Distraction Osteogenesis of the Lower Extremity with Use of Monolateral External Fixation

A Study Of Two Hundred And Sixty-One Femora And Tibiae*

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ABSTRACT

We reviewed the results of distraction osteogenesis of 114 femora and 147 tibiae that had been lengthened to treat a variety of diagnoses. The femora had been lengthened an average of eleven centimeters (range, 3.5 to 17.0 centimeters), or 48 per cent (range, 8 to 86 per cent) of the original femoral length. The average total time for the treatment of the femora (use of the fixator and any subsequent immobilization) was 257 days (range, 105 to 420 days). There were 114 complications related to the femoral lengthenings, which led to eighty-seven additional operations. The tibiae were lengthened an average of nine centimeters (range, 3.0 to 15.6 centimeters), or 41 per cent (range, 9 to 100 per cent) of the original tibial length. The average total time for the treatment of the tibiae was 268 days (range, 110 to 497 days). There were 196 complications related to the tibial lengthenings, which led to 219 additional operations. The Achilles tendon was lengthened during or after seventy-three (50 per cent) of the tibial lengthenings.

The femoral lengthenings that were performed to treat a limb-length discrepancy were associated with significantly higher rates of complications overall ($p = 0.010$) and additional operations ($p = 0.023$) for each percentage of length gained than those that were performed to treat achondroplasia or another skeletal dysplasia. The femoral lengthenings that were performed to treat short stature (of an endocrine or idiopathic etiology) were also associated with higher rates of complications overall and additional operations than those performed to treat skeletal dysplasias, but the rates were lower than those for lengthenings performed to treat limb-length discrepancy. The rate of complications overall associated with femoral lengthening in patients who were fourteen years old or more was significantly higher than that associated with lengthening in patients who were less than fourteen years old ($p = 0.047$). Femoral lengthening through the metaphysis was associated with significantly higher rates of

complications overall (p = 0.031) and additional operations (p = 0.042) for each percentage of length gained than femoral lengthening through the diaphysis.

The tibial lengthenings that were performed to treat Turner syndrome and idiopathic short stature were associated with significantly higher rates of complications overall (p= 0.026) and additional operations (p = 0.003) for each percentage of length gained than those performed to treat skeletal dysplasias. The rate of joint-related problems (p=0.044) and that of additional operations (p = 0.053) after tibial lengthening in patients who were fourteen years old or more were significantly higher than those rates after tibial lengthening in patients who were less than fourteen years old. The site of the tibial osteotomy did not affect the rate of complications or additional operations.

The femoral healing indices (in terms of both days per centimeter [p = 0.002] and days for each percentage of length gained [p = 0.019]) were significantly higher in the patients who were fourteen years old or more than in those who were less the fourteen years old. These values could not be used to predict an increase in the complications because of poor bone formation. The results of the present review suggest that the use of healing indices to gauge the final outcome of distraction osteogenesis is questionable; we were unable to discern significance or clinical importance from appropriately adjusted values.

INTRODUCTION

In the United States, the Wagner method of limb-lengthening was used predominantly from 1970 to 1990; however, it was associated with a high rate of complications, including infection, non-union, and failure of fixation[1,10,25,29,31,34,38]. Soviet and European surgeons, in the early 1980s, began to lengthen bones with the use of slow, gradual distraction after an osteotomy or corticotomy, obviating the need for bone-grafting and decreasing the prevalence of delayed consolidation and non-union.

Reports of distraction osteogenesis have varied greatly in terms of quality, criteria used for evaluation, size of the study group, characteristics of the patients (such as demographic data, diagnosis, and the bone lengthened), technique of lengthening (unilateral, bilateral, or ipsilateral; unifocal or bifocal; and distraction osteogenesis or distraction epiphyseolysis), and type of fixator used (monolateral or ring). The variability of the designs makes it difficult to compare the different studies or to draw conclusions. Reviews of the results in larger groups of patients from Europe[3] or the Soviet Union[26,27] have lacked sufficient detail, making it difficult to draw any valid conclusions from the data. Finally, most studies have combined the results of distraction osteogenesis of the tibia and the femur.

Since 1980, we have used monolateral external fixation to lengthen the long bones of the lower extremity in patients who have a limb-length discrepancy or who are of short stature secondary to dysplasia or an endocrine or idiopathic condition[5]. Our indications for and techniques of limb-lengthening have remained consistent. We reviewed the results of distraction osteogenesis for femoral and tibial lengthening and performed a statistical analysis to determine the effect of etiology, age, and site of the osteotomy on the outcome as well as on the prevalences of complications and of additional procedures.

MATERIALS AND METHODS

We performed a retrospective analysis of the results of 114 femoral and 147 tibial lengthenings that were performed between February 1980 and March 1995 in 121 patients. Thirty-two patients had bilateral femoral and tibial lengthening, fourteen had bilateral femoral lengthening, thirty had bilateral tibial lengthening, twenty-two had lengthening of one femur, and twentythree had lengthening of one tibia. No patient had simultaneous lengthening of the ipsilateral tibia and femur.

The medical records were reviewed to obtain demographic data and to determine the diagnosis, age at the time of the lengthening, number of days from the osteotomy to the onset of distraction, number of days of distraction, time needed for maturation of the callus, total duration for which the fixator was used, and total duration of treatment (the duration for which the fixator was used as well as the duration of subsequent immobilization). We recorded complications such as neurovascular injury, premature consolidation of the osteotomy site, pin-track infection that necessitated intravenous administration of antibiotics or removal of the pin, and non-union. Secondary operative procedures included osteoclasis for premature consolidation, manipulation to correct angulation or to exchange the fixator, removal of a pin due to infection, operative stabilization of a fracture of the lengthened bone, operative stabilization and bone-grafting of a non-union, tenotomy to treat contracture or subluxation of the hip joint, manipulation or arthrotomy to treat contracture or subluxation of the knee, lengthening of the Achilles tendon to treat equinus contracture, and corrective osteotomy to treat unacceptable residual malalignment.

All of the radiographs were made with the same technique, distance, and machine. The initial length of the bone was measured on the preoperative radiograph and the length gained was measured on the radiograph made after completion of the distraction. The immediate postoperative radiograph was used to document the level of the osteotomy as proximal or distal metaphyseal or diaphyseal (the middle half of the femur or tibia). Serial radiographs were examined for coronal axial malalignment of more than 10 degrees before removal of the fixator; sagittal malalignment could not be assessed because of overlapping of the fixator and the bone on the lateral radiographs. Radiographs were also evaluated for fracture or deformation of the lengthened bone after the fixator was removed.

The percentage of lengthening was calculated by dividing the length gained by the total length of the bone as measured on the radiographs. The rate of distraction in millimeters per day was determined by dividing the length gained by the total number of days of distraction. The healing indexes was calculated by dividing the total duration of treatment (the duration for which the fixator was used and the duration of any subsequent immobilization) in days by the total amount of length gained in centimeters or by the percentage of length gained. These indices were determined only for segments that were not treated with internal stabilization and bone-grafting for non-union of the osteotomy site.

Operative Technique and Lengthening Protocol

None of the patients had more than one lengthening osteotomy performed in each bone. Before the osteotomy, the fixator was placed on the lateral aspect of the femur or on the anteromedial aspect of the tibia. A Wagner external fixator was used for ninety-six femora and 100 tibiae; an Orthofix fixator (Orthofix, Verona, Italy), for two femora• and three tibiae; and a Monotube external fixator (Howmedica, Rutherford, New Jersey), for sixteen femora and forty-four tibiae. Two pins were placed proximally and two were placed distally in all of the bones. Most of the pins that were used with the Wagner and Monotube fixators were placed with a hand-drill. Orthofix screws were used with the Orthofix fixator.

Percutaneous osteotomy was performed as previously described[5]. Forty-seven of the femoral osteotomies were performed in the proximal metaphysis; forty-five, in the diaphysis; and twenty-two, in the distal metaphysis. One hundred and three of the tibial osteotomies were performed in the proximal metaphysis, and forty-four were performed in the diaphysis. One to three centimeters at the junction of the distal and middle thirds of the fibular diaphysis was resected in conjunction with all tibial lengthenings. The distal part of the fibula was stabilized with an external fixator pin or with a screw placed from the lateral aspect of the leg in order to prevent proximal migration.

The lengthening protocol closely followed that de-scribed in previous studies[3,15]. Patients were encouraged to walk, with partial weight-bearing, as often as possible. After an average waiting period of nine days, distraction was begun at the rate of one millimeter per day in two 0.5-millimeter increments. The pin sites were cleaned daily with soap and water; when inflammation at a pin site was resistant to local tare, treatment with oral administration of antibiotics was begun. Six femora and twenty-seven tibiae were treated with intravenous administration of antibiotics or with removal of the pin. The patients were followed in the clinic every two to three weeks, and physical and radiographic examinations were performed to detect and treat common problems and complications. Throughout the lengthening period, the patients were encouraged to keep the knee fully extended as much as possible during the day. The patients who had a femoral lengthening used a knee immobilizer or a posterior splint at night to prevent flexion contractures and posterior subluxation of the knee, and the patients who had a tibial lengthening used a solid ankle-foot orthosis at night to avoid tightness of the heel cord. Physical therapy with active-assisted and passive range-of-motion exercises was begun when the desired length was obtained and the fixator was locked.

Occasionally, the maximum excursion of a fixator was reached before the desired length was attained and the original fixator was exchanged for a longer one. Once lengthening was completed, the fixator was locked and the patients were encouraged to increase their activities and weight-bearing. Fixators other than the Wagner device were converted to dynamic status to improve maturation of the bone. Most of the devices and pins were removed with the patient under general anesthesia. Forty-one (36 per cent) of the 114 femora needed additional immobilization in an above-the-knee cast or a splint for an average of forty-eight days (range, fifteen to 210 days) to prevent or treat a fracture of the callus. Eighty-nine (61 per cent) of the 147 tibiae needed additional immobilization in an above-the-knee cast for an average of thirty-seven days (range, fifteen to 254 days). The patients were followed for an average of four years (range, two to eleven years) in order to detect any secondary problems, such as residual joint stiffness, malalignment, or residual limb-length inequality (Figs. 1-A through 2-C).

Statistical Analysis

We evaluated the outcome for each segment rather than for each patient because a poor result for one segment should not influence the result for another segment, which may have been lengthened without complications in the same patient. Additionally, we analyzed the femoral and tibial lengthenings separately as the results and complications are different. We examined the effect of several preoperative and treatment parameters, including the diagnosis, the age at the time of the lengthening, and the site of the osteotomy (the test variables) on the rate of complications, the need for additional procedures, and the healing indices (the outcome variables).

Test Variables

Femoral lengthenings: Seventy-nine femora were in patients who were less than fourteen years old (range, four years to thirteen years and ten months old), and thirty-five were in patients who were fourteen years old or more (range, fourteen years and two months to twenty-three years old). The diagnoses included achondroplasia (fifty-six femora; Group A), another skeletal dysplasia (twenty-two; Group B), short stature (fourteen; Group C), and limb-length discrepancy (twenty-two; Group D) (Table I). Sixty-nine of the osteotomies were metaphyseal and forty-five were diaphyseal.

Tibial lengthenings: Sixty-five tibiae were in patients who were less than fourteen years old (range, three years to thirteen years and eleven months old), and eighty-two were in patients who were fourteen years old or more (range, fourteen years and four months to twenty-eight years old). The diagnoses included achondroplasia (fifty-four tibiae; Group A), another skeletal dysplasia (eighteen; Group B), short stature (thirty-four; Group C), short stature secondary to an endocrine condition (seventeen; Group D), and a limb-length discrepancy (twenty-four; Group E) (Table I). There were 103 proximal metaphyseal and forty-four diaphyseal osteotomies.

Outcome Variables

The outcome variables included the frequency of problems related to the callus (such as deformity of the lengthened bone without fracture after removal of the fixator, fracture of the callus, and non-union of the lengthened bone), problems related to a joint (contracture or subluxation of the hip or knee or contracture of the Achilles tendon that necessitated operative treatment), the number of complications overall, and the total number of additional operations. The healing indices in terms of centimeters and percentage of length gained were used to quantitatively assess bone-healing among the different test variables for the segments that did not have internal fixation and bone-grafting to treat a non-union. The observed frequency of each variable for each segment was divided by the percentage of length gained. The resultant normalized values are a representation of the rate of complications or additional procedures for each percentage of length gained.

Statistical analysis was performed with the chi-square analysis, the t test, the F test, and the Wilcoxon rank-sum test when appropriate. Correlation coefficients and significance were estimated in terms of the relationship of the length gained in centimeters and as a percentage with the respective healing indices. The influence of the length gained was also normalized in the analysis of the effect of diagnosis, age, and location of the osteotomy on the healing indices. Because of a significant relationship between the length gained and the healing indices, a multivariate analysis with analysis of covariance testing was performed. In this analysis, the observed healing indices in terms of centimeters and in terms of percentage were adjusted by the covariables of the length gained in centimeters or as a percentage, respectively. The effect of the three test variables was then determined with use of the adjusted values as out-come variables. The alpha level for significance was set at 0.05.

RESULTS

Femoral Lengthenings

Fifty-one femora in thirty-one male patients and sixty-three femora in thirty-seven female patients were lengthened. Forty-six patients had both femora lengthened and twenty-two patients had one femur lengthened. The average age at the time of the lengthening procedure was eleven years (range, four to twenty-three years). The diagnoses included achondroplasia (fifty-six femora), metaphyseal chondrodysplasia (twelve), congenital short femur (twelve), pseudoachondroplasia (eight), traumatic or infectious growth arrest (seven), idiopathic short stature (six), precocious puberty (four), multiple epiphyseal dysplasia (two), pseudohypoparathyroidism (two), Turner syndrome (two), Klippel-Trénaunay syndrome (one), congenital coxa vara (one), and hemihypertrophy (one) (Table I).

The average time from the osteotomy to the start of the distraction was nine days (range, one to nineteen days). The average duration of distraction was 112 days (range, thirty-two to 186 days), and the average rate was 1.1 millimeters per day (range, 0.4 to 2 0 millimeters per day). The fixators were in place for an average of 237 days (range, 101 to 420 days), and the total duration of treatment (the duration for which the fixator was used as well as the duration of any subsequent immobilization) was 257 days (range, 105 to 420 days). The average amount of lengthening was eleven centimeters (range, 3.5 to 17.0 centimeters), or 48 per cent (range, 8 to 86 per cent) of the original femoral length. The average healing indices were twenty-four days per centimeter (range, thirteen to sixty days per centimeter) and seven days for each percentage of length gained (range, three to twenty-six days for each percentage of length gained). A strongly negative hyperbolic relationship was noted between the healing indices (in terms of centimeters and percentage) and the amount of length gained (in terms of centimeters and percentage) ($r = -0.71$ and $r = -0.88$) (Figs. 3 and 4). The femora that gained more length (in terms of centimeters and percentages) had significantly lower healing indices (in terms of centimeters and percentage) ($p < 0.001$ for both).

Complications and Additional Procedures

There were a total of 114 complications, an average of one complication per femur. Forty-five of the 114 femoral lengthenings were not associated with a complication, thirty-five were associated with one complication; twenty-four, with two complications; nine, with three complications; and one, with four complications. The complications included coronal axial malalignment (thirty-three), severe contracture or subluxation of the hip (thirty-three), fracture of the lengthened bone (twenty-eight), associated contracture or subluxation of the knee (nine), severe pin-track infection (six), premature consolidation (three), and non-unions at the site of the distraction (two). The coronal axial malalignment, which occurred before the fixator was removed, was always due to varus angulation. There were no neurovascular complications.

Fifty-two of the 114 femora had no additional operative procedures (except for removal of the fixator). Of the remaining sixty-two segments, forty needed one additional operation, nineteen needed two, and three needed three, for a total of eighty-seven additional operations (0.76 per femur). The procedures included internal fixation with bone-grafting because of a nonunion (two), femoral osteoclasis (three), removal of a pin (four), internal fixation for a fracture through the callus (five), corrective osteotomy (eight), closed manipulation with the patient under anesthesia and application of a cast (six) or open release or application of a fixator across the knee (three) for the treatment of subluxation or contracture of the knee, manipulation of the fixator because of angulation or exchange of the fixator (twenty-three), and tenotomy for the treatment of a contracture or subluxation of the hip (thirty-three). Of the thirty-three tenotomies, seventeen consisted of release of the rectus femoris and sometimes the iliotibial band (hip flexors), two were isolated releases of the adductor longus, and fourteen were combined releases of the hip flexors and adductors. Hamstring releases were not performed to treat flexion contractures of the knee.

Statistical Analysis of the Complications and Additional Operations

We assumed that the amount of length gained may bias the results of comparison between subgroups. Femora that gained more length are expected to have a higher rate of joint-related problems and therefore a higher rate of complications overall and of additional operations. Therefore, when we analyzed the test groups to determine the effect of diagnosis, age, and the location of the osteotomy on the outcome, we defined the outcome as the observed rate of complications and the rate of additional procedures divided by the individual percentage of femoral length gained (Table II). Each subgroup was tested to determine the average number of callus-related problems, joint-related problems, complications overall, and additional operations for each percentage of length gained.

The diagnosis was noted to have an important effect on the prevalence of complications and additional procedures. Femoral lengthening to treat a limb-length discrepancy was associated with more callus-related problems ($p = 0.003$), joint-related problems ($p = 0.044$), complications overall ($p = 0.010$), and additional procedures ($p = 0.023$) for each percentage of length gained than lengthening to treat achondroplasia or another skeletal dysplasia. The rates of complications overall and of additional operations associated with lengthening to treat short stature secondary to an endocrine or idiopathic condition were lower than those associated with lengthening to treat a limb-length discrepancy and higher than those associated with lengthening to treat any skeletal dysplasia; however, these differences were not found to be significant, with the numbers available. Only the difference between the rate of callus-related problems associated with lengthening to treat short stature and that associated with lengthening to treat achondroplasia or another skeletal dysplasia was significant ($p = 0.003$).

Lengthening of the femur in patients who were four-teen years old or more was associated with a significantly ($p = 0.047$) higher rate of complications overall for each percentage of length gained than that in patients who were less than fourteen years old. The older patients also had a higher rate of callus-related problems, joint-related problems, and additional operations for each percentage of length gained, but these differences were not found to be significant with the numbers available. Finally, metaphyseal osteotomies were associated with a higher rate of complications overall ($p = 0.031$) and additional operations ($p = 0.042$) for each percentage of length gained compared with the diaphyseal osteotomies.

Statistical Analysis of the Healing Indices

We performed analysis of covariance to test for the effect of diagnosis, age, and the location of the osteotomy on the healing indices (Table III). The older the patient at the time of the lengthening, the greater the increase in the healing indices, independent of the amount of lengthening. The average adjusted healing indices for the segments in patients who were fourteen years old or more were 26.0 days per centimeter and 7.7 days per percentage of length gained, whereas the average adjusted indices for the segments in patients who were less than fourteen years old were 22.3 days per centimeter and 6.5 days per percentage of length gained. These differences were significant ($p = 0.002$ and 0.019, respectively).

Tibial Lengthenings

Ninety-five tibiae in fifty-five female patients and fifty-two tibiae in thirty male patients were lengthened. Sixty-two patients had both tibiae lengthened simultaneously and twenty-three patients had one tibia lengthened. The average age of the patients at the time of the lengthening was thirteen years (range, three to twenty-eight years). The diagnoses included achondroplasia (fifty-four tibiae), idiopathic short stature (eighteen), Turner syndrome (sixteen), fibular hemimelia (twelve), precocious puberty (eight), traumatic or infectious growth arrest (eight), spondyloepiphyseal dysplasia (six), pseudoachondroplasia (six), metaphyseal chondrodysplasia (six), pseudohypoparathyroidism (five), hypothyroidism (four), tibial hypoplasia (two), poliomyelitis (one), and Ewing sarcoma (one).

The average time from the osteotomy to the start of distraction was ten days (range, four to twenty days). The average duration of distraction was 101 days (range, forty to 200 days), and the rate was 0.9 millimeter per day (range, 0.3 to 1.5 millimeters per day). The average time that the fixator was in place was 229 days (range, ninety-nine to 450 days), and the total duration of treatment was 268 days (range, 110 to 497 days). The average lengthening was nine centimeters (range, 3.0 to 15.6 centimeters), or 41 per cent (range, 9 to 100 per cent) of the original tibial length. The average healing indices were thirty-two days per centimeter (range, fourteen to 134 days per centimeter) and 8.1 days for each percentage of length gained (range, two to thirty-five days for each percentage of length gained). The relationship of the healing indices (in terms of centimeters and percentage) to the amount of length gained (in terms of centimeters and percentage) demonstrated a strongly negative hyperbolic correlation ($r = -0.70$ and $r = -0.78$) that was significant ($p < 0.001$ for both) (Figs. 3 and 4). Similar to the femora, the tibiae that gained more length had lower indices.

Complications and Additional Procedures

There was a total of 196 complications, an overall rate of 1.33 complications per tibia. Forty-two of the 147 tibial lengthenings were not associated with a complication; forty-two were associated with one complication; thirty-eight, with two complications; twenty-two, with three complications; and three, with four complications. The complications included associated equinus contracture (seventy-three); coronal axial malalignment, all with increased valgus angulation, before the fixator was removed (forty-nine); severe pin-site infection (twenty-seven); non-union (fifteen); fracture (thirteen) and deformation of the callus (six) after removal of the fixator; contracture or subluxation of the knee (eight); and premature fibular consolidation (four). There was no instance of premature consolidation of the tibia. One patient who had fibular hemimelia sustained an intraoperative injury to the peroneal nerve that resulted in a permanent deficit and was refractory to microsurgical reconstruction. All thirteen fractures of the lengthened bone and all six deformations of the callus without a fracture that occurred after removal of the fixator were treated with an above-the-knee cast.

Thirty-six tibiae had no additional operative procedures (except for removal of the fixator), thirty-nine needed one additional operation, forty needed two, thirty needed three, and two needed five, for a total of 219 additional operations (1.5 per tibia). The procedures included lengthening of the Achilles tendon (seventythree), removal of a pin (twenty-seven), manipulation or exchange of the fixator (sixty-one), a corrective osteotomy to treat residual malalignment (thirty), internal fixation with bone-grafting to treat non-union (fifteen), manipulation of the knee (eight), fibular osteoclasis because of premature consolidation (four), and microsurgical reconstruction of the peroneal nerve (one). The seventy-three lengthenings of the Achilles tendon were performed during or after the distraction period; prophylactic lengthening was not performed. The eight subluxations or contractures of the knee were treated with closed manipulation and application of a cast with the patient under general anesthesia.

Statistical Analysis of the Complications and Additional Operations

As in the analysis of the femoral lengthenings, the observed rates of callus-related problems, joint-related problems, complications overall, and additional operations for each tibia were normalized by the percentage of length gained before the effects of diagnosis, age, and the location of the osteotomy were evaluated (Table IV). Statistical analysis of the number of these complications for each percentage of length gained revealed important findings. The tibial lengthenings that were performed to treat short stature secondary to Turner syndrome or an idiopathic condition were associated with significantly higher rates of complications overall ($p = 0.026$) and additional operations ($p = 0.003$) than those performed to treat achondroplasia or another skeletal dysplasia. The lengthenings performed to treat a limb-length discrepancy were associated with significantly higher rates of complications overall ($p = 0.026$) and additional operations ($p = 0.003$) than those performed to treat achondroplasia.

The tibial lengthenings in patients who were fourteen years old or more were associated with significantly higher rates of joint-related problems ($p = 0.044$) and additional operations ($p = 0.053$) for each percentage of length gained than those in patients who were less than fourteen years old. The lengthenings in patients who were fourteen years old or more also were associated with higher rates of callus-related problems and overall complications, but we could not detect significant differences with the numbers avail-able ($p > 0.05$). There were no differences in the rates of complications or additional procedures for each percentage of length gained with regard to the location of the osteotomy.

Statistical Analysis of the Healing Indices

Analysis of covariance testing for the effect of diagnosis, age, and the location of the osteotomy on the healing indices for the tibial lengthenings did not show any significant differences, with the numbers available (Table V).

Comparison of Femoral Healing Indices with Tibial Healing Indices

The average healing indices were twenty-four days per centimeter and 6.8 days for each percentage of length gained for the femora and thirty-two days per centimeter and 8.1 days for each percentage of length gained for the tibiae. Initially, the difference in the healing potential between the two bones appeared to be significant. However, multivariate analysis showed that the average adjusted healing indices were 26.7 days per centimeter and 7.3 days for each percentage of length gained for the femora and 29.4 days per centimeter and 7.6 days for each percentage of length gained for the tibiae. There were no significant differences between these adjusted values.

DISCUSSION

The indications for lengthening reflect cultural differences between the people of Europe and South America and those of Canada and the United States. In Europe and South America, increasing the height of a markedly short patient makes it possible for the individual to use public telephones, restrooms, and other facilities.[35,42] The results of distraction osteogenesis are currently assessed on the basis of the amount of length gained, the prevalence of associated complications or additional procedures, and quantitative parameters such as the healing index[15]. Except for the length gained, the outcome measures are based on subjective assignment of end points[17] and changing definitions of the complications.[6,11,21,36,43] Quantitative parameters such as the healing index depend on subjective end points and the amount of length gained[18]. Furthermore, comparison between different series of patients is difficult because of differences in diagnosis, lengthening techniques, and types of external fixation as well as the tendency to combine the results of femoral and tibial lengthenings.[8,12,13,18,212627,32,37,41,43,44]

In the present study, the femora were lengthened an average of eleven centimeters, or 48 per cent of the original femoral length, and the tibiae were lengthened an average of nine centimeters, or 41 per cent of the original tibial length. The femora of patients who were of short stature secondary to skeletal dysplasia or an endocrine or idiopathic condition were lengthened an average of twelve centimeters (54 per cent of the original femoral length), and the tibiae of these patients were lengthened an average of ten centimeters (46 per cent of the original tibial length). These results are similar to those of previous reports of increases in length of as much as 58 per cent after tibial and femoral lengthenings in patients who have achondroplasia.[4,15,39] In contrast, the average lengthening of the femora and tibiae in patients who were treated for limb-length discrepancy was seven centimeters (19 per cent of the original femoral length) and six centimeters (21 per cent of the original tibial length), respectively.

Although the gains in length are impressive, the results must be evaluated in the context of the extended time needed for consolidation of the bone (approximately 260 days) and the fact that complications occur and additional procedures are needed. Femoral lengthening with the use of distraction osteogenesis has been associated with rates of complications of as high as 119 per cent (eighty-three complications in seventy femora).[8,14,21,27,43] The reported rates of complications for tibial lengthening with the use of distraction osteogenesis have been as high as 167 per cent (twenty complications in twelve tibiae).[12,13,19,26,32,37,40,44] It appears that the rates of complications in the present study are concordant with these reported rates. Direct comparison of our results with previously published findings is impossible because of differences in the classification of complications, the diagnoses, the presence of associated limb deformities, and the amount that the segments were lengthened.

The primary limitation to extensive limb-lengthening is increased tension in the quadriceps, hamstrings, hip adductors, and triceps surae muscles leading to softtissue contractures and occasionally to instability of the joints.[16,24] Subluxation of the hip has been noted to occur in the presence of preexisting acetabular dysplasia.[45] Subluxation of the knee is frequently reported after lengthening of a congenitally shortened femur,[20,22,29] and, in such conditions, instability of the knee is commonly associated with aplasia of the cruciate ligament[28] and hypoplasia of the femoral condyles.[23] In the present series, tenotomy of the hip flexors or adductors was needed after 29 per cent (thirty-three) of the 114 femoral lengthenings and operative treatment of contracture or subluxation of the knee was needed after 8 per cent (nine). Previous studies of femoral lengthenings with the use of distraction osteogenesis[21,24,38,43] demonstrated joint-related problems after as many as 46 per cent (thirty-two) of seventy procedures, and operative treatment was needed for these problems after 23 per cent (sixteen) of the seventy procedures. Other authors have reported operative release for contracture of the ankle or knee after as many as 25 per cent (eight) of thirty two tibial lengthenings.[7 9,12,13,30,37,44,46] In the present series, lengthening of the Achilles tendon was performed during or after 50 per cent (seventy-three) of the tibial lengthenings, and manipulation of the knee and application of a cast to treat a flexion contracture was performed after 5 per cent (eight). These prevalences are somewhat higher than those in other reports[7,9,12,13,30,37,44,46] probably because of the greater tibial length gained in our study. Lengthening of the Achilles tendon is a relatively minor procedure that permits additional lengthening and allows the patient to maintain a plantigrade foot.

Patients who had a femoral length discrepancy had higher rates of complications and additional operations for each percentage of length gained than those who had achondroplasia or another skeletal dysplasia. Other authors who have reported on distraction osteogenesis to treat unilateral shortening of the lower extremity caused by congenital, infectious, or neurological conditions have also noted an increased overall prevalence of these problems.[12,13,21,22,38,41] A limb-length discrepancy was more difficult to correct with distraction osteogenesis than short stature was. Furthermore, it was easier to lengthen the femora in patients who were of short stature when the short stature was due to a skeletal dysplasia than when it was due to an idiopathic or endocrine condition. Similar to the femoral lengthenings, the tibial lengthenings in patients who had a limb-length discrepancy were associated with higher rates of complications overall and additional procedures than those in patients who had achondroplasia. Furthermore, the rates of complications and additional procedures were greater in patients who were of short stature secondary to Turner syndrome or an idiopathic condition than in patients who had achondroplasia or another skeletal dysplasia. This finding confirms the conclusions reached by Trivella et al.[46] who noted a high rate of complications in sixteen patients who had Turner dwarfism treated with distraction osteogenesis.

Patients who were fourteen years old or more had a higher rate of complications for each percentage of length gained in every femoral and tibial test group; additionally, the femoral lengthenings in patients who were fourteen years old or more were associated with significantly more complications overall for each percentage of length gained than those in patients who were less than fourteen years old. Interestingly, significantly higher rates of joint-related problems and additional operations were noted after the tibial lengthenings in the older patients. Perhaps the higher rate of joint-related problems reflects diminished soft-tissue elasticity compared with the elasticity in patients who were less than fourteen years old.

The metaphyseal lengthenings were associated with slightly higher rates of complications overall and additional procedures for each percentage of length gained compared with the diaphyseal lengthenings. These higher rates may be due to the need for periarticular placement of the pins after the metaphyseal osteotomy[2]. Placement of the osteotomy site in the femoral or tibial diaphysis did not increase the observed or adjusted rates of callus-related problems or the healing indices. These findings are at variance with those of reports that have implied that rates of osseous complications are higher in association with diaphyseal osteotomies.[2,8,17,33]

The total time needed for the treatment of the tibiae was longer than that needed for the femora; however, this effect disappeared when greater amounts of lengthening were compared (Fig. 5). Multivariate analysis showed that the healing indices for the tibiae were uniformly higher than those for the femora. On the basis of this information, physicians who perform staged bilateral tibial and bilateral femoral distraction osteogenesis to treat non-rhizomelic short stature may be advised to perform the tibial lengthenings before the femoral lengthenings. Performing the tibial lengthening when the patient is younger may diminish the rate of joint-related problems as well as the time needed for the site of the osteotomy to consolidate.

The healing indices were related to the amount of length gained in centimeters and to the percentage of length gained; increased length was associated with decreases in these parameters. This relationship makes intuitive sense as the calculation of healing indices is dependent on the length gained; relative increases in length can be expected to decrease the healing indices. In the present study, we utilized multivariate analysis to exclude the effect of length gained on comparisons of groups based on diagnosis, age, and the location of the osteotomy. Most previous investigators who used healing indices as an outcome parameter failed to do this; therefore, the conclusions of those studies may not be valid.[1,3,4,7,15,19,21,30,32,37,43,44,46]

In the present study, femora that were lengthened to treat a limb-length discrepancy had a slightly higher average adjusted healing index in terms of centimeters and an almost significantly higher ($p = 0.066$) average healing index in terms of percentage. This finding implies clinical importance as these femora also had significantly higher rates of callus-related problems. In contrast, although the femoral healing indices differed between the two age-groups, the two groups were not found to differ significantly with regard to callus-related problems. Similarly, multivariate analysis of the tibial healing indices in the different subgroups based on diagnosis, age, and the location of the osteotomy yielded no significant or consistent findings.

We concluded that distraction osteogenesis can be used to obtain impressive gains in the lengths of the femur and tibia, but the cost is increased treatment time and complications. Bone is uniformly produced regardless of the location of the osteotomy or the length gained. The diagnosis was found to have important implications, with increased rates of complications for each percentage of length gained in femora and tibiae that were treated because of a limb-length discrepancy. Femoral and tibia] lengthenings that were performed to treat short stature secondary to Turner syndrome or an endocrine or idiopathic condition were associated with more problems than those performed to treat short stature secondary to skeletal dysplasias. The latter group had the lowest rate of complications for each percentage of length gained.

In societies where excessive short stature secondary to dysplasia is a functional handicap, limb-lengthening with the use of distraction osteogenesis may be useful. However, obtaining the amount of length that is needed to produce a major increase in stature increases the prevalence of complications and additional procedures, a problem similar to that encountered in patients who had a limb-length discrepancy. The femora and tibiae in patients who were fourteen years old or more were associated with higher rates of complications than those in patients who were less than fourteen years old. The femora in older patients were associated with higher rates of complications overall, whereas the tibiae in those patients were associated with higher rates of joint-related problems and additional operations. Age increased the femoral healing indices; however, the clinical relevance of these values with regard to the rates of callus-related problems is questionable. Healing indices may be useful only as a rough estimate of the duration of treatment required for each proposed procedure.

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Table 1. Diagnoses						
Diagnosis	**Femora**			**Tibiae**		
	No. of Patients	**No. of Femora**	**Test Group**	**No. of Patients**	**No. of Tibiae**	**Test Group**
Achondroplasia	28	56	A	27	54	A
Spondyloepiphyseal dysplasia	—	—		3	6	B
Pseudoachondroplasia	4	8	B	3	6	B
Metaphyseal chondrodysplasia	6	12	B	3	6	B
Multiple epiphyseal dysplasia	1	2	B	—	—	
Idiopathic short stature	3	6	C	9	18	C
Turner syndrome	1	2	C	8	16	C
Precocious puberty	2	4	C	4	8	D
Pseudohypoparathyroidism	1	2	C	3	5	D
Hypothyroidism	—	—		2	4	D
Klippel-Trénaunay syndrome	1	1	D	—	—	
Congenital short femur	12	12	D	—	—	
Congenital coxa vara	1	1	D	—	—	
Hemihypertrophy	1	1	D	—	—	
Post-traumatic growth arrest	4	4	D	4	4	E
Infectious growth arrest	3	3	D	3	4	E
Fibular hemimelia	—	—		12	12	E
Tibial hypoplasia	—	—		2	2	E
Poliomyelitis	—	—		1	1	E
Ewing sarcoma	—	—		1	1	E
Total	68	114		85	147	

Table 2. Complications And Additional Procedures After Distraction Osteogenesis Of The Femur

		Callus-Related Problems		**Joint-Related Problems**		**Complications Overall**		**Additional Operations**	
Test Variable	No.	No.	Average No. per Percentage of Length Gained	No.	Average No. per Percentage of Length Gained	No.	Average No. per Percentage of Length Gained	No.	Average No. per Percentage of Length Gained
Diagnosis*									
Achondroplasia	56	14 (25%)	0.004	28 (50%)	0.008	60 (107%)	0.017	41 (73%)	0.011
Another skeletal dysplasia	22	1 (5%)	0.001	4 (18%)	0.004	15 (68%)	0.018	14 (64%)	0.015
Short stature	14	5	0.018			10	0.032	9	0.030
Limb-length discrepancy	22	10 (45%)	0.018	10 (45%)	0.026	29 (132%)	0.063	23 (105%	0.062
			p = 0.003		p = 0.044		p = 0.010		p = 0.023
Age*									
<14 yrs.	79	19 (24%)	0.007	25 (32%)	0.009	70 (89%)	0.025	57 (72%)	0.023
≥14 yrs.	35	11 (31%)	0.010	17 (49%)	0.011	44 (126%)	0.035	30 (86%)	0.027
			p = 0.30		p = 0.42		p = 0.047		p = 0.34
Location of osteotomy*									
Proximal or distal metaphysis	69	20 (29%)	0.011	25 (36%)	0.012	75 (109%)	0.036	58 (84%)	0.032
Diaphysis	45	10 (22%)	0.004	17 (38%)	0.006	39 (87%)	0.016	29 (64%)	0.012
			p = 0.17		p = 0.59		p = 0.031		p = 0.042

*Statistical analysis was performed on the frequency of complications and additional procedures divided by the percentage of length gained.

Table 3. Summary Analysis Of The Effect Of Test Variables On The Average Healing Indices After Distraction Osteogenesis Of The Femur

		Average Length Gained		**Observed Healing Index**		**Adjusted Healing Index#**	
Test Variable	No.*	Centimeters	Per cent	Days/ Centimeter	Days/ Per Cent	Days/ Centimeter	Days/ Per Cent
Diagnosis*							
Achondroplasia	56	13.3	63.2	20.8	4.5	24.8	7.9
Another skeletal dysplasia	22	11.5	47.1	23.5	6.2	25.0	7.3
Short stature	14	10.2	29.2	24.8	9.0	24.5	7.4
Limb-length discrepancy	20	6.6	19.4	32.9	12.3	27.7	9.3
						p = 0.518	p = 0.066
Age*							
<14 yrs.	77	10.9	49.3	23.7	6.2	22.3	6.5
≥14 yrs.	35	12.5	45.0	24.6	8.0	26.0	7.7
						p = 0.002	p = 0.019
Location of osteotomy*							
Proximal or distal metaphysis	67	11.0	41.9	24.9	7.8	24.0	6.6
Diaphysis	45	12.0	56.9	22.7	5.3	23.5	6.5
						p = 0.657	p = 0.793

*Analysis was performed on the femora that had consolidation of the distraction site without operative stabilization or bone-grafting.
#Statistical analysis was performed on the observed average adjusted through analysis of covariance testing with length gained (with respect to centimeters or percentage) as a covariable.

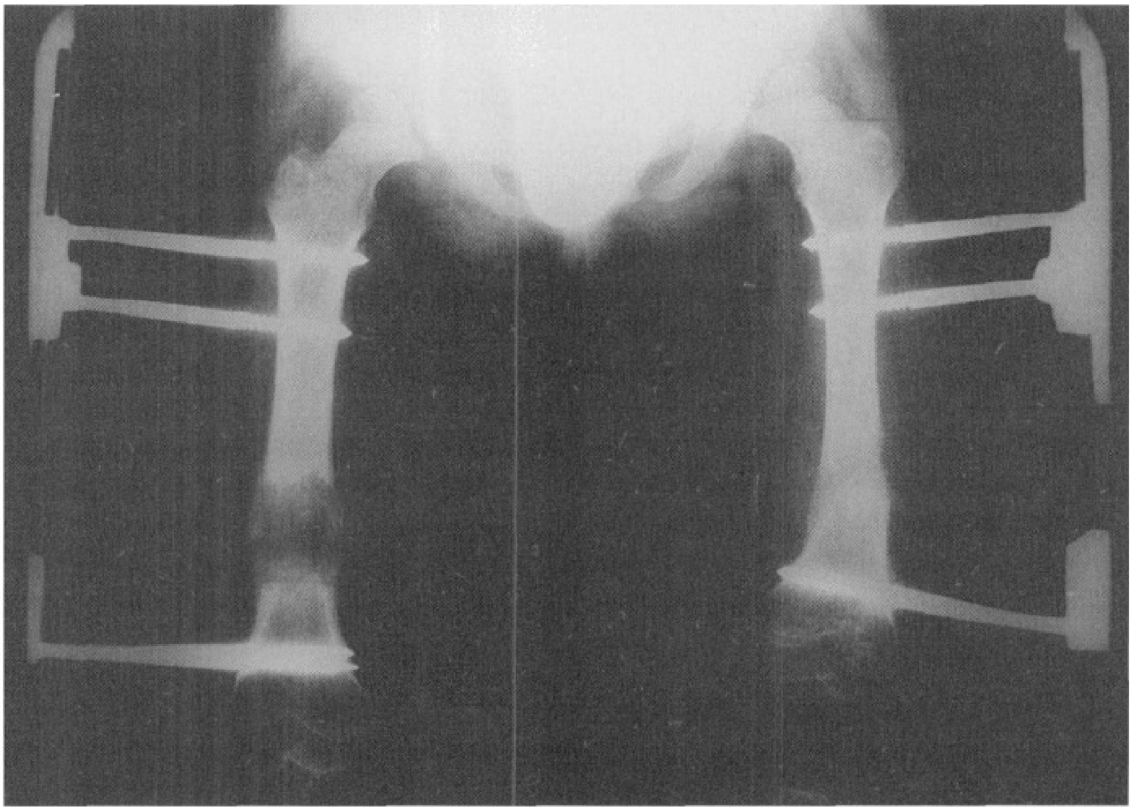
Table 4. Complications And Additional Procedures After Distraction Osteogenesis Of The Tibia									
		Callus-Related Problems		**Joint-Related Problems**		**Complications Overall**		**Additional Operations**	
Test Variable	No.	No.	Average No. per Percentage of Length Gained	No.	Average No. per Percentage of Length Gained	No.	Average No. per Percentage of Length Gained	No.	Average No. per Percentage of Length Gained
Diagnosis*									
Achondroplasia	54	14 (26%)	0.005	32 (59%)	0.011	81 (150%	0.028	82 (152%)	0.029
Another skeletal dysplasia	18	1	0.001	12	0.020	22	0.032	29	0.043
Short stature	34	10 (29%)	0.012	21 (62%)	0.027	49 (144%	0.060	54 (159%)	0.070
Short stature secondary to an endocrine condition	17	4	0.008	6	0.012	17	0.034	28	0.057
Limb-length discrepancy	24	5 (21%)	0.012	10 (42%)	0.021	27 (113%	0.055	26 (108%)	0.053
			p = 0.28		p = 0.37		p = 0.026		p = 0.003
Age*									
<14 yrs.	65	12 (18%)	0.007	31 (48%)	0.012	90 (138%	0.039	90 (138%)	0.038
≥14 yrs.	82	22 (27%)	0.009	50 (61%)	0.022	106 (129%	0.042	129 (157%)	0.055
			p = 0.28		p = 0.044		p = 0.34		p = 0.053
Location of osteotomy*									
Proximal metaphysis	103	25 (24%)	0.008	57 (55%)	0.020	128 (124%	0.042	145 (141%)	0.050
Diaphysis	44	9 (20%)	0.007	24 (55%)	0.011	68 (155%	0.037	74 (168%	0.041
			p = 0.61		p = 0.21		p = 0.51		p = 0.72
*Statistical analysis was performed on the frequency of complications and additional procedures divided by the percentage of length gained.									

Table 5. Effect Of Test Variables On The Average Healing Indices After Distraction Osteogenesis Of The Tibia

		Average Length Gained		**Observed Healing Index**		**Adjusted Healing Index#**	
Test Variable	No.*	Centimeters	Per cent	Days/ Centimeter	Days/ Per Cent	Days/ Centimeter	Days/ Per Cent
Diagnosis*							
Achondroplasia	49	11.5	62.1	26.7	5.1	37.8	9.1
Another skeletal dysplasia	18	8.8	39.7	39.1	7.8	38.5	8.3
Short stature	28	8.6	30.5	32.3	10.1	30.9	9.2
Short stature secondary to an endocrine condition	13	9.8	29.8	25.6	8.5	29.4	7.4
Limb-length discrepancy	24	5.9	21.3	41.2	11.9	28.4	9.5
						$p = 0.081$	$p = 0.397$
Age*							
<14 yrs.	60	9.0	47.2	33.0	7.0	32.1	7.7
≥14 yrs.	72	9.5	37.2	31.3	9.0	32.3	8.2
						$p = 0.956$	$p = 0.410$
Location of osteotomy*							
Proximal metaphysis	93	9.5	39.3	30.1	8.6	31.0	7.9
Diaphysis	39	9.0	47.7	36.8	6.9	35.9	7.6
						$p = 0.081$	$p = 0.599$

* Analysis was performed on the tibiae that had consolidation of the distraction site without operative stabilization or bone-grafting.

[#]Statistical analysis was performed on the observed average adjusted through analysis of covariance testing with length gained (with respect to centimeters or percentage) as a covariable.



Figures 1-A and 1-B. A four and a half-year-old girl with achondroplasia who had bilateral femoral osteotomy and application of a fixator for distraction osteogenesis.
Figure 1-A. Radiograph made two months after the osteotomies, showing premature consolidation of the left femur. A second osteotomy was necessary.

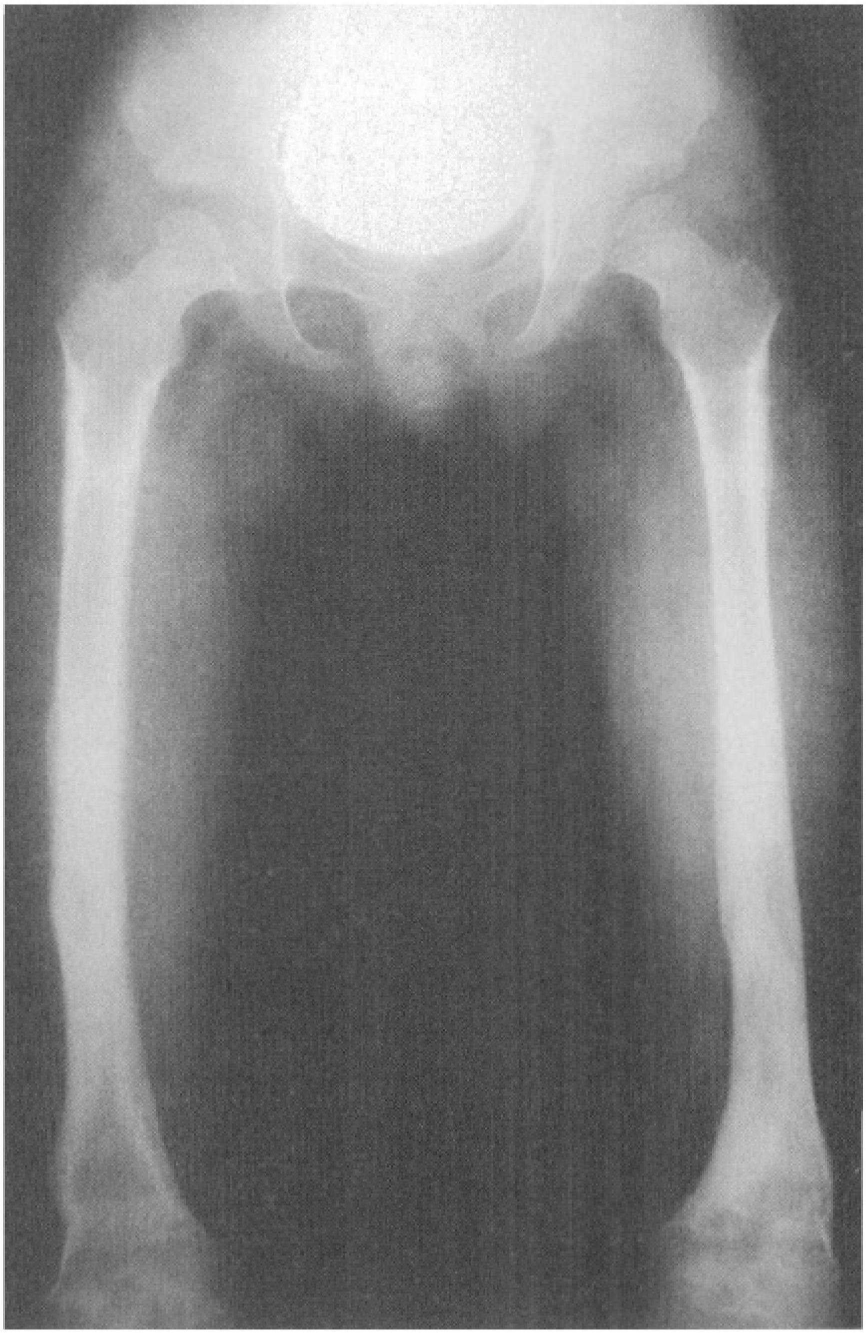
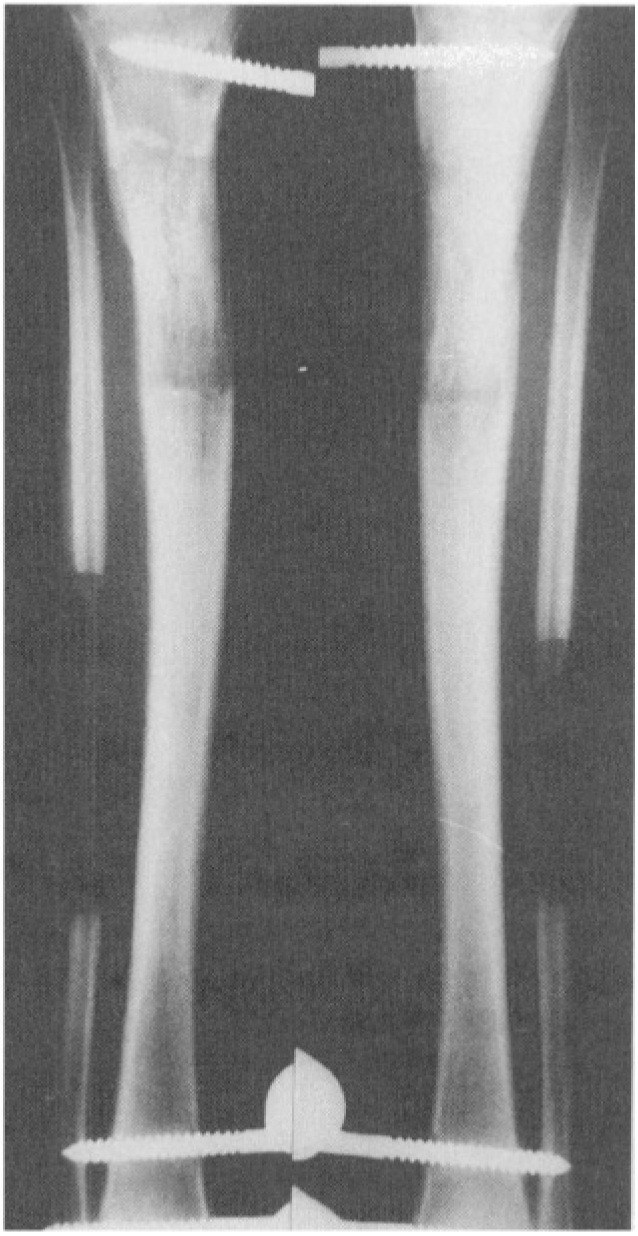


Figure 1-B. Radiograph made eight months after the first osteotomy. The left femur had been lengthened 12.3 centimeters, and the right femur had been lengthened 11.7 centimeters. At that time, she had bilateral release of the rectus femoris and iliotibial band to treat hip flexion contractures. Radiographs made at a later follow-up evaluation demonstrated excellent callus formation. The patient subsequently had bilateral tibial and humeral lengthenings.



Figures 2-A, 2-B, and 2-C. A fourteen-year-old girl who had bilateral tibial osteotomy and application of a fixator for lengthening to treat idiopathic short stature.
Figure 2-A. Radiographs made nine months after the osteotomies. The fixators were locked after the right tibia had been lengthened 6.5 centimeters and the left tibia had been lengthened 7.0 centimeters. There was excellent coronal alignment and good callus formation.

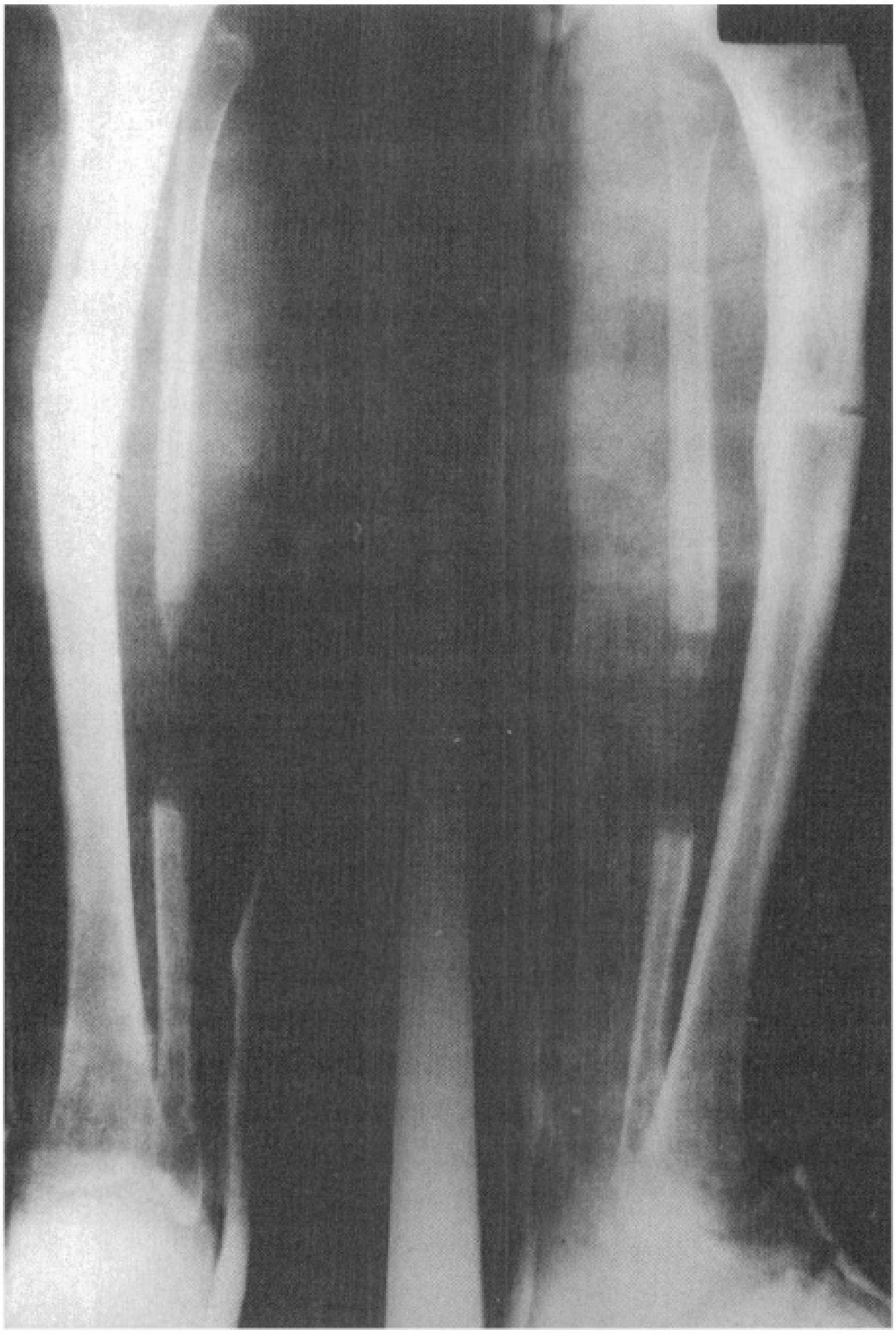


Figure. 2-B. Anteroposterior and lateral radiographs made thirteen months after the osteotomies. The patient had a non-displaced, transverse fracture of the callus of the left tibia, which may have resulted from excessive anterior angulation of the distraction site with anterior bowing of the area of callus formation. The fracture was treated with immobilization in a cast, and the patient had concurrent bilateral lengthening of the Achilles tendon.

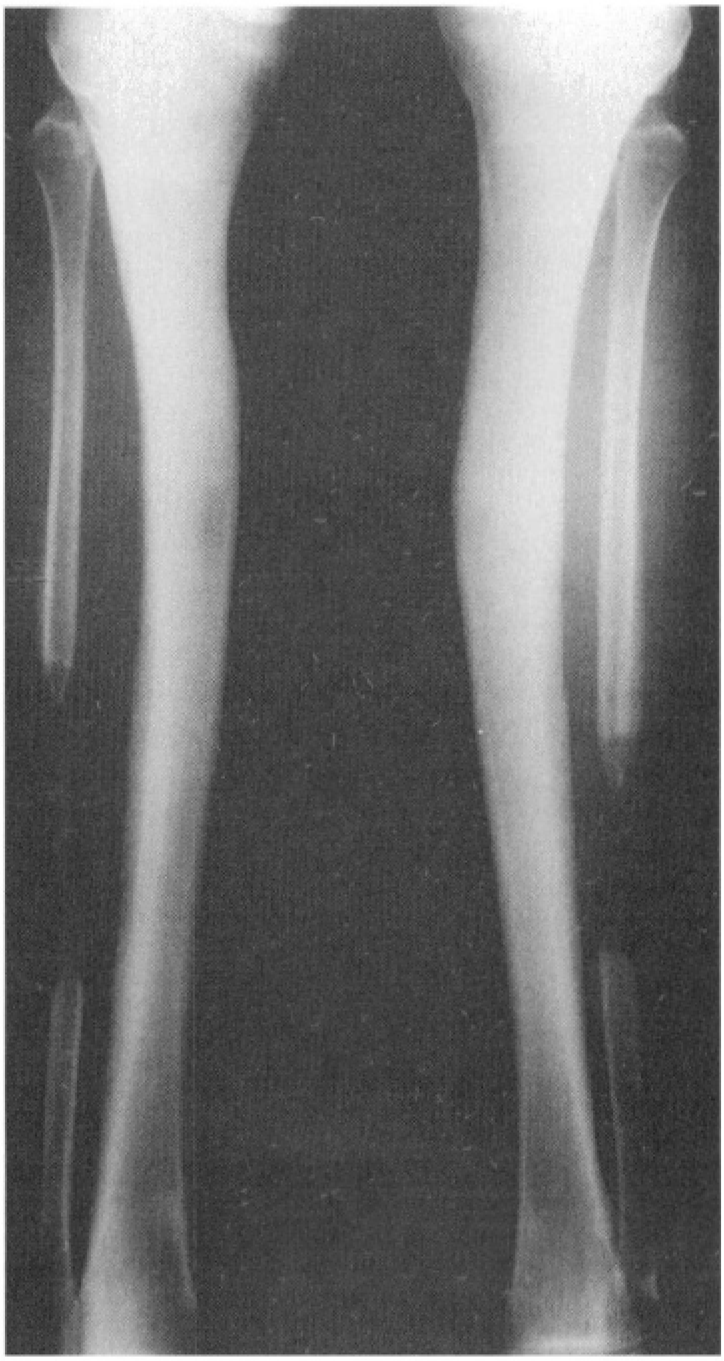


Figure 2-C. The fracture healed uneventfully, and radiographs made two and one-half years later do not show any additional deformity.

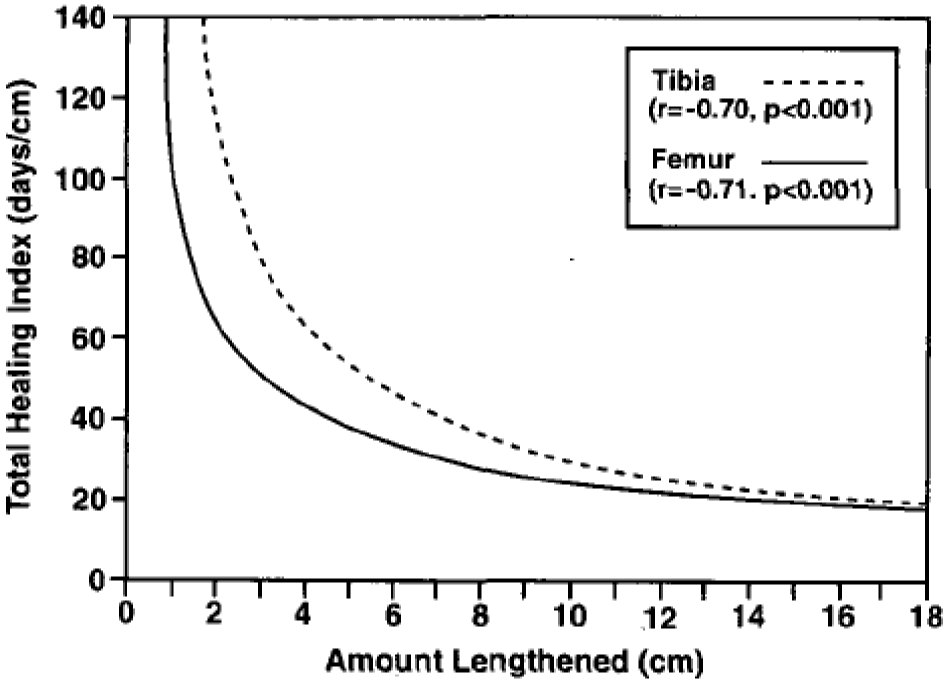


Figure 3. Graph showing the relationship between the healing index, in terms of centimeters, and the amount of length gained. There is a strongly negative hyperbolic relationship for both the tibiae and the femora. The femora and the tibiae that gained less length had significantly higher healing indices.

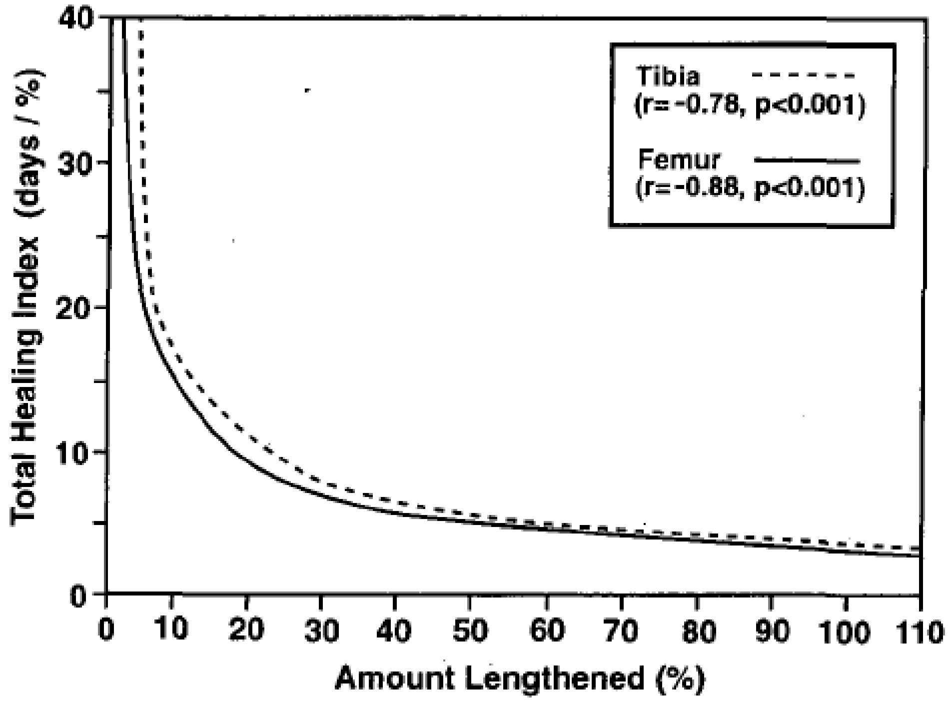


Figure 4. Graph showing the relationship between the healing index; in terms of percentage, and the percentage of length gained. There is a strongly negative hyperbolic relationship for both the tibiae and the femora. The femora and the tibiae that gained less length had significantly higher healing indices.

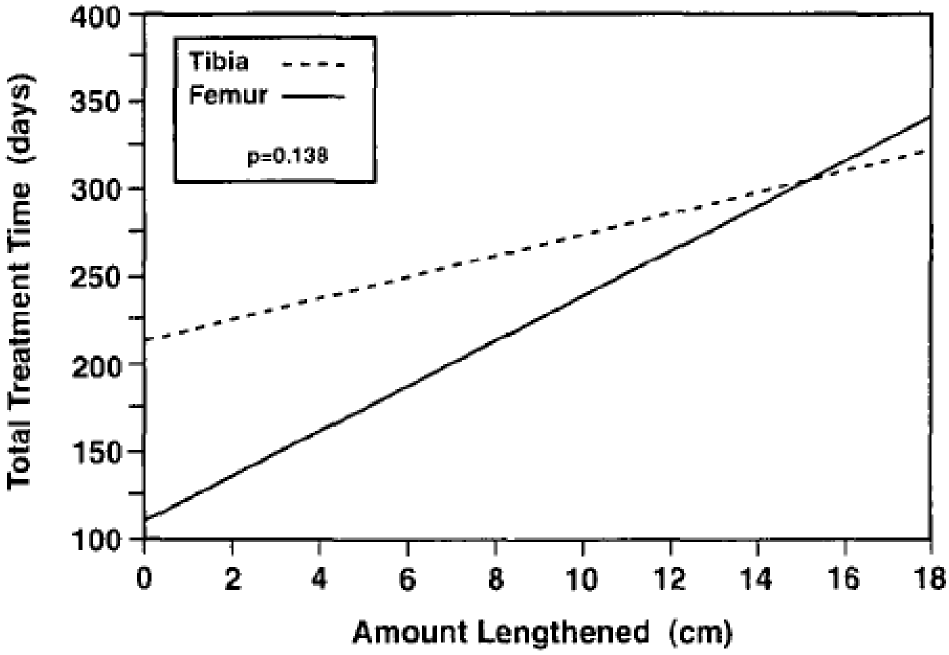


Figure 5. Graph showing the relationship between the average total duration of treatment and the amount of length gained. The duration of treatment needed for the tibial lengthenings was longer than that needed for the femoral lengthenings but not significantly so. The differences are more pronounced for relatively small amounts of length gained and diminish for comparatively large amounts of length gained.