

Femoral lengthening with a motorized intramedullary nail

A matched-pair comparison with external ring fixator lengthening in 30 cases

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Purpose — We assessed whether an intramedullary lengthening device would reduce the problems normally associated with the external fixation technique. We also wanted to determine whether it is a reliable construct for limb lengthening and deformity correction in the femur.

Patients and methods — We conducted a matched-pair comparison of 30 femoral lengthenings, 15 with a motorized intramedullary nail (the nail group) and 15 lengthenings with an external ring fixator (the fixator group). The patients were matched based on age, sex, amount of lengthening, and the etiology of leg length discrepancy. Mean lengthening was 35 (25–55) mm in the nail group and 38 (15–75) mm in the fixator group. Outcome measures were: lengthening and alignment achieved, consolidation index, knee range of motion (ROM), and complications.

Results — The pairs in this matched-pair study were similar in terms of age, sex, diagnosis, and amount of lengthening. The planned amount of lengthening was achieved in all patients in both groups and axis correction was considered sufficient. The mean radiographic consolidation index in the nail group, at 1.5 (0.9–3.0) months/cm, was better than the mean value for the fixator group (1.9 (0.9–3.4) months/cm) ($p = 0.01$). Knee ROM was better in the nail group during the lengthening, 6 weeks after lengthening was completed, and 6 months after lengthening was completed ($p < 0.001$). A larger number of complications were observed in the fixator group than in the nail group.

Interpretation — A lengthening nail may be superior to external fixation in femoral lengthening, when the anatomical conditions and the complexity of the deformity allow the use of an intramedullary nail.

Distraction osteogenesis is most often performed using an external fixator (Ilizarov and Trokhova 1973, Ilizarov 1997), which is associated with certain disadvantages such as pin-tract infections, reduced range of motion (ROM) in adjacent joints, risk of fracture after frame removal, and a lack of tolerance by the patients—especially in femoral lengthenings with ring fixators (Paley 1990, Faber et al. 1991). In order to reduce the time in the external fixator, several techniques with early removal of the frame have been developed, including lengthening over a nail (Bost and Larsen 1956, Paley et al. 1997), lengthening and then nailing (Faber et al. 1991, Rozbruch et al. 2008), and lengthening and then plating (Harbacheuski et al. 2012).

Further progress has been made by the development of mechanical intramedullary lengthening devices (Guichet 1999, Cole et al. 2001) and motorized intramedullary lengthening devices (Betz et al. 1990, Baumgart et al. 1997). Lengthening with a fully implantable motorized and remote-controlled intramedullary nail is a new method. We assessed whether the introduction of the intramedullary lengthening device has led to a reduction in the problems normally associated with the external fixation technique, and whether it is a reliable construct for limb lengthening and deformity correction in the femur.

Patients and methods

We conducted a matched-pair comparison of 30 femoral lengthenings: 15 lengthenings with a motorized intramedullary nail (the nail group) and 15 lengthenings with an external ring fixator (the fixator group).

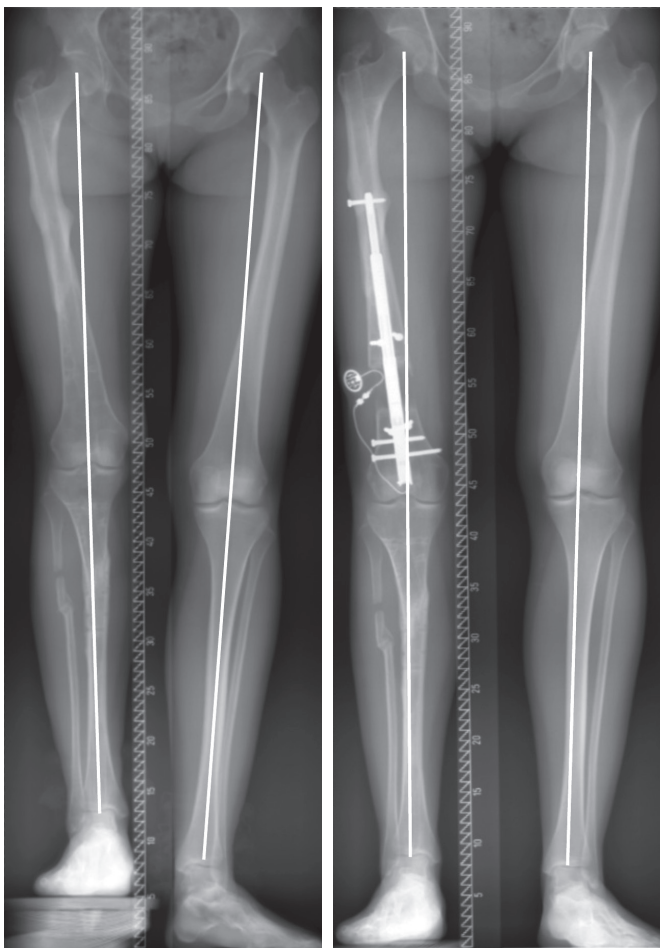


Figure 1. Femoral lengthening with a retrograde intramedullary nail (nail group: pair 6).

Nail group

We performed 15 femoral lengthenings with a motorized intramedullary nail (Fitbone) in 15 patients (9 men) between November 2011 and May 2013. These 15 consecutive cases were evaluated prospectively and were included in the present study. The mean age of the patients at the time of operation was 29 (15–61) years. The mean follow-up time after lengthening was completed was 18 (9–27) months. 10 patients had a posttraumatic shortening whereas 5 patients had a congenital condition. 8 patients had a pure shortening and 7 patients had a biplanar deformity.

The Fitbone device is a fully implantable, motorized intramedullary lengthening nail (Telescope Active Actuator; Wittenstein Intens GmbH, Igersheim, Germany). The system consists of the intramedullary lengthening nail connected to a subcutaneously placed receiver. The energy needed for the distraction process is transmitted from the outside by an external control unit and a transmitter, which is placed on the skin over the implanted receiver. Transmission of power activates the motor inside the nail. The motor delivers the torque, which

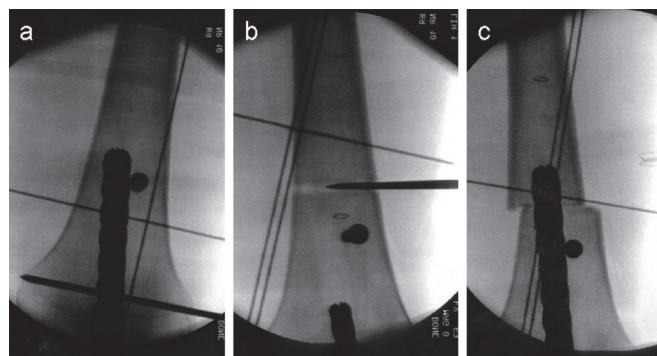


Figure 2. Intraoperative radiographs performed with the image intensifier. a. Reaming of the distal fragment according to the preoperative planning and placement of a blocking screw to allow for controlled axis correction after the osteotomy. b. Percutaneous osteotomy with a drill and osteotome. c. Angulation of the distal fragment and advancement of the straight and rigid reamers into the proximal fragment.

is transformed through a gear and spindle mechanism to an axial movement (Baumgart et al. 1997).

All the patients in the nail group were operated by retrograde technique (Figure 1). Preoperative planning and controlled intraoperative correction of malalignment and potential torsional deformities were done based on the reverse planning method, as described by Baumgart (2009). The “Baumgart method” includes reaming of the medullary canal in a preplanned way using rigid, straight reamers, and the use of blocking screws to guide the reamers intraoperatively and to maintain the acutely performed deformity correction, taking the subsequent lengthening process into consideration (Figures 2 and 3).

The osteotomies in this group were performed in a percutaneous manner with fan-shaped drilling using a 4-mm drill bit and completion of the osteotomy (corticotomy) with a 10-mm osteotome. Lengthening at a rate of 0.9 mm/day (3×0.3 mm/day) was initiated 8 days after surgery. The lengthening of the nail was performed by means of an external control unit, which was operated by the patient after receiving oral and written instructions. Weight bearing of up to 20 kg was permitted until bony consolidation. Full weight bearing was permitted when at least 3 cortices of the regenerate were consolidated on radiographic examination (Figure 4).

Fixator group

Between 2005 and 2012, we performed 68 femoral lengthenings (in 68 patients) with the Taylor Spatial Frame (TSF) external ring fixator. Based on our matching criteria, 15 patients (9 of them men) were selected for comparison with the nail group. The mean age of these 15 patients at the time of surgery was 27 (12–61) years. Mean follow-up after lengthening was completed was 39 (24–87) months. 10 patients had posttraumatic shortening, 1 patient had post-infectious shortening, and 3 patients had congenital shortening. 1 patient with short stature had been lengthened earlier on the contralateral

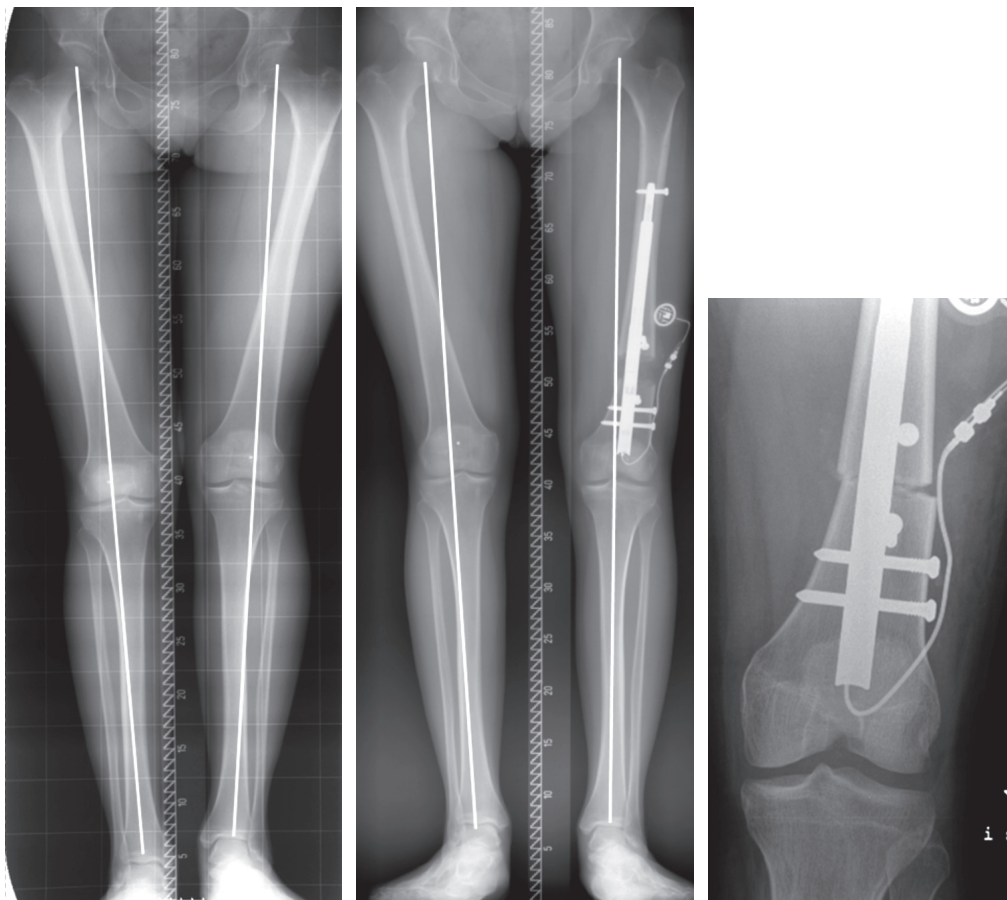


Figure 3. A patient in the nail group (pair 7). Preoperative deformity parameters included shortening and a slightly valgus deformity. Lengthening along the anatomical axis would have increased the valgus deformity. Intraoperative variation was necessary for axis correction and to achieve a perfect mechanical axis after lengthening was completed.

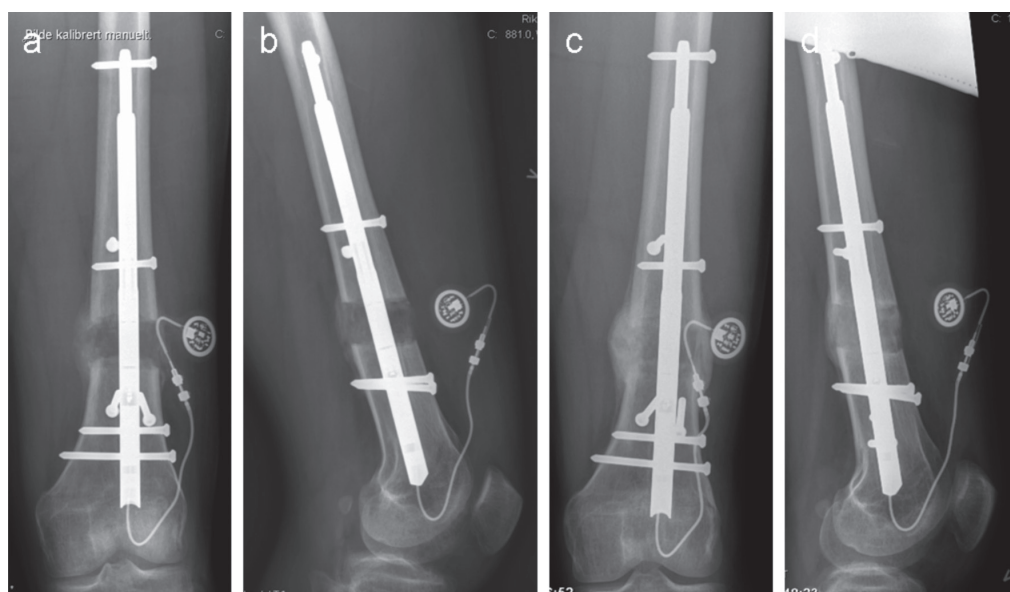


Figure 4. AP and lateral radiograph when lengthening was completed (panels a and b) and 6 weeks later (panels c and d) (nail group; pair 3).

side. In the fixator group, 1 patient had pure shortening whereas 8 patients had a biplanar deformity and 6 had a triplanar deformity.

The TSG is a circular external fixator, where the rings are attached to each other by 6 telescopic struts, creating a hexapod (Smith and Nephew, Memphis, TN). By varying the strut lengths, the relative orientation of the rings is changed and uniplanar or multiplanar deformities of length, angulation, translation, or rotation can be corrected (Taylor 2014).

In the fixator group, the frames were pre-constructed based on the “chronic” correction mode, which means that frames with specific strut lengths were built pre-operatively according to deformity parameters, limb size, and the planned mounting parameters. In cases of residual deformity at the end of lengthening, the “total residual” mode was used for further correction. After the frame was applied to the patient’s femur, an osteotomy was performed by the drilling and osteotome technique. Lengthening of 1 mm/day was initiated 8 days after surgery. Full weight bearing was permitted at any time during treatment with the TSG.

Matching and evaluation

The patients were matched based on age, sex, amount of lengthening, and the etiology of leg length discrepancy (Table 1). The matching was performed in the same way as described by Paley et al. (1997). A table was assembled for each group, including anonymous patient data on age, gender, amount of

Table 1. Patient data for the 15 matched pairs

Pair	Age, years		Sex		Lengthening, mm		Etiology of LLD	
	Nail	Fixator	Nail	Fixator	Nail	Fixator	Nail	Fixator
1	21	28	M	M	30	35	Posttraumatic	Posttraumatic
2	30	32	M	M	30	30	Posttraumatic	Posttraumatic
3	17	14	M	M	30	36	Posttraumatic	Posttraumatic
4	37	39	M	M	40	27	Idiopathic	Posttraumatic
5	61	61	M	M	25	30	Posttraumatic	Posttraumatic
6	26	20	F	F	50	30	Posttraumatic	Posttraumatic
7	26	22	F	F	30	25	Idiopathic	Hypoplasia
8	16	16	M	M	35	45	Cong. fem.def	Cong. fem.def
9	20	15	F	F	30	30	Posttraumatic	Seq. osteomyelitis
10	15	14	M	M	55	75	Posttraumatic	Posttraumatic
11	21	12	F	F	55	45	Posttraumatic	Posttraumatic
12	42	34	F	F	30	40	Clubfoot	Short stature
13	41	41	M	M	25	15	Posttraumatic	Posttraumatic
14	22	14	M	M	30	50	Cong.fem.def	Cong.fem.def
15	42	48	F	F	40	50	Posttraumatic	Posttraumatic
Mean	29	27			35	38		
range	15–61	12–61			25–55	15–75		

Cong. fem. def: congenital femoral deficiency.

lengthening, and diagnosis—blind to any results or complications related to any of these patients. Based on these tables, the best possible selection of matched pairs was made.

Outcome measures were: lengthening and alignment achieved, consolidation index, knee range of motion (ROM), and complications.

Long standing anterior-posterior and lateral radiographs from the pelvis to the feet were obtained on all patients preoperatively, at the end of lengthening, and at the latest follow-up. Deformity analysis was done based on the malalignment test and malorientation test, as described by Paley (2005). For this purpose, mechanical axis deviation (MAD), leg length discrepancy (LLD), mechanical lateral distal femoral angle (mLDFA), and medial proximal tibia angle (MPTA) were measured.

Radiographic consolidation of the regenerate was assumed when at least 3 of 4 cortices showed sufficient bone formation on AP and lateral radiographs. Consolidation time was defined as the time from the osteotomy to radiographic consolidation. At the endpoint “radiographic consolidation”, the frame was removed in the fixator group and full weight bearing was allowed in the nail group. Consolidation index was defined as the time from the osteotomy to radiographic consolidation divided by the lengthening distance achieved (in centimeters). Passiv ROM in the knee was evaluated for each patient preoperatively, during lengthening, 6 weeks after lengthening was completed, and 6 months after lengthening was completed. For this purpose, patients were assessed by physiotherapists and measurements were done with a goniometer. Complications were graded into problems, obstacles, and sequelae according to Paley et al. (1990, 1997).

Statistics

Statistical analyses were done based on the paired-samples

t-test and the Wilcoxon signed-rank test. Any p-values less than 0.05 were considered statistically significant.

Results

Matching

The mean pairwise age difference between the matched pairs was 4 (0–9) years. In 3 of these pairs, the nail patient had reached skeletal maturity (age 20–22 years) and the fixator patient had not (age 12–15 years). All pairs had the same sex and had the same diagnosis (n = 11) or a similar diagnosis (n = 4). The preoperative LLD was 39 (25–60) mm in the nail group and it was 40 (15–75) mm in the fixator group. The mean amount of lengthening achieved in

the nail group was 35 (25–55) mm and that in the fixator group was 38 (15–75) mm. The mean pairwise difference in lengthening achieved was 10 (0–20) mm. Mean follow-up was 39 (24–87) months in the fixator group and 18 (9–27) months in the nail group.

Surgical procedure

There were no intraoperative complications in either of the 2 groups, and none of the patients had any significant blood loss intraoperatively or postoperatively. Mean duration of surgery was 194 (120–330) min in the nail group and 95 (75–125) min in the fixator group (p < 0.001).

Lengthening and axis correction

The planned amount of lengthening was achieved in all patients in both groups. No loss of length was found during further follow-up. At the latest follow-up, 5 patients in the nail group had a residual LLD of ≥ 1 cm (mean 14 (10–20) mm) and 7 patients in the fixator group had a residual LLD of ≥ 1 cm (mean 11 (10–15) mm). None of these LLDs were caused by technical failure. In 4 patients in the nail group, the residual LLD was intended. 3 patients felt more comfortable with being somewhat shorter in the affected extremity. These 3 patients had had LLD over a long period of time without using shoe augmentation (nail group: pairs 2, 4, and 9). 1 patient in the nail group had stiffness in the ankle joint on the affected side due to clubfoot sequelae, and a residual LLD of 1.5 cm was intended (nail group: pair 14). 1 patient in the nail group (pair 10) had lengthening because of a complete growth plate injury in the distal femur with subsequent LLD. He showed more residual growth than expected on the contralateral side after lengthening was completed, resulting in an 18-mm LLD at maturity. Thus, 4 patients in the fixator group

Table 2. Deformity parameters preoperatively and at the latest follow-up for both groups

Pair	Leg length discrepancy, mm				Frontal plane alignment, degrees				Sagittal plane alignment, degrees			
	Nail		Fixator		Nail		Fixator		Nail		Fixator	
	Pre-op	FU	Pre-op	FU	Pre-op	FU	Pre-op	FU	Pre-op	FU	Pre-op	FU
1	30		30		4 valgus		8 valgus				10 rec	
2	40	10	30		4 valgus		7 valgus					
3	30		36	10								
4	60	20	27				13 varus		7 pro		10 pro	
5	25		40	10	16 varus		14 valgus	2 valgus				
6	50		50	10			3 varus	8 varus				
7	30		25		7 valgus		10 valgus	4 valgus				
8	30		45	10	4 valgus		5 valgus					
9	40	10	30				12 valgus					
10	55	18	75		3 varus		24 valgus	3 varus				
11	55		45	15	9 varus	5 varus	15 valgus	4 varus			15 rec	
12	30		50	10	6 varus	4 varus	5 valgus					
13	25		15		15 varus	3 varus	9 varus					
14	45	15	50	10	5 valgus		12 valgus					
15	40		50				7 varus		26 pro		23 rec	
Mean	39		40									
range	25–60		15–75									

Pre-op: preoperatively; FU: follow-up; pro: procurvatum; rec: recurvatum.

were lengthened before skeletal maturity. In 2 of these patients (fixator group: pairs 8 and 14), the underlying pathology of the affected extremity caused some recurrent LLD, and in the other 2 patients growth in the contralateral extremity after lengthening was completed was more than expected (fixator group: pairs 3 and 11). 3 patients in the fixator group (pairs 5, 6, and 12) did not fully gain the intended lengthening due to pain and/or contracture during lengthening. Axis correction was considered sufficient in both groups (Table 2, Figures 5 and 6); however, 4 patients in the nail group and 6 patients in the fixator group had minor residual deformities (Figures 7 and 8), whereas 1 patient in the nail group developed a procurvatum deformity during lengthening due to insufficient placement of blocking screws (Figure 8).

Consolidation index

The mean radiographic consolidation index in the nail group was 1.5 (0.9–3.0) months/cm, which was faster than in the fixator group (1.9 (0.9–3.4) months/cm; paired-samples t-test: $p = 0.01$; Wilcoxon signed-ranks test: $p = 0.04$).

Knee ROM

ROM in the knee on the affected side was similar between the matched pairs before treatment was initiated; however, it was statistically significantly better in the nail group during the lengthening, 6 weeks after lengthening was completed, and 6 months after lengthening was completed (Table 3).

In the nail group, almost all the patients had full extension and at least 90 degrees of knee flexion during the lengthening period. 6 weeks after lengthening was completed, almost all the patients with nail lengthening had regained full ROM (Figure 9). In the fixator group, knee ROM



Figure 5. A patient with a biplanar deformity (shortening and valgus) after physeal injury (fixator group: pair 10), which was corrected with the Taylor Spatial Frame.

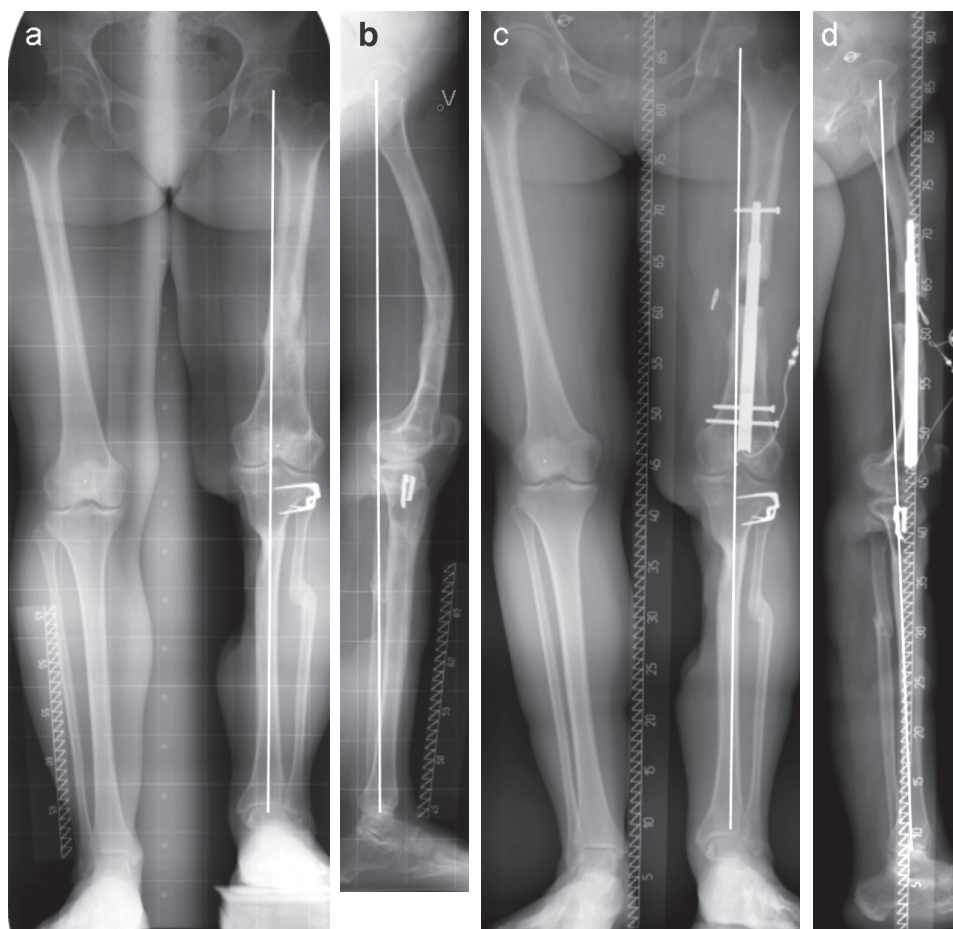


Figure 6. A patient in the nail group (pair 15) with postraumatic deformity including shortening and procurvatum.

during lengthening was statistically significantly reduced with a mean flexion ability of 26° (5–60). 6 months after frame removal, 6 patients still had less than 90 degrees of flexion. 5 of them required open surgery ($n = 3$) or closed mobilization of the knee ($n = 2$).

Complications

1 patient in the nail group had a superficial infection related to the antenna and 9 patients in the fixator group had pin-tract infections. All these infections resolved with oral antibiotics, and they were classified as problems according to Paley et al. (1990). 4 obstacles occurred in the nail group and 9 in the fixator group, and all had to be resolved operatively. Due to migration of locking screws, 3 patients had to be revised in the nail group and 1 patient was reoperated due to an insufficient connection of the subcutaneously placed receiver. In the fixator group, 1 patient sustained a fracture at the most proximal half-pin and was treated by extension of the frame. 2 patients in the fixator group wanted removal of the frame before consolidation due to discomfort, and the frames were converted to plate fixation, whereas 1 patient received autologous bone transplantation at the same time. 1 patient sustained a quadriceps tendon rupture

caused by a fall a few months after removal of the frame. The tendon was sutured and it healed without sequelae. 6 patients in the fixator group had substantially reduced ROM in the knee 6 months after removal of the frame; 2 of them improved with intensive physiotherapy and closed mobilization of the knee under general anesthesia, and 3 were operated with a Judet procedure (Judet et al. 1956). 1 patient developed a septic arthritis in the knee shortly after the Judet procedure, which was resolved by arthroscopic wash-out twice and intravenous antibiotics. 1 patient refused further surgery to improve knee ROM and had less than 90 degrees of flexion at the latest follow-up, which was considered to be a sequela.

Discussion

Controlled lengthening and axis correction could be achieved with both techniques, whereas the initial deformities were more complex in the external fixator group. The TSF external ring fixator showed a high

degree of accuracy in deformity correction and lengthening, which confirms the findings of other authors (Manner et al. 2007). Currently available lengthening nails are telescopic and allow pure lengthening. However, the present study and other investigations (Krieg et al. 2011, Al-Sayyad 2012) have shown that correction of existing axial and torsional malalignment and/or expected malalignment due to lengthening along the anatomical axis can be done intraoperatively, based on the reverse planning method as described by Baumgart (2009).

Consolidation of the regenerate was somewhat faster in the nail group. Earlier studies have shown faster healing of the regenerate—both in lengthening over a nail (Paley et al. 1997) and in lengthening and then nailing (Rozbruch et al. 2008)—than in external fixation. This indicates that the presence of an intramedullary device may be advantageous in terms of healing after lengthening compared to external fixation. However, Rozbruch et al. (2008) assumed that the reaming through the regenerate before insertion of an intramedullary nail may give enhanced bone healing. In a previous study, no difference in bone healing was observed when lengthening and then plating was compared with conventional external fixator lengthening (Harbacheuski et al. 2012).

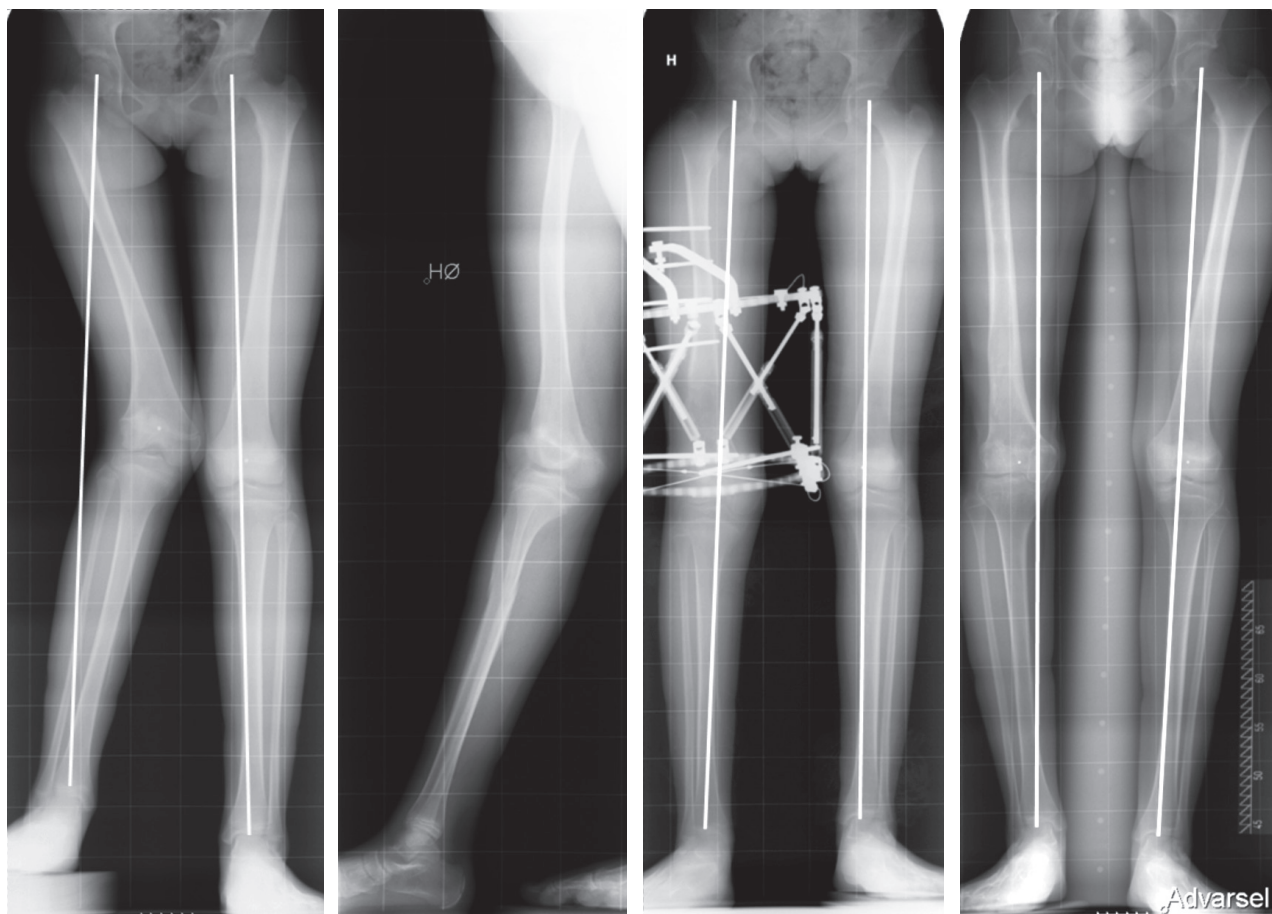


Figure 7. A patient with complex deformity after physeal injury (fixator group: pair 11). Initial deformity parameters included shortening, valgus and recurvatum deformity in the femur. The radiographs from latest follow-up (far right) show some overcorrection into varus deformity on the affected side.

We defined radiographic consolidation of the regenerate as the presence of 3 cortical columns. The endpoint “radiographic consolidation” allowed full weight bearing in the nail group and removal of the frame in the fixator group. With the intramedullary nail in place when full weight bearing is initiated, it provides load-sharing and protects the bone against fracture. For this reason, it can be assumed that full weight bearing in the nail group would be allowed earlier than removal of an external fixator after lengthening. Thus, the endpoints “radiographic consolidation” in the nail group and the external fixator group are not fully comparable.

The most important difference between the lengthening techniques was the rehabilitation of the patients in terms of knee ROM during lengthening and after lengthening was completed, which confirms the results of a similar study (Paley et al. 1997). In lengthening with an intramedullary nail, no transmuscular fixation is present, allowing early recovery of full ROM in the knee, whereas several patients in the fixator group required surgical procedures to reach at least 90 degrees of knee flexion. Our findings suggest that difficulties usually associated with the use of external fixation can be avoided when using a

motorized nail. 2 previous studies have compared conventional ring fixator lengthening with limb lengthening and then nailing (LATN), and with lengthening and then plating (LTP) (Rozbruch et al. 2008, Harbacheuski et al. 2012). In these studies, no difference was found in knee ROM between groups. However, values were only given for preoperative and postoperative ROM, and not over the course of treatment.

Fewer complications were observed in the nail group, whereas most complications in the fixator group were related to reduced knee ROM and the need for additional surgery. Surgical time was longer in the nail group. However, the lengthenings with a motorized nail that are included in this study were our first 15 consecutive cases. A learning curve can be expected, with a gradual reduction of surgical time. Nevertheless, it can be assumed that the surgical time for a retrograde femoral nail with intraoperative axis correction would still exceed the surgical time for an external fixator. Intraoperative axis correction can be demanding; reaming and placement of blocking screws must be done with care.

A limitation of the present study was that the lengthening nails might still have to be removed, and the matched-pair

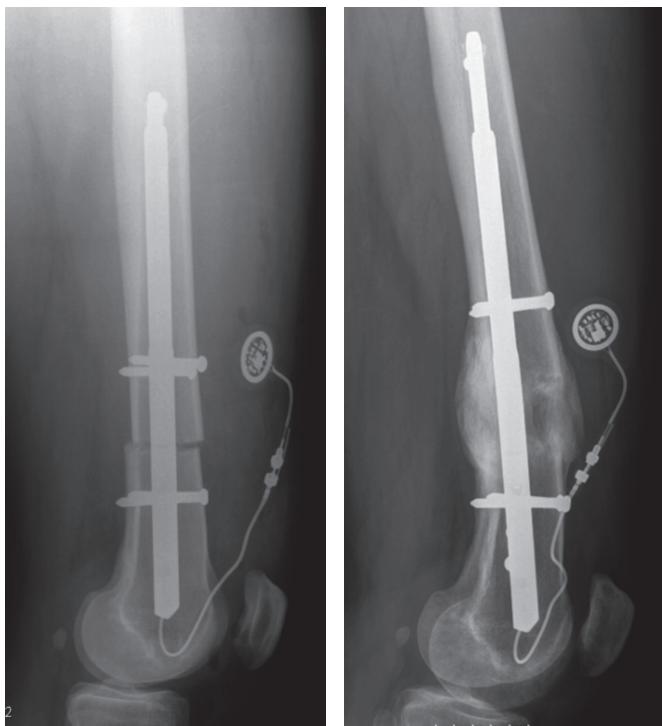


Figure 8. A patient in the nail group (pair 4) with a relatively spacious femoral canal. Procurvatum deformity occurred throughout the course of lengthening. The proximal fragment rotated at the plane of the single proximal locking screw. Blocking screws in the proximal fragment in the frontal plane should have been placed to avoid this angulation.

analysis does not include eventual problems that might occur during or after removal of the nails. Furthermore, the follow-up time in the fixator group was longer.

In summary, the intramedullary lengthening nail and external fixator showed similar results in terms of lengthening and deformity correction, with fewer complications in the nail group. Healing of the regenerate was significantly faster in

Table 3. Knee joint motion: before, during, and after lengthening.

ROM	Nail	Fixator	p-value ^a	Mean pairwise difference (95% CI)
Preoperatively				
Extension (°)	5 (6)	9 (6)	0.09	-4 (-9 to 0)
Flexion (°)	137 (8)	132 (14)	0.15	5 (-2 to 11)
During lengthening				
Extension (°)	-3 (5)	1 (5)	0.08	-4 (-8 to 0)
Flexion (°)	87 (16)	26 (18)	< 0.001	61 (48 to 73)
6 weeks after lengthening completed				
Extension (°)	0 (3)	3 (6)	0.08	-3 (-6 to 0)
Flexion (°)	113 (13)	40 (27)	< 0.001	73 (56 to 89)
6 months after lengthening completed				
Extension (°)	4 (3)	5 (4)	0.5	-1 (-4 to 2)
Flexion (°)	136 (9)	76 (40)	< 0.001	60 (34 to 83)

^a Paired t-test for differences in extension and flexion

the nail group. Most importantly, the rehabilitation in terms of knee ROM was clearly better in the nail group. Despite the fact that the present study has some limitations, we therefore conclude that a lengthening nail may be superior to external fixation in femoral lengthening, when the anatomical conditions and the complexity of the deformity allow the use of an intramedullary nail.

JH and SH performed the surgeries and examined the patients at follow-up. JH wrote the manuscript. ØG and AD evaluated the patients' ROM at each outpatient visit, and they revised the manuscript. HS also revised the manuscript and assisted with the surgery.

No competing interests declared.



Figure 9. A patient in the nail group (pair 8) demonstrating active ROM in the knee 6 weeks after lengthening was completed.

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