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Degenerative Lumbar Spondylolisthesis With Spinal Stenosis: A Prospective, Randomized Study Comparing Decompressive Laminectomy and Arthrodesis With and Without Spinal Instrumentation

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Study Design. This prospective study analyzed the influence of transpedicular instrumented on the operative treatment of patients with degenerative spondylolisthesis and spinal stenosis.

Objectives. To determine whether the addition of transpedicular instrumented improves the clinical outcome and fusion rate of patients undergoing posterolateral fusion after decompression for spinal stenosis with concomitant degenerative spondylolisthesis.

Summary of Background Data. Decompression is often necessary in the treatment of symptomatic patients who have degenerative spondylolisthesis and spinal stenosis. Results of recent studies demonstrated that outcomes are significantly improved if posterolateral arthrodesis is performed at the listhesed level. A meta-analysis of the literature concluded that adjunctive spinal instrumentation for this procedure can enhance the fusion rate, although the effect on clinical outcome remains uncertain.

Methods. Seventy-six patients who had symptomatic spinal stenosis associated with degenerative lumbar spondylolisthesis were prospectively studied. All patients underwent posterior decompression with concomitant posterolateral intertransverse process arthrodesis. The patients were randomized to a segmental transpedicular instrumented or noninstrumented group.

Results. Sixty-seven patients were available for a 2-year follow-up. Clinical outcome was excellent or good in 76% of the patients in whom instrumentation was placed and in 85% of those in whom no instrumentation was placed ($P = 0.45$). Successful arthrodesis occurred in 82% of the instrumented cases *versus* 45% of the noninstrumented cases ($P = 0.0015$). Overall, successful fusion did not influence patient outcome ($P = 0.435$).

Conclusions. In patients undergoing single-level posterolateral fusion for degenerative spondylolisthesis with spinal stenosis, the use of pedicle screws may lead to a higher fusion rate, but clinical outcome shows no improvement in pain in the back and lower limbs [Key words: degenerative spondylolisthesis, lumbar stenosis, posterolateral fusion, transpedicular instrumentation]
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Junghanns,[14] in 1931, was the first to describe degenerative lumbar spondylolisthesis. He defined the entity of lumbar vertebral spondylolisthesis without a pars interarticularis defect as "pseudospondylolisthesis." Newman[19] noted that listhesis of the vertebral body with an intact neural arch was usually caused by degenerative arthritis of the lumbar facet joints. Since these early descriptions, degenerative lumbar spondylolisthesis has been extensively studied, but operative management remains controversial. Surgical options reported include decompression,[3,4] decompression and arthrodesis,[8,10] and decompression and arthrodesis with spinal instrumentation.[28]

In the past, the recommended surgical procedure for this condition was decompressive lumbar laminectomy alone. However, in 1991, Herkowitz and Kurz[10] published a randomized prospective study comparing the results of decompressive lumbar laminectomy alone with lumbar laminectomy with posterolateral arthrodesis. Fifty patients were assigned alternatively to the two treatment groups and were evaluated for a mean of 3 years after surgery. The results of this study indicated that those patients who had concomitant arthrodesis had an statistically significant improvement in clinical outcome. Although pseudarthrosis was noted in nine patients (36%) in the arthrodesis group, all patients in

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whom pseudarthrosis developed had a good or an excellent result.

Recently, several surgeons[1,22,28] have advocated the addition of spinal instrumentation in the operative management of patients with degenerative spondylolisthesis and spinal stenosis. The theoretical advantage of instrumentation is postulated to be an increased fusion rate, decreased rehabilitation time,[9] and, most importantly, an improved patient outcome. However, the indications for the use of spinal instrumentation remain controversial.

To determine these indications, a randomized prospective study was performed, involving patients with degenerative spondylolisthesis a single level associated with lumbar spinal stenosis. This study compared the results of decompression and arthrodesis alone with those of decompression and arthrodesis combined with instrumentation at the level of the arthrodesis.

■ Materials and Methods

Sixty-eight consecutive patients, who agreed to participate in a clinical study approved by the Human Investigational Committee at William Beaumont Hospital, Royal Oak, Michigan, are included in this report. All patients had a clinical diagnosis of degenerative spondylolisthesis and spinal stenosis. Most patients (94%) complained of back pain, which usually was aggravated by activity and relieved by rest. All patients had significant buttock and leg pain before the surgical procedure. The most common leg complaints were due to neurogenic claudication. Typically, patients complained of pain, numbness, tingling, weakness, cramping, or burning, beginning in the low back and buttocks and radiating into one or both legs after walking. All patients had undergone a trial of nonoperative treatment for at least 3 months before surgery. Nonoperative treatment included physical therapy (passive modalities and aerobic exercise) and nonsteroidal antiinflammatory drugs, if tolerated. Patients were recommended for surgery if they had failed nonoperative treatment and continued to have significant pain and/or significant daily activity restrictions due to neurogenic claudication or radicular pain.

All patients were noted on plain radiographs to have a single-level degenerative lumbar spondylolisthesis, and imaging studies (computed tomographic myelogram and/or magnetic resonance imaging) demonstrated spinal stenosis at the level of the spondylolisthesis. No patients had undergone prior lumbar spinal surgery.

The patients were assigned randomly to one of two treatment groups: Decompressive laminectomy and single level autogenous bilateral lateral intertransverse process arthrodesis, or decompressive laminectomy and single level bilateral lateral autogenous intertransverse process arthrodesis with transpedicular instrumentation. Randomization occurred at the time the decision was made to proceed with surgical intervention, by the withdrawal of a card from an envelope which indicated either instrumentation or no instrumentation. Randomization was performed by a medical assistant, not by the treating physician.

There were 55 women and 13 men. Seven men and 28 women had instrumentation placed, and 6 men and 27 women had an arthrodesis performed without instrumentation. The ages of the patients who had instrumentation ranged from 53 to 86 years (mean, 69 years) and those of the patients who did not have instrumentation, from 52 to 80 years (mean, 66 years). In the entire study, 5 patients were 80 years of age or older (4 instrumentation, 1 noninstrumentation). Seven patients were smokers (four instrumentation, three noninstrumentation).

The operation was performed at L4–L5 in 69 patients, at L3–L4 in 6 patients, and at L5–S1 in 1 patient. Informed, written consent was obtained from each participant. Before the operation, plain radiographs of the lumbosacral spine (including anteroposterior, lateral, left and right oblique, standing lateral, and standing flexion–extension lateral) were obtained for all patients and were repeated at the most recent follow-up evaluation. Preoperative and follow-up radiographic films were analyzed to determine the amount of spondylolisthesis, in millimeters, on the lateral radiographs; the amount of sagittal motion, in millimeters, on the flexion–extension lateral radiographs;[7,18,25] and the total amount of angular motion, in degrees, between the adjacent vertebral end plates at the operative location seen on flexion–extension radiographs.

Arthrodesis was deemed successful if final follow-up radiographs demonstrated a continuity in the fusion mass between the cephalad and caudad transverse processes. Pseudarthrosis was determined to be present if there was no continuity in the fusion mass or if lateral flexion–extension radiographs demonstrated greater than 2° of angular motion between the adjacent end plates or greater than 2 mm of sagittal motion at the location of the spondylolisthesis. (Figure 1, A and C).

Decompression of the central canal and nerve roots was performed by removing half of the cephalad and the caudad lamina of the involved vertebra, together with bilateral medial caudad and cephalad facetectomy. The technique of spinal arthrodesis was that described by MacNab and Dall[16] and by Wiltse[26] for a single-level bilateral intertransverse process arthrodesis. The outer table of the iliac crest was exposed through the same skin incision that was used for the decompression and arthrodesis. Strips of cortical–cancellous and cancellous bone were harvested from the outer and middle tables of the iliac crest and were placed across the transverse processes,[27,28] after decortication of the transverse processes with a bur or a rongeur.

Pedicle screws (VSP, Acromed, Cleveland, OH) were placed at the location of the spondylolisthesis, according to the method of West et al.[24] The point of insertion of the screw was at the junction of the middle of the transverse process and the superior facet. The cortical bone at the starting point was perforated with a bur, and a pedicle probe was used to locate the transpedicular canal and to create a channel through the pedicle into the vertebral body for subsequent placement of the screw. Under fluoroscopic visualization, a tap was then directed into the pedicle, followed by screw placement. The width of the pedicle in the axial plane had been determined before surgery. The largest screw that would fit within the pedicle was then inserted. Generally, the entry hole was tapped approximately 1 mm less than the screw length to afford better bone purchase by the screw. After the four screws were placed, two plates (Acromed) were bolted in position with lock nuts. Care was taken to assure that the plate did not extend proximally to the cephalad screw, to avoid impingement on the unfused superior facet.

Before the operation, all patients rated pain in the back and

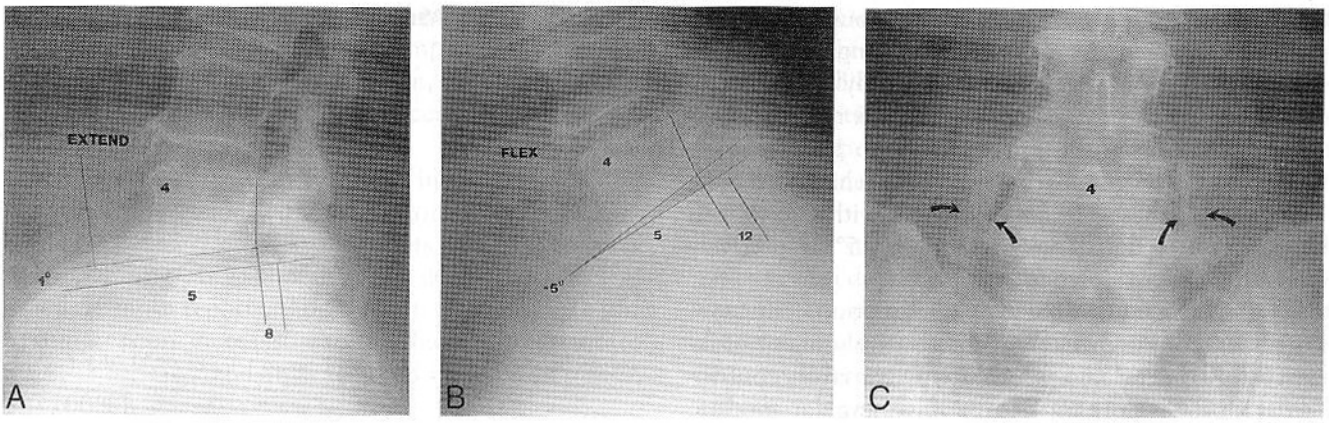

Figure 1. **A,** Two-year postoperative lateral extension radiograph demonstrating 8 mm of subluxation at L4–L5. **B,** Two-year postoperative lateral radiograph demonstrating an increase of the subluxation to 12 mm during flexion. **C,** Two-year postoperative anteroposterior radiograph demonstrating clefts (arrows) in the lateral fusion mass between L4 and L5.

lower limbs (including that in the buttocks) on a visual analog scale, ranging from 0 (no pain) to 5 points (severe pain). Pain in the back was rated separately from that in the lower limbs. The scoring procedure was repeated at the final follow-up examination.

The operative results were rated as excellent, good, fair, or poor, as previously described.[10] The result was considered to be excellent if the patient resumed unrestricted activity and had near complete relief of pain in the back, lower limbs, or both. A good result indicated that there was occasional discomfort in the back or lower limbs, necessitating occasional nonnarcotic medication. Patients with a good result had significant improvement, compared with the preoperative condition, and had resumed unrestricted activity. A fair result was defined as intermittent discomfort in the back, lower limbs, or both; improvement compared with the preoperative condition; restriction of activities; and an occasional need for nonnarcotic medication. The patients who had a poor result had marked discomfort in the back, lower limbs, or both, necessitating nonnarcotic and occasional narcotic medication. The patients in this category noted no improvement compared with the preoperative condition and had significant restriction of activities.

All clinical and radiographic assessments were made by examiners other than the treating surgeons. Radiographs were independently examined by two orthopedic surgeons. If the reported fusion status differed between the examiners, the radiographs were reexamined and a consensus reached.

The clinical results of the operation and radiographic findings were analyzed with the use of Student's *t* test of independent samples, Mann–Whitney test, sign test, and Fisher's exact test.

The same postoperative treatment was used for both groups of patients. Walking was permitted on the first postoperative day and progressed during the first 4 to 6 weeks after surgery. Exercises on a stationary bike or in-water therapy began at 6 to 8 weeks, and exercises for flexion of the spine and strengthening of the abdominal muscles were added at 10 to 12 weeks. No brace or corset was used after surgery in either group. The duration of follow-up ranged from 2 to 3 years (mean follow-up, 28 months).

■ Results

All patients who were randomized to the instrumented group had four pedicle screws successfully implanted at the time of surgery. There were no intraoperative findings that required withdrawal of a patient from the study, nor did any patient's random assignment change at the time of surgery.

Clinical outcome, assessed according to relief of pain and increase in activity, was excellent or good in 78% of the patients who had instrumentation placed and in 85% of those patients who had no instrumentation placed. Statistical analysis revealed no significant difference in the results between the two groups (Fisher's exact test with midpoint *P* correction, $P = 0.45$).

In the instrumented group, 80% of the patients rated preoperative leg pain at 4 or 5 (average, 4), and 74% rated back pain at 4 or 5 (average, 4). At final follow-up, 64% rated leg pain at 0 or 1 (average, 1), and 58% rated back pain at 0 or 1 (average, 1). Statistical analysis showed significant reduction in leg pain ($P < 0.001$) and in back pain ($P < 0.001$).

There was also a significant reduction of pain in the noninstrumented group. Before surgery, 89% of the patients rated leg pain at 4 or 5 (average, 4); at final follow-up, 75% rated leg pain at 0 or 1 (average, 1). Initial back pain in this group was rated at 4 or 5 by 65% of the patients (average, 4); at final follow-up 53% reported pain at 0 or 1 (average, 2).

Successful arthrodesis occurred in 83% of the instrumented spines *versus* 45% of the noninstrumented ones, a statistically significant result ($P = 0.0015$). However, successful fusion was not predictive of successful patient outcome ($P = 0.435$).

Before surgery, both groups averaged 3 mm of sagittal motion (range, 2–18 mm) and 9° of angular motion (range, 0–11°) on lateral flexion and extension radiographs. The spondylolisthesis measured 8 mm in the in-

strumented group and 7 mm in the noninstrumented group, as demonstrated by neutral standing preoperative lateral radiographs. After surgery, spondylolisthesis decreased in the instrumented group to 6 mm, whereas sagittal and angular motion decreased to 1 mm and 1°, respectively. The noninstrumented group had no change in spondylolisthesis at final follow-up, with sagittal and angular motion decreasing to 2 mm and 5°, respectively (Table 1).

The significant, continued angular motion in the noninstrumented group reflected the relatively high nonfusion rate. To determine which, if any, variables contributed to pseudarthrosis, preoperative angular motion, spondylolisthesis, and sagittal motion were analyzed and related to fusion outcome. Combining both groups of patients (instrumented and noninstrumented), preoperative angulation averaged 8° in those patients who eventually had a successful fusion, compared with 11° in those in whom pseudarthrosis developed ($P = 0.066$; Student's t test of independent samples). Preoperative spondylolisthesis ($P = 0.28$) and sagittal motion ($P = 0.18$) were not statistically significant in fusion outcome (Table 2).

There were no new peripheral (lower motor neuron) neurologic deficits after surgery in either group. No patients required early hardware removal because of persistent radicular pain, and no postoperative infections developed. Of the eight patients with poor results, five underwent further lumbar surgery at least 1 year after the index procedure. Two patients (one instrumented, one noninstrumented) required decompressive lumbar laminectomy at a spinal location different from that of the original surgery. One patient had hardware removed for persistent low back pain, and solid fusion was confirmed during the second surgery. One patient in the noninstrumented group, with persistent low back pain and pseudarthrosis, had a second attempt at arthrodesis, this time with instrumentation. In one patient (instrumented group) recurrent stenosis and pseudarthrosis developed, requiring a second decompression, instrumentation, and arthrodesis. There was only one screw failure (S1) in an asymptomatic patient, with solid fusion seen on radiographic film and an excellent clinical outcome.

Seven original participants in the study could not be located or refused to return at the required 2-year follow-up (five instrumented, two noninstrumented), and one patient died (cause unrelated to the surgical procedure) before the 2-year review. In that these patients did not complete the study, their data are not included in this report.

Table 1. Data on the 68 Patients

	Instrumentation (N = 35)		No Instrumentation (N = 33)	
	Preoperative	Postoperative	Preoperative	Postoperative
Result				
Excellent		20 (57%)		16 (49%)
Good		7 (21%)		12 (36%)
Fair		4 (12%)		1 (3%)
Poor		4 (12%)		4 (12%)
Mean scores for pain (points)				
Back	4	1	4	2
Lower limbs	4	1	4	1
Mean olisthesis (mm)	8	6	7	7
Mean sagittal motion on flexion and extension (mm)	3	1	3	2
Mean angulation (°)	9	1	9	5

Table 2. Factors Affecting Fusion Rate

	Successful Arthrodesis	Pseudarthrosis
Instrumentation	29 (83%)	6 (18%)
No instrumentation	15 (45%)	18 (55%)
Preoperative		
Olisthesis (mm)	8	7
Angulation (°)	8	11
Motion (mm)	3	4
Postoperative		
Olisthesis (mm)	7	7
Angulation (°)	1	8
Motion (mm)	1	3

Discussion

The majority of patients with spinal stenosis and degenerative spondylolisthesis respond to nonoperative treatment. For the patients in whom this regimen fails to produce improvement, the goals of surgery are relief of pain and improvement in quality of life. Previously, surgical management of this condition consisted of decompressive lumbar laminectomy alone.[4] However, recent studies[3,9,10,20] have produced results substantiating the value of arthrodesis with decompressive laminectomy.

The critical issue regarding instrumentation after intertransverse process arthrodesis in this condition is not only whether the rate of fusion will increase, but whether clinical outcome will also be improved. It is true that the purpose of arthrodesis is to obtain solid fusion, but it is also true that a good clinical outcome can be achieved without solid bony fusion.[10] Numerous studies[2,23] have outlined the difficulty in determining fusion status from radiographs, and methods for evaluating the fusion mass vary widely. The only accurate method is visual inspection, which is usually not practical. In the current study, the fusion mass was evaluated as critically as possible, using plain radiographs—hence, the low reported fusion rate, which is contrary to the high clinical success rate. The increased cost and complication rate associated with spinal instrumentation should be weighed against the successful outcome demonstrated in this report.

A recent meta-analysis[17] of the published literature on degenerative spondylolisthesis included 889 patients from 25 publications. Reported studies were classified

into the following groups: posterior decompression without arthrodesis, posterior decompression with arthrodesis but without instrumentation, and posterior decompression with arthrodesis and pedicle instrumentation.

Evaluation of the clinical results in the group undergoing decompression without arthrodesis revealed that 69%[1,3,4,6,8,10,12,13,15,20,21] of patients had a satisfactory outcome. Progressive slipping after decompression was noted in most reports. Addition of arthrodesis to the decompression increased the satisfactory outcome to 90%,[1,8,10,15,20,28] and 86% achieved solid fusion (range, 30–100%).

In this meta-analysis, five studies were included that described decompression with intertransverse process arthrodesis and instrumentation.[1,5,11,23,28] There was no statistically significant difference in fusion rate ($P = 0.08$) between the group without instrumentation and the group with pedicle screws. Although the fusion rate was higher with instrumentation (93% *versus* 86%) the clinical outcome was better in the noninstrumented group (90% *versus* 86%).

The current series is the largest prospectively randomized study reporting on the use of pedicle screws for one diagnosis. Fusion rate was markedly increased in the instrumented group; however, there was no statistically significant difference in clinical outcome between the two groups. These conclusions are in agreement with those reported by other surgeons.[1,28] Although pseudarthrosis developed in 55% of the noninstrumented patients, the clinical result was excellent or good in 15 of these 18 patients (83%). Radiographic fusion status did not affect clinical outcome. These results are in agreement with those obtained by Herkowitz and Kurz[10] and may be related to the development of a fibrous fusion that provides sufficient structural support to prevent progressive spondylolisthesis.

In an attempt to identify those patients who were more likely to have pseudarthrosis, preoperative radiographic findings were analyzed. The only variable that approached statistical significance was preoperative angular motion at the location of the spondylolisthesis. In the 44 patients in whom successful fusion was achieved, the preoperative angulation averaged 8°, whereas angulation in the 24 patients with nonfusion averaged 11° before surgery ($P = 0.066$).

Prior prospective studies evaluating the use of pedicle screws in patients with spinal stenosis and degenerative spondylolisthesis were compared with the results reported here. Zdeblick[28] reported on 124 patients undergoing lumbar or lumbosacral fusions for five degenerative conditions. The patients were randomized to one of three groups: Group 1, posterolateral fusion, using autogenous bone graft only; Group 2, autogenous posterolateral fusion, supplemented by a semirigid pedicle screw–plate fixation system; and Group 3, posterolateral autogenous fusion with a rigid pedicle screw–rod fixation system. Overall, the rigid pedicle fixation group had a significantly higher percentage of successful fusions (95%) than did the noninstrumented group (65%). Additionally, better clinical results were seen in the instrumented group (95% excellent or good) compared with those in the noninstrumented group (71% excellent or good).

A second study by Bridwell et al,[1] reported on 44 patients with degenerative spondylolisthesis who underwent surgery, primarily for spinal stenosis. Patients were classified into one of three groups: Group 1, no arthrodesis performed; Group 2, Posterolateral arthrodesis without instrumentation; and Group 3, posterolateral arthrodesis with instrumentation. If excessive motion (more than 10° of angular motion or 3 mm of translational motion) at the slip location was noted on preoperative radiograph, the patient was not randomized but was automatically assigned to receive instrumentation. Results were an 87% fusion rate in the instrumented cases *versus* a 30% rate in noninstrumented cases. Functional status was improved in 83% of those patients receiving instrumentation. In contrast with previous results, there was no significant difference in clinical outcome between Groups 1 and 2 (33% *vs.* 30% successful clinical outcome, respectively). The 30% clinical success noted in the fused and noninstrumented group is markedly lower than the 90% satisfactory outcome reported in the meta-analysis review of the literature. No explanation for this is apparent from the study data presented.

In summary, the results of the current study demonstrate that transpedicular instrumentation improves the fusion rate, after posterolateral fusion for patients with degenerative spondylolisthesis. However, clinical outcome assessed in terms of relief of pain and increase in activity is unchanged whether or not instrumentation is used.

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