Hydroxyapatite Coating of External Fixation Pins to Decrease Axial Deformity During Tibial Lengthening for Short Stature

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Background: Tibial valgus, a known complication of leg lengthening with external fixation techniques, has been related to the stability of the bone-fixator system and, in particular, to pin loosening. A hydroxyapatite coating has been reported to enhance the quality of the bone-pin interface. The aim of this study was to compare the prevalence of axial deformity after tibial lengthening with hydroxyapatite-coated external fixation pins with the prevalence after tibial lengthening with uncoated pins.

Methods: We conducted a prospective study of thirty-four symmetrical tibial lengthening procedures in seventeen pathologically short patients. One limb of each patient was lengthened with use of hydroxyapatite-coated pins and the other, with standard uncoated pins; the sides of the operations were randomly selected. The bone angle in the frontal plane was measured before the operation and at the end of the fixation period, and the difference between these measurements was compared between the lengthening procedures performed with coated pins and those performed with uncoated pins.

Results: The mean valgus deviation of the tibia was 5.5° in the group treated with hydroxyapatite-coated pins and 12.5° in the group treated with uncoated pins (p = 0.023). With the numbers available, other factors previously related to the development of valgus deformity did not differ significantly between the two groups.

Conclusion: Tibias that are lengthened with the use of hydroxyapatite-coated external fixation pins are less prone to axial deviation in the frontal plane than are those treated with uncoated pins.

Level of Evidence: Therapeutic study, Level 1a (randomized controlled trial [significant difference]). See instructions to Authors for a complete description of levels of evidence.

Clinical success or failure of limb lengthening is gauged by the amount of length produced, the quality of bone generated, and the avoidance of complications during and after the lengthening process. These complications have been classified, according to their location, as external fixator disorders, bone and lengthening callus disorders, joint complications, muscle contractures, neurovascular injuries, and psychological disorders. Bone and fracture complications, and particularly axial deviation, have been related to instability of the lengthening apparatus. The characteristic direction of deviation depends on the bone that is involved and the level of the osteotomy. Osteotomies of the proximal part of the tibia—the most usual osteotomies in leg-lengthening procedures—tend to result in valgus and procurvatum deformities that are caused by the imbalance between muscle forces on the different sides of the bone. In the proximal part of the tibia, the bulk of the calf musculature is located posteriorly and laterally. As the distraction increases, these muscles become increasingly tight and the tibia tends to deviate into valgus and procurvatum. Axial deviation has been reported in association with bone lengthening with ring fixators, but it appears to be slightly more frequent with nail fixators, probably as a result of the asymmetrical placement of the apparatus. Several authors have associated the presence of osteolysis around external fixation pins with an increased prevalence of axial malalignment. Other factors related to this complication with monolateral fixators are the age of the patient, the diagnosis, the number of pins, the diameter of the pins, the use of proximal "T" clamps (which allow anterior placement of the lengthener), the level of the tibial osteotomy, premature consolidation or an incomplete tibial osteotomy, premature consolidation or an incomplete fibular...
osteotomy[1,10], nonparallel placement of the fixator, the amount of lengthening[12,13], and fracture of the regenerate bone[14,15].

It has been stated that hydroxyapatite coating of external fixation pins enhances the quality of the bone-pin interface, thereby reducing the prevalence of loosening[16]. The aim of this study was to ascertain whether the improvement in bone-pin fixation obtained with hydroxyapatite coating decreases the amount of axial deviation after leg-lengthening for short stature. To our knowledge, this is the first study examining the relationship between the use of hydroxyapatite-coated pins and complications of lengthening procedures.

Materials and Methods

We conducted a prospective, randomized trial that included seventeen patients, eight boys and nine girls, who underwent a total of thirty-four symmetrical tibial lengthening procedures to treat short stature between 1995 and 1997. The average age (and standard deviation) at surgery was 12 ± 2.9 years. Eleven patients had achondroplasia; two, hypochondroplasia; two, metaphyseal dysplasia; one, Turner syndrome; and one, Russell-Silver syndrome. The mean height of the patients before lengthening was 117.7 ± 13.8 cm.

The patients and their parents were informed of the characteristics and objectives of the study and gave their written consent. The study design was approved by the hospital ethics committee.

All screws were standard steel Orthofix (Bussolengo, Verona, Italy) 6-mm cortical pins with tapered threads (6 mm to 7 mm), and half of them were coated with hydroxyapatite by a plasma-spraying technique (Osteotite® Orthofix). Prior to each operation, one tibia was randomly selected to be lengthened with the use of hydroxyapatite-coated pins. The contralateral limb of the same patient was lengthened with uncoated pins.

The prevalence and amount of axial deviation were compared between the lengthening procedures with the two types of pins. The design of the study obviated the influence of variables related to the patient (e.g., age and ethnicity) or the lengthening frame (number of pins, diameter of the pins, and type of clamps) since they were identical in both groups. Other variables previously related to axial deviation were compared between the groups to rule out confounding factors.

Surgical Technique

The Orthofix diaphyseal limb-lengthener set was used. Lengthening was obtained by callostasis[17] by means of percutaneous metaphyseal osteotomy. Bone segments were always lengthened symmetrically[18]. One patient underwent simultaneous lengthening of both humeris and tibiae.

The fibula was fixed to the tibia with an AO screw placed just proximal to the distal tibiofibular syndesmosis, under image intensifier control. A 5° or 3° excisional osteotomy was performed at the middle third of the fibula. Six cortical pins—three in each clamp—were implanted in the anteromedial surface of the tibia, at 45° from the coronal plane, after predrilling with a 4.8-mm drill bit as recommended by the manufacturer. A template was used to guide the insertion of the pins. Implantation through both cortices—with excision of at least two threads of the screw from the second cortex—was confirmed with use of the image intensifier.

In some patients, the small size of the tibia necessitated placement of the proximal pin into the epiphysis. After the body of the lengthener was applied, an osteotomy was performed, under fluoroscopic control, through a 2-cm anterior incision 2 cm distal to the distal pin of the proximal clamp. Completeness of the osteotomy was confirmed visually. Performing the osteotomy with the fixator in situ avoided displacement of the fragments. Percutaneous lengthening of the Achilles tendon was routinely carried out[19,20].

Postoperative care did not include any type of spica, and walking with crutches was encouraged as soon as it was not too painful. Elongation was initiated on the fourth day after the surgery, at a rate of 0.25 mm every six hours. Patients were evaluated at the outpatient clinic monthly during the lengthening period and every two months during the consolidation period.

The criteria for fixator removal was evidence of medullary recanalization—three of the four possible cortices being visible on two orthogonal radiographs[21].

Radiographic Analysis

Routine monitoring was performed exclusively with plain radiographs. Only preoperative and postoperative radiographs were used for this study; precision was determined by ensuring a standard amount of overlap of the fibula and tibia at the ankle and knee joints. Lateral radiographs were less helpful because of the superposition of the fixator frame.

The initial length and bone angle of the tibia in the frontal plane were measured on the preoperative radiograph. The length was measured from the center of a tangent to the tibial plateau to the center of a tangent to the tibial plateau[22]. The bone angle was measured by comparing lines perpendicular to the above mentioned tangents, which should be parallel[23]. The distance from the osteotomy site to the tibial plateau and the angle between the axis of the fixator body and the mechanical bone axis were measured on the immediate postoperative radiograph. The level of the osteotomy was calculated as a percentage of the total bone length[1]. Axial deviation was calculated as the arithmetical difference between the initial bone angle and the angle at the end of the fixation period, with positive values representing varus and negative values representing valgus. Tibial length was also measured on the final radiograph.

Biomechanical Analysis

The strength of the bone-pin interface was evaluated, at the time of removal of the fixator, by measuring the pin extraction torque (the angular force applied to accomplish the first twist of extraction)[24]. An adapter was manufactured to connect the pin tips to an electronic torque-measuring wrench (Electronic Screwdriver DigitoBl 1520/15; BLM, Cusano Milanino, Italy). The extraction torque, expressed in Nm, was used as a quantitative variable, and the pins with an extract
tion torque of ≤150 Nm° were considered to be loose°.

Statistical Analysis

The prevalence and amount of axial deviation were compared between segments lengthened with coated pins and those lengthened with uncoated pins. The prevalence of other variables that have been previously reported to be related to axial deviation was also compared between groups.

Statistical analysis was performed with the use of the Statistical Package for the Social Sciences (SPSS) software version 9.0.0 for Windows (SPSS, Chicago, Illinois, 1999). For all tests, the results were considered significant when the p value was <0.05. Quantitative variables were expressed as the mean and standard deviation. The Shapiro-Wilk test was applied to test the hypothesis that a variable had a normal distribution. Crossovers were used to compare qualitative measurements. When the minimum expected count was 25, the more conservative between Pearson chi-square and its continuity correction was used to calculate the alpha error value. When the minimum expected count was <5, the Fisher exact test was used to calculate the alpha error value. The Mann-Whitney U test was used as a parametric test to study relationships between the means of two independent groups. The independent-samples t test was used as a parametric test to compare the means of two groups of cases. When the Levene test showed significance, variances were assumed to be unequal; conversely, when the Levene test did not show significance, variances were assumed to be equal.

Results

The external fixator was removed at an average of 533.4 ± 147.7 days. The distraction osteogenesis achieved an average of 15.1 ± 2.7 cm in length, and an average of 83.6% of the original bone length was gained. The average bone-healing index° was 40.2 ± 14.8 days/cm, and the average total healing index (time in the fixator and of cast immobilisation when necessary per centimeter gained)° was 41.9 ± 16.1 days/cm. One patient (Case 7), a seventeen-year-old girl with achondroplasia, had a considerable delay in consolidation of the right tibia, with a fixation time of more than thirty-nine months and a total healing index of 111.8 days/cm (see Appendix).

The average distance from the tibial osteotomy site to the tibial plateau was 65.5 ± 17.5 mm, or 34.1% of the initial bone length. The average coronal angle between the fixator and the tibia was 0.5 ± 3.6°, and this angle was >5° in five of the thirty-four limbs (two of the seventeen treated with coated pins and three of the seventeen treated with uncoated pins).

None of these results differed significantly between the group treated with coated pins and that treated with uncoated pins.

No incomplete tibial or fibular osteotomies, episodes of premature consolidation, or fractures of regenerated bone were observed. Structural failure of the frame occurred in five limbs (three with coated pins and two with uncoated pins). It was possible to exchange the fixator without later incidents in all five.

The average preoperative bone angle was 5.9° ± 9.7° of varus. Ten segments (five with coated pins and five with uncoated pins) had a preoperative varus angle of >10°, and none had a preoperative valgus angle of >10°. The average final bone angle was -3.6° ± 14.8° (valgus): -0.9° ± 12.5° in the group with coated pins and -6.2° ± 15.5° in the group with uncoated pins (no significant difference). Nineteen segments had a final angle of >10°; fourteen in valgus and five in varus.

All segments with a final varus angle of >10° had an initial varus angle of >15°, and all but one had axial deviation into valgus.

It was necessary to perform a closed manipulation with the patient under anesthesia because of coronal axial malalignment in three limbs, all treated with uncoated pins. The final angle remained >10° in two of them, even though good initial correction had been obtained. Subsequently, twenty ribbons (57%)—seven treated with coated pins and thirteen treated with uncoated pins (no significant difference)—had a documented angulation of >10° and/or had manipulation of the fixator during the lengthening procedure. In two, an osteotomy was performed later to correct residual valgus angulation.

The average coronal axial deviation was -9.5° ± 10.4° (valgus): -6.5° ± 8.5° in the group treated with hydroxyapatite-coated pins and -12.5° ± 11.5° in the group treated with uncoated pins (p = 0.023). Twenty-six (79%) of the segments—ten treated with coated pins and sixteen treated with uncoated pins (p = 0.039)—had axial deviation of >5° during the procedure. Of these twenty-six segments, twenty-three had valgus angulation and three had varus (see Appendix).

The average extraction torque was 780.1 ± 2106.3 Nm°2 for the coated pins and 41 ± 104 Nmm° for the uncoated pins (p < 0.001). Seven (7%) of the 102 coated pins and ninety-seven (95%) of the 102 uncoated pins were considered to be loose (p < 0.001). At least one-half of the pins loosened after nineteen lengthening procedures (two of those with coated pins and all seventeen of those with uncoated pins; p < 0.001). Axial deviation was >5° after eighteen of these nineteen procedures; conversely, axial deviation was >5° after only eight of the remaining fifteen lengthening procedures (p = 0.011).

Discussion

Diverse factors are involved in axial deviation of bone segments during leg-lengthening. However, a degree of compliance of the bone-fixator system is necessary for a deviation to occur. In other words, no deviation would be possible if the pins of the external fixator were perfectly anchored to the bone and to the fixator and there was absolute rigidity of all components. This compliance can be due to structural failures of the fixator body or clamps, to failure of the bone-pin interface, or merely to the bending of pins. Therefore, improvement of the quality of the bone-pin interface should lessen the amount of axial deviation in leg-lengthening processes.

The mechanical and anatomical axes of the tibia coincide and are defined as the line drawn from the center of the knee to the center of the ankle°. When a deviation exists, it can be measured as the angle between the anatomical axes of...
the proximal and distal bone segments. However, in this study, the coronal tibial angle was measured as the angle between lines perpendicular to the articular surfaces of the tibial plateau and tibial shaft. These surfaces are tilted into slight valgus (approximately 3°) in relation to the horizontal plane but should be parallel. We chose this measurement for two reasons. The first was the difficulty encountered in drawing the anatomical axes of the proximal and distal segments after a massive bone lengthening, when the regenerated bone can be more than four-fifths of the final length. In this situation, the remodeling of elongation callus can create the image of an apparently straight bone when anatomical axes are observed, while the possible tilt of articular surfaces may be missed. The second reason was that the angle between the coronal tibial axes of bone segments is a combination of true angulation and translation. The translation of bone segments during lengthening occurs when the fixator is not parallel to the bone axis and is not attributable to mechanical failure of fixation (i.e., pin loosening). Furthermore, pure translation has no influence on the parallelism between proximal and distal articular surfaces. Thus, for the purpose of the present study, the angle between perpendiculars to the proximal and distal articular surfaces was considered a better indicator of failure of the fixator system.

The final coronal bone angle has been widely used to evaluate the results of bone lengthening. In skeletal dysplasias, however, the tibia frequently has an initial varus deformity, especially in patients with achondroplasia. Therefore, if this angulation is not corrected at the time of surgery, then the deviation into valgus produced during lengthening can be correct, at least partially, the preexisting deformity. In these cases, although the axial deviation is beneficial to the patient, it still indicates some degree of fixation failure, and the final coronal bone angle becomes a poor indicator of the deviation produced during the process. Given the objective of this study, the difference between the initial and final coronal bone angle was used to measure the axial deviation.

In previous reports, final coronal bone angles of 5° or more frequently of more than 10° have been considered to be major complications of lengthening procedures. In our series, the amount of axial deviation and the prevalence of deviation of more than 15° were significantly higher in segments lengthened with uncoated pins than in those lengthened with hydroxyapatite-coated pins. Seven of the seventeen segments treated with uncoated pins had a deviation of more than 15°; whereas only one of the seventeen treated with coated pins did. The direction of angulation was mainly into valgus, but a varus deviation of more than 5° was observed in three segments. Although the typical deviation after proximal tibial osteotomies is into valgus, cases of varus deformity after tibial lengthening have previously been reported.

In a report by Leyes et al., the pedoextension coronal angle between the fixator and the axis of the tibia as well as the level of the tibial osteotomy were found to be significantly associated with a negative outcome (a final coronal bone angle of more than 10° or the need for manipulation). In the present series, neither of these variables differed significantly between the two treatment groups.

In this study, 95% of the uncoated pins were found to be loose at the time of removal. While loosening of the pins decreased the stiffness of the frame, only three of the seventeen fixators in which uncoated pins had been used had to be removed before consolidation, and no fixator was removed less than six months after application. When the bone pin interface had deteriorated, the lengthening itself can maintain the stability of the construct: when the distraction force separates loosened groups of pins, they achieve a position of secondary stability at the expense of allowing axial deviation of the bone segments. Consequently, loosening will not be patent until the distraction force has ceased, in the late consolidation phase or at the time of fixator removal, as observed in the present study.

Although angulation of bone during tibial lengthening is influenced by many factors, the use of hydroxyapatite-coated external fixation pins decreases the amount and prevalence of axial deviation.

Appendix

A table showing the raw data on seventeen patients is available with the electronic versions of this article, on our web site at www.jbjs.org (go to the article citation and click on “Supplementary Material”) and on our quarterly CD-ROM (call our subscription department, at 781-449-9780, to order the CD-ROM).

References

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