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Improved extraction torque of hydroxyapatite-coated pedicle screws

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Abstract Loosening of the screws is a problem in instrumentation with pedicle screws. Coating with hydroxyapatite improves the holding characteristics for metal implants, but the possible effects on the anchorage of pedicle screws have not been described. In this study, seven patients were operated on with spinal instrumentation using four stainless steel pedicle screws. Hydroxyapatite-coated screws were used in either the upper or the lower of the instrumented levels. The insertion torque was measured. In four cases the screws were removed after 10–22 months and the extraction torque was measured. The mean insertion torque was found to be significantly greater in the hydroxyapatite-coated screws (107 Ncm) than in the standard screws (76 Ncm). In three cases, the extraction torque for the hydroxyapatite-coated screws exceeded the range for the torque wrench (600 Ncm), while the con-

ventional screws were loose (< 5 Ncm). In one case, the extraction torque was 475 and 550 Ncm for the coated screws, and 5 and 25 Ncm for the conventional screws. The difference in extraction torque was significant. Hydroxyapatite coating was shown to have improved the purchase of pedicle screws very effectively. By using fully coated screws, as in the present study, extraction was extremely difficult compared to extraction of conventional stainless steel screws, which were regularly loose. By reducing the area of the screws that is coated, it may be possible to achieve an enhanced purchase while extraction will be easier when compared to fully coated screws.

Key words Hydroxyapatite · Pedicle screw · Fixation · Extraction torque

Introduction

Loosening of screws is a frequent problem in spinal instrumentation with pedicle screws [10, 11]. It is often only noted as a radiolucency surrounding the pedicular screws, but in many cases loosening of the screws causes an unstable situation and loss of correction.

Hydroxyapatite (HA) has been used in different preparations in numerous animal studies in order to improve implant fixation, but the implants have mainly been un-

loaded. In a clinical study on hemicallositis for osteoarthritis of the knee, coating of external fixation screws with plasma-sprayed HA gave a significantly better purchase for the screws, and prevented loosening of the screws in all cases but one [9]. In an experimental study on sheep, HA coating of loaded external fixation pins led to significantly lower radiographic pin tract rarefaction, better bone-implant contact based on histologic examination and greater force needed to remove the implants [1]. Coating of pedicular screws with plasma-sprayed HA has been used clinically [7], but the effects on radiolucent

zones or the anchorage of the screws has not been described.

The purpose of this study was to report our initial experience with HA-coated pedicle screws when compared to standard stainless steel screws.

Materials and methods

In a pilot study, seven patients were operated on with two-level fusions instrumented using four pedicle screws. The use of the screws was approved by the regional ethical committee at Uppsala University. The Posterior Fixator System (Nordopedic, Uppsala, Sweden) was used for the instrumentations. In each patient, two standard screws (wrought stainless steel SAF 2507), and two screws of the same type coated with plasma-sprayed HA (CAM Implants B.V., Leiden, Netherlands) were used (Fig. 1). According to the manufacturer, the cristallinity of the HA was 55%. One new HA-coated implant was analysed for material composition in a JEOL JSM 5800 scanning electron microscope equipped with a Link ISIS energy dispersive X-ray system (SP Swedish National

Fig. 1 Hydroxyapatite- (HA-) coated screw (*left*) and standard screw (*right*)

Testing and Research Institute, Borås, Sweden). The uncoated implant part that was semi-quantitatively analysed demonstrated a composition of 63% Fe, 26% Cr, 7% Ni and 4% Mo. The semi-quantitative analysis of the coating revealed 43 weight% oxygen, 39% calcium, 17% phosphorus and about 0.5% magnesium.

The diameter of the screws was 5 or 6 mm, and the length was 55–70 mm. The coated screws were used in either the upper or the lower of the instrumented levels in a randomised fashion.

In four patients, the screws were removed after 10, 14, 15 and 22 months, respectively. The indication for removal was remaining back pain in three cases, and in one case the instrument was removed to make possible a planned magnetic resonance imaging (MRI) scan. The remaining three patients had minimal remaining back pain, and there was not any indication for removal. The four patients who had their screws removed are described below.

The indications for operation were postdiscectomy syndrome in two cases, and spinal stenosis and fracture of T12 in one case each. Three of the four patients were female. Their mean age was 33 years (Table 1). The operations were performed by three different surgeons. Standard anatomical landmarks were used for identification of the pedicles, and fluoroscopy was used for confirmation of the positions of the screws. A pedicle probe was used for the preparation, and the holes were tapped with a tap of the same size as the screw. Postoperative radiographic examinations were performed, and all screws were judged to be correctly placed. The fusions were healed by the time of extraction of the screws in all patients.

The insertion and extraction torque was recorded using the same torque gauge manometer in all cases, which had a range of 5–600 Ncm (Eduard Wille GmbH & Co, Wuppertal, Germany).

Two screws that had been removed with bone still attached made it possible to analyse the bone-implant interface histologically. The specimens for the histologic evaluation were immersed in 4% neutral buffered formaldehyde followed by dehydration in graded series of ethanol, diluted resins and finally embedding in pure resin (Technovit VLC 7200, Kulzer, Germany). The polymerised samples were then cut along the long axis of the screws, using Exakt equipment (Exakt Apparatebau, Norderstedt, Germany), and 100 µm-thick ground sections were microradiographed qualitatively. The specimens were then further ground to approximately 10 µm and routinely stained with toluidine blue and Levaï Lazko [3, 6].

The histological analysis was carried out using a Leitz Aristoplan light microscope equipped with a Leitz Microvid unit connected to a PC and a mouse, enabling the observer to make measurements directly in the eye-piece of the microscope.

For the statistical analysis, the Mann-Whitney U-test and Fisher's exact test were used. Torque is given as average $\pm$ standard deviation. $P < 0.05$ was considered significant.

Table 1 Hydroxyapatite (HA) coating of pedicular screws: details of four patients instrumented with standard stainless steel and HA screws, showing screw insertion and extraction torque values

Pat. no.	Gender	Age	Indication	HA screws		Std screws		Implantation time (months)	Insertion torque HA (Ncm)	Insertion torque std (Ncm)	Extraction torque HA (Ncm)	Extraction torque std (Ncm)
				Level	Diameter (mm)	Level	Diameter (mm)					
1	F	17	Fracture T12	T11	5	L2	6	15	90/110	50/50	475/550	5/25
2	F	37	Postdiscectomy syndrome	L4	6	L6	6	14	110/160	60/70	e	b
3	M	45	Spinal stenosis	L4	6	S1	6	10	50/70	70/70	e	b
4	F	35	Postdiscectomy syndrome	L4	6	S1	6	22	145/150	80/145	e	b

[e exceeding range of torque wrench (> 600 Ncm), b below the range of torque wrench (< 5 Ncm)]

Results

The mean insertion torque was 107 ± 37 Ncm for the HA-coated screws and 76 ± 29 Ncm for the standard screws ($P < 0.05$).

In three patients, the maximum torque for the HA-coated screws exceeded the upper range (600 Ncm) for the torque manometer, while the standard screws were completely loose, i.e. the screws rotated when the torque gauge manometer was applied. No reading could therefore be taken, as the torque necessary for extraction of the standard screws was below the lower limit for the torque wrench (< 5 Ncm). The HA-coated screws in those three patients could not be removed with the conventional screwdriver, but in two of them, it was possible to remove the screws, with great difficulty, using an AO universal chuck with T-handle. In one patient the screws had to be removed together with a thin zone of the surrounding bone by using a cannulated drill, as the chuck was not strong enough. In one patient, the extraction torque for the HA-coated screws was within the range of the torque wrench, at 475 and 550 Ncm, respectively, while the corresponding torque for the standard screws was 5 and 25 Ncm. The two HA-coated screws that could be removed with the torque wrench had a diameter of 5 mm, while the screws that could not be removed with the torque wrench were all 6 mm in diameter. No complications were noted after the removal of the screws.

As the maximum extraction torque in 6/8 of the HA screws exceeded the upper limit for the torque wrench, it was not possible to establish the exact value for the extraction torque necessary for those screws. However, even if those screws are attributed with 600 Ncm as the extraction torque, i.e. a gross underestimation of the real value, the difference in extraction torque between the groups was significant ($P < 0.01$).

The histologic examination of the two screws extracted with surrounding bone demonstrated an irregular HA coating intermingled with bone-stained acellular tissue, reaching out at some distance from the coating layer. When observed with the aid of a polarizing filter, the acellular tissue did not polarize. There was a clear demarcation between this tissue and the normally polarizing bone structure (Fig. 2).

The implants were surrounded by a more lamellar bone tissue in the outer portions, whereas in the vicinity of the implants the tissue was more woven.

The thickness of the HA coatings was measured using the microscope for 78 different areas in each screw. In the two screws that were extracted (screws A, B), the coating was $15 \mu\text{m}$ thick on average. Two additional screws with the same batch number were examined: one unused screw (C) and one screw that was screwed out immediately after the insertion (D). The thicknesses of the coatings were 40 and $36 \mu\text{m}$, respectively.

The distribution of the HA coating in screws A and B was uneven, so that the coating was thinner or absent in

Fig. 2 A 6-mm pedicle screw (A), extracted 14 months after implantation, demonstrating an irregular HA coating (B) intermingled with bone-stained acellular tissue (D), and in the outer parts surrounded by lamellar bone tissue (C). The HA coating is thinner or absent in the part of the thread that is directed away from the tip of the screw (*right part of picture*). The white line represents a distance of $200 \mu\text{m}$

the parts of the threads that were directed away from the tip of the screws. A similar distribution was found in the unused screw and in screw D.

Discussion

Improvement of the purchase of HA-coated implants from implantation to extraction was first described in 1996 by Caja and Moroni in an experimental study of external fixation in sheep [1]. Similar results were also described in a clinical study by Magyar et al. [9]. In their study, no adverse effects of using HA-coated screws were found.

Our pilot study, however, demonstrates an obvious problem with HA coating when used for a different application: coating of pedicle screws. As far as we know, these problems with HA coating have not been described previously.

As the thickness of the HA coating of the screws was on average $40 \mu\text{m}$, the holes for the coated screws were “undersized” by approximately $80 \mu\text{m}$. This is equal to approximately 1–2% of the screw diameter. In a previous experimental study on dogs, the initial pull-out strength of pedicle screws was significantly decreased by “oversizing” the holes by 20%. After 6 weeks there was no significant difference [12]. We do not believe that our findings, 10–22 months after implantation, could be explained by the slightly greater diameter of the coated screws. The surface roughness of plasma-sprayed HA-coated implants is generally three to four times greater than the roughness of machined metal implants [13]. The insertion torque for the HA-coated screws exceeded the insertion torque for the standard screws by 41%, and this is probably related

to the surface roughness. The extraction torque was markedly increased in the HA-coated screws, while it was markedly decreased in the standard screws, so that the average extraction torque was at least 25 times greater in the HA-coated screws. Therefore, we do not believe that the difference on extraction could be related to surface topography.

The extreme purchase of the pedicle screws may be related to the type of bone bed in the human pedicle. Earlier studies have indicated different bone reactions to HA-coated implants in different kinds of bone beds [5]. The threaded portion of the screws used in this study is placed in cancellous bone in the vertebral body and the anterior part of the pedicle. On the histological examination of our case, however, the screws were surrounded by lamellar bone (Fig. 2).

The patients in our study were quite young, and this may be a factor of importance, though in an experimental study on sheep, age was not a dominant factor in the development or failure of implant osseointegration [4].

The properties of the HA coating could also be an important factor, as different commercially available HA coatings may give different tissue reactions [2]. In a previous experimental study, the only one of the compared coats that showed significantly more bone-to-implant contact than commercially pure titanium were the two that originated from the company that made the coating of our screws [5].

When compared to an unused screw and a screw that was screwed out immediately after insertion, the HA coating was markedly thinner in the screws that had been implanted in the pedicles for 14 months, with a reduction to less than half the original thickness. The remaining HA

coating was thinner, or even absent, on the parts of the threads that were directed away from the tip of the screws. In earlier studies, the distribution of the remaining HA coating has also been uneven, and different reasons have been suggested, such as problems in the plasma-spray coating process, the possibility that the coat may be sheared off during the insertion, or differences in resorption due to higher vascularity in cancellous bone than in cortical bone [8]. In our study, the coating was not affected by the insertion. Our conclusion is that the plasma-spraying process resulted in a somewhat uneven coating, and that more than half of the coating was resorbed during the implantation period.

We believe that HA coating of screws will become a very efficient method for enhancement of pedicle screw fixation. In this pilot study, HA coating of pedicle screws has been very effective in improving the purchase of the screws – in fact so effective that removal of the screws has been a problem. The presently studied design, with the whole threaded portion of the screw being HA coated, should be used cautiously. Still it could probably be very useful in patients with osteoporosis or in spinal surgery for metastases and other tumours. On the basis of the findings in the present study, it would seem interesting to explore the possible use of pedicle screws with less extensive coating, in order to obtain an adequate enhancement of the purchase in the vertebra, while still not making extraction too difficult if it becomes necessary.

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