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Anterior lumbar interbody fusion: Does stable anterior fixation matter?

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Abstract The purpose of this study was to compare the outcome of anterior lumbar interbody fusion without instrumentation (uninstrumented ALIF) against that with stable anterior cage fixation using Hartshill horseshoe instrumentation (ALIF-HH) for similar severity of disc disease. Between April 1994 and June 1998 the senior author N.R.B. performed 29 instrumented ALIF procedures with a Hartshill horseshoe cage (ALIF-HH). Between 1990 and 1998, the other senior author (J.M.H.), together with another senior consultant orthopaedic surgeon, performed 27 noninstrumented ALIF procedures using corticocancellous iliac crest autograft. All the patients in both groups had single-level fusion. An independent assessor (S.M.) performed the entire review. The mean follow-up was 4.7 years (2.3–7.9 years) in the uninstrumented ALIF group and 3.0 years (2.1–4.4 years) in the ALIF-HH group. There was subsidence of graft in four patients in the uninstrumented ALIF group. It is

reasonable to assume that there was no pseudarthrosis in the ALIF-HH group. This difference was statistically significant (two-sided P -value = 0.0425). On subjective score assessment, there was a satisfactory outcome (score ≤ 30) of 87.5% (21 patients) in the uninstrumented ALIF group and 85.2% (23 patients) in the ALIF-HH group ($P > 0.05$). On classification by the Oswestry Index into four categories, we found no difference in outcome between the two groups: 83.3% ($n=20$) had a satisfactory outcome (defined as Excellent or Better) with ALIF and 77.8% ($n=21$) had a satisfactory outcome with ALIF-HH using the Oswestry Disability Index for post-operative assessment ($P > 0.05$). The results of this study indicate that the Hartshill horseshoe cage does improve the fusion rate, but does not affect clinical outcome.

Keywords Hartshill horseshoe · Anterior lumbar fusion · Cage

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Introduction

Fusion for lumbar disc degeneration can be done through an anterior or posterior approach. Posterior fusion is often supplemented with instrumentation. The success rates of anterior lumbar interbody fusion (ALIF) reported in the literature are quite variable. Penta and Fraser [27] reported a 68% rate of patient satisfaction and a 72.4% overall fusion

rate at a minimum follow-up of 10 years. Tiusanen et al. [32] used posterior external fixators for stabilisation in ALIF. Solid fusion was obtained in 71% of patients, and 74% of patients were clinically very much improved at a minimum follow-up of 2 years (mean 5 years). Turner et al. [35] analysed 47 articles and found that on average 68% of patients had achieved a satisfactory outcome after lumbar fusion surgery (range 16–95%). Inoue and Watanabe [16] in 1982 reported on a large series of 350 patients

who underwent anterior discectomy and interbody fusion for lumbar disc herniation. They achieved a 94.3% fusion rate, but the clinical results were good in only 73% of patients.

Posterior fusion and instrumentation is a satisfactory method of treatment for low back pain. However, the outcome may be disappointing if the disc itself is the cause of pain. Flynn and Hoque [7], Stauffer and Coventry [29], and Newman and Grinstead [24] have reported complications of graft extrusion, compression and instability contributing to pseudarthrosis associated with interbody graft without rigid fixation. The Hartshill Horseshoe cage was designed to overcome these problems [22]. It is a horseshoe-shape cage made of titanium that is inserted after removal of the disc in anterior lumbar interbody fusion. Tricortical iliac crest graft is inserted within the confines of the implant. The cage is stabilised by inserting screws into lumbar vertebral bodies through holes in the implant. To standardise the results of this study to those recently reported in the literature [27, 32], we used validated objective scores and also assessed the compensation status and psychological distress of our patients.

The purpose of this study was to compare the outcome of anterior lumbar interbody fusion without instrumentation (noninstrumented ALIF) against ALIF with stable anterior cage fixation using Hartshill horseshoe instrumentation (ALIF-HH) for similar severity of disc disease.

Materials and methods

Between April 1994 and June 1998 the senior author N.R.B. performed 29 instrumented anterior lumbar interbody fusion procedures with a Hartshill horseshoe cage (ALIF-HH). Between 1990 and 1998 the other senior author (J.M.H.), together with another senior consultant orthopaedic surgeon, now retired, performed 27 noninstrumented anterior interbody fusion procedures (noninstrumented ALIF) using corticocancellous iliac crest autograft. The final follow-up control and all the data were obtained for 27 patients who had ALIF-HH and 24 patients who had noninstrumented ALIF. All the patients in both groups had single-level fusion. An independent assessor (S.M.), who was not the operating surgeon, performed the entire review. Pre-operative radiographic assessment included plain radiographs, magnetic resonance imaging (MRI) scans and provocative discography in all the patients. The inclusion criteria for the patients were:

- Severe symptoms of low back pain not responding to medication, rehabilitation and conservative treatment
- Low back pain present for at least 2 years
- Minimum follow-up of 2 years
- Age range of 25–67 years
- Positive provocative discography and MRI scan correlating with patient's symptoms and signs

The exclusion criteria for the patients were:

- Disc herniation, spinal stenosis, and isthmus spondylolisthesis
- Previous spinal operations such as fusion, decompression or discectomy

The selection criteria were the same for the two procedures. We wanted to know the clinical outcome and fusion rate with either procedure.

Table 1 Magnetic resonance imaging (MRI) classification of disc degeneration (modified from Paaanen et al. [26])

Grade	Characteristics
1	Bright signal intensity, provocative discography positive
2	Grey signal intensity
3	Dark signal intensity + annular tears
4	Disc prolapse, loss of disc height, instability, and osteophytes

Table 2 Demographic and clinical data of the patients with non-instrumented anterior lumbar interbody fusion (ALIF) and the patients with ALIF plus Hartshill horseshoe cage (ALIF-HH)

Parameter	Noninstrumented ALIF	ALIF-HH
Age (years)	38.5 (30–52)	45 (25–67)
Females (<i>n</i>)	16	16
Males (<i>n</i>)	8	11
Duration of back pain (years)	13.1 (3.2–22)	8.8 (2.1–32)
Duration of leg pain (years)	8.9 (2.2–19)	7.8 (0–32)
Smokers (<i>n</i>)	14	15
Fused level (<i>n</i>)		
L5-S1	10	11
L4-L5	14	14
L2-L3	0	2

The MRI scans were graded from 1 to 4, using a modification of the classification proposed by Paaanen et al. [26] (Table 1). Fourteen segment levels in the noninstrumented ALIF group and 18 segment levels in the ALIF-HH group had grade 4 degeneration, while the rest of the levels had grade 3 degeneration.

Patients were briefed about the discography procedure and consent was obtained. Patients were given prophylactic antibiotics and local anaesthetic. Needles (18-G outer and 22-G and 25-G inner discography needles) were placed in the three lower mobile segments of the lumbar spine in each subject through a posterolateral approach. A water-soluble contrast (Omnipaque) was used for disc injections. Additional levels were also tested in some patients. Needle placement was checked on fluoroscopic images to ensure it was in the central one-third of the disc in the caudal/rostral, anterior/posterior planes and in line with the spinous processes in the left/right plane. Anteroposterior views of vertebral endplates were also obtained with a modified Ferguson view.

Twelve patients in the noninstrumented ALIF group and ten patients in ALIF-HH group had paraesthesia, and non-dermatome sensory deficit in their lower limbs. There was no radiculopathy, and power, tone and reflexes were normal in all the patients. Patient data were collected after surgery for pain intensity, work capacity, walking distance, smoking habits, and workers' compensation. There was no difference in the demographic characteristics, MRI disc degeneration or level of segments fused between these two groups ($P < 0.05$) (Table 2). The segment to be fused was decided by MRI and provocative discography. All the patients in both the groups had typical concordant pain on provocative discography.

Post-operatively, all patients were mobilised in a Boston thoracic lumbar sacral orthosis (TLSO) for 12 weeks.

Radiological and clinical improvement was compared between the two groups, on the basis of improvement of back pain, and work capacity. Patients were asked to fill out questionnaires covering demographic details, walking distance and items on current employment. They were also asked to complete a 10-point visual analogue pain scale, with 0 indicating "no pain at all" and 10 indicating

Table 3 Follow-up symptoms and function of patients in the two groups (mean scores with ranges in parentheses) and benefits/compensation status. There were no significant differences ($P>0.05$) between the two groups on any of the parameters (VAS visual analogue scale, *MSPQ* Modified Somatic Perception Questionnaire, *ZDS* Zung Depression Scale)

Parameter	ALIF	ALIF-HH
Walking distance (m)	1211.6 (274–1646)	1185.3 (91–1646)
Oswestry score	32.2 (10–74)	33.3 (0–82)
Subjective score	25.2 (10–48)	22.9 (8–50)
Distress score (MSPQ+ZDS)	22.7 (4–84)	31.1 (6–99)
VAS	4.6 (1–10)	4 (0–10)
Pain drawing	4.5 (0–18)	5.6 (0–36)
Compensation	7	9
Benefits	11	13

ing “maximum pain possible”. They were asked to give their opinion regarding the outcome of the surgery using a “core set” of six questions as proposed by Deyo et al. [4], which covers pain symptoms, back-related function, generic well-being, disability (social role), and satisfaction with care, and provides an overall assessment of pain function and quality of life. The minimum score was 10 and the maximum 50. A post-operative score of ≤ 30 was considered to be a good overall outcome. This score also measured the subjective improvement of the patients, and is shown as subjective score in Table 3. A pain drawing was used for the patients to show the site of pain. They were asked to describe the characteristics of the pain, which was scored as: numbness =4, pin prick =3, burning =2, or stabbing =1. Patients were subjectively scored on the following parameters after the operation: excellent =3, better =2, same =1, worse =0. Objective assessment was made using the Oswestry Disability Questionnaire [6]. A psychometric measure incorporating the Modified Somatic Perception Questionnaire (MSPQ) [23] and the Zung Depression Scale (ZDS) [36] was used to assess psychological distress at review. A combined score from 0 to 99 is calculated, and distress is defined as a score of 29 or more for men and 33 or more for women. Pre-operative and post-operative scores were available for all these patients. Sickness and disability benefit was also recorded for each patient before the operation and at last follow-up.

The patients’ radiographs obtained pre-operatively, immediately after surgery and at last follow-up were considered for measurement of the posterior intervertebral disc height (PIVDH). PIVDH was measured to the nearest millimetre, selecting the narrowest posterior distance between the endplates according to Holte et al. [14]. The difference in magnification on different radiographs was corrected for by multiplying each PIVDH by the magnification ratio, which was calculated by dividing the posterior vertebral body height of L5 on the pre-operative lateral radiograph by posterior vertebral body height of L5 on the corresponding film. Segmental lordosis was measured on each lateral radiograph, as the anterior intervertebral disc height appeared too inaccurate due to the cage obscuring the endplates [21].

Surgical technique

The operation is performed through a direct anterior retroperitoneal approach (Pfannenstiel) for L5-S1 and a standard anterolateral retroperitoneal approach for the other lumbar levels.

In the case of ALIF-HH, the above procedure is done and peripheral cortical rim is retained over the upper and lower surface of the adjacent vertebrae to seat the horseshoe cage. Tricortical iliac

Fig. 1 Hartshill horseshoe cage for anterior lumbar interbody fusion

Fig. 2 Noninstrumented anterior lumbar interbody fusion

crest bone autograft was used for fusion, along with small pieces of cancellous graft packed firmly in the horseshoe (Fig. 1).

In patients who had noninstrumented interbody fusion, tricortical iliac crest autografts were placed in the intervertebral disc space (Fig. 2).

Radiologic evaluation

Fusion was assessed by plain and stress radiographs. Computed tomographic (CT) scan was done in patients with persistent symptoms and inconclusive radiographs. Patients in both groups who had unsatisfactory clinical outcome were investigated with bone scan, CT scan, and MRI scan for pseudarthrosis, in addition to the above assessment.

Union was defined as solid or pseudostiff when there was bony trabecular continuity and there was less than 4° mobility between the segments on flexion-extension stress radiographs. The union was defined as probable when the bony trabecular continuity was not very clear, but there was less than 4° mobility between the adjacent fused segments. Nonunion was defined as visible gap, graft collapse, and motion greater than 4° [30].

Statistical analysis

The differences observed between the groups were analysed using the chi-square test, two-by-two Fisher exact test and Mann-Whitney U test.

Results

The mean follow up was 4.7 years (2.3–7.9 years) in the ALIF group and 3.0 years (2.1–4.4 years) in ALIF-HH group.

Fusion

There was no evidence of nonunion on these investigations in the ALIF-HH group. Radiological trabecular continuity is difficult to see with the titanium implant. The patients who had a satisfactory outcome did not have any plain radiographic evidence of implant loosening, broken screw, implant failure or osteolysis around the screws or the cage. There was no subsidence in the ALIF-HH group. The pre-operative PIVDH was 5.4 ± 2.6 mm (range 0–11 mm), which increased to 6.8 ± 2.5 mm (range 2–14 mm) immediately after operation, with a final PIVDH of 6.6 ± 2.4 mm (range 1–13 mm). Pre-operative segmental lordosis averaged $10^\circ \pm 5.1^\circ$ (range -1° to 22°) and increased to $12.2^\circ \pm 4.8^\circ$ (range 2° – 25°) post-operatively. Segmental lordosis at last follow-up was $12.0^\circ \pm 4.7^\circ$ (range 2° – 23°). There was insignificant loss of lordosis or PIVDH between immediate post-operative films and those obtained at last follow-up ($P > 0.05$).

Four patients in the uninstrumented ALIF group had obvious nonunions on radiographic assessment. Two of these patients had no improvement and one was worse at last follow-up, according to the classification of outcome by the Oswestry Disability Index. The pre-operative PIVDH was 5.2 ± 2.2 mm (range 1–10 mm), which increased to 6.6 ± 2.3 mm (range 2–12 mm) immediately after operation, with a final PIVDH of 5.2 ± 2.0 mm (range 1–10 mm). Pre-operative segmental lordosis averaged $9.2^\circ \pm 5.0^\circ$ (range -2° to 21°), and increased to $11.2^\circ \pm 4.2^\circ$ (range 2° – 21°) post-op-

eratively. Segmental lordosis at last follow-up was $9.6^\circ \pm 4.5^\circ$ (range 1° – 19°). There was loss of lordosis or PIVDH between immediate post-operative films and those obtained at last follow-up, although this did not reach statistical significance ($P > 0.05$). There was significant subsidence in the four patients with nonunion, and they almost went back to the pre-operative values of PIVDH and lordosis.

It is reasonable to assume that there was no pseudarthrosis in the ALIF-HH group. This difference was statistically significant (two-sided P -value 0.0425).

Complications

There was one post-operative case of pneumonia and one superficial infection in the noninstrumented ALIF group, which settled with antibiotics. One patient in the ALIF-HH group had severe sciatica due to impingement by the screw used to stabilise the Hartshill cage. She was re-operated 3 weeks later and the screw was placed in the vertebral body, thus relieving her symptoms. There was one patient who had deep vein thrombosis (DVT) in the ALIF-HH group, which settled down with anticoagulants. Two patients in the noninstrumented ALIF group had urinary tract infections, which were successfully treated with antibiotics. One patient in the uninstrumented ALIF group had persistent iliac crest donor site pain for 6 months.

Clinical outcome

On subjective score assessment, the rate of satisfactory outcome (score ≤ 30) was 87.5% (21 patients) in the noninstrumented ALIF group and 85.2% (23 patients) in the ALIF-HH group ($P > 0.05$). On classification by the Oswestry index into Excellent, Better, Same or Worse, we found no difference in outcome between the two groups: 83.3% (20 patients) had a satisfactory outcome (Excellent/Better) with noninstrumented ALIF and 77.8% (21 patients) had a satisfactory outcome with ALIF-HH ($P > 0.05$) (Table 4).

Seven patients (29.2%) went back to their original duties and six patients (25%) went back to light duties after the noninstrumented ALIF operation. Six patients (22.2%) went back to original duties and eight patients (29.6%) went back to light duties or changed to less strenuous jobs

Table 4 Outcome gradings based on the patients' Oswestry scores. There was no significant difference ($P=0.7315$) between the two groups in the rate of satisfactory outcome (Better/Excellent)

Outcome	ALIF	ALIF-HH
Excellent	14	17
Better	6	4
Same	2	5
Worse	2	1

after the ALIF-HH operation. Thus, there was a 54.2% improvement in working ability in the noninstrumented ALIF group and 51.8% improvement in ALIF-HH group ($P>0.05$).

Pain and function

The mean back and leg pain measured by visual analogue scale (0–10) was 4.6 in the noninstrumented ALIF group and 4 in the ALIF-HH group. At last follow-up, two patients had back pain and one had leg pain in the noninstrumented ALIF group. Two patients said that their symptoms were the same after operation and two patients said their symptoms were worse after operation. In the ALIF-HH group, two patients had back pain and two had leg pain at last follow-up. Five patients said that their symptoms were the same and one said that their symptoms were worse after the operation.

There was no significant difference in the mean Oswestry score between the noninstrumented ALIF and the ALIF-HH group of patients ($P>0.05$). The psychological profile and walking distance of the two groups of patients was not dissimilar ($P>0.05$). The mean post-operative subjective score (quality of life assessment) was 25.2 in the noninstrumented ALIF group and 22.9 in ALIF-HH group. There was no statistical difference between the pain improvement measured with visual analogue scale, pain drawing, Oswestry score and subjective score between the two groups. There was no difference in the functional and psychological improvement between the patients of these two groups (Table 3).

Eleven patients in the noninstrumented ALIF group were on disability benefit, of whom two did not improve and two were worse at last follow-up (36.4% unsatisfac-

tory outcome). Thirteen patients in the noninstrumented ALIF-HH group were on disability benefit, of whom four did not show any improvement, and one was worse after the operation (38.5% unsatisfactory outcome). There were seven patients on workers' compensation in the noninstrumented ALIF group, of whom one was worse and two did not show any improvement after operation (42.8% unsatisfactory outcome). Nine patients in the ALIF-HH group were on workers' compensation, of whom one was worse and three did not improve after the operation (44.4% unsatisfactory outcome). There were no significant differences in outcome within either group between the patients on compensation and those not on compensation. However, when we looked at the two groups combined and compared all the patients who had compensation with all those who did not, we found a significant difference in clinical outcome (Table 5). We found a similar trend for comparisons between patients who were on disability or welfare benefit versus those who were not (Table 6).

Discussion

The overall fusion rate in noninstrumented ALIF was 20/24 (83.3%). There was no nonunion in patients who had stable fixation of motion segments with the Hartshill horseshoe cage (ALIF-HH). Patients who had persistent pain or had unsatisfactory outcome underwent a thorough radiological evaluation for nonunion, with stress flexion-extension radiographs, radioisotope bone scan, CT scan, and MRI scan. The latter investigation did not show any significant progressive degenerative disc changes in adjacent mobile segments of lumbar spine. However, radiological trabecular continuity is difficult to see with the titanium implant. Therefore, it is difficult to assess how many patients who had satisfactory clinical outcome did not have bony fusion. Although biomechanically an implant should fail if there is nonunion, we did not have any failure or radiolucency around the screws or the cage at a minimum follow-up of 2 years. This leads us to assume that the motion segment is rigidly fixed, which can happen if there is a solid union at that level. We therefore assumed that the fusion rate in this group was 100%. Tiusanen et al. [32] found that when they used three tricortical bone grafts for ALIF they had 100% fusion.

Fusion rates in the literature on anterior interbody fusion vary between 19 and 96%, depending on the fixation technique, the bone graft used, and the method of fusion evaluation [2, 7, 9, 12, 13, 15, 18, 19, 21, 22, 24, 27, 29, 32]. Corticocancellous bone grafts were used in many of these reported techniques to achieve anterior fusion [17, 21, 25]. Post-operative problems such as height loss, graft collapse, and pseudarthrosis led to the development of carbon-fibre cages [1, 33] and titanium rings [18, 22] filled with cancellous grafts. The Hartshill horseshoe cage in this study achieves immediate stabilisation, and the screws in

Table 5 Outcome according to the Oswestry score (Satisfactory: Excellent/Better; Unsatisfactory: Same/Worse) as per compensation, for all patients in both groups. The difference in outcome between the patients with compensation and those without was highly significant ($P=0.0065$)

Outcome	Compensation, n (%)	Non-compensation, n (%)
Satisfactory	9 (56.2%)	32 (91.4%)
Unsatisfactory	7 (43.8%)	3 (8.6%)

Table 6 Outcome according to the Oswestry score as per disability benefit for all patients in both groups. The difference in outcome between the patients on disability benefits and those not on benefits was highly significant ($P=0.0065$)

Outcome	Benefits, n (%)	No benefits, n (%)
Satisfactory	15 (62.5%)	26 (96.3%)
Unsatisfactory	9 (37.5%)	1 (3.7%)

the superior and inferior vertebral bodies provide rigid fixation. It avoids the need to perform posterior stabilisation, which is often required with other cages or bone grafts for ALIF [5, 21, 33]. The cage also prevents graft sinkage through the vertebral endplates, it prevents graft extrusion, and it opens up the neural foramina and recreates the normal lordosis of the lumbar segment.

Freebody et al. [8] and Flynn and Hoque [7] found that radiological fusion does not correlate strongly with clinical outcome in anterior fusion. We found that there was a statistically significant difference between the fusion rate in the two groups. However, our clinical outcomes were not very different. Three out of the four patients (75%) who had documented obvious nonunion had an unsatisfactory outcome with noninstrumented ALIF. Clinically, the rate of satisfactory outcome in the noninstrumented ALIF group was 83.3% and that in the ALIF-HH group was 77.8%. Although the presence of a pseudarthrosis did show a trend towards inferior clinical outcome, it was not foolproof. Factors other than nonunion play a part in clinical outcome. It is possible that these patients had a significant psychosocial element affecting their outcome. Compensation status was almost of statistical significance ($P=0.059$) in the non-instrumented ALIF group. Disability benefit was a significant psychosocial factor in the noninstrumented ALIF group ($P<0.031$). We did not find this difference in the ALIF-HH group, due to a type 2 error. All patients in both groups who were on compensation or benefits showed a significantly inferior outcome ($P<0.05$) (Table 5, Table 6). Just over half the patients in each group resumed some kind of work. Greenough et al. [10, 11] have shown that compensation significantly affects the outcome after low back surgery. Tandon et al. [31] have shown that patients with chronic back pain become dependent on welfare benefits, and due to this often do not want to return to work. Therefore, pain, function and working ability are affected by psychosocial factors, and it is very difficult to get clinical results better than 85%.

Unlike in anterior fusion, there is evidence in the literature that radiographic posterior or posterolateral fusion correlates significantly with clinical outcome [10, 20, 29, 34]. These conflicting results may be explained by objective fusion, which would prevent movement between adjacent vertebrae. Rolander [28] found in vitro that a rigid posterior fusion will still allow compressive movements at the disc, and thus, in theory, a nonunion posteriorly would allow considerably more movement. Suk et al. [30] found that adding interbody fusion to posterolateral fusion significantly improved clinical outcome. A nonunion anteriorly will perhaps consist of a firm fibrous union, probably 1 or 2 mm thick, which would allow very limited movement under a compressive load. Therefore, a nonunion anteriorly may still abolish disc space movement to a sufficient degree to relieve pain, provided the graft does not collapse, but a nonunion posteriorly might not. In which case, although the Hartshill horseshoe cage provides theoretical advantages, clinically it would not matter.

Although loss of PIVDH has been reported by several authors [3, 21], the clinical outcome has not been affected. Several authors [21, 30, 32] have attempted to improve the fusion rate by posterior instrumentation to stabilise the motion segment. This procedure has the disadvantage of adding to morbidity and the complication rate, because a successful fusion would require two incisions, prolonged anaesthetic time and possibly a greater degree of blood loss. This can be avoided or minimised by anterior interbody fusion using the Hartshill horseshoe cage, which provides immediate stability, and a conducive biomechanical environment for fusion.

Although the fusion rate could perhaps be improved by stable anterior fixation with this cage, the question remains of how to improve the clinical outcome close to 100%. As yet there has been no surgical treatment that can guarantee a good clinical outcome in these patients due to several known and unknown factors that cause low back pain and symptoms.

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