Hydroxyapatite-coated external-fixation pins

THE EFFECT ON PIN LOOSENING AND PIN-TRACK INFECTION IN LEG LENGTHENING FOR SHORT STATURE

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Pin loosening and infection are inherent complications of external fixation. This study deals with their effects of using either hydroxyapatite (HA)-coated or uncoated external fixation pins in leg-lengthening procedures on patients of short stature.

We used HA-coated pins on one side and uncoated pins on the other (randomly determined) in 28 bilateral lengthenings undertaken in 23 patients. A total of 322 pins was used. The mean implantation time was 530 days and the mean lengthening achieved was 78% of initial bone length. Mean extraction torque was 7611.6 Nmm degree⁻¹ for HA-coated and 85.4 Nmm degree⁻¹ for uncoated pins ($p < 0.001$). The rate of pin loosening was 4% (7/161) for HA-coated and 80% (129/161) for uncoated pins ($p < 0.001$). There was no statistically significant difference in the incidence of pin-track infection between the two groups.

The use of HA coating appears to be an effective method of reducing the incidence of pin loosening in external fixation with a long implantation time and for mechanically highly stressed procedures such as leg lengthening for short stature.

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The distance between the body of the fixator and the bone makes the pins the critical mechanical link in external-fixation owing to the force which must be transmitted through them to the frame.¹ The bone-pin interface is the site at which the highest stress concentration occurs.² Frame stiffness and the technique of pin insertion are the most frequently considered of several factors in pin loosening.³ Diminution of extraction torque with time is observed, however, even in ideal conditions.^{4,5} Many attempts have been made to improve the mechanical characteristics of the pins, but the only biological approach to improve the bone-pin interface has been the use of a bioceramic coating such as hydroxyapatite (HA).⁶⁻¹⁰

Leg lengthening in patients of short stature is associated with long periods of pin implantation and high mechanical loads. As a result, complications are frequent and some are related to lack of stability of the construct or loosening of pins.^{11,12}

The aim of this study was to show whether the use of HA-coated pins could produce clinical, mechanical and radiological improvements compared with standard uncovered pins in patients being treated for short stature by bilateral leg lengthening. Bilateral leg lengthening is a particularly useful clinical model for studying a variety of variables as a control

group is always present. A literature search failed to reveal any previous reports of the use of HA-coated pins for lengthening or long-standing external fixation procedures.

Patients and Methods

Between 1995 and 1997, a prospective, randomised, clinical study was undertaken in patients of short stature for whom leg lengthening was proposed. The objectives of the study were explained to each patient and his or her parents and their written consent to participate in the study obtained. The study design was approved by the hospital ethics committee.

We included 23 patients, 12 boys and 11 girls with a variety of diagnoses (Table I). The mean age at surgery was 12.7 ± 3 years and the mean height was 120 ± 14 cm. Of 56 bone segments lengthened (28 bilateral); 36 were tibial, ten were femoral and ten were humeral. Two types of external fixation pins were used; uncoated Orthofix tapered 6 to 5 mm steel pins (Bussolengo, Verona, Italy) and Osteotite pins, identical to the Orthofix, but with HA-coating of their threads by a plasma-spray (Orthofix).

The side on which the coated pins were to be used was randomly selected by the toss of a coin prior to the surgical procedure. For each coated pin, a conventional pin was placed in

Table I. Details of the 23 patients who underwent leg lengthening for short stature

Case	Gender	Diagnosis	Bone segments lengthened
1	M	Achondroplasia	Tibiae
2	M	Achondroplasia	Tibiae
3	M	Achondroplasia	Tibiae
4	M	Achondroplasia	Tibiae
5	M	Achondroplasia	Tibiae
6	F	Metaphyseal dysplasia (Schmid)	Tibiae
7	F	Achondroplasia	Tibiae
8	F	Achondroplasia	Tibiae
9	M	Spondyloepiphyseal dysplasia	Femora
10	F	Achondroplasia	Tibiae
11	M	Achondroplasia	Tibiae
12	F	Achondroplasia	Humeri Femora
13	F	Achondroplasia	Tibiae
14	F	Hypochondroplasia	Tibiae Humeri
15	M	Achondroplasia	Humeri Femora
16	M	Achondroplasia	Humeri Femora
17	M	Achondroplasia	Humeri Femora
18	F	Turner's syndrome	Tibiae
19	M	Hypochondroplasia	Tibiae
20	F	Metaphyseal dysplasia (McCusick)	Tibiae
21	F	Achondroplasia	Tibiae
22	F	Turner's syndrome	Tibiae
23	M	Russell Silver's syndrome	Tibiae

Fig. 1

Photograph of the electronic screwdriver (Digitork 1520/15, BLM, Cusano Milanino, Italy) which was used to measure the final insertion torque and initial extraction torque for each pin.

the same site on the opposite side in the same patient. In this way 322 pins were implanted (161 of each type) and considered for study. The Orthofix lengthener set (Bussolengo) was used and the surgical lengthening technique was similar to that described by De Bastiani et al,¹³ with a percutaneous metaphyseal osteotomy. Lengthening, which was

always symmetrical, was tibial in 17 patients, femoral in one patient, simultaneous femoral and humeral in four and simultaneous humeral and tibial in one (Table I).¹⁴ Pins were inserted according to the standard Orthofix technique.

In all tibial lengthenings a screw was inserted above the tibiofibular syndesmosis; a fibular resection osteotomy undertaken and the lengthener placed anteromedially. Six pins were inserted in all patients. The percutaneous osteotomy was carried out near the proximal pins and the procedure completed by percutaneous lengthening of the tendo Achillis. The femoral procedure was similar with six pins being inserted (five in case 9), but the procedure included a proximal tenotomy of the sartorius, rectus femoris, and adductor longus and release of the fascia lata in its middle third. Finally, in the humerus, only five pins were inserted (four in case 12), three proximally and two distally to avoid the risk of damage to the radial nerve.

No post-operative immobilisation was used and weight-bearing with crutches was encouraged from the fourth post-operative day, depending on patient tolerance. The time for removal of the lengthener was based on the radiological appearance of the regenerated bone (three cortices at least 1 mm thick and medullary cavity reformed).¹⁵ Lengtheners and pins were removed in the out-patient clinic, sometimes under light sedation.

Torque measurements were made with an electronic wrench (Electronic Screwdriver DIGITORK 1520/15, BLM, Cusano Milanino, Italy), which allowed insertion and extraction measurements (Fig. 1). These were recorded as Nmm degree⁻¹ (Newton millimetres per degree). An adaptor was constructed to adapt the wrench to the pins. Torque measurements were made once pins had been implanted prior to attaching the lengthener (insertion torque) and at the time of removal of the fixator (extraction torque). Both measurements were compared between coated and uncoated pins.

Extraction torque was also considered as a qualitative variable, with pins being labelled as loose when the extraction torque was ≤ 150 Nmm degrees.⁻¹ This value was obtained as the mean extraction torque of pins that showed bicortical osteolysis which has been considered as a criterion for severe loosening.⁵

Insertion torque was related to extraction torque by means of Pettine's loosening index

$$\frac{(\text{insertion torque} - \text{extraction torque})}{\text{insertion torque}} \times 100$$

which is considered to be 0 when extraction torque does not vary compared with insertion torque, and 100 if loosening is complete (extraction torque = 0 Nmm degree⁻¹).⁵ Pettine's index may be negative when extraction torque is greater than insertion torque.

The pin-tracks were clinically assessed monthly in all patients during the lengthening period, and every two months during the bone healing period, except in patients

Table II. Pin-track infection: classification of Checketts et al¹⁶

	Grade	Clinical appearance	Response to treatment
Minor infections	1	Slight redness Little discharge	Better pin-site care
	2	Redness Discharge Soft-tissue pain and tenderness	Better pin-site care Antibiotic
	3	Grade 2 not responding treatment	Re-siting pin
Major infections	4	Soft-tissue infection involving several pins	External fixation must be abandoned
	5	Osteomyelitis	External fixation must be abandoned
	6	Breakdown and discharge after the completion of treatment Bone sequestrum	Curettage of pin-track

Table III. The mean lengthening achieved, mean duration of pin insertion, clinical results, biomechanical results and radiological results for 23 patients with short stature who underwent leg lengthening with HA-coated and uncoated external-fixation pins

		Type of pin		p value
		HA-coated* (n=161)	Uncoated (n=161)	
Mean lengthening (%)		77.8 ± 25	77.6 ± 25.6	–
Mean insertion duration (days)		548.8 ± 179.7	512.3 ± 151.4	–
Clinical results, number (%)				–
Minor infections*	1	25 (16)	23 (14)	–
	2	72 (45)	75 (47)	–
	3	0	4 (3)	–
	4	6 (4)	9 (6)	–
Major infections*	5	0	0	–
	6	0	0	–
Pins retrieved before healing		6 (4)	13 (8)	–
Skin necrosis		14 (9)	27 (17)	0.045
Biomechanical results				
Mean insertion torque (Nmm degree ⁻¹)		1454.8 ± 1267.8	2313.3 ± 1702.1	<0.001
Mean extraction torque (Nmm degree ⁻¹)		7611.6 ± 3101.1	85.4 ± 194.2	<0.001
Pin loosening, number (%)		7 (4)	129 (80)	<0.001
Mean Pettine's index (%)		-2342.8 ± 3388.7	92.9 ± 36.6	<0.001
Radiological results, number (%)				
Entry cortex osteolysis		11 (7)	35 (22)	<0.001
Exit cortex osteolysis		1 (1)	10 (6)	<0.001
Bicortical osteolysis		6 (4)	52 (32)	<0.001
Bone apposition		117 (73)	35 (22)	<0.001

* According to Checketts et al¹⁶

with a pin-track complication where closer control was advisable. The clinical appearance of the pin-track and its response to treatment were assessed according to Checketts, Otterburn and Maceachern¹⁶ (Table II). Skin necrosis was clinically defined as absence of skin between two contiguous pins due to an infective process. All pins with a grade of more than 0 (Table II) were cultured. The number of coated and uncoated pins which required removal due to loosening was recorded.

Bony reaction around the pins was studied on the antero-posterior radiological view. Osteolysis of the bone cortex was considered to be present if a radiolucency of at least 0.5 mm was observed on both sides of the pin in a cortex.⁴ Bone apposition was considered to be present when a cortical enlargement of 1 mm compared to its adjacent cortex was observed, and to be endosteal or periosteal depending on its location.¹⁷ The incidence of both osteolysis and bone

apposition was evaluated bilaterally at the entry, exit or both cortices.

Statistical analysis consisted of comparison of the described variables between HA-coated or uncoated pin types and was undertaken using the statistical package SPSS 9.0.0 (SPSS Inc., Chicago, Illinois), Windows version. Quantitative variable values were expressed as mean and standard deviation. The differences obtained were considered significant at 5% ($p < 0.05$). Normality tests were carried out for all variables and, depending upon the results obtained, the relationship among variables was studied by non-parametric or parametric tests. Contingency tables were applied for qualitative variable analysis. The statistical test selected depended on the category number. Chi-squared or chi-squared c was considered for dichotomic variables. In the case of polytomic variables Pearson's chi-squared statistic was used. Student's *t*-test was used as a

Table IV. The aetiology of the pin-track infections which occurred following leg lengthening using HA-coated and uncoated external fixation pins.

Organism	Positive cultures (%)	Pins
<i>Staphylococcus aureus</i>	262 (50.5)	132
<i>Pseudomonas aeruginosa</i>	98 (18.9)	55
<i>Proteus mirabilis</i>	48 (9.2)	19
<i>Eschericia coli</i>	27 (5.2)	17
<i>Corynebacterium</i> spp.	26 (5.0)	26
Coagulase-negative <i>Staphylococcus</i>	24 (4.6)	23
Other	34 (6.5)	32
Total	519 (100)	

parametric test for quantitative variables and the Mann-Whitney U test as a non-parametric test. Variances were considered not equal if the Levene test showed significant statistical differences, and the opposite when no significant differences were shown.

Results

The mean lengthening percentage achieved was 78% (SD 25); 64% (SD 10) in humeri, 68% (SD 17) in femora and 84% (SD 27) in tibiae. No statistically-significant difference was observed between lengthenings with HA-coated or

uncoated pins (Table III). The mean duration of insertion was 530 ± 167 days.

We removed 19 pins before bone healing because of evident loosening without a statistically significant difference between the two groups (Table III). Neither was there a statistically significant difference between the types of pin with regard to the frequency and severity of infection (Table III). As for the organism isolated (Table IV), there was again no statistically-significant difference between coated and uncoated pins except for *Pseudomonas aeruginosa*, which was found in 20 of 161 (12%) uncoated pins and in 35 of 161 (22%) HA-coated pins ($p = 0.037$).

As shown in Table III skin necrosis was observed around 13% of pins; 17% uncoated and 9% HA-coated ($p = 0.045$). The mean insertion torque was 2313.3 Nmm degree⁻¹ for uncoated pins and 1454.8 Nmm degree⁻¹ for HA-coated pins ($p < 0.001$). The mean extraction torque was 85.4 Nmm degree⁻¹ for uncoated pins and 7611.6 Nmm degree⁻¹ for HA-coated pins ($p < 0.001$). Compared with 4% of HA-coated pins 80% of uncoated pins developed loosening ($p < 0.001$). The mean Pettine index was 92.9% for uncoated pins and -2342.8% for HA-coated pins ($p < 0.001$). Osteolysis at the entry cortex was seen in 14.3% of all pins; 22% uncoated and 7% HA-coated ($p < 0.001$). It was seen at the exit cortex in 3.4% of all pins; 6% uncoated and 1% HA-coated ($p < 0.001$). Bicortical osteo-

Fig. 2a

Fig. 2b

Plain radiographs of a boy with achondroplasia (case 5) showing the distal group of tibial pins. a) The right side; uncoated pins showing bicortical osteolysis. b) the left side; HA-coated pins showing no osteolysis, but endosteal and periosteal bone apposition.

Fig. 3a

Fig. 3b

Plain radiographs of a boy with spondyloepiphyseal dysplasia (case 9) showing distal groups of femoral pins. a) the right side; HA-coated pins showing no osteolysis, but periosteal bone apposition. b) the left side; uncoated pins showing bicortical osteolysis.

lysis (Figs 2 and 3) was present in 18% of all pins; 32% uncoated, 4% HA-coated ($p < 0.001$). Bone apposition either endosteal or periosteal was seen in 22% of uncoated and 73% of HA-coated pins ($p < 0.001$).

Discussion

Several papers have compared HA-coated and uncoated pins in humans, and shown improvement in fixation using HA-coated pins. These studies have been conducted in tibial fractures, distal radial fractures, progressive correction of upper tibial osteotomies, a multicentre study on long-bone fractures, correction of upper tibial osteotomies and bone transport.^{6,8-10} The implantation time of the pins in these reports varied between 49 and 186 days. To our knowledge no study has been published previously on the use of HA-coated pins in lengthening procedures, where the implantation time and the mechanical load are maximal. The implantation time in this study was 530 ± 167 days. A symmetrical lengthening clinical study was used in which every HA-coated pin had its own control pin in the opposite side in a randomised fashion.

The comparison between pin types showed that the insertion torque was significantly lower in HA-coated pins, a finding which has been reported previously.^{9,10} An explanation for this may be the abrasive effect of the ceramic on bone which makes thread tapping easier.¹⁸ The extraction

torque for HA-coated pins was almost 90 times higher compared with uncoated pins. The incidence of pin loosening was 18 times higher in uncoated pins. Most of the HA-coated pins showed an extraction torque value higher than the insertion value. By contrast, uncoated pins showed a lower extraction than insertion torque, as has been reported previously.^{6-10,18}

Osteolysis in all locations (entry cortex, exit cortex or bicortical) was significantly higher for uncoated pins, as has been shown previously in experimental and clinical studies.^{8,19}

The reported incidence of pin-track infection in bone lengthening varies greatly in the literature, probably due to problems of definition.²⁰ Severe infection is rare. However, in two recently published series where more than 1000 pins were studied, the incidence of severe infection varied between 0% and 3%.^{12,21} In our series, according to the classification of Checketts et al,¹⁶ minor infection occurred in 75% of the lengthened segments (60.6% of pins) and major infection in 10.7% of the procedures (5.9% of pins). Moroni et al,^{8,10} reported fewer minor and major infections for HA-coated pins compared with uncoated pins. In our study, no statistically significant difference was observed in the severity of infection between HA-coated and uncoated pins.

More than 94% of our positive cultures were distributed among six different bacteria (Table IV). Except for the

Corynebacterium, the remainder were described by Mahan et al²² as the most virulent and probably responsible for pin loosening. As reported in previous series, *Staphylococcus aureus* was the most frequently isolated organism.^{23,24} Surprisingly, *Pseudomonas aeruginosa* was the second most common in our study whereas in the literature it is reported to account for less than 2% of infections.²² It was more frequent in HA-coated pins, for which there was no explanation. The incidence of skin necrosis was higher in uncoated than in HA-coated pins. This difference as has been suggested by Shin et al²⁵ may be related to the presence of ceramics in the extra-osseous pin shaft where the coating may improve soft-tissue tolerance to the implant. Some authors have suggested that HA-coating because of its effect on sealing the interface or its resistance to *S. aureus* bacterial adhesion, may prevent infection but we found no evidence for this in our study.^{26,27}

The ability of HA-coating to prevent pin loosening, even in the presence of infection, seems to support the theory that pin loosening and infection are initially two different complications which may be coincidental.

The results of this study have shown the ability of HA to maintain or even improve pin extraction torque in a clinical bone-lengthening model. This ability was maintained for a period of 18 months even in a stability-demanding procedure such as bone-lengthening where a mean lengthening of 75% of initial bone length was obtained. The use of HA did not significantly increase the risk of pin-track infection.

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