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ORTHOPAEDIC SURGERY

# Comparative study of callus progression in limb lengthening with or without intramedullary nail with reference to the pixel value ratio and the Ru Li's classification

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**Abstract**
*Introduction* Callus progression is a great concern during limb lengthening. In this study, we investigated the difference in callus progression between tibial lengthenings with and without intramedullary nail.
*Method* Seventy tibiae in 38 patients with an average age of 24 years were lengthened with Ilizarov external fixator and nail; 56 tibiae in 40 patients with an average age of 28.6 years were lengthened with the same Ilizarov external fixator but without nail. The callus progression was compared with reference to pixel value ratio (PVR) and Ru Li's classification. Statistical analysis was performed to compare the variation trend of PVR and incidence of various callus pathways (particular patterns of callus progression as outlined in Ru Li's classification) and shapes of each aspect of callus between the two groups.
*Results* The trend of PVR was not statistically different in posterior, lateral and medial aspects of the callus between the two groups, but averagely lower in the anterior aspect in the group without nail than that with nail. The group without nail presented less incidence of homogeneous pathway, greater incidence of heterogeneous pathway; also greater incidence of fusiform callus, less incidence of cylindrical callus.
*Conclusion* It was concluded that with nail, the callus underwent a more favorable progression and even longer lengthening could be allowed.

**Keywords** Tibial lengthening · Ilizarov · Nail · Pixel value ratio

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## Introduction

Ilizarov technique has been used widely in limb lengthening [1]. However, the long duration of external fixators has been notorious as a main contributor to complications. In order to reduce it, Paley and Herzenberg [2] developed the technique of combined use of intramedullary nail and external fixator, which allowed early removal of the fixator and rehabilitation. Comparative studies between lengthenings with and without nail were quite limited and mainly on the complications of each modality [2, 3]. Actually, callus progression is also a great concern to the surgeons during lengthening. However, no reports are currently available to characterize the impact of nail on callus progression. According to our opinion, the nail may pose effects on the callus progression in at least two ways: one, by providing the additional mechanical support to the regenerate; the other, constituting a negative aspect, is certain degree of jeopardization to the intramedullary circulation. Several classifications on the callus morphology have been proposed to describe the callus progression, among which the Ru Li's classification is distinguished for its detailed morphological characterization and the outcome-predictive ability [4]. As a more objective parameter, pixel value ratio (PVR), in our previous study has demonstrated the efficiency in describing the callus progression and easy to apply [5, 6]. We appreciated more and more strength of using PVR and the Ru Li's classification combined clinically.

We hereby hypothesize that the callus progression could be altered with the use of nail when compared with that without nail. And callus progression was compared between these two scenarios with reference to the parameter of PVR and the Ru Li's classification.

## Patients and methods

A total of 126 tibial lengthenings (78 patients) performed at our institution from 2004 to 2008 were included in the study. All patients were skeletally mature at the time of the procedure. They were non-smokers and were not on non-steroidal anti-inflammatory drug (NSAID) therapy. Patients with metabolic disorders, infection of callus were excluded.

The patients were grouped according to being lengthened with (Group A) or without (Group B) intramedullary nail. Treatment choice depended on the tibial morphology and socioeconomic status of the patients.

Group A had 70 tibiae (2 left, 4 right and 32 bilateral) in 38 patients (38 males) with an average age of 24 years (range17–52 years); Group B involved 56 tibiae (11 left, 13 right and 16 bilateral) in 40 patients (18 males, 22 females) with an average age of 28.6 years (range 16–52 years).

The disease spectrum is shown in Table 1.

### Operative techniques

All operations were performed by the same senior surgeon. All the tibiae were lengthened with Ilizarov hybrid fixators (U&I, Seoul, Korea). The common peroneal nerve was released prophylactically. The fixators were constructed in a similar way, i.e., three rings were mounted to the tibiae. The proximal and distal rings were secured to the tibia with wires plus Schanz screws in Group A (Fig. 1). In Group B, one or two Schanz screws were added to the middle ring to secure the alignment. Low energy osteotomy was carried out using multiple drill holes.

In Group A, an AO intramedullary unreamed nail with a diameter 1 or 1.5 mm narrower than the isthmus of tibiae was inserted without reaming so as to protect local blood supply after the osteotomy and locked proximally. Fibular corticotomy was done at the junction of middle and distal one-third.

For the tibiae with one center of rotation of angulation (CORA) in the proximal metaphysis the osteotomy was performed very near to the CORA (mostly distal to it because the CORA area was occupied by wire and Schanz screw). The angulation was gradually corrected while lengthening; for those with two CORAs, like in achondroplasia, bifocal osteotomy was performed. The proximal osteotomy was similar to the one CORA scenario whereas

**Table 1** Disease spectrum of patients in both groups

| Group A | | Group B | |
|---|---|---|---|
| Disease | Number of patients | Disease | Number of patients |
| LLD (polio) | 3 | LLD (polio) | 7 |
| LLD (hemiatrophy) | 2 | LLD (hemiatrophy) | 1 |
| Turner syndrome | 1 | Turner syndrome | 2 |
| Hypochondroplasia | 1 | Hypochondroplasia | 2 |
| ISS | 14 | ISS | 2 |
| LLD (algoneurodystrophy) | 1 | LLD (encephalomalacia) | 1 |
| FSS | 16 | LLD (osteochondomatosis) | 1 |
| | | LLD (postraumatic) | 5 |
| | | LLD (cerebral palsy) | 6 |
| | | LLD (idiopathic) | 1 |
| | | LLD (DDH) | 1 |
| | | Achondroplasia | 7 |
| | | Genu varum (idiopathic) | 2 |
| | | Gene valgum (posttraumatic) | 2 |
| Total | 38 (70 tibiae) | Total | 40 (56 tibiae) |

*LLD* leg length discrepancy, *ISS* idiopathic short statue, *FSS* familial short statue

**Fig. 1** The clinical picture of a patient in Group A

the distal osteotomy was performed very near to the distal CORA (usually proximal to it) and was not lengthened but the angulation was acutely corrected. Correspondingly, bifocal osteotomy was done to the fibulae at the same levels.

## After treatment

All the patients underwent supervised physiotherapy beginning 1 day after the operation during their stay in the hospital. This included active and passive stretching of joints for at least 2 h every day or more as tolerated. Whenever at rest or during sleep, a stirrup was used to maintain the feet at the neutral position (Fig. 1). The pin sites were cleaned with sterile saline and alcohol daily. Oral antibiotic were prescribed when early infection was detected.

The distraction was initiated at the rate of 0.25 mm, four times a day 7 days after corticotomy. Patients were followed at 2-week intervals during lengthening and 4-week intervals during consolidation. At each follow-up, the standard anterior-posterior (AP) and lateral radiographs of the tibiae were obtained with StarPACS, Infinitt, PiView STAR, 5.0.6.0 (INFINITT Co, Ltd, Seoul, Korea) and with Young's method to optimize the visualization of the regenerate [7]. When the desired length had been achieved, the intramedullary nails were interlocked with screws and the external fixators were removed. In the lengthenings without nail, the patients were allowed full weight-bearing when three cortices in the regenerate were visible radiographically, and in the lengthenings with nail, it was two cortices were visible radiographically [8].

If equinus deformity of feet developed and could not be corrected by physiotherapy alone, the patients were operated again (usually 3–4 months postoperatively when interlocking screws could be inserted simultaneously in Group A) by recession of gastrocnemius and soleus (Vulpius procedure). The feet then were kept in dorsiflexion with stirrup. If the correction was inadequate, another "U" shaped frame was applied to the feet for further gradual correction. In this situation, the removal of external fixator was delayed until the equinus was completely corrected.

The complications encountered during operation and follow-up were also documented according to the Paley's classification [9]. A problem is defined as a complication that can be fully resolved by non-operative means at the end of the treatment. For example, the problem of pin-site infection indicates that the infection is cured by oral or intravenous administration of antibiotics before fixator removal; an obstacle is defined as a complication that is fully resolved by operative means at the end of the treatment. For example, an equinus deformity that is corrected by intramuscular recession or foot frame application before fixator removal; a sequela is defined as a complication that remains unresolved or recurs after the end of the treatment. For example, an equinus deformity that remains unresolved or recurred after fixator removal.

## Measurement of pixel value and PVR

The cortex of the host bone and the regenerate were divided as medial and lateral aspects on the AP radiograph, and anterior and posterior aspects on the lateral radiograph. The range of interest (ROI) was defined before the measurement of pixel value. Three ROIs were delineated on the regenerate, proximal and distal host bone on each aspect of the

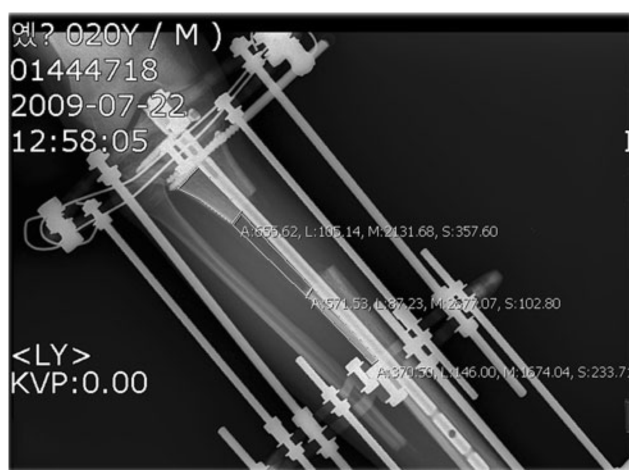


**Fig. 2** Delineation of ROIs of regenerate and the adjacent host bone. The mean pixel value was shown automatically by the pixel lens on the tool panel (marked with "M")

tibiae. The ROI of the proximal segment was defined as the area from proximal Schanz screw or ring (the one encountered first) to the proximal border of regenerate; the ROI of distal segment was defined as the area from the distal border of the regenerate to the middle ring or the Schanz screw

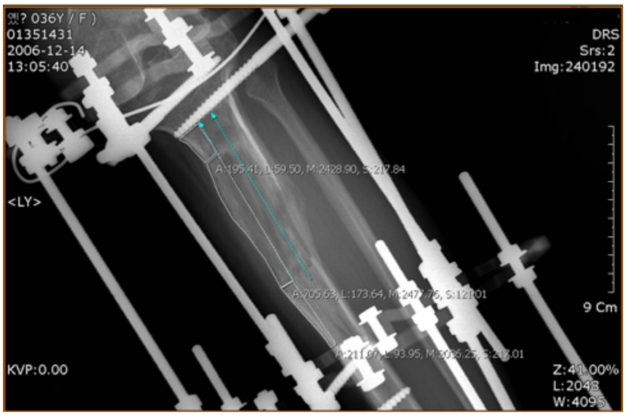


**Fig. 3** In Group B, an intramedullary nail was supposed in existence (marked with *two blue lines in the middle*), and the three ROIs were delineated in the same pattern with those in the group with nail

attached to the middle ring (the one encountered first) (Fig. 2). The pixel value could be demonstrated by the tool of pixel lens on the tool panel of PiView STAR (Fig. 2).

In order to evolve a consistent measurement modality, in Group B, measurements were performed in the peripheral area as in Group A as if an imaginary nail was in place (leaving a vacancy of 8 mm wide in the intramedullary canal) (Fig. 3). For those lengthenings where bone grafting was performed, only those callus before the bone grafting was measured because the grafting could definitely alter the pixel value significantly.

Pixel value ratio was calculated according to the following formula:PVR = (pixel value of proximal host bone + pixel value of distal host bone)/2/pixel value of the regenerate.

## Morphological description of callus

The Ru Li's classification [4] was used to evaluate the regenerate morphologically. The callus pathways and shapes outlined in this classification, which had been described in detail [8, 10], were documented for each radiograph. The described callus pathways are sparse, homoge-

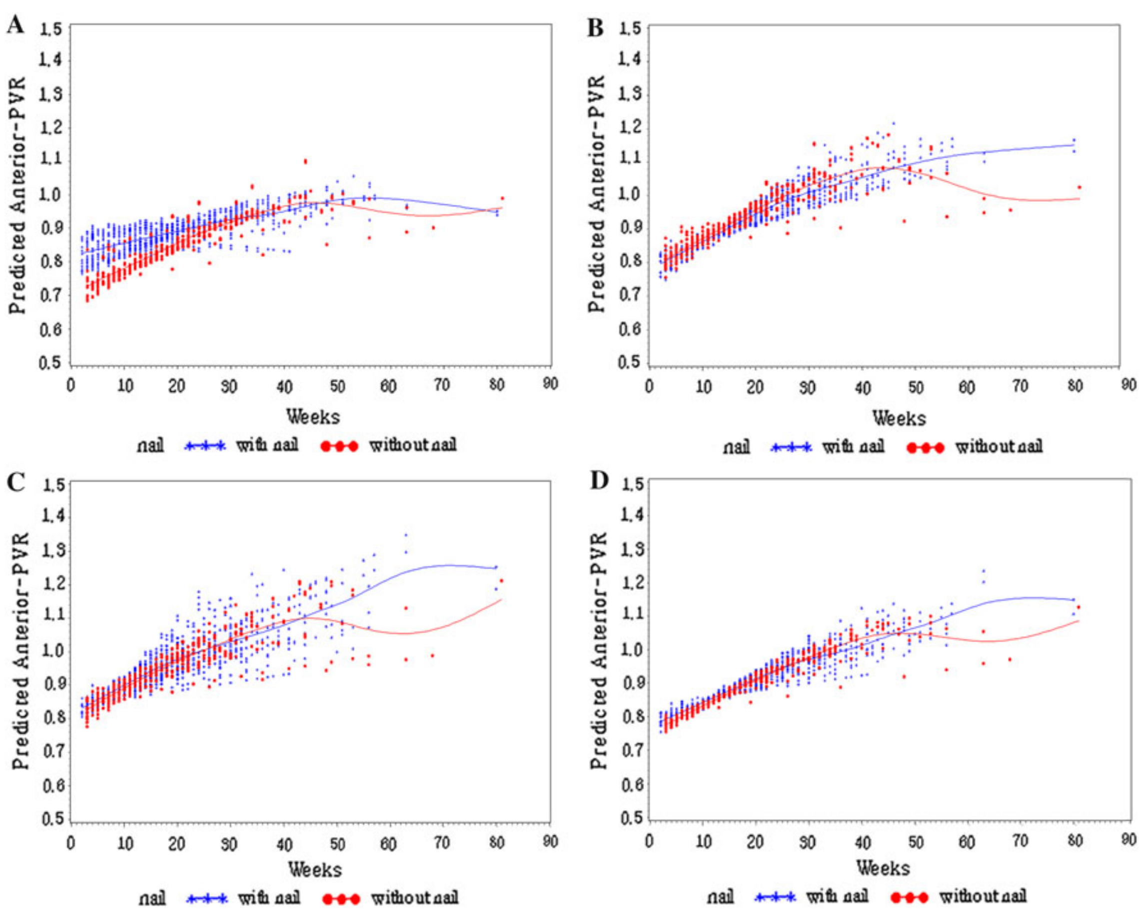


**Fig. 4** PVR variation over time in the four aspects of callus. **a** PVR was averagely lower in the Group B than that in Group A (exact significance was 0.0249) in the anterior aspect; **b**, **c** and **d** PVR was not different between the two groups in the posterior, lateral and medial aspects of callus

neous, heterogeneous and lucent and the callus shapes are fusiform, cylindrical, concave, lateral and central.

The following parameters were also documented: (1) the external fixator index (EFI) that was calculated as the duration of external fixator divided by the total gain in length(month/cm); (2)the healing index that was calculated as the duration needed for two aspects in Group A (three aspects in Group B) to reach PVR of 1.0 divided by the total gain in length (month/cm); (3) the incidence of various pathways and shapes in anterior, posterior, lateral and medial aspects of the callus in each group, it was calculated as the number of occurrence of a specific pathway and callus divided by the number of tibiae observed.

### Statistics

With SAS statistical package (Version 9.2, SAS Institute Inc., Cary, NC, USA), we fitted the mixed model to compare the trend of PVR variation as to the anterior, posterior, lateral and medial aspects of the callus, respectively, between the two groups and the significant test level was set as 0.05; we conducted the Fisher's exact test to analyze the difference in the incidence of various callus pathways and callus shapes in each aspect between the two groups and the significant test level was also set as 0.05.

## Results

In anterior aspect of the callus in Group B, PVR was averagely lower over time than that in Group A ($P < 0.001$) (Fig. 4a), but not different in posterior, lateral and medial aspects of the callus in Group B compared with those in Group A ($P > 0.05$) (Fig. 4b–d).

In Group A, the mean gain in length was $76.5 \pm 15.9$ mm, the mean duration of external fixator was $34.4 \pm 13.1$ weeks, the mean EFI was $1.1 \pm 0.5$ month/cm and the mean healing index was $1.5 \pm 0.5$ month/cm. In Group B, the mean gain in length was $54.8 \pm 26.1$ mm, the mean duration of external fixator was $33.2 \pm 13.6$ weeks, the mean EFI was $1.7 \pm 1.4$ month/cm and the mean healing index was $1.8 \pm 1.4$ month/cm.

Two hundred and ten complications occurred in Group A with mean incidence of 3.0 per segment; 190 complications occurred in Group B with mean incidence of 3.4 per segment and corresponding management was carried out (Table 2).

Group B presented significantly different pathways in the four aspects compared with Group A, i.e., less incidence of homogeneous pathway, greater incidence of heterogeneous pathway (Table 3); as to the callus shape, Group B presented greater incidence of fusiform callus, less incidence of cylindrical callus (Table 4).

**Table 2** Complications encountered and the management during operation and follow-up in both groups

| Complications (management) | Group A (70 tibiae) | Group B (56 tibiae) |
|---|---|---|
| Problems | | |
| Pin-site infection (antibiotics) | 24/70 | 20/56 |
| Knee contracture (physical therapy) | 15/70 | 10/56 |
| Obstacles | | |
| Pin-site infection (debridement plus antibiotics) | 6/70 | 0/70 |
| Equinus (Vulpius procedure or foot frame application for distraction) | 46/70 | 23/50 |
| Prophylactic nerve release (as routine) | 70/70 | 56/56 |
| Delayed consolidation (bone marrow, platelet-rich plasm injection or bone grafting) | 23/70 | 6/56 |
| Knee contracture (intramuscular recession of hamstring muscles, or with distraction with Ilizarov technique) | 3/70 | 1/56 |
| Axial deviation (adjust the external fixator to realign the fragments) | 10/70 | 18/56 |
| Nail impingement (change wires, realign the fragments) | 1/70 | 0/56 |
| Premature consolidation (reosteotomy and distraction) | 0/70 | 1/56 |
| Sequelae | | |
| Pin-site infection (debridement and antibiotics) | 1/70 | 0/70 |
| Equinus (Vulpius procedure) | 7/70 | 0/70 |
| Delayed consolidation (bone marrow, platelet-rich plasm injection or bone grafting) | 1/70 | 2/56 |
| Axial deviation (reosteotomy and fixation) | 1/70 | 11/56 |
| Tibiofibula subluxation (no treatment) | 2/70 | 1/56 |
| Callus subsidence (reosteotomy and distraction if marked length discrepancy exists) | 0/70 | 30/56 |
| Total | 210/70 | 190/56 |

**Table 3** Incidence of callus pathways in both groups

| Aspects | Callus pathways | Group A (70 tibiae) | Group B (56 tibiae) |
|---|---|---|---|
| Anterior | Homogeneous | 61/70*(1) | 26/56 |
| | Heterogeneous | 8/70*(2) | 23/56 |
| | Lucent | 1/70 | 5/56 |
| | Sparse | 0/70 | 2/56 |
| Posterior | Homogeneous | 68/70*(3) | 36/56 |
| | Heterogeneous | 1/70*(4) | 15/56 |
| | Lucent | 1/70 | 5/56 |
| | Sparse | 0/70 | 0/56 |
| Lateral | Homogeneous | 69/70*(5) | 38/56 |
| | Heterogeneous | 0/70*(6) | 13/56 |
| | Lucent | 1/70 | 5/56 |
| | Sparse | 0/70 | 0/56 |
| Medial | Homogeneous | 60/70*(7) | 30/56 |
| | Heterogeneous | 10/70*(8) | 21/56 |
| | Lucent | 0/70*(9) | 5/56 |
| | Sparse | 0/70 | 0/56 |

* The incidence of a specific callus pathway in Group A is statistically different from the counterpart in Group B

(1), (2), (3), (4), (5), (6), (7), (8) $p < 0.001$; (9) $p = 0.016$

**Table 4** Incidence of callus shapes in both groups

| Aspects | Callus shapes | Group A (70 tibiae) | Group B (56 tibiae) |
|---|---|---|---|
| Anterior | Fusiform | 0/70*(1) | 5/56 |
| | Cylindrical | 54/70 | 41/56 |
| | Central | 0/70 | 1/56 |
| | Lateral | 2/70 | 3/56 |
| | Concave | 14/70 | 6/56 |
| Posterior | Fusiform | 2/70*(2) | 10/56 |
| | Cylindrical | 68/70*(3) | 44/56 |
| | Central | 0/70 | 0/56 |
| | Lateral | 0/70 | 1/56 |
| | Concave | 0/70 | 1/56 |
| Lateral | Fusiform | 2/70*(4) | 11/56 |
| | Cylindrical | 68/70*(5) | 44/56 |
| | Central | 0/70 | 0/56 |
| | Lateral | 0/70 | 0/56 |
| | Concave | 0/70 | 1/56 |
| Medial | Fusiform | 1/70*(6) | 8/56 |
| | Cylindrical | 57/70 | 44/56 |
| | Central | 0/70 | 0/56 |
| | Lateral | 2/70 | 2/56 |
| | Concave | 10/70*(7) | 2/56 |

* The incidence of a specific callus shape in the Group A is statistically different from the counterpart in Group B

(1) $p = 0.016$; (2) $p = 0.004$; (3) $p = 0.001$; (4) $p = 0.002$; (5) $p = 0.001$; (6) $p = 0.010$; (7) $p = 0.042$

## Discussion

Callus progression is of paramount importance during limb lengthening. It influences two key decision making steps: how to distract the callus and when to remove the fixator.

The Ru Li's classification assumes great significance in indicating of callus progression, potential problems and prompt intervention [4]. Usually, the homogeneous pathway indicates a good prognosis. Other pathways, heterogeneous, sparse and lucent pathways are inclined to have a fair or even poor prognosis [11]. These may require surgeons to slow down the lengthening or even apply compression. Our previous study also concluded this point consistently [10]. In this study, the callus was divided into four aspects to increase accuracy of description.

The findings confirmed our hypothesis that callus progression was positively altered with use of the nail. Since the intramedullary circulation has long been emphasized by Ilizarov [1], a major concern was the jeopardization of local blood supply by nail application. Seemingly, the unreamed nail does not influence it to the extent that callus was compromised.

Similar construction of the Ilizarov fixators is an important premise to perform such a comparative study. A particular configuration of external fixator could result in distinct inter-fragmentary motion (IFM) of the fracture and force distribution [12–14]. In this study, all the tibiae were applied with fixator of Ilizarov hybrid type in a similar way. The additional use of nail in Group A could significantly increase axial stiffness of the whole structure [15] and accordingly IFM could be altered under such an improved mechanical climate. Hence the callus progression manifested differently, i.e., greater incidence of homogeneous callus pathway in Group A. Even the callus classified as homogeneous pathway in Group B was actually less homogeneous than that in Group A (Fig. 5).

The advantage of using nail could be even more prominent with consideration that the lengthening amount is usually greater in Group A compared with that in Group B (76.5 vs. 54.8 mm), and greater elongation did not compromise callus progression (Fig. 6). However, in our previous lengthenings without nail, longer lengthenings involved more compromised callus [10].

Multiple studies have supported the rationale of using PVR to reflect the mechanical characteristics in the following logistical sequence: first the mineral matrix of the regenerate closely correlates the bending rigidity of the callus [16]; secondly, a linear relationship has been revealed between the mineral matrix density and PVR [6]. Additionally, in our previous clinical study, PVR has also been

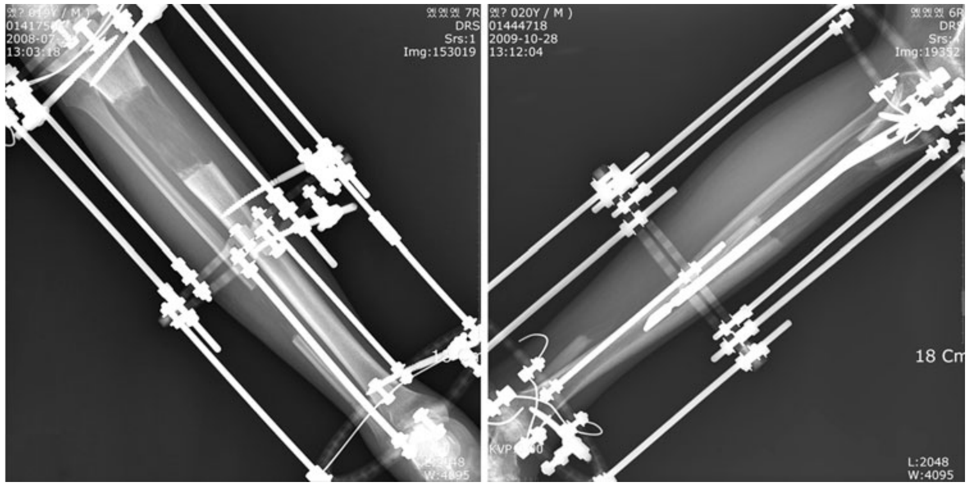


**Fig. 5** Even though the callus in both groups could be classified as homogeneous, the callus in Group B was actually less homogeneous than that in Group A

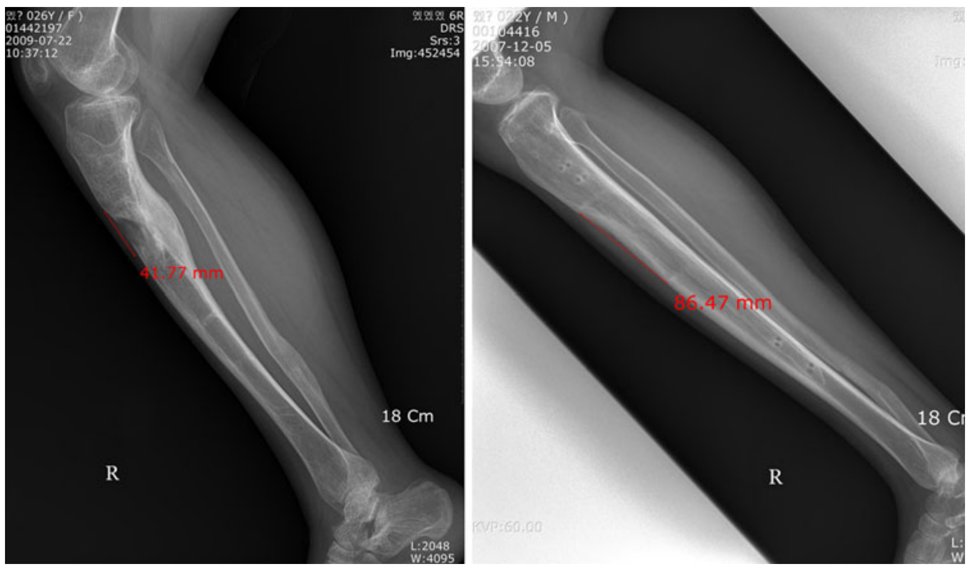


**Fig. 6** Even though lengthening amount is greater in Group A (*right*, 86 mm) than that in Group B (*left*, 42 mm), the callus presented better profile in Group A (little bit concave but homogeneous pathway for the anterior aspect) compared with that in Group B (concave and lucent pathway for the anterior aspect)

tested as a reliable parameter to reflect the maturity progression of callus [8]. It not only demonstrated the different progression rates on the lateral, posterior, medial and anterior aspects of the callus but also suggested a time frame to remove the external fixator safely. PVR also possesses an advantage of being highly objective. The main error of PVR measurement lies in the delineation of ROI but it could be diminished significantly with strict rules established (see patients and methods) [3, 8, 17].

We adopted the same measurement modality in Group B with Group A. Delineation of ROIs in Group B was made on the peripheral area with a imaginary nail in the center (Fig. 3). This was done so as to minimize the systematic error because the measurements could be uncomparable and distorted by disproportional involvement of the medullary part of the tibia.

This study is limited by its retrospective nature and the heterogeneity of cases. Group A was mainly patients of ISS and FSS, however, Group B included more patients of achondroplasia. It is a reasonable concern that pathogenesis of achondroplasia, i.e., point-mutated fibroblast growth factor receptor 3 (FGFR3) resulting in accelerated chondrocytic apoptosis, could retard the callus maturity. However, the following evidence may relieve the concern to some extent: (1) according to our observation and other studies, in those cases of achondroplasia, the callus maturity progress during fracture healing is not delayed compared with normal individuals [10, 18]; (2) the intramembarous ossification in the callus during lengthening absolutely predominates over the endochondral ossification [19], and lack of FGFR3 mainly influences adversely the endochondral ossification. This is also reflected by the fact that long bones in achondroplasia presented significantly short in length (endochondral ossification by growth plate) but relatively normal transverse width (intramembarous ossification by periosteum).

The infected cases were excluded in this study because pathology related to the infection could alter the bone density. The temporal demarcation actually could not be readily given because the infection might be occult early and last for a period of time. In our series, the deep infection rate was around 2% in the lengthenings without nail and 7% in those with nail. For them, we removed the nail and applied local and general antibiotics until the infection was distinguished. Bony reconstruction ensued. In other studies, the nail-related deep infection rate was 3–15% [2, 20].

Overall, use of nail could make the callus progression in a more favorable way, particularly in the vulnerable anterior aspect, and allow even greater elongation clinically.

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**Conflict of interest** Each author certifies that he or she has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article.

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