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Hydroxyapatite coating enhances fixation of loaded pedicle screws: a mechanical in vivo study in sheep

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Abstract Loosening of the pedicle screws with subsequent non-union or loss of correction is a frequent problem in spinal instrumentation. In a clinical pilot study, coating of pedicle screws with plasma-sprayed hydroxyapatite (HA) resulted in a significant increase of removal torque. An experimental study was performed to investigate the effects of HA coating on the pull-out resistance. Thirteen sheep were operated on with destabilising laminectomies at two levels, L2-L3 and L4-L5. Two instrumentations with four pedicle screws in each were used for stabilisation. Uncoated screws (stainless steel) or the same type of screws coated with plasma-sprayed HA were used in either the upper or the lower instrumentation in a randomised fashion. Four sheep were examined immediately after the application of the screws, three sheep at 6 weeks and four sheep at 12 weeks. Two sheep were euthanised early due to complications. The pull-out resistance was recorded in two HA-coated and two standard screws in each animal. The maximum

pull-out resistance was higher for the HA-coated screws at 0 weeks ($P < 0.02$) and at 12 weeks ($P < 0.01$) when compared to the uncoated screws, while there was no significant difference between the groups at 6 weeks. We believe that the higher pull-out resistance for HA-coated screws at 0 weeks was mainly caused by differences in surface roughness, while the difference at 12 weeks was due to a favourable bone reaction around the HA-coated screws. At 12 weeks, the average stiffness was significantly higher for the HA-coated screws, while there was no significant differences in stiffness between the two screw types at 0 and 6 weeks. Energy to failure was significantly higher for coated screws when compared to the uncoated screws at all three time points. HA coating improves fixation of loaded pedicle screws, with increased pull-out resistance and reduced risk of loosening.

Keywords Hydroxyapatite · Pedicle screws · Fixation · Pull-out

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Introduction

Several clinical studies have indicated that instrumentation with pedicle screws will increase the fusion rate when compared to uninstrumented techniques [35, 36]. In an experimental study in sheep, instrumentation with transpedicular screws increased the healing rate and enhanced

the bone healing process of posterolateral fusions when compared to fusions with autologous bone without instrumentation [10].

Screw loosening and subsequent instability is a significant problem in spinal instrumentation [22, 24], as it may cause loss of correction or non-union. The problem is most obvious in cases with slow bone healing, as the instrument will be subjected to loading for a long period of

time. In order to improve the holding characteristics for pedicle screws different concepts have been tried, including alterations in thread design and screw shape as well as surface modifications of the screws to enhance bone apposition [7, 13, 14, 15, 27]. Hydroxyapatite coating (HA) is one such surface modification that has been suggested as a method to improve the bone-implant interface and perhaps also increase the strength of the surrounding bone. Loading might alter the fixation strength gained by HA coating, as the material is osteoconductive and has the capacity to replace fibrous membrane with bone around loaded implants [28]. Plasma-sprayed HA coatings have been shown to be effective for enhancement of the holding strength of external fixation pins when used for stabilisation of tibial fractures [19].

Evaluation of mechanical holding strength for pedicle screws in bone is usually done either as a torsional test or as a pull-out test. As pedicle screw systems usually include a connecting rod between the screws in the different vertebrae, the screws are locked with respect to rotation. It therefore seems that pull-out overload is a clinically more relevant failure mode when compared to torsion. The outer thread diameter of the screw and the shear strength of the bone surrounding the screw, especially at the outer end of the thread, are the most important factors for pull-out resistance [12]. The outer thread diameter of the screw is limited by the size of the pedicle. The bone mineral density is an important factor for the shear strength of the bone and the pull-out resistance [4].

If HA coating could increase the amount and density of bone surrounding the screw, and the bone apposition, it might also enhance pull-out resistance. The effects of HA coating on pull-out resistance of unloaded pedicle screws have been examined in an experimental study in dogs, where plasma-sprayed HA coating did not improve pull-out resistance after 6 weeks [29]. The effects of HA coating on pull-out strength of loaded pedicle screws have not previously been described. As, in a previous clinical study, the present authors measured a significant enhancement of extraction torque when using HA-coated [25] pedicle screws, we considered it important to examine the effects on pull-out resistance when using the same type of HA coating. The sheep spine has been described as a valid biomechanical model for the human spine, and also as an alternative when evaluating spinal implants [32]. Due to these biomechanical similarities between ovine and human spines, a sheep model was chosen for the study.

The aim of this study was to compare the holding strength for stainless steel pedicle screws with or without HA coating when used in loaded spinal instrumentations in sheep.

Materials and methods

Thirteen adult female sheep, 2 1/2 years old and of similar weight (59–63 kg), were used in this study. Nine sheep were operated on,

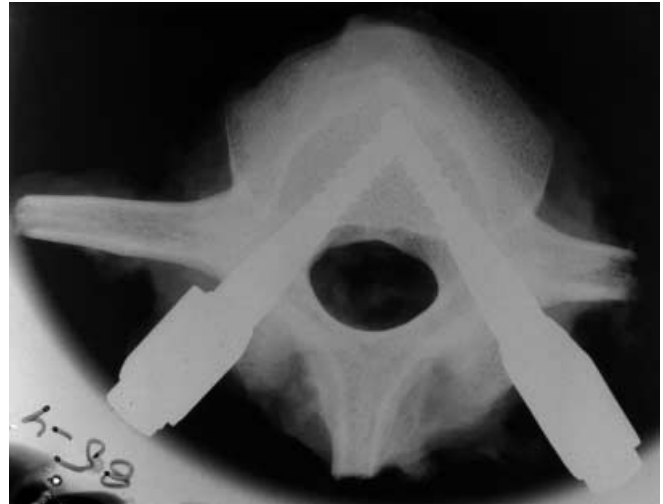


Fig. 1 Radiograph demonstrating an axial view of pedicle screws in L4

while four additional sheep, killed for other reasons, served as 0-week controls. The study was approved by the Uppsala regional ethical committee for animal experiments.

Anaesthesia was induced with thiopental sodium and maintained with nitrous oxide and 2% isoflurane under assisted ventilation. During surgery, prophylactic benzylpenicillinprocaine was administered intravenously. The posterior elements and transverse processes were exposed through a midline incision. Destabilisation was performed with laminectomies and excision of the facet joints between the second and third and the fourth and fifth lumbar vertebrae. All the posterior elements were removed, leaving only the intervertebral discs connecting the segments. The cortical bone was penetrated with an awl, and the pedicle holes prepared with a probe and then tapped with a 4-mm tap, corresponding to the entire length of the screw. Transpedicular screws were applied bilaterally from the second to the fifth lumbar vertebrae. Two instrumentations with four pedicle screws in each (Posterior Fixator Mini System, Nordpedic, Uppsala, Sweden) were used for the instrumentations. In a randomised fashion, standard screws (wrought stainless steel SAF 2507, 4×40 mm) or the same type of screws coated with plasma-sprayed HA (CAM Implants B.V., Leiden, Netherlands) were used in either the upper (L2-L3) or the lower (L4-L5) instrumentation (Fig. 1). In all, each animal had four HA coated and four uncoated standard screws, and thus served as its own control. According to the manufacturer, the coating thickness was approximately 45 µm, the crystallinity 55% and the density >95%. No attempt was made to achieve fusion between the vertebrae; instead, all bone fragments from the destabilisation were carefully removed in order not to get a fusion of any segment. The positions of the screws were documented with lateral and antero-posterior radiographs. The subcutaneous tissue and the skin were closed in separate layers. The same two surgeons performed all surgical procedures. Pedicle screws were applied in an identical manner in the four fresh spines from sheep of the same type and size, to serve as 0-week controls.

Two animals were euthanised early due to deep wound infection in one and postoperative neurological disturbance in the other. The remaining seven animals completed the study period. Three animals were sacrificed at 6 weeks and four animals at 12 weeks. The spines were removed en bloc, and the testing was performed directly on the fresh spines. Two screws of each type from each animal were used for the mechanical testing. The soft tissues were removed from the fresh specimens and, as the connecting rods

were removed, it was noted if any screw was apparently loose. The specimens were divided with an oscillating saw through the levels of the discs and facet joints, leaving the vertebra with the pedicle screw in situ for pull-out testing.

A servo-hydraulic material testing machine was used for the tests (Mini Bionix 858, MTS Corp, Minneapolis, Minn., USA). The specimens were placed in the testing machine vertically aligned along the screw axis. The free end of the screw was attached by a hydraulic grip to the testing machine. A purpose-built fixture that 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 Corp, Minneapolis, Minn., USA). Based on the data collected the maximum pull-out load (N), stiffness (N/mm), and energy (Nmm) to failure was calculated for each screw. Two stiffness values were determined: "stiffness A" was defined as the tangent of the slope for the early linear portion of the load-displacement curve, while "stiffness B" was defined as the quotient between maximum load and the displacement produced by that load. The area under the load-displacement curve to the maximum load defined energy to failure.

For the statistical evaluation, the Wilcoxon signed-rank and Fisher's exact tests were used. *P*-values less than 0.05 were considered statistically significant.

Results

For the seven animals that completed the study, there were no macroscopic signs of infection or other complications during the time from surgery until sacrifice. In all, when the four sheep that served as 0-week controls were included, 44 screws (22 HA coated and 22 uncoated) were available for mechanical testing.

Five of the 28 screws that had been implanted for 6 or 12 weeks were considered to be loose when the rods were removed. All of these were standard screws, with a maximum pull-out resistance of less than 505 N. None of the HA-coated screws was judged as loose, and the maximum pull-out resistances all exceeded 1440 N. Thus, 5/14 standard screws were loose, compared to 0/14 of the HA-coated screws (Fisher's exact test, $P < 0.05$).

A typical load-displacement curve for an HA-coated screw in the 12-week group is shown in Fig. 2. The screw was firmly attached, with good bone apposition and a maximum pull-out load of 2320 N.

The maximum pull-out resistance was significantly higher for the HA-coated screws at 0 weeks ($P < 0.02$) and at 12 weeks ($P < 0.01$) when compared to the uncoated screws, while there was no significant difference between groups at 6 weeks (Fig. 3). The increase in pull-out resistance during the first 6 weeks was significant for both the HA-coated ($P < 0.0003$) and the uncoated ($P < 0.02$) screw types. At 12 weeks, the maximum pull-out load for the coated screws was significantly higher when compared to the baseline values at 0 weeks ($P < 0.0001$), while the average pull-out load for the uncoated screws at 12 weeks was not significantly higher than the maximum load at 0 weeks. From 6 to 12 weeks the maximum pull-out load for the coated screws increased, while the corresponding

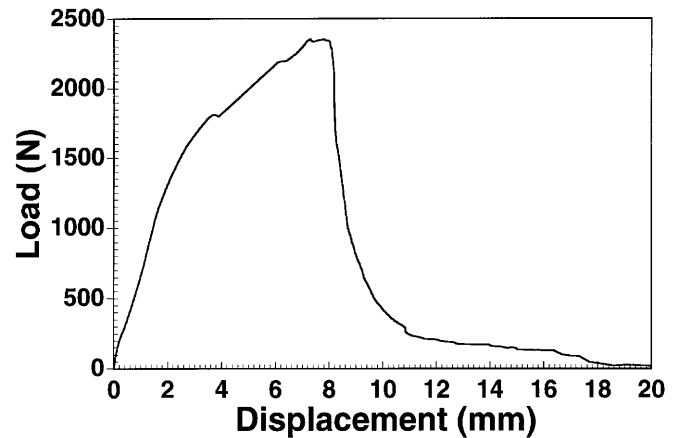


Fig. 2 Load-displacement curve for a hydroxyapatite- (HA-) coated pedicle screw obtained during pull-out test 12 weeks after spinal instrumentation in sheep

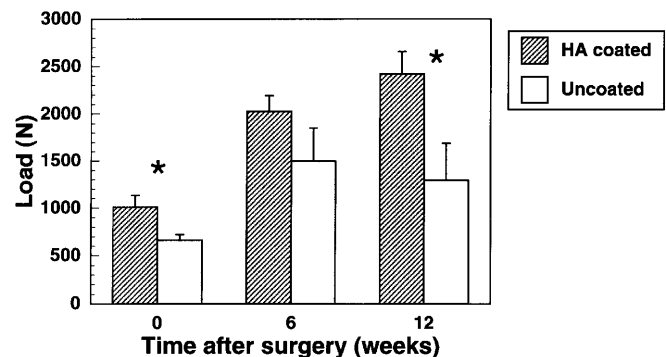


Fig. 3 Maximum pull-out load (average \pm SEM) for HA-coated and uncoated stainless steel pedicle screws at different time points following insertion in sheep vertebrae (* indicates a statistically significant difference)

difference for the uncoated screws was a slight decrease, although neither change was significant.

At 12 weeks, "stiffness A" was significantly higher for the HA-coated screws when compared to the uncoated screws, while there was no significant difference between the two screw types at 0 and 6 weeks. For the HA-coated screws "stiffness A" did not change significantly during the first 6 weeks, while at 12 weeks it was significantly higher when compared with the same type of screw at both 0 and 6 weeks. For the uncoated screws there was no significant difference in "stiffness A" between the three time points studied (Fig. 4A). When stiffness was defined as the quotient between maximum load and the displacement at that load, "stiffness B", there was no significant difference between the treatment groups at any time point. For HA-coated screws "stiffness B" was significantly higher at 12 weeks when compared to 0 and 6 weeks, while for uncoated screws there was no significant difference at any of the time points (Fig. 4B).

Energy to failure was significantly higher for coated screws when compared to the uncoated screws at all three

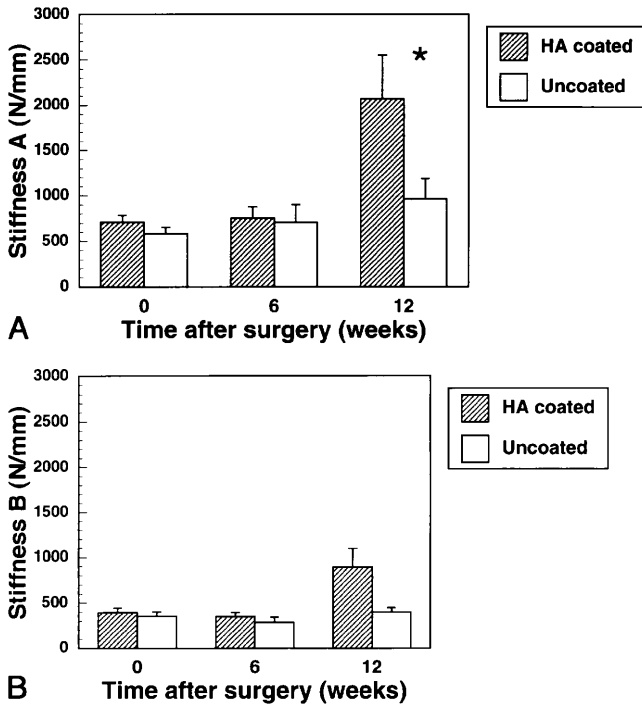


Fig. 4 Stiffness during pull-out (average±SEM) of HA-coated and uncoated stainless steel pedicle screws at different time points following insertion in sheep vertebrae, presented as “stiffness A”, defined by the tangent of the slope for the early linear portion of the load-displacement curve (A), and “stiffness B”, defined as the quotient between maximum load and the displacement produced by that load (B) (* indicates a statistically significant difference)

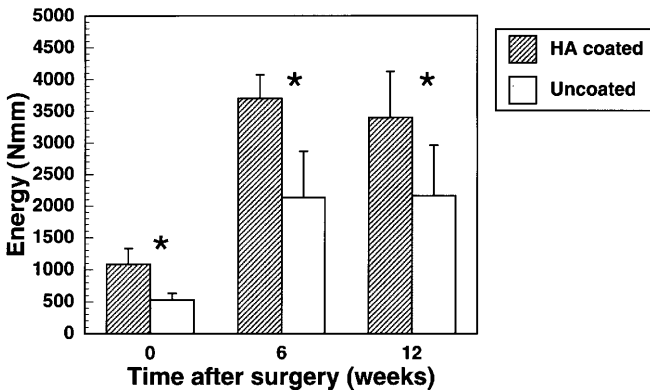


Fig. 5 Energy to failure (average±SEM), defined as the area under the load-displacement curve to the maximum load, for HA-coated and uncoated pedicle screws when subjected to pull-out load at different time points following insertion in sheep vertebrae (* indicates a statistically significant difference)

time points. For both screw types the energy to failure increased significantly from 0 to 6 weeks, while there was no additional significant increase from 6 to 12 weeks for either screw type (Fig. 5).

Discussion

The significance of instrumentation with pedicle screws on the healing rate of spinal fusions has been a matter of controversy. In some studies no differences could be found in the healing rates of instrumented and non-instrumented fusions [1, 30]. However, a significant increase in bone healing has been found in other clinical studies [8, 35, 36] as well as in animal models [10], and the Cochrane review of lumbar surgery stated that there is strong evidence that instrumented fusion may produce a higher fusion rate [9]. Regardless of the effect on healing of the fusions, instrumentation with pedicle screw systems is of great value for stabilisation in spinal tumour surgery and fractures.

Numerous animal models have been used to study spinal biomechanics and implant fixation, with sheep and canine models being the most frequently used [11]. The ovine spine resembles the human spine more than the canine spine in size, pedicle diameter, and in cancellous bone quality [11]. Due to this, and the description of the sheep spine as a reasonable anatomical and biomechanical model for evaluation of spinal instrumentation [32, 33], we decided to use a sheep model for this study. Previous studies on pedicle screw fixation strength have often been performed on unloaded screws. As loading might affect the pin-bone interface, and hence the holding strength over time, we considered it important with respect to clinical implications that the experimental model used included loading of the pedicle screws. None of the sheep showed any signs of fusion between the segments at the time of harvesting. Due to the instability in the spine created at the time of surgery, and the fact that all animals were mobile during the study period, it seems reasonable to believe that the instruments had been subjected to loading through the entire observation period.

The mechanism of loosening of pedicle screws has been described as a cyclic toggling under caudocephalad loads [16, 23, 38]. Whether removal torque or pull-out strength best reflects this clinical failure of pedicle screws remains a matter of debate. Some authors claim that axial pull-out represents bone strength, and not screw failure, as seen in the clinical situation [3], while other researchers believe that unscrewing is not a failure mode seen clinically [29]. As the screws in the system used in the present study were connected to the interconnecting rods in such a way that rotation of the screws was prevented, a pull-out load was considered to better reflect the clinical failure mode. Even though pull-out along the axis of the screw is a simplification of failure in the clinical situation, it reflects the magnitude of screw purchase [17], and it provides a basis for comparing different pedicle screw designs [34]. Several researchers have tried to find a correlation between pull-out strength and maximum torque for pedicle screws; however, the results have given a mixed outcome, with some studies reporting a good agreement

[5, 37] and others finding no significant agreement between the two loading modes [14, 21]. In an earlier clinical study of HA-coated pedicle screws, a marked increase of removal torque was seen when compared to conventional uncoated screws [25]. In the present animal study it therefore seemed important to study the effects of HA-coating on the pull-out strength.

Earlier experimental studies have demonstrated a significant improvement on the purchase of loaded external fixation pins resulting from HA coating [2, 18, 20]. In an experimental study on dogs, however, coating of unloaded pedicle screws with plasma-sprayed HA gave no improvement of the pull-out resistance of the screws after 6 weeks [29]. Stainless steel pedicle screws have been compared to titanium alloy (Ti-6Al-4V) screws in a study of loaded spinal instrumentations in mini-pigs. After 3 months, the maximal removal torque was significantly higher, while there was no significant difference in the pull-out strength, stiffness or energy to failure between the groups [3].

In contrast to the findings by Spivak et al. [29], the pull-out resistance for both HA-coated and standard screws in this study approximately doubled in 6 weeks. This corresponds well with the findings by Schatzker et al., who described a similar increase of the push-out resistance at 6 weeks for unloaded screws inserted into canine femurs, but a decrease of the push-out resistance between 6 and 12 weeks [26]. In the present study there was an increase in the maximum pull-out load for the HA group for each time period, while for the uncoated screws there was a decrease, although insignificantly, in maximum pull-out load between 6 and 12 weeks. The lack of significance between 6 and 12 weeks might in part have been due to the limited number of screws in the 6-week group reducing the statistical power. The pull-out resistance was significantly higher in the HA group than in the uncoated group at 12 weeks. This could probably be related to a resorption of the bone surrounding the standard screws under loaded conditions. The improved purchase of the HA-coated screws over time was interpreted as having been caused by increased bone formation around the HA screws and enhanced bone apposition.

The significantly improved pull-out resistance for the HA-coated screws in this study might be related to the loading of the screws within this experimental model, or to the animal model used. Another important factor is the type of HA coating and its properties. Different commercially available plasma-sprayed HA coatings may exhibit

different mechanical and histologic characteristics [6]. In a previous clinical study, we found a substantial increase in removal torque of pedicle screws coated with plasma-sprayed HA [25]. The same manufacturer that did the coating of the screws in the present study applied the coating of the screws in that study. As the coating of the screws gives an increase in the diameter of the screws, the relative "undersizing" of the tapped holes could be considered as an explanation of the increased mechanical strength. The increase in screw diameter is approximately 80 μm , or 2% of the original screw diameter. In a previous experimental study on dogs, "oversizing" the holes by 20% significantly decreased the initial pull-out strength of pedicle screws, while after 6 weeks there was no significant difference [29]. We do not believe that the minimal "undersizing" of the holes could explain the differences at 12 weeks.

The "undersizing" could possibly be of importance for the significant difference in pull-out resistance in the 0 week group, as there was obviously no biological effect that could explain this finding. Apart from "undersizing" of the insertion hole, the increase in surface roughness caused by the HA coating might also have contributed to the significantly higher holding strength for the HA-coated implants when pulled out immediately after insertion. A four-fold increase in surface roughness has been described for plasma-sprayed HA implants when compared to the roughness of machined titanium implants [31], which is markedly greater than the surface roughness of stainless steel screws [3]. Approximately one-third of the HA coated part of the screw is unthreaded, and we believe that the differences between the 0-weeks groups can mainly be explained by differences in surface roughness. The differences between the HA-coated screws and the standard screws at 6 weeks were not significant, and we believe that the fact that only three animals could be examined at 6 weeks contributed to this inability to disclose whether or not a true difference existed at this time point.

Conclusion

In this study, coating pedicle screws with plasma-sprayed HA resulted in improved fixation in a loaded system, with increased pull-out resistance and reduced risk of screw loosening.

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