Original Article

Acute Deformity Correction and Lengthening Using the PRECICE Magnetic Intramedullary Lengthening Nail

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Abstract

Background: External fixators have been used to treat patients with limb length discrepancy with deformity. Implantable intramedullary (IM) lengthening nails are an attractive alternative achieving accurate results with fewer complications than external fixators. We report on PRECICE™ nail utilization for simultaneous lower limb lengthening and acute deformity correction. **Materials and Methods:** A retrospective institutional study included a total of 22 segments (13 femurs, 9 tibias; mean age = 17 years) that underwent simultaneous acute deformity correction and lengthening using fixator-assisted nailing and the PRECICE™ IM nail between 2012 and 2015. **Results:** All segments were corrected with mean final mechanical axis deviation 0.8 cm (0–2.0 cm). Femoral segments achieved frontal plane correction from a preoperative mean lateral distal-femoral angle of 86° to a postoperative mean of 89°; and a sagittal plane correction from a preoperative mean posterior distal femoral angle of 76° to a postoperative mean of 84°. Tibial segments achieved frontal plane correction from a preoperative mean medial proximal tibial angle of 94° to a postoperative mean of 89°; and a sagittal plane correction from a preoperative mean posterior proximal tibial angle of 72° to a postoperative mean of 79°. Rotational malalignment was corrected in all cases based on clinical examination of the rotational profile. The mean length achieved was 4.7 cm. One femoral segment (4.5%) did not achieve the lengthening goal. The mean consolidation index was 42 days/cm. Mean distraction index was 0.7 days/mm. **Conclusions:** Internal lengthening can permit both lengthening and acute deformity correction, with appropriate preoperative planning, using fixator assisted nailing techniques.

Keywords: *Acute deformity correction, bone lengthening, intramedullary nail*

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Introduction

Limb length discrepancy (LLD) is often accompanied by angular and/or rotational deformity. These may be secondary to congenital, developmental, postinfectious, posttraumatic, and other etiologies.[1] Conventionally, both the LLD and the deformity correction have been simultaneously achieved with the use of external fixators.[2] However, external fixators have many drawbacks such as pin tract infections, joint contractures, and regenerate bone healing problems requiring prolonged external fixation times.[3] In addition, direct comparisons of external fixators and nails for lengthening resulted in a strong patient preference of nails, as there were fewer complications and greater comfort.[4,5] In an effort to reduce the time in an external fixator, lengthening over the nail (LON), lengthening and then nailing, or lengthening and then plating have been developed.[6-8] The latest advance is in systems utilizing fully implantable intramedullary (IM) nails as an alternative to external fixation, designed for the aim of lengthening only.[9-11]

Combined lengthening and moderate acute deformity correction can be accomplished through the same osteotomy as long as the deformity is no more than about 15° and the osteotomy is in the region of the deformity.[1] For reasons of patient comfort and acceptability, IM nails are preferred over external fixators when acutely correcting deformities and lengthening, as long as the anatomy of the segment, the type and the degree of the deformity permit.[12,13] A magnetically actuated IM lengthening nail (Phenix Medical, France) had been used for lengthening with acute deformity correction.[3] Fitbone IM lengthening nail (Wittenstein, Ingersheim, Germany) had been also used to acutely correct femoral

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deformities while simultaneously lengthening.[14] Recently, there have been reports of using the PRECICE™ for this as well.[15,16]

Several techniques for planning deformity correction with lengthening are available. Retrograde deformity correction was first described as a planning technique by Baumgart in 2009.[17] Alternative planning methods have been shown to have similar success.[16] The aim of the current study is to report our results after lengthening with acute deformity correction utilizing the fully implantable PRECICE™ IM lengthening system (NuVasive Specialized Orthopedics Inc., Aliso Viego, CA, USA).

Materials and Methods

This retrospective study was performed at one hospital and received institutional review board approval. All patients underwent surgical operation for femoral or tibial lengthening using the PRECICE™ nail in the period between January 2012 and August 2015, and a total of 181 segments were initially identified. Patients without concomitant acute deformity correction by the lengthening nail, patients who were planned to undergo deformity correction at the time of lengthening nail removal, and those who were skeletally immature with gradual deformity correction were all excluded. The only patients included in the study were those who underwent PRECICE™ lengthening and acute deformity correction as part of the same procedure at the same osteotomy site as the lengthening.

The outcomes measured were the amount of lengthening achieved, distraction index (DI; the length achieved in mm divided by lengthening duration in days), consolidation index (CI; number of days from surgery until consolidation divided by the length of the regenerate in cm), limb alignment, and the complications encountered. Limb alignment was evaluated for radiological pre- and post-operative lateral distal femoral angles (LDFA) and posterior distal femoral angles (PDFA) (in femoral segments), medial proximal tibial angles (MPTA) and posterior proximal tibial angle (PPTA) (in tibial segments), mechanical axis deviation (MAD) and clinical rotational alignment (in all segments). Consolidation was defined as radiological healing of 3 out of 4 cortices in anteroposterior (AP) and lateral views. For tibial cases, a healed fibula was considered as a cortex in the tibia.

Surgical technique

Preoperative digital AP long-standing and lateral radiographic imaging and analysis was performed to measure the LLD and identify the angular deformity parameters. This was performed using the hospital's picture archiving and communication system (PACS, eFilm, Merge Healthcare Incorporated, Chicago, Illinois, USA). The rotational deformity was assessed by preoperative examination using the torsional profile clinical examination of Staheli *et al*.[18] Identification of the osteotomy level and the nail entry site was planned to provide acute deformity correction and lengthening based on the principles of deformity correction[18] and safe application for PRECICE™ nail design. Specifically, the far tip of the nail is required to be at a certain minimum distance from the apex of the angular deformity (osteotomy level), equal to 3 cm plus the amount of the desired lengthening plus 4–5 cm minimum additional safe distance for mechanical stability. This ensures the female component of the nail remains at least 5 cm into the moving fragment after lengthening.

The fixator assisted nailing (FAN) technique was used for all cases.[19,20] This was performed by inserting two 6 mm external fixation pins (one in the proximal segment and the other in the distal segment) in one plane (frontal plane for varus or valgus deformity; sagittal plane for procurvatum or recurvatum deformity) in the optimal position out of the intended nail path and simulating the deformity present. Another two similar external fixation pins were inserted in the second plane in patients who had an oblique plane deformity [Figure 1]. The rotational deformity was typically controlled using two pins [Figure 2]. Based on the preoperative planning, the trajectory for the nail entry point was with a 1.8 mm K-wire. Next, a 3/32" Steinman pin was advanced into the IM canal under biplanar fluoroscopic control. This was followed by opening the entry tunnel using an 8 mm cannulated rigid reamer over the Steinman pin. The complete osteotomy was then made through a one cm incision at the planned site using multiple drill holes and an osteotome. This was followed by acute deformity correction in all planes. The position was maintained by attaching adjustable monolateral fixator units to the pins and tightening the nuts. Next, the 3 mm bead tipped guidewire was then inserted into the IM canal, followed by flexible reaming in 0.5 mm increments until the canal was over-reamed by 2 mm above the diameter of the nail. The PRECICE™ nail was then inserted gently and locked proximally and distally. If necessary, additional blocking screws were used in the proximal and/or the distal fragment to prevent malalignment and loss of correction

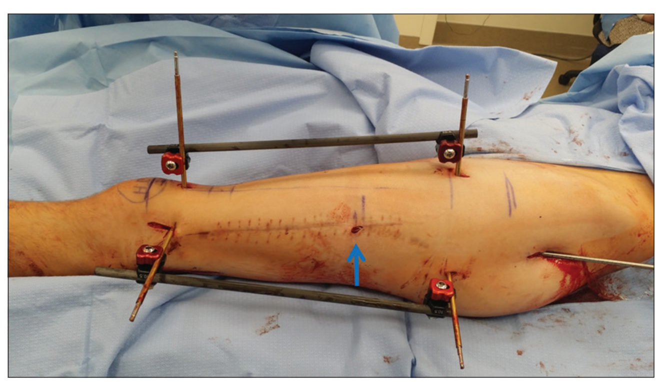

Figure 1: Fixator assisted nailing antegrade femur technique to correct two planes of deformity before intramedullary reaming and nail insertion. The arrow points to the osteotomy (used with permission)

after lengthening.[21,22] The external fixator was removed before leaving the operation room.

The patients were instructed to start distraction with the external remote control on the 5th (femoral patients, at the rate 1 mm/day) or 7th postoperative day (tibial patients, at the rate 0.75 mm/day). The rate was adjusted according to the regenerate quality observed during postoperative follow-up clinic visits every 2 weeks during the lengthening phase. During the consolidation phase, patients were radiographed monthly. The patients were prescribed physical therapy (3–5 times per week) to facilitate joint motion and to prevent joint contractures or subluxations. Night-time knee extension bracing was utilized. For tibial lengthening, the ankle was braced at night also. Patients were allowed partial weight-bearing using a crutch or walker (18–22 kg) until consolidation was observed radiographically. At this point, full weight-bearing was allowed as tolerated.

Results

A total of 18 patients (8 males and 10 females) with 22 segments (12 femurs and 10 tibias) were included in the current study; ten of these segments have been previously reported in another series on the use of internal lengthening (blinded reference for now). The average age at index surgery was 17 years (range, 8–49 years). IM PRECICE™ lengthening nails were inserted with the aim of acute deformity correction and a mean lengthening goal of 4.8 cm (range, 1–6.5 cm). The etiologies of the short, deformed segments included congenital femoral deficiency and/or fibular hemimelia (11 segments), achondroplasia (4 segments), posttraumatic (1 segments), skeletal dysplasia (2 segments), history of club foot (2 segments), Marfan syndrome (1 segment), and Legg Calve Perthes disease (1 segment). Femoral nails were inserted antegrade to correct rotational deformities in 4 segments, and retrograde to correct distal femoral deformities in 8 segments. All tibial nails (n = 10) were inserted antegrade [Figures 3 and 4].

Seventeen segments (10 femurs and 7 tibias) had a deformity in the frontal, sagittal, or axial plane (4 valgus, 3 varus, 2 procurvatum, 4 external rotation, and 4 internal rotation). Five segments (2 femurs and 3 tibias) had multiplanar deformity (oblique plane deformity ± rotational deformity). The mean angular deformity in 13 segments was 8° (range, 5°–11°) and the mean rotational deformity in 10 segments was 18° (range, 10°–45°), noting that 4 segments have oblique plane (frontal and sagittal) deformity; while two segments had a combination of angular and rotational deformity [Table 1]. The complexity of the deformities was classified according to the LLRS AIM Index classification.[23] There were 16 segments with mild complexity (10 femurs and 6 tibias), and 6 segments with moderate complexity (2 femurs and 4 tibias).

The mean follow-up period for all segments was 4.1 years (range, 2.2–7.7 years). All segments achieved the desired deformity correction with a mean MAD of 0.8 cm (range, 0–2.0 cm) compared to the preoperative mean MAD of 1.3 cm (range, 0–2.7 cm). Femoral segments achieved frontal plane correction from a preoperative mean LDFA of 86° (range, 79°–99°) to a postoperative mean of 89° (range, 88°–91°); and a sagittal plane correction from a preoperative mean PDFA of 76° (range, 75°–77°) to a postoperative mean of 84° (range, 82°–86°) [Figure 5]. Tibial segments achieved frontal plane correction from a preoperative mean MPTA of 94° (range, 87°–100°) to a postoperative mean of 89° (range, 87°–91°); and a sagittal plane correction from a preoperative mean PPTA of 72° (range, 65°–76°) to a postoperative mean of 79° (range, 75°–82°) [Figure 6]. Rotational malalignment was corrected in all cases based on clinical examination of the rotational profile. The mean lengthening achieved was 4.7 cm (range, 1–6.5 cm). One femoral segment out of the total cohort (4.5%) did not achieve the initial lengthening goal. They achieved 2.8 cm out of 5 cm goal due to the development of knee rotatory subluxation nearly in the middle of the lengthening period, which required a halt in lengthening to allow physiotherapy to regain the normal knee configuration. The patient will

Figure 2: Intraoperative rotational deformity correction (used with permission)

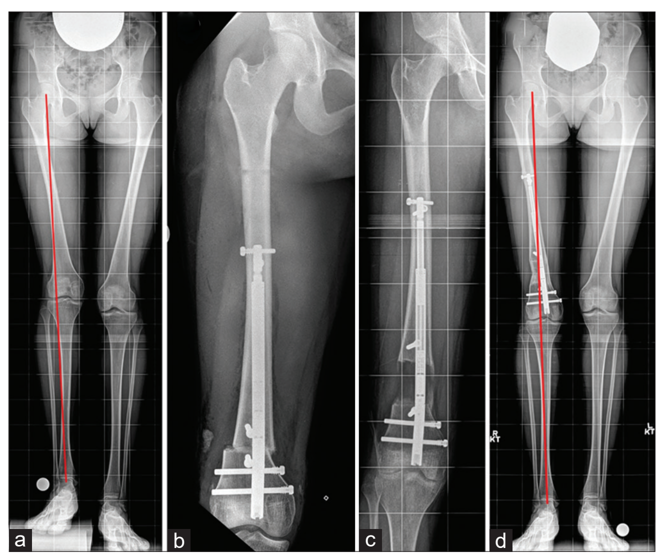

Figure 3: (a-d) 20-year-old female with right-side congenital femoral deficiency (a) 4.5 cm femoral discrepancy with 11° distal femoral valgus deformity. (b) Immediate postretrograde acute deformity correction and PRECICE™ nail insertion. (c) After complete distraction. (d) Consolidation of the regenerate and restoration of length and limb alignment (used with permission)

Figure 4: (a-h) 14-year-old female with right-side congenital femoral deficiency/fibular hemimelia (a and b) 3.5 cm femoral discrepancy, 7° femoral valgus, with 6 cm right tibial discrepancy (9° valgus, 3° procurvatum, 10° ITT) (c and d) Immediate postacute deformity correction and PRECICE™ nail insertion femur and tibia. (e) After complete distraction. (f) Consolidation of regenerate. (g and h) After nail removals. Length and limb alignment achieved (used with permission)

require knee ligament reconstruction before performing future femoral re-lengthening.

All segments achieved consolidation with a mean CI of 42 days/cm (range, 17–108 days/cm). The mean DI was 0.7 days/mm (range, 0.4–1.2 mm/day). Mean femoral CI was 33.8 days/cm (range, 17.3–58.9 days/cm) while it was 51.6 days/cm (range, 24–108 days/cm) for the tibial segments, without a significant difference between both; (P = 0.08), though a trend was apparent. In addition, there was not a significant difference regarding mean DI between femoral and tibial segments; 0.7 mm/day (range, 0.4–0.9 mm/day) and 0.65 mm/day (range, 0.4–1.2 mm/day), respectively (P = 0.30) [Table 2].

Ten segments (6 femurs and 4 tibias) out of 22 (45%) encountered complications. Four segments (3 femurs and 1 tibia) had delayed union of the regenerate; three were treated by rod dynamization and bone marrow stem cell injection or bone graft, while the other one was treated with vitamin supplementation. Two femoral segments developed knee rotatory subluxation, one treated by ligament reconstruction, while the other was treated by physical therapy and discontinued the lengthening process.

Table 1: Patient demographics and results

Age	Gender	Etiology	Bone	Frontal deformity (°)		Sagittal deformity (°)	Rotational deformity (°)	
				Valgus (*n*=9)	Varus (*n*=3)	Procurvatum (*n*=6)	IR (*n*=6)	ER (*n*=4)
20	Female	CFD	Femur	11	-	-	-	-
16	Female	CFD	Femur	9	-	-	-	-
15	Female	CFD	Femur	6	-	-	-	-
15	Female	Marfan syndrome	Tibia	6	-	-	-	-
19	Female	Achondroplasia	Femur	-	7	-	-	-
19	Female	Achondroplasia	Femur	-	10	-	-	-
19	Male	Perthes	Tibia	-	8	-	-	-
12	Female	Growth arrest	Femur	-	-	9	-	-
49	Male	CFD/FH	Tibia	-	-	10	-	
14	Female	CFD/FH	Femur	7	-	3	-	-
11	Male	Post-traumatic growth arrest	Femur	5	-	4	-	-
15	Male	CFD, FH	Tibia	10	-	8	-	-
15	Male	CFD/FH	Tibia	5	-	-	10	-
18	Female	CFD/FH	Tibia	-	-	-	20	-
14	Female	CFD/FH	Tibia	9	-	3	10	-
13	Female	Clubfoot/LLD	Tibia	-	-	-	20	-
12	Female	Achondroplasia	Femur	-	-	-	10	-
12	Female	Achondroplasia	Femur	-	-	-	10	-
9	Male	CFD	Femur	-	-	-	-	20
20	Male	Skeletal dysplasia	Tibia	-	-	-	-	15
20	Male	Skeletal dysplasia	Tibia	-	-	-	-	15
8	Female	CFD	Femur	-	-	-	-	45
Mean values (range)					8° (5°-11°)			18° (10°-45°)

IR: Internal rotation, ER: External rotation, CI: Consolidation index, CFD: Congenital femoral deficiency, FH: Fibular hemimelia

One distal femur segment developed a decubitus ulcer over the posterior calf from the knee immobilizer, leading to tibial nerve irritation, which was treated with a tarsal tunnel decompression; full nerve recovery and lengthening goals were achieved. Rod failure with premature consolidation occurred in one tibial segment 1.5 months after lengthening, treated by re-osteotomy and exchange of the lengthening rod. One tibial segment underwent removal of painful and prominent screws. Finally, one tibial segment had a loss of rod fixation with rod migration and resultant valgus deformity due to patient noncompliance and early weight-bearing. This was treated by acute deformity correction using the FAN technique. The PRECICE™ nail was exchanged for a regular trauma nail while correcting alignment and maintaining length.

Discussion

Distraction osteogenesis with external fixators is an accepted method used to achieve gradual correction of angular or rotational deformities with simultaneous lengthening the limb.[24] Gradual deformity correction has been recommended for large deformities as it is safer for neurovascular structures and allows for satisfactory bone formation.[25,26] Simultaneous acute deformity correction and lengthening has been described as a treatment method, within limits.[27-29] The circular Ilizarov and monolateral external fixators have been associated with successful outcomes while correcting lower limb deformities and LLD.[1,30-32] Fixator-assisted acute deformity correction, and subsequent LON is another method utilized to treat lower limb deformities and LLD.[29,33] Recently, the PRECICE™ fully implantable IM lengthening nails have been developed to avoid complications associated with external fixators.[11] Although gradual lengthening is the gold standard for accurate correction, inexperienced hands, we believe acute IM nail correction is acceptable and may be preferred by patients.[5]

Table 2: Comparison between femoral and tibial outcomes

	Femur (*n*=12)	Tibia (*n*=10)	*P*
Length achieved (cm)	5.4 (2.1-6.5)	3.9 (1-6.5)	0.04
DI (mm/day)	0.7 (0.4-0.9)	0.65 (0.4-1.2)	0.30
CI (days/cm)	33.8 (17.3-58.9)	51.6 (24-108)	0.08

DI: Distraction index, CI: Consolidation index

Previous attempts to achieve simultaneous acute deformity correction and lengthening have been reported using IM lengthening devices. Reported mean CI using the IM skeletal kinetic distractor was 36 days/cm, and the mean length achieved was 4.3 cm (28/57 segments underwent acute correction with lengthening).[34] The reported mean CI using the Phenix nail in 3/10 segments was 27 days/cm, and the mean length achieved was 4.6 cm.[3] The mean CI was 24 days/cm and the mean length achieved was

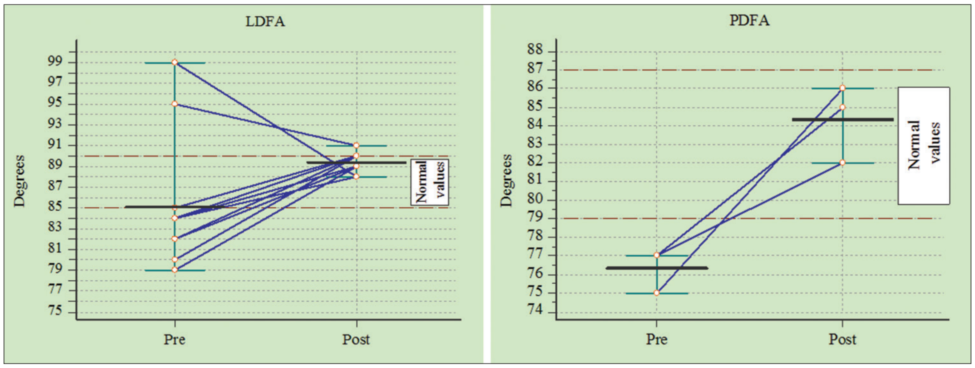

Figure 5: Femoral frontal (lateral distal femoral angles) and Sagittal (posterior distal femoral angles) deformity parameters before and after correction (used with permission)

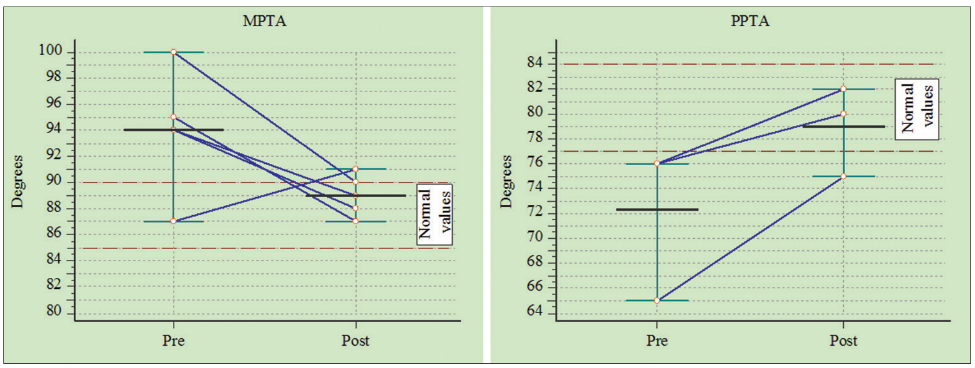

Figure 6: Femoral frontal (lateral distal femoral angles) and Sagittal (posterior distal femoral angles) deformity parameters before and after correction (used with permission)

4.8 cm using the Fitbone nail in 3/14 segments.[35] Another study reported a mean CI was 32 days/cm and the mean length achieved was 5.8 cm using the Fitbone nail in 9/25 segments.[14] The current study included 12 femurs and 10 tibias; all underwent acute deformity correction and lengthening. The mean CI was 42 days/cm and the mean length achieved was 4.7 cm [Table 3]. It seems to be the current study is worse than others reported in terms of CI. However, the other studies reported their CI based on the total number of segments in their cohorts (lengthening only and lengthening/acute deformity correction). The percentage of patients who underwent simultaneous acute deformity correction and lengthening in their cohorts ranged between 21% and 37%. Also, the majority of our cohort (16 out of 22 segments; 73%) had congenital and dysplastic etiologies, generally thought to be more complex than other etiologies and associated with longer healing times.[36-40]

The mean CI of 42 days/cm in the current study is also comparable to what is reported in the literature for acute deformity correction and lengthening using monolateral external fixators. Donnan *et al*.[41] reported a mean CI of 55.5 days/cm in their series (57 segments; 46 femurs and 11 tibias).[1] Noonan *et al*. reported a mean CI of 52 days/cm, in their series (40 segments; 22 femurs and 18 tibias).[42] On the contrary, two other studies reported a lower mean CI (39 days/cm and 28 days/cm) when using the monolateral external fixator for lengthening procedures, although these two studies achieved a greater bone length than our study (mean value between 6.6 and 9.8 cm vs. 4.5 cm).[42,43] This might be due to the fact that there has been reported to be an inverse relationship between the regenerate length and the CI. In other words, the CI rises as the length gap decreases.[44] Noonan *et al*. observed a statistically significant effect in reducing the CI while increasing the regenerate length.[41]

Described osteotomies for deformity correction include opening wedge, closed wedge, or dome osteotomy. Kamegaya *et al*. in their series following acute angular deformity correction using unilateral external fixators, reported nonsignificant difference between open wedge osteotomy in cases with angular deformities <20° and dome osteotomy for angular deformities >20°.[2] In the current study, the mean angular deformity in all segments was 8° (range, 5°–11°) and the multiple drill hole technique was used in all cases to open the wedge while keeping some bone contact at the osteotomy site. We did not observe a relation between the amount of the deformity corrected and successful healing. Similar results were observed by Noonan *et al*., while acutely correcting lower limb deformities of a mean of 19° before lengthening.[41] Recently, a study concluded that acute deformity correction, in general, does not affect bone healing when using the newer IM lengthening

Table 3: Acute deformity correction and lengthening with different intramedullary lengthening nails

Author	Number of segments with CADCAL/total (%)	Femurs (%)	Tibias (%)	Type of the nail	Mean length achieved (cm)	Mean CI (days/cm)	Mean follow up (years)
Current study	22/22 (100)	12 (55)	10 (45)	PRECICE	4.7	42	4.1
Kenawey (2011)	28/57 (37)	24 (86)	4 (14)	ISKD	4.3	36	1.9
Thaller (2014)	3/10 (30)	1 (33)	2 (67)	Phenix	4.6	27	0.5
Küçükkaya (2015)	9/25 (36)	9 (100)	0	Fitbone	5.8	32	2.6
AL-Sayyad (2012)	3/14 (21)	3 (100)	0	Fitbone	4.8	24	1.6

CADCAL: Combined acute deformity correction and lengthening, CI: Consolidation index, IM: Intramedullary, ISKD: IM skeletal kinetic distractor

devices.[45] They noticed prolonged CI in the group of patients underwent deformity correction and lengthening with the LON, more than those with the fully implantable lengthening nails (39 days/cm and 31 days/cm, respectively; $P < 0.05$).[43] This may be due to impairment of the periosteal blood supply, which has been reported to be more important than IM blood supply for bone healing.[44,45] Donnan *et al*. concluded that there was a positive relationship between the degree of maximum deformity correction and the CI of the regenerate after lengthening. This relationship was only significant in patients who had >30° of acute correction in any plane, which increased the likelihood for poor bone healing by 7 times.[1]

There are several limitations to our study. This is a retrospective study with a relatively short follow-up period. Futhermore, the relatively small number of segments in our study may be considered a limitation. However, this number represents approximately 17% of the total number of patients who have undergone PRECICE™ limb lengthening at our institute during the initial 3 years of availability.

Conclusions

Based on our results, we conclude that lower limb lengthening with simultaneous acute deformity correction through the same osteotomy is relatively safe and should be considered when addressing the problems of short and deformed limbs. Acute deformity correction plus lengthening in our study did not appear to affect the quality of regenerate, nor increase the rate of complication compared to the literature. We did not modify the latency period in our patients, compared to nondeformity lengthening patients. The new advanced technology of the PRECICE™ IM lengthening system has helped surgeons to lengthen limbs and make some corrections to acute angular, rotational, or combined deformity. Despite some complications, including delayed regenerate maturation and subluxation of the knee, the results presented with this system have met expectations. Further studies are needed to determine the limits of deformity correction and lengthening using fully implantable IM lengthening devices.

One potential disadvantage to using of the magnetic lengthening nail is the strength of the smallest nail. Previous studies had demonstrated a 50% rate of nail deformation when the smallest nail was utilized.[46,47] Although this complication was not assessed in the current study, we have used at least 10.7 mm nails whenever possible to limit this potential complication.[48] Future investigations into nail size and deformation will help illuminate the nature of this complication. In summary, our results determined that internal lengthening can permit both lengthening and acute deformity correction, with appropriate preoperative planning, using fixation assisted nailing techniques.

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Conflicts of interest

Shawn C. Standard and John E. Herzenberg are consultants for NuVasive Specialized Orthopedics.

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