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Foraminal Stenosis and Single-Level Degenerative Disc Disease

A Randomized Controlled Trial Comparing Decompression With Decompression and Instrumented Fusion

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Study Design. A randomized controlled trial with 5-year outcome data.

Objective. To compare clinical outcomes following spinal decompression (Group 1) with those following decompression and instrumented posterolateral fusion (Group 2) and decompression and instrumented posterolateral fusion plus transforaminal interbody fusion (TLIF) (Group 3).

Summary of Background Data. Decompression is frequently advocated for the relief of nerve root stenosis in the presence of degenerate disc disease. It is uncertain if spinal fusion is also necessary.

Materials and Methods. Following completion of a standardized physiotherapy program, 44 patients with single-level disc disease were randomly assigned to 1 of 3 surgical groups. In those patients undergoing instrumentation, segmental pedicle screw fixation was used to stabilize the spine. Titanium interbody cages filled with autologous bone were inserted into patients in Group 3. Spinal disability, quality of life, and pain were assessed before surgery, and then at 1, 2, and 5 years by an independent researcher.

Results. At 2 years, 82% of the patients were pain free or moderately improved. Disability (Low Back Outcome Score and Roland Morris index) were both better in Group 1, but only Low Back Outcome Score was better in Group 2 ($P < 0.05$). By 5 years, although patients in all 3 groups showed some improvements in all the ratings used (Low Back Outcome Score, SF-36 Physical Functioning, and Roland Morris score), only Group 1 patients showed significant changes in all 3 outcomes ($P < 0.05$). There was no difference in any score between groups ($P > 0.05$). Two had secondary surgery for adjacent level stenosis (Group 2 and 3). One patient (Group 1) underwent subsequent lateral mass fusion for chronic pain. No patient required revision surgery for instrumentation failure, cage displacement, or pseudarthrosis. Evidence of at least unilateral lateral mass bone graft incorporation was evident in 95% of Groups 2 and 3.

Conclusions. The results are encouraging in that almost all patients had improved by 5 years. However, it is a concern that no significant additional benefit has been noted from the more complex surgery. This suggests that patients are optimally treated by decompression alone, with the proviso that further operations may be required.

Key words: decompression, disability, posterolateral fusion, randomized, spinal fusion, transforaminal lumbar interbody fusion. **Spine 2007;32:1375–1380**

Foraminal stenosis is caused by a reduction in the space available for the exiting root within its canal by osseous and ligamentous hypertrophy[1]; and root decompression as an isolated procedure generally produces, at least in the short-term, a favorable outcome. However, following surgery, in the presence of degenerative disc disease, there is a potential risk of loss of disc height and recurrent foraminal stenosis. To limit this risk, it has been suggested that spinal fusion of the affected level is appropriate.[2] Whether that fusion should be instrumented is, however, uncertain,[3–6] and there is only moderate evidence from randomized controlled trials that instrumentation improves fusion rate.[7]

A simple posterolateral fusion with or without instrumentation may be adequate,[8–10] although it is well recognized that in the absence of anterior column support the inserted bone graft may not consolidate.[11] Better results ought to be obtained with a circumferential fusion, yet the evidence for this is weak.[12] The side effects of a more invasive approach, even if a posterior lumbar interbody fusion[13–16] is performed rather than an anterior interbody fusion,[17–19] are significant. Dural manipulation can lead to at least some epidural fibrosis,[20] and the facet joints may be damaged.[21] To circumvent these problems, Harms and Rolinger[22] suggested placement of bone graft and titanium mesh *via* a transforaminal approach into a disc space distracted by pedicle screw instrumentation (TLIF).[22,23] It was suggested that this approach offered better vision into the disc space and clearance of material, and would increase the prospect for fusion. Moreover, an increase in disc space height may increase foraminal size. However, the procedure is more extensive, with potentially greater blood loss and clinical outcome may be unchanged.[24]

Aims

The primary aim of this trial was to compare surgical outcomes following simple nerve root decompression

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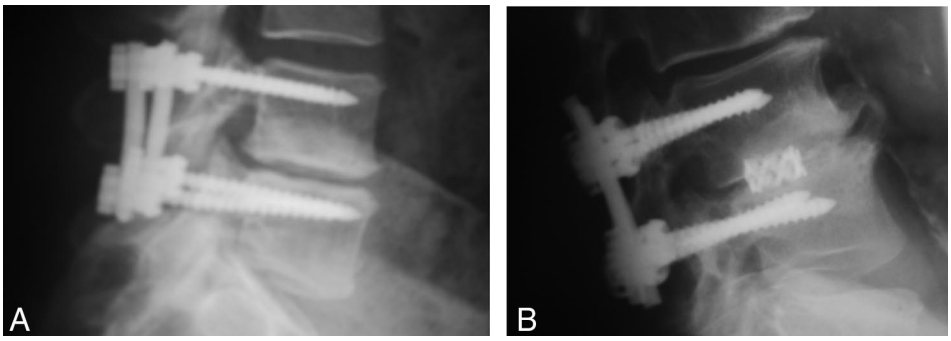

Figure 1. Surgical treatment. **A**, Lateral radiograph showing posterolateral instrumentation (Group 2). **B**, Lateral radiograph showing posterolateral fusion + TLIF (Group 3).

with those following decompression augmented by fusion. Secondarily, the study was designed to allow a comparison between an instrumented pedicular posterolateral fusion (180°) with that of an instrumented posterolateral fusion coupled to a TLIF (360°).

■ Materials and Methods

Patients. The design of the study was a randomized, controlled trial. Between January 1998 and August 2001, 44 consecutive patients were enrolled who had both 1) single-level degenerative disc disease and 2) evidence of associated foraminal stenosis. All the patients had suffered from some backache over the preceding 5 years, yet this was not the main presenting feature and not a reason for fusion *per se*.

Twenty-four were men and 20 were women, with a mean age of 57 years (range, 34–75 years). All the patients were white and 12 were current or previous smokers. Thirteen were retired and 10 were housewives. The remainder held heavy manual[7] or light industrial jobs,[14] but 12 of these were off sick. One man had a compensation claim pending.

All patients complained of unilateral or bilateral leg pain with or without positive nerve root tension signs, associated muscle weakness, and/or sensory loss. All patients had undergone a period of conservative therapy, including physiotherapy and generally one of acupuncture, chiropractic treatment, or massage, over at least the 3 months before admission. Plain radiographs and MR images were obtained in all subjects to diagnose intraforaminal or extraforaminal nerve root compromise, in association with single-level degenerative disc disease.

Patients were excluded if they had 1) degenerative spondylolisthesis of Grade II or greater at the level of the degenerative disc or at an adjacent level, 2) vertebral translocation in excess of 1 cm, 3) disc space narrowing of greater than 50% proximal or distal to the level of proposed fusion, or 4) any form of malignancy.

The trial was approved by the Lothian Ethics Committee, Edinburgh, UK.

Clinical Evaluation. With informed consent, patients were assessed by an independent researcher to gain background information and then asked to complete the following outcome assessment scores: SF-36,[25] EuroQol–VAS (health state),[26] Low Back Outcome Score (LBOS) with Visual Analogue Score (VAS),[27] Dallas Pain Questionnaire,[28] and Roland and Morris disability score (R and M).[29] These assessments were repeated 1, 2, and 5 years after surgery. Type of treatment was randomly allocated immediately before surgery from shuffled, closed, opaque envelopes (50 × 3 interventions), that were numbered 1 to 150 and opened in sequence.

Radiographic Evaluation. Before surgery, 2 examiners calculated the height of the affected disc in each patient, from micrometer measurements of the distances between the anterior and posterior edges of the adjacent endplates on a supine lateral radiograph. The Farfan index (anterior + posterior disc height/disc diameter) was used to assess disc height[30,31] and the presence of any transitional vertebra noted.[32] At 2 years, the disc height measurements were repeated and spinal fusion assessed from an anteroposterior radiograph centered on the op-

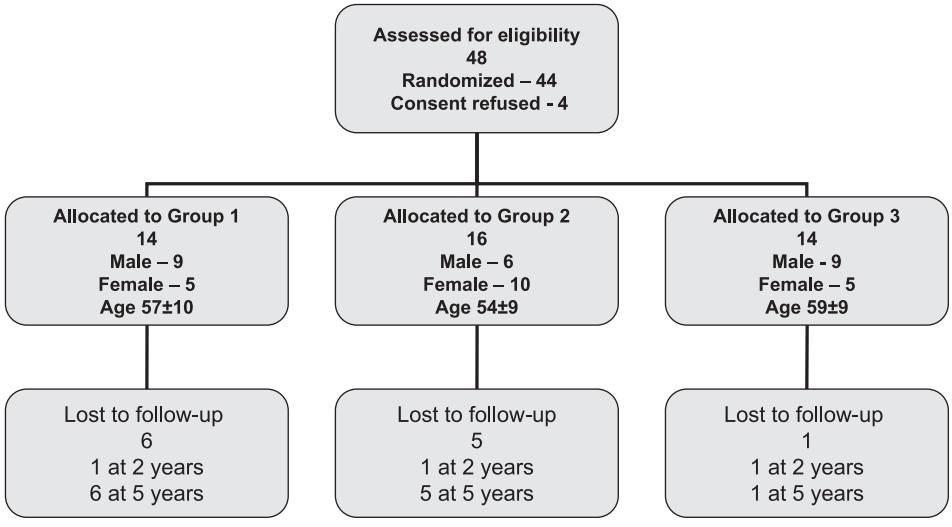

Figure 2. Flow diagram: Progress of all trial patients.

Table 1. Level Affected and Changes in Disc Height With Surgery

	Group 1	Group 2	Group 3
L3–L4	0	2	3
L4–L5	9	9	8
L5–S1	5	5	3
Farfan: pre	0.26 ± 0.08	0.18 ± 0.12	0.23 ± 0.20
Farfan: post (2 yr)	0.20 ± 0.18	0.18 ± 0.17	0.28 ± 0.22

Values are mean ± SD. There was no significant difference in Farfan index by group or time.

erated disc.[33] Posterior bone trabecular bridging was scaled according to the degree of bone incorporation: bilateral, A; unilateral, B; uncertain, C; and resorption, D.[34] Fusion was judged to be present if there was a continuous bony bridge on at least 1 side (A or B),[35] and in patients from Group 3 if a solid anterior bar of bone was present within or anterior to the cages. Cage migration and settling were noted. The 3 observers were not blinded and any dispute was resolved by discussion.

Operative Technique. The 3 groups were treated as follows:

Group 1. Single or bilateral foraminotomy with nerve root decompression at the affected level. A minimal microdiscectomy, excising any subligamentous fragment and any loose fragment from the disc space, was performed if a disc bulge was contributing to the stenosis. No patient had a sequestered fragment.

Group 2. As Group 1 with a posterolateral instrumented pedicular fusion (Figure 1A: Moss-Miami, DePuy Ltd., Warsaw, IN). Autologous graft was harvested from the iliac crest on the side opposite to that of maximal symptoms and laid along the lateral masses and into the facet joints.

Group 3. As Group 2 with TLIF. Through a far lateral approach, the affected root was exposed and the lateral aspect of the inferior articular facet resected to allow visualization of the margin of the disc. By interval distraction on the contralateral rod and between the ipsilateral screws access to the disc space was gained and the cartilaginous endplates excised. After placement of anterior graft, 2 circular titanium interbody cages, of 16 mm diameter, were rolled into as near a symmetric position as possible (Figure 1B).[23,36] Additional graft was laid posterolaterally.

All surgery was performed by the same surgeon (J.N.A.G.) in a laminar ventilated theater. Each patient received antibiotic prophylaxis (1.5 g cefuroxime at induction of anesthesia, plus

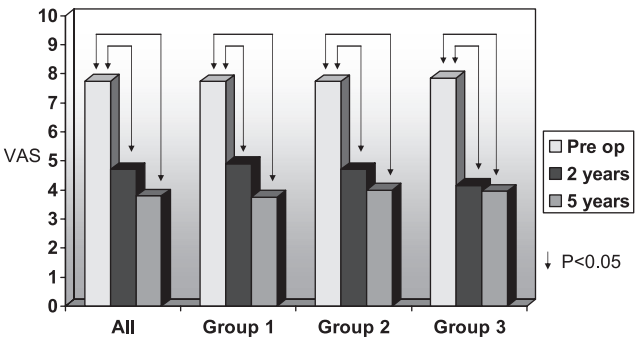

Figure 3. VAS scores for backache (LBOS).

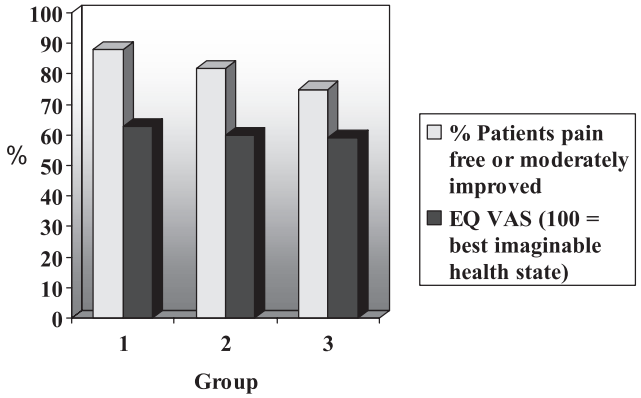

Figure 4. Patient satisfaction and EuroQol-VAS score at 5 years.

750 mg at 8 and 16 hours). After surgery, patients were rested overnight then mobilized as symptoms allowed under supervision of a physiotherapist.

Statistical Methods. Trial size was initially based on the assumption that a clinically significant result would be an improvement by 75% of patients in the experimental groups (2 and 3) by 1 level on the LBOS, *i.e.*, move from "poor" (<30) to "fair" (30–49) or from "good" (50–64) to "excellent" (>65).[27] If in comparison only 35% of patients in the control group improved by the same margin, then the number of patients required in each of the 3 treatment groups was 20. This sample size would be sufficient to provide validity at a power of 80% and an α level of 0.05.

Analysis of the results was by intention to treat. Since the postoperative pain scores were not normally distributed, the nonparametric Kruskal-Wallis test was used to test differences between groups and the Wilcoxon Signed Rank test to compare data over the time periods. Results were considered significant at $P < 0.05$. All analyses used SPSS (version 11.0, Chicago, IL).

■ Results

The progress of patients through the trial is shown in Figure 2. Each of the groups was similarly constituted. Two of the patients in Group 1, 2 in Group 2 and 1 in Group 3 had a Grade I spondylolisthesis. At 5 years, 32 patients were available for clinical review. There had been 3 deaths and 3 patients had secondary surgery. The remaining losses to follow-up were due to hospitalization (1), refusal to complete the outcome assessments (1), and loss of contact (4).

Table 2. Outcome Data for All Subjects

	Preoperative	2 Years	5 Years
LBOS	18 ± 9	31 ± 18*	36 ± 18*
RM	15 ± 5	11 ± 7*	11 ± 7*
DPQ			
Daily activities	71 ± 14	53 ± 25*	52 ± 25*
Work/leisure activities	73 ± 17	57 ± 31*	56 ± 32*
Anxiety/depression	48 ± 23	38 ± 29	36 ± 27*
Social interest	45 ± 22	36 ± 29	34 ± 29*

Values are mean ± SD.
*$P < 0.05$.

Table 3. SF-36 for All Subjects

	Preoperative	2 Years	5 Years
Physical Functioning	30 ± 21	48 ± 30*	42 ± 25*
Role-Physical	9 ± 25	38 ± 44*	36 ± 44*
Bodily Pain	23 ± 15	39 ± 26*	44 ± 28*
General Health	57 ± 19	56 ± 24	50 ± 23
Vitality	34 ± 21	43 ± 25	41 ± 22
Social Functioning	45 ± 24	62 ± 32*	63 ± 31*
Role-Emotional	49 ± 46	62 ± 42	69 ± 45
Mental Health	58 ± 23	62 ± 21	64 ± 21

Values are mean ± SD.
*$P < 0.05$.

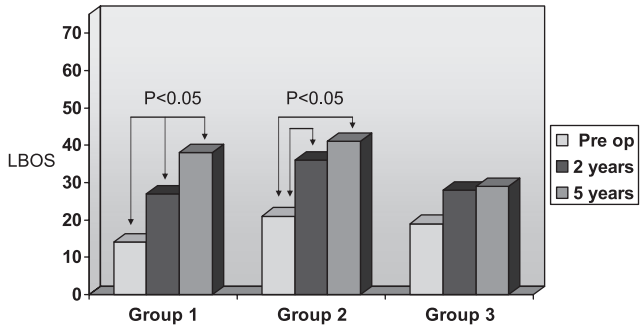

Figure 6. Changes in LBOS.

Increasing complexity of surgery was associated with longer anesthesia and surgery (from 2.0 ± 0.5 hours in Group 1 to 4.8 ± 1.0 hours in Group 3), and greater blood loss (from 340 ± 348 mL in Group 1 to 1575 ± 1032 mL in Group 3). Although there were no intraoperative complications requiring secondary intervention, recovery was slower following fusion. Delay in mobilization was reflected by an increased in-patient stay that averaged 2, 4, and 5 days, respectively.

A transitional vertebra was present in 7 patients with the disc proximal to it affected in each instance. The five with a transitional vertebra from Groups 2 and 3 all developed a solid posterolateral fusion, as did 95% of the remainder (26 of 28) at 2 years (Grade A or B, at least a unilateral bar of bone). The presence of an anterior interbody fusion was less clearly evident with solid bone incorporation anterior to the cage only apparent in 6 of the 13 patients assessed (follow-up radiographs were not available from 1 patient). There was no improvement in Farfan index in any group or difference between groups (Table 1), nor a significant change in the ratio between anterior and posterior disc height ($P > 0.05$).

Revision surgery was performed in 3 patients. Two had secondary decompressive laminectomy at 23 months and 7 months for adjacent level stenosis (Groups 2 and 3, respectively). At 29 months, 1 patient (Group 1) underwent an instrumented lateral mass fusion at the previously decompressed level for chronic pain.

At 2 years, the mean VAS for backache for all patients was 4.6 ± 2.3, which was 40% less than the preoperative value. This improvement was still present at 5 years (Figure 3) and was accompanied by an average 80% patient rating of satisfaction (Figure 4). EuroQol VAS patient rating of their health status was maintained at around 60% best imaginable health state in all groups (mean preoperative value 54%, not significant). These results mirrored those from the Dallas Pain Questionnaire assessment (Table 2) and a similar trend was seen in SF-36 Bodily Pain (Table 3). An improved quality of life overall was reflected by a significant improvement in all aspects of SF-36, except General Health, Vitality, Role-Emotional, and Mental Health (Table 3; Figure 5). LBOS improved similarly in both Groups 1 and 2 (Figure 6), with most patients moving from a "poor" (0–29) to "fair" (30–49) rating. R and M score improved from the preoperative value only in Group 1 (Figure 7). There was no significant difference between groups for any parameter at any time interval.

Before surgery, 92%, 91%, and 82% of the patients in Groups 1 to 3, respectively, were taking at least 1 oral strong analgesic or anti-inflammatory agent. This compared with values of 69%, 83%, and 64%, respectively, in the groups at 2 years. Before surgery, only 12 of 21 patients with jobs were working. The remaining 23 patients were retired or at home. Seven workers had returned to their jobs 2 years after treatment with a similar number from each group. Costs for primary surgery were 53% and 80% greater in Group 2 and 3 than in Group 1, with 63% and 60% of the costs attributable to that of the implants (Group 3 had significantly higher theater, surgical, and anesthetic tariffs). Taking into account the need for revision surgery, the total incremental costs were 43% and 68%, respectively (Table 4).

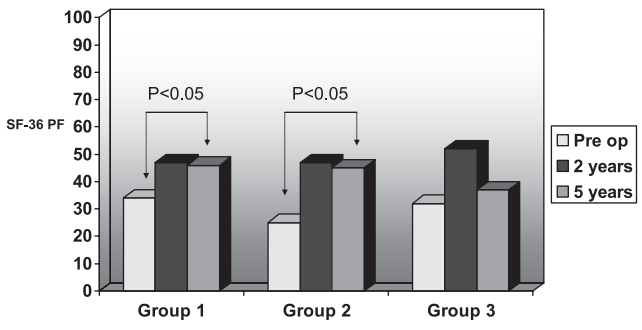

Figure 5. Changes in SF-36.

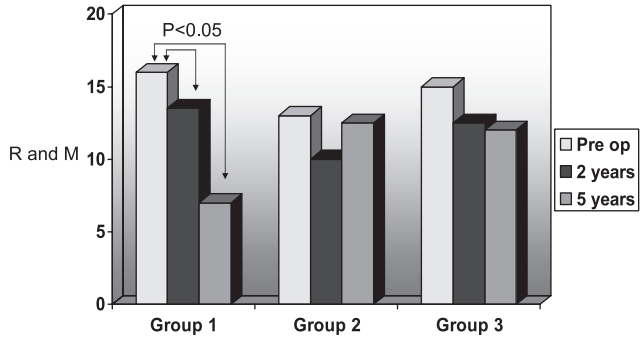

Figure 7. Changes in Roland and Morris Disability Score.

Table 4. Estimated Comparative Costs (£)

	Group 1	Group 2	Group 3
Inclusive care cost*	5966	9117	10,748
Length of stay (days)	2	4	5
Instrumentation costs	0	1980	2880
Revision surgery factor†	1.11	1.04	1.03
Mean direct cost per patient	6617	9490	11,121

*Based on British United Provident Association (BUPA) rate June 2006; fee includes hospital accommodation, surgical fees, and instrumentation costs.
†[(Total Group costs + Revision costs)/n]/Total Group costs.

■ Discussion

Since the primary procedure in all patients was root decompression, it was to be expected they would improve to some extent whatever other procedures were performed, and this indeed was the case. It is encouraging that that benefit is still evident at 5 years, but it is clear that many of the patients had developed other comorbidities with ageing, such as cardiac disease. These had impinged on their quality of life and may have limited their perceived benefits from surgery. This may explain why subgroups of the SF-36 results are not maintained.

If it is accepted that degenerative disc disease in the presence of foraminal stenosis may be a cause of future pain, it is rational to prevent further disc collapse and recurrent foraminal stenosis by instrumentation. However, analysis of our early results in the instrumented groups did not suggest that we were improving the patients' outcomes.[37] Even taking into account the possibility of a Type II error (*i.e.*, that we had simply not included sufficient numbers of patients to show a significant difference), it seemed that any differences would at best be marginal and probably not clinically relevant, although we accept that there was no nonsurgical "control" group. With the introduction of new and potentially better technologies in 2002,[38–41] recruitment was terminated. The patients were observed for a further 3 years to ensure that any benefits were not time dependent.

Whether the presence of a fusion either posteriorly alone[18] or if coupled with an interbody fusion[42] actually influences long-term outcome is uncertain. Our results suggest at least posterior union occurred in most patients, but it is difficult to be certain without further imaging by CT or MR. Anterior fusion was even less clearly demonstrated than posterior fusion, with solid bone incorporation anterior to the cage noted in only half the patients in Group 3. This equates with reports that fusion within an interbody cage may be incomplete in up to 20% of individuals.[43,44] Although the presence of a nonunion *per se* does not correlate with failure to maintain foraminal height, the lack of improvement in Farfan index is important. This suggests that distraction of the disc space during instrumentation is not maintained. There may be some bone remodeling in the absence of anterior support and some "settling" of the cages.

TLIF was associated with a longer in-patient stay and significantly greater theater cost, although these might be less with newer minimally invasive approaches.[45] Overall, our results compared unfavorably with those of Lowe *et al*,[36] who reported a 28% point increase in Oswestry Disability score at 2 years in 40 patients.

■ Conclusion

Patients with foraminal stenosis and single-level degenerative disease universally improved with surgery, and this improvement was maintained at 5 years. However, no obvious additional benefit was noted by combining decompression with an instrumented fusion. It is probably appropriate in this subset of patients to offer decompression alone and accept that a few patients will require secondary surgery at a later date.

■ Key Points

- Patients were randomized to spinal decompression with or without fusion.
- A total of 82% of all patients were pain free or moderately improved at 2 years.
- Posterolateral fusion was solid in >90% of those stabilized.
- At 5 years, there was improvement in LBOS and SF-36 Physical Functioning, but there was no difference between groups.
- Decompression alone was probably adequate.

Acknowledgments

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