Femoral Lengthening in Children—A Comparison Between Magnetic Intramedullary Lengthening Nails and External Fixators

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Background: Femoral lengthening can be achieved using external fixators or intramedullary lengthening nails. The purpose of this research was to compare the outcome of femoral lengthening in children using PRECICE magnetic lengthening nails with lengthening external fixators.

Methods: Retrospective analysis of 50 children who had femoral lengthening. Group A included patients who had lengthening with external fixation, patients in Group B had lengthening with PRECICE intramedullary lengthening nails. Each group included 25 patients. The sample strictly included children aged between 11 and 17 years. Patients in each group were matched according to age and indication for lengthening whether congenital or acquired conditions. The outcomes focused on the ability to achieve target length, healing index, residual malalignment, length of hospitalization following the osteotomy surgery, and encountered complications.

Results: Mean patient age was 14.7 years for each group. The length gain was 42 ± 12 mm for Group A and 41.6 ± 8 mm for Group B ($P = 0.84$). Lengthening nails achieved the target length more accurately compared with external fixation ($P = 0.017$). The healing index was significantly higher in group A with 53.2 ± 19 days/cm compared with 40.2 ± 14 days/cm in group B ($P = 0.03$). Group A had significantly higher complications than group B ($P < 0.0001$). There was no statistically significant difference in the final coronal malalignment between the 2 groups ($P = 0.2$). The mean length of stay was 9.2 ± 5.8 days for group A and 4.2 ± 3.3 days for group B ($P = 0.0005$).

Conclusion: Magnetic lengthening nails are clinically effective for femoral lengthening in the pediatric population. Compared with external fixation, healing index and complications were more favorable with PRECICE nails. Further research is required to study the cost-effectiveness of this technique.

Level of Evidence: Level IV—case series.

Key Words: magnetic nails, femoral lengthening, external fixators

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Distraction osteogenesis using external fixation is a well-recognized technique for limb lengthening. External fixators provide versatile, reproducible, relatively cheap, and effective options for bone lengthening. External fixators allow joint spanning when required.[1] However, external fixators are associated with many complications. These complications include pin site infections, joint contractures, subluxation, and regeneration problems (delayed union, nonunion, early consolidation).[2,3] The prolonged treatment time of external fixators was reported to cause significant limitations to children's activities and lifestyles.[4]

The increased emphasis on improving the quality of life of children and their families during treatment stimulated the development of motorized lengthening nails. PRECICE lengthening nails (Nuvasive Specialized Orthopedics Inc., Aliso Viejo, CA) have become very popular in limb lengthening. PRECICE nails are magnetic telescopic titanium intramedullary lengthening nails. The rate of distraction is controlled with external remote control. This is thought to be more convenient for the patients than the traditional methods of lengthening.[5] There are different designs of PRECICE nails, including antegrade and retrograde as well as straight and trochanteric entry, which adds to the versatility of the system.

Magnetic lengthening nails were reported to have more effectiveness and fewer complications than external

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fixators in adult populations.[6,7] However, there is limited evidence to support the use in the pediatric population. That evidence includes reports from noncomparative research[8,9] and studies that have included both pediatric and adult populations.

We report the outcome of femoral lengthening children using PRECICE lengthening nails in comparison with external fixators. This is thought to be the only comparative study to focus exclusively on children and to include age-matched and diagnosis-matched samples in the 2 groups.

METHODS

Inclusion criteria for this retrospective case note review included children who underwent femoral lengthening using either external fixators or PRECICE nails, aged between 11 and 17 years at the time of surgery, with a follow-up of at least 12 months postoperatively. Patients who had lengthening of more than 1 segment contemporaneously were excluded. Both monolateral and circular external fixators were included in this study, while the PRECICE nail group included antegrade and retrograde femoral nails.

Notes were reviewed to identify patients' demographics, indications for femoral lengthening, lengthening goal, length of hospital stay, and complications. Radiographs were reviewed by the authors to identify the length gained in mm, healing index (HI: days from index surgery to healing of 3 of 4 cortices divided by length of the regenerate in cm), and residual malalignment as assessed by the mechanical axis deviation (MAD). Accuracy was defined as achieving a length gain within 5 mm of the target length.

Patients were divided into groups based on the treatment they received; Group A (external fixation) and Group B (lengthening nails). The groups included age and diagnosis-matched children. The matching was conducted manually. First by identifying the patients who met the inclusion criteria from the lengthening nail cohort. Then the external fixation database was searched to identify patients matching the selected patients from Group A. The diagnosis was matched based on congenital or acquired indications for femoral lengthening. When 2 eligible patients met the matching criteria in the external fixation group, the patient who had the procedure more recently was selected.

Descriptive statistics were used to present the relevant data. Multivariant linear regression analysis was used to compare HI and length gain. Simple logistic regression was used for MAD and to study the accuracy of the device in achieving the target length. Complications were analyzed using the Pearson χ^2 test. Length of hospital stay was analyzed using the 2-sample Wilcoxon rank-sum (Mann-Whitney) test and confirmed with t test. In all the statistical analyses, means and SD were reported, P-value <0.05 was regarded as significant.

Local Research and Development Department and NHS Health Research Authority (HRA) approvals were obtained before commencing the study.

TABLE 1. Patient Demographics

	External Fixation (Group A)		PRECICE Nail (Group B)	
Variables	**Mean**	**SD**	**Mean**	**SD**
Age, Y	14.75	1.96	14.74	1.4
Male, %	60		68	
Implant type	6 Monolateral (LRS) 19 Circular fixators		13 Antegrade 12 Retrograde	

RESULTS

Twenty-five femora met the inclusion criteria from the nailing group. External fixation database included 62 femora legible for the study, notes for these 62 cases were reviewed, age and indication for surgery were matched to the lengthening nails sample. The mean age for each group was 14.7 years, Group A included 15 males while Group B included 17 males. 11 patients in each group had the lengthening procedures to treat congenital conditions. Demographics are summarized in Table 1. Indications for lengthening are summarized in Table 2. Group A included 6 monolateral fixators and 19 circular fixators. Group B included 13 antegrade and 12 retrograde PRECICE nails. All the antegrade nails were trochanteric entry point nails. All the retrograde femoral nails were done following distal femur physeal closure. Eight femurs in each group had a Pelvic support osteotomy.

The target length for group A was 48 mm (SD = 12) and 45 mm (SD = 9) for group B. The length gain was 42 mm (SD = 12) for Group A and 41.6 mm (SD = 8) for Group B. The difference in the length gain between the 2 groups (0.4 mm) was neither clinically nor statistically significant ($P = 0.84$).

Lengthening nails were found to be more accurate in achieving the target length compared with external fixation ($P = 0.017$). Intolerance to external fixation and joint stiffness were the most frequent causes for not achieving the target length, while joint subluxation was the reason for not achieving the target length in 1 femur. In group B, locking screw failure and poor regenerate resulted in not achieving the target length.

TABLE 2. Indications for Femoral Lengthening

Indication of Lengthening	External Fixation (Group A)	PRECICE Nail (Group B)
Congenital		
Congenital femoral deficiency (CFD)	7	6
Hemihypertrophy	2	2
Others (skeletal dysplasia)	2	3
Total	11	11
Acquired		
Postinfection sequalae	8	6
Postavascular necrosis femoral head	2	4
Post-traumatic sequalae	2	2
Developmental	2	2
Total	14	14

TABLE 3. Results

Variables	External Fixation (Group A) Mean	SD	PRECICE Nail (Group B) Mean	SD	*P*
Target length (mm)	48	12	45	9	
Achieved length (mm)	42.0	12	41.6	8	0.84
Healing index (d/cm)	53.2	19	40.2	14	0.03
Accuracy (achieving target ± 5 mm, n)	14/25		22/25		0.017
Length of stay (d)	9.2	5.8	4.2	3.3	0.0005
Abnormal MAD (n)	6		3		0.2

MAD indicates mechanical axis deviation.

HI was 53.2 ± 19 days/cm and 40.2 ± 14 days/cm for groups A and B, respectively. HI was significantly related to the age of the patient, diagnosis, and the lengthening device when the 2 groups were combined. A year increase in the age was found to increase the HI by 3.5 days/cm ($P = 0.018$), congenital indications for femoral lengthening were associated with more HI ($P = 0.037$), lengthening nails reduced HI by 10.6 days/cm compared with external fixation ($P = 0.03$), sex did not have a statistically significant effect on HI ($P = 0.96$).

Residual deviation of the mechanical axis was noted in 6 patients in group A compared with 3 in group B. However, this difference was not statistically significant ($P = 0.2$). Outcomes were summarized in Table 3.

There was no statistically significant difference between monolateral and ring fixations with regards to HI, length gain, MAD, the accuracy of achieving the target length. In the same way, there was no difference between antegrade and retrograde nails (Table 4 summarized the effects of different device designs on the outcomes).

Length of stay was significantly higher in group A (9.2 ± 5.8 d) compared with group B (4.2 ± 3.3 d) ($P = 0.0005$).

Group A had more reported complications compared with group B ($P < 0.0001$). Group A had 19 recorded adverse events in 16 patients, 6 of which were treated surgically. Adverse events occurred in 2 patients from Group B, 1 needed further surgery. Adverse events are listed in Table 5.

TABLE 4. The Effect of Device Designs on Different Outcomes

Outcome	External Fixation Designs (Monolateral vs. Circular Fixators)	Nail Designs (Antegrade vs. Retrograde)
HI	Not significant ($P = 0.75$)	Not significant ($P = 0.77$)
Length gain	Not significant ($P = 0.4$)	Not significant ($P = 0.6$)
MAD	Not significant ($P = 0.3$)	Not significant ($P = 0.59$)
Accuracy of achieving target length ± 5 mm	Not significant ($P = 0.4$)	Not significant ($P = 0.06$)

HI indicates healing index; MAD, mechanical axis deviation.

TABLE 5. Complications of Femoral Lengthening

	External Fixation (Group A) Events	Affected Segments	PRCICE Nail (Group B) Events	Affected Segments
Problems				
Pin sites infection	12	9	0	0
Obstacles				
Deep infection	1	1	0	0
Screw failure	0	0	1	1
Pin loosening	1	1	0	0
Nonunion	2	2	1	1
Contractures	1	1	0	0
Loss of length	0	0	1	1
Complications				
Fracture postremoval	1	1	0	0
Joint subluxation	1	1	0	0
Total adverse events and affected segments	19	16	3	1

DISCUSSION

The goal of lengthening nails is achieving target length with the least number of problems and complications. Lengthening nails are currently being used off-label in the pediatric population. This might be related to the limited evidence of the outcomes in this age group. Szymczuk et al,[10] compared the outcome of femoral lengthening with magnetic lengthening nails to monolateral external fixation in children with CFD. The included patients aged between 5.6 and 13.2 years for the external fixation group and 10.5 and 20.3 years for the lengthening nail group. Black et al,[11] conducted similar research. The sample included patients aged between 12.3 and 18.8 years in the external fixation group and 15.5 and 21.2 years in the lengthening nail group. Both studies concluded that lengthening nails were more effective and safer compared with external fixation. However, both studies compared younger patients in the external fixation groups to older patients in the lengthening nails groups. A recent noncomparative report on 43 femoral lengthening procedures with PRECICE nails in children concluded PRECICE nails to be safe and effective.[9]

This study compared the outcomes of femoral lengthening nails in young people (11 and 17 y) to external fixation. Patients in the 2 groups were matched for age. Femoral lengthening in patients with congenital longitudinal deficiency is associated with a higher incidence of complications compared with patients with acquired conditions.[10] Therefore, the diagnosis was matched in the 2 groups in this study.

Both interventions led to similar length gains. However, lengthening nails were more accurate than external fixation. This might suggest that lengthening nails were more tolerable than external fixators.

We found HI to be significantly better in Group B, this was in line with the reported literature.[6,10] However, these studies reported lower overall HIs. This might be related to different definitions of healing in different studies. Healing was defined in this series as cortical

continuity in 3 cortices on 2 orthogonal radiographs. In addition to the intervention, age and indication of lengthening were reported to affect HI.

Sex, type of the external fixator (circular or monolateral), type of lengthening nails (antegrade or retrograde) did not have a significant effect on HI, length gain, residual malalignment, and accuracy of achieving the target length. These findings might help researchers in designing future comparative studies. In this series, retrograde nails were reserved for older children with fused distal femoral physis. Other indications for retrograde nails included distal deformity correction, altered proximal femur anatomy (eg, pelvic support osteotomy), and proximal metalwork.

The external fixation group had a significantly longer length of hospital stay. Training for pin site care, difficult mobilization with the external fixators, and pain control could be some of the limiting factors for early discharge with external fixation.

The reported complications per lengthening session were significantly lower in this series (for both groups) compared with the literature.[10,11]

The adverse effects linked to lengthening nails can be broadly divided into device and nondevice-related complications. Device-related complications include (1) distraction-related problems (eg, failure to control rate, failure to distract). (2) Stability-related problems (eg, nail bending, breakage of the nails or their components). (3) Other device-related problems (eg, corrosion and soft tissue reactions). Nondevice-related complications include delayed healing and changes in the alignment of the limb.[12] In this series, none of the patients had distraction-related problems. However, there was a case of a collapse of the gained length following achieving the desired length in a patient with osteogenesis imperfecta. This was related to loosening of the distal locking screws, with delayed union following replacement of locking screws necessitating exchange nailing to a rigid intramedullary nail. Another patient had trochanteric bursitis following the initial surgery, no surgical intervention was required. We routinely remove the lengthening nails following the course of the treatment. Corrosion was not observed during the extraction procedures. Muscle contractures and joint stiffness were not reported, possibly related to our current practice of release of the iliotibial band at the time of osteotomy and extensive physiotherapy and rehabilitation.

Most adverse events in the external fixation group did not require surgery; the events that required surgical management included pin loosening, fracture, nonunion, hip subluxation, manipulation of a stiff knee, and deep infection. A total of 12 adverse events were treated in outpatient clinics, such as pin site infection, stiffness, increased pain, and poor tolerance to the device.

Unlike external fixators, lengthening nails produce lengthening along the femoral anatomic axis. This might change MAD and overall limb alignment. Burghardt et al,[13] suggested that 1 cm of lengthening produces an increase of MAD by 1 mm. In our series, we utilized multiple techniques such as Poller screws,[14] reverse planning[15] ± acute correction of pre-existing deformities, and external fixator assisted nailing to ensure satisfactory alignment. In the presented cohort, there was no significant difference in the final MAD between the 2 groups.

Femoral head avascular necrosis is one of the serious complications linked to antegrade femoral nailing in children. Hammouda et al[8] reported no cases of avascular necrosis in their cohort of children treated with trochanteric entry nails. No cases of postoperative avascular necrosis following antegrade nails were encountered in the presented study.

Femoral external fixators offer the option to span the knee joint, which provides knee protection especially in cases of congenital longitudinal deficiency. In this study, all the children in the nails group had strict physiotherapy and night splinting in addition to regular radiographic surveys during the distraction phase, and the distraction rate was adjusted accordingly. None of our cohorts had prelengthening knee ligament reconstruction and no cases of knee subluxation were recorded.

Magnetic nails have been recently criticized. The recent generation of PRECICE nails (STRYDE) are thought to be associated with osteolysis, periosteal reaction, and pain.[16] STRYDE nails were introduced to the UK market in 2019 as an upgrade from the PRECICE nails. Unlike PRECICE nails which are made from titanium, STRYDE nails are manufactured from stainless steel. This was to enable early full weight-bearing. STRYDE nails were expected to improve the quality of life of the patients and enable bilateral simultaneous lengthening. The main concern with STRYDE nails was corrosion at the telescopic junction of the nail, which might be linked to the aforementioned adverse effects.[16] STRYDE nails were recently recalled for further research. Only PRECICE nails were used in this study. No osteolytic changes near the junction of the telescoping portion of the nail were observed in this study sample.

There are several limitations to this study. First, the sample size was relatively small. However, this was partly because of the rarity of the condition, study design which relied on matching, and the strict inclusion criteria. Second, the external fixation sample was selected manually. However, this was done to enable the matching. Despite that, it was not possible to fully match the specific indication for lengthening beyond the congenital and acquired stage. Third, since this was a retrospective notes review, the frequency of the adverse events might have been underreported. This could have mainly affected mild adverse events such as pin site infections, pain, and discomfort. This did not apply to more serious complications which are observed radiologically or from further surgical/admission records.

CONCLUSION

PRECICE lengthening nails are clinically effective for femoral lengthening in adolescent populations. Compared with external fixation, the HI and complication rate are more favorable with the lengthening nails. Further research is required to study the cost-effectiveness of this technique.

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