Hydroxyapatite coating improves fixation of pedicle screws

A CLINICAL STUDY

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We investigated the effects of hydroxyapatite (HA) coating on the purchase of pedicle screws. A total of 23 consecutive patients undergoing lumbar fusion was randomly assigned to one of three treatment groups. The first received uncoated stainless-steel screws, the second screws which were partly coated with HA, and the third screws which were fully coated. The insertion torque was recorded. After 11 to 16 months, 21 screws had been extracted. The extraction torque was recorded. Radiographs were taken to assess fusion and to detect loosening of the screws.

At removal, the extraction torques exceeded the upper limit of the torque wrench (600 Ncm) for many HA-coated screws. The calculated mean extraction torque was 29 ± 36 Ncm for the uncoated group, 447 ± 114 Ncm for the partly-coated group and 574 ± 52 Ncm for the fully-coated group. There were significant differences between all three groups ($p < 0.001$). There were more radiolucent zones surrounding the uncoated screws than the HA-coated screws ($p < 0.001$). HA coating of pedicle screws resulted in improved fixation with reduced risk of loosening of the screws.

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The aim of internal fixation of the spine is to correct deformity and to stabilise the spine until fusion has occurred.¹ The advantages of pedicle instrumentation include the ability to control all three columns of the spine from a posterior approach and a possible reduction in the number of segments which need to be fused.² To achieve this a firm

anchorage is required, and one of the complications of instrumentation is loss of fixation, especially in osteopenic vertebrae.² Several studies have indicated that loosening of the screws is common with spinal instrumentation using pedicle screws.^{3,4}

Different methods of improving the purchase of these screws have been investigated including modifications of the design of the thread, the shape and their surface.⁵⁻¹⁰ Application of plasma-sprayed hydroxyapatite (HA) to the screws has been studied since coating of other implants has shown good short-term results.¹¹ The coating of external fixation pins with plasma-sprayed HA has been found to be useful in experimental¹² and clinical^{13,14} studies, with improvement of the bone-implant interface and mechanical fixation and reduced rates of infection. In order to reduce loosening of the implant HA-coated pedicle screws were studied in an animal model with instrumentation of a destabilised lumbar spine. When compared with coated screws, 12 weeks after implantation, HA coating was associated with a significantly increased pull-out resistance and a higher bone-implant contact.^{15,16} Coating of stainless-steel pedicle screws with HA has been used in a clinical study, with a significantly increased torque of the screws on removal.¹⁷ Extraction data were available from four patients only, however, and the design of the pilot study with two HA-coated and two uncoated screws at each instrumentation did not address the question as to whether HA coating improves the purchase of all screws. There were also difficulties in extracting the HA-coated screws.¹⁷ This may increase the incidence of complications if the implants need to be removed. We have therefore investigated whether HA coating of a part of the thread would give an improved purchase of the screw without making it difficult to remove later.

We prospectively studied the mechanical and radiological characteristics of two different extents of HA coating of pedicle screws when compared with uncoated stainless-steel screws.

Patients and Methods

Between October 1997 and June 1999, 23 (14 women and 9 men) consecutive patients who were to undergo instrumented one- or two-level lumbar or lumbosacral fusion for

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degenerative disorders agreed to participate in the study (Table I) which was approved by the medical Ethical Committee of Uppsala University. The indications for surgery were spinal stenosis in ten patients, spondylolisthesis in nine and chronic disabling low back pain in four. The mean age of the patients was 56 ± 12 years. There were 14 two-level fusions and nine at one level; four screws were used in each operation. The vertebrae involved were L3 (12 screws), L4 (24 screws), L5 (30 screws) and S1 (26 screws), and the Posterior Fixator System (Nordopedic, Gothenburg, Sweden) was used.

By opening an envelope immediately before surgery, the patients were randomly assigned to receive one of three types of screw; uncoated screws (wrought stainless steel SAF 2507; eight patients), those in which the distal 50% of the threads was coated with plasma-sprayed HA (partly coated group; nine patients) and those in which the entire implanted portion of the screw was coated (fully-coated group; six patients). The plasma-sprayed coating was applied by CAM Implants B.V., Leiden, The Netherlands (Fig. 1). The thickness of the coating was as determined by the manufacturer, approximately $45 \mu\text{m}$, and the crystallinity was 55%. The material composition of the screws and coating has been previously analysed.¹⁷ The diameter of the screws was 6 mm and the length between 55 and 77 mm.

Partial or total laminectomy was undertaken in all patients except two, and both of these were in the partly-coated group.

The mean ages were 58, 55 and 53 years, respectively, for the three groups. Two patients in the uncoated screw group, two in the partly and one in the fully HA-coated group were smokers (>2 cigarettes/day). All implants were to be extracted one year later.

Insertion of pedicle screws. Standard anatomical landmarks were used for the identification of the pedicles, and fluoroscopy to confirm the position of the screws. A pedicle probe was used and the holes were tapped to the same diameter as the screw and to the entire depth of insertion. In 21 patients, the surgery was done by the same surgeon, and in these the insertion torque was recorded using a torque gauge manometer with a range of 5 to 600 Ncm (Eduard Wille GmbH & Co, Wuppertal, Germany). The recordings were made as soon as the entire threaded portion of the screw had been introduced.

Radiological assessment. Anteroposterior (AP) and lateral radiographs were taken before, after, at three and six months after surgery and before extraction. All postoperative radiological 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, to assess fusion and to record radiolucent zones around the screws. The radiographs were examined by a radiologist without knowledge of the type of screw used or the intraoperative evaluation of healing. The HA coating is not visible on the radiographs. Fusion was assessed on those taken between 11 and 16

Table I. Details of the 23 patients treated by lumbar fusion

	Gender	Age (yrs)	Diagnosis	Cranial level	Caudal level
Uncoated screws	F	74	Stenosis	L3	L5
	M	54	Olisthesis	L5	S1
	F	50	Stenosis	L4	L5
	F	66	Stenosis	L3	L5
	M	65	Olisthesis	L4	S1
	F	67	Stenosis	L3	L5
	F	48	Olisthesis	L5	S1
	F	40	Olisthesis	L4	S1
Partly HA-coated screws	M*	54	Low back pain	L4	S1
	F	51	Olisthesis	L4	S1
	M	44	Stenosis	L5	S1
	F	57	Stenosis	L4	L5
	M	37	Olisthesis	L5	S1
	F	69	Stenosis	L3	L4
	M*	75	Stenosis	L3	L5
	M	56	Olisthesis	L4	S1
Fully HA-coated screws	F	57	Low back pain	L4	S1
	F	44	Olisthesis	L5	S1
	F	81	Stenosis	L3	L5
	M	46	Low back pain	L4	S1
	M	60	Low back pain	L4	L5
	F	59	Stenosis	L4	L5
	F	31	Olisthesis	L5	S1

* lost to follow-up

Fig. 1

Photograph showing the 6×70 mm pedicle screws: (upper) uncoated; (middle) partly HA-coated; and (bottom) fully HA-coated.

months after operation, and was defined as continuous bony bridging at all instrumented levels on at least one side. Nonunion was defined as absence of bony bridging on at least one level bilaterally, and doubtful union as the absence of signs of nonunion when fusion could not be clearly visualised. A wide radiolucent zone surrounding the screws was defined as a lucency of more than 1 mm (Fig. 2). A thin radiolucent zone was defined as a lucency of 1 mm or less.

Extraction of pedicle screws. After a mean of 12.4 months (11 to 16), the instruments were removed in 21 patients. One patient did not undergo extraction because of other disease, and one was lost to follow-up. The two patients who did not have instruments extracted did not have meas-

Fig. 2

AP radiograph of instrumentation with uncoated pedicle screws 12 months after implantation showing wide radiolucent zones in L3 and thin zones in L5.

urements of torque at insertion and thus data from both insertion and extraction were available for 19 patients. For technical reasons, no measurements of the torque at the time of extraction could be taken for four screws in three patients in the partly-coated group and for one in the fully-coated group. The extraction torque was recorded with the same torque gauge manometer as the insertion torque. The maximum extraction torque was recorded. During surgery, fusion was evaluated by manipulating the fused area. In doubtful cases the fusion mass was explored. All extraction procedures and recordings of extraction torque were carried out by the same surgeon (BS).

Statistical analysis. For the statistical evaluation the Kruskal-Wallis, the Mann-Whitney U and the chi-squared tests for three independent samples were used. P values of less than

0.05 were considered to be statistically significant. The values given are the mean values $\pm$ one standard deviation.

Results

The mean insertion torque was 76 ± 41 Ncm for uncoated, 56 ± 22 Ncm for partly-coated and 122 ± 74 Ncm for fully-coated screws. The insertion torque for fully-coated screws was significantly higher than that for the uncoated and the partly-coated screws, respectively. There was no significant difference between the uncoated and the partly-coated screws. The insertion torques for the L3-S1 vertebrae were analysed separately, and there were no significant differences between the levels. The recordings of extraction torque are shown in Figure 3. The upper range of the torque wrench was 600 Ncm. The extraction torque exceeded this figure in three of 24 screws in the partly-coated group and in 18 of 23 screws in the fully-coated group but in none of the 32 in the uncoated group. These values were related to 600 Ncm for the statistical analysis. This resulted in the calculations of the mean extraction torque for the partly-coated and the fully-coated groups in particular being lower than the true values. The values of mean extraction torque were 29 ± 36 Ncm for the uncoated group, 447 ± 114 Ncm for the partly-coated and 574 ± 52 Ncm for the fully-coated group. There were significant differences between all three groups ($p < 0.001$). The purchase of the screw, expressed as the recorded maximum torque, increased from insertion to extraction for 21 of 22 screws in the partly-coated and all of 19 screws in the fully-coated group. The maximum torque decreased from insertion to extraction for 31 of the 32 screws in the uncoated group, while the torque was unchanged for one screw. There was no difference in extraction torque when analysed by age or by level. Some of the fully-coated screws were difficult to extract while there was no difficulty with the extraction of uncoated and partly-coated screws. There were no infections during follow-up or at removal of the implant.

Fig. 3

The maximum extraction torque for the three types of screw. Each symbol indicates one screw. The upper limit of the torque gauge manometer is 600 Ncm.

Radiologically, all screws were judged to be correctly placed in the pedicles and the vertebral bodies. There were no failures of the hardware such as fracture of a screw or rod, angulations or disconnections. Wide radiolucent zones surrounded eight and thin radiolucent zones nine of the 32 uncoated screws and one of 28 partly-coated screws. No radiolucent zones were seen in the fully-coated group. There was a significant difference in the presence of zones between the uncoated group and the partly- and fully-coated groups ($p < 0.001$), while there was no significant difference between the partly-coated and the fully-coated groups. All wide radiolucent zones were surrounded by a thin sclerotic margin. Several, but not all, of the thin radiolucent zones had a sclerotic margin. The fusions were deemed to have healed radiologically in 14 of the 21 patients evaluated, while five were considered to be ununited and two as doubtfully united. Of the fusions which were radiologically ununited two were confirmed as nonunions during surgery, while the other three were judged to have healed. The two doubtful unions and all 15 radiological unions were also assessed as healed during surgery. Both nonunions were in the uncoated group, and had zones surrounding one of four and two of four screws, respectively.

Discussion

Several clinical¹⁸⁻²⁰ and experimental studies²¹ have indicated that instrumentation with pedicle screws increases the rate of healing of a spinal fusion. Under many circumstances, such as in fractures and tumours of the spine, the stability of the instrumentation is of considerable importance in determining outcome, and in these circumstances an improvement in the purchase of the screws implies a reduced risk of complications.

The use of HA coating of pedicle screws has been described by Lapresle and Missenard¹⁰ but they did not comment on the purchase of the screws or on the incidence of radiolucent zones. The use of HA coating in our study resulted in a marked increase in the strength of the anchorage and a significant decrease in the incidence of radiolucent zones when compared with uncoated screws. Partly-coated screws had extraction torques which were significantly lower than those for fully-coated screws. All but one partly-coated screw had an extraction torque of at least 350 Ncm, i.e., a firm purchase. For certain situations such as in palliative surgery for tumours of the spine, fully-coated screws could be useful. For most patients, however, the additional improvement of anchorage with the fully-coated screws is not necessary, and may lead to difficulty with their extraction.¹⁷ The type of coating used is an important factor. Different commercially available HA coatings may give different tissue reactions,^{22,23} and the results of different extents of coating in this study may not be applicable to other HA coatings.

The use of screw fixation may carry particular problems

in the sacrum,²⁴ but in our study all but one HA-coated sacral screw were firmly anchored when removed between 11 and 16 months after insertion. Also, all but one HA-coated screw increased their maximum torque from insertion to extraction, including the sacral screws. Thus, HA coating was effective for improving the purchase of screws in the sacral and lumbar vertebrae.

The influence of increasing age on the effects of HA-coated implants has been examined in experimental studies. In a study in sheep, the results of coating on bone formation around the implants were comparable in young and old individuals.²⁵ In rats, the effects of coating decreased with age.²⁶ In another study from the same centre it was demonstrated that HA-coated titanium implants were superior to uncoated titanium implants in old rats, indicating that HA-coated implants may be useful for the osseous response in bone of poor quality.²⁷ In our study, we found no difference in the purchase of coated screws between older and younger patients, with very good purchase in the oldest patients.

Surface roughness differs between coated and uncoated screws. A fourfold increase in the roughness of plasma-sprayed HA-coated implants when compared with machined titanium implants has been described,²⁸ and the surface roughness of stainless steel is lower than that of machined titanium. There was an approximately fivefold increase in torques for the coated screws between insertion and extraction, while the purchase of the uncoated screws decreased. Thus, it seems unlikely that the differences in extraction torque were due to variation in surface roughness. The plasma-sprayed HA coating gives an increased diameter of the coated screws of approximately 2% when compared with the uncoated. Considering the increase in purchase with the passage of time for the coated screws, compared with the decrease for the uncoated screws, we think that it is unlikely that 'oversizing' caused the differences in extraction torque. The increase in anchorage with the passage of time for the coated screws is probably due to a biological effect, with a better bone apposition when compared with uncoated screws. In an animal model,¹⁶ HA coating of loaded pedicle screws resulted in better bone apposition after implantation for six and 12 weeks and the coating of the screws was applied by the same manufacturer who applied the coating in our study.

Nevertheless, the differences in insertion torque between the fully-coated screws and the other types of screw are probably related to the differences in surface roughness and the relative 'oversizing' of the HA-coated screws. It is thus surprising that the insertion torque for the partly-coated screws was not higher than that for the uncoated screws. We believe that this could be related to the distribution of the coating and the method of recording the insertion torque. Most of the insertion torque is probably generated in the pedicle where the screw is surrounded by more cortical bone. The coating of the partly-coated screws covered the 50% of the threads closest to the tip of the

screw. When the reading of insertion torque was taken, the HA-coated part of the screw had already passed the pedicle, and was in the cancellous bone of the vertebral body. The fully HA-coated screw still had its coated portion in the pedicle when the measurement was made, which may have caused the higher insertion torque.

In our study, HA coating of pedicle screws resulted in improved fixation of the screws with a reduced risk of loosening. Coating of a part of the screw is sufficient for most applications, while the further increase in purchase with fully-coated screws may be useful for certain indications, such as surgery for tumours or in patients with osteoporosis.

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