Clinical Outcomes of Circumferential Spinal Fusion Do Not Match Radiological Results Despite Rigorous Patient Selection

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Citation

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Abstract

This is a retrospective study of 43 consecutive patients undergoing 3600 lumbar spinal fusion with a minimum follow-up of two years using validated outcome measures, a chart review and an independent radiological review.

Patients were selected for surgery by fulfilling a number of criteria thought to increase the likelihood of successful outcome, using the biopsychosocial model of back pain as the prime discriminant.

Outcome measures consisted of: The Low Back Outcome Score (LBOS), a Patient Satisfaction Score, the Schnee modification of the Prolo Economic Score, radiological fusion status two years after surgery and a description of the complications sustained.

Only 36 (83.7%) patients had 'good' or 'excellent' results, as defined by the LBOS, however 40 (93%) patients were "satisfied" with their outcome. Post-operative radiographs revealed that spinal fusion was present in all 43 cases at all instrumented levels.

Despite technical radiological 'success', about a sixth of patients undergoing a 3600 fusion for chronic low back pain progress to a sub-optimal outcome, using standard disease-specific outcome measures. Subjective satisfaction ratings more closely reflect the radiographic results. Patients who score sub-optimally using standard outcome tools often have confounding physical and psychosocial attributes that can be established before surgery.

In patients with chronic back pain who might benefit from 3600 spinal fusion, application of very careful selection criteria seems likely to positively influence the subjective outcome.

INTRODUCTION

Lumbar spine fusion has been increasingly used to treat painful degenerative lower back conditions in the last two decades. The introduction of pedicle screw instrumentation improved posterior fusion rates. It also meant that anterior interbody fusion rates, using femoral ring allografts or anterior interbody fusion cages in combination with posterior instrumentation, improved compared to the traditional, Cloward-type, anterior fusion using sculpted bone grafts. Despite early promise results using stand-alone anterior threaded fusion cages have not matched the success of circumferential fusions. The commonest indications for fusion surgery are post-discectomy instability, idiopathic degenerative disc disease and spondylolisthesis.

There is support from the Swedish Lumbar Spine Study Group for fusion as a treatment for low back pain, but strong scientific evidence proving that spinal fusion is an effective intervention in painful degenerative lumbar conditions is awaited.[1] This has been highlighted in a recent Cochrane review. Ten trials comparing instrumented to non-instrumented fusion were analysed. It was found that although instrumented fusion provided higher fusion rates this did not necessarily improve the clinical outcome.[2] The review found that there were major weaknesses in study design with emphasis on technical success rather than patient centred outcome. However, it is the almost universal experience of surgeons well-versed in the treatment of back pain, that a few patients do spectacularly well with a spinal fusion. How to identify these few from the huge numbers of patients presenting with low back pain is the key to surgical success.

Notwithstanding the Cochrane Review criticisms, if it is accepted that spinal fusion can be an appropriate treatment for highly selected patients with back pain, it is possible to achieve it in a number of ways. In general terms however, the procedure should address the known biomechanical and physico-chemical abnormalities that are thought to cause back pain. The sagittal alignment of operated levels should ideally be restored and the source of pain within the disc removed. Posterolateral fusion, with or without instrumentation (PLF) [3] cannot generally achieve these aims although it has become the "Gold Standard" for lumbar spine fusion. Posterior lumbar interbody fusion (PLIF) [4,5], transforaminal lumbar interbody fusion (TLIF) [6,7], anterior lumbar interbody fusion (ALIF) [8] and circumferential (or 360°) fusion.[9,10] all have the advantage of reconstructing the anterior column hence removing the discogenic source of pain, restoring sagittal alignment and resisting shear forces, particularly at L4/5 and L5/S1 [11] and as a result ought to be able to achieve better results than PLF. Once the surgery has been completed a good post-operative rehabilitation with a positive relationship between the patient, therapist and the surgeon is also vital to optimise clinical outcomes. Patients who co-operate with the post-operative regime are in general more likely to achieve a good outcome than those who are unco-operative as long as the selection for operation is correct and surgical execution has been meticulous.

However, even when these three factors (selection, execution and rehabilitation) have been optimised there can still be a mismatch between clinical and radiological success. Patient satisfaction is the most important determinant of any surgical procedure and may not be related to technical success. This is true in general orthopaedics as well as spinal surgery. An objective outcome using a defined end-point such as evidence or otherwise of prosthetic failure on an x-ray or revision arthroplasty, can confirm technical "success" or "failure", but even when there is a no objective evidence of failure the patient may be dissatisfied and rate their outcome as sub-optimal.[12]

The aim of this study is to review the clinical and radiographic results of 360° fusions using an established pedicle screw system and a radiolucent anterior interbody fusion cage. Results are assessed using well validated clinical and radiological outcome tools and the relationship between these outcomes is examined.

PATIENTS AND METHODS

PATIENTS

Between October 1997 and October 2001, circumferential spinal fusion using Diapason® pedicle screw instrumentation (Stryker) and Brantigan® anterior interbody fusion cages (DuPuy) was performed on 43 patients with chronic low back pain. These patients were selected for surgery by the senior author (NB) from his private and public (National Health Service - NHS) practices. The same selection criteria were used for all patients. All patients were operated on by the senior author who is an orthopaedic surgeon specialising in spinal surgery (Table 1).

Figure 1

Table 1: Patient demographics

Patients	No.	Mean age & range	Spondylo	DDD	PDI	L3/4	L4/5	L5/S1	L4-S1
Male	16	36.6; 32 - 54	6	7	3	1	3	9	3
Female	27	39.4; 31 - 63	6	14	7	1	6	15	5
All	43	38.8; 31 - 63	12	21	10	2	9	24	8

Key: Spondylo = spondylolisthesis
DDD = idiopathic degenerative disc disease
PDI = post-discectomy instability

Patients had clinical and radiographic evaluation in a spinal clinic for a minimum of two years. Follow-up was at six weeks, three, six, twelve and twenty-four months post-operatively at which a full clinical evaluation was carried out and plain antero-posterior (AP) and lateral standing radiographs were taken. The x-rays from the two-year follow-up clinic visit were independently reviewed by two orthopaedic surgeons to determine whether fusion was present. The criteria used to establish fusion in patients with radiolucent interbody implants in conjunction with pedicle screw instrumentation are those described by Brantigan and Steffee.[4]

- Trabeculae seen bridging the interbody gap with isodense bone in the cage and the adjacent vertebral bodies
- Anterior and/or posterior sentinel signs
- No lucencies around the pedicle screws
- No lucencies around the cages
- Integration of the cage with the endplates and silhouetting of the cage
- No detectable movement on flexion and extension lateral x-rays

All six of these criteria needed to be met to allow the

observers to conclude that there was fusion.

The final follow up was by postal questionnaire and outcome measures used were:

- Low Back Outcome Score 13
- The Prolo Economic Score (after Schnee) 14
- A Patient Satisfaction Score composed of the
    - A subjective pain-relief assessment 15
        - NASS Patient Satisfaction Index 16 modified to include an assessment of whether the patient would recommend the operation to a friend or family member
        - An assessment of the patient's level of satisfaction with the process of their care before and after surgery 17

Analysis of the outcome data was by descriptive statistics.

SELECTION CRITERIA FOR SURGERY

Patients were selected by fulfilling a number of strict criteria that are thought to have a positive influence on the clinical and radiological outcomes of spinal fusion. These are listed in Table 2.

When patients were initially seen in the spinal clinic a full history and examination was carried out including an assessment of disability using the Waddell and Main Disability Index and Abnormal Illness Behaviour Scores [18,19] Patients who failed to meet selection criteria 1 and 6 – 11 were not considered for circumferential fusion and were treated in other ways. If patients were obese at presentation, but otherwise fulfilled the criteria for investigation possibly leading to surgery, they were given time and encouragement to lose weight and if they achieved a body mass index (BMI) of less than 30 within twelve months of their initial assessment they were further investigated.

Figure 2

Table 2: Selection criteria for circumferential fusion

Criterion	Requirement to be met for surgical treatment
1. Age	Older than 20 and younger than 65
2. Body Mass Index (BMI)	Less than 35
3. Smoking	Not smoking for three months before surgery and an agreement to abstain for at least six months after surgery
4. Duration of back pain	Greater than two years
5. Results of conservative treatment	No lasting benefit from physiotherapy lasting for at least six months; No lasting benefit from facet joint injections at the index level; No lasting benefit from intradiscal therapy at the index level
6. MRI findings	Disease limited to one or two levels and confirmed by provocative discography with a normal disc which is neutral to discographic provocation immediately cephalad to the most proximal painful level
7. Metabolic bone disease	None including osteoporosis. If patient was at risk of osteoporosis a DEXA was scan performed and any patient with bone mineral density of > -1 standard deviation from the mean for age was excluded
8. Litigation	Not considered for surgery if on-going claim for any musculo-skeletal complaint
9. State disability and workers compensation	Not considered for surgery if medically retired due to back pain or undergoing / recently concluded occupational claim for back pain
10. Waddell and Main Abnormal Illness Behaviour Symptoms	None allowed except one admission to hospital as an emergency if it was for retention of urine due to pain thought to be secondary to cauda equina compression and investigated as such
11. Waddell and Main Abnormal Illness Behaviour signs	Two out of possible eight allowed as long as generalised over-reaction to examination was not one

If patients were smokers they were given the opportunity to stop, with appropriate pharmacological and psychological support. Abstinence was required for three months before surgery and patients were encouraged to maintain their abstinence for at least six months after surgery. Only one reformed smoker started smoking again in the post-operative period.

The biopsychosocial model has become the most powerful discriminative tool in our practice in selecting patients for any intervention for back pain. Patients with considerable abnormal illness behaviour and a mismatch between their physical symptoms and signs and their disability scores were not considered for elective surgery for chronic back pain. They are offered education, functional restoration and drug therapy for their pain. Occasionally they are referred to the pain clinic for minimally invasive treatments. However, the psychosocial profile as exemplified by abnormal illness behaviour symptoms and signs was not used to penalise patients if they had a genuine organic cause for their pain.[20] Rather it guided pre-intervention therapy and in some cases, when the profile improved with non-interventional techniques, allowed the patient to become a candidate for surgical intervention.

Using this triage system, 50% of patients were selected out of the intention-to-treat (by surgery) group by the end of their initial assessment. Those remaining underwent non-invasive treatment consisting of progressive walking and swimming programmes and remedial exercise supervised by a physiotherapist or remedial therapist. After a further six months of treatment, 50% of this group were excluded from consideration for surgery, either because they had improved sufficiently to not need an operation, or because they had not

complied with the rehabilitation programme and therefore would be unlikely to cope with a similar post-operative regime.

Of the 25% of the original group of patients left, more than a third declined further investigation when they were asked directly if they would have surgery should the investigations suggest it would be appropriate. 15% of patients then went on to have x-rays and MRI scans, of whom half had multiple levels of degenerative change that immediately precluded them from single or two-level surgical intervention. Of the remainder, facet joint injections and discography were used as minimally invasive tests. The patients were made aware that the injections were tests to try to identify possible pain sources in the lumbar spine and to try to establish a correlation between their MRI findings and their symptoms. If there was a therapeutic benefit, that was a bonus. However, we have found that about 60% of patients who have positive, concordant discograms who are concurrently treated with intra-discal steroids and those with good initial relief from facet injections, will go on to have lasting pain relief and do not need surgery. If there is a good result from these investigations, further physiotherapy is prescribed in the anticipation that clinical improvement will occur if a patient has a pain-free spine and can make their muscles function well irrespective of the appearances of the intervertebral discs on MRI.

Patients who had a good first response to injections, but had a recurrence of pain, were offered a second injection of the same kind to ensure that the first result was not the result of a placebo effect. If they had a second good, but ultimately temporary, result they were offered either intra-discal electro-thermo-coagulation (IDET) or facet joint rhyzolysis, followed by further exercise therapy. By the time this investigatory process had been completed, fewer that 1% of the original cohort of patients who presented to the clinic were candidates for surgery.

Although eventually all patients had back pain for more than two years by the time of surgery, for many when they presented, it had been present for a shorter time. However, the timetable for investigations and conservative treatment was such that by the time they had completed a comprehensive course of physiotherapy and gone through the various diagnostic blocks to establish the correlation between MRI findings and symptoms, more than two years had passed from the first onset of pain.

A further full clinical assessment was made of patients in the weeks prior to surgery to ensure that during the investigatory phase of their treatment they had not developed inappropriate disability or abnormal illness behaviour. If they had deteriorated psychosocially to a significant extent, they were excluded from surgery and offered further cognitive behavioural therapy based functional restoration.

OPERATIVE TECHNIQUE

Circumferential fusion was used for those patients who had low back pain with neurological deficit and no significant static radicular pain or whose radicular pain came on with axial loading of a degenerate disc. These patients did not need to have intra-canal surgery and indirect decompression by distraction and anterior interbody stabilisation was thought to be sufficient to relieve radicular symptoms.

A Wiltse posterior approach was used in all cases. Diapason pedicle screws were inserted and were connected with contoured rods, under bi-planar image intensifier control and Neurosign 800 (Magstim Company) active motor nerve monitoring (Figure 1). Distraction was applied to restore the normal sagittal profile. The posterior bony structures were decorticated and autograft from the iliac crest was used to provide the fusion mass. Part of the harvested bone was put aside for the anterior interbody fusion.

Figure 3

Figures 1a & 1b: Neurosign 800 motor-neurone monitoring

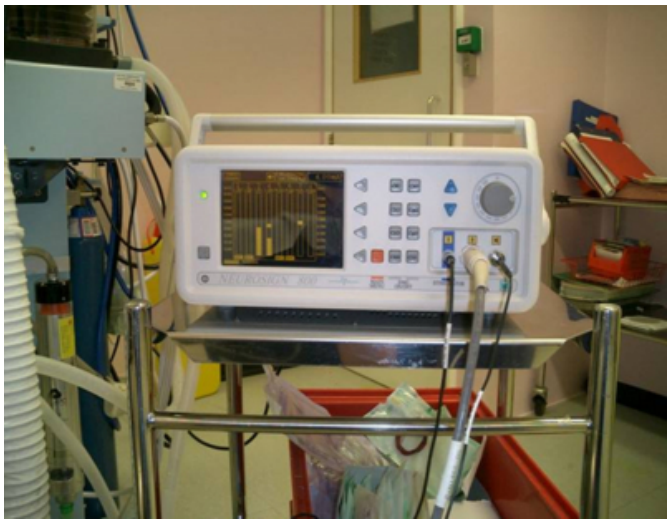
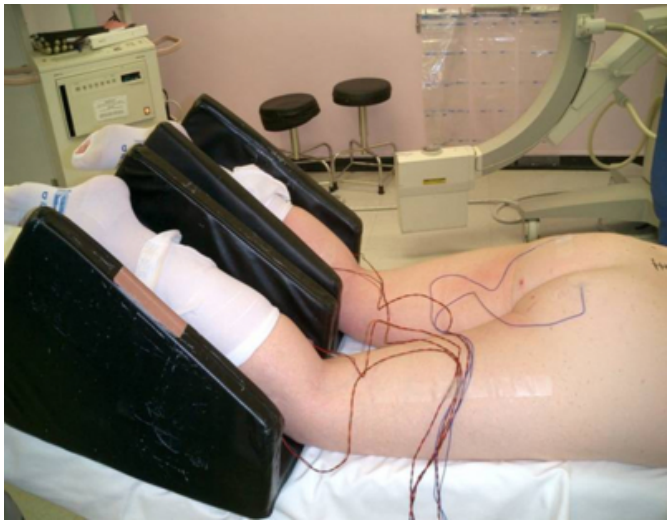


Figure 4



The anterior fusion was carried out through a trans-peritoneal approach for single level L5/S1 operations and a retroperitoneal approach for all other procedures. The relevant discs were fully excised except for the peripheral annulus and all the cartilage was removed from the end plates to reveal bleeding bone. The Brantigan ALIF instrumentation was used to assess the size of the interbody space and an appropriate cage was packed with autograft and impacted into the space. Residual bone chips were used to fill the annulotomy defect anterior to the cage.

The senior author had used the Diapason pedicle screw instrumentation for several years prior to the start of this study and therefore was familiar with its technical demands. The Brantigan ALIF cage was chosen as the anterior implant on biomechanical grounds as the modulus of elasticity of the cage is close to cortical bone and therefore load-sharing between the bone graft and the cage is much more likely than when threaded metal cages are used. In addition, the Brantigan cage is radiolucent and in the mid to late 1990's it was thought that fusion could be adequately assessed using plain radiographs with radiolucent interbody devices.

Postoperatively, patients were mobilised within 24 - 48 hrs and after discharge from hospital wore a rigid lumbo-sacral, custom-built orthosis for 3 months. Their rehabilitation consisted of a progressive walking programme for 6 weeks followed by intensive physiotherapy to restore core stability, flexibility and spinal muscular stamina lasting for up to a further three months.

POST-OPERATIVE CLINICAL EVALUATION

Formal clinical review of patients was at regular intervals of 6 weeks, 3 months, 6 months, 1 year and 2 years after the surgery. Symptoms of pain and disability were recorded as well as sexual function for men. All the patients were examined for range of motion of the spine, neural tension, presence of an abdominal wall hernia, presence of a sympathectomy effect in the left leg and peripheral neural deficits.

Final review was by postal questionnaire at least six months after the two-year clinical follow up. The mean follow up was 3.5 years (range 2.5 – 6.0 years).

POST-OPERATIVE RADIOGRAPHIC EVALUATION

Standing AP and lateral radiographs of the lumbo-sacral spine were taken at each clinic visit with additional flexion and extension lateral views at the two year visit. The final follow up radiographs were evaluated independently by two orthopaedic surgeons for fusion using the criteria listed above. In patients with operations at multiple levels, assessment of fusion included all the levels operated on.

RESULTS

TECHNICAL RESULTS

35 fusions were performed at a single level and eight performed at two levels (Table 1).

L5/S1 fusion alone was performed in 24 (55.8%) patients, L4/5 fusion alone in nine (20.9%) and L3/4 fusion in two (4.7%). Eight patients had an L4-S1 fusion (18.6%). There were no fusions above the L3/4 segment. Analysis of the post-operative radiographs at the two-year follow up revealed that spinal fusion was present in all of the 43 cases, at all operated levels (100%) according to the Brantigan and Steffee criteria (Figures 2a & 2b). Further investigations were carried out in the six patients with poor outcomes on the LBOS, including fine-cut CT scanning of operated levels. These scans confirmed that a solid interbody fusion was present in each case thus supporting the validity of the radiological assessments.

Figure 5

Figures 2a & 2b: Antero-posterior and lateral x-rays of an L5/S1 360° fusion showing a solid arthrodesis

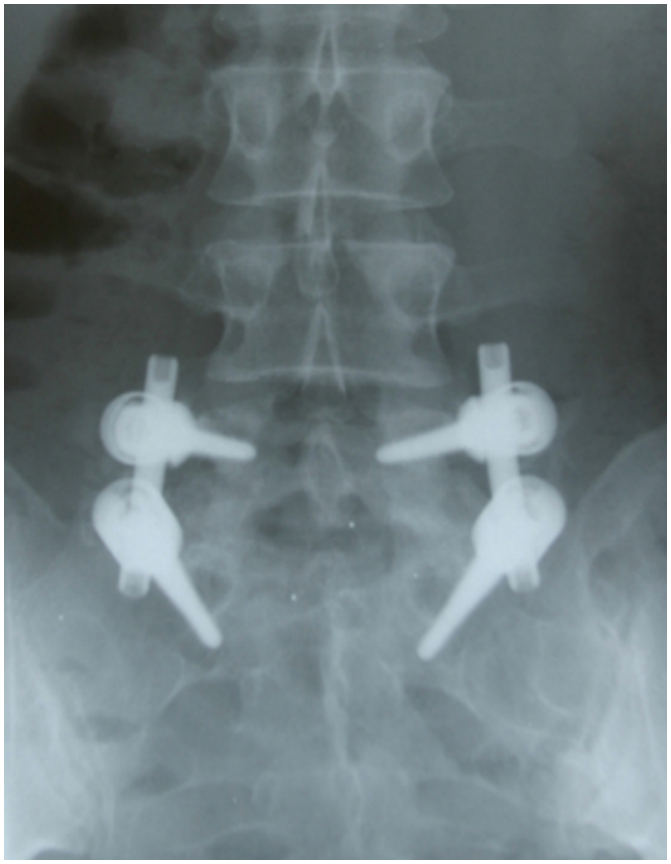
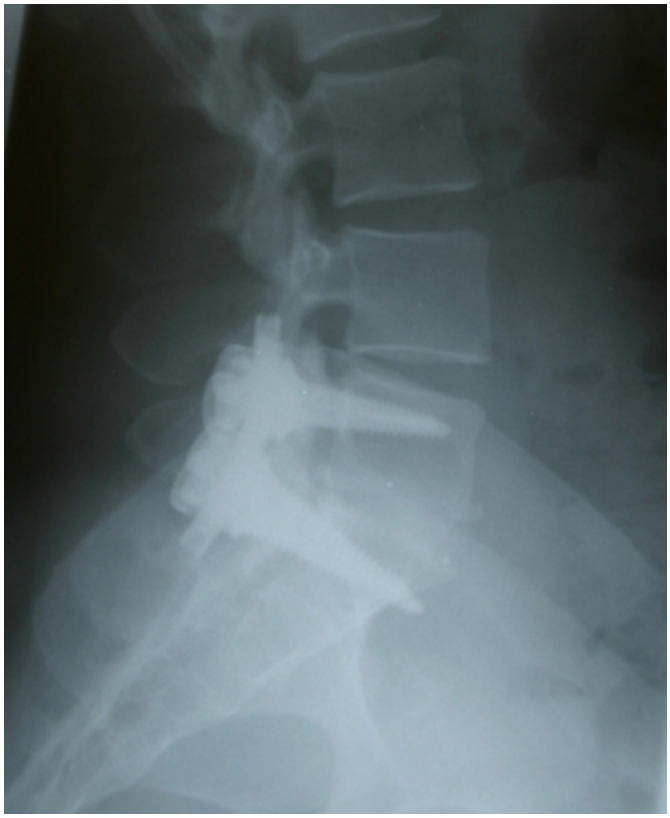


Figure 6



The complication rate at final follow-up was 4.7%. The most common early complication was sympathetic dysfunction in the left leg (eight cases – 18.6%), none of which lasted greater than four months. One incisional hernia (2.3%) required repair using a mesh four years after the index procedure, with a very satisfactory outcome for the patient. Six patients (14%) had persistent bone-graft site pain up to one year after surgery, but only one (2.3%) had symptoms beyond one year due to pain felt over the Cluneal nerves. There were no cases of deep infection, clinical deep vein thrombosis or pulmonary embolus. There were no cases of retrograde ejaculation in the men or permanent neurological injury in the whole group.

The mean duration of hospital stay post-operatively was nine days (range 8 -12).

CLINICAL RESULTS

42 patients returned the questionnaires (97.7%). Analysis of the results showed that there was a disparity between the patients' satisfaction rating and the LBOS score (Table 3). 36 (83.7%) patients were rated as having 'good' or 'excellent' outcomes according to the LBOS and 39 respondents (90.7%) rated themselves as having "complete" or "good" relief of their presenting pain (Tables 2 and 3).

40 patients (93%) stated that they would opt to have a circumferential fusion again, for the same symptoms, if guaranteed the same post-operative result. 40 patients (93%) stated they would recommend the treatment to a friend or family member with similar trouble.

Figure 7

Table 3: Summary of Outcomes

LBOS Outcome	Number of Patients (%)	Pain Relief	Number of Patients (%)	Satisfaction rating	Number of Patients (%)	Prolo Score	Number of Patients (%)
Excellent	29 (67.4%)	Complete	32 (74.4%)	Would have surgery again	40 (93%)	E4 & E5	41 (95.3%)
Good	7 (16.3%)	Good amount	7 (16.3%)	Would recommend operation to a friend	40 (93%)	E1 – E3	1 (2.3%)
Fair	5 (11.6%)	Little	2 (4.6%)	No problems with process of care	41 (95.3%)	Non-responder	1 (2.3%)
Poor	1 (2.3%)	None or worse	1 (2.3%)				
Non-responder	1 (2.3%)	Non-responder	1 (2.3%)				

41 (95.3%) patients returned to full-time normal work or full-time work that was lighter than their pre-operative occupation (E4 and E5 on the Prolo scale defining "success"). One patient did not return to work and assuming the non-responder did not, two patients had failed outcomes using this score.

Five patients had a "fair result" and one had a "poor result" based on the LBOS. One patient was lost to follow-up and was presumed to have a poor outcome. Of the seven detectable failures, two had evidence of a more generalised osteoarthritis causing significant musculoskeletal pain outside of the lumbar spine in the years after their spinal operations and as a result scored badly on the LBOS three and four years after their lumbar surgery. One of these did not return to work, whilst the other was able to return to a lighter job compared to his pre-morbid occupation. One male patient had had three previous posterior spinal operations (two decompressions and an attempted fusion), but was still running his own business before surgery although on regular narcotic medication. Although he said that he had a worthwhile result from his surgery, he scored relatively low on the LBOS as he was not able to regain pain-free spinal motion, although he did return to full-time work within eight weeks of surgery. One woman developed intractable, bilateral leg pain in the S1 distribution in the few weeks prior to surgery without obvious static compression of the nerves on MRI in addition to her constant severe low back pain. Despite having a complete decompression of the roots by front and back surgery (as shown on a post-operative MRI) she was unable to get measurable pain relief and scored badly on the LBOS. Another had only a fair outcome with a borderline acceptable psychosocial profile before surgery, although all of her provocative tests indicated a genuinely painful post-discectomy instability at L5/S1. She developed worsening abnormal illness behaviour in the months after her surgery as a result of adverse life events and her back pain recurred despite good evidence on CT and plain films twelve months after surgery that she had solidly fused. When reviewed five years after operation she was found to be as bad as she was before her operation, hence her low LBOS. The last patient who did not have a successful result had an L5/S1 post-discectomy instability that on provocation was painful with normal discs cephalad. He did not disclose to us, even on direct questioning, that he was involved in active litigation. On this basis he would have been excluded from surgery and offered functional restoration rather than an invasive procedure. Although he had some improvement after surgery his LBOS at final follow-up was less than 25/75 indicating a "poor" outcome. Confounding this score, he was able to return to work albeit doing a less vigorous job than before the onset of his back trouble. At his last review, the litigation had still not been settled.

DISCUSSION

The objective of spinal fusion for back pain is to remove a patient's pain source and restore spinal function. The latter is achieved by rendering the spine pain-free and allowing normal spinal movement at non-fused levels without debilitating spasm. However, the correlation between a good technical result (i.e. a radiographic spinal fusion) and a successful clinical outcome is by no means absolute.

In this series, we used a well-established pedicle screw system with which the senior author was fully familiar and an established (outside the USA) radiolucent anterior interbody fusion cage. In the mid-1990's there was an explosion in the number of interbody fusion devices available to the spine surgeon, mostly made of metal. All the metal cages had the same flaw though, that being the inability to detect fusion within the cage on plain radiographs. Indeed, in some circles these cages came to be known as "Bone Coffins" as it was considered that they merely acted as intervertebral spacers and no biological fusion occurred within the cage. We attempted to avoid such a major confounding factor to the accurate assessment of fusion by our choice of implants.

All of our patients obtained a radiographic fusion (according to the Brantigan and Steffee criteria), which is similar to previous studies.[21, 22, 23] However only 83.7% of patients had a "good" or "excellent" result based on the LBOS. Slosar et al. [10] found only a 62% satisfaction rate in patients who had a circumferential fusion for painful disc syndromes even though all patients had technically successful surgery. The literature in general offers a similarly confusing picture with some series of posterior or postero-lateral fusions indicating a good correlation between radiographic fusion and clinical outcome [24, 25, 26] and other series of patients undergoing anterior fusion showing a poor correlation. [27, 28]

When there is a poor correlation between technical and clinical results it may be due to the well-known difficulty in assessing fusion, especially when results are reported by the operating surgeon. However, we believe it is much more likely to be because the "wrong" patients have been selected for surgery. Historically, the biopsychosocial model of back pain has not been widely used to help select patients for surgery. In our series it was used as a primary discriminant tool to screen out patients who were likely to have a small biological contribution to their overall pain load and who would therefore not have a significant benefit from an invasive procedure. We tried to minimise further selection errors by using strict exclusion criteria, but even with this rigorous approach we were not able to achieve good clinical results in a sixth of our patients, according to the LBOS.

Patients with a number of diverse painful musculo-skeletal or neurogenic problems can confound the LBOS. Because it is a disease-specific, physician-generated outcome tool, it may not be able to offer as sensitive as assessment of outcome as a generic, subjective device. We found that a number of patients, who were considered failures according to the LBOS, actually were satisfied with their surgical outcomes, but had other reasons for persistent disability. In this case, the generic tool has detected the benefit the patients felt in terms of their specific pre-operative complaints, whilst the disease-specific tool was unable to do this because of the presence of confounding symptoms. Satisfaction with the outcome of a medical procedure is recognised as being associated with increased patient compliance, increased self-help and maintenance of a continuing effective relationship with the healthcare provider.[29, 30] In short, in this context, it can describe the "Low Back Winner" as opposed to the "Low Back Loser", at least in terms of surgery. Since the biopsychosocial model of low back pain dictates the parameters that define the "winners" and "losers" in a surgical context, it is only natural to expect it to significantly assist in the triage of patients and ultimately decide on who is likely to benefit from surgery, all other things (i.e. execution of the procedure and subsequent rehabilitation) being equal. However, it does demand that the technical element of the treatment is satisfactory and can be proved to be satisfactory. It has been argued that if patients' expectations of the outcome of a spinal procedure is high, the satisfaction level ultimately may be relatively low if the intervention does not produce a dramatic improvement in symptoms.[31] The implication being that spinal surgery may be ineffective in treating patients with low back disorders. Only by objectively proving that we have done what we meant to do, can this be refuted, and in such studies, objective outcomes measures should be included to support such arguments. It does not matter how many disease-specific and generic outcome tools are used in assessing patients before and after an intervention, if the aim of surgery is not met, i.e. that the nerve roots are decompressed or that an arthrodesis has not been achieved, then these tools will have no value whatsoever.

To prove that we had achieved the primary technical aim of surgery, i.e. that there was an arthrodesis, two independent orthopaedic surgeons assessed the radiographs applying the Brantigan and Steffee criteria rigidly. This had a two-fold benefit; firstly we could prove to our satisfaction that whatever the outcome clinically, the radiological outcome was in no doubt and secondly that operating surgeon bias was eliminated. We are aware that fine-slice CT scanning is now considered superior to plain radiographs in assessing the results of interbody fusion,[32] although when the patients in this study were assessed this was not universally accepted and the standard follow up protocol at our institution was plain radiographs. Even though the correlation between radiological fusion and findings at surgery has been found to be poor by some authors [33] the reliability of radiological signs of fusion compared to a second-look operation has been well established for radiolucent interbody fusion cages 4 giving us confidence that by applying the criteria rigidly we could accurately detect fusion.

In our choice of implants for these patients, we were well aware of the issues surrounding carbon fibre reinforced cages particularly in respect of the lack of FDA approval in the United States. However, after a discussion between the senior author and the cage inventor in early 1997, it was

clear that there were compelling biomechanical and radiological arguments to use the cage. The technical results have justified that belief and are supported by other recent reports that have shown high fusion rates using the Brantigan ALIF cage [34, 35]. The clinical success in these studies was not as high as in our group of patients. Given the screening they had undergone, we were treating a group of highly motivated and committed patients with minimal psychosocial debility. In Zelle et al.'s report 34 the low clinical success rate compared to the high radiological success rate is ascribed to high depression scores in their patients. In our centre these patients would not have been selected for fusion until the issues surrounding and driving their depression had been satisfactorily addressed. Good evidence indeed that it is the selection of patients that directly influences the outcome of surgery when the technical success rates i.e. radiographic fusion, are high. In addition, included in Christiensen et al.'s study 35 were smokers and failed back patients – again, exclusion criteria in our centre. The discrepancy between clinical and radiological results being derived solely from selection criteria, when fusion has been achieved, is clearly demonstrated in these two studies. With a biomechanically inferior construct these authors may have had a greater parity between their clinical and radiological outcomes which would have lent weight to the argument against fusion for chronic back pain. However, the results send a positive message to those spinal surgeons who recognise that there are occasions when patients can benefit from spinal fusion for chronic low back pain. In our centre, during the period of this study, more than 4000 patients were seen in the Spinal Clinic with low back disorders, with only 0.7% coming to surgery for a 360° fusion.

By utilising more stringent selection criteria and reporting the experience of a single spinal surgeon, we feel our study, whilst incorporating fewer numbers than other similar reports, removes some of the identified patient barriers to surgical success.

This study has the limitations associated with a retrospective review. There was no control group and one patient was lost to follow up. Final follow was based on a postal questionnaire. However, all patients were reviewed clinically and radiographically at a minimum of two years after operation and strict inclusion criteria were used. Our results using a circumferential fusion compare favourably with others in the literature. Patient satisfaction is high and there is a 100% radiological fusion rate in our series with a relatively low complication rate.

Our experience with the patients reported here who had a sub-optimal result has enabled us to further refine our selection criteria. Highlighting these failures and emphasising the importance of patient selection may improve the outcome of circumferential lumbar spinal fusion in the future.

CONCLUSIONS

This study presents the clinical and radiological findings of a highly selected cohort of patients who underwent 360° fusion for chronic low back pain using a biomechanically sound combination of posterior pedicle screw instrumentation and a carbon fiber reinforced anterior interbody fusion cage. There is a discrepancy between objective, physician-derived, disease-specific outcome measures and the radiological assessment of fusion. This discrepancy diminishes when subjective measures of satisfaction are used as an outcome measure.

In conjunction with other recent studies using similar outcome instruments, it is clear that by very carefully selecting patients for surgery, using the biopsychosocial model as a primary discriminant tool, improved outcomes can be achieved. However, it is unlikely that spinal fusion for chronic low back pain will ever achieve a better than 95% success rate using subjective outcome criteria.

This study strongly suggests that very careful patient selection is the most important predictor of successful clinical outcome in 360° fusions and that subjective outcome measures correlate better with technical success than disease-specific, physician-derived outcome tools.

KEY POINTS

- A retrospective study of the outcome of 360° lumbar spinal fusion using validated clinical and radiological outcome measures.
- A better correlation exists between subjective satisfaction scores and radiological results that between physician-derived, disease-specific outcome scores and x-rays.
- In conjunction with other recent studies using similar outcome instruments, evidence is presented that it is the careful selection of patients, not the radiological result that most significantly

influences the outcome of lumbar spinal fusion.

CORRESPONDENCE TO

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