# Lengthening With Monolateral External Fixation Versus Magnetically Motorized Intramedullary Nail in Congenital Femoral Deficiency

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**Background:** Limb lengthening for congenital femoral deficiency (CFD) with or without fibular hemimelia can be performed with both external and internal devices. The purpose of this study is to compare clinical outcomes of femoral lengthening utilizing monolateral external fixation versus a magnetically motorized intramedullary nail in patients with CFD with or without fibular hemimelia.

**Methods:** This retrospective review included 62 patients with femoral lengthening, 32 patients had monolateral external fixation (group A), 30 patients had internal lengthening nail (group B). Mean age in years was 9.4 ± 3.8 and 15.4 ± 4.9 for groups A and B, respectively. Mean follow-up in years was 4.47 ± 2.7 and 1.86 ± 0.7 years for groups A and B, respectively.

**Results:** Mean lengthening achieved was 5.6 ± 1.7 and 4.8 ± 1.4 cm for group A and group B, respectively ($P = 0.052$). Mean distraction index was 0.7 ± 0.2 mm/d for group A and 0.7 ± 0.2 mm/d for the group B ($P = 0.99$). Mean consolidation index for group A was 29.3 ± 12.7 and 34.8 ± 11.2 d/cm for group B ($P = 0.08$). Mean arc of motion before surgery and at final follow-up were similar between groups ($P = 0.35$). Group A had significantly less range of motion at the end of distraction ($P = 0.0007$) and at consolidation ($P < 0.0001$). Both groups had similar rates of obstacles and complications. A significant difference between groups was found in the total problems ($P < 0.001$) specifically with pin site/superficial infection ($P < 0.0001$).

**Conclusions:** The intramedullary nail had superior range of motion during the lengthening phase and at consolidation and an overall lower problem complication rate, while maintaining similar distraction and healing indices to monolateral external fixation. Internal lengthening nails represent a significant advance in technology for CFD lengthening.

**Level of Evidence:** Level IV—therapeutic.

**Key Words:** bone lengthening, intramedullary nail, complication, monolateral external fixation, leg length discrepancy, limb lengthening, magnet

(*J Pediatr Orthop* 2017;00:000–000)

Congenital femoral deficiency (CFD) with or without fibular hemimelia (FH) are congenital deformity disorders of the lower limb and may be associated with other congenital anomalies. Mild to moderate cases can be treated with joint reconstruction followed by lengthening procedures.[1] Severe cases may be treated with a rotationplasty reconstruction or amputation and prosthetic rehabilitation.[2–4] Potential or actual instability of the hip and/or knee may be treated by acetabulopasty and cruciate ligament reconstruction.[5]

Monolateral external fixation is a well-recognized method for limb lengthening in patients with CFD.[1] Complications associated with external fixation include pin site infections, joint contractures and subluxation, or regenerate problems (delayed union, nonunion, premature consolidation, or fracture postframe removal).[6–9] External fixation over an intramedullary (IM) nail, referred to as lengthening over a nail, has been used to decrease the fixator time and stabilize the regenerate during the consolidation phase after frame removal. However, lengthening over a nail has been associated with increased risk of deep infections and does not eliminate the problem of external-fixator–associated complications.[6,10–12] Fully implantable, telescopic, motorized IM nails have become an attractive alternative as they reduce common complications associated with external fixation and are more accepted by patients for reasons such as decreased discomfort, bulk, and scarring.[12–17]

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This study was performed at Sinai Hospital of Baltimore, Baltimore, MD.

No external funds were received to conduct the study or prepare the manuscript.

V.L.S., A.I.H., M.G.G., S.C.S., and J.E.H: The following organizations supported our institution's annual course for orthopedic surgeons: Acumed, Brainlab, Baxter, DePuy Synthes, Integra, Merete Technologies, MHE Coalition, NuVasive Specialized Orthopedics, Orthofix, OrthoPediatrics, Smith & Nephew, Stryker, and Zimmer Biomet. The following companies supported our institution's non-profit organization, which provides financial assistance to our patients: CS Medical Supply, Metro Prosthetics, and Stryker. In addition, S.C.S.: Consultant at NuVasive Specialized Orthopedics. Royalties from NuVasive Specialized Orthopedics and Pega Medical. J.E.H.: Consultant at NuVasive Specialized Orthopedics, Orthofix, Orthopediatrics, and Smith Nephew. Research support from NuVasive Specialized Orthopedics.

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DOI: 10.1097/BPO.0000000000001047

The femoral monolateral external fixators provide the ability to bridge the knee by including stability at the knee center of rotation and an upper tibial component of the fixator frame; the bridging component is hinged thereby allowing motion during physical therapy (PT) and activity. This helps to maintain full extension of the knee joint range of motion (ROM) and thus decreases the occurrence of muscle contractures as well as knee stiffness, subluxation, and dislocation. IM nails do not have this additional capability but are fully implantable providing easier rehabilitation postoperatively.

Increased rates of complications secondary to femoral lengthening have been reported in patients with congenital etiologies.[6,18] Prince and colleagues examined the ROM and complications associated with the use of monolateral fixation for femoral lengthening in patients with CFD and FH. They reported no significant difference in hip and knee flexion and extension postoperatively; however, 32% of patients had complications requiring treatment with surgical intervention.[1] IM lengthening in CFD and FH patients was studied by Shabtai et al,[14] and although the procedure was accurate, 39% of patients experienced complications requiring surgical intervention. Black et al[19] compared circular external fixation to IM lengthening in CFD patients and concluded that overall IM lengthening had fewer complications than external fixation (28 patients total; 14 patients in each group). The study by Black and colleagues is very similar to the current study, but reports on much fewer patients and on an US Food and Drug Administration (FDA) unapproved device (compassionate use basis at the time of the study, but recently the device has received FDA approval; FITBONE; Wittenstein Intens, Ingersheim, Germany).

The purpose of this study is to compare the clinical outcomes of femoral lengthening utilizing LRS monolateral external fixation (Orthofix International NV, Lewisville, TX) versus PRECICE IM magnetically motorized nail (NuVasive Specialized Orthopedics Inc., Aliso Viego, San Diego, CA) in CFD patients with and without FH.

## METHODS

This retrospective study was approved by our institutional review board. The inclusion criteria were as follows: diagnosis of CFD with or without FH, history of femoral lengthening using either monolateral external fixation (group A) or the IM PRECICE nail (group B), and minimum 1-year follow-up after index surgery (Figs. 1, 2). Patients were included who underwent surgery between January 2006 and January 2015. Some of the patients identified were also previously included in prior articles from our institution.[1,14,16]

The chart review identified patient demographics, history of prior hip or knee surgeries,[5] follow-up period, ROM, and complications. Prior hip or knee procedures noted included super hip procedure, super knee procedure, dega osteotomy, pelvic osteotomy, and acetabular osteotomy. Knee ROM was assessed before index surgery, postdistraction completion, postconsolidation, and at final follow-up. It is the standard at our institution to measure ROM utilizing a goniometer. Radiographic review was performed using either traditional or digital films and confirmed by clinical notes from which we identified the preoperative femoral lengthening goal, lengthening achieved, and dates of completed distraction and consolidation. Adverse events were classified as problems, obstacles, or complications.[6] For group A patients with concomitant tibial external fixation, complications related to the tibia component were excluded. All patients included in this study were either Paley classification type 1A or type 1B converted to type 1A via the super hip procedure.[1]

The distraction index (length of regenerate in mm divided by duration of distraction in days) and the consolidation index (CI; days from index surgery till consolidation divided by length of the regenerate in cm) were compared in both groups. Consolidation was defined as radiographic evidence of healing of 3 of 4 cortices.

Statistical analyses were performed using MedCalc for Windows, version 15.0 (MedCalc Software, Ostend, Belgium). Results are expressed as the mean ± SD or percentage as indicated. A 2 tailed $t$ test was utilized for the comparison of means of independent samples. The $\chi^2$ test was utilized to compare proportions expressed as a percentage and the fisher exact test was performed when the observed sample was $< 5$. The results were considered statistically significant when $P < 0.05$.

### Surgical Technique

All procedures were performed at our institution by the 2 senior attending surgeons using the same technique with standardized postoperative care, PT, and follow-up schedule.

Most patients had a prior Dega osteotomy, and in some cases, proximal femoral reconstruction.[1] The fascia lata was used for reconstruction of the anterior and/or posterior cruciate ligaments in unstable knees. The same basic technique was used for all patients undergoing monolateral external fixation (group A). Three proximal and 3 distal half-pins were inserted into the femur perpendicular to the mechanical axis of the proximal and distal femoral segments. The external fixator was applied with a hinge knee component to bridge the knee and fixed to a proximal tibial ring with 3 additional half-pins. This was followed by femoral osteotomy using the multiple drilling technique at the planned preoperative site (the junction of the middle and distal femoral segments). Fourteen patients had an additional Taylor Spatial Frame to correct concomitant tibial deformity with or without tibial lengthening. In 25 cases, a prophylactic Rush rod (Rush Pin LLC, Meridian, MS) was inserted into the femur after frame removal to protect the regenerate bone from fracture after frame removal.

At our institution, modern circular frames are used for the tibia but not the femur in nonsignificant deformity cases. We find that monolateral external fixators are useful for patients who require only lengthening of the femur without deformity correction and who will be weight-bearing after surgery. The modern circular frames

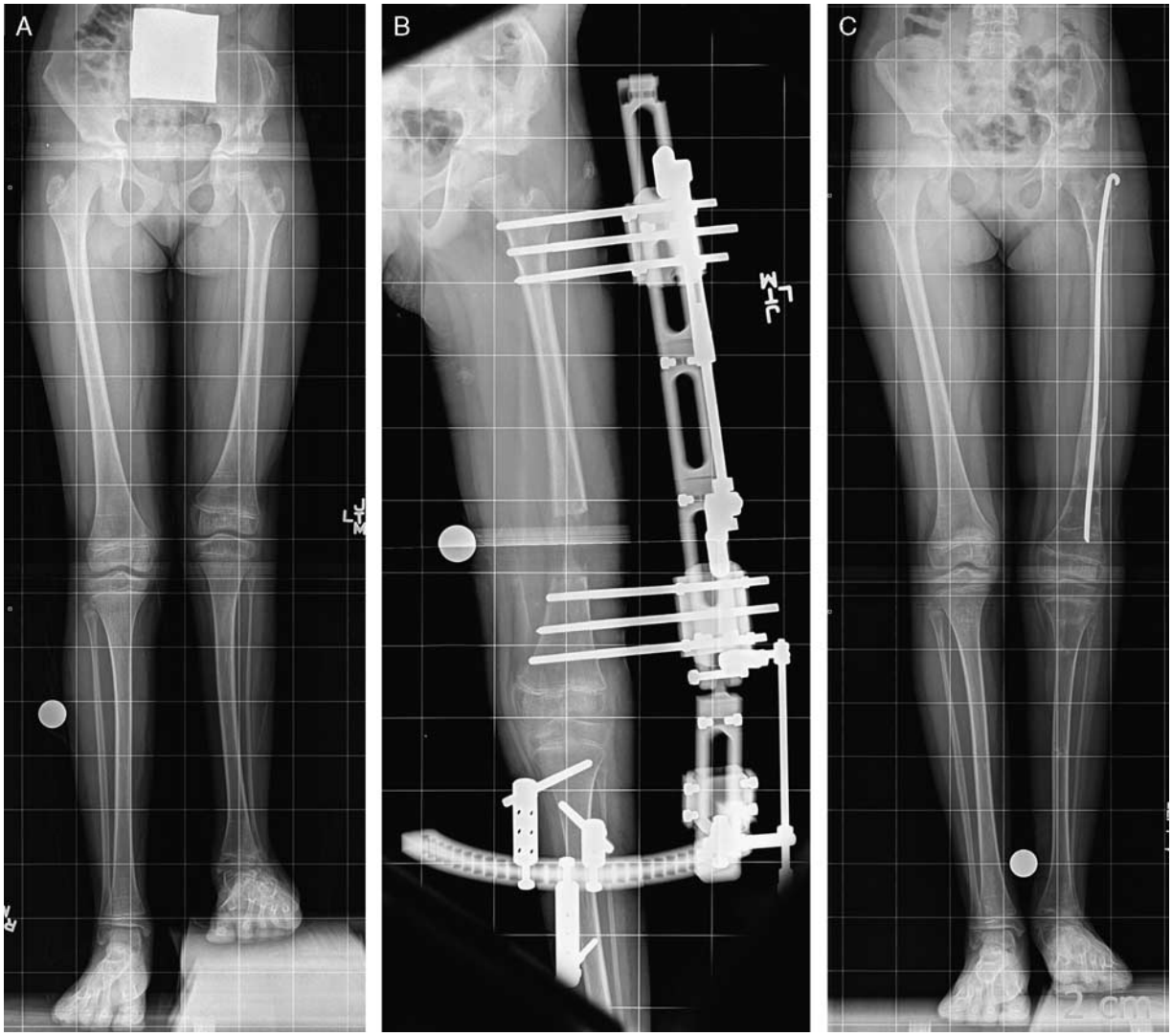


**FIGURE 1.** A–C, An 10-year-old female with congenital femoral deficiency and a 5-cm femoral discrepancy underwent treatment with monolateral external fixation. Preoperative anteroposterior (AP) radiograph with a 7-cm lift (A), AP radiograph during the lengthening phase of treatment (B), AP radiograph after fixator removal with a Rush rod in place to prevent fracture (C) Copyright 2017, Rubin Institute for Advanced Orthopedics, Sinai Hospital of Baltimore.

are not only bulky, but they do not allow the patient to ambulate normally as the frame impinges the contralateral limb. Physiotherapy in circular femoral fixation is more difficult as the patients are not as easily positioned prone or flat supine for therapy. Therefore, for femoral lengthening, we prefer monolateral over circular fixation.

In group B patients, preoperative identification of the length and diameter of nail was performed to match the size of the femoral segment. A 1-cm incision was made at the planned osteotomy site. The IM canal was vented by making multiple drill holes at the osteotomy. This was followed by progressive reaming of the IM canal up to 2 mm over the diameter of the selected nail. An osteotome was used to completely cut the bone at the osteotomy level followed by insertion of the proper IM nail, which was then locked proximally and distally using locking screws. Acute distraction of 1 to 2 mm of the nail was performed intraoperatively with the external remote controller (ERC) magnetic field generator to document proper functioning of the magnetic lengthening mechanism.

Both groups of patients underwent transection of the tensor fascia tendon at the level of the superior pole of the patella to facilate lengthening and to prevent posterolateral rotary subluxation.

## Postsurgical Care

After a latency of 5 to 7 days postoperatively, all patients were instructed to distract the osteotomy site by 0.75 to 1.0 mm/d either by the ERC or mechanical turns. The rate was adjusted according to the regenerate quality. All patients were instructed to follow-up every 2 weeks

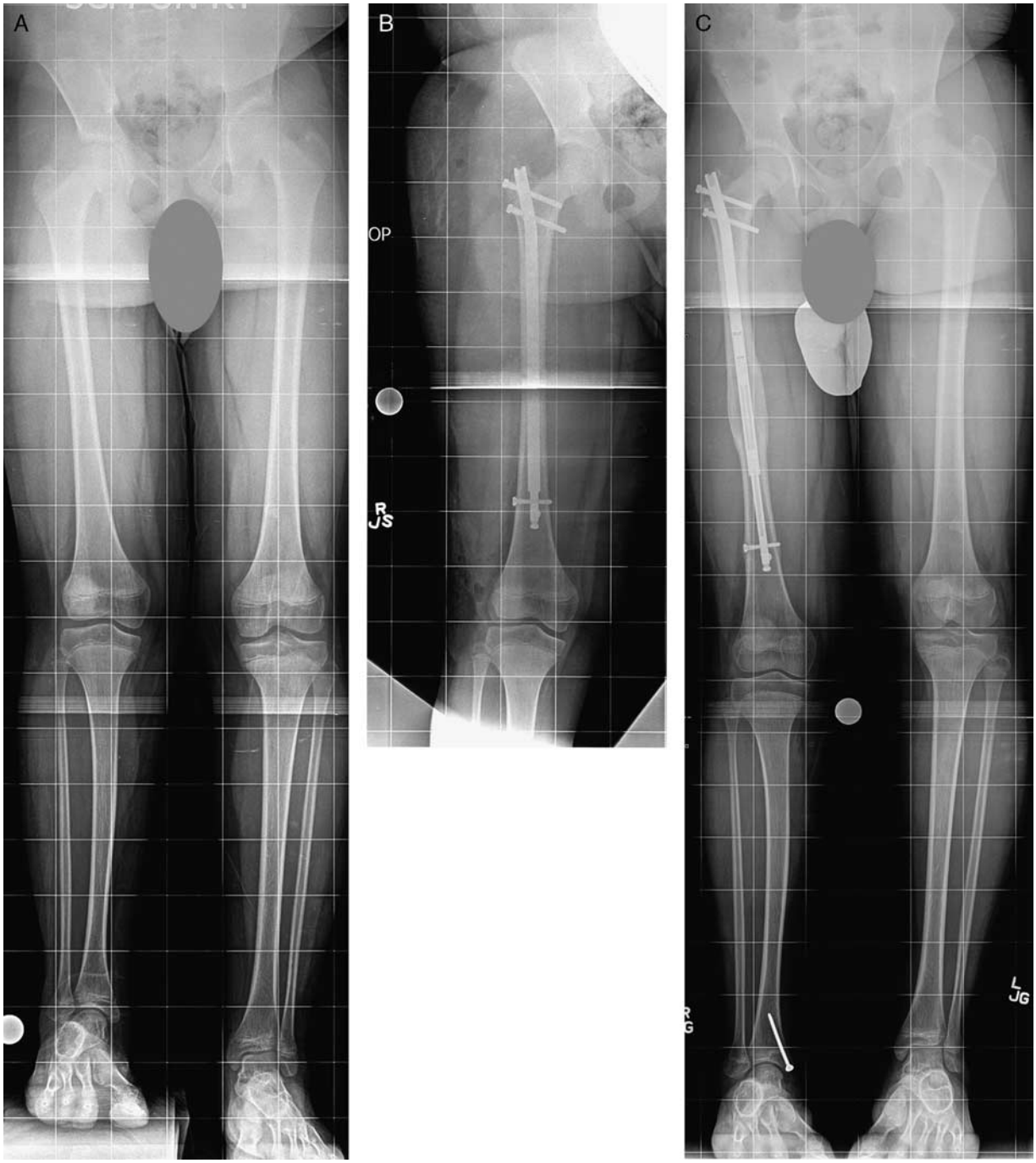


**FIGURE 2.** A–C, An 11-year-old male with congenital femoral deficiency and a 5.5-cm limb length discrepancy underwent intramedullary nail lengthening. Preoperative anteroposterior (AP) radiograph with a 5-cm lift (A), AP radiograph immediately after nail insertion (B), AP radiograph after complete consolidation (C) Copyright 2017, Rubin Institute for Advanced Orthopedics, Sinai Hospital of Baltimore.

during the distraction phase and every month during the consolidation phase. Radiographs were taken regularly that included both anteroposterior (AP) and lateral views of the femur and, if necessary, long AP films of the lower extremities to assess the limb length discrepancy (LLD) and limb alignment. Patients were prescribed 1000 mg of calcium/day and 1000 to 3000 IU of vitamin $D_3$/day to promote healing.

PT was prescribed at minimum 1 hour daily, 4 to 5 times/week, during the distraction phase and 3 to 4 times/week during the consolidation phase. It was stressed to all patients that they must maintain full extension throughout the

lengthening phase and at least 45 degrees of flexion. If patients were unable to maintain the appropriate ROM regardless of fixation (lacking 40 to 45 degrees of extension), further steps were considered including reduction of lengthening rate/amount, optimizing PT regimens, additional splinting, and finally possible return to the operating room for muscle releases. Both groups were allowed partial weight-bearing until consolidation and then were allowed full weight-bearing. The reason that we do not permit unrestricted weight-bearing is that we are fearful of loosening/breakage of external fixator pins in the frame cases and broken rods in the PRECICE cases. For group A, pin site care included cleansing with antibacterial soap and wrapping with gauze sponges. Oral antibiotics were prescribed for patients with symptoms and signs of superficial pin tract infections.

## RESULTS

Patients with CFD/FH who underwent femoral lengthening were stratified to group A (32 patients with monolateral external fixation) and group B (30 patients with the IM nail). Significant difference was observed between both groups regarding age and follow-up period (Table 1). Group A had significantly less ROM at the end of distraction ($P = 0.0007$) and postconsolidation ($P < 0.0001$). There is no difference in ROM between groups at final follow-up (Table 2).

For group A, the lengthening goal was achieved in 28 (88%) of 32 patients; 2 patients had slow healing and 2 patients had premature consolidation. For group B, the lengthening goal was achieved in 26 (87%) of 30 patients; 2 patients had subluxation (1 knee and 1 hip) and 2 patients had delayed union.

Adverse events are listed in Table 3. Group A had 26/32 (81%) affected segments and developed 58 events: 12 patients had 1 event, 9 patients had 2 events, 2 patients with 3 events, 3 patients had 4 events, and 2 patients had 5 events. Group B had 18/30 (60%) affected segments and a total of 31 events: 8 patients had 1 event, 7 patients had 2 events, and 3 patients had 3 events. Both groups had similar rates of obstacles and complications. The only significant difference between groups was found in the total problems ($P < 0.001$), specifically with pin site/superficial infection ($P < 0.0001$).

## DISCUSSION

Limb lengthening in patients with CFD with/without FH is a challenge to orthopaedic surgeons, especially for severe cases.[3] In the literature, femoral lengthening in these patients is associated with an increased incidence of complications compared with patients with other etiologies, regardless of method used for lengthening.[14] The goal of our study was to compare the outcomes of femoral lengthening in patients with CFD with/without FH utilizing the external monolateral fixator (LRS) versus the internal IM lengthening nail (PRECICE).

There are several limitations to this study. First, the number of patients in both groups is relatively small. This is due to the rarity of patients with LLD due to CFD with or without FH that undergo lengthening. Second, the mean age and length of follow-up of both groups is significantly different. At our institution, the motorized IM nail has only been used for patients older than 9 years as the procedure requires a trochanteric entry point and also because the 8.5-mm diameter PRECICE nail has only recently became available. Monolateral external fixation can be used in younger children, as young as 3 years. The difference in follow-up between groups is secondary to the fact that the PRECICE nail is new technology. The vast majority of complications occur during the lengthening period and within the first 6 to 12 months after surgery; therefore, it is unlikely that late complications in the IM group would alter the findings of this study. Third, as this is a chart review, the number of complications reported is dependent on the dictation. Despite the possibility that our pin tract infections are likely underreported, it was still shown to be significant in comparison with the motorized IM nail.

Group A did appear to have a slightly better mean length achieved than group B; this is likely due to the 3 group B patients who had to prematurely stop lengthening due to subluxation and delayed union only achieving 53% to 83% of their desired length. Subluxation is always a risk in CFD patients who undergo lengthening procedures.

**TABLE 1.** Patient Demographics and Prior Procedures

| Variables | Group A (N = 32) Monolateral Fixation | Group B (N = 30) IM Nail | *P* |
|---|---|---|---|
| Age (y) | 9.42 ± 3.83 | 15.4 ± 4.94 | < 0.0001 |
| Male patients (%) | 10 (31) | 14 (47) | 0.30 |
| Femoral lengthening goal (cm) | 5.58 ± 1.82 | 4.97 ± 1.43 | 0.15 |
| Lengthening achieved (cm) | 5.55 ± 1.74 | 4.75 ± 1.40 | 0.052 |
| Distraction index (mm/d) | 0.7 ± 0.17 | 0.7 ± 0.18 | 0.99 |
| Consolidation index (d/cm) | 29.33 ± 12.68 | 34.77 ± 11.23 | 0.08 |
| Follow-up (y) | 4.47 ± 2.73 | 1.86 ± 0.67 | < 0.0001 |
| No. patients with ≥ 1 prior super hip procedure (%) | 11 (34) | 8 (27) | 0.55 |
| No. patients with ≥ 1 prior super knee procedure (%) | 10 (31) | 6 (20) | 0.33 |
| No. patients with ≥ 1 prior Dega/pelvic/Ganz osteotomy (%) | 12 (38) | 4 (13) | 0.16 |

Values are presented as n (%) or mean ± SD.
IM indicates intramedullary.

**TABLE 2.** Arc of Motion

| | Group A (32 Segments) Monolateral Fixation (degrees) | | Group B (30 Segments) Telescopic IM Nail (degrees) | | |
|---|---|---|---|---|---|
| **Range of Motion** | **Extension** | **Flexion** | **Extension** | **Flexion** | ***P*** |
| Preoperative | 0.47 ± 2.18 | 123.3 ± 12.2 | 0.83 ± 3.1 | 127.7 ± 22.9 | 0.35 |
| Postdistraction | −0.6 ± 4.3 | 69.9 ± 30.2 | 0.93 ± 3.3 | 96.3 ± 28.2 | 0.0007 |
| Postconsolidation | 0.74 ± 4.9 | 81.3 ± 30.1 | −0.4 ± 2.1 | 121.5 ± 23.1 | < 0.0001 |
| Final follow-up | −0.7 ± 4.8 | 120.2 ± 19.9 | −0.4 ± 2.0 | 119.6 ± 16.5 | 0.90 |

IM indicates intramedullary.

With the external fixator, this is mitigated by spanning the knee with a hinged external fixator construct. With the IM lengthening nails, we rely on dynamic splinting in full extension. The first stage of knee subluxation is the development of a knee contracture; vigilant splinting is crucial. In the CFD population, the most feared risks are hip or knee subluxation. Preoperative preparation of the acetabular coverage by Dega or other pelvic osteotomy usually prevents hip subluxation with the goal to keep the center edge angle above 20 degrees.[20,21] For the knee, mild instability can be treated with extension bracing during lengthening. Higher grades of instability are best treated with preoperative anterior cruciate ligament/posterior cruciate ligament reconstruction and bracing.

We found that the CI for group B was 34.7 d/cm (SD ± 11.2), which is within the range reported by other studies using IM lengthening nails such as the ISKD nail (36 d/cm)[22] and the Fitbone nail (45 d/cm).[23] We reported a CI of 29.3 d/cm (SD ± 12.7) for group A patients, which is less than reported by Prince et al[1] who used monolateral external fixation (39 d/cm), Catagni and colleagues who used the Ilizarov technique (44.9 d/cm)[24] and Horn and colleagues who used the Taylor spatial frame (57 d/cm).[23] At our institution, we performed the osteotomy at the middle lower third of the femur, which is a preferable site for healing due to its proximity to the metaphysis.

While preoperative flexion was similar between both groups, a significant difference was observed at the end of lengthening and at consolidation. This phenomenon is supported by various studies in the literature, which have also observed a decrease in ROM with external fixation, although some also report a regain in ROM after removal of the fixator.[1,6,8] Others report continued ROM reduction postremoval.[24] Group B had an overall better retention of ROM over the course of treatment and after removal, which is supported by prior studies.[14,22,23] The difference observed between the 2 methods could be due to the tethering effect that the external fixator pins have on the musculature throughout the treatment, impacting the ability of the knee joint to move properly.[6] The IM nail does not have this restricting effect and the

**TABLE 3.** Events

| | Group A (32 Segments) Monolateral Fixation [n (%)] | | Group B (30 Segments) Telescopic IM Nail [n (%)] | | |
|---|---|---|---|---|---|
| **Event Category** | **Total Events** | **Affected Segments** | **Total Events** | **Affected Segments** | ***P*** |
| Problem | 32 (55.2) | 20 (62.5) | 8 (25.8) | 7 (23.3) | < 0.001 |
| Pin site/superficial infection | 21 (36.2) | 13 (40.6) | 1 (3.2) | 1 (3.3) | < 0.0001 |
| Frame/rod failure | 2 (3.4) | 2 (6.3) | 0 | 0 | 0.49 |
| Delayed union | 3 (5.2) | 3 (9.4) | 3 (9.7) | 3 (10.0) | 0.99 |
| Contractures | 3 (5.2) | 3 (9.4) | 4 (12.9) | 4 (13.3) | 0.70 |
| Premature consolidation | 2 (3.4) | 2 (6.3) | 0 | 0 | 0.49 |
| Nerve compression | 1 (1.7) | 1 (3.1) | 0 | 0 | 0.99 |
| Obstacle | 20 (34.5) | 10 (31.3) | 19 (61.3) | 11 (36.7) | 0.66 |
| Deep tissue infection | 1 (1.7) | 1 (3.1) | 0 | 0 | 0.99 |
| Subluxation | 1 (1.7) | 1 (3.1) | 2 (6.5) | 2 (6.7) | 0.61 |
| Frame/rod failure | 2 (3.4) | 2 (6.3) | 2 (6.5) | 2 (6.7) | 0.99 |
| Delayed/malunion | 5 (8.6) | 4 (12.5) | 7 (22.6) | 7 (23.3) | 0.33 |
| Contractures | 5 (8.6) | 4 (12.5) | 5 (16.1) | 5 (16.7) | 0.73 |
| Preconsolidation | 4 (6.9) | 4 (12.5) | 1 (3.2) | 1 (3.3) | 0.36 |
| Screw failure | 1 (1.7) | 1 (3.1) | 0 | 0 | 0.99 |
| Nerve compression | 1 (1.7) | 1 (3.1) | 2 (6.5) | 2 (6.7) | 0.61 |
| Complication | 6 (10.3) | 5 (15.6) | 4 (12.9) | 4 (13.3) | 0.99 |
| Frame/rod failure | 2 (3.4) | 2 (6.3) | 0 | 0 | 0.49 |
| Fracture postremoval | 3 (3.4) | 3 (9.4) | 0 | 0 | 0.23 |
| Shortening postremoval | 1 (1.7) | 1 (3.1) | 0 | 0 | 0.99 |
| Subluxation | 0 | 0 | 2 (6.5) | 2 (6.7) | 0.23 |
| Delayed/malunion | 0 | 0 | 2 (6.5) | 2 (6.7) | 0.23 |
| Total | 58 | 26 (81.3) | 31 | 18 (60.0) | 0.07 |

IM indicates intramedullary.

musculature can continue to function freely and maintain adequate ROM. Although this difference was observed at the end of lengthening and at the consolidation time point, there was no difference in ROM at final follow-up. These results suggest that ROM is better maintained during the lengthening phase allowing for more efficient rehabilitation and ROM return.

The complication rates that required return to the OR were lower than reported by other studies that used the Paley classification system such as Prince et al[1] and Oostenbroek et al[25] with rates of 50% and 69%, respectively. There is little data available for comparing complication rates using the Paley classification for the motorized IM nail. In our study, 14/32 (44%) of group A patients and 12/30 (40%) of group B patients had to return to the operating room to treat the complications.

Group A had significantly more adverse events than group B; pin site/superficial infections were the main contributor. Both groups had similar rates of obstacles and complications. The number of adverse events per lengthening session between the 2 groups was significantly different with 1.80 (SD ± 1.07) events per lengthening session for group A and 1.00 (SD ± 1.03) events per lengthening session for group B; ($P = 0.02$). Black et al[19] used their own classification system to compare circular fixation to the Fitbone IM nail in CFD patients. They reported the number of adverse events per lengthening session to be significant at 2.4 ± 1.3 for circular fixation and 1.2 ± 1.1 for the motorized nail ($P = 0.02$). In their study, no significant difference was reported in the total number of complications, although category I complications (defined as minimal intervention required; treatment goal still achieved such as pin-tract infections and mild joint contractures) were significantly different between the groups. Eleven of 14 (79%) circular fixator patients had category I complications as compared with 5/15 (33%) IM patients ($P = 0.03$), the majority of which were due to pin tract infections.

Delayed union of the regenerate was dynamized in several ways depending on whether it was classified as a problem or an obstacle. If the delayed union was a problem, group A femurs were dynamized with modification of the frame while group B femurs were dynamized by compression of the regenerate by using the ERC. If delayed union was an obstacle, it was dynamized by removing the screws to allow increased load transfer to the regenerate bone.

The distraction index and CI were similar in both groups whereas the ROM was better retained during the lengthening phase and at consolidation. The overall problem complication rate was significantly lower with the IM lengthening nail. These findings in conjunction with patient and surgeon preference can help with decision making in regards to which lengthening technique to use. Further studies will be needed to continue to analyze the various techniques to help determine the best course of treatment for this unique patient population. Another important consideration is age of the patient. The PRECICE nail is not as practical in children with CFD younger than 9 years, whereas the monolateral external fixator can be used as early as 3 years.

In summary, we feel that the IM lengthening nail represents a significant advance in technology for CFD lengthening. The increased potential for knee subluxation must be guarded against by strict bracing protocols, and in cases of preoperative radiographic instability, prophylactic knee ligament reconstruction.

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