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What Are the Potential Benefits and Risks of Using Magnetically Driven Antegrade Intramedullary Lengthening Nails for Femoral Lengthening to Treat Leg Length Discrepancy?

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Abstract

Background Limb lengthening with magnetically driven intramedullary lengthening nails is a fast-developing field and represents an alternative to external fixators. Although previous studies have assessed the application of magnetically driven intramedullary lengthening nails, these studies have been heterogenous regarding the nailing approach, the bone treated, and the implant type; they also have analyzed relatively small patient groups at short follow-up durations.

Questions/purposes (1) Is femoral lengthening with magnetically driven antegrade intramedullary lengthening nails accurate and precise? (2) What are the most common complications of treatment? (3) What factors are associated with unplanned additional surgery?

Methods We retrospectively analyzed the longitudinally maintained database of our orthopaedic teaching hospital to identify all patients who underwent surgery for leg length discrepancy (LLD) between October 2014 and April 2019. In total, we surgically treated 323 patients for LLD of 2 cm or more. Of those 55% (177 of 323) were treated with distraction osteogenesis with magnetically driven intramedullary lengthening nails, 18% (59 of 323) with external fixation, and 27% (87 of 323) with epiphysiodesis around the knee. Based on that, 29% (93 of 323) of patients underwent unilateral femoral distraction osteogenesis with magnetically driven antegrade femoral lengthening nails and were eligible for analysis. No patient was excluded, and 3% (3 of 93) were lost before the minimum study follow-up of 2 years, leaving 97% (90 of 93) for analysis. Patients with a distal femoral deformity were treated via a retrograde femoral approach (10% [33 of 323]) or with external fixators (3% [10 of 323]) and were not included in this study. Distraction osteogenesis with magnetically driven intramedullary lengthening nails was not considered for patients with deep tissue infection, those with bone dimensions considered to be too small in relation to the available implants, and for patients younger than 8 years. This study included 90 patients (44 females, 43 left femora) treated for a median (interquartile range) preoperative LLD of 39 mm (32 to 52) at a median age of 15 years (14 to 17).

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The study was approved by University Hospital Muenster, Muenster, Germany (registration number: 2019-368-f-S).

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The same limb lengthening system was applied in all patients. The median (IQR) follow-up was 35 months (24 to 78). Data were acquired through a chart review performed by someone not involved in the surgical care of the included patients. Data acquisition was supervised and curated by two of the involved surgeons. Accuracy was calculated as 100 – [(achieved distraction in mm – planned distraction in mm) / (planned distraction in mm) x 100] and precision as 100 – (relative standard deviation of accuracy). Treatment-associated complications were summarized descriptively and characterized as complications resulting in unplanned additional surgery or those not resulting in unplanned surgery. To analyze the risk of unplanned additional surgery by entity, we calculated odds ratios (ORs) comparing the incidence of unplanned additional surgery in the different entity cohorts with the idiopathic LLD cohort as a reference. By calculating ORs, we analyzed the risk for unplanned additional surgery depending on sex, age, surgery time, and previous lengthening. Due to the lack of long-term evidence about motorized lengthening nails remaining in situ and concerns about potential implant-related adverse effects, removal was routinely scheduled 1 year after consolidation. For implant removal, 92% (83 of 90) of patients underwent planned additional surgery, which was not recorded as an adverse event of the treatment. Ninety-seven percent (87 of 90) of patients completed lengthening with the implant remaining in situ until the end of distraction. The median (IQR) distraction length was 37 mm (30 to 45) with a median distraction index of 0.9 mm/day (0.7 to 1.0) and median consolidation index of 31 days/cm (25 to 42).

Results The calculated accuracy and precision were 94% and 90%, respectively. In total, 76% (68 of 90) of our patients experienced complications, which resulted in 20% (18 of 90) of patients undergoing unplanned additional surgery. The most common complication overall was adjustment of the distraction rate in 27% (24 of 90) of patients (faster: 16% [14 of 90]; slower: 11% [10 of 90]) and temporary restriction of knee motion, which occurred in 20% (18 of 90) of our patients and resolved in all patients who experienced it. The most serious complications were bacterial osteomyelitis and knee subluxation, which occurred in 3% (3 of 90) and 1% (1 of 90) of our patients, respectively. With the numbers available, we found only one factor associated with an increased likelihood of unplanned additional surgery: Patients with postinfectious LLD had higher odds of unplanned additional surgery than patients with idiopathic LLD (7% [1 of 15] versus 50% [3 of 6], OR 14.0 [95% CI 1.06 to 185.49]; p = 0.02). However, we caution readers this finding is fragile, and the confidence interval suggests that the effect size estimate is likely to be imprecise.

Conclusion Femoral distraction osteogenesis with magnetically driven antegrade intramedullary lengthening nails appears to be an accurate and reliable treatment for femoral lengthening. However, depending on the etiology, a high risk of unplanned additional surgery should be anticipated, and a high proportion of patients will experience temporary joint stiffness. We recommend close orthopaedic follow-up and physiotherapy during treatment. This treatment of LLD can be considered alongside other nails, external fixators, and epiphysiodesis. Multicenter studies comparing this with other approaches are needed.

Level of Evidence Level IV, therapeutic study.

Introduction

The application of magnetically driven intramedullary lengthening nails for gradual limb lengthening via distraction osteogenesis in patients with leg length discrepancy (LLD) has become an established alternative to external fixators [2, 7, 12, 17]. Magnetically driven intramedullary lengthening nails are relatively new and provide a more comfortable method for limb lengthening compared with external fixators; this approach also avoids pin site infections and soft tissue tethering [4, 5, 9, 13, 16, 21, 24].

Recent studies have shown accurate distraction and few complications with magnetically driven intramedullary lengthening nails [4, 13, 19, 21, 26, 28]. However, the designs of published studies are limited by a relatively short follow-up, and these studies are heterogenous regarding nail approach, treated bone, and applied types of lengthening nails [5, 13, 18].

We therefore asked: (1) Is femoral lengthening with magnetically driven antegrade intramedullary lengthening nails accurate and precise? (2) What are the most common complications of treatment? (3) What factors are associated with unplanned additional surgery?

Patients and Methods

Study Design and Setting

We retrospectively analyzed the longitudinally maintained database of our orthopaedic teaching hospital to identify all patients who underwent surgery for LLD between October 2014 and April 2019. Of those, we considered patients who underwent unilateral femoral distraction osteogenesis with magnetically driven antegrade femoral lengthening nails as potentially eligible for this study.

Patients

Between October 2014 and April 2019, we surgically treated 323 patients for LLD of at least 2 cm at our

department. Of those, 55% (177 of 323) were treated with distraction osteogenesis with magnetically driven intramedullary lengthening nails, 18% (59 of 323) with external fixation, and 27% (87 of 323) with epiphysiodesis around the knee. Based on that, 29% (93 of 323) underwent unilateral femoral distraction osteogenesis with magnetically driven antegrade femoral lengthening nails and were eligible for analysis. No patients were excluded, and 3% (3 of 93) were lost before the minimum study follow-up of 2 years, leaving 97% (90 of 93) for analysis (Fig. 1).

In all 90 patients, straight femoral lengthening along the anatomical axis of the femur was conducted without additional deformity correction (Fig. 2), except for torsional correction in patients with femoral retroversion such as in congenital femoral deficiency. Patients with a distal femoral deformity were treated via a retrograde femoral approach (10% [33 of 323]) or with external fixators (3% [10 of 323]) and were not included in this study. Distraction osteogenesis with magnetically driven intramedullary lengthening nails was not considered for patients with deep tissue infection, in those with bone dimensions deemed too small in relation to the available implants, and in patients younger than 8 years [8].

Descriptive Data

This study includes 90 patients (44 females, 43 left femora) treated for a median (interquartile range) LLD of 39 mm (32 to 52) at a median age of 15 years (14 to 17). The most common reasons for LLD were: fibular hemimelia (22% [20 of 90]), idiopathic (17% [15 of 90]), posttraumatic (13% [12 of 90]), and congenital femoral deficiency (12% [11 of 90]) (Table 1). The median follow-up duration of the studied cohort was 35 months (24 to 78).

Patients with an LLD less than 2 cm were treated with insoles or shoe lifts. If patients favored nonoperative treatment, shoe lifts were applied to equalize the LLD up to 5 cm. Patients with a predicted LLD more than 20 cm were treated with an orthoprosthesis, considering the need of multiple lengthening operations during childhood that would be necessary for leg length equalization. All patients who underwent nonoperative treatment were excluded from the study.

Preoperative and Postoperative Clinical and Radiographic Evaluation

We acquired clinical information such as pain, hip and knee ROM, and treatment-related complications from hospital records. AP full-length standing radiographs were obtained for all patients preoperatively and after consolidation. Biplanar radiographs of the femur were taken every second week with the patient under distraction and after consolidation. Three authors (AF, MN, DT) conducted the deformity analysis and LLD measurements using established techniques known for good interrater reliability as previously described [20]. Data were acquired through a chart review performed by someone not involved in the surgical care of the included patients (MN, DT). Data acquisition was supervised and curated by two of the involved surgeons (AF, BV). All measurements were conducted using calibrated radiographs with the PACS® system (GE Healthcare) and the postprocessing software TraumaCad® (Brainlab).

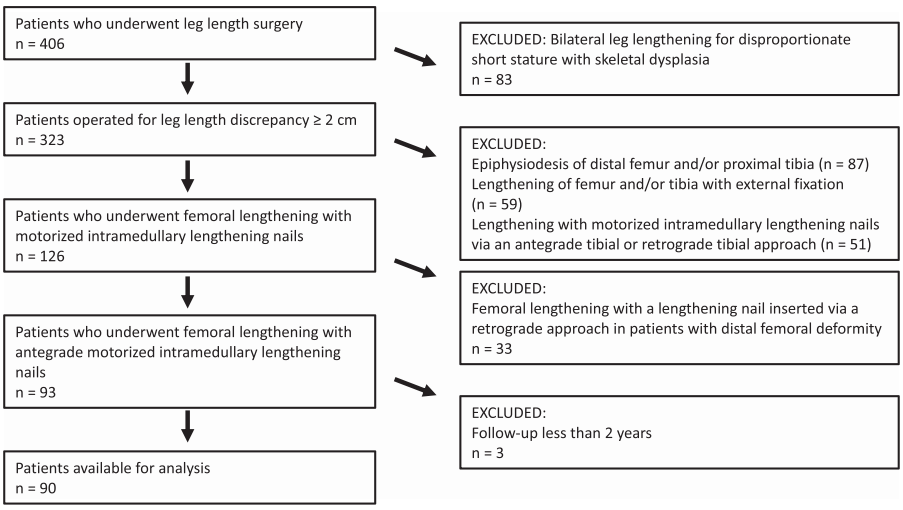

Fig. 1 This STROBE diagram shows the inclusion and exclusion of patients in this study.

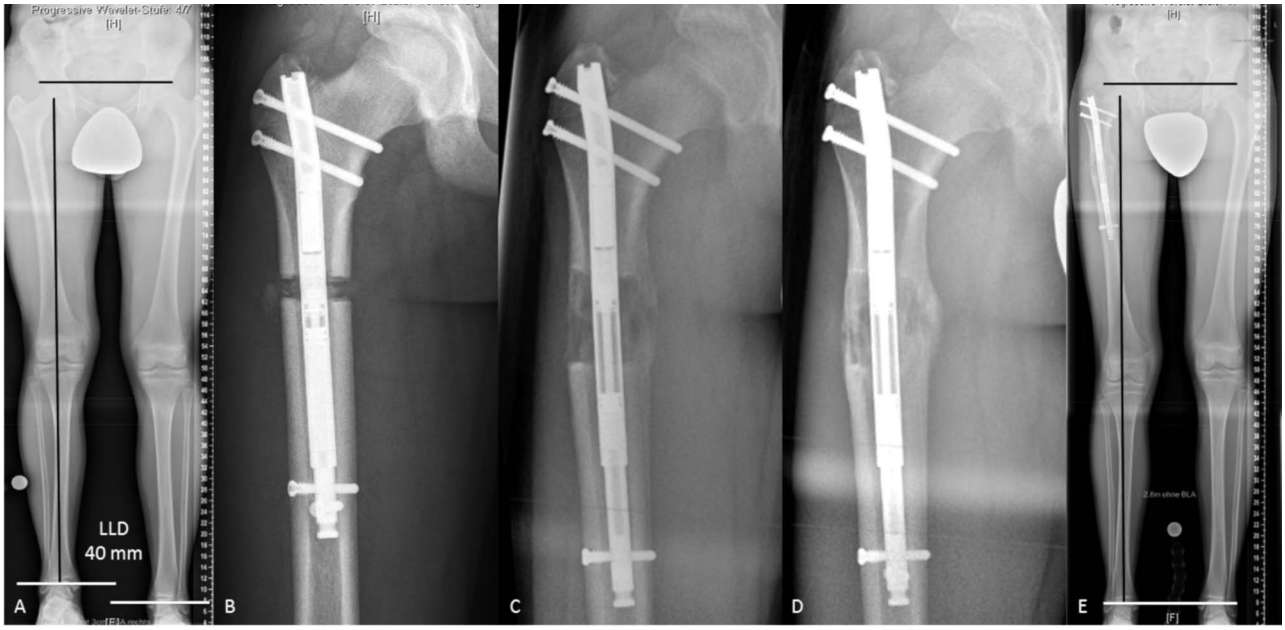

Fig. 2 A-F A 16-year-old boy had idiopathic right-side leg shortening. (**A**) A preoperative AP long standing radiograph shows a leg length discrepancy of 40 mm. (**B-D**) AP radiographs of the right femur show gradual femoral distraction by magnetically driven intramedullary lengthening nails implanted via an antegrade approach (**B**) 2 weeks (10 mm), (**C**) 4 weeks (30 mm), and (**D**) 6 weeks (40 mm) after surgery. (**E**) Postoperative AP long standing radiograph shows equalization of the leg length.

Surgical Technique and Perioperative Parameters

All femoral lengthening procedures were conducted with the magnetically driven second-generation PRECICE® P2 limb lengthening system (NuVasive Specialized Orthopedics Inc) (Fig. 2). After successful lengthening, 92% (83 of 90) of patients had implants retrieved after a median (IQR) of 17 months (14 to 21). We performed preoperative planning using calibrated AP full-length standing and biplanar femoral radiographs. Patients were placed in the supine position on a traction table for lengthening nail implantation using an antegrade technique with small incisions (Fig. 3). Intravenous prophylactic antibiotics were given preoperatively. All nails were inserted via trochanteric entry [8, 11] (Fig. 4A) without concomitant iliotibial band lengthening or tenotomy. In patients with an open trochanteric apophysis, we either

Table 1. Causes of leg-length discrepancy (n = 90)

Cause of LLD	Total
Idiopathic	17 (15)
Fibular hemimelia	22 (20)
Congenital femoral deficiency	12 (11)
Posttraumatic	13 (12)
Tumor	9 (8)
Postinfectious	7 (6)
Congenital clubfoot	6 (5)
Hemihypertrophy	8 (7)
Secondary LLD related to previous femoral surgeries	7 (6)
Osteogenesis imperfecta	1 (1)
Congenital knee dislocation	1 (1)
Hemiparesis	1 (1)
Other	3 (3)

Data presented as % (n).

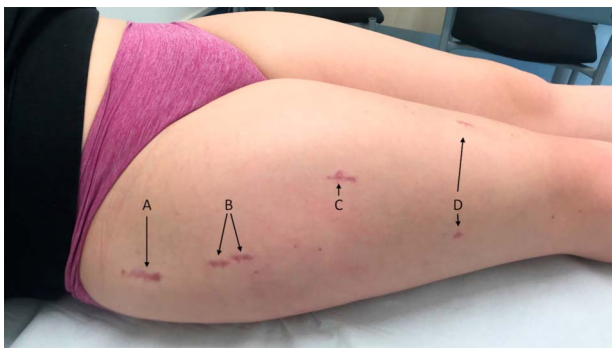

Fig. 3 A 14-year-old girl had a congenital femoral deficiency. In this photograph, the letters A-D indicate the scars of the skin incisions after antegrade implantation of a magnetically driven intramedullary lengthening nail. "A" indicates the nail entry site, "B" indicates where the proximal locking bolts are, "C" indicates the osteotomy site, and "D" indicates where the distal locking bolts are.

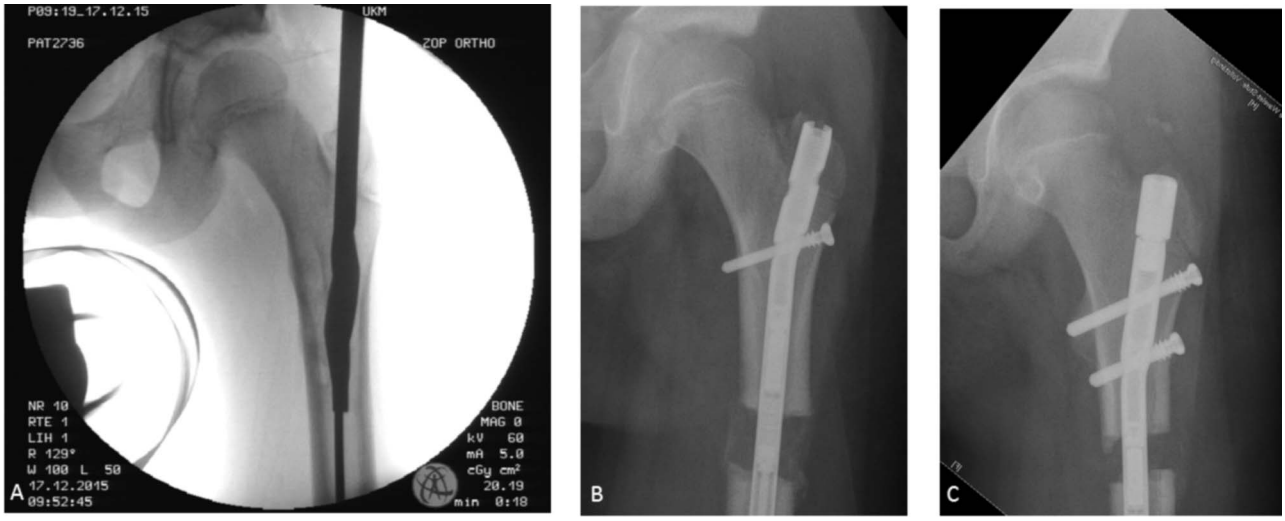

Fig. 4 A-C (A) The trochanteric approach for preserving the femoral head's blood supply in immature patients with open apophysis is shown. (**B**) An entry-related defect of the apophyseal growth plate was bridged by a nail and only single proximal locking distal to the apophysis. (**C**) An entry-related defect of the apophyseal growth plate was bridged by a nail cap that enabled double proximal locking distal to the apophysis. Both techniques avoid potential growth disturbances by preventing transphyseal ossification.

positioned the nail proximal enough to bridge the physeal defect caused by the approach and performed proximal locking with one bolt (Fig. 4B) or used a nail cap (Fig. 4C). To control femoral torsion, we inserted 3-mm K-wires proximally at the height of the lesser trochanter posteriorly to the nail's pathway and distally level with the patella. Before corticotomy, intramedullary reaming was conducted once using a guided flexible 7.5-mm reamer. Corticotomy was then performed in a multiple drill-hole technique (4.5-mm drill) with subsequent cortical chiseling using a 10-mm Lambotte osteotome. The intramedullary canal was reamed up to 1.5 to 2 mm wider than the diameter of the planned nail. After the inserted nail was locked, lengthening of 1 mm was performed before the end of surgery with the external remote controller in a sterile plastic bag, which was verified by an image intensifier. We acquired surgery-related parameters (Table 2) and implant type information (Table 3) from the surgical records.

Postoperative Lengthening and Follow-up Protocol

The postoperative latency period was 7 days, and the initial distraction rate was set to 1 mm/day. Patients were allowed partial weightbearing with 20 kg under distraction, with physiotherapy at least once per week during lengthening.

Table 2. Surgery-related parameters

Type of surgery	% (n)	Time from incision to suture in minutes, median (IQR)	Fluoroscopy time in seconds, median (IQR)	Documented blood loss in milliliters, median (IQR)
Nail implantation (all) (n = 90)		109 (86-128)	132 (78-198)	0 (0-100)
With other concomitant procedures	23 (21)	124 (89-155)	132 (66-258)	100 (0-250)
Without other concomitant procedures	77 (69)	102 (85-119)	132 (78-192)	0 (0-50)
Implant removal (all) (n = 83)		62 (40-100)	66 (24-90)	0 (0-0)
With other concomitant procedures	46 (38)	104 (71-136)	72 (24-144)	0 (0-0)
Without other concomitant procedures	54 (45)	43 (34-58)	30 (18-72)	0 (0-0)

Table 3. Implant information

Length in mm (n)	Diameter in mm (n)	Stroke[a] in mm (n)
160 (1)	8.5 (31)	50 (74)
215 (70)	10.7 (41)	80 (16)
230 (1)	12.5 (18)	
245 (12)		
275 (4)		
305 (1)		
335 (1)		

[a]Stroke = maximum lengthening capacity of the nail.

Distraction was routinely conducted without additional external bracing. For lengthening nail implantation, the patients were hospitalized for a median (IQR) of 9 days (6 to 10). Under distraction, patients were followed every second week in the outpatient clinic. Once the lengthening goal was achieved, a consolidation period of 6 weeks was initiated. Full weightbearing was allowed after consolidation of at least three of four cortices was confirmed on biplanar radiographs. Due to the lack of long-term evidence about motorized lengthening nails remaining in situ and concerns about potential implant-related adverse effects, removal was routinely scheduled 1 year after consolidation.

A total of 92% (83 of 90) of patients underwent planned additional surgery for implant removal, which was not recorded as an adverse event of the treatment.

Primary and Secondary Outcomes

Our primary study goal was to evaluate accuracy, precision, and reliability of distraction osteogenesis with magnetically driven intramedullary lengthening nails and to investigate complications of the treatment.

Accuracy and Precision

Accuracy (100 – [(achieved distraction in mm – planned distraction in mm) / (planned distraction in mm) x 100]), precision (100 – (relative SD of accuracy)) and reliability ((lengthening nails in situ until osseous consolidation / total implanted lengthening nails) x 100) were calculated as previously described [15, 24, 29]. LLD was measured on calibrated AP full-length standing radiographs (Fig. 2A-C). The osteotomy level (distance from the tip of the greater trochanter to the osteotomy site) was measured on the first postoperative radiograph. The amount of achieved distraction was measured via an implant-calibrated technique (Fig. 5) [27]. The distraction index was determined by dividing the achieved length (in mm) by the duration of lengthening (in days). The consolidation index was calculated by dividing the time from surgery until osseous consolidation and full weightbearing (in days) by the distraction length (in cm). One patient in whom the lengthening nail was reduced to the initial length because of osteomyelitis was excluded from consolidation and distraction index calculations. Prolonged osseous consolidation was defined as a consolidation index greater than two SDs. The mechanical axis deviation and joint orientation angles (lateral proximal femoral angle [LPFA], medial proximal femoral angle [MPFA], mechanical lateral distal femoral angle [mLDFA], and anatomic lateral distal femoral angle [aLDFA]) were measured according to the Paley method [20].

Ninety-seven percent (87 of 90) of lengthening procedures were completed with the lengthening nail remaining in situ until the end of the distraction period, showing a good reliability of the implant. No intraoperative complications occurred during nail implantation (n = 90) or removal (n = 83). No nail or locking bolt breakage was observed during the study period. No radiographic signs of entry-related avascular necrosis of the femoral head were observed. The osteotomy was conducted at a median (IQR) level of 10 cm (90 to 117) distal from the tip of the greater trochanter.

The median (IQR) difference between the preoperatively planned median distraction length of 40 mm (30 to 50) and the achieved median length of 37 mm (30 to 45) was 1 mm (range 0 to 4). The calculated accuracy and

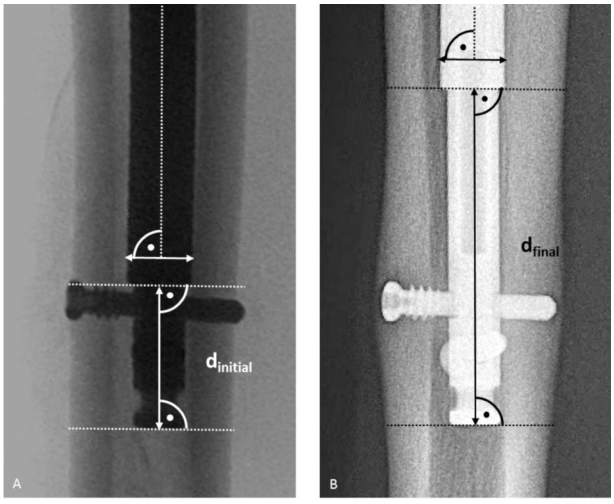

Fig. 5 A-B Nail distraction was measured (**A**) intraoperatively and (**B**) at the follow-up examination on AP radiographs. Calibration was performed based on the diameter of the female part of the nail (P2: either 8.5 mm, 10.7 mm, or 12.5 mm). The length of the exposed male part of the nail was measured intraoperatively ($d_{initial}$) and at the follow-up interval (d_{final}). The total nail distraction was defined as the difference between d_{final} and $d_{initial}$.

Table 4. Distraction parameters

Assessed parameter	Results
Planned distraction in mm	40 (30-50)
Achieved distraction in mm	37 (30-45)
Planned distraction speed in mm/day	1
Time under distraction in days	45 (34-58)
Time under consolidation in days	49 (42-84)
Time to full weightbearing postoperatively in days	108 (89-138)
Distraction index in mm/day	0.9 (0.7-1.0)
Consolidation index in days/cm	31 (25-42)
Accuracy in %	94
Precision in %	90
Reliability in %	98

Data presented as median (IQR), unless otherwise indicated.

precision were 94% and 90%, respectively (Table 4). The median time under distraction was 45 days (34 to 58), with a median of 49 days (42 to 84) under consolidation. The median time from the date of surgery to full weightbearing was 108 days (89 to 138). The median distraction and consolidation index were 0.9 mm/day (0.7 to 1.0) and 31 days/cm (25 to 42), respectively (Table 4). The mean preoperative mechanical axis deviation was 0 ± 17 mm compared with a mean mechanical axis deviation after completion of lengthening of -2 ± 17 mm. The mean preoperative and postlengthening joint orientation angles were within physiological margins (Fig. 6). In 21% (19 of 90) of operations, concomitant interventions were performed with the index operation: 8% (7 of 90) removal of implants from previous surgeries, 7% (6 of 90) simultaneous torsional correction, 4% (4 of 90) distal femoral or proximal tibial hemiepiphysiodesis, and 1% (1 of 90) tibial osteotomy to correct valgus deformity. Blood transfusion was not necessary in all operations.

Complications

Treatment-associated complications were summarized descriptively and characterized as complications resulting in unplanned additional surgery or those not resulting in unplanned surgery.

Information about pain during lengthening was subclassified as follows: no analgesic use, pain relief with an oral NSAID, or NSAID with oral opioid analgesics. ROM limitations were quantitatively assessed and classified as temporary during lengthening and persistent after the end of distraction.

Our secondary study goals were to compare the risk of unplanned additional surgery between different patient

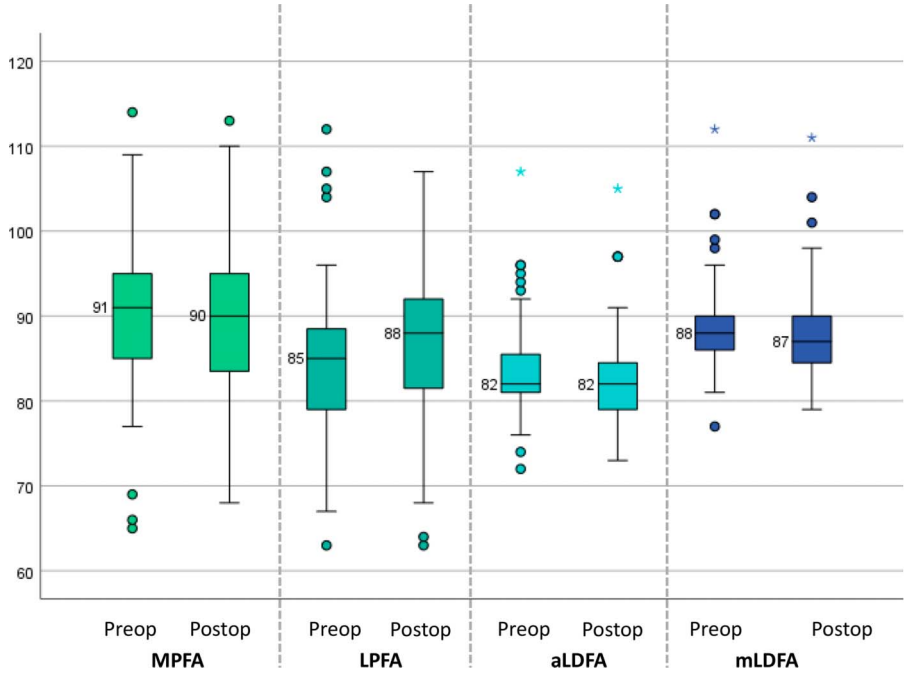

Fig. 6 Box plot graphs depicting the pre- and postoperatively assessed median joint orientation angles. Postoperative measurements were conducted after completed lengthening. MPFA = medial proximal femoral angle; LPFA = lateral proximal femoral angle; aLDFA = anatomic lateral distal femoral angle; mLDFA = mechanical lateral distal femoral angle.

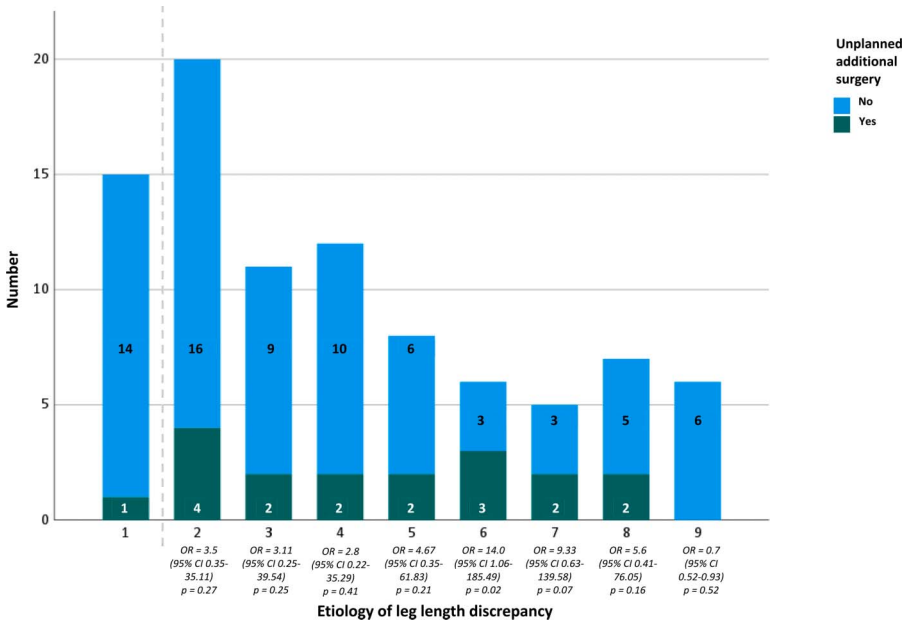

Fig. 7 Stacked bar graph showing the frequency of unplanned additional surgery by entity. Odds ratios with corresponding 95% confidence interval and p values are depicted for the risk of unplanned additional surgery of the entities 2 through 10 each compared with the reference group with idiopathic leg length discrepancy. Etiology of leg length discrepancy: 1 = idiopathic, 2 = fibular hemimelia, 3 = congenital femoral deficiency, 4 = posttraumatic, 5 = tumor, 6 = postinfectious, 7 = congenital clubfoot, 8 = hemihypertrophy, 9 = other.

cohorts (Fig. 7). We used odds ratios (ORs) to compare the risk of unplanned additional surgery between the following dichotomous parameters: sex (male or female), side (left or right), age (younger than 16 years or 16 years and older), length of surgery (≤ 90 minutes or > 90 minutes), concomitant surgeries with nail implantation (yes or no), and previous lengthening of the femur (yes or no) (Fig. 8).

Ethical Approval

The study was approved by our institutional review board on July 1, 2019 (registration number: 2019-368-f-S) and was conducted according to the principles of the World Medical Association Declaration of Helsinki, 1964.

Statistical Analysis

We assessed normal distribution with the Shapiro-Wilk test. Descriptive statistics were performed using mean with SD for normally distributed continuous variables, median with IQR for non-normally distributed continuous variables, and numbers with percentages for binary variables. Mean values were compared using the paired t-test and dichotomous variables were compared using the chi-square test. ORs are reported with 95% confidence interval and a p value. The level of significance was set at an α value of < 0.05. All statistical tests were conducted using SPSS 25 (IBM Corp).

Results

Accuracy and Precision

The calculated accuracy (defined as: 100 – [(achieved distraction in mm – planned distraction in mm) / (planned distraction in mm) x 100]) and precision (defined as: 100 – (relative standard deviation of accuracy)) with the use of antegrade magnetically driven intramedullary lengthening nails were 94% and 90%, respectively.

Complications of Treatment

In total, 76% (68 of 90) of our patients experienced complications of varying severity, which resulted in 20% (18 of 90) of patients undergoing unplanned additional surgery. The most common complication overall was adjustment of the distraction rate in 27% (24 of 90) of patients (faster: 16% [14 of 90]; slower: 11% [10 of 90]) and temporary

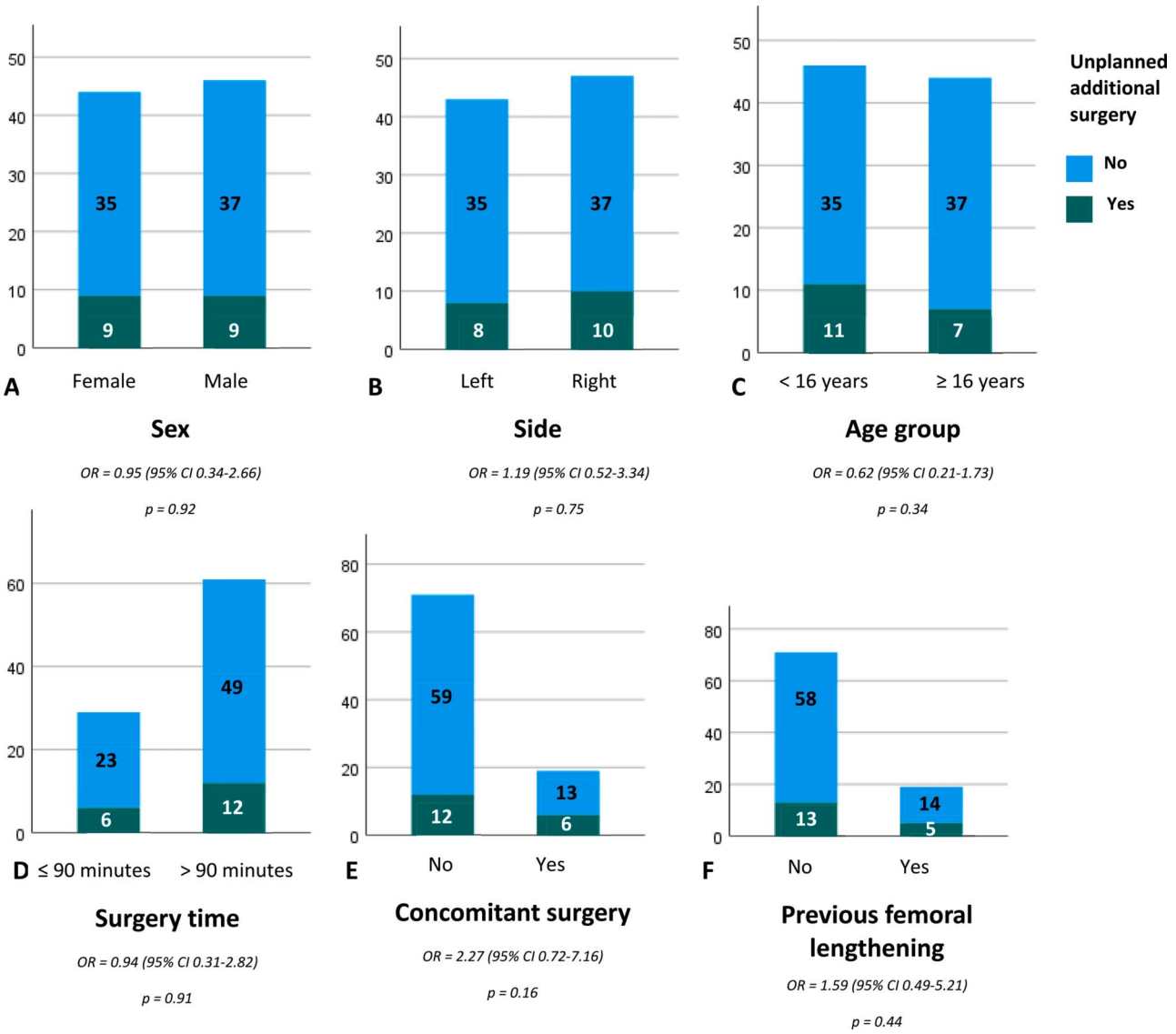

Fig. 8 Stacked bar graphs showing the frequency and risk of unplanned additional surgery between dichotomous categories.

restriction of knee motion, which occurred in 20% (18 of 90) of our patients. This stiffness resolved in all patients who experienced it (Table 5). Under distraction, 1% (1 of 90) of patients achieved a satisfactory analgesic level by combining oral NSAIDs with oral opioid analgesics. Complications of intermediate severity occurred in 13% (12 of 90) and included prolonged time to osseous consolidation in 6% (5 of 90) of patients and premature consolidation and/or insufficient distraction of the lengthening nail resulting in unplanned additional surgery during the

Table 5. ROM limitations of the knee and hip observed at consolidation, which were all subsequently resolved by physiotherapy

Loss of knee ROM				Loss of hip ROM	
Loss of flexion in °	**Total (n = 11)**	**Loss of extension in °**	**Total (n = 7)**	**Flexion in °**	**Total (n = 2)**
0-30	44 (8)	0-5	6 (1)	0-30	0 (0)
30-60	6 (1)	5-10	28 (5)	30-60	100 (2)
60-90	11 (2)	10-15	0 (0)	60-90	0
> 90	0	> 15	6 (1)	> 90	0

Data presented as % (n); in our study, 20% (18 of 90) of patients lost knee ROM and 2% (2 of 90) lost hip ROM.

lengthening period in 8% (7 of 90) of patients (Fig. 9A). The most serious complications were bacterial osteomyelitis and knee subluxation, which occurred in 3% (3 of 90) and 1% (1 of 90) of our patients, respectively (Table 6). To restore ROM, the patient with knee dislocation was treated by extensive reconstructive surgery (Fig. 9B-C). In the most severely affected patient with osteomyelitis, the lengthening nail was gradually reduced to the initial length of the bone because of insufficient callus formation, and then explanted without achieving the lengthening goal. During implant removal, debridement was performed by intramedullary reaming and local antibiotic application. Osseous healing was achieved through oral antibiotic treatment for 4 weeks and external fixation for 2 months. One of the other patients (1% [1 of 90]) was diagnosed with bacterial osteomyelitis after the femur was successfully

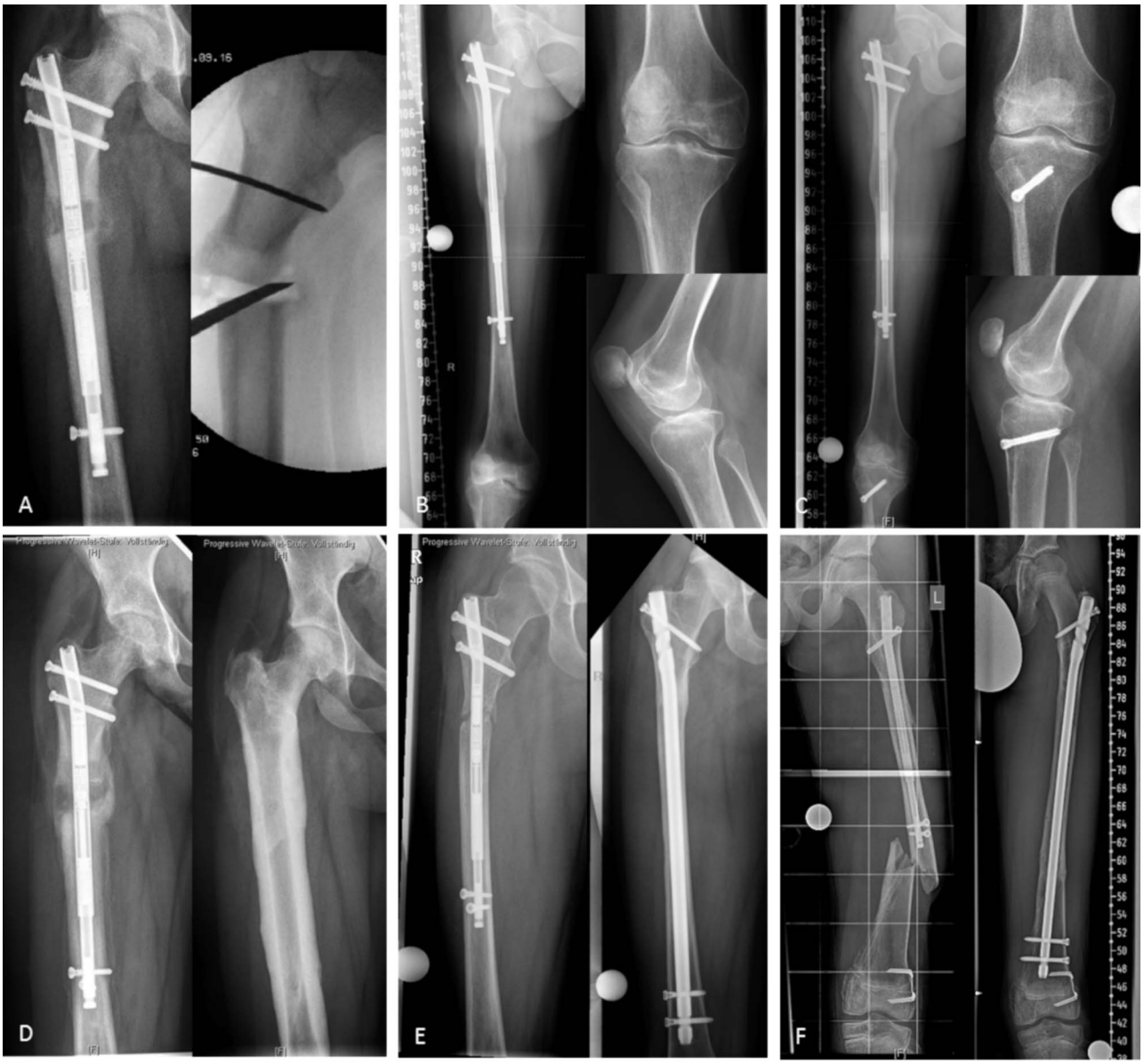

Fig. 9 A-F These radiographs show complications resulting in additional surgery: (**A**) premature consolidation, especially of the medial femoral cortex, treated by re-osteotomy; (**B**) persistent knee dislocation in a patient with congenital femoral deficiency; (**C**) osseous consolidation after reconstructive surgery of the dislocated knee; (**D**) osseous consolidation after implant removal in a patient with bacterial osteomyelitis during distraction who was treated with local debridement at the time of implant removal and oral antibiotics; (**E**) nonunion with subsequent nail exchange; and (**F**) femoral fracture in a patient with Ollier disease treated by implant removal, closed reduction, and intramedullary stabilization.

Table 6. Reasons for and type of unplanned additional surgery related to femoral lengthening

Reason	Number (n = 18)
Premature callus consolidation	7
Re-osteotomy without lengthening nail exchange (n = 3)	
Re-osteotomy with lengthening nail exchange (n = 3) (intraoperative testing showed malfunctioning)	
Nail explantation and completion of lengthening over nail with external fixator (n = 1)	
Nonunion	4
Implant removal, intramedullary reaming and antegrade trauma nail implantation	
Implant-related fracture	3
implant removal, closed reduction, and intramedullary trauma nail stabilization	
Bacterial osteomyelitis	3
Implant removal without achieving lengthening goal (n = 1)	
Lengthening completed; infection treated at the time of implant removal (n = 1)	
Implant removal and change to lengthening over trauma nail with external fixator (n = 1)	
Knee subluxation	1
ROM restored by reconstructive surgery	

lengthened and treated with local debridement at the time of implant removal and oral antibiotics (Fig. 9D). In the third patient (1% [1 of 90]), the lengthening nail was removed and the desired amount of lengthening was achieved via external fixator and oral antibiotics. Nonunion occurred in 4% (4 of 90) of patients (Fig. 9E); 3% (3 of 90) of patients sustained a femoral implant-related fracture (one had adequate trauma during recreational soccer and two had inadequate trauma with preexisting osteopenia) (Fig. 9F). The planned amount of distraction was missed by more than 1 cm in 3% (3 of 90) of lengthening procedures (median 14 mm, IQR 13 to 17). The reasons were incorrect radiographic measurement in 2% (2 of 90) of patients and knee flexion contracture in 1% (1 of 90) of patients.

Factors Associated with Unplanned Additional Surgery

With the numbers available, we found only one factor associated with an increased likelihood of unplanned additional surgery: Patients with postinfectious LLD had higher odds of unplanned additional surgery than patients with idiopathic LLD (7% [1 of 15] versus 50% [3 of 6], OR 14.0 [95% CI 1.06 to 185.49]; p = 0.02). However, we caution readers that this finding is fragile, and the confidence interval suggests that the effect size estimate is likely to be very imprecise. With the numbers available, the following factors were not associated with an increased odds of unplanned additional surgery: idiopathic LLD compared with fibular hemimelia (7% [1 of 15] versus 20% [4 of 20], OR 3.5 [95% CI 0.35 to 35.11]; p = 0.27), idiopathic LLD compared with congenital femoral deficiency (7% [1 of 15] versus 22% [2 of 9], OR 3.11 [95% CI 0.25 to 39.54]; p = 0.25), idiopathic LLD compared with posttraumatic LLD (7% [1 of 15] versus 17% [2 of 12], OR 2.8 [95% CI 0.22 to 35.29]; p = 0.41), idiopathic LLD compared with post-tumor resection–associated LLD (7% [1 of 15] versus 25% [2 of 8], OR 4.67 [95% CI 0.35 to 61.83]; p = 0.21), idiopathic LLD compared with postinfectious LLD (7% [1 of 15] versus 50% [3 of 6], OR 14.0 [95% CI 1.01 to 185.49]; p = 0.02), idiopathic LLD compared with clubfoot-associated LLD (7% [1 of 15] versus 40% [2 of 5], OR 9.33 [95% CI 0.63 to 139.58]; p = 0.07), idiopathic LLD compared with hemihypertrophy (7% [1 of 15] versus 29% [2 of 7], OR 5.6 [95% CI 0.41 to 76.05]; p = 0.16), idiopathic LLD compared with the other entities of LLD (7% [1 of 15] versus 0% [0 of 6], OR 0.7 [95% CI 0.52 to 0.93]; p = 0.52), females compared with males (20% [9 of 44] versus 24% [9 of 37], OR 0.95 [95% CI 0.34 to 2.66]; p = 0.92), left femur lengthened compared with right femur lengthened (23% [8 of 35] versus 27% [10 of 37], OR 1.19 [95% CI 0.52 to 3.34]; p = 0.75), age younger than 16 years compared with age older than 16 years (31% [11 of 35] versus 19% [7 of 37], OR 0.62 [95% CI 0.21 to 1.73]; p = 0.34), no concomitant surgery compared with concomitant surgery at nail implantation (20% [12 of 59] versus 46% [6 of 13], OR 2.27 [95% CI 0.72 to 7.16]; p = 0.16), previous lengthening of femur compared with no previous lengthening of femur (22% [13 of 58] versus 36% [5 of 14], OR 1.59 [95% CI 0.49 to 5.21]; p = 0.44), and surgery time less than 90 minutes compared with longer than 90 minutes 21% (6 of 29) versus 20% (12 of 61), OR 0.94 (95% CI 0.31 to 2.82); p = 0.91).

Discussion

Patients with an LLD of 2 cm or more may be treated by distraction osteogenesis with external fixators or intramedullary lengthening nails. Because external fixation has some serious shortcomings, including pin site infection and soft tissue tethering, lengthening with intramedullary lengthening nails has emerged as a potential alternative. However, published studies have differed in terms of nail

approach, treated bone, and applied devices (PRECICE®, ISKD® [Orthofix], or Fitbone® [Orthofix]) [5, 13, 18]. To our knowledge, no large studies have used a consistent approach to solely analyze intramedullary femur lengthening with antegrade nails. We found that with magnetically driven intramedullary lengthening accurate distraction osteogenesis is possible. However, the treatment remains challenging, and an important factor associated with complication rates of treatment appears to be the underlying etiology of LLD.

Limitations

Although the study design is homogenous in terms of the operative approach and implant, the underlying conditions are diverse and limit comparability based on pathologic findings. To identify more potential risk factors of treatment, prospective, groupwise, and comparative study designs are needed. Beyond that, there were three main types of bias in this study. The most important is selection bias. Other treatments were in use during the same time span for similar indications, including retrograde femoral lengthening nails, external fixators, epiphysiodesis, and nonoperative treatment. The usual effect of selection bias on a study about a new treatment is that it may increase the apparent benefits of the new treatment and de-emphasize its potential harms. We tried to mitigate this bias by using consistent indications for the magnetically driven intramedullary lengthening nail. We also caution the reader about transfer bias; minimum follow-up was 2 years, which is longer than in preexisting studies but in general still relatively short, and so more complications may yet occur. Also, 3% (3 of 93) of patients were lost to follow-up before 2 years. In general, the missing may be more likely to have experienced a complication than the accounted for. Assessment bias was caused by the following main factors: The patients were treated by the same authors who assessed and interpreted the data, patient-reported outcomes were not used, and functional information such as ROM was retrospectively acquired from hospital records and might be biased by inconsistency between the examining physician and documentation. In general, these kinds of bias would be expected to make a new treatment appear better than it is. Measurements may suffer from interobserver reliability bias since no intraclass correlation was conducted. However, previous studies have shown good interobserver reliability of the employed measurement parameters [20] and were therefore not reassessed in this study. Finally, deformity of the sagittal and transversal plane was not analyzed.

Accuracy and Precision

We found that the calculated accuracy and precision in this study were 94% and 90%, respectively. Our results confirm that magnetically driven intramedullary lengthening nails are reliable for straight femoral lengthening, with nail insertion via an antegrade approach for lengthening of the femur along its anatomical axis. For standardized reporting and better comparability of lengthening parameters, we argue in favor of an implant-referenced measurement technique [27]. Wagner et al. [29] reported an accuracy of 97% with a precision of 92%, while Nasto et al. [19] found an accuracy of 91%. The median (IQR) consolidation index of this study (31 days/cm [25 to 42]) is comparable to previously reported values by Horn et al. [13] (1.1 months/cm), Szymczuk et al. [26] (34.8 days/cm), Calder et al. [5] (29 days/cm), and Fragomen et al. [7] (1.0 months/cm). However, in prior studies, often the method of measuring the distraction distance was not or was inconsistently described, even though it is crucial for calculation of the aforementioned parameters [5, 13, 24, 26]. In our opinion, measuring the callus length between the irregular surface of a drill-hole corticotomy is susceptible to measurement inaccuracy and should be avoided. Therefore, we recommend an implant-referenced measurement technique that minimizes measuring inaccuracy related to magnification or vague reference points such as irregular osseous borders of the corticotomy. In this study, the preoperative mechanical axis deviation and joint orientation angles after completed lengthening showed no large differences [20, 23]. Most values remained within the margins of physiologic limb alignment, and there was no tendency toward pathologic valgus malalignment because of femoral lengthening along the anatomic axis. This finding is supported by recent observations of other studies [3, 16, 29]. However, others argue that a retrograde femoral insertion reduces the risk of mechanical axis deviation shifts associated with lengthening via an antegrade femoral nail [1, 6, 10]. A greater distraction distance than the median distance of 37 mm reported in this study might provoke clinically relevant shifts of the mechanical axis deviation. To further investigate this matter, a different study design is needed, one that implements biomechanical and radiographic approaches. Intramedullary lengthening nails are straight and not anatomically preformed. Although one might anticipate that the femoral bow would interfere with these types of implants, in the studied cohort, mostly short implants were used, which did not interfere with the femoral bow (they were used in combination with a proximal metadiaphyseal osteotomy level, which may also have helped) [5].

Complications of Treatment

In our study, 1 in 5 patients (20% [18 of 90]) underwent an unplanned reoperation, and more than 90% had a planned secondary operation to remove the lengthening nail, which

we did not consider a complication but nonetheless is important to report. A total of 20% (18 of 90) developed limited knee ROM, which typically resolved over 6 months. The most serious complications observed in this study were knee subluxation (1% [1 of 90]) resulting in extensive reconstructive surgery and bacterial osteomyelitis (3% [3 of 90]) that in one patient eventually resulted in consolidation with antibiotics and external fixation after having retracted the initially gained length. Some authors favor a concomitant soft tissue release; that is, release of the iliotibial band with antegrade femoral lengthening to minimize the risk of joint subluxation [5, 25]. In our study, concomitant soft tissue release was not performed, and the observed proportion of unplanned additional surgery because of joint stiffness (1%) was not higher than that in other studies [19, 26, 29]. Although braces and casts were not routinely applied during the lengthening period in this cohort, they can be beneficial for selected patients with congenital deformities [5, 13]. Although most ROM restrictions can be corrected by slowing the distraction rate and intensifying physiotherapy [7, 19, 26], hip or knee subluxation luckily are very rare but represent a very serious complication. The observed frequency of 3% (3 of 90) bacterial osteomyelitis in this study is comparable to that reported by Paley et al. (4%) [22] and Nasto et al. (3%) [19]; smaller studies, perhaps not surprisingly, did not observe this relatively uncommon complication [5, 13, 26]. We suggest a preoperative assessment of patients with postinfectious LLD or LLD related to previous open fracture, specifically to try to rule out preexisting low-grade infection, using imaging and, if needed, biopsy.

Premature callus consolidation was the most common reason for unplanned additional surgery in our study (8% [7 of 90]). In 3% (3 of 90), re-osteotomy and exchange of the lengthening nail was performed to treat technical implant dysfunction of unclear origin. We recommend that surgeons ensure correct implant function during the index procedure to minimize this likelihood. In this study, the observed proportion of unplanned additional surgery of 20% (18 of 90) is comparable to previous proportions ranging from 14% to 27% [5, 13, 14, 22, 26]. Temporary joint stiffness remains a common complication of intramedullary lengthening. Although limb lengthening with magnetically driven lengthening nails seems reliable in terms of achieving the desired length of distraction [5, 13, 19, 26, 27], an unplanned additional surgical procedure remains a serious complication, even if treatment concludes without new pathologic findings or permanent sequelae. A recent systematic review of treatment with externally controlled lengthening nails has shown that complications can occur in one of three patients even though ultimately the treatment goal is still achieved [9]. We emphasize that even if the goal of lengthening is achieved, the course of treatment until then can be troublesome for an important proportion of patients.

Factors Associated with Unplanned Additional Surgery

With the numbers available, the only factor we found that was associated with an increased likelihood of unplanned additional surgery was postinfectious LLD (compared with idiopathic LLD). But the confidence interval around our estimate of the odds increase here was extremely wide, and it came very close to being a no-difference finding. As earlier noted, we think that patients who are at particular risk for infection—especially those who have had prior infection—should have a work-up to exclude persistent infection before distraction osteogenesis with an intramedullary nail. We suspect that some of our no-difference findings on the analysis of factors associated with unplanned additional surgery may turn out to be relevant when pooled into future systematic reviews; the most likely among these might be patients with prior radiochemotherapy and LLD due to tumor resection or patients with congenital clubfoot–associated LLD. However, until or unless that occurs, it is impossible to know with confidence. To date, there are no studies of which we are aware that have performed a systematic risk stratification analysis to identify etiology-based risk factors for unplanned additional surgery associated with distraction osteogenesis using lengthening nails. Future studies should include multicenter analysis with higher sample sizes and comparable operative approaches to further investigate risk factors based on pathology.

Conclusion

Femoral distraction osteogenesis with magnetically driven antegrade intramedullary lengthening nails appears to be an accurate and reliable treatment for femoral lengthening along its anatomical axis. However, depending on etiology, a high risk of unplanned additional surgery should be anticipated, and a high proportion of patients will experience temporary joint stiffness. We recommend close orthopaedic follow-up visits and physiotherapy during treatment. This treatment of LLD can be considered alongside other nails, external fixators, and epiphysiodesis. Multicenter studies using consistent treatment protocols that compare this with other approaches are needed.

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