks to the patient, the technique is considered useful, effective, and beneficial. In the treatment of long-bone fractures, internal fixation has clearly been shown useful in decreasing deformities; obtaining biologic union, both primarily and in pseudarthrosis repair; obviating extended hospitalization; and reducing the morbidity associated with prolonged immobilization.[1]

The modern concept of posterior internal fixation of the spine is generally attributed to Harrington. His instrumentation was used first for the treatment of scoliosis and later for trauma. Before his invention, scoliosis surgery was followed by a 30% to 40% pseudarthrosis rate,[2] with a progressive loss of curve correction over time. The introduction of Harrington instrumentation dramatically changed these results. In a long-term surveillance of patients treated with posterior arthrodesis and Harrington instrumentation for scoliosis, the pseudarthrosis rate was reported to range from 1% to 15%.[3]

Later, posterior Harrington instrumentation was used to reduce and stabilize fractures. Combined with a fusion, this technique allowed better anatomic correction of deformities and, more important, early

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mobilization of patients; provided protection of the neurologic elements from progressive kyphotic deformities; and was associated with an overall reduction of mental, physical, and financial costs of care.

The difficulties with Harrington instrumentation included loss of fixation in 5% to 20% of cases because of hook disengagement; fracture of the rods at the junction between the smooth and ratcheted portions; limited ability to deal with the rotational component of deformity; the risk of new deformity, such as flat back in the lumbar spine; limited ability to effectively treat subluxations, such as in degenerative spondylolisthesis; and inability to perform short-segment fixation following laminectomy.[4]

To address and correct some of these deficiencies, devices that allowed segmental fixation of the posterior elements were proposed and designed. Luque introduced the concept of segmental fixation, which allowed correction of deformities in multiple planes. Though extremely useful and still performed in patients with neuromuscular scoliosis, this type of fixation has a number of drawbacks, including the need to pass multiple sublaminar wires, which have the potential to cause dural tears, neurologic compromise, and wire breakage within the canal. In addition, these devices have only a limited ability to control or resist axial forces.

The next generation of instrumentation to segmentally fix the spine was developed to take advantage of some of the lessons learned from the Luque sublaminar wiring technique, as well as to decrease some of its complications. These systems initially involved hook fixation to laminae in multiple locations, allowing greater segmental control of the spine while avoiding the passage of wires into the spinal canal. The new techniques, first introduced by Cotrel and Dubousset, markedly advanced the surgeon's ability to alter spinal alignment in three dimensions while increasing the rigidity of fixation. Unfortunately, hook-lamina segmental fixation remains dependent on the presence of intact laminae and facets and may be technically difficult to apply over multiple adjacent segments, particularly those encountered in degenerative conditions affecting the lumbar spine.

Although the use of pedicle screws and facet screws was first reported in the 1940s, the success and acceptance of the technique were limited.[5] In retrospect, use of these newer techniques was hindered by the lack of appropriate instrumentation and the ability to monitor screw placement by intraoperative fluoroscopy. In the past decade there has been a major interest in using pedicle screws fixed to rods or plates because these devices enhance rigidity, are applicable to both short- and long-segment fusion, do not require intact posterior elements, and are thought to markedly improve the fusion rate.

Today, there are more than 16 devices that use the pedicle for screw-bone fixation. The use of pedicle-screw fixation devices in the lumbar spine, however, is still considered investigational or experimental by the Food and Drug Administration (FDA) except in cases of high-grade spondylolisthesis.

Biomechanics of Pedicle Screws

The pedicle has been described as the "force nucleus" of the spine, where the posterior elements converge before their communication with the more anterior vertebral body.[6] The pedicle, as the strongest portion of the vertebral body, is ideal as a point of force application for segmental fixation. Proper insertion of bone screws into the pedicle avoids canal intrusion, which is necessary with hooks and sublaminar wires, and does not rely on posterior elements. Also, with the use of screw-rod or screw-plate constructs, the surgeon has the ability to apply distracting, compressing, lordosing, derotating, and/or anteriorly or posteriorly directed forces, depending on the clinical situation and the spinal abnormality treated. Biomechanical studies have shown constructs employing screws securely placed in the pedicles to be more rigid than other forms of internal fixation. Furthermore, rigid fixation allows earlier mobilization of the patient, often using less rigid external orthotic support.

As interest in spinal fixation devices has increased over the past decade, so has research into the biomechanical characteristics of various spinal constructs. Studies have been performed in human and animal spines. The usual experiments are based on a corpectomy and/or acute fracture model. Devices are tested under cyclic loading, applied in either a destructive or a nondestructive testing mode. The performance of a variety of devices and the mechanical characteristics of the screws and their connecting elements have been evaluated.

In a calf model involving an L3 corpectomy, Chang et al[7] found that four different pedicle-fixation devices provided greater torsional rigidity and greater reduction of strain with flexion loading than did the Harrington system or Luque sublaminar wires. The latter two were less rigid on axial loading than fixation devices secured through the pedicle.

Gaines et al[8] evaluated a variety of posterior spinal constructs and determined that Harrington rods, whether or not supported by

Edwards sleeves or sublaminar wires, were weak in torsion. Much of the strength was dependent on the ligamentotaxis obtained through the anterior longitudinal ligament. Luque rectangles fixed to the spine with sublaminar wires resisted rotation, but performed poorly when subjected to axial loading, flexion, and/or extension. Variable screw placement (VSP) plates fixed with bone screws in the pedicle were rigid in all modes tested.

Puno et al[9] also found that the VSP device was the most rigid, followed by bone screws in the pedicle fixed to rods. All were stronger than the Luque sublaminar construct.

Screw design offers varying degrees of fixation strength within the vertebral pedicle. In general, the larger the minor diameter (inner shank width), the greater the flexoral rigidity, or bending strength. Screw breakage secondary to bending fatigue appears to be the primary mode of failure. The pull-out strength of a screw, which is of less importance as a cause of pedicle-screw failure in nonosteoporotic bone, is determined by the difference between the diameter of the outer-screw thread and the diameter of the inner core; the larger this difference, the stronger the pull-out strength. Screw-thread design (i.e., buttress versus tooth) appears to be unimportant; however, a smaller thread pitch (i.e., 2 mm versus 3 mm) confers a slightly stronger pull-out screw strength.

In general, use of fully threaded screws and insertion of screws deeper within the vertebral body improve overall pull-out strength. Although penetration of the anterior lumbar vertebral body cortex improves screw pull-out strength by approximately 20% to 25%, it may be that this benefit is outweighed by the risk of vascular injury. Therefore, the recommended depth of screw insertion is between 50% and 80% of the width of the anteroposterior (AP) diameter of the vertebral body.[10-12] Bone screws for use with the Edwards, VSP, and Texas Scottish Rite Hospital (TSRH) systems, as examples, have a thread length and pitch that provide the strongest pull-out strength when placed securely within the pedicle.

The AO Schanz screw, when used with the internal fixator and placed deep within the body, has very little thread within the pedicle and works more on a cantilever principle than does pure pedicular fixation. As an intermediate, the original Cotrel-Dubousset screw has a thick inner core and a very thin thread (outer diameter); as a result, it provides more of a cantilever effect in the pedicle than do the screws in some other systems.

Clinical Experience

Although biomechanical data indicate a greater strength of fixation for pedicle screws than for traditional devices as measured by flexoral, compression, and torsional rigidity, the true value of pedicle screws can be determined only if these qualities translate to an improved fusion rate and enhanced patient outcome.

The majority of clinical studies have included patients with diverse pathologic conditions and diverse outcome measures but have not included concurrent controls. In 1986, Louis[13] reported on 266 patients who underwent posterolateral fusion supplemented with the use of bone screws that were placed in the pedicle and fixed to a plate. Surgery had been performed for the treatment of lumbar spondylosis, failed disk surgery, and symptomatic pseudarthrosis. He reported a 97% rate of successful fusion in this group of patients.

Edwards[14] reported on 50 patients who underwent posterolateral fusion with his modular pedicle-screw instrumentation. This group included 23 patients with pseudarthrosis, 10 patients with spondylolisthesis, 7 with "instability," 7 with fractures, and 3 with degenerative scoliosis. At radiographic follow-up after a period of more than 2 years, 96% of the patients who had not undergone previous surgery were found to have a solid fusion, compared with only 84% of those who underwent reoperation.

West et al[15] reported on 62 patients who were treated with VSP instrumentation for lumbar degenerative disk disease, spondylolisthesis, and symptomatic pseudarthroses. Their study placed importance on patient satisfaction and functional outcome at follow-up. Overall, fusion was successful in 90% of the patients, with the majority reporting a marked improvement in postoperative pain as well as improvement in functional status. Two thirds of the patients eventually were able to tolerate a full-time work schedule.

In a survivorship analysis, McAfee et al[16] reviewed the data on 120 patients who underwent fusion for disorders of the lumbar spine supplemented with either a VSP device (n = 78) or Cotrel-Dubousset instrumentation with bone screws placed in the pedicle (n = 42). At the 10-year follow-up, 22 of the 526 pedicle screws placed were found to be either bent or broken. However, the incidence of successful fusion was 90%, and the instrument survival rate was 80%.

It must be pointed out that not all studies support the routine use of instrumentation to supplement and enhance fusions. Bernhardt et al[17] reviewed the data on 45 patients who underwent posterolateral fusion with (n = 18) or without (n = 27) VSP instrumentation for degenerative lumbar disease with instability. At follow-up, 70%

of the patients in whom instrumentation was not used had good to excellent results, and the nonunion rate was 26%. These results were not significantly different from those obtained in patients in whom instrumentation was used; 76% had good to excellent results, and the incidence of pseudarthrosis was 23%.

Zuckerman et al[18] retrospectively reviewed 871 patients who underwent posterolateral fusion with or without instrumentation for symptomatic lumbar instability and lumbar-disk herniation between 1978 and 1986. Patients were selected and matched into four equal groups of 30 in order to evaluate the efficacy of fusion alone as compared with fusion with Knodt rods, Harrington distraction rods, or VSP instrumentation. At follow-up, 80% of the patients who underwent posterolateral fusion without instrumentation reported good to excellent results, compared with 70% of those with VSP instrumentation. Although patients treated with pedicle fixation had the lowest pseudarthrosis rate (10%) among all groups, this result was not statistically significantly different from that in the group who did not undergo fixation.

Zdeblick[19] prospectively randomized 124 patients with symptomatic degenerative conditions of the lumbosacral spine into three matched study groups. One group underwent posterolateral fusion with autogenous bone graft, a second group underwent a similar fusion supplemented with a semirigid internal fixation system that included a Luque plate and pedicle screws, and the third underwent posterolateral fusion supplemented by a rigid construct employing TSRH screws fixed to rods. At follow-up after an average of 16 months, 64% of patients in the no-fixation group were found to have successful fusions, and 71% of those patients had good to excellent clinical results. In the semirigid fixation group, 77% of patients had successful fusion, with 87% of them having good to excellent results. In the rigid-fixation group, there was successful fusion in 95% of cases, with a 95% rate of good to excellent results.

In a prospective, randomized study, Lorenz et al[20] examined a group of patients who underwent fusion with or without instrumentation for back pain related to a primary diagnosis of lumbar degenerative disk disease. A solid fusion was reported in all patients who underwent fusion supplemented by VSP instrumentation. Eighty percent reported a decrease in pain, and 87% returned to work. There was no evidence of instrumentation failure at follow-up, which exceeded 2 years. In contrast, patients who underwent fusion without instrumentation had a 20% incidence of pseudarthrosis and a 50% decrease in pain. Only 47% returned to work.

The studies of Zdeblick[19] and Lorenz et al,[20] coupled with the majority of the retrospective studies already described, suggest that rigid internal-fixation devices fixed to the spine through bone screws to the pedicles have greater efficacy than more traditional forms of lumbar instrumentation. Limited rigid fixation applied through the pedicle also decreases the morbidity that results from fusing more spinal motion segments than necessary while not sacrificing rigidity of fixation.

Complications

The minor and major complications related to pedicle-screw insertion have been reviewed extensively. Whitecloud et al[21] reviewed the data on 40 patients who underwent VSP instrumentation for various degenerative and traumatic lumbar disorders. The average follow-up period was 20 months. They reported an overall minor/major complication rate of 45%, with that number increasing to 63% in patients who had undergone a previous operation. Most complications were minor and resolved before the patient's discharge. Nerve-root irritation developed in 2 patients (5%) due to misplacement of screws. The rate of superficial and deep wound infection was 7.5%. Overall, implant failure occurred in 7 patients (17.5%) due to breakage of pedicle screws.

West et al[22] reviewed 124 consecutive cases in which VSP instrumentation was used in a population that was similar to that in the study by Whitecloud et al.[21] A 29% complication rate was reported for the first 50 cases, and a 26% complication rate for the last 74 cases. The majority of these complications were minor, although it was found that 36 of the 783 screws were misplaced, as determined on postoperative radiographs, and 2 screws caused neurologic impairment.

A significant learning curve in properly inserting pedicle screws has also been shown by Weinstein et al[23] and Gertzbein and Robbins.[24] This is related to the difficulty of placing a screw blindly down the small bony tube of the pedicle, which is surrounded by neural tissues medially and inferiorly and vascular structures anteriorly.

The incidence of neurologic injury from misplaced screws has been documented in the literature to range from 0% to 12%.[25] The Morbidity and Mortality Committee of the Scoliosis Research Society reported a 3.2% rate of neurologic injury in its survey of members who used bone screws for the treatment of various spinal disorders (unpublished data, 1987).

Infection is a major concern in any spine surgery and is particularly so in instrumented fusions. The reported infection rate with decompression without fusion is 1%. When a fusion is added, the infection rate increases to 2%. For fusions with instrumentation, the rate escalates to 6% to 7%.[20] The rate of deep infection at the inception of pedicle-screw fixation is relatively high. This is apparently due to longer operating time, reflecting surgeons' unfamiliarity with this new form of internal fixation, combined with prolonged use of radiographic assistance in the operating room. With greater experience, less reliance on fluoroscopy and radiographic aids, and shorter operative times, the incidence of deep infections appears to be decreasing.

Pedicle-screw implants are associated with several drawbacks intrinsic to their design and application. Due to the bulky profile of the implants and their elevation off the posterior elements, slender patients may complain of soft-tissue irritation, as well as a bothersome prominence when wearing clothing. Another disadvantage of pedicle-screw fixation is the potential impingement on the unfused superior facet joint. Often, the capsule or a portion of the facet is violated during placement of the superior screw or application of the plate or rod. This, along with the biomechanical effect of a subjacent rigid segment, may lead to accelerated symptomatic degenerative changes at the unfused segment over time. In addition, the presence of bulky internal fixation adds to the difficulty of radiographic evaluation of the fusion status and significantly limits postoperative imaging of the involved levels with computed tomography (CT) and magnetic resonance (MR) imaging due to metallic artifact, even with the use of titanium implants.

Many clinical investigators have noted a high incidence of hardware failure with pedicle-screw implant systems. Screw-breakage rates were approximately 30% in some studies.[25] This has been attributed to many factors, including poor design of the early devices, incorrect screw-plate alignment, prestressing of the screw-rod or screw-plate construct, lack of anterior load sharing in the presence of anterior-column instability, and improper choice of implants (screws or fixation system).

Matsuzaki et al[26] reviewed the data on 57 patients with lumbar degenerative disease. Modification of a VSP system was used in all patients. Of the 297 screws placed, 17 broke (6% complication rate).

In a limited study in which the results were dependent on response to a mailed questionnaire, Esses et al[27] surveyed a group of spine surgeons. Of the 617 case-report forms that were completed, 18 (3%) mentioned screw breakage.

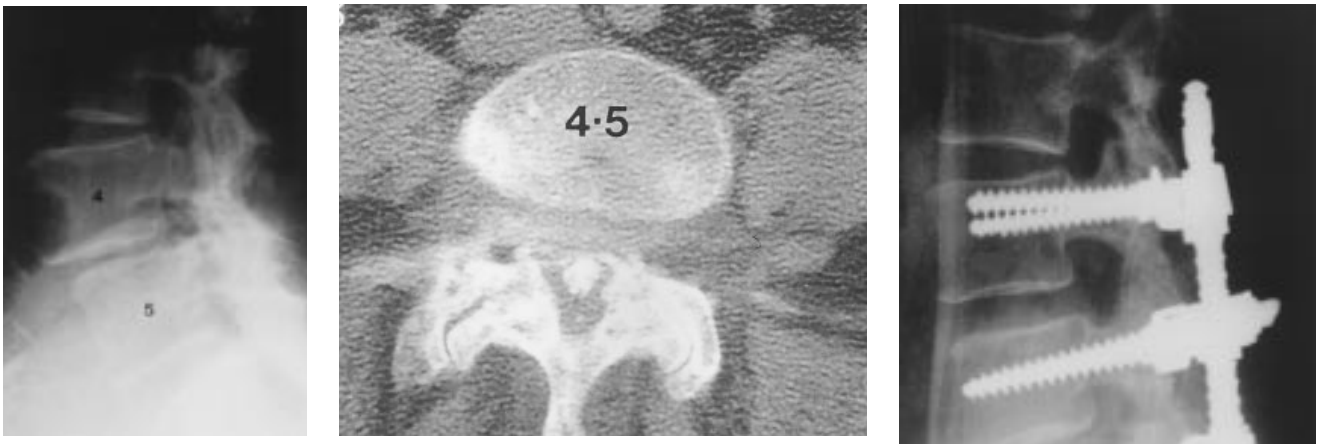
Hsu et al[25] reported on 76 patients who underwent fixation through the pedicle, primarily for lumbar degenerative disease, including spondylolisthesis. At follow-up, 16 patients (21%) were found on radiographic examination to have one or more broken screws.

The application of internal fixation, especially pedicle-screw systems, prolongs the operative procedure and, therefore, increases the amount of total blood loss. The natural tamponade effect of the posterior paraspinal muscles against the decorticated posterior elements and bone graft is reduced by their elevation relative to the large, often bulky posterior-instrumentation devices. The placement of hardware after decortication may therefore prolong the amount of blood loss before graft placement and wound closure. In addition, adequate decortication may be sacrificed to prevent weakening of potential fixation sites, and the space available for bone graft may be reduced by the instrumentation itself. The creation of free space due to the interposition of internal-fixation devices removes an additional sealant and safeguard against formation of a cerebrospinal fluid fistula or pseudomeningocele after a dural sheath injury.

Use in Treatment of Spondylolisthesis

Progressive vertebral slippage and angulation have been reported in up to 33% of radiographically solid posterior fusions in patients with spondylolisthesis.[28,29] It has been proposed that the lack of axial support across the L4-5 (Fig. 1) or L5-S1 (Fig. 2) disk spaces, particularly with high-grade slips, increases the anterior-inferior shear forces at this level. In addition, there are excessive tensile forces in the plane of the posterior fusion mass due to the anterior shift of the axis of rotation of the cephalic lumbar spine as it moves forward over the more caudal vertebral element. Bone fixation through the pedicles affords the ability to rigidly fix, and possibly reduce, a mobile spondylolisthetic segment, thereby improving the biomechanics of the maturing fusion. These same issues occur to a lesser extent in posterolateral fusions.

Kabins et al[30] reviewed the data on 41 patients with disorders of the lumbar spine. Fifteen of the patients had degenerative spondylolisthesis and underwent decompression and posterolateral fusion with VSP instrumentation. They compared their results with those of Herkowitz and Kurz,[31] who reported on patients with degenerative spondylolisthesis treated with decompression with or without fusion. At follow-up, Kabins et al found no



A B C

Fig. 1 **A,** Lateral plain radiograph depicts L4-5 spondylolisthesis. **B**, A CT scan at the L4-5 disk space reveals significant central and lateral recess stenosis. **C,** Radiograph obtained after decompression, reduction, and fusion with pedicle instrumentation from L3 to L5, which resulted in marked resolution of lower-extremity claudication.

increase in the degree of slip in patients treated with VSP instrumentation.

In contrast, in the series of Herkowitz and Kurz, 22% of the patients who underwent fusion and 65% of those not treated with fusion demonstrated slip progression. However, the progression of slip did not correlate with clinical outcome. In addition, pseudarthrosis developed in one third of the patients, which is considerably higher than the 3% incidence in the patients of Kabins et al.

Kim et al[32] evaluated 89 consecutive adult patients with spondylolisthesis. They found no significant benefit in terms of fusion success between patients treated without instrumentation (75% had successful fusion) and those who underwent fusion plus spine fixation through the pedicles (67% had successful fusion).

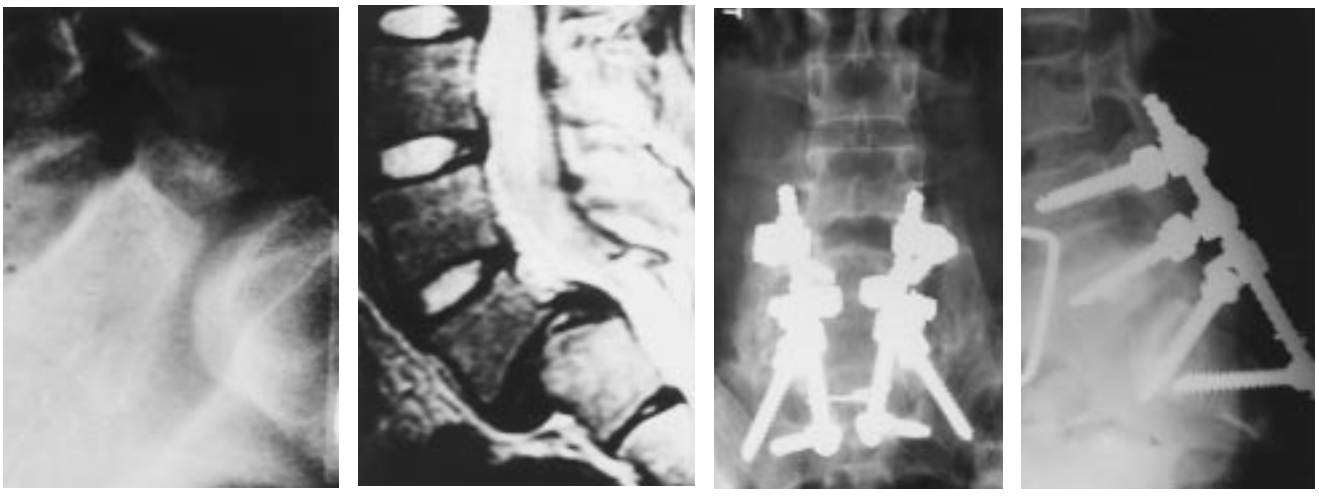


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Fig. 2 Lateral plain radiograph **(A)** and sagittal MR image **(B)** reveal a grade II isthmic spondylolisthesis at the L5-S1 level in a symptomatic 16-year-old patient. Patient underwent a successful decompression, reduction, and posterolateral fusion from L4 to S2 with pedicle fixation, depicted on AP **(C)** and lateral **(D)** radiographs.

The indications for reducing an isthmic spondylolisthesis also are controversial. Edwards[33] reported excellent correction of degree of slip and angulation with the use of his modular instrumentation to obtain graded reduction of high-grade isthmic spondylolisthesis. His review of 25 patients with L5-S1 spondylolisthesis (grades II to IV in 18 cases and spondyloptotic in 7) revealed better than 95% mean slip correction and a greater than 91% rate of maintenance of slip correction at the time of fusion.

The problems associated with instrumentation for treatment of spondylolisthesis are significant and include longer operative times, a potential for neurologic impairment from misplaced screws, and an overall increased infection rate. Furthermore, instrumenting one motion segment may not be adequate to maintain reduction across a spondylolisthetic segment. Generally, fixation at two segments below the slip level is necessary to maintain reduction. In a case of isthmic spondylolisthesis, fixation to the sacrum is also somewhat difficult because of the steep angle of L5 relative to S1 and the difficulties encountered in placing a plate and/or stiff rod across the angled and translated segment.

Use in Trauma Management

The use of pedicle fixation to obtain reduction and rigid stabilization while preserving lordosis is an attractive alternative to distraction instrumentation in unstable lumbar fractures, particularly those involving the more distal lumbar vertebrae. To date, few clinical studies have addressed the biomechanical feasibility of two-segment posterior stabilization in terms of pedicle-screw implant survival, fusion success, and functional status (Fig. 3).

An et al[34] reviewed the data on 31 low lumbar-burst fractures (L3 through L5) treated with a body cast, short-segment pedicle fixation, Harrington distraction rods, or Luque rodding with sublaminar wires. Patients treated with short-segment pedicle fixation reported less low back pain than those with longer instrumented fusions; in addition, greater vertebral body height and lumbar lordosis were maintained. Harrington distraction rodding was effective in restoring vertebral height but not lumbar lordosis. Luque rodding was ineffective in restoring and maintaining vertebral body height and was only moderately effective in obtaining lumbar lordosis.

McLain et al[35] reported on 19 patients who underwent short-segment screw fixation through the pedicle for unstable thoracolumbar and lumbar fractures. Only 11 patients underwent two-segment stabilization above and below the level of injury. At an average follow-up of 15 months, 10 patients demonstrated some form of treatment failure, 7 patients had implant breakage with resultant kyphosis, and 3 patients had kyphosis due to osseous collapse or vertebral translation without hardware failure. The

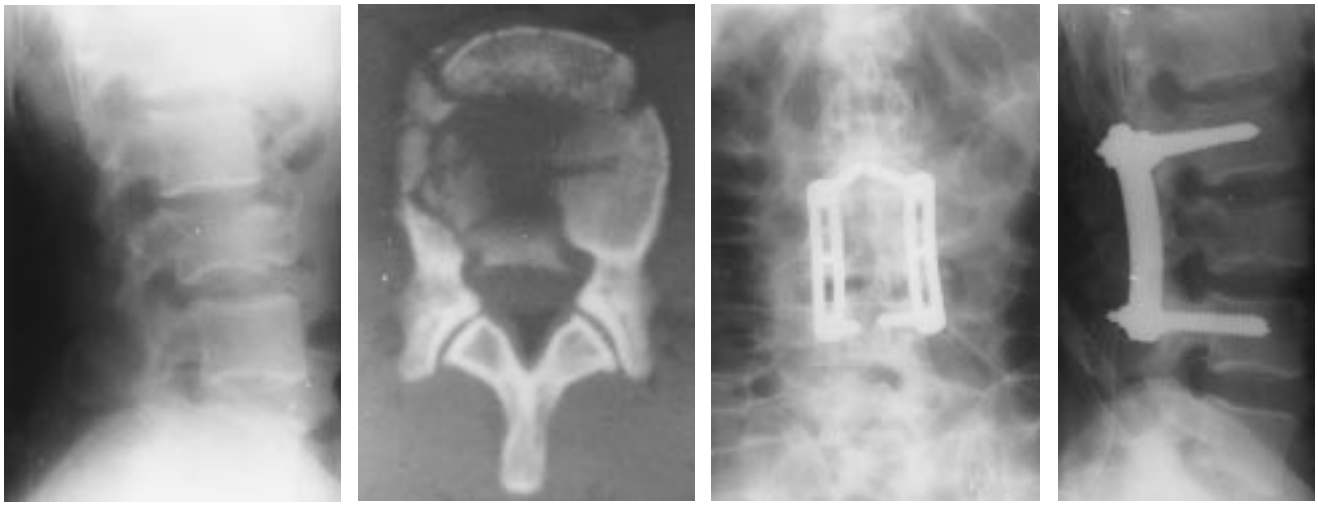


Fig. 3 Lateral plain radiograph **(A)** and transaxial CT scan **(B)** reveal an L3 burst fracture with approximately 30% canal occlusion. Postoperative AP **(C)** and lateral **(D)** radiographs depict posterolateral fusion with short-segment pedicle-screw fixation from L2 to L4.

authors concluded that deliberate prestressing of the screws and in situ bending of the rods in the presence of untreated anterior column instability contributed to the high rate of failure. However, this may be related more to improper choice of systems than to failure of the instrumentation as related to mechanical weaknesses of the design.

This and other studies highlight the mechanical limitations of rigid posterior segmental systems that are used in an attempt to fixate three-column fractures perpendicular to the long axis of the vertebral column without adequate anterior-column stability. This is in contrast to Edwards' reports of long-term success in terms of pain relief, obtaining fusion, and maintaining alignment with short-segment rods and hooks supplemented with polyethylene sleeves, which provide anterior and rotational vectors for three-point reduction and support.[4, 14]

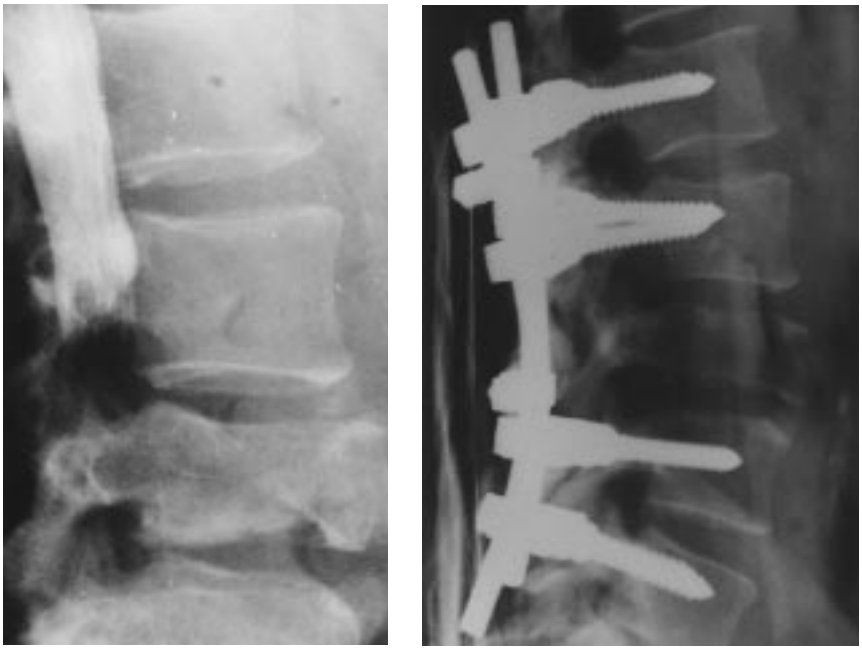
Ebelke et al[36] performed a survivorship analysis on 21 patients with lumbar-burst fractures who underwent two-segment fusion with VSP instrumentation. In the 8 patients who underwent an additional anterior- or middle-column grafting procedure, there was no evidence of implant failure at an average follow-up of 27 months. The remaining 13 patients underwent posterior stabilization and fusion without anterior bone grafting. At the 18-month follow-up, only 49% of the implants had survived.

These data must be considered carefully before attempting short-segment stabilization of unstable thoracolumbar-burst fractures with use of a posterior approach with bone screws in the pedicle. Appropriate contouring, realignment, and maintenance of three-point fixation are mandatory to avoid the creation of excessive distraction and anterior vector forces. On the basis of well-designed studies in which specific patient cohort groups were carefully followed up, it appears that the choice of instruments may be less critical than the reestablishment of physiologic lordosis with appropriate forces. Additionally, postoperative immobilization may help prevent late collapse of unstable fracture configurations without the need for increasing the number of motion segments that are instrumented and immobilized.

Current Indications for Pedicle-Screw Fixation

The majority of patients who undergo surgery for degenerative conditions of the lumbar spine, including herniated disks or spinal stenosis, do not require additional lumbar-spine fusion. Conditions that either are intrinsically unstable due to tumor or trauma or are predisposed to postoperative instability may ultimately warrant consideration for surgical stabilization by means of a posterolateral fusion. Once a decision to perform a surgical fusion has been made, the supplemental use of internal fixation should be considered.

Currently, the indications for the use of pedicle-screw fixation of the lumbar spine are limited but include the following: (1) stabilization of degenerative spondylolisthesis after a decompressive laminectomy; (2) reduction and stabilization of isthmic or degenerative spondylolisthesis with or without decompression; (3) surgical stabilization of selected unstable lumbar-burst fractures, particularly low lumbar-burst fractures; (4) extensive decompression or resection of primary or metastatic neoplastic lesions of the lumbar spine (Fig. 4);



A B

Fig. 4 **A,** A lateral plain myelogram reveals complete dye cutoff at the L3 level as a result of a pathologic burst fracture in a patient with acute cauda equina syndrome. **B,** Radiograph obtained after anterior L3 corpectomy with anterior strut grafting from L2 to L4 and posterolateral fusion with use of pedicle-screw instrumentation from L1 to L5.

(5) surgical revision of symptomatic lumbar pseudarthrosis, particularly in a compression mode; (6) radiographically confirmed segmental instability after decompressive procedures (Fig. 5); (7) certain instances of retrolisthetic instability with disk-height collapse and facet subluxation, particularly after surgical decompression; (8) surgical stabilization and possible correction of adult degenerative lumbar scoliosis (Fig. 6); and (9) certain cases of axial rotational instability with symptomatic nerve-root irritation in which derotation and segmental stabilization are indicated.

We believe that the benefits of pedicle-screw devices outweigh their potential risks because they allow greater rotational control of the spine than can be achieved with other devices and provide rigid fixation in the lower lumbar spine and sacrum without loss of lordosis. Pedicle-screw devices allow the use of limited instrumentation of the lumbar spine over a few levels. Furthermore, they have greater stiffness in flexion and rotation than other devices, allowing active distraction and/or compression to a degree not attainable with nonsegmental pedicle-screw systems.

FDA Status

At the time of this writing, use of pedicle screws in the lumbar spine is limited by the FDA to cases involving symptomatic high-grade spondylolisthesis. A number of systems have screws that are approved for use in the sacrum, but the situation is distinctly different from that of anterior vertebral-body screws, which are approved devices.

Currently, the FDA, physicians, and manufacturers face a regulatory dilemma. From the FDA standpoint, it is clear that no systems are approved for use in the lumbar pedicle, except for high-grade spondylolisthesis and in very strict research protocols. Nevertheless, the use of pedicle screws by spine surgeons has become common practice, particularly in the treatment of tumors, trauma, and spondylolisthetic conditions.

To address this problem, a scientific committee was established. This committee included representatives of the FDA, the American Academy of Orthopaedic Surgeons, the North American Spine Society, the Scoliosis Research Society, the American Association of Neurologic Surgeons, and the Spinal Implant Manufacturer Group. The scientific panel prepared a multipage, multiquestion study to evaluate the safety, efficacy, and outcomes related to the use of bone screws in the pedicle to treat thoracolumbar and lumbar fractures and degenerative spondylolisthesis. The questionnaires were distributed to all interested

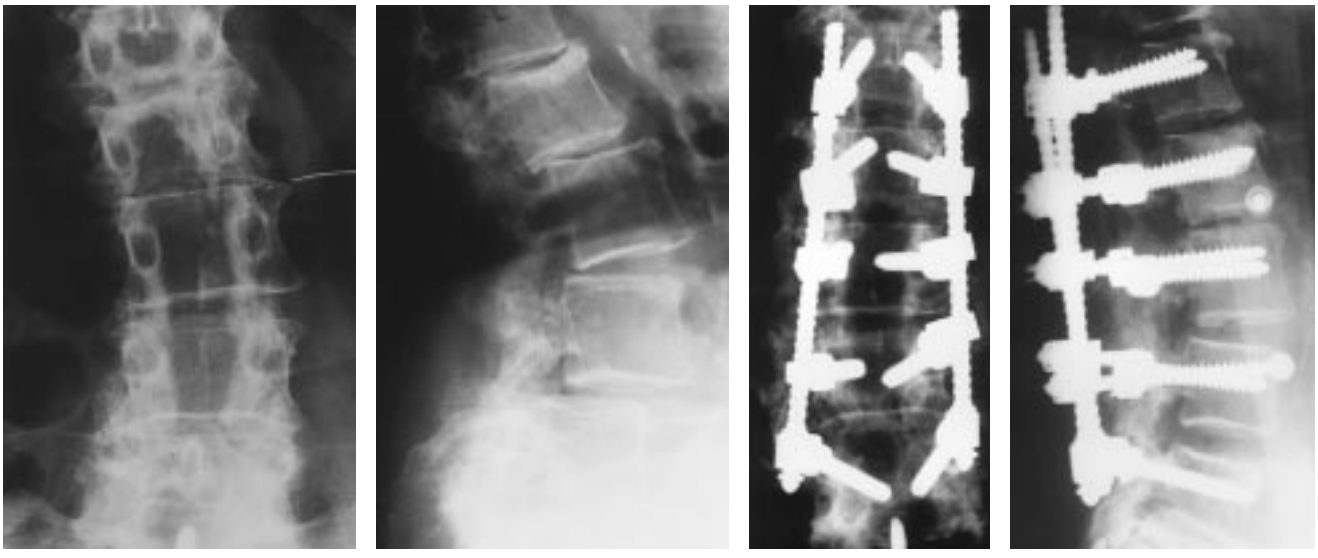


Fig. 5 **A,** This AP plain radiograph illustrates an extensive laminectomy and facetectomy from L1 to L4 for spinal stenosis. **B,** Two years later the patient began to experience significant low back pain with the return of lower extremity pain. Lateral plain radiograph reveals significant postlaminectomy iatrogenic instability with retrolisthesis at L2-3 and anterolisthesis at L3-4 and L4-5. The patient subsequently underwent reduction and posterior lumbar fusion with pedicle-screw instrumentation from L1 to L5, as depicted on these AP **(C)** and lateral **(D)** radiographs.

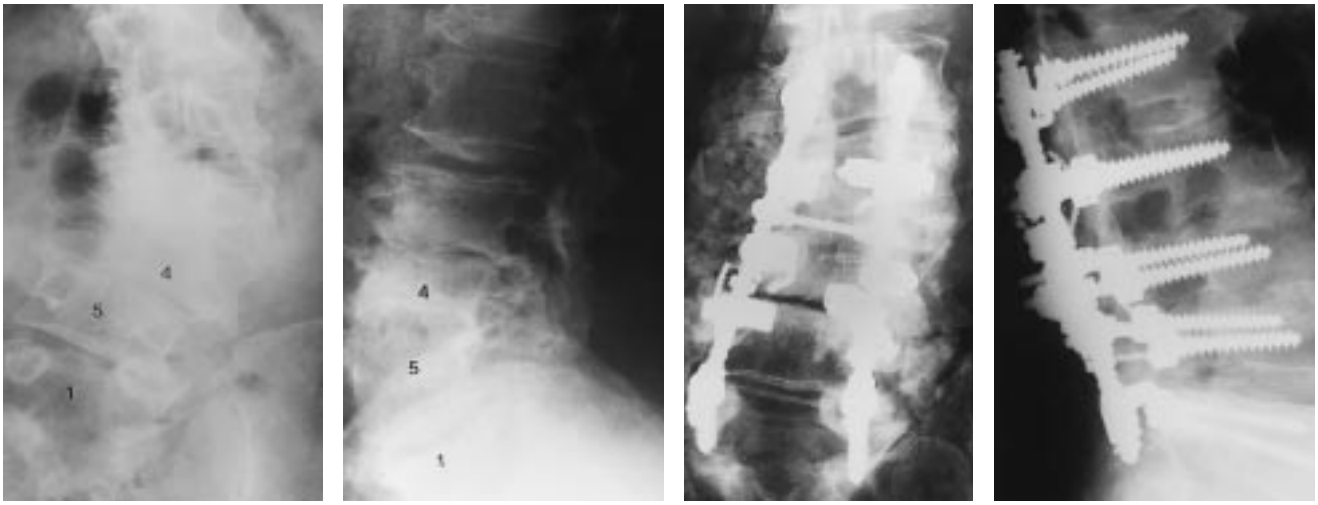


Fig. 6 Anteroposterior (AP) **(A)** and lateral **(B)** plain radiographs of an adult patient with neurogenic claudication reveal a left lumbar degenerative scoliotic curve with significant lateral listhesis at L4-5. The patient underwent a posterior lumbar decompression with partial reduction of the L4-5 lateral listhesis and posterolateral fusion from L2 to S1 performed with use of pedicle-screw fixation, as depicted in AP **(C)** and lateral **(D)** radiographs.

spinal surgeons who volunteered to participate and who had inserted ten or more pedicle-screw devices prior to 1991. The data for this cohort historical study of pedicle-screw fixation in thoracic, lumbar, and sacral spinal fusions were then collated by the scientific committee and tabulated by an independent medical research institute. Concurrently, members of the scientific committee reviewed all of the available literature related to surgery for degenerative spondylolisthesis and thoracolumbar trauma to develop a report and to help develop controls against which the surgical results could be compared. Nearly 3,500 cases met the appropriate criteria. The results were presented to the Orthopaedic and Rehabilitation Advisory Committee Panel.

On the basis of the results of the study and the presentation to the panel, the panel recommended that pedicle-screw devices be down-classified from class III to class II and designated specifically for use in treatment of degenerative spondylolisthesis, postoperative spondylolisthesis, and fractures, which constitute the diagnoses that were studied and presented from the cohort study. These recommendations were formally presented to an FDA advisory panel. After examining all the data, the advisory group agreed that the pedicle screw should be down-classified to a class II device for use in the treatment of the spinal disorders included in the study. At this time, their recommendation serves only as a recommendation to the main body of the FDA. It does not automatically or legally change the status of pedicle screws or their usage.

Summary

The indications for posterior instrumentation of lumbar and lumbosacral spine conditions are primarily related to deformity and instability resulting from trauma, tumors, spondylolisthesis, segmental instability, scoliosis, and lateral listhesis. The primary goals are to facilitate fusion, decrease pain, and increase patient mobility. Controversial indications include fusion and instrumentation as treatment of "low back pain" and use following excision of herniated disks.

Currently, there are a number of alternatives available for lumbar fixation. Hooks and rods are primarily used for upper lumbar and thoracolumbar fractures but are relatively contraindicated after laminectomy, in the presence of central stenosis, and when fixation is required to L4, L5, or (particularly) the sacrum.

Sublaminar wires have limited indications at this time. They cannot be used concurrently with laminectomies or in the presence of severe central stenosis, nor can they be fixed easily to the sacrum without adding the ilium to the fusion construct.

Screws used within the pedicles have several important indications. They provide optimal fixation to the sacrum and the L4 and L5 vertebral bodies after a laminectomy. They are also useful for low lumbar fractures, as well as certain rotational deformities. Relative contraindications include osteoporosis, active infection, and weakening or absence of pedicles due to pathologic or surgical conditions. Screw fixation appears at this time to be preferred for the treatment of (1) low lumbar fractures; (2) degenerative or isthmic spondylolisthesis when the use of instrumentation is chosen; (3) lumbar scoliosis or kyphosis, particularly with a lateral listhesis; and (4) any L5 or sacral fixation.

A database has been developed and reported in the literature to support the use of pedicle fixation. Unfortunately, most of these data are retrospective and poorly controlled. These data do appear, however, to be convincing in terms of the safety and efficacy of the use of pedicle screws in the lumbar spine. The risks are real and significant but appear controllable and definable, particularly in the hands of experienced physicians.

It is essential, particularly at this time, to advise the patient of the known risks and benefits of the instrumentation and to advise the patient that the use of pedicle screws is still under study and is not yet approved by the FDA except in certain specific situations. Ultimately, the surgeon must exercise his or her best judgment as to the specific use of these devices.

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