Original Article

Multicentre Review of Intramedullary Lengthening Nails: A Middle-Income Country Perspective

Abstract

Background: Lengthening nails (ILN) are an established method of limb reconstruction for leg length discrepancy (LLD). Literature on these nails is predominantly from developed countries, with more accessible resources for the procurement of devices and post-operative therapies. This paper aims to present the results and lessons learned from four tertiary level limb reconstruction units working within two middle-income countries (MIC). **Methods:** Ethical approval was obtained from all four units. All ILN (PRECICE II, NuVasive, USA) undertaken between 2013 and 2020 were included. Demographics, etiology, surgical approach, and information about the planned versus achieved correction were compared. Data on time to consolidation and complications were recorded with a 12-month minimum follow-up. Complications were classified according to the Black *et al*. criteria. **Results:** Sixty limb segments lengthened in 56 patients, of which 46 were femora, 12 tibiae and two humeri. Etiology of LLD was predominately posttraumatic (33%), congenital (26%), and growth plate injuries (22%). Mean distraction length was 46 mm (20–90 mm). Fifty-four segments (90%) had <5 mm discrepancy of planned distraction lengths. Mean healing index was 34.6 days/cm (range: 18–180 days/cm). Thirteen patients experienced complications, of which ten required further surgery. **Conclusion:** The findings of our work support the use of intramedullary ILN in MIC with equivalent complication rates and healing indices compared to the literature. Patient compliance and remote geography were not an issue during treatment. The lack of access to weekly rehabilitation therapy did not seem to impact the majority of patients. Reusing nails for extensive LLD cases were safe but should be used with caution.

Keywords: *Limb length discrepancy, limb lengthening, magnetic intramedullary nails*

William D. Harrison, Maritz Laubscher[1], Saleh Al Saifi[2], Ahmed Abdelaziz[2], Annette-Christi Barnard[3,4], Franz Birkholtz[3,4], Nando Ferreira

Department of Surgical Sciences, Division of Orthopaedic Surgery, Faculty of Medicine and Health Sciences, Stellenbosch University, [1]Department of Surgery, Orthopaedic Research Unit (ORU), Division of Orthopaedic Surgery, University of Cape Town, Cape Town, [3]Walk-A-Mile Centre, Pretoria, South Africa, [4]Department of Orthopaedics, University of Pretoria, Pretoria, South Africa, [2]Lower Limb Deformity Unit, Al-Razi Orthopaedic Hospital, Al Ahmadi, Kuwait

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Address for correspondence:
Prof. Nando Ferreira, Department of Surgical Sciences, Division of Orthopaedics, Faculty of Medicine and Health Sciences, Tygerberg Hospital, Stellenbosch University, Cape Town, South Africa.
E-mail: nferreira@sun.ac.za

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Introduction

Most literature on intramedullary lengthening nails (ILN) has been published from developed countries, with generally better access to funding for implants, rehabilitation, and research resources. Concerns about the use of ILN in low- or middle-income countries (MICs) focus on whether the increased upfront cost of the implant can be justified when cheaper external fixation options are available. This economic rationale is now questioned as to the complications, and prolonged healing index from external fixation may have significant cost implications in the long term.[1,2] Level III evidence from North America demonstrates that ILN have on average, one fewer unscheduled operations (2.1 vs. 3.1, $P < 0.001$) when compared to monolateral lengthening over a nail (LON).[3] A cost analysis from the same authors demonstrated that, although ILN had higher upfront costs, they were on average cheaper than LON overall ($44,449 vs. $50,255, $P = 0.4$) but did not reach statistical significance.[3]

There are also perceived difficulties in MIC's with access to therapies, patient geography limiting travel to a tertiary hospital, patient education levels impacting compliance, and potentially access to electricity at home to power the external lengthening module. As with any complex orthopedic surgery, surgeon experience, patient selection and early identification of complications are crucial during ILN treatment.

This article aims to assess the outcomes of ILN from four centers at public-funded and private-funded hospitals in MICs. The hypothesis being that outcomes from MICs are equivalent to developed nations reported in the literature. The secondary aims were to provide guidance for limb reconstruction surgeons in other MICs about how they can anticipate and respond to some of the more unique challenges that face their patient group.

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Methods

A multicenter retrospective review of all consecutive patients who had segmental ILN between June 2013 and December 2020 was conducted. The PRECICE II (NuVasive, San Diego, USA) is exclusively featured in this study. It uses a magnet-controlled telescopic rod to affect internal lengthening. Medical records and serial radiographs across four limb reconstruction centers were included for review. Individual institutional ethics review board approval was obtained before data collection. Data were pooled from all four institutions using a preagreed data pro forma for demographics and outcome metrics.

Inclusion criteria

All patients undergoing intramedullary lengthening were included; irrespective of age, pathology, or the need for adjacent deformity correction in another segment.

Parameters evaluated included age, sex, bone involved, side, pathology, associated deformity correction, previous surgical interventions, size of nail used, length discrepancy, duration of lengthening, lengthening accuracy, time to radiological consolidation, healing index (days/cm), duration of follow-up, anticipated and unexpected complications, and the need for unscheduled further surgery. Complications were classified according to the Black *et al*. criteria, which is the most commonly adopted classification in ILN literature [Table 1].[4,5]

Preoperative planning

The coronal plane was assessed with full length weight bearing radiographs and the sagittal plane was assessed with segmental radiographs, including a lateral knee view with the knee in full extension. Segmental analysis was performed to identify the source of length discrepancy. Deformity analysis was undertaken as described by Paley and Herzenberg.[6]

Where lengthening without acute deformity correction was planned, the osteotomy level was calculated according to the manufacturer's recommendations to ensure that the entire regenerate at the end of lengthening was overlying the thicker outer part of the nail.[7] Where deformity correction was planned, in addition to lengthening, the osteotomy level was calculated to ensure that the proximal and distal medullary canals were aligned and could accommodate an intramedullary nail. The effect of lengthening along the anatomic axis of the femur was considered during planning.[8] Retrograde femur lengthening with deformity correction was calculated according to reverse planning methods as described by Baumgart.[9]

Table 1: Complications classified according to the modified Black criteria 4

Grade	???
I	Minimal intervention required and, treatment goal still achieved
II	Substantial intervention required and, treatment goal still achieved
IIIA	Failure to achieve treatment goal with no new pathology or sequelae
IIIB	Failure to achieve treatment goal and/or new pathology or permanent sequelae

Surgical technique

The surgery steps were undertaken according to the manufacturer recommendations and, for brevity, are not described.[7] Poller blocking screws were judiciously used to functionally narrow the medullary canal and either maintain a deformity correction or stabilize the nail in capacious metaphyseal bone.[10] All four centers used the De Bastiani predrilled osteotomy technique.[11] At the completion of the surgical procedure, a 1 mm test lengthening in theater was performed to ensure that the nail was functional.

Postoperative management

All patients observed a latency period of between 5 and 7 days, after which lengthening was attained at increments of 0.33 mm, three times/day. When joint stiffness was encountered, the rate of lengthening was reduced or lengthening stopped temporarily to allow increased physiotherapy. During the active lengthening period, weight-bearing on the operated limb was limited to protecting the ILN internal mechanisms.

Following surgery and during the lengthening process, physiotherapy was used to maintain the range of motion of the adjacent joints. Due to the diverse geography of this multicenter study, access to and intensity of physiotherapy were variable. Unsupervised, home exercise programs were frequently used due to no or limited access to outpatient physiotherapy. The individual physiotherapy records for patients were not available. Once the final lengthening was achieved, weight bearing was progressed to full at all four centers.

After the regenerate was consolidated, defined as when more than three cortices are more than 2 mm thick, the ILN was considered for removal.[12] Cases with a very large LLD that could not be addressed with a single nail lengthening underwent sequential lengthening using the same nail; in these cases, the PRECICE nail was removed and reversed using the PRECICE Fast Distractor device. A new osteotomy was created and the nail re-inserted.

Results

Fifty-six patients with 60 lengthened segments were included for review. To the author's best knowledge, this represents all the ILN performed in South African public hospitals and all cases in Kuwait. The final cohort comprised 29 men and 27 women with a mean age of 23.7 years (range: 7–65, standard deviation ± 12). No patients undergoing ILN were excluded. The anatomical

segmental undergoing lengthening included 46 femora, 12 tibiae, and two humeri [Table 2].

The surgical technique in terms of antegrade versus retrograde approach was used, or whether acute deformity correction or a reverse planning method was undertaken is detailed in Table 3.

All nails passed the 1 mm in theater test lengthening, and no nails were found to be faulty.

Lengthening planned versus lengthening attained is subanalyzed in Table 3. The median difference between planned lengthening and lengthening achieved was 0 mm, with a range of 10 mm under lengthening and 20 mm over lengthening. Six segments (10%) had a >5 mm discrepancy between a planned and actual length attainment. The clinical assessment following completed treatment demonstrated that seven cases had residual length discrepancies. This did not include three pediatric cases deliberately overlengthened as a part of the deformity analysis and growth forecast. One patient required early cessation of their lengthening nail as he was involved in a high energy motor vehicle collision that bent the nail at the level of the regenerate, requiring explant and re-nailing with a standard trauma nail. This patient was 31 mm short of their initial treatment goal.

There was no requirement for custom-made ILN within this series. Ordering of the correct lengthening nail was required within 3 weeks of the planned operation date.

The healing index was widely variable from 18 to 180 days/cm with a mean of 34.6 days/cm. Segments with a healing index >30 days/cm (n = 17) were typically seen in younger patients (mean age of 19 years) and were exclusively in the femur or the two humeri segmental lengthenings. There was no discernable difference in the healing index of antegrade or retrograde approaches or whether a deformity correction had been undertaken. Antegrade femoral lengthening had a mean bone healing index of 36.6 days/cm (range: 18–108 days/cm). There was an outlier of 108 days/cm, once excluded the mean bone index was 31.2 days/cm. Retrograde femoral lengthening had a mean bone healing index of 38.1 days/cm (range: 15–89 days/cm). Tibial lengthening had a mean bone healing index of 75.9 days/cm (range: 34–180 days/cm). Humeral lengthening (only two cases) both had a bone healing index of 18 days/cm.

The mean follow-up at the time of writing was 13.2 months (range: 12–47 months). A breakdown of complications is listed in Table 4. There were seven unscheduled revision procedures which included two for premature consolidation, one for delayed consolidation, one to stabilize and align the regenerate, two for trauma-related problems, and one for deep infection. Nine complications did not require further surgery including two patients with premature consolidation of the fibula during tibial lengthening leading to loss of fibula length, two patients with adjacent joint stiffness leading to a long-term problem, two patients with delayed consolidation requiring extended observation, two patients with severe pain during distraction

Table 2: Participant demographic information

	***n*=56**
Age	23.7±12 (7-65)
Sex	
Male	29 (55%)
Female	27 (45%)
Segment lengthened	
Femur	46 (77%)
Tibia	12 (20%)
Humerus	2 (3%)
Reason for lengthening	
Post-traumatic LLD	18 (32%)
Congenital LLD	15 (27%)
Growth plate injury	12 (21%)
Cosmetic	4 (7%)
Tumour-related	3 (5%)
Other	4 (7%)

LLD: Limb Length Discrepancy

Table 3: Lengthening outcome and complications

	***n* (%)**	**Lengthening planned (mm)**	**Lengthening achieved (mm)**	**Complications**
Femur	46			
Antegrade	18 (40)	52 (25-80)	50 (25-80)	1 nail failure, 1 periprosthetic fracture, 2 premature consolidation
Antegrade with ADC	5 (12)	35 (20-50)	37 (25-50)	1 amputation
Retrograde	22 (30)	57 (20-90)	57 (20-90)	1 periprosthetic fracture, 1 premature consolidation, 2 stiff joints
Retrograde with ADC	8 (12)	46 (30-60)	47 (30-60)	1 PFJ impingement, 1 slow regenerate
Tibia	12			
Without ADC	10	32 (25-40)	32 (25-40)	1 deep injection (HIV positive), 1 premature and 1 delayed consolidation
With ADC	1	40	35	None
Retrograde	1	40	30	None
Humerus	2	30 (30-30)	33±0 (33-33)	Lengthening continued at patient request
Total	60	45.9±18 (20-90)	44.4±18 (20-80)	

ADC: Acute deformity correction, HIV: Human immunodeficiency virus, PFJ: Patellofemoral joint

Table 4: Complications according to Black *et al.* criteria[4]

	n=17	Descriptor
I	6	2 delayed consolidations, 2 broken screws, 2 painful distractions requiring slower rate
II	5	1 grafting of regenerate, 1 premature consolidation, 1 late implant sepsis requiring removal (otherwise successful), 1 stiff joint requiring aggressive therapy but overall successful. 1 broken screw requiring surgery
IIIA	3	2 under lengthened segments (both 10 mm short); 1 due to premature consolidation and 1 due to periprosthetic fracture
IIIB	3	1 aggravation of hip OA with no subluxation, 1 mechanical failure of the nail, 1 amputation

OA: Osteoarthritis

that required a slower rate of lengthening, and one patient with broken interlocking screws near the distal tibia.

The two patients with joint stiffness both had femoral lengthening of 80 mm each. One patient had Gaucher's disease and developed worsening hip osteoarthritis. The second patient had posttraumatic growth arrest of the distal femur and developed long-term hip and knee stiffness, refractory to extensive physiotherapy.

One adolescent patient had a through-knee amputation following sequelae of a complex open tibia fracture which was unrelated to the femoral lengthening nail she underwent for a malunion (with femoral bone loss) sustained as a part of the same injury as the tibia.

There were 26 (43%) patients with the lengthening nail *in situ* after consolidation. At least 13 patients failed to return to follow-up following consolidation and two patients have refused to have further surgery. It should be noted that the majority of these cases were followed up during the COVID-19 pandemic. There were no complications in any patients following radiological consolidation. The decision to leave the nail *in situ* did not lead to any medium-term complications. Two cases had removal of the lengthening nail and exchange to a trauma nail (one for a periprosthetic fracture between two implants and the other previously mentioned patient who bent the lengthening nail following a high-energy road traffic collision). One patient had plating of his regenerate following cosmetic lengthening of both tibias, without complication. Patients who underwent sequential or extensive lengthening in a segment were not automatically considered for secondary stabilization, and no complications were seen as a result of this decision.

Discussion

This series incorporates cases performed in public and selected private hospitals in South Africa and Kuwait. Nine cases included in this paper have already been reported in an early user series published by Birkholtz and de Lange.[13] Although Kuwait is considered a high-income country, the Kuwaiti cases were government-funded procedures for the poorest members of the population and all surgeries were performed a South African visiting surgeon.

Government sector hospitals in South Africa purchase ILN on a centralized tender. However, the price of ILN in private and government hospitals in South Africa is equivalent to high-income countries around the world. The cost-effectiveness and clinical benefits of intramedullary lengthening devices compared to external devices are gathering evidence.[2,3,14,15] The remit of the study is not to help answer that question but to present the unique considerations and patient outcomes in a middle-income country health-care system.

In previous ILN series, antegrade femoral lengthening had consistently better bone healing index (literature mean of 33 days/cm) and fewer complications, whereas retrograde nailing seems to be better for distal femoral deformity correction (literature mean of 40 days/cm).[16-18] Healing index has also been shown to be quicker for ILN compared to monolateral external fixator rails used for femoral lengthening in a small comparative series of 13 patients in each treatment arm (31 vs. 47 days/cm, respectively).[14] The bone healing index for each segment in this series is equivalent to those stated in other series.[16,18,19]

From our data, the healing index was widely variable from 18 to 180 days/cm with a mean of 34.6 days/cm. Consolidation was defined by preagreed criteria, but the assessment was undertaken independently by each surgeon and with no interobserver analysis. The consolidation index is influenced by several factors including anatomy, age, smoker history, comorbidities, method of corticotomy, and method of distraction. The healing index for lengthening has been shown to be excellent in the humerus (mean: 25 days/cm) and slowest in the tibia (mean: 57 days/cm).[16] The tibial bone healing index in this series was 75.9 days/cm, but once two 180 days/cm outliers were excluded, the mean was 55 days/cm.

Patient selection in terms of the orthopedic, social, and psychological factors is a critical factor in any limb reconstruction procedure. Patient counseling and informed consent are as crucial in developing countries as it is elsewhere. Literacy and the patient's primary language needs consideration when supplying information leaflets or providing an emergency point of contact. Time must be spent with the patient after the surgery to explain, demonstrate, and assess the patient understanding of the External remote controller (ERC) lengthening schedule. Although rural patient geography is a factor to consider, it did not impact patient compliance with lengthening, detection of complications, or overall outcomes for this study. Follow-up schedules need to be carefully planned

while lengthening. Patients from remote locations or lacking home access to electricity were occasionally kept as inpatients during lengthening to access physiotherapy and reduce time in transit. There were no reported instances of patients failing to return the ERC device.

Human immunodeficiency virus (HIV) status was not routinely assessed preoperatively. One patient known to be HIV positive had the only recorded deep infection, which occurred secondary to an infected tattoo. This patient achieved their treatment goal but did require explant and continued to consolidate thereafter. One consideration is the use of local antibiotics around the lengthening nail in cases with active infection.[20] The infection rate of 1.7% (n = 1) in our study is equivalent to the current literature of 0.8%.[5]

Two patients had scheduled re-utilization of ILN for staged lengthening on the same segment. The implants were explanted, and the lengthening mechanism wound back with the ERC on the table and then re-inserted, with no apparent complications. The ability to re-use a lengthening nail in the same patient is clearly an advantage in a more resource-constrained healthcare system. The sequential lengthenings were done consecutively, rather than the "sleeper nail" technique reported by Eltayeby *et al*.[21] This does go against manufacturer recommendations and should be mentioned to the patient as a duty of candor. Explanted latest generation PRECICE STRYDE nails have been shown to generate metal debris, and their re-use has been cautioned.[22] In the event of a local complication from lengthening nail re-use, there needs to be access to either another lengthening nail or an appropriate strategy to continue the planned reconstruction. The re-use of ILN must be done on the table as a single stage. Re-sterilization of the ILN must not be undertaken, as steam or ethylene oxide will not reach the internal mechanism of the nail.

There were no cases of nail-related clinical metallosis, intrinsic catastrophic nail failure, or local bone lysis in this series of sixty segmental lengthenings. The prior iteration of the PRECICE nail from NuVasive had been recalled from the manufacturer owing to concerns about the metal interface of the motorized units. However, the PRECICE II used in this study did not have the same design flaw and was re-instated for use with caution.

Joint contracture during lengthening is a challenging complication to manage and can lead to deformation of the regenerate and joint subluxation. Risk factors for joint contracture are female sex, postaxial limb deficiencies, and retrograde femoral lengthening in particular.[5] Access to physiotherapy in developing nations, especially for outpatients in rural areas, can be limited. Despite this, joint contracture rates were just 3.5% (n = 2) in this series. Joint contracture occurs in 5% of cases within the literature, and subluxation is less common at 0.6%.[5] Strategies to overcome this hurdle include prolonged inpatient admission during critical phases of treatment, remote therapy through smart devices, and patient-lead therapy through education. Anecdotally, by virtue of necessity, many of these patients remain very active during their rehabilitation, which may account for the limited contractures seen in our series. Between the four units in this series, there was no systematic approach to soft-tissue release intraoperatively. Prophylactic soft-tissue release of the iliotibial band (Yount's procedure) to prevent abduction deformity at the hip has been recommended for femoral lengthening of >40 mm.[14] This may be more important for congenitally short femurs rather than posttraumatic LLD.

Leaving the ILN *in situ* is not recommended by the manufacturers. The NuVasive product information states, "PRECICE implant removal is recommended at 1 year provided radiological evidence of full bone consolidation is present. Each surgeon must determine the appropriate time for removal of the PRECICE implant based on their clinical evaluation of the patient."[7] Ultimately, the decision to go back to theater for nail removal is a patient choice, and they must make an informed decision. However, the cost and time constraints of routine nail removal need to be considered. From this series, 43% (n = 26) of nails remain *in situ*, and there have been no medium-term complications resulting from that. However, this is a relatively high number of nails remaining *in situ* compared to the literature.[14] Only two patients have a documented refusal to have the nail removed. Thirteen have not returned for follow-up after having achieved consolidation. There are 11 patients who do not have a planned date for removal. Sixteen (61%) patients who have still have the ILN *in situ* consolidated during the period of the COVID-19 pandemic when elective clinics and theater in South Africa were heavily restricted.

The complication rate of 28.3% per segment (n = 17) is below the mean complication rate of 34% seen in a systematic review of 983 segments in the literature undergoing ILN.[5] This may reflect the under-reporting of minor complications as a consequence of this retrospective method. It may also reflect the global learning curve that surgeons and implant designers have made in recent years to preempt and identify early, avoidable complications.

Limitations

This multicenter study is level IV evidence and does not address many pertinent questions that need to be established in lengthening nail surgery. Without prospective data, collection, and patient-reported outcomes, some nuanced issues have not been captured. Patient follow-up in South Africa has been shown to be poor in the trauma setting; however, this has not been assessed in elective orthopedic care.[23] The variation seen in the healing index may reflect an interobserver bias, and a formal Kappa analysis was not performed. A structured cost analysis of ILN compared to traditional external fixator lengthening would be particularly helpful within a developing nation setting.

Cost justification will become increasingly important as lengthening nail technology develop for bone transport. Nine patients reported in this series have been presented as a part of a mini-series by one of the co-authors.[13] This has implications on any future systematic review of ILN in the literature.

Conclusion

The findings of our work support the use of ILN in MIC with equivalent complication rates seen in other, more developed nations. Future work on ILN in developing nations should focus on the length of inpatient stay, access to physiotherapy, frequency and distance travelled for hospital encounters, in-depth patient epidemiology, social support, access to transport, educational attainment, work status, and smoking status and economic deprivation. The global literature should also agree a standardized reporting method and develop patient reported and functional outcomes for patients undergoing limb lengthening.

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Conflicts of interest

There are no conflicts of interest.

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