Greater frequency of distraction accelerates bone formation in open-wedge proximal tibial osteotomy with hemicallotasis

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Background In chickens, increased distraction frequency stimulates bone formation in distraction osteogenesis.

Patients and methods We investigated the effect of two different distraction frequencies on bone formation in the distracted portion, and on the time of removal of the fixator, in open-wedge osteotomies of the proximal tibia with hemicallotasis (HCO). The study included 20 consecutive patients (20 knees) who underwent HCO for medial osteoarthrosis of the knee. 10 knees were distracted at a rate of 0.25 mm four times a day (the 4-step group); and the other 10 knees were distracted at a rate of 0.125 mm eight times a day (the 8-step group).

Results There were no significant differences in the preoperative FTAs or the correction angles between the two groups. At all intervals until 6 weeks after the completion of distraction, bone mineral density in the distraction gap was significantly higher in the 8-step group than in the 4-step group. The average time in external fixation was 78 (SD 5) days in the 8-step group as compared to 89 (SD 6) days in the 4-step group, a significantly shorter time.

Interpretation Our findings indicate that an increase in the distraction frequency in HCO provides better bone formation, resulting in a shorter external fixation period.

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Recently, tibial open-wedge osteotomy with hemicallotasis (HCO), a progressive distraction technique using an external fixator, has gained interest (Turi et al. 1987, Fowler et al. 1991, Magyar et al. 1998, 1999, Klinger et al. 2001, Weale et al. 2001, Gerdhem et al. 2002). HCO has several advantages over conventional high tibial osteotomy such as closed-wedge or dome osteotomy, including a smaller incision, easier acquisition of accurate correction, and allowance of earlier mobilization and weight bearing (Fowler et al. 1991, Klinger et al. 2001). In addition, we have shown that HCO lead to only little shortening of the patellar tendon and less distortion of the proximal tibia postoperatively, implying an easier subsequent conversion to TKA (Nakamura et al. 2001). In HCO, however, a long time in external fixation is required to achieve sufficient bone formation. The longer the period of external fixation, the greater is the incidence of pin-tract infection or inflammation (Burny 1979). In a recent study of tibial lengthening using a chicken model, we have demonstrated that an increase in distraction frequency provides better bone formation in distraction osteogenesis (Mizuta et al. 2003). Based on this experimental observation, we then investigated how the increase in the distraction frequency affects bone formation in HCO. In this prospective trial, we have compared the bone mineral density (BMD) of the distracted portion using dual-energy X-ray absorptiometry, and also the total length of time in fixation, between two groups of patients undergoing different frequencies of distraction.

Patients and methods

20 consecutive patients (20 knees) who underwent open-wedge osteotomy of the proximal tibia with hemicallotasis (HCO) for medial osteoarthrosis of the knee between September 1998 and July 2000 were enrolled in this study after informed consent. The first 10 patients underwent distraction at a rate of 0.25 mm 4 times a day at 7 a.m., 12 a.m., 5 p.m., and 10 p.m. (the 4-step group). The other 10 underwent distraction at a rate of 0.125 mm 8 times a day, every two hours from 7 a.m. to 9 p.m. (the 8-step group). Each group included 9 women and 1 man. In both groups, mean age at surgery was 64 years (range 56–75 in the 4-step group, and 55–77 in the 8-step group). The preoperative femorotibial angle (FTA) was measured on the anteroposterior (AP) radiograph while standing on the involved side, focussing on the distal pole of the patella facing forward. The correction angle was determined preoperatively so that the mechanical axis connecting the center of both the femoral head and the ankle joint would pass through a point 70% of the distance from the medial edge of the proximal tibial plateau, measured by a supine AP radiograph of the whole lower extremity on the operated side (Ogata et al. 1991).

In all patients, we used the procedure described by Turi et al. (1987). Under fluoroscopic control, two pins (Orthofix 6/5 mm cancellous screws) were inserted transversely from the medial into the lateral aspect of the proximal tibial plateau, and two pins (Orthofix 6/5 mm cortical screws) were inserted distally in the diaphysis. After making a 3-cm longitudinal skin incision on the tibial tuberosity and carefully stripping off the periosteum, we performed a tibial osteotomy at the middle level of tuberosity as far as approximately the medial 80% of the transverse cortex width, leaving the lateral cortex continuity. A hemicallotasis device (Orthofix, Tokibo, Japan) was used for the fixation. In cases with a correction angle of more than 15°, fibulectomy was performed to protect the peroneal nerve and incongruence in the proximal tibiofibular joint due to upper displacement of the fibula head. The same surgeon (HM) performed all operations. Active knee motion and weight bearing were allowed (as tolerated) on the day after surgery. All patients had antibiotic prophylaxis for the first week after surgery and received pin site cleaning twice a week until pin removal. Distraction was started 2 weeks after surgery. All of the distraction procedures were performed by the same person (EN). During distraction, non-weight bearing was applied to avoid fracture in the lateral cortex of the osteotomized portion (Ohsawa et al. 1997). At the time of achieving the planned correction, the fixator was locked. After this, weight bearing was encouraged.

BMD evaluation

Using dual-energy X-ray absorptiometry (QDR-4500, Hologic, Inc, Waltham, MA), BMD in the distraction gap was checked at the time distraction was completed and at intervals of 1 week until the removal of the fixator. In the supine position on the table, the operated tibia was placed at neutral rotation while the diaphyseal bone axis was placed parallel to the scanning plane shown by the laser cross-hair indicator, and scanned by anteroposterior projection with a beam distance of 62.5 cm. On pilot scanning, the positioning of the tibia was adjusted using a special apparatus so that the projection was directed to superimpose both the anterior and posterior osteotomized ends of the tibia. This positioning was kept the same for each patient. A 50-mm length of bone, setting the distracted segment at the center, was scanned at a speed of 1 mm per second.

All scans were performed using the metal removal software (Hologic, Inc, Waltham, MA) to eliminate the effect of the metal pins from the bone mass measurement. Point and line resolution were 0.111 mm and 0.056 mm, respectively, as a default. From the data obtained, BMD were measured using the analyzer (preinstalled standard interactive software version 8.26a, Hologic Inc., Waltham, MA) on the workstation in the system component. On the DEXA image, the distraction gap was defined as a triangular space surrounded by both proximal and distal osteotomized ends and a straight line connecting their medial ridges. The proximal undistracted portions were defined as the rectangular space with the length on the x-axis including both medial and lateral cortex, and 10 mm proximally on the y-axis from the level of the proximal osteotomized medial ridge. The distal undistracted portions were defined as the

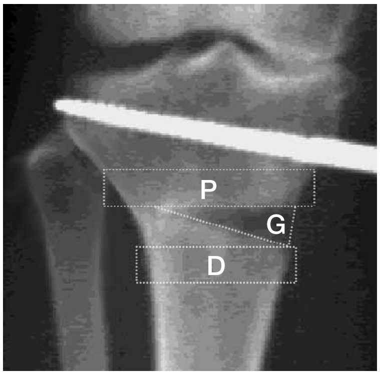

Figure 1. Representative DEXA image. The proximal undistracted portion (P) and the distal portion (D) were defined as the 10-mm high rectangular space adjacent to the proximal and distal osteotomized ends, respectively. The distraction gap (G) was defined as a triangular space surrounded by both proximal and distal osteotomized ends and a straight line connecting their medial ridges. The %BMD of the distraction gap was calculated as the relative ratio of the averaged BMD of the proximal and distal undistracted portions.

rectangular space with the length on the x-axis including both medial and lateral cortex, and 10 mm distally on the y-axis from the level of the distal osteotomized medial ridge (Figure 1). We set the region of interest on each of the above-defined locations at the time of completion of distraction, when we could observe the osteotomized ends on the image most definitely, and recorded the pixel values on the x- and y-axis of the interest regions. Using these initial values recorded at the time of the completion of distraction, we kept a consistent setting of the measurement areas for the BMD measurements that followed in a given patient. After setting the regions of interest in the above-mentioned manner, the BMDs of each location were measured. In order to eliminate interindividual differences, the percentage BMD (%BMD) of the distraction gap was calculated as the relative ratio to the averaged BMD of the proximal and distal undistracted portions using a modification of the method described by Hamanishi et al. (1994). All BMD measurements were performed by one of us (SK) who was not involved in the operation. To keep the consistency of the region of interest on the DEXA image, he knew the patient number but was blinded as to the treatment group. BMD measurements were undertaken three times and the reproducibility of BMD was within 2.8%.

Determining of the start of dynamization and the timing of fixator removal

To determine the start of dynamization, we used the following criteria: 1) the %BMD in the distraction gap was more than 85, 2) mineralized callus, regardless of its density, was observed in the whole space of the distraction site on the AP radiograph. Dynamization was started when both criteria were fulfilled simultaneously. In practice, the AP radiograph was taken at the time the %BMD in the distraction gap first exceeded 85. Dynamization was commenced if the radiographic finding fulfilled the above-mentioned condition. If not, dynamization was postponed until the findings on the radiograph taken every week after that met the criteria. This decision was made by one of the authors (SK) who was blinded as to the treatment group. The fixator removal was performed uniformly 3 weeks after the start of dynamization in all patients.

Statistics

The data are presented as means (SD). The Mann-Whitney U-test was used to compare the FTAs and the correction angle between the groups. The change in the FTAs after the completion of distraction to one year after surgery in each group was analyzed with a one-way ANOVA and the Mann-Whitney U-test. To compare the BMDs in the distraction gap after the completion of distraction between the groups, the averaged BMDs of the proximal and distal undistracted portions, and %BMDs, were analyzed using a two-way ANOVA with the follow-up period and the distraction frequency as factors. When there was no significant interaction between the follow-up period and the distraction frequency, the effects of frequency were analyzed separately at each time point by the Mann-Whitney U-test. We also compared the time from surgery to the completion of distraction, the time from the completion of distraction to the start of dynamization, and the total time in fixation between the groups using the Mann-Whitney U-test. Statistical significance was set at $p = 0.05$. Power analysis of this study revealed that the statistical power exceeded 80% for the %BMDs at all intervals examined (two-tailed t test).

Table 1. Correction angle (degrees) and change in FTA in each group. Mean (SD)

	4-step	8-step
Correction angle	13 (3.2)	16 (4.8)
FTA		
Preoperative	183 (3.2)	184 (3.5)
At completion of distraction	169 (1.5)	168 (1.8)
At start of dynamization	169 (1.5)	168 (1.8)
At fixator removal	169 (1.8)	168 (1.6)
At 1 year	169 (1.8)	168 (1.6)

Results

There were no significant differences between the groups in the FTAs pre- or postoperatively, or in the correction angles (Table 1). In each group, there was no significant change in the FTAs between the time of completion of distraction and 1 year after surgery.

Analysis of the averaged BMD of the proximal and distal undistracted portions, and the %BMD using two-way ANOVA with the follow-up period and the distraction frequency as factors, revealed no significant correlation between these two factors. There were no significant differences between the groups in the averaged BMD of the proximal and distal undistracted portions at each time point (Table 2). In contrast, when distraction was completed, the %BMD in the 8-step group was approximately 20% higher than in the 4-step group (Figure 2). No patients in the 4-step group showed a %BMD above 85, whereas three in the 8-step group did. At all times until 6 weeks after completion of the distraction, the %BMD of the 8-step group was higher than that of the 4-step group.

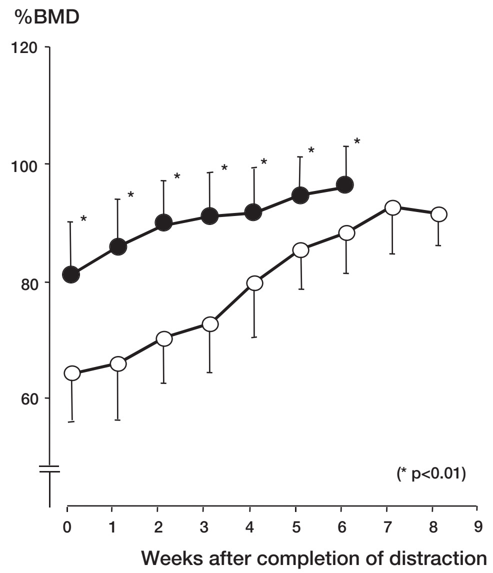

Figure 2. Changes in %BMD in the distraction gap (mean SD) after the completion of distraction in the 4-step group (○) and in the 8-step group (●).

The median time from surgery to the completion of distraction was 38 (SD 2) days in the 4-step group and 37 (SD 6) days in the 8-step group. The median time from the completion of distraction to the start of dynamization was 30 (SD 6) days in the 4-step group and 20 (SD 2) days in the 8-step group ($p < 0.001$). At the time the %BMD in the distraction gap first exceeded 85, radiographic

Table 2. Change in the averaged BMD of the proximal and distal undistracted portions, and in the BMD of the distraction gap after the completion of distraction in each gorup (mean SD, g/cm^2)

Weeks	Averaged BMD of the proximal and distal undistracted portions 4-step	8-step	BMD of the distraction gap 4-step	8-step
0	0.71 (0.21)	0.72 (0.20)	0.45 (0.13)	0.57 (0.17)
1	0.71 (0.21)	0.71 (0.22)	0.47 (0.15)	0.61 (0.18)
2	0.71 (0.22)	0.72 (0.20)	0.50 (0.16)	0.63 (0.16)
3	0.71 (0.21)	0.71 (0.21)	0.52 (0.16)	0.65 (0.17)
4	0.71 (0.22)	0.72 (0.21)	0.56 (0.17)	0.65 (0.17)
5	0.71 (0.21)	0.71 (0.21)	0.60 (0.17)	0.67 (0.18)
6	0.71 (0.23)	0.71 (0.23)	0.62 (0.19)	0.68 (0.22)
7	0.71 (0.24)	–	0.65 (0.20)	–
8	0.71 (0.21)	–	0.62 (0.22)	–

findings met the criterion for starting dynamization in all patients of the 4-step group and in 6 patients of the 8-step group. 4 patients in the 8-step group required one week before radiographic findings met the criterion and the dynamization was commenced. The median total time in fixation was 89 (SD 6) days in the 4-step group and 78 (SD 5) days in the 8-step group. The latter result was thus shorter by an average of 11 days (p = 0.002).

We observed two cases of pin-site inflammation: one patient in each group had inflammation without any organism being cultured. The inflammations were settled with daily cleaning and washing, and classified as grade 1 according to the Otterburn classification (Saleh and Scott 1992). We encountered no fracture in the lateral cortex of the osteotomized portion and saw no signs of any other complications.

Discussion

We found that BMD of the distracted portion in the 8-step group was higher than in the 4-step group at all time points examined. There is some discrepancy in the literature about the effect of distraction frequency on bone formation during distraction osteogenesis in animals: some authors have reported better osteogenesis during high-frequency distraction (Ilizarov 1989, Paccione et al. 2001), while others have observed no stimulatory effect on bone formation from increased distraction frequency (Welch et al. 1998). In an earlier study, we investigated the effect of distraction frequency on bone formation using skeletally mature chickens, which are bi-pedal like humans, and found that BMD of the distraction site was enhanced by distraction at higher frequency (Mizuta et al. 2003). Our findings in the present study are thus consistent with our previous experimental results.

In the 4-step group, the average period in external fixation was 89 days. A similar period was reported in previous studies of HCO with a distraction frequency of 4 times per day (Magyar et al. 1998, Klinger et al. 2001, Gerdhem et al. 2002). In contrast, the 8-step group had a median 78 days of fixation, significantly shorter than that of the 4-step group. When to start dynamization and remove the fixator during distraction osteogenesis is usually determined by plain radiographs, which are qualitative and somewhat subjective. For a more quantitative and objective assessment, we used criteria which included bone densitometric data in addition to radiographical information on the distraction gap, referring to the data shown by Maffulli et al. (1999). Whether or not our criteria are optimal cannot be determined from the present study. However, no patient had a loss of the correction angle at 1 year after surgery, indicating that the callus fulfilling our criteria possesses sufficient mechanical strength for dynamic loading and the subsequent removal of fixation.

Our study was not randomized. We allocated the first 10 patients to the 4-step group and the latter 10 to the 8-step group because we thought that different protocols for patients essentially being treated together might cause anxiety. To provide more conclusive results, randomized controlled trials should be performed as a next step.

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No competing interests declared.

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