Posterolateral spinal fusion at unintended levels due to bone-graft migration

No effect on clinical outcome in 19/130 patients

Finn B Christensen[1], Malene Laursen[1], John Gelineck[2], Ebbe S Hansen[1] and Cody E Bünger[1]

Departments of [1]Orthopedic Surgery, Spine Section, [2]Radiology, University Hospital of Aarhus, Nørrebrogade 44, DK-8000 Aarhus C, Denmark. E-mail: fbc@dadlnet.dk
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ABSTRACT – In a prospective randomized study, we evaluated the risk of lumbar posterolateral spinal fusion at an unintended level due to bone graft migration. 130 patients underwent fusion supplemented by pedicle screw fixation (Cotrell-Dubousset, 64 patients) or uninstrumented fusion (66 patients). This was assessed by two independent observers on antero-posterior, and lateral radiographs taken 1 year after surgery. All patients had ben operated on at the preoperatively planned levels. Both observers agreed that fusion had taken place at an unintended level in 19 cases (14%). We found a tendency towards a higher risk of this "complication" when using supplementary pedicle screw fixation. The functional outcome, assessed by the Dallas Pain Questionnaire and the Low Back Pain Rating scale, was similar in patients having fusion at an unintended level and in patients fused only at the intended levels. There was no difference between the two groups concerning reoperation rates, postoperative smoking or social status.

We conclude that unintended fusion occurs and tends to be commoner with the use of pedicle screw instrumentation. However, this complication seems not to affect the functional outcome if fusion has taken place at the intended level.

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In spinal fusion, preparation of the fusion site and handling of the tissue bed are vital to ensure a successful arthrodesis. In general, the larger the surface area decorticated for fusion, the greater the availability of potential osteogenic cells and the greater the contact area exposed to support a bony bridge large enough to carry a mechanical load.

In the preparation of the soft tissue bed and space for supplementary pedicle screw instrumentation, it is often necessary to dissect partly the erector spinae muscles from the bony elements of adjacent segments. This raises the question whether this dissection of the adjacent segment will cause migration of the graft to a neighboring segment, and create fusion at an unintended level. To our knowledge, no paper has yet evaluated whether fusion occurs at unintended levels after bone-graft migration.

This study aimed to evaluate the risk of a posterolateral spinal fusion on an unintended segment with or without the use of pedicle screw fixation.

Material and methods

This study comprised 130 prospectively randomized patients (mean age 45 (20–67) years, 69 men) allocated to posterolateral spinal fusion with or without pedicle screw fixation, and 1-year radiological and 5-year clinical follow-ups (Thomsen et al. 1997). The patients suffered from lumbar or lumbosacral instability, defined s severe chronic motion-induced back pain and isthmic spondylolisthesis grades 1–2, primary degeneration or degeneration following decompressive surgery. Exclusion criteria included previous fusion, age less than 20 or more than 70 years, metabolic bone disease, co-morbidity, and psychosocial instability.

A 20-number-per-block randomization procedure was used, the two surgical procedures blinded by being placed in two envelopes.

64 patients were randomized to the Cotrel-Dubousset-supplemented pedicle screw fusion (CD) group and 66 to the non-CD, posterolateral intertransverse fusion (non-CD) group. The patients were in prone position with initial localization of the correct level by fluoroscopy before skin incision. Bilateral dissection of the lamina and transverse processes was done before iliac crest bone was harvested through the same incision. Instrumentation was then performed, using fluoroscopy. After decortication, the bone graft was placed and packed between the transverse processes or sacrum. The wound was closed in layers over suction drainage.

In 1 patient, randomized to the CD group, screw insertion was abandoned because of dysplastic pedicles, and 1 patient in the non-CD group died of unrelated causes within the first year. Both patients were therefore excluded from this study. Later in the study, 1 patient in the CD group died of unrelated causes and 2 patients (1 in each group) were excluded for non-compliance (they did not attend the clinic for the follow-up visit). The data were prospectively collected by the responsible surgeons, who completed records before and after surgery, at discharge, and at the 1-, 2- and 5-year follow-ups in the outpatient clinic. All the data were continuously stored in our spine-surgery database.

Two independent observers (one skeletal radiologist and one orthopedic surgeon) evaluated the spine fusion with A-P and lateral radiographs taken at the 1-year follow-up, using the Christensen et al. (2001) classification. All the radiographs' identification labels were covered and given a random case number. The observers were told about the number and level of intended fusion. Each level and side was judged separately. "Fusion" was defined as continuous intertransverse bony bridges. Only when the 2 observers agreed was the case classified as "fused". Any doubt excluded the case as "fused". "Doubtful fusion" indicated suboptimal quality at one or more levels, including a fusion mass hidden by the instrumentation, and "non-union" indicated definitely no fusion at one or more of the intended levels.

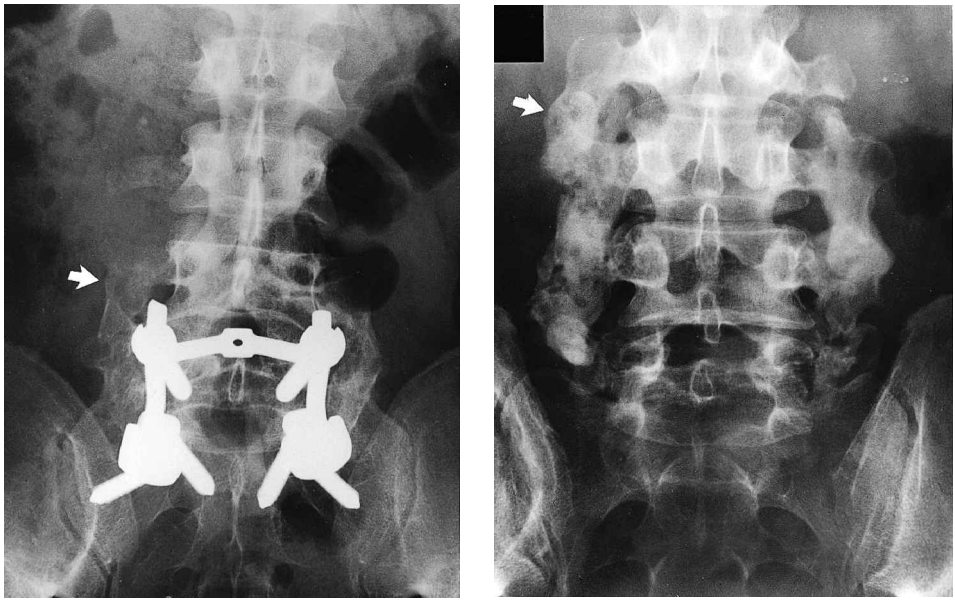
Functional outcome was assessed with the Dallas Pain Questionnaire (DPQ) (Lawlis et al. 1989) and Low Back Pain Rating scale (LBPR) (Manniche et al. 1994). The DPQ assesses the functional effect of chronic spinal pain divided into four types: daily activities, work-leisure activities, anxiety-depression, and social concerns. The validity of the DPQ for clinically assessing a group of patients with low back pain has recently been established by comparing it with 6 alternative psychometric tests (Hadjipavlou et al. 1997, Thacker et al. 1997). The questionnaire was completed by the patient, independently of the surgeons, on the day before the operation, at the 1-, 2- and 5-year follow-ups. It was scored with secretarial assistance by an independent observer. The LBPR was completed at the 5-year follow-up.

Statistics

The Person chi-square and Mann-Whitney-Wilcoxon rank sum tests were used. A 5% two-tailed limit of statistical significance was used for all calculations. SPSS/PC was the statistical software. The agreement between the two observers was evaluated with kappa statistics. The maximum value of kappa is 1, which represents perfect agreement and if there is only chance agreement, the value of kappa is zero. According to the recommendations of Fleiss (1981), a value of kappa exceeding 0.75 represents excellent agreement, values between 0.4 and 0.75 fair to good agreement, and values less than 0.4 poor agreement.

Results

Agreement between the two observers as regards the scoring of fusion at unintended levels was 94% (kappa 0.79), which can be classified as excellent. Surgery had been performed on all patients at the preoperatively planned levels. The 2 observers agreed that in 19 patients (15%) fusion had also taken place at an unintended level (mean age 45 years, 11 men) (Figure). Of these patients, 16 had been scheduled to receive a one-level fusion (6 L4-L5, 10 L5-S1) and 3 a two-level fusion (L4-S1) (Table 1). 17 of the 19 patients were solidly fused at the intended level. 2 patients were classified as doubtfully fused and were among the instrumented



Antero-posterior radiographs taken at the 1-year follow-up showing an unintended posterolateral fusion (arrows) adjacent to an intended posterolateral fusion with or without pedicle screw instrumentation, respectively.

Table 1. Summary of patient characteristics in the "unintended" and "intended" fusion groups

	Unintended	Intended
Gender (females/males)	8/11	52/57
Age (year) mean	45	45
(range)	(27–61)	(20–67)
Diagnosis		
Isthmic spondylolisthesis grades I–II	7	27
Degenerative instability	12	82
Previous decompressive surgery	8	44
Operated level(s)		
1 level	16	62
2 levels	3	36
3 levels		11
One level		
Above L5–S1	6	15
L5–S1	10	47
Postop. cigarette consumption		
Non-smokers	9	41
Smokers	10	68
CD-pedicle screw instrumentation	13	49
Spinal fusion at intended levels	17	86
Reoperations		
Implant removal	2	7
Fusion	2	8
Decompression		2
Herniated disc		1
Social status		
Work	7 (37%)	35 (33%)
Pension	8 (42%)	42 (39%)

group. 88 of the 109 patients (81%) were solidly fused in the intended level group. 13 of the patients with fusion at an unintended level were randomized to supplemental CD-instrumentation. This indicates an increased risk of this complication with pedicle screw instrumentation ($p = 0.06$). Using the described indication for diagnosing fusion, 77% of the CD-instrumented patients and 86% of the non-CD-instrumented patients had radiologically confirmed fusion ($p = 0.3$). 8 of the 19 patients with an unintended fusion had undergone previous decompressive surgery.

There was no significant difference between the 2 groups before or at follow-up in any of the DPQ types of functional outcome (Table 2). No differences in back and leg pain were found between the 2 groups at the 5-year follow-up analyzed with LBPR (Table 3). To the question: "Would you go through the operation again, now that you know the course and the result?" 78% of the unintended fusion patients answered "yes" and 77% of the intended fusion patients said "yes". Unintended fusion levels did not affect the reoperation rate or social status (Table 1).

4 experienced spinal surgeons performed the operations and the case frequency of fusion at an

Table 2. DPQ scores (median values, range) in the categories of daily activities, work-leisure activities, anxiety-depression, and social concerns. The maximum score for the worst possible status is 100 and the minimum score for the best possible status is 0 for each of the 4 categories. The levels of significance indicated are the values at 1 year, 2 years and 5 years compared to the preoperative value

	Daily activity		Work-/leisure		Anxiety		Social activities	
	Median (range)	n	Median (range)	n	Median (range)	n	Median (range)	n
Intended fusions								
Preoperative	57 (12–93) p<0.001	105	60 (10–100) p<0.001	105	40 (0–95) p=0.01	105	33 (0–0)	105
1 year after surgery	36 (0–96) p<0.001	105	43 (0–100) p<0.001	105	30 (0–95) p<0.001	105	20 (0–95) p=0.02	104
2 years after surgery	39 (0–93) p<0.001	105	45 (0–100) p<0.001	105	25 (0–100) p<0.001	103	20 (0–95) p<0.001	103
5 years after surgery	39 (0–102)	91	35 (0–100)	91	20 (0–90)	90	18 (0–85)	91
Unintended fusions								
Preoperative	63 (27–81) p=0.05	19	75 (20–90) p=0.06	18	40 (10–100) p=0.07	19	45 (5–70)	19
1 year after surgery	51 (0–96) p=0.08	18	65 (0–100)	18	33 (0–95)	18	13 (0–85)	18
2 years after surgery	51 (0–102) p=0.02	18	68 (0–100) p=0.01	18	35 (0–90)	19	10 (0–90)	19
5 years after surgery	45 (0–99)	18	41 (0–100)	18	23 (0–95)	18	28 (0–85)	18

Table 3. Median Low Back Pain Rating Scale scores at 5-year follow-up in patients with or without an unintended spinal fusion.

	Unintended (n 18)	Intended (n 91)
Low back pain		
Pain now	4	4
Worst pain in the last 14 days	7	5
Mean pain in the last 14 days	5	4
Leg pain		
Pain now	3	3
Worst pain in the last 14 days	3	3
Mean pain in the last 14 days	2	2

Range was 0–10 in all subsets
There were no significant differences in pain between the 2 groups

unintended level was distributed equally among the surgeons.

Discussion

Performance of the right operation at the wrong level or an inadequate operation at the right level obviously makes for a less successful surgical outcome. In this study, surgery was performed in all patients at the preoperatively planned levels. A surprisingly high number of patients (15%) showed fusion at an unintended fusion level and, two thirds of these were from the CD-instrumentation group. This could be explained by the need to dissect partly the erector spinae muscles from the bony elements at the adjacent segments making room for insertion of supplemental pedicle screw instrumentation. Another possible factor is dissection of a wrong level, which was detected by fluoroscopy at instrumentation. It would seem desirable to mark the correct level after skin and fascia incision. The surgeon should therefore try to minimize trauma to the soft tissue at the neighboring segments, but the application technique used when placing the bone graft may also be important. The change in the motion pattern of adjacent unfused segments has been shown to be more marked when using supplementary spinal instrumentation (Ha et al. 1993). These changes may play a role in causing unintended spinal fusion. The release of osteogenic precursor cells may also be higher in the pedicle screw instrumentation group due to insertion of pedicle screw implants. It could also be a spinal manifestation of periarticular ossification (PAO),

commonly seen after arthroplasties, especially of the hip (Sodemann et al. 1988, Nilsson 1992, Persson et al. 1998, Ebinger et al. 2000). Risk factors for periarticular ossification after total hip arthroplasty include previous surgery, ankylosing spondylitis, and patients operated on for fresh fractures or other posttraumatic conditions (Ahrengart 1991). Could it be that patients with fusion at an unintended level have a higher biological capacity for bone formation? We analyzed gender, age, cigarette consumption, diagnosis, and fusion level and found no difference between patients with and or without an unintended fusion. However, the high fusion rate in the patients with an unintended fusion level indicates a good fusion capacity or a substantial amount of bone graft before surgery. When we analyzed working status and reoperation rates, the results were by no means worse in those with an unintended fusion.

The fusion at an unintended level had no influence on the functional outcome at the 5-year follow-up, as assessed by the Dallas Pain Questionnaire.

It seems that patients with an unintended fusion level had pain relief and show good functional outcome if fusion also occurs at the intended level. However, we still believe that fusion at unintended levels should be regarded as a complication, which may be prevented by careful dissection only at the right level.

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