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A method to evaluate the in vivo behaviour of lumbar spine implants

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Abstract The aim of the study was to design a method for evaluating the stabilizing effect of different lumbar spine implants in vivo, and to apply this method to a comparison of plates versus rods in lumbar spine posterolateral fusion using transpedicular screw fixation. Fourteen patients, seven operated on with transpedicular plates and screws (VSP), and seven operated on with rods and screws (Diapason), matched according to number of levels fused, had tantalum markers inserted in the vertebrae at surgery, enabling roentgen stereophotogrammetric analysis (RSA). Mean patient age was 45 (range 33–56) years. In each group, two patients underwent fusion between L4 and L5, three between L5 and S1, and two from L4 to S1. In three patients, concomitant nerve root decompression was performed using a facet joint preserving technique. RSA was performed 4 weeks after surgery. This interval was chosen to allow enough time for soft tissue healing, but not fusion healing, to occur. RSA was performed in supine and standing position without any mobility provocation, in line with the postoperative regimen given. Movements between the outermost vertebrae of the fusion were calculated along the transverse, vertical and sagittal axes. The method of measurement along these three axes has previously been determined to be accurate to 0.3, 0.6 and 0.7 mm, respectively. One patient stabilized with rods and screws between L5 and S1 displayed a sagittal translation of 1.01 mm but no mobility along the transverse or vertical axes. In the remaining 13 patients, positional change from supine to standing did not provoke any intervertebral mobility above the RSA accuracy along any of the axes. With the limited provocation described, in line with the postoperative regimen for lumbar fusion patients, plates with transpedicular screws and rods with transpedicular screws both seem to give adequate intervertebral stability in posterolateral lumbar fusions.

Key words Lumbar spine · Posterolateral fusion · Transpedicular fixation · Stereophotogrammetry · Intervertebral translation

Introduction

There are many ways to fuse the lumbar spine, and indications vary, especially concerning degenerative disorders. The fact that indications vary and often have not been sufficiently validated must, however, not draw our interest from the technical aspects of the procedure, which ideally involves minimal trauma, has few complications and yields a high fusion rate.

The abundance of implants on the market and techniques used today further emphasize a need to evaluate and compare implant behaviour. Biomechanical in vitro testing unquestionably forms the basis for this evaluation, and there are abundant data available about the in vitro behaviour of spinal implants. However, human prerequisites and behaviour are more variable than a testing machine, hence it would seem to be of interest to explore the performance of a spinal device once it has been implanted in the patient.

The aim of our study was to develop a method, using roentgen stereophotogrammetric analysis (RSA) [16], by which the inherent stabilizing effects of different spinal implants and different surgical techniques can be compared in vivo. We chose to set the time of mobility determination at 4 weeks after surgery, on the rationale that soft tissue healing would have occurred but no bony healing, i.e. the immobilization of the vertebrae fused is dependent mainly on the implant. In the present study this method was applied as a comparison between instrumentation with either plates or rods fixed with transpedicular screws in posterolateral lumbar fusion.

Materials and methods

Patients

Fourteen patients with a mean age of 45 (range 33–56) years were included (Table 1). All patients had longstanding intractable lumbar pain, resistant to nonsurgical treatment. Seven patients were operated on with transpedicular plates and screws of the VSP system by Steffee [17] (Fig. 1). Seven patients were operated on with rods and screws using the Diapason [12] technique (Fig. 2). The patients in the two groups were matched according to number of levels fused. In each group, two posterolateral fusions were performed with bilateral transpedicular screws in L4, L5 and S1, three with screws in L5 and S1 and two with screws in L4 and L5. The patients were instructed to keep the trunk straight for 4 months postoperatively, and were given a soft lumbosacral orthosis with dorsal rigid reinforcement, mainly as a regimen reminder.

Surgery

Through a central skin and muscle incision, the posterolateral surface of the planned fusion segments was exposed. In three cases concomitant nerve root decompression was performed with facet joint preserving technique.

The transpedicular screws were placed centrally in the pedicles with the aid of an image intensifier. The dimensions of the screws in the lumbar vertebrae were 6.25 and 7 mm in the sacrum for the plates, and 6.7 and 8 mm respectively for the rods. After insertion of the plates or rods, the previously decorticated posterolateral surfaces were covered with cancellous bone grafts [8] harvested through the same incision from the dorsal part of the iliac crest.

To enable RSA follow-up the outermost vertebrae included in the fusion had 0.8-mm tantalum markers inserted at standardized locations [9]: in the sacrum, in the spinous processes and in the transverse processes or the pedicles of the lumbar vertebrae (Fig. 3). In the cases with central decompression, the tantalum markers were implanted in the remaining parts of the vertebral lamina.

Roentgen stereophotogrammetric analysis

Evaluation of the stability of implant fixation was performed by means of roentgen stereophotogrammetric analysis (RSA) [16]. RSA was performed 4 weeks after surgery. This time interval was chosen with a view to achieving soft tissue healing and reduced pain, but not bony fusion healing [9], enabling the evaluation of the inherent stability of the implant.

RSA was performed in supine and standing positions without orthosis. No load or movement provocation was included, in line with the postoperative instructions, in order not to jeopardize the surgical result.

The radiographic set-up (Fig. 4.) enabled simultaneous exposure of two X-ray films by two X-ray tubes angled 40 degrees to each other. A reference and calibration box made of Plexiglas, with 0.8-mm tantalum markers at known positions, was placed between the patient and the film. With this set-up, calibration and patient measurement could be achieved at the same exposure.

The two-dimensional film positions of the markers in the patient and the calibration box were digitized into a computer programme that allowed conversion to three-dimensional positions [16]. The change between the three-dimensional positions of the markers in each vertebra, induced by positional change from

Table 1 Description of patients operated on with either plates or rods

Case no.	Gender	Age at surgery	Diagnosis	Screw levels	Concomitant decompression
Plates					
P1	Male	44	Pain postdecompression	L4+L5+S1	No
P2	Male	37	Pain postdecompression	L4+L5+S1	No
P3	Female	33	Degenerative disc disease	L5+S1	No
P4	Male	37	Degenerative disc disease	L5+S1	No
P5	Female	44	Degenerative disc disease	L5+S1	No
P6	Male	46	Degenerative disc disease	L4+L5	No
P7	Male	43	Spondylolysis	L4+L5	Yes
Rods					
R1	Male	53	Degenerative disc disease	L4+L5+S1	Yes
R2	Male	50	Pain postdecompression	L4+L5+S1	No
R3	Male	53	Pain postdecompression	L5+S1	No
R4	Male	44	Degenerative disc disease	L5+S1	No
R5	Female	51	Degenerative disc disease	L5+S1	No
R6	Male	57	Pain postdecompression	L4+L5	No
R7	Female	56	Degenerative disc disease	L4+L5	Yes

Fig. 1 A, B The VSP (plates and screws) instrument

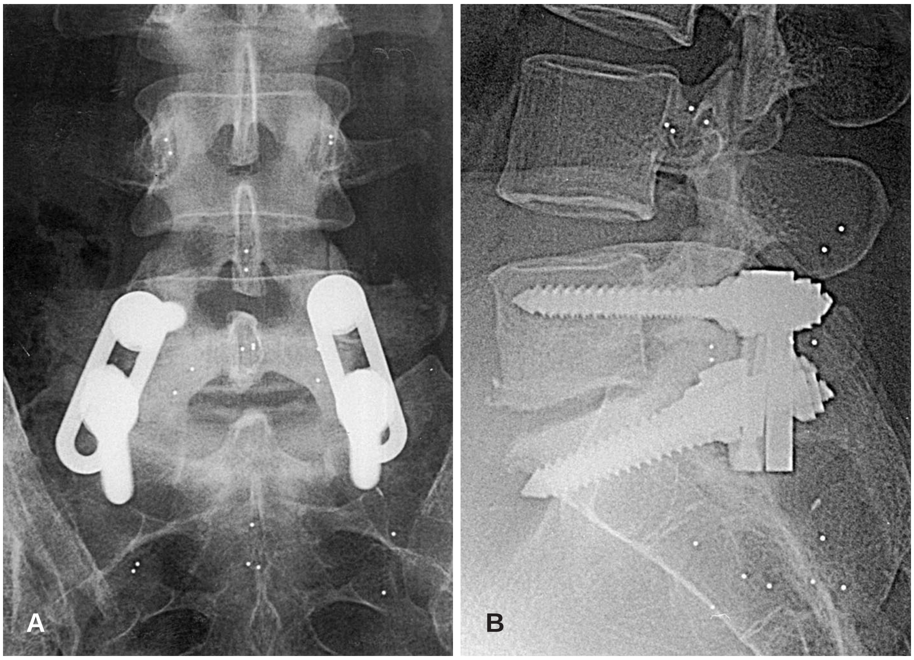
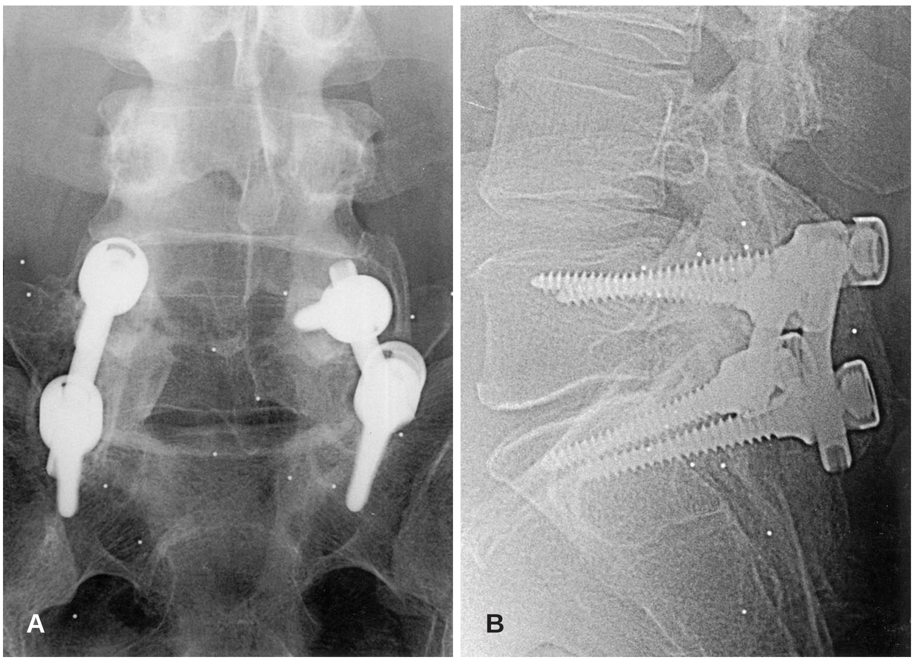


Fig. 2 A, B The Diapason (rods and screws) instrument



supine to standing, represented the translatory movements in three planes of one vertebra relative to another.

This method has previously been determined accurate to 0.3, 0.6 and 0.7 mm, along the transverse, vertical and sagittal axes respectively [9]. Intervertebral translations induced by positional change from supine to standing were not considered significant unless exceeding these values.

Results

One patient (R4) stabilized with rods and screws between L5 and S1 displayed a sagittal translation of 1.01 mm, but no mobility along the transverse or vertical axes (Table 2). In the remaining 13 patients, positional change from supine to standing did not provoke any intervertebral mobility above the RSA accuracy along any of the axes. No difference in screw placement was noted on radiographs that

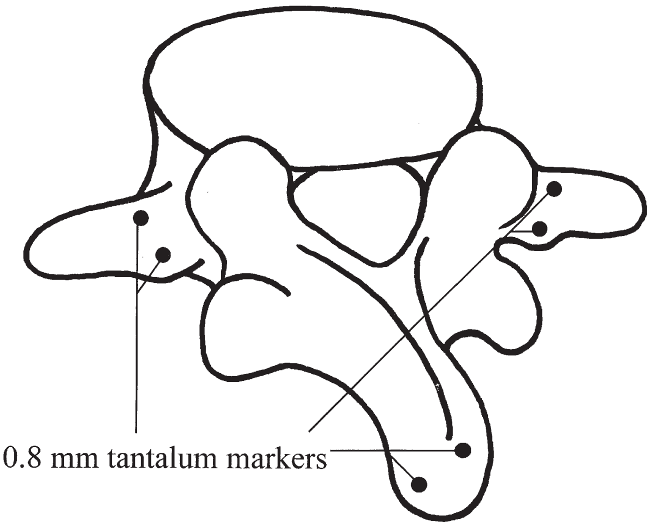


Fig. 3 The placement of the tantalum markers

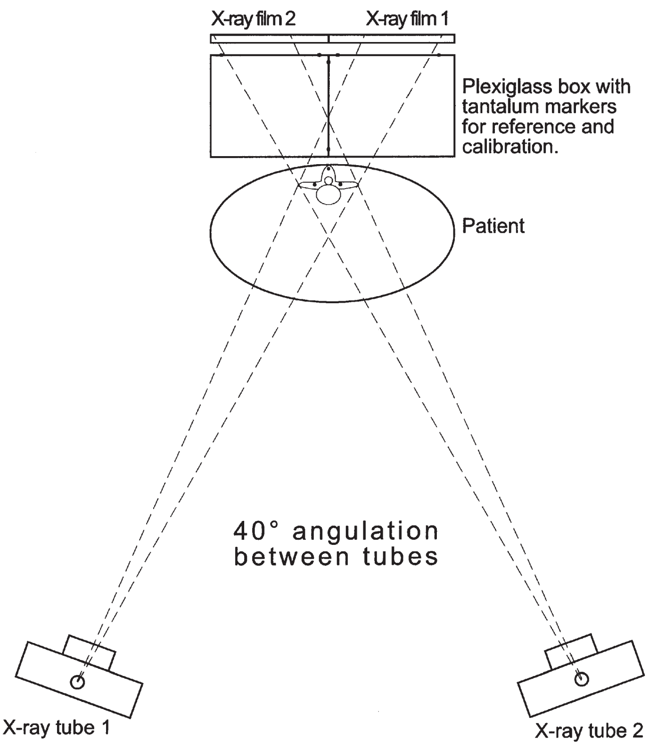


Fig. 4 The roentgen stereophotogrammetric analysis (RSA) radiographic set-up

could explain the difference between case R4 and the other cases.

Discussion

Transpedicular screw fixation systems are becoming increasingly popular in conjunction with lumbar spine fusion to obtain immediate fusion stability. Biomechanical testing of spinal implants has been very abundant [7], but the in vivo behaviour of internal fixation systems is not as well known, and has previously mainly been evaluated by radiography or surgical exposure of the fusion. Radiographic comparison of the in vivo efficacy of different spinal implants and fusion methods has a significant level of false-positive and false-negative findings [3, 4]. Surgical exploration of the fusion is, on the other hand, often impractical and traumatic to the patient, and it does not yield any longitudinal information on the actual stabilizing effect of the implant. Therefore an investigational method that is as accurate and objective as possible is desirable.

One of the most important characteristics of a spinal implant is the degree of immobilization provided of the fixed segment after instrumentation. As an objective method to determine the in vivo stability of the fixed segments, RSA can be used. RSA has been proven to be a highly accurate method of determining the mobility between vertebrae [9]. The main drawbacks of the method are that it is expensive and time consuming, from surgery to the final analysis, which makes it unsuitable for studies of large patient series.

The purpose of this study was to demonstrate a method to determine the ability of different implants and fusion techniques to stabilize the spine. This is why we only present the 4 weeks postoperative RSA measurements. RSA at a later date can be, and has been, used to determine fusion rate [11]. Increased information about the ability of an instrument to stabilize the spine could be achieved by preoperative RSA; however, this is impractical unless you operate in two stages or perform preoperative external fixation.

Table 2 Intervertebral translations in millimetres

Case no.	Transverse axis	Vertical axis	Sagittal axis
Plates			
P1	0.04	0.12	0.52
P2	0.05	0.13	0.36
P3	0.09	0.1	0
P4	0.23	0.05	0.14
P5	0.12	0.08	0.04
P6	0.1	0.02	0.22
P7	0.04	0.04	0.12
Rods			
R1	0.22	0.16	0.56
R2	0.09	0.1	0.15
R3	0.17	0.17	0.4
R4	0.13	0.17	**1.01**
R5	0.02	0.31	0.51
R6	0.21	0.45	0.31
R7	0.07	0.46	0.3
Accuracy in each plane	0.3	0.6	0.7

Previous RSA studies have shown that the intervertebral mobility before and after uninstrumented posterolateral fusion can amount to several millimetres [2, 10], and the healing speed is rather slow, sometimes exceeding 6 months [9]. Uninstrumented posterolateral fusion has a variable healing rate, but is a valid alternative for treating isthmic spondylolisthesis [1, 6, 15].

Whether transpedicular screw fixation in lumbar spine fusions increases the healing speed, rate and outcome is a matter of debate: positive [13, 20] as well as negative [5, 14, 18] reports exist in the literature. An increased complication rate and increased operating costs are, however, well known and may call into question their routine use [19, 21]. This study shows that two different transpedicular fixation systems can yield a very stable situation in the early postoperative period following instrumented fusion in degenerative conditions. It does not give information about longer-term strength or stability that may be influenced by material fatigue, screw loosening and/or fusion healing. Therefore, we plan to follow these patients with repeat RSA at 6 months and 12 months postoperatively, to see whether differences in stability between the systems occur over time as the bony fusion proceeds. At these follow-ups it will even be possible to perform RSA in flexion provocation. This is, however, not the purpose of the present study.

The study design described may be useful in future studies for comparing different implant and fusion types in varying clinical situations. The results of the present study on the stabilizing effect of transpedicular screw fixation cannot be applied to situations such as extensively destabilized degenerative disorders [11], or fractures and tumours, which remain to be studied.

Conclusion

The current study demonstrates that transpedicular screw fixation with either plates or rods can yield adequate stabilisation for one- and two-segment posterolateral fusions in degenerative disorders. The study also confirms that RSA can be used to compare the stabilising effect of different spinal implants and fusion types.

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