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The PRECICE nail system: The initial Kuwaiti experience

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ABSTRACT

Objectives: The PRECICE system is an implantable limb lengthening intramedullary nail with remotely magnetically controlled distractors indicated for limb length discrepancy (LLD) and short stature treatment. This study reports the initial experience of the Kuwaiti deformity correction unit in utilizing the PRECICE system.

Methods: Ten patients (four females and six males) were included in this study. All cases were operated using the PRECICE nail system (five antegrade femoral nails, three retrograde femoral nails, and two tibial nails). All surgeries were performed during January 2019 to February 2020.

Results: The mean age of participants was 20 years (12–33 years), with a 21.6 kg/m^2 mean body mass index (17–28). LLD etiologies (mean LLD = 39 mm) were congenital (n = 2), developmental (n = 2), post-traumatic non-union (n = 1), post-traumatic malunion (n = 1), post-traumatic physeal arrest (n = 1), and post-deformity correction and lengthening of the contralateral side with circular frame (n = 3). The mean distraction rate was 0.97 mm/day (range: 0.75–1.2 mm/day). Mean lengthening was 39 mm (range: 20–60 mm). Healing was confirmed at 76 days on average (range: 50–120 days). All patients reached full consolidation to regenerate bone, normal alignment, and normal joint orientation. Antegrade femur lengthening was done in five patients. One patient with a previous knee fixed flexion deformity of 25° improved to a 5° lag of extension. No complications were observed during the lengthening procedures. All the patients were followed up for a minimum of 12 months.

Conclusion: The PRECICE nail system was successful in lengthening cases with different etiologies, achieving target lengths without complications. All the patients had reported excellent functional outcomes.

Keywords: Intramedullary nail, Lengthening, Limb length discrepancy, PRECICE® nail, Deformity correction, Non-union

INTRODUCTION

Limb length discrepancy (LLD) can arise from various factors. These factors can be congenital or acquired.[1] Common acquired causes are seen in children and adolescents as growth plate arrests, mostly due to internal clinical entities or external direct forces.[2] Adults can acquire deformities due to osteomyelitis, traumas, malunions, or non-unions.[3-5] A. Codivilla initially described the modern-day concept of LLD and later Ilizarov further influenced the principles of limb equalization using external fixators.[6] His work was the cornerstone for the newer devices that evolved with time to face growing challenges in orthopedic surgery.[7,8]

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The PRECICE system (NuVasive, San Diego, USA) is one of the newly developed technologies used in the treatment of LLD.[8] The nail itself was first introduced to patients in 2011 and gained the U.S Food and Drug Administration approval in the same year.[8] It started gaining world recognition soon after and has been further developed after addressing some pitfalls in the first version to produce a new improved version in 2013.[8] The nail is placed within the desired bone, and magnetically lengthened externally by the patient, nurse, or treating surgeon.[9,10] The rate and length of correction needed can be manipulated accordingly. It has been used successfully and reliably in many types of conditions like deformities, as well as LLD corrections and height lengthening.[10,11]

The PRECICE nail system is available in different lengths, diameters, strokes, angulations, and entry points.[12,13] These features accommodate for various needs and challenges that one might face in clinical practice. Although this versatility is useful to utilize, tailoring these various features can present quite a challenge in itself.

It is important to note that distraction osteogenesis through a fixator applied externally is an established technique for lower limb lengthening.[13-15] However, these treatments have had high complication rates, amounting to at most 3.2 complications per patient.[16,17] The pins or wires that penetrate the soft tissues trigger such complications as pain, pin-site infection, muscle transfixation, immobility, reduced joint movement, and scarring.[18,19] Removal of the external fixator puts the patient at risk of further complications, including malalignment or fracture.[20] Therefore, minimizing complications and improving patient comfort have necessitated the introduction of limb lengthening using fully implantable bone lengthening nails.[21] Magnetically-driven (PRECICE) or motorized FITBONE (Orthofix, Texas, USA) bone lengthening nails were made using mechanically-driven lengthening nails.[2,22,23] A couple of case-controlled studies have made comparisons between these nails and external fixation (13–15 patients), with the largest series involving 92 patients.[24-26] However, most reports of complications of PRECICE lengthening nails and FITBONE are small case series.[27-30] The popularity of motorized intramedullary lengthening nails has increased tremendously in recent years, leading to the hypothesis that the literature may now contain more standardized data on complications.

This is why the authors aimed at reporting their initial unit's experience with the PRECICE nail. The aim was to investigate the functional outcomes and complications observed in the study group.

MATERIALS AND METHODS

The PRECICE nail system was used on ten patients seen in the deformity correction clinic in Al Razi Orthopaedic Hospital, Kuwait. This deformity correction unit is the only clinic in the country that offers this service. The data were prospectively collected during January 2019 to February 2020 as the patients underwent corrective surgeries using the PRECICE nailing system. The patients who had LLD that needed correction had various etiologies underlying their deformities.

The Arabic version of the Middle-East Lower Limb Score[31] was used for all the patients as a patient-reported outcome measure pre- and post-correction to validate the patient's own subjective response.

Patients were followed up for 12 months post-surgical intervention to record complications and functional outcomes clinically and radiographically.

A total of ten patients (four females and six males) were included in this study. All the cases were corrected using the PRECICE nail system (five antegrade femoral nails, three retrograde femoral nails, and two tibial nails). Pre-operative planning for each case was performed regarding femoral or tibial lengthening, the nail entry point in the femoral cases (antegrade or retrograde), nail angulation (10° or straight), nail diameter (8.5, 10.7, and 12.5 mm), nail stroke (30, 50, or 80 mm), nail length, and osteotomy level. Patient factors (age, medical and surgical history, body mass index (BMI), LLD etiology, soft tissue size, and smoking status were accounted for in our planning.

RESULTS

Pre-operative target lengths were achieved. The mean age of the patients was 20 years (range, 12–33 years). The mean BMI of the patients was 21.6 kg/m^2 (range, 17–28). The etiologies of LLD were congenital (Congenital short femur) (n = 2), developmental (a case of hypophosphatemia and a case of rickets) (n = 2), post-traumatic non-union (n = 1), post-traumatic malunion (n = 1), post-traumatic physeal arrest (n = 1), and post-deformity correction and lengthening of the contralateral side with circular frame (n = 3) [Table 1].

The mean latency period (time between the osteotomy and starting the distraction osteogenesis) was 7.8 days (range, 5–10 days). The mean distraction rate was 0.97 mm/day (range, 0.75–1.2 mm/day). Mean lengthening was 39 mm (range, 20–60 mm). Healing was confirmed at a mean of 76 days (range, 50–120) days. The mean time to full weight-bearing was 14.7 weeks (range, 10–23 weeks). All patients reached full consolidation, normal alignment, and normal joint orientation by the end of the study [Table 2]. The knee range of motion was maintained in five patients (antegrade femur lengthening). One patient with a previous knee fixed flexion deformity of 25° improved to 5° of extension lag (retrograde femur lengthening). Two patients lost 20° of flexion during the early post-operative period and 5° of extension (retrograde femur lengthening). This loss was

Table 1: A summary of relevant details for all the cases included in this study.

No	Age	Gender	BMI	LLD etiology	LLD in mm	Follow-up
Case 1	12	F	17	Congenital short femur	50	16
Case 2	16	M	20	Post-traumatic physeal arrest	40	16
Case 3	23	M	22	Post-traumatic non-union	50	12
Case 4	15	M	19	Congenital short femur	40	12
Case 5	20	F	28	Developmental (Hypophosphatemia)	60	12
Case 6	22	M	21	Post-traumatic malunion	30	12
Case 7	16	M	20	Developmental (Rickets)	20	12
Case 8	33	F	23	Post-deformity correction and lengthening of contralateral femur with circular frame	30	12
Case 9	19	F	22	Post-deformity correction and lengthening of contralateral tibia with circular frame	30	12
Case10	24	M	24	Post-deformity correction and lengthening of contralateral tibia with circular frame	40	12
Mean	20		21.6		39	12.8

Age in years, gender (M: Male – F: Female), BMI: Body mass index in Kg/m^2, LLD: Limb length discrepancy, LLD in millimeter, post-operative follow-up in months for ten cases with femoral LLD with mean for each item.

Table 2: A summary of the key parameters reported.

No	Latency period	Distraction rate	Healing in (days)	FWB (days)	MELLS Pre-operative	MELLS Post-operative
Case 1	5	1.2	110	20	39 (Good)	10 (Excellent)
Case 2	10	0.75	70	14	63 (Fair)	10 (Excellent)
Case 3	10	0.75	80	15	45 (Good	6 (Excellent)
Case 4	7	1	70	14	58 (Good)	12 (Excellent)
Case 5	10	1	120	23	89 (Poor)	17(Excellent)
Case 6	7	1	60	13	70 (Fair)	12 (Excellent)
Case 7	5	1	50	10	76 (Poor)	10 (Excellent)
Case 8	7	1	60	12	76 (Poor)	4 (Excellent)
Case 9	7	1	60	12	33 (Good)	4 (Excellent)
Case 10	10	1	80	14	41 (Good)	4 (Excellent)
Mean	7.8	0.97	76	14.7	59	9

FWB: Full weight bearing, MELLS: Middle east lower limb score

regained later with extensive physiotherapy. One patient needed a pre-distraction technique (defined by the difference of leg length determined by radiographic images)[7] for the nail before the procedure to consider enough nail length for passing the non-union site of the previous trauma. No complications regarding pain during lengthening, failure of distraction, or hardware failure were reported [Figures 1-6].

DISCUSSION

Although the PRECICE nail system is relatively expensive, this high price has dissuaded surgeons from using it in their clinical practice.[10] Many centers have published their experiences on a small number of patients using the PRECICE nail system.[10,11] The results in the literature provided so far are promising, yet long-term complications of this system remain unknown.[12] However, when compared to the complications of other intramedullary systems, as well as the complications reported from circular frames, the PRECICE system has been found to have less device-related complications.[32-34] This has been reflected well by our patient's satisfaction with the surgery and their compliance with the post-operative requirements.[34] Although the literature has reported nail distraction failures due to the embedded magnet,[12] this study did not note such a problem. Distraction-related severe pain was not reported in this study as well. This was in keeping with the literature.[35-38] The range of motion of the cohort in this study improved well without difficulties due to the hospital's aggressive physiotherapy regimen. There was no delay in bone consolidation in all of the cohort of this study. This finding, too, was consistent with other similar studies in the literature.[12,34,35,39]

One of the major advantages of the PRECICE system is the lengthening mechanism, which is controlled externally, as well as the control of the distraction rate.[40,41] Schiedel *et al.* in

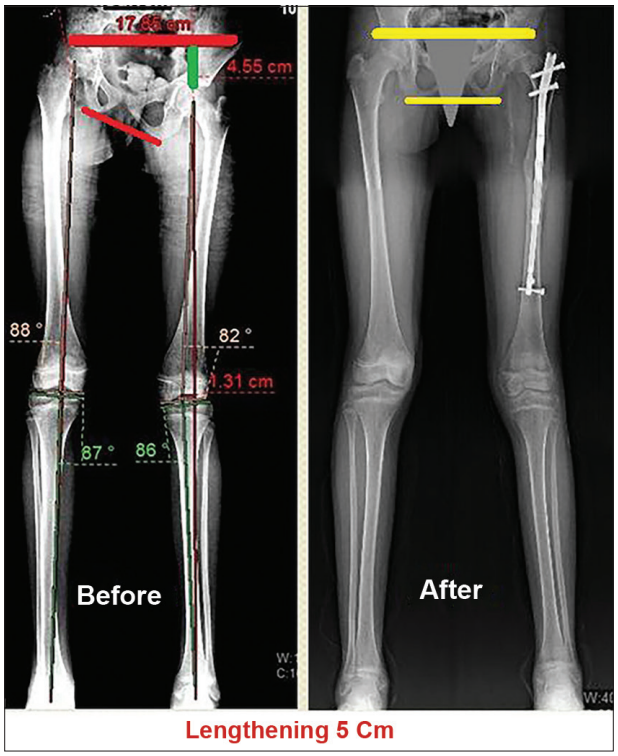

Figure 1: Case 2, congenital short femur (Limb length discrepancy pre- and post-correction).

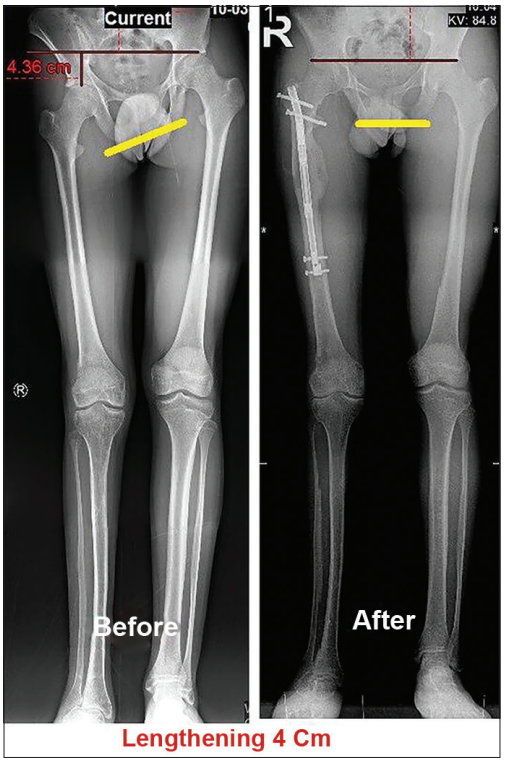

Figure 3: Case 4, congenital short femur (Limb length discrepancy pre and post correction).

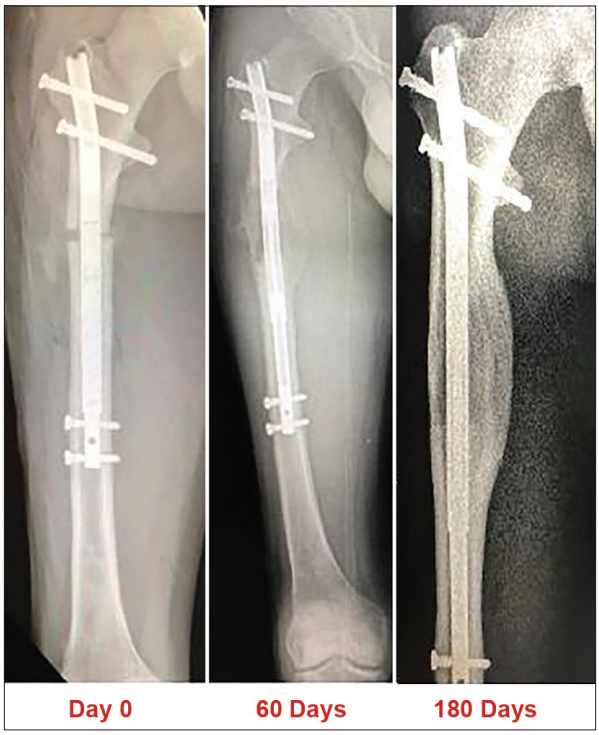

Figure 2: Case 2, congenital short femur (Chronological progression after correction).

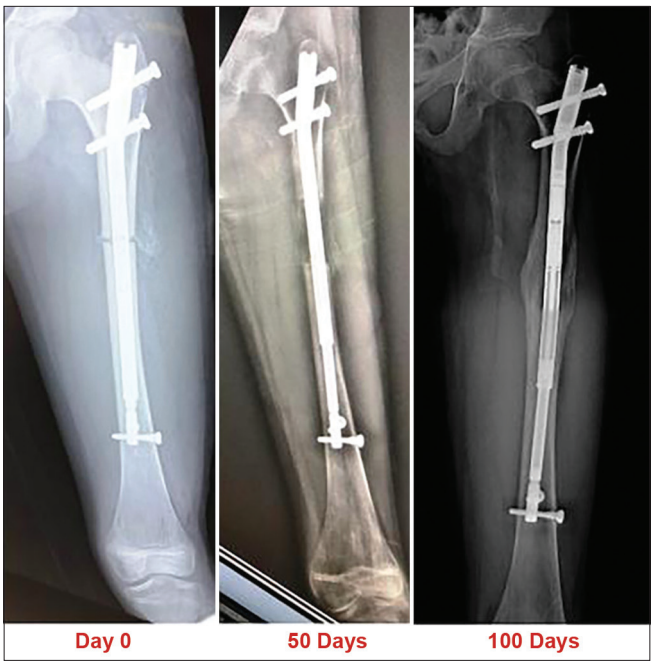

Figure 4: Case 4, congenital short femur (Chronological progression after correction).

their study found a discrepancy between the length measured radiologically and the length displayed on the external

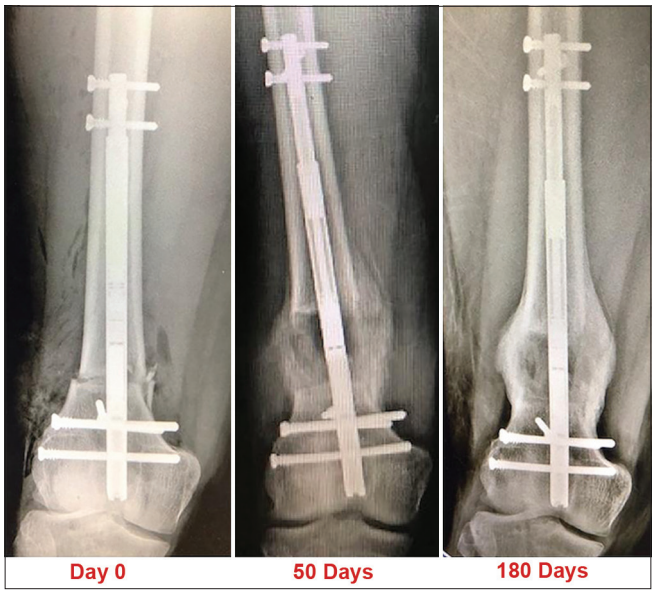

Figure 5: Case 8, Post-deformity correction and lengthening of the contralateral femur with circular frame (Limb length discrepancy pre- and post-correction).

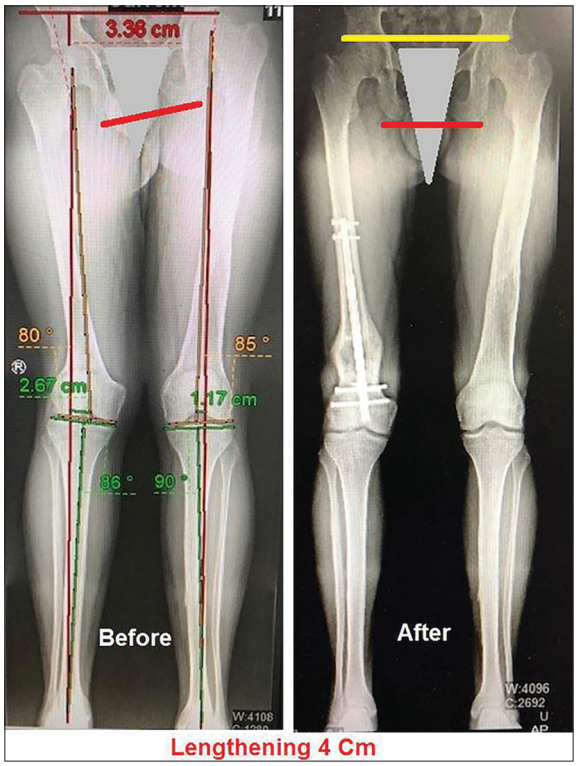

Figure 6: Case 8, post-deformity correction and lengthening of the contralateral femur with circular frame (Chronological progression after correction).

remote controller (ERC) monitor. This occurred in ten cases out of 23 in their study, while the regenerate bone was 10% shorter on average than anticipated. They have suggested possible reasons for that, as there might be an inadvertent displacement of the ERC during the lengthening procedure or the lengthening performance in an outpatient setting by the patient in the absence of the clinician. It is also worth knowing that the PRECICE system should not be applied in patients whose BMI exceeds 35. This is because the soft tissue thickness causes an increase in the distance between the ERC and the nail. This increasing distance may interfere with the rotations of the nail through the magnet.[41]

The previous versions of internal lengthening devices have had diverse mechanisms of operations, such as a linear actuator with an external electronic controller,[42] a spring and ratchet system powered by voluntary limb movement (rotations),[43,44] as well as a roller-clutch threaded rod assembly powered by rotations of the limb in intramedullary skeletal kinetic distractor (ISKD, Orthofix Inc, Lewisville, TX, USA).[45]

The mechanism notwithstanding, the primary cause of complications appears to be inaccurate control of distraction for clinical use.[46] The manufacturer claims that nail distraction can be controlled accurately through a customized programmable ERC.[47] It is, however, worth knowing that a magnet-powered internal lengthening appliance is a novel technology, with limited literature as per its clinical efficacy.[46-49]

The present study had a few limitations. First, the study sample size was small; however, this is attributed to the fact that this nail system has just been made available in the country. Second, the short follow-up period is another limitation of this study; however, it is shared by many other studies done on the PRECICE system because it is a relatively recent development. Another major limitation in this study is reflected in the different etiologies and the large age spectrum. The authors cannot establish full validity of the results due to these pitfalls, but the results still account as a reference and valuable addition to the literature. The cost of the PRECICE nail is evidently much higher than the use of external fixators and circular frame models. In this study, we did not address the cost-effectiveness of the PRECICE nail compared to other treatment modalities. Another noteworthy consideration is the possibility of pseudotumor formation in titanium implants. Surgeons using this devise should be vigilant of such a concern.

CONCLUSION

The PRECICE nail system is a valid and useful tool for LLD correction surgeries. The patients who participated in this study had an excellent outcome. Therefore, we recommend that this would be the treatment of choice for the indicated cases.

AUTHORS' CONTRIBUTIONS

SS conceived the idea for this project. All authors contributed equally to this research. All authors made substantial contributions to the conception and design, data acquisition, analysis and interpretation. AK was involved in drafting the manuscript and making critical revisions for important intellectual content. All authors have critically reviewed and approved the final draft and are responsible for the manuscript's content and similarity index.

ETHICAL APPROVAL

Ethical approval was obtained from the Ministry of Health, Kuwait, Research and publication office. Committee Reference Number: 2019/1065 (May 14, 2019).

Declaration of patient consent

The authors certify that they have obtained all appropriate patients consent forms. In the form, the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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