Pediatric Lower Limb Lengthening Using the PRECICE Nail: Our Experience With 50 Cases

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Background: Limb lengthening using intramedullary externally controlled motorized devices is becoming increasingly popular. There is limited literature regarding their use in the pediatric and adolescent population. This study reviews outcomes on 50 consecutive cases of intramedullary lower limb lengthening surgery in this population.

Methods: A retrospective review of all pediatric and adolescent patients treated in our institution by intramedullary lengthening for lower limb length discrepancy using the PRECICE and STRYDE intramedullary lengthening nails between 2013 and 2019. All patients were operated by a single surgeon. Data were prospectively recorded. We report on nail accuracy and reliability, consolidation index, time to full weight-bearing from completion of lengthening, joint range of movement, ASAMI bone and functional scores, presence of problems, obstacles and complications, and patient reported outcome measures (PROMS).

Results: Fifty cases (43 femoral and 7 tibial nails) were performed in 42 patients (20 males, 48% and 22 females, 52%). Six patients had bilateral lengthening and 2 patients had sequential lengthening. There were 28 antegrade femoral, 13 retrograde femoral and 5 tibia PRECICE nails, 2 tibial and 2 femoral PRECICE STRYDE nails. Mean age at surgery was 15 years old (12 to 17). Mean preoperative length discrepancy was 49 mm (20 to 90). Mean achieved lengthening was 46.5 mm (20 to 80). Mean percentage lengthening was 12.6% (5% to 25%). Nail accuracy was 96% and reliability 90%. Average distraction rate was 0.92 mm/d for femur and 0.64 mm/d for tibias. Consolidation index was 28 d/cm (18 to 43) and 39 d/cm (20 to 47), respectively. Time from completion of lengthening to independent full weight-bearing as observed in clinic was 45 days (21 to 70) and 34.2 days (23 to 50), respectively. ASAMI bone and functional scores were favorable and PROMS demonstrated high patient satisfaction levels. No significant complications were observed.

Conclusions: We have demonstrated excellent clinical results and high patient satisfaction with intramedullary lengthening in a pediatric/adolescent population. We highly recommend thorough preoperative preparation, patient education, and a multidisciplinary approach.

Level of Evidence: Level IV.

Key Words: PRECICE intramedullary limb lengthening system, pediatric deformity, limb length discrepancy, limb reconstruction

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Since 1983 when Bliskunov[1] developed the first telescopic nail, there has been significant progress in our understanding of bone lengthening and important technological advances leading to the development of motorized externally controlled lengthening devices.[2] They have become an attractive option for the pediatric and adolescent population[3] in view of the unique issues encountered with traditional external fixation methods.[4]

The PRECICE nail (NuVasive Inc., San Diego, CA) uses the magnetic expansion control system, as in spinal distraction rods. Different versions available such as antegrade and retrograde as well as straight and 10-degree bend entry, allow for applications in different patient groups. The latest generation's (STRYDE) stainless-steel composition potentially allows weight-bearing throughout treatment. Favorable outcomes have been reported[5–7] and indications for treatment are expanding.[8,9]

The literature on their use in pediatric population is limited to case reports and small series. There is lack of guidance on the perioperative management of these patients and limited reports on outcomes. A large number of these devices have been implanted in our unit in a pediatric and adolescent population. We have previously reported in our experience with adults.[8] This paper is a retrospective review of prospective data and to our knowledge is the largest single center, single surgeon series to date. The aim is to report in our experience and provide insights and tips on management as well as to review clinical, radiologic, and functional outcomes.

METHODS

Approval was granted by our institutional Research and Development Department (201920-96). All eligible cases from 2013 to 2019 were included.

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The authors declare no conflicts of interest.

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Inclusion criteria consisted of: (1) lower limb lengthening surgery using the PRECICE intramedullary limb lengthening system, (2) age below 18 years at the time of surgery, (3) follow-up to consolidation available. Written informed consent was obtained at enrolment for surgery.

During initial assessment, standing leg length radiographs with the pelvis balanced using blocks and the patella facing forward and lateral radiographs of individual bones are obtained. Documentation of hip, knee, and ankle range of movement (ROM) is performed in all clinic visits. A preoperative visit to a Specialist Limb Reconstruction Nurse to explore practical aspects and identify early any potential issues. Patients are educated on the use of external remote controller. They are seen by members of the multidisciplinary team such as physiotherapist and occupational therapists. They receive education on mobility aids and postoperative exercises.

All procedures were performed by the lead author (P.C.) using a standardized technique as per the manufacturers recommendations.[10] Low energy corticotomies were performed. Half a millimeter intraoperative distraction was performed to check the device. Tibial and retrograde femoral lengthenings were only performed in skeletally mature patients and trochanteric entry nails were used in patients with open growth plates.

Physiotherapy starts from day 1 with partial weight-bearing (< 20 kg) and ROM exercises. Throughout lengthening patients receive weekly sessions. This is increased to twice weekly if joint stiffness develops. For patients with congenital longitudinal limb deficiency we employ a bracing protocol to avoid issues with knee instability and subluxation. An extension brace is worn at all times until 1 month after lengthening completion and only removed twice daily for knee ROM exercises.

Lengthening starts after a 5-day latency period. Rate is routinely set at 0.33 mm 3 times a day for femoral and 0.33 mm twice a day for tibial lengthening. For patients with longitudinal deficiencies and concerns for hip and knee subluxation we set the femoral rate at 0.33 mm twice a day. In cases where severe pain or joint stiffness develops we advocate on reducing the rate accordingly (0.33 mm twice a day) and increase the frequency of physiotherapy sessions. We advocate similar changes to tibial rate. Should these measures fail, we temporarily stop the lengthening for a 1-week period following which we resume at a reduced rate if appropriate.

Patients attend biweekly follow-up visits with clinical assessment and radiographs to completion of lengthening. During consolidation, monthly visits with radiographs and following this 3 monthly visits as appropriate until implant removal. All patients are encouraged to gradually progress to full weight-bearing (FWB) over a 4-week period following completion of lengthening. They are reviewed in clinic with radiographs and if satisfactory, are allowed to continue.

Our database and electronic patient records were used to collect general demographics (age, sex, etiology), joint ROM, time to FWB and all problems, obstacles and complications.[11] Our digital Picture Archive and Communications System (McKesson Corp., San Francisco, CA) was used to determine preoperative and postoperative limb length discrepancy (LLD) and mechanical axis deviation (MAD). Radiologic measurements were performed by a single author (A.D.I.).

TABLE 1. ASAMI Modification of Paley Criteria

	Bone Result	Functional Result
Excellent	Bone union, no infection, deformity <7 deg. Lower limb discrepancy <2.5 cm	Ability to perform previous ADL, no pain or mild pain No limp, no soft tissue sympathetic dystrophy, knee or ankle joint contracture <5 deg. Loss of ankle or knee motion <15 deg.
Good	Bone union, failure to meet 1 of the other criteria	Almost all ADL with minimal difficulty No pain or mild pain, failure to meet 1 of the other criteria
Fair	Bone union, failure to meet 2 of the other criteria	Most ADL with minimal difficulty No pain or mild pain, failure to meet 2 of the other criteria
Poor	Nonunion or refracture, failure to meet 3 of the other criteria	Significantly limited ADL Significant pain requiring narcotics, failure to meet 3 of the other criteria

ADL indicates activities of daily living; ASAMI, Association for the Study and Application of Methods of Ilizarov.

We report on nail accuracy (ratio between achieved and planned lengthening), reliability (ratio between number of successfully ended treatments and number of implanted devices),[12] and consolidation index, defined as days from index surgery till consolidation divided by length of the regenerate in centimeters.[13,14] Consolidation was defined as radiographic evidence of healing of 3 of 4 cortices. Mean rate of lengthening was defined as the total length gained (mm) divided by time to completion (d). We recorded time to FWB in all our patients and defined a WB ratio as the period to FWB (d) divided by the achieved lengthening (mm). Nail removal times were recorded.

The ASAMI (Association for the Study and Application of Methods of Ilizarov) modified[12,15] bone and functional classification scores were used (Table 1).

There are no validated patient reported outcome measures (PROMS) for this cohort of patients. Landge et al[16] proposed a questionnaire for adults following lengthening by different treatment modalities to assess their satisfaction and compare them. Ours is the first study to assess pediatric patient preference and satisfaction with regards to lower extremity lengthening. We employed a similar questionnaire with modifications to make it relevant and understandable to children (Appendix 1, Supplemental Digital Content 1, http://links.lww.com/BPO/A319). The questionnaire was delivered through telephone interviews.

All categorical variables are expressed as frequency (%) and continuous variables are reported as mean (range).

RESULTS

Fifty cases (43 femoral and 7 tibial nails) in 42 patients (20 males, 48% and 22 females, 52%) were included.

TABLE 2. Underlying Etiology for Limb Deformity

Etiology	No. Cases
Posttraumatic growth arrest	7
Leri Weill dyschondrosis	2
Congenital femoral deficiency	5
Post septicemia growth arrest	2
Post pelvis Ewing sarcoma excision	1
Hemihypertrophy	5
Ollier disease	1
Fibula hemimelia	3
Spondyloepiphyseal dysplasia	3
Short stature	6
Intrauterine growth restriction with multiple neonatal osteopenic fractures	1
Curry Jones syndrome	1
Fibrous dysplasia	2
Perthes disease	1
Post slipped capital femoral epiphysis	1
Post hip joint sepsis	2
Achondroplasia	2
Congenital talipes equinovarus	3
Post ankle joint sepsis	1
Idiopathic/unknown	1

Six patients had bilateral lengthening and 2 sequential lengthening. There were; 28 antegrade femoral, 13 retrograde femoral and 5 tibia PRECICE nails, 2 tibial and 2 femoral PRECICE STRYDE nails.

Mean age at surgery was 15 years old.[12–17]

Table 2 shows the etiologies for treatment. The usual indication for lengthening is LLD. Where alternative treatments are available such as growth modulation, the decision to proceed with lengthening is based on the patient's bone age, predicted height at maturity, and a discussion on the risks and benefits of the options available. Bilateral lengthening for short stature is available for patients with functional limitations due to their stature, who have undergone extensive preoperative assessment and psychological evaluation and counseling.

Table 3 summarises our result. Overall nail accuracy was 96%. Nail reliability was 98% as there was 1 case where a femoral PRECICE nail was inserted but a decision made not to proceed with lengthening as new onset mental health issues raised concerns with compliance. By the time of submission, 42 patients (84%) had their nails removed. Nail removal time from surgery was 23.7 months (13 to 48 mo) for both groups. We advocate that nail removal should be performed at least 12 months following implantation. The wide time range reflects on patient factors and list availability. Following removal we advise on avoidance of any strenuous high impact activities for a 4-week period. Employing this regime we have not encountered any intraopertaive or postoperative difficulties or complications.

TABLE 3. Summary of Results for Femoral and Tibial Intramedullary Lengthening

	Femoral Nails (n = 43)	Tibial Nails (n = 7)
Preoperative limb length discrepancy (mm)	51.5 (25-90)	35 (20-50)
Achieved lengthening (mm)	48.1 (25-80)	35 (20-50)
Bone lengthening (%)	13 (6-25)	10 (6-20)
Distraction rate (mm/d)	0.92 (0.67-1)	0.64 (0.58-0.66)
Consolidation index (d/cm)	28 (18-43)	39 (20-47.2)
Days to full weight-bearing from lengthening completion	45 (21-132)	34.2 (23-50)
Full weight-bearing index (d/cm)	21.7 (14-38)	28 (21-33)

Values reported as mean (range).

The ASAMI bone score showed 41 excellent, 8 good, and 1 fair results. The ASAMI functional score showed 35 excellent, 11 good, 3 fair, and 1 poor results.

There was MAD of >2 mm in 13 cases. It has been suggested that a shift of >10 mm is clinically significant.[17] This was observed in 4 cases. Significant (>5% valgus/recurvatum) malalignment was observed in 1 case of tibial lengthening.

Our patients reported low pain scores throughout lengthening (5, range 2 to 9) and consolidation periods (2, range 0 to 6). Sixty-six percent reported no significant impact on activities of daily living (ADL) despite weight-bearing limitations. Eighty percent were satisfied with the cosmetic appearance. Ninety-two percent were satisfied with treatment results and felt they achieved their goals. Eighty-eight percent would choose to undergo this treatment again. There were 12 patients who previously had lengthening treatment with an external fixator. They reported favorable outcomes for intramedullary nails for effect on ADLs, return to function, pain, and cosmesis. They would all choose a nail over an external fixator.

Problems, Obstacles, and Complications

As per Paley criteria problems are difficulties arising during the course of treatment that resolve without surgical intervention. In 7 cases (14%) joint stiffness developed during lengthening that resolved by temporarily slowing down or stopping distraction and increasing the frequency of physiotherapy. One patient had to be admitted for inpatient physiotherapy due to concerns with compliance.

Obstacles are difficulties requiring operative intervention with complete resolution by completion of treatment. Two femoral nails (4%) required removal of prominent locking bolts following consolidation as they were causing discomfort. One patient that underwent bilateral femoral lengthening for short stature developed bilateral knee fixed flexion deformities of 20 degrees. She had Botulinum toxin injections to her hamstrings and serial casting with complete resolution. One patient with femoral fibrous dysplasia underwent lengthening with retrograde nail. We routinely exchange to a standard trauma nail following consolidation to reduce the risk of subsequent fracture. The lengthening nail was slightly prominent radiologically but caused no symptoms and was exchanged earlier.

Complications are all intraoperative complications and those that arise during the course of treatment that do not resolve after completion. One patient developed a sacral sore from the under table heater that resolved with

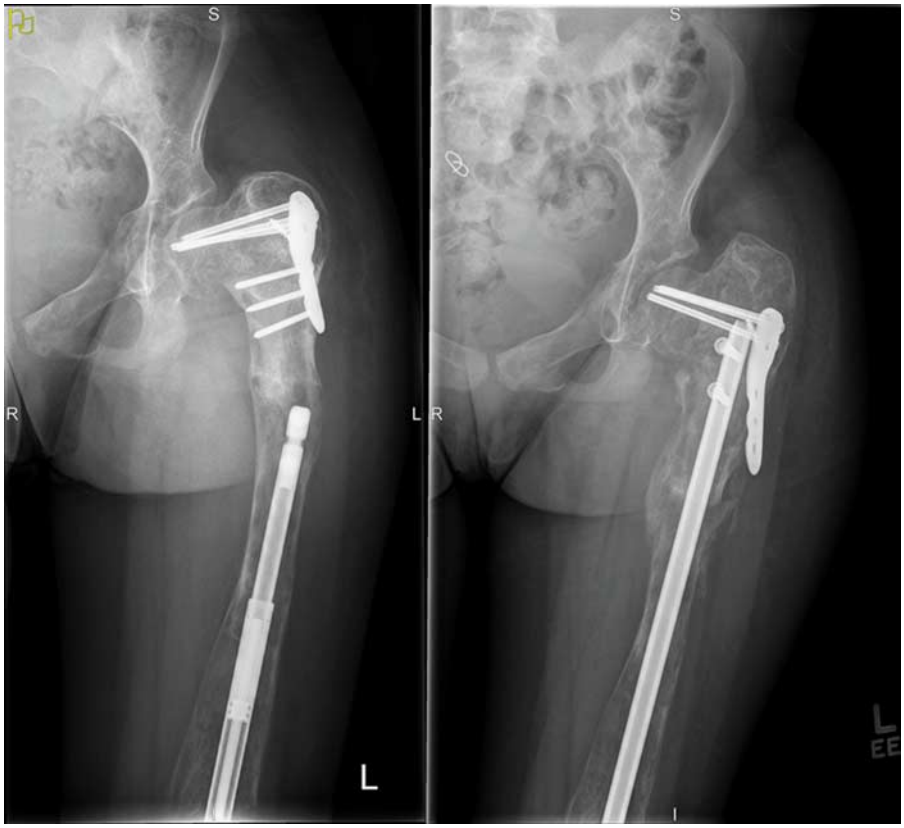

FIGURE 1. Periprosthetic fracture proximal to lengthening nail in a patient with fibrous dysplasia. Managed by exchange to trauma nail overlapping the proximal locking plate.

no treatment. One patient with fibrous dysplasia who had previously undergone a proximal femoral osteotomy with locking plate fixation, sustained a periprosthetic fracture distal to the plate and proximal to the retrograde nail during the last stages of lengthening. The lengthening device was exchanged to a standard trauma nail with intraoperative external fixation assistance but 30 mm of length were lost at the fracture site (Fig. 1).

One patient who had an antegrade femoral nail for congenital short femur, had preexisting valgus and patella alta and developed recurrent patella subluxation as a result of 8 mm mechanical axis shift. This was anticipated and discussed preoperatively. A decision not to address the distal femoral valgus during lengthening was made to allow the option of bridging the knee by an external fixator if there were concerns for subluxation. Following lengthening completion, he underwent temporary hemiepiphysiodesis and symptoms resolved (Fig. 2).

A patient with no comorbidities developed a deep venous thrombosis 4 months following completion of lengthening. Following a course of anticoagulation the condition resolved with no further issues. This is the only case of venous thromboembolism that we have encountered and to our knowledge there are no reports on the literature. We routinely employ mechanical prophylaxis in our patients; sequential compression devices on the contralateral leg intraoperative and thromboembolism deterrent stockings for a 2-week period following surgery. We only prescribe weight adjusted chemical prophylaxis (low molecular weight heparin) to adolescents with additional risk factors until they are mobile.

DISCUSSION

The main aim of intramedullary limb lengthening surgery is achieving adequate length with the least amount of problems and complications. There is increasing emphasis on minimizing disruption to patients and families and achieving high satisfaction rates as per PROMS.[8,16]

Nail accuracy, reliability, and consolidation index in our study are similar to published results.[6,8,18,19] We have encountered cases of joint stiffness when over 30 mm of lengthening were performed. Previous studies have shown that joint stiffness becomes an issue with increasing length and over 10% of original bone length.[20,21] We have not observed this 10% value in our series as we have often performed lengthening beyond this without issues. The 30 mm value observed may be related to the frequency of outpatient attendances. We feel this value is more applicable to our clinical practice and use it to inform our patients. We take various steps to prevent stiffness. If joint ROM is limited preoperative, if the underlying etiology dictates or if

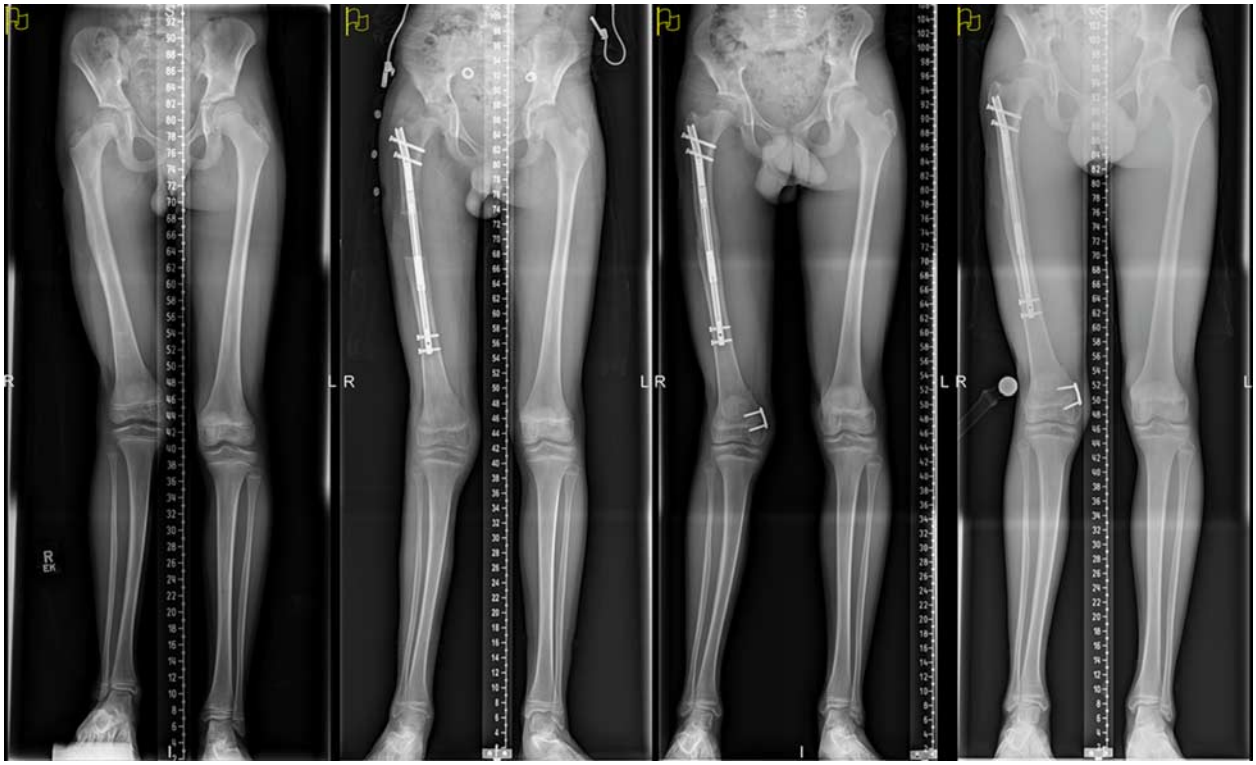

FIGURE 2. Serial radiographs of case of mechanical axis deviation following lengthening in a patient with congenital short femur. Managed with temporary hemiepiphysiodesis.

significant lengthening is planned (> 10% bone length) we perform soft tissue releases during surgery. We adjust rates as previously discussed. With short breaks from lengthening (up to 7 d) no cases of premature consolidation were encountered, as previously described.[22]

Patients proceed to FWB within a 4-week period following completion of lengthening rather than consolidation. We have not encountered issues such as regenerate deformation or nail breakage and believe that this early load bearing regime allows for shorter consolidation period due to stimulation. One of the limitations is that these intervals are again dependent on outpatient attendances affected by service provision.

We treated 8 patients with congenital longitudinal limb deficiency with established risks of developing knee flexion contractures and knee subluxation.[7,13] Adequate surgical techniques, preventive measures, and early detection of signs of subluxation can lead to good functional results.[13] None of our patients had previous reconstructive stabilization surgery. All patients received a knee brace and regular physiotherapy. Biweekly radiographs with knee shoot through views were obtained. Rate of lengthening was adjusted. No episodes of subluxation were encountered, even in knees found to be unstable preoperatively. Mindler et al[23] reported comparable outcomes in their cohort employing a similar regime. No cases of hip subluxation were encountered. A patient with a dislocated hip developed worsening pain and 3 years following lengthening underwent total hip arthroplasty. This was anticipated and discussed before lengthening. This group of patients presents significant challenges with lengthening but lower complication rates are reported with intramedullary devices.[24]

Lengthening along the femoral anatomic axis creates changes on limb alignment and MAD. It has been suggested that 1 mm of lateral shift occurs with every 1 cm of lengthening.[25] Kirane et al[6] commented on the effects of osteotomy levels and tendencies for segmental malalignment because of soft tissue deforming forces. Ways to plan and anticipate those changes and techniques such as the resolution anatomic axis planning have been proposed to determine the optimal osteotomy level and nail orientation to counteract these effects.[26] Use of Poller screws is a useful technique in improving frontal and sagittal plane alignment.[27] Fixator-assisted nailing has a role in dealing with preexisting deformities. We employ these techniques as appropriate.

Use of femoral antegrade nails in children has raised concerns about the risk of damaging the femoral head blood supply.[28] Hammouda et al[29] reported favorable outcomes with use of trochanteric entry nails and no cases of avascular necrosis. We did not observe any case of avascular necrosis nor any alterations in trochanteric and femoral neck anatomy.

Regenerate formation during distraction osteogenesis has been extensively studied. If underlying pathology or significant lengthening may compromise regenerate we observe closely and adjust distraction rate. Even in cases of poor regenerate during lengthening there

was significant improvement following completion. This is commonly the case in the proximal tibia osteotomy due to the approach and limited soft tissue coverage. Prolonged latency periods have been advocated following large intraoperative deformity corrections due to the effect on periosteum which is the dominant blood supply following reaming. We have not encountered any regenerate issues on pediatric patients.

We did not encounter any magnet-related complications as previously described.[30] We do not perform complete release of the anterior compartment following tibial osteotomies and have not encountered any case of compartment syndrome in this group. We did not encounter any cases of superficial or deep infections in our study despite some patients previously having surgical procedures with frames for lengthening and deformity corrections.

Proposed advantages of the STRYDE nail and early weight-bearing are the ability to maintain a more physiological gait pattern throughout treatment, improved muscle conditioning, reduced joint stiffness, and improved ability to perform ADLs. Another advantage is the potential of performing simultaneous bilateral limb lengthening. In our limited experience we have found this to be the case.

PROMS are increasingly popular. Others authors have reported favorable outcomes with intramedullary lengthening devices.[8,16] We developed a short questionnaire tailored to our population to address their specific needs and demands. Effect on activity limitation, ability to continue with tasks such as schooling during treatment and feelings regarding self-perception and image are of paramount importance in this group. Our PROMS are not validated and were administered retrospectively and therefore recall bias is possible.

Our data show that with thorough preoperative planning and preparation, surgeon experience, meticulous operative technique, vigilance through all stages of care and patient and family education, intramedullary lengthening surgery is a safe and reliable mode of treatment in the under 18s with excellent patient reported outcomes.

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