The significance of radiolucent zones surrounding pedicle screws

DEFINITION OF SCREW LOOSENING IN SPINAL INSTRUMENTATION

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We examined the radiographs from a prospective clinical study of fixation by pedicle screws and those from an experimental study in a sheep model. In the clinical study, instruments were removed from 21 patients after implantation for 11 to 16 months and the extraction torques of the screws were recorded. A structured protocol was used for the radiological examinations. In the experimental study, loaded pedicle screw instrumentations were implanted in the sheep for six or 12 weeks. After radiological examination the pull-out resistance and the histological characteristics were studied.

In the clinical study, all screws with radiolucent zones had a significantly reduced mean extraction torque compared with screws without radiolucent zones (16 ± 10 Ncm v 403 ± 220 Ncm; $p < 0.0001$). In the experimental study the mean maximum pull-out resistance for the screws with radiolucent zones was significantly lower than for those with no radiolucency (243 ± 156 N v 2214 ± 578 N; $p = 0.0006$) and the mean bone-to-screw contact was reduced for screws with zones compared with those without zones ($8 \pm 9\%$ v $55 \pm 29\%$; $p = 0.0002$).

Our findings showed that all screws with radiolucent zones had low extraction torques or low pull-out resistance. A radiolucent zone is a good indicator of loosening of a pedicle screw.

Pedicle screws are often used for fixation in spinal surgery. The Cochrane review¹ of surgery of the lumbar spine stated that there was strong evidence that instrumented fusion produced a higher rate of fusion, although there was other evidence that it may be associated with higher rates of complications. Pedicle screws often become loose causing loss of fixation. In the clinical situation, the evaluation of the screw-bone interface is made by radiological examination. Many studies have focused on the rate of complications of fixation by pedicle screws and there are several reports on the frequency of loosening of screws.²⁻⁷ There is a considerable variation in the reported frequency of loosening, probably because of the varying designs of studies and different definitions of loosening.

In an experimental study, Schatzker, Horne and Sumner-Smith⁸ examined the radiological and histological effects of movement on bone screws. Movement was found to result in the production of fibrous tissue surrounding the screws, which resulted in a radiologically discernible radiolucent 'halo' around the screw. This is a definite sign of loosening of the screw.⁸ To the best of our knowledge, the

mechanical consequences of radiolucent zones have not previously been described, nor has the frequency of loose screws without any radiological signs of loosening been defined.

Our aim therefore was to define the relation between radiolucent zones and the purchase of the screws, expressed either as the extraction torque or the pull-out resistance. As a second goal, we attempted to evaluate the correlation between the radiological appearance and the histological characteristics of the screw-bone interface.

Patients and methods

Our study was divided into two parts, clinical and experimental. In the first we used the radiological examinations from a prospective clinical study of fixation by pedicle screws, and in the second those from an experimental study in a sheep model.

Clinical study. The study had ethical approval. Between October 1997 and June 1999, 23 consecutive, elective patients with degenerative disorders of the spine were assigned to the study. There were 14 women and nine men with a mean age of 56 ± 12 years. All the instrumentations were four-screw construc-

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tions bridging one or two levels between L3 and S1. The indications for surgery were spinal stenosis in ten patients, spondylolisthesis in nine and chronic disabling low back pain in four. The Posterior Fixator System (Nordopedic, Gothenburg, Sweden) and stainless-steel (SAF 2507) pedicle screws with a diameter of 6 mm and a length of 55 to 75 mm were used. In 13 patients, the screws were coated with plasma-sprayed hydroxyapatite (CAM Implants BV, Leiden, The Netherlands). The holes for the pedicle screws were prepared in a standard manner. After 11 to 16 months, the instruments were extracted in 21 of the 23 patients. The maximum extraction torques of the pedicle screws were recorded using torque gauge with a range of 5 to 600 Ncm (Eduard Wille GmbH & Co, Wuppertal, Germany). Because of technical problems, no recordings of the extraction torque could be taken in five screws in four patients. The same surgeon (BS) made all recordings for the remaining 79 screws. The healing of the fusion was evaluated during surgery by attempting to move the fixed segments manually and in doubtful cases also by exploration of the fusion masses. In two patients, the fusions were not healed; the remaining 19 were judged to have healed.

Conventional lateral and anteroposterior (AP) radiographs were taken before and at three and six months after surgery and before extraction of the instruments. Apart from the pre-operative radiographs, all examinations also included two lateral views with cranial and caudal angulations and two AP oblique views according to a study protocol, in order to evaluate the position of the screws and radiolucent zones around the screws. The radiographs were evaluated by a radiologist (MP-M) without knowledge of the extraction torque. A wide radiolucent zone surrounding the screws was defined as >1 mm, disregarding the length of the lucency. A thin radiolucent zone was defined as a width of ≤ 1 mm. The mean thickness of the hydroxyapatite coating used was 45 μ m. The coating was not visible on the radiographs and did not affect the evaluation of radiolucencies. This also applied to the hydroxyapatite-coated screws in the experimental study.

Experimental study. This study also had ethical approval. We used nine adult female sheep of similar age and weight. All the surgical procedures were performed under general anaesthesia using prophylactic antibiotics. Destabilisation of the spine was performed by laminectomies and excision of the facet joints between the second and third and the fourth and fifth lumbar vertebrae. The cortical bone was penetrated by an awl, the pedicle holes were prepared with a probe and tapped with a 4 mm tap along the entire length of the screw. Transpedicular screws with a length of 40 mm and a diameter of 4 mm were applied bilaterally from the second to the fifth lumbar vertebrae. Two instrumentations with four pedicle screws (Posterior Fixator Mini System; Nordopedic) in each were mounted, with one instrumentation bridging the L2-L3 and one the L4-L5 level. Half of the screws used were coated with plasma-sprayed hydroxyapatite (CAM Implants BV). The subcutaneous tissues and

the skin were closed in separate layers. The same two surgeons performed all the surgical procedures.

Three animals were killed at six weeks and four at 12 weeks. Two animals had to be killed as a result of complications, one after one week because of neurological disturbance and the other after two weeks due to a severe deep infection. They were excluded from the study.

The soft tissues were removed from the fresh specimens and after the radiological examination the connecting rods were removed. The specimens were divided with an oscillating saw through the discs and facet joints. In a randomised fashion, four screws from each animal were used for pull-out testing and four for histomorphometrical analysis.

For the pull-out testing, a servohydraulic material testing machine was used (Mini Bionix 858; MTS Corporation, Minneapolis, Minnesota). The specimens were placed in the testing machine vertically aligned along the axis of the screw. The free end of the screw was attached by a hydraulic grip to the testing machine. A purpose-built fixture which ensured stable fixation of the vertebrae was attached to the load cell. Axial pull-out was applied at a rate of 0.5 mm/s while load and displacement were recorded at a sampling rate of 50 Hz (Teststar II data acquisition with software Testware SX version 3.1; MTS Corporation). Based on the data collected the maximum pull-out load (N) was calculated for each screw.

For the histomorphometrical evaluation, the implants with surrounding bone were immersed in 4% neutral-buffered formaldehyde followed by dehydration in a graded series of ethanol and diluted resins and finally embedded in pure resin (Technovit VLC 7200, Kulzer, Germany). The polymerised samples were cut in the long axis of the screws using the Exakt equipment (Exakt Apparatebau, Norderstedt, Germany). The specimens were then ground to a final thickness of approximately 10 μ m and surface stained with Toluidine Blue.⁹

The analysis was carried out using a Leitz Aristoplan (Wetzlar, Germany) light microscope equipped with a Leitz Microvid unit connected to a PC and a mouse which allowed the observer to perform histomorphometrical measurements directly in the eye-piece of the microscope. An objective of 10 x, i.e. a magnification of 100 x, and a zoom of up to 2.5 x were used for the quantitative histomorphometry. The aim was to study all 12 complete screw threads to establish the percentage of bone-impact contact and the relative amount of bone in an area defined as the area between the screw and a line connecting the top of the threads, and the area reflecting a mirror image of that area (thread and mirror area). Parts of some of the specimens were missing after the preparation and therefore calculations could not be made for bone-implant contact in 22 and for the amount of bone in the thread and mirror area in 27 of the 336 threads.

The radiological examination was performed after removal of all soft tissues from the lumbar spines immedi-

Table I. Details of the results of the clinical study. The definition of a loose screw was an extraction torque of 40 Ncm or less

Screws	No zone	Zone	p value	Patients	No zones	zones	p value
Not loose	51	0	<0.0001	No loose screw	12	0	<0.0001
Loose	10	18		Loose screws	1	8

Fig. 1

Lateral radiograph from the experimental study. Radiolucent zones are seen around the screws at L2-L3 (upper instrumentation), while no zones can be seen at L4-L5.

ately after the animals had been killed. All of the screws were assessed radiographically using two lateral and two AP views with both cranial and caudal angulations. The radiographs were evaluated by a radiologist (MP-M) without knowledge of the mechanical or the histological findings with respect to the position of the screws and radiolucent zones. If a radiolucent zone was noted the maximal width of the zone was recorded irrespective of the length of the lucency.

Statistical analysis. All values are given as the mean $\pm$ 1 SD. For the statistical evaluation the Mann-Whitney U-test and Fisher's exact test were used. P values of <0.05 were considered to be statistically significant.

Results

Clinical study. All the screws were judged to be correctly placed in the pedicles and in the vertebral bodies. No failures of hardware such as fracture of the screws or rods, angulations or disconnections could be detected. On the radiographs taken the day before extraction of the instruments, thin radiolucent zones surrounded ten screws and wide zones surrounded eight of the 84 screws. No zones were seen around the five screws in which no reading of the extraction torque could be taken. The mean extraction torque for the screws with radiolucent zones was 15 ± 10 Ncm, while that for the screws without zones was 403 ± 220 Ncm ($p < 0.0001$). The difference in means was 388 Ncm (95% confidence interval (CI) 283 to 490). Since there were no recorded extraction torques between 40 and 75 Ncm, the screws could be divided into two groups, those with an extraction torque ≤ 40 Ncm (18/18 screws with radiolucent zones and 10/61 screws without zones), and those with an extraction torque ≥ 75 Ncm (51/61 screws without zones) as shown in Table I. There was no difference in the extraction torque between the screws with wide radiolucent zones and those with thin zones (14 and 15 Ncm, respectively, $p = 0.61$). In the two patients in whom the fusions had not healed, three of the eight screws had radiolucent zones.

In the eight patients in whom stainless-steel pedicle screws without coating had been used radiolucent zones were noted in seven and around 17 of 32 screws. These were most easily detected on the AP oblique views and were seen in these views in all cases of loosening. On the lateral views, including several cranial and caudal angulations, the zones were detected in less than half of the cases.

Experimental study

Mechanical evaluation. No misplaced screws were detected. Radiolucent zones of 2 to 3 mm in width were seen surrounding five of 28 screws. The mean maximum pull-out resistance for the screws with radiolucent zones was 243 ± 156 N, while that for the screws without zones was 2214 ± 578 N ($p < 0.001$). The difference in means was 1971 N (95% CI 1428 to 2514). None of the screws with radiolucent zones had a pull-out resistance exceeding 505 N while that for the screws without zones was 1175 N or more (Fig. 1).

Histomorphometrical evaluation. Radiological examination revealed radiolucent zones of width 1 to 4 mm surrounding nine of 28 screws. The mean bone-implant contact was $8 \pm 9\%$ (0 to 21) for the screws with radiolucent zones and $55 \pm 29\%$ (4 to 94) for those without zones ($p < 0.0005$). The

Fig. 2a

Fig. 2b

Light micrographs showing a) one of the screws without radiolucent zones in the experimental study and b) a screw with radiolucent zones from the experimental study (from L3 in Figure 1). (Toluidine Blue, $\times 3$)

difference in means was 47% (95% CI 26 to 68). The mean amount of bone in the thread and mirror area was $16 \pm 21\%$ (0 to 53) for the screws with radiolucent zones and $65 \pm 13\%$ (18 to 79) for those without zones ($p < 0.0001$). The difference in means was 49% (95% CI 35 to 62) (Fig. 2).

Discussion

The most striking finding of our study was the high frequency of radiolucent zones surrounding the pedicle screws in the clinical study and the strong correlation between radiolucent zones and clinical loosening of the screws. Of the uncoated stainless-steel screws, 53% showed radiolucent zones and all of the screws with zones had a low extraction torque, meaning that they were all loose and could be removed without the use of a screwdriver. The overall frequency of radiolucent zones in the clinical part of our study was 21%, because of the very low rate (2%) of zones surrounding the hydroxyapatite-coated screws.

There have been many reports of complications of fixation by pedicle screws including the frequency of loosening of screws. McAfee et al⁶ reported a study of 526 pedicle screws of which 3% were broken but none was loose. In an analysis by Esses et al² of 617 patients treated by members of the American Back Society, the rate of loosening was 0.81% and of breakage 2.9%. This study included an extensive review of the literature with a frequency of loosening varying from 0.6% to 11%. In a retrospective study by Yuan et al⁷ of 2153 patients treated for degenerative spondylolisthesis loosening was observed in 2.8% and breakage in 2.6%. These studies with low rates of loosening and breakage of the screws do not comment on the radiological methods or the criteria for evaluating loosening. In three studies with thorough descriptions of the radiological examinations the rate of loosening was 21%, 18% and 27%, respectively.³⁻⁵ The incidence of breakage was 6%, 21% and 16%, respectively. In most of the studies stainless-steel screws had been used which were of different designs and from different manufacturers. It seems unlikely

that the differing results could be explained by differences in materials and designs of screw. We believe that the disparities could be explained by the differences in design of study and definitions of loosening and the wide variation in the length of follow-up. We also believe that the high frequency of detected radiolucencies in our study is explained by the use of multiple radiographic views.

In the clinical part of our study, the probability that the radiological examination would detect a loose screw with the radiographic views used was 64%. Thus, the sensitivity of the examination was 64%, while the specificity was 100%. The sensitivity of the examination when applied clinically (the probability of detecting at least one loose screw in a patient with one or several loose screws) was 89%, and the specificity 100%.

Different methods were used for evaluating the purchase of the screws in the clinical and the experimental parts of our study. Loosening of pedicle screws has been described as being caused mainly by cyclic caudocephalad toggling at the bone-screw interface.¹⁰⁻¹² Both removal torque¹³ and pull-out resistance¹⁴ have been used to evaluate the purchase of pedicle screws after implantation in vivo. The screws in the two different systems used in our study were connected to the rods in such a way that rotation of the screws was prevented. The pull-out strength could be considered to reflect the mode of failure and was recorded in the experimental part of the study. In the clinical situation pull-out could not be used and instead removal-torque was recorded. The radiolucent zones were strongly associated with low extraction torques and low pull-out resistances. Several clinical studies have indicated that instrumentation by pedicle screws increases the healing rate of spinal fusion^{7,15,16} and the Cochrane review of lumbar surgery stated that there was strong evidence that instrumented fusion produced a higher rate of fusion.¹ This improved fusion rate depends on the stability of the instrumentation, and the anchorage of the screws is an important factor for stability. The association between radiolucent zones and an inferior anchorage of the screws means that radiolucent

zones surrounding pedicle screws are highly relevant in the clinical situation.

The AP oblique views, giving a slightly oblique axial view of the screws, seem to be the best for the detection of loosening of pedicle screws in the clinical situation. The reason for this may be the increase in the difference in density between intact bone and zones with this projection, resulting in geometrical 'compression' of zones along the x-ray beam.

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