The results of limb lengthening by callus distraction using an extending intramedullary nail (Fitbone) in non-traumatic disorders

S. Singh, A. Lahiri, M. Iqbal

From Tan Tock Seng Hospital, Singapore

Limb lengthening by callus distraction and external fixation has a high rate of complications. We describe our experience using an intramedullary nail (Fitbone) which contains a motorised and programmable sliding mechanism for limb lengthening and bone transport. Between 2001 and 2004 we lengthened 13 femora and 11 tibiae in ten patients (seven men and three women) with a mean age of 32 years (21 to 47) using this nail. The indications for operation were short stature in six patients and developmental or acquired disorders in the rest.

The mean lengthening achieved was 40 mm (27 to 60). The mean length of stay in hospital was seven days (5 to 9). The mean healing index was 35 days/cm (18.8 to 70.9). There were no cases of implant-related infection or malunion.

Distraction osteogenesis is an established treatment for managing orthopaedic limb deformity and can be attributed to the work of Ilizarov. The three main principles are gradual rhythmic distraction, the use of a ring fixator to produce the distraction force and the preservation of the blood supply by means of a low-energy corticotomy.

Nevertheless, the method is not without complications, the most common of which is pin-track infection, followed by pain during limb lengthening, possible neurovascular damage, muscle contracture after pin or wire transfixation, loss of appetite, depression, joint stiffness, damage to the articular cartilage, recurrent deformity and osteoporotic stress fracture after removal of the external fixator.

There are two main methods for avoiding these complications, namely early removal of the external fixator, or no external fixation. However, the potential consequences of the spread of pin-track infection to the intramedullary canal on exchange of a frame for an intramedullary nail are severe. The combination of an unreamed intramedullary nail and unilateral external fixation has been shown to be associated with a prolonged consolidation index compared with the use of a simple external fixator system, and may be associated with fatigue fracture of the intramedullary nail.

Intramedullary lengthening without the use of external fixation was described by Baumgart, Betz and Schweiberer. Good clinical outcomes have been reported for intrinsically-driven self-lengthening nails. The mechanical forces required to achieve distraction osteogenesis along these nails are generated by the patient’s limb movements. Additionally, electrically-driven intramedullary lengthening nails are available, with a motorised sliding mechanism powered by an internal electrical supply. These offer precise and physically less demanding lengthening. The motorised gear can be easily activated by the push of a button on a portable transmitter.

The successful use of the Fitbone motorised intramedullary nail (Wittenstein Igersheim, Germany) was reported in 12 femoral lengthenings in 1997. We describe our early clinical experience with this device and our modification of the surgical technique.

Patients and Methods

A retrospective study was performed of ten patients in whom the Fitbone nail had been used between 2001 and 2004. There were seven men and three women with a mean age of 32 years (21 to 47). The mean follow-up was 3 years (1 to 4). Lengthening of the femur or tibia or both was undertaken. We used a total of 24 Fitbone nails, 13 femoral and 11 tibial. The indication for surgery in six patients was constitutional short stature and, in the remainder, developmental problems such as congenital fibular hemimelia with shortening of 5 cm, Perthes’ disease with shortening of 4 cm, poliomyelitis with shortening of 4.5 cm.
and congenital hypoplasia of the femur with shortening of 4 cm. For the patients with constitutional short stature the desired gain in height was between 5 cm and 9 cm. The mean pre-operative height for the constitutional short stature group was 163 cm (162 to 165) for men and 154 cm (152 to 155) for women. All patients in the group with constitutional short stature underwent a pre-operative psychological assessment. Details of the patients are given in Table I.

### Design of the nail

The Fitbone is a fully implantable, motorised intramedullary nail for limb lengthening and bone transport which can be precisely extended through a gear-and-spindle mechanism. The proximal and distal ends of the nail are secured to the bone by interlocking screws during extension of the nail to produce distraction of the bone without rotational deformity. It is available in two versions. The Fitbone Slide Active Actuator has a slide hole and external diameter of 13 mm allowing lengthening of up to 85 mm and bone transport of up to 200 mm. The Fitbone Telescopic Active Actuator is a telescopic version with a diameter of 10 mm in the shaft and 12 mm near the knee joint. There is a straight version in situ and/or proximal tibia close to the metaphysis.

### Pre-operative planning

The size of the nail required and the level of the osteotomy are established for each patient. Selection of the nail is based on the length of the bone, the diameter of the medullary canal and the site of the osteotomy. The length of the limb is accurately measured by CT teleoentgenography. The entry point of the intramedullary nail is carefully determined to accommodate the straight bone without rotational deformity. The nail is left in situ until the regenerated bone consolidates.

### Operative technique

Under general anaesthesia the patient is placed in the supine position. A tourniquet is used when implanting a tibial nail, but deflated during reaming of the intramedullary canal. The image intensifier is used to transcribe the pre-operative radiological measurement of the nail template and planned level of the osteotomy on to the patient’s limb, using skin staples to mark the level of the joint line, the site of the osteotomy and length of the proposed nail on the patient’s leg. A longitudinal incision of 3 cm is made just above the tip of the greater trochanter for the antegrade approach. A transverse incision of 2 cm just below the inferior pole of the patella is used for retrograde femoral or tibial insertion. The osteotomy is performed using an intramedullary saw at the level of the distal femur and/or proximal tibia close to the metaphysis.

The femoral and tibial nails are introduced after over-reaming by 1.5 mm or 1 mm, respectively. Fitbone instrumentation uses straight rotary reamers in increments of 0.5 mm to expand the intramedullary canal for the passage of the nail after the osteotomy. The osteotomy is carried out early in the procedure and the reaming is gradual to reduce the risk of fat embolisation.
Post-operative care. Drains are removed on the second post-operative day. Daily distraction of 1 mm is begun on the third post-operative day for the femur and on the fifth post-operative day for the tibia. Weight-bearing of up to 20% of the patient's body-weight is started during the distraction phase. The patient is taught to control the distraction using the transmitter. Aggressive physiotherapy such as quadriiceps, hamstring and tendo Achillis strengthening is required. Progression to full weight-bearing is delayed until consolidation is observed radiologically. Radiographs are obtained every two weeks until the formation of callus is seen. The extent of the lengthening is confirmed by radiographs and CT. The duration from osteotomy to full healing, defined as the ability to bear full weight, is recorded. From these results the healing index (time to full union divided by the obtained lengthening) is calculated in days per centimetre.

Results

Our ten patients received a total of 24 nails. Two (cases 2 and 6) each had four nails implanted during one operation. Another (case 3) had bilateral femoral lengthening followed by bilateral tibial lengthening at an interval of six months. The mean operating time was 144 minutes per nail (range 165 to 630). No intra-operative problems or complications occurred.

Post-operatively, the mean length of stay in hospital was seven days (5 to 9). The mean lengthening was 40 mm per nail (27 to 60). The mean total increase in height in patients with constitutional short stature was 56.9 mm (40 to 95). Extension of the nail was achieved without difficulty in all except two patients (cases 2 and 6) in whom it would not advance beyond 32 mm and 27 mm, respectively. The mechanical axes of the limbs were preserved. There was no angular deformity in any patient.

Full weight-bearing was resumed after a mean of eight months (8 to 12). This depended on the number of nails used. The mean healing time (time between operation and full weight-bearing) per nail was 241 days (136 to 358). The mean healing index was 35 days/cm (18.8 to 70.9) which was comparable with that of other studies.¹ The results are summarised in Table I.

Complications. No patient developed a local infection. One (case 6) had a delayed union for which bone grafting and exchange to a larger nail to achieve the desired distraction degree of lengthening was performed. Another (case 9) had bilateral tibial cancellous bone grafting with bone obtained from the iliac crest. There were two nails (both in patients with congenital abnormalities; cases 4 and 10) which had to be exchanged for stronger and larger nails as the internal gears were not powerful enough for distraction. No problems were experienced with the subcutaneous antenna or the connecting wire to the motor.

The anticipated lengthening was achieved in all except two patients (cases 2 and 6). All patients reported that they were satisfied with their outcome.

There were two patients who had restricted knee movement, most marked after the femoral lengthening but they regained a full range of movement after one year. Also some tightness of the fascia lata occurred with femoral lengthening but settled with physiotherapy. In tibial lengthenings some initial restriction in the range of movement occurred but resolved fully after physiotherapy. No patient required release of either the hamstrings or tendo Achillis. Other minor complications included scar adhesion in two patients, failure of distal fibular migration with tibial lengthening by 8 mm in one patient and limb-length discrepancy of 10 mm after lengthening for constitutional short stature in one patient.

Discussion

Lengthening of a limb by distraction callotasis using an external fixator is a widely accepted technique.³ It is not without complication³⁻⁵ and the long period with the external fixator in place delays rehabilitation and interferes with normal daily activities.

Using the Ilizarov method³ for cosmetic limb lengthening of bilateral tibiae, Catagni et al⁶ had higher complication rates including superficial pin-track infections, angular deformity, requirement for lengthening of the tendo Achillis, nonunion of the corticotomy requiring bone grafting, and collapse of the regenerated bone. The external fixators were retained for over nine months followed by the use of a fibreglass cast or a brace for six weeks. The Fitbone method can be used for either tibial or femoral lengthening and interferes less with activities of daily living.

Lengthening over a nail, or a combination of intramedullary nailing with temporary external fixation, may reduce the duration of external fixation and the risk of infection, but there is still a risk although reduced, of joint stiffness.¹¹

The main advantages of intramedullary lengthening are the reduced risk of joint stiffness, infection and pain. Greater comfort and tolerance have been reported.¹⁰ Several intramedullary nail systems are available for this purpose. Two of these using Bliskunov (Medical Centre Bonamed, Kiev, Ukraine) and the Albizzia nails (DePuy Australia Pty Ltd, Mount Waverly, Australia), require considerable movement at the hip to initiate lengthening. Pain has been reported during rotational movements for lengthening using the Albizzia nail.⁹ The intramedullary skeletal kinetic distractor nail-lengthening system is better tolerated because less rotation is required to obtain lengthening.¹⁰ However, the main disadvantage is that lengthening proceeds in a relatively uncontrolled manner.

In contrast, the Fitbone nail with its implantable motorised drive lengthens only when it is activated via the antenna. It is possible to control the rate of distraction to minimise pain and to obtain the best callus response. The Fitbone system was well tolerated. There was minimal or no pain on lengthening and no case of infection. All patients achieved their lengthening goal except for two who had femoral lengthening, one of whom required an exchange to a larger nail to achieve the desired distraction length.
All patients with femoral lengthening achieved bony consolidation (Figs 1 and 2). Two with tibial lengthening required supplementary bone grafting. It is recommended that distraction of the tibia takes place at a slower rate of 0.5 mm to 0.75 mm per day in order to aid formation of callus. Recently, Baumgart et al.\textsuperscript{12} published a case report of simultaneous femoral and tibial lengthenings using the Fitbone technique for a patient with Ollier’s disease as the first part of staged treatment to correct a leg-length discrepancy of 17.4 cm.
Lengthening for short stature in certain countries using external fixation is becoming increasingly popular. However, this can result in significant long-term complications. \(^{13}\) Internal limb lengthening using the Fitbone technique is a viable alternative for patients who seek this procedure after careful psychological screening and preoperative counselling. Nevertheless, limb lengthening using the Fitbone system should only be performed by a surgeon who is familiar with the principles of callus distraction.

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References