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Plate fixation adds stability to two-level anterior fusion in the cervical spine: a randomized study using radiostereometry

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Abstract This study evaluated whether addition of a cervical spine locking plate (CSLP) in two-level disc fusions improved the postoperative stability and reduced the time to healing. Radiostereometric analysis was used to obtain precise recordings of the three-dimensional motion between the fused vertebrae. Eighteen consecutive patients were operated on with excision of two adjacent cervical discs and anterior horseshoe grafting with autologous bone (Smith Robinson technique). Nine patients were randomized to stabilization with autologous bone grafting and CSLP plate fixation and nine patients to grafting without fixation. Clinical symptoms in terms of pain in the neck and the arm were analysed preoperatively and after 1 year using a visual analogue scale (VAS). The patients operated without a plate dis-

played increased rotations around the transverse axis, corresponding to the development of a kyphosis [mean value no plate/plate 14.4°/0.8° (repeated measure ANOVA: $P < 0.01$)]. The mean compression was 3.2 mm larger in patients operated without a plate (repeated measure ANOVA: $P < 0.01$). Patients operated without a plate had more arm pain at the 1-year follow up ($P < 0.05$, Mann-Whitney U test). The VAS score for neck pain did not differ significantly between the two groups. Plate fixation could not be demonstrated to increase the healing rate, promote more rapid fusion or influence the frequency of graft complications.

Key words Anterior cervical plate · Cervical disc disease · Radiostereometry

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Introduction

Treatment of cervical spondylosis and herniated discs with anterior discectomy and interbody fusion has been reported to relieve pain and improve function [2, 23, 27, 28]. This surgical procedure seems also to be successful when two levels are fused simultaneously. However, the frequency of pseudoarthrosis and graft extrusion is higher after fusion of multiple levels than after single-level fusion [3, 8, 18, 23, 26]. Stabilization of the fusion and the graft with a plate might theoretically reduce the number of these problems. In a previous study we found that the use of the cervical spine locking plate (CSLP) in single-level

fusions gave somewhat better stability than was recorded in controls without a plate [31]. However, in cases of two-level fusions, two bone grafts are subjected to remodeling and the lever arms are longer, which probably influences the postoperative stability and therefore increases the potential advantages of a plate. In this study we evaluated, whether addition of a CSLP in two-level disc fusions improved the postoperative stability and reduced the time to healing. Radiostereometric analysis was used to obtain precise recordings of the three-dimensional motions between the fused vertebrae.

Table 1 Number of cases examined with radiostereometric analysis

Time of postoperative follow-up	Plate	No plate
1 day	9	9
2 weeks	8 ^a	7 ^b
6 weeks	8 ^c	7 ^b
3 months	8 ^d	7 ^b
6 months	8 ^c	7 ^b
12 months	8 ^c	7 ^b

^a One patient did not attend, but attended all other examinations

^b Two patients excluded due to marker loosening

^c One patient excluded due to marker loosening

^d One patient excluded due to marker loosening; in one patient only the proximal segment could be evaluated due to marker loosening in distal segment

Methods

Between January 1994 and September 1995, 18 consecutive patients (11 women, 7 men; mean age 44 years, range 25–57 years) were operated on with excision of two adjacent cervical discs and anterior horseshoe grafting using autologous bone (Smith Robinson technique). All patients had pain and neurological symptoms corresponding to MRI-verified herniated discs and/or spondylosis at two levels. The median time between onset of symptoms and operation was 36 months (range 1–180 months).

Nine patients (5 women, 4 men) were randomized to stabilization with autologous bone grafting and CSLP plate fixation, and nine patients (6 women, 3 men) to grafting without fixation. Randomization was done with closed envelopes.

The cervical spine was approached through a transverse anterior incision on the left side of the neck. The anterior longitudinal ligament was excised over the disc space, and the anterior half of the disc was removed macroscopically. The remaining posterior part of the nucleus pulposus and the herniated fragment was removed using a microscope. The posterior longitudinal ligament was only removed if a disc fragment was found to be located behind the ligament. Before grafting, three to seven tantalum markers (0.5 or 0.8 mm in diameter) were implanted after pre-drilling through the cortex. Markers were inserted into all three vertebrae included in the fusion. The graft was harvested from the left anterior iliac crest. After surgery, patients operated without a plate were treated with a Philadelphia collar for 6 weeks and those operated with plate fixation, with a soft collar for 6 weeks. The patients were examined with radiostereometry the day after surgery and after 2 weeks and 6 weeks. They were examined clinically and with radiostereometry at 3, 6, 12 and 24 months postoperatively (Table 1). This study was approved by the local ethical committee.

Radiostereometric analysis (RSA)

Radiostereometric examinations were carried out in the supine position using a uniplanar technique. Two roentgen tubes with central beams crossing at 40° at the level of the cervical spine were used to simultaneously expose a pair of radiographs. A reference Plexiglas cage supplied with tantalum markers was placed between the patient and the roentgen films. The cage markers defined the laboratory coordinate system and were used to calculate the position of the roentgen foci. At the subsequent evaluation, the three-dimensional coordinates of the patient markers were determined at each examination [13, 22].

The mathematical computations were made using a software package (UmRSA, RSA Biomedical Innovations, Umeå, Sweden)

Table 2 Mean difference, standard deviation (SD) and 99% confidence limits in 13 double examinations

	Difference (mean)	SD	99% confidence limits (mean + 2.8 SD)
Translations (mm)			
Anterior-posterior	0.15	0.10	0.43
Proximal-distal	0.09	0.09	0.34
Medial-lateral	0.23	0.22	0.85
Rotations (°)			
Transverse axis	1.33	0.95	4.0
Longitudinal axis	0.71	1.07	3.7
Sagittal axis	0.55	0.51	2.0

[15, 24] mainly based on RSA according to Selvik [22]. All movements were related to the laboratory coordinate system defined by the cage. The vertebra distal to the fusion on each of the two levels was used as fixed reference segment. The movements were calculated separately as the total movement between the most distal and the most proximal vertebra and over each fused level. In this presentation we mainly report the motions between the two vertebrae at the end of the fusions. The rotations were calculated in the order flexion-extension (rotations around the transverse axis), left-right rotation (longitudinal axis) and left-right tilt of the head (sagittal axis). In the following text, rotation between the postoperative examination and the following ones into flexion or extension is labeled kyphosis and lordosis, respectively. The relative translation of the centre of gravity of the most proximal vertebra was recorded in all but four cases, where only two markers were available in the most proximal vertebra. In these cases the mean value of these two markers were taken to represent translations, whereas rotations at the distal level not could be evaluated. Translations were measured as:

1. Medial-lateral translations (left-right)
2. Proximal-distal translations (compression)
3. Anterior-posterior translation

The accuracy of RSA is dependent on several factors. Some of the most important are the stability, spacing and number of the markers [13]. The degree of marker instability is expressed in millimetres as the mean error of rigid body fitting. In this study only values below 0.34 mm were accepted. The spacing of the markers is expressed as a configuration number, reflecting how far from a straight line the markers are distributed [13, 24]. The reproducibility of the method was calculated by repeat stereoradiographic examinations on the same day in 13 patients at different times during the follow-up period, corresponding to 13 double examinations. We calculated the 99% confidence limits for significant translations and rotations as the absolute mean value \pm 2.8 SD based on a normal distribution (Table 2).

Conventional radiographic examinations were carried out up to 1 year after the operation. Clinical symptoms in terms of pain in the neck and the arm were analysed preoperatively and after 1 year using a visual analogue scale (VAS).

Statistical methods

The statistical methods used are indicated in the text for each calculation. If not otherwise stated, the calculations are based on the combined motions over the two segments.

Table 3 Rotations and translation at 2 weeks, 6 weeks, 3 months, 6 months and 12 months: median (range)

	2 weeks		6 weeks		3 months		6 months		12 months ^a	
	Plate	No plate	Plate	No plate	Plate	No plate	Plate	No plate	Plate	No plate
Translations (mm)										
Medio-lateral (-right, +left)	0.0 (-0.3 1.0)	0.2 (-0.4 1.2)	0.1 (-0.8 0.9)	0.5 (-0.7 1.5)	0.3 (-0.7 1.4)	0.7 (-1.4 2.0)	0.1 (-0.5 1.1)	0.8 (-1.5 2.2)	-0.1 (-0.3 1.1)	0.8 (-1.6 2.2)
Proximal-distal (-distal, +proximal)	-0.3 (-0.5 0.4)	-0.7 (-1.6 -0.2)	-0.6 (-1.1 1.1)	-1.6 (-4.3 -0.8)	-0.6 (-0.8 1.7)	-3.6 (-7.3 -1.2)	-0.6 (-1.5 1.0)	-3.8 (-7.7 -1.0)	-0.7 (-1.3 1.5)	-3.0 (-7.9 -1.1)
Anterior-posterior (-posterior, +anterior)	0.3 (-1.0 1.0)	0.1 (-0.2 1.2)	0.2 (-0.9 1.3)	0.1 (-1.0 1.1)	0.0 (-2.4 0.8)	-0.3 (-4.2 1.6)	-0.2 (-2.7 1.1)	-0.3 (-4.4 2.1)	0.2 (-3.3 0.6)	-0.5 (-5.0 2.4)
Rotations (°)										
Transverse axis (-lordos, +kyphos)	-0.2 (-5.6 2.4)	2.3 (1.2 4.4)	-0.7 (-4.6 5.6)	4.2 (3.6 16.3)	0.5 (-6.1 3.4)	8.8 (4.4 31.3)	-2.0 (-3.7 4.7)	10.3 (4.6 33.1)	-0.2 (-5.1 5.5)	8.6 (5.6 34.7)
Longitudinal axis (+left rotation, -right rotation)	0.2 (-1.7 4.8)	0.7 (-0.7 2.2)	0.6 (-2.4 2.3)	0.3 (-1.5 5.1)	-0.6 (-2.0 4.3)	1.7 (-1.1 9.4)	-0.7 (-2.6 2.6)	1.6 (-0.7 8.9)	-0.8 (-1.8 2.5)	2.5 (-1.2 8.9)
Sagittal axis (-left tilt, +right tilt)	-0.9 (-1.9 1.8)	0.6 (-5.7 2.2)	-1.1 (-1.6 1.6)	-1.6 (-4.6 2.3)	-1.2 (-2.5 1.9)	-2.6 (-9.0 2.4)	0.5 (-2.0 1.1)	-3.4 (-8.2 2.5)	-1.0 (-2.3 3.0)	-2.6 (-7.8 2.5)

^a Number of patients who could be analysed at 12 months: plate/no plate, translations: 8/7; rotations: 7/4

Results

Two patients, both without a plate, had to be excluded from the RSA evaluation because of loosening of the talar markers. In a further patient the markers of the most distal vertebrae were unstable between 6 weeks and 6 months postoperatively, but stabilized after that time. In this patient the movements could be calculated only for the most proximal segment. The loosening of markers probable occurred because they were located too close to the cortex or because of a local high rate of bone remodeling.

The patients operated without a plate displayed increased rotations around the transverse axis (motions over both levels), corresponding to the development of a kyphosis (repeated measure ANOVA: $P < 0.01$). At 1 year this kyphosis reached a mean of 14.4° (range: 5.6° – 34.7°), while those with a plate had a mean *lordosis* of 0.8° (range: -5.0° – 5.5°) (Table 3, Fig. 1).

The mean compression or distal translation of the most proximal vertebrae was significantly larger in patients operated without than in those with a plate (repeated measure ANOVA: $P < 0.01$). At 1 year the mean compression in the groups with and without a plate were 0.6 mm (range: -1.3 – 1.5 mm) and 3.8 mm (range: -1.1 to 7.9 mm), respectively (Table 3, Fig. 2).

The medial-lateral and anterior-posterior translations and the rotations around the longitudinal and sagittal axes did not differ between the two groups (Table 3, repeated measure ANOVA).

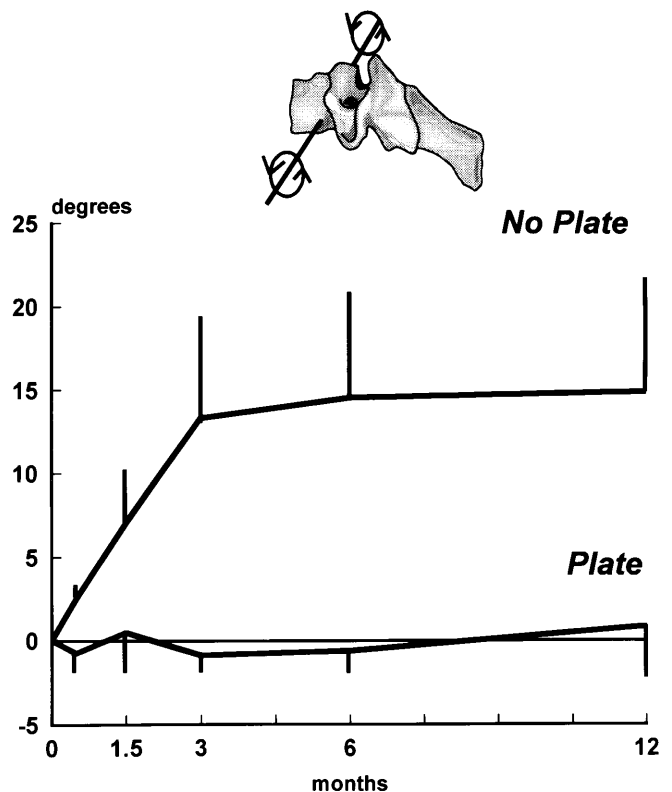


Fig. 1 Mean deformation in rotation about the transverse axis of the two most proximal vertebrae in the fusion segments. Bars represent standard error of the mean (plate vs no plate: $P < 0.01$). Positive values indicate rotation into kyphosis

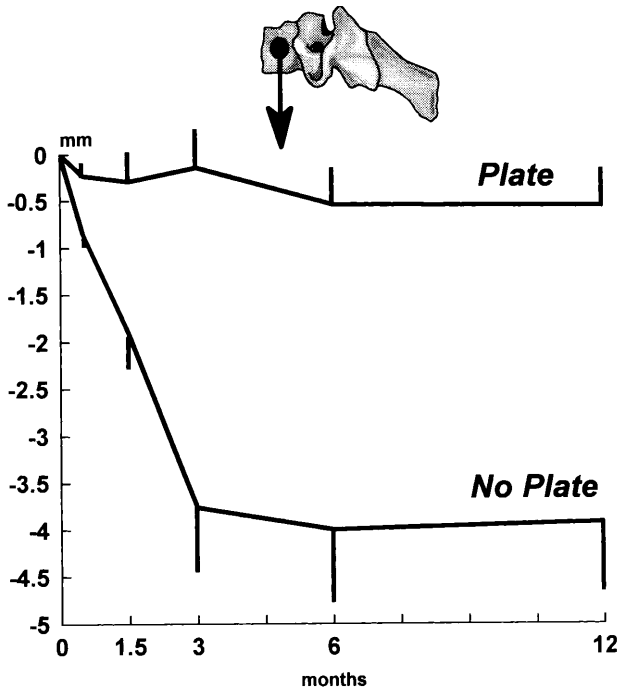


Fig. 2 Mean distal translation (negative value indicates compression) of the two most proximal vertebrae in the fusion segments. Bars represent standard error of the mean (plate vs no plate: $P < 0.01$)

The motions (translations and rotations) did not differ between the proximal and distal levels in either of the two groups (Wilcoxon signed-rank test).

Between the 6th and the 12th postoperative month, two patients, one with and one without a plate, displayed motions above the individual detection limits. In the patient with a plate, rotations around the transverse (5.1°) and longitudinal (5.0°) axes were noted at the upper level, and translations (0.4 mm) and rotations (4.9°) in relation to the longitudinal axis at the lower level. The other patient, without a plate, showed significant proximal-distal translation (0.8 mm) at the lower level. As regards the patient who could not be analysed until after 6 months, no significant motions were recorded between the 6th and 12th month.

Evaluation of conventional radiographs indicated that all the fusions had healed after 1 year. Clinically, patients

operated without a plate had significantly more arm pain at the 1-year follow up ($P < 0.05$, Mann-Whitney U test, Table 4). The VAS score for neck pain did not differ between the two groups ($P = 0.45$).

Discussion

Presently there are a few methods available for measuring in vivo movements in the cervical spine [1, 5, 9–11, 14, 16, 17, 25]. RSA is a technique with high accuracy to obtain in vivo three-dimensional measurements from radiographs [12, 21]. That is why this technique was chosen for our study. In the present RSA application we had problems in obtaining sufficient scatter of the markers in some cases, partly because the posterior part of the vertebra was not available for insertion of markers. This mainly affected the accuracy of the rotations, especially when evaluated in the individual case. However, in the two groups of patients under study, the marker configuration was found to be equal, allowing a relevant comparison to be made.

The use of plate fixation in multilevel disc surgery is generally believed to reduce the rate of graft complications and pseudoarthrosis [6, 7]. The present study did not show any differences in the healing rate of the fusion between those operated with and those without a plate. None of the patients developed pseudoarthrosis on conventional radiographs. However, two patients displayed minor, although significant, movements between the 6th and the 12th month. Robinson et al. [20] and Bohlman et al. [3] reported pseudoarthrosis in 10–20% of around 50 cases, respectively, who had been operated with anterior fusion of two levels, whereas Ripa et al. [19] noted the same complication in only 2 of 98 cases. The comparatively high rate of pseudoarthrosis in two-level discectomies combined with fusions is thought to be caused by a more extensive surgery with more damage to the vessels and the soft tissues. This could be expected to affect the incorporation of the two grafts negatively, compared with fusion of a single level. From a theoretical standpoint, the risk of pseudoarthrosis could be expected to at least double. In two-level surgery, the surgeon destabilizes two levels, resulting in a more complex biomechanical situation where the action of the lever arms over the fused segments may be difficult to predict. Hypothetically, when a

Table 4 Median (range) visual analogue scale score for arm and neck pain

	Preoperatively		3 months		6 months		12 months	
	Plate	No plate	Plate	No plate	Plate	No plate	Plate	No plate
Pain in the arm	5.1 (3.1–8.6)	5.8 (3.7–7.8)	2.4 (0–6.5)	3.2 (0.5–8.3)	2.6 (0.5–6.4)	4.1 (0.5–7.1)	1.7* (0–3.7)	4.6 (0.4–6.5)
Pain in the neck	6.3 (3.7–8.3)	6.3 (3.3–9.9)	2.1 (0–6.0)	3.3 (0.1–8.7)	3.3 (0–6.0)	2.7 (0.4–8.9)	2.4 (0–6.7)	4.6 (0.5–7.7)

* $P < 0.05$, Mann-Whitney U-test

single-level fusion results in a certain degree of kyphosis, that kyphosis will be smaller than in two fusions, if each develops the same amount of kyphosis. In a previous RSA study on single-level anterior discectomy and fusion without the use of a plate [31], we recorded a median kyphosis of 5.7° after 1 year. In the present study the kyphosis in the corresponding group reached a median value of 8.6°, and there was no significant difference in motions during healing between the upper and lower levels. Thus, the above hypothesis seems to be verified in the present study. The comparatively wide scatter of the results noted in the group of patients without a plate could have several explanations. Factors related to the patient, such as the healing capacity of the bone and especially the bone quality, are certainly important. It could be that some deformities which have reached a certain limit tend to progress to pronounced deformities, as noted in one of our patients, due to other factors such as changes of the lever arms and/or devascularization and destabilization related to the more extensive surgery. The clinical effect of a pseudoarthrosis is unclear [18, 26, 30]. Several authors found no obvious association between pseudoarthrosis and clinical failure [8, 20, 29], whereas others reported better clinical results in patients, where the fusion healed [26, 30]. Because of the high rate of success for these procedures, the analysis of unsuccessful treatments is difficult, which may explain the conflicting results reported in the literature.

Another theoretical benefit of plate fixation is prevention of graft dislodgment. The incidence of this complication in interbody fusion is reported to be 1–2% [8, 18, 23, 26]. In some studies the incidence has been reported to be higher in multilevel interbody fusions than in single-level fusions [7]. In our study there was no such event.

Breig [4] showed that cervical kyphosis dramatically increases the tensile forces within the spinal cord. This increased tension leads to a diminution in the calibre of blood vessels that supply the spinal cord, which may result in intramedullary ischaemia. Maintaining cervical lordosis decreases the tensile forces within the spinal cord and the cervical rootlets. Thus, a deformation of 15° towards kyphosis from the normal lordotic position, as observed in the group of patients without a plate in the current study, was the most probable reason for the increased symptoms of arm pain. This finding supports the use of an

anterior plate in two-level disc surgery. The decrease in postoperative deformity and pain obtained with plate fixation should justify the increased surgical time and increased costs associated with the use of a plate.

The patients operated without a plate developed an axial compression of 3.5–4 mm, compared with 1 mm in the group with a plate. It is unclear whether this increased compression had any clinical effects. Theoretically, compression is likely to be advantageous for the healing process. Thus, the patients without plate fixation should heal more rapidly and show a higher rate of fusion compared to the patients with a plate. In our study this was not demonstrated. Despite the use of a collar, the group without a plate developed kyphosis directly after surgery. After 6 weeks, when the collar was removed, the kyphosis had reached a mean value of 7°, and increased linearly up to about 13° at 3 months. Thereafter, a minor progression occurred. This finding may to some extent question the potential stabilizing effect of the collar. However, this question was not specifically addressed in our study and we can not exclude the possibility that the kyphosis would have been still greater if no collar had been used at all.

Connolly et al. [7] compared fusion with and without plate fixation and found that the overall graft complication rate, i.e. pseudoarthrosis, graft collapse and delayed union, decreased by using a plate. They found that these complications occurred predominantly at the lower level in a two-level fusion. In the present study no significant difference between the two levels in any of these different aspects was found, either clinically or with RSA.

In summary, plate fixation could not be demonstrated to increase the healing rate, promote more rapid fusion or influence the frequency of graft complications. The use of anterior plate fixation in two-level degenerative cervical spine surgery did, however, have other important effects. After 1 year the pain in the arm was reduced, probably because the development of postoperative kyphosis was almost totally prevented. Further, the amount of compression was reduced without any signs of delayed healing.

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