ORIGINAL ARTICLE

Regenerate Deformity with the Precice Tibial Nail

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Abstract

Limb lengthening by distraction osteogenesis is an accepted orthopaedic surgical technique. The Precice intramedullary lengthening system is the most recent innovation in limb lengthening. Early results have been favourable in femoral lengthening but there is little reported on the outcome in tibial lengthening. The aim of this study is to present our early results of Precice tibial lengthening, and the stepwise evolution of our surgical technique.

Materials and methods: A case series of 17 consecutive tibial lengthenings were prospectively analysed. Healing index, length achieved, range of motion, and complications were recorded. The initial cases followed the recommended surgical technique. Progressive regenerate deformity during lengthening required changes to the surgical method.

Results: No cases were lost to follow-up. All the nails lengthened at the desired rate. There were no complications of infection or poor regenerate formation. Progressive valgus and procurvatum was prevented in later cases by the positioning of Poller blocking screws at the time of nail insertion.

Conclusion: The tibial Precice nail is successful in obtaining length and good regenerate formation. The recommended technique was insufficient to control the deforming forces from the lower limb muscle compartments during lengthening. We therefore recommend the addition of multiple blocking screws in an amended technique.

Keywords: Blocking screw, Bone lengthening, Deformity correction, Internal lengthening nail, Intramedullary nail, Limb lengthening, Poller screw, Precice, Tibia, Tibial osteotomy.

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Introduction

Limb lengthening by distraction osteogenesis is performed commonly by external fixation using either ring fixators or monolateral devices and produce satisfactory results.[1–3] Unfortunately, external fixators can be cumbersome and difficult for patients. In addition, complications such as pin-site infection, muscle tethering, regenerate deformity and fracture, and prolonged immobilisation times, have driven the development of new techniques.[3]

The total time with an external fixator *in situ* has been reduced through intramedullary nailing, such as lengthening over a nail[4,5] or lengthening followed by insertion of a nail once the requisite length has been achieved.[6] Fully implantable lengthening implants remove the need for an external fixator completely.

Early intramedullary lengthening devices such as the Albizzia nail (DePuy, Villeurbanne, France) utilise a ratchet mechanism which requires a significant arc of rotation of the leg between bone segments to produce femoral lengthening.[7] Another mechanical ratchet nail, the Intramedullary Skeletal Kinetic Distractor (ISKD, Orthofix, Verona), utilises smaller rotations and is monitored through an external magnet detector. ISKD tibial lengthenings were, however, complicated by implant failure, poor bone formation, and failure to achieve lengthening.[8,9]

The first motorised nail, the Fitbone Nail (Wittenstein Intens, Igersheim, Germany), uses a gear-spindle system driven by transcutaneous electrical induction, via an external device and a subcutaneous internal antenna attached by a tunnelled wire to the nail. This produced accurate lengthening but complications including implant failure and subcutaneous antenna irritation have been reported.[10,11]

The Precice intramedullary lengthening system (originally Ellipse Technologies Inc., CA, USA now NuVasive Inc., CA, USA) is the most recent innovation in internal limb lengthening. It is a telescopic internal lengthening device with an outer casing of titanium alloy (Ti-6Al-4V). A rare earth magnet within the nail connects to a gear box and screw shaft assembly. Two rotating rare earth magnets contained in an external remote controller (ERC) cause rotation of the implant magnet and thus can either lengthen or shorten the nail with sub-millimeter accuracy.[12]

Reported results of the Precice nail have been favourable both in femoral and tibial lengthening.[12–19] Our results, however, despite being excellent in the femur, demonstrated bending of the regenerate column in the tibial segment during lengthening despite accurate placement. The aim of this study is to present our results and the stepwise evolution of our surgical technique. This retrospective review of 17 Precice tibial lengthenings undertaken in skeletally mature patients is the largest single series using the Tibial Precice nail. We believe the modifications to the published surgical technique will enable new users to avoid the complications we have encountered with this device.

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Materials and Methods

From June 2014 to April 2017 a prospective data collection was performed on the first 17 consecutive tibial lengthenings in 14 patients using the Precice nail. The patient group was made up of 9 males and 5 females. Three patients underwent bilateral lengthenings. The age range was from 18–52 years, with a median age of 21 years, including 11 right tibias and 6 left tibias. Aetiologies underlying need for surgery included post traumatic shortening (4), unilateral talipes equinovarus (1), tibial pseudarthrosis (1), posteromedial bowing (1), Leri Weil dyschondrosteosis (1), Turner's syndrome (2), fibula hemimelia (1), hemihypertrophy (1), pseudoachondroplasia (1), and congenital short stature (1). No cosmetic lengthenings were done. The patient details are summarised in Table 1.

Surgical planning and size selection of the Precice nail were done using long-leg standing radiographs where pelvic obliquity from unequal leg lengths was levelled using blocks. In addition, standard anteroposterior (AP) and lateral radiographs of the tibia were used.[20] Calibration and measurement were done using McKesson PACs software (McKesson Corp., San Francisco, USA).

The procedures were performed by one of the two senior authors who are both experienced limb reconstruction surgeons.

Surgical Technique

The surgery was performed under a general anaesthetic, without the use of a tourniquet. The technique is similar to that described by the implant manufacturer[21] and to previously published methods for infrapatellar antegrade nailing for tibial fractures.[12,15,17]

Firstly, a distal syndesmosis screw is inserted, crossing 3 cortices, in a transverse orientation. Proximal tibia-fibula fixation was performed in 3 of 17 cases using a small lateral incision, from the fibular head into the tibial metaphysis, and aimed posteriorly to avoid the nail when later inserted. The indication for using this proximal screw was a normal anatomical location of the fibular head before lengthening. In the remaining 14 cases where the fibula was overgrown or was in an abnormal anatomical position, no fixation was used.

A mid-diaphyseal oblique fibular osteotomy was performed through a longitudinal lateral incision, with a small oscillating saw cooled with saline.

The planned tibial osteotomy site was approached through a small longitudinal anterior incision and pre-drilled. Completion of this osteotomy was deferred at this point in time. Drilling facilitates not only completion of the osteotomy later on but vents the tibia. Extrusion of reaming debri is thought to provide bone graft. We considered the optimum position to be the junction of the proximal metaphysis and diaphysis from our previous experience with lengthening by external fixation. This is compatible with guidance from the manufacturer regarding osteotomy site choice relative to desired lengthening and nail design.

The nail entry point is based on preoperative planning, utilising either a medial parapatellar approach and entry point below the medial tibial spine or a patella tendon splitting approach enabling a more lateral entry point. The optimal entry point is one whereby the guide wire can pass straight down the canal, close to the straight lateral cortex, permitting passage of the nail after sequential reaming. In cases where length is the only deformity being corrected, the tibial canal is widened with flexible reamers. The guide wire is then removed and the nail inserted as a trial. If trial insertion is successful, the nail is removed and the osteotomy completed. The nail is then re-inserted. In cases where a simultaneous angular deformity correction is undertaken, the osteotomy is placed at the centre of rotation of angulation (CORA). In this scenario, the osteotomy is completed at this stage so as to correct the deformity acutely and then reaming undertaken. Sequential reaming is performed to a diameter 2 mm greater than the outer diameter of the nail. This minimizes trauma to the internal mechanism of the nail during insertion.

In the first six cases, nail position and alignment were satisfactory. One patient (case 4) required an open reduction of the osteotomy site to pass the nail. This was due to posterior comminution of the osteotomy. Complications with alignment in case 7 led to a change of surgical technique. It was during lengthening of case 7 the regenerate deformed into valgus (Fig. 1). Analysis of the immediate postoperative radiograph indicated the proximal part of the nail had displaced medial to the initial insertion point after the osteotomy, leading to a minor valgus alignment. This was thought to increase with subsequent lengthening. In cases 8–10, temporary blocking wires were therefore placed medially, laterally and posteriorly during trial insertion of the nail so as to maintain nail position and alignment of the tibia after the tibial osteotomy was completed and the nail locked (Fig. 2). This was successful in maintaining alignment throughout subsequent lengthening.

In cases 11–13 however a progressive valgus deformity occurred during lengthening, despite intraoperative blocking wires maintaining initial anatomical alignment. Permanent blocking screws were positioned to prevent deformity in all remaining cases in the series (Fig. 3). These are placed in the coronal plane to prevent valgus, and in the sagittal plane to prevent procurvatum.

Two proximal locking bolts are inserted using the jig attachment. The distal locking bolts are placed free hand ensuring correct rotation of the limb. It is imperative to ensure that the proximal bolt threads are fully engaged in the near cortex and that some of the bolt protrudes through the far cortex. No end cap is used as it impedes removal of the nail.

Following wound closure and dressing application, the magnet is identified under image intensifier and marked on the skin with an indelible marker. The nail is then tested by lengthening 1 mm and confirmed through C-arm imaging by visualising distraction of the gear box.

Postoperative Regime

Physiotherapy to regain knee and ankle range of motion, commenced day 1 post-surgery, was undertaken as comfort permitted. Regular clinical examination assessed pain levels, range of motion, and altered neurology. Patients were instructed to be strictly non-weight bearing. After a latent period of 6 days, lengthening commenced at a rate of 0.33 mm twice a day.

Outcome Data

Clinical and radiological review, undertaken every 2 weeks during lengthening and every 4 weeks thereafter, allowed assessment of regenerate bone formation. Any axis deviation was documented. Partial weight bearing was allowed once length was achieved and on satisfactory progress of bone formation. Full weight bearing was encouraged when 3 out of 4 cortices in the regenerate column were seen on radiographs. Target length and achieved length were recorded. The modified healing index was calculated as the period of time with the nail *in situ* (days) divided by the lengthening achieved (in cm); time of nail *in situ* was recorded when the level

Table 1: Patient cohort table with demographics and results

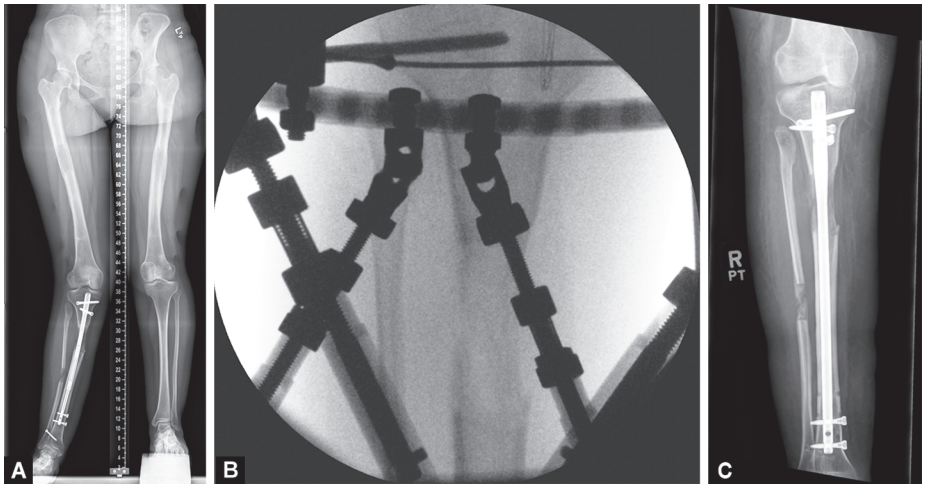
Pt no	*Age*	*Sex*	*Side*	*RON Time in situ (months)*	*Nail size (mm)*	*Fibular fixation*	*Fibular migration (cm)*	*Diagnosis*	*Length Target (cm)/ Achieved/%*	*ROM knee and ankle*	*Healing Index (days/ cm)*	*Complication*	*Blocking method*
1	36	F	R	No	10.7 × 315	Proximal + distal	0	PMTB	4.0/4.0/12.8%	Full	60	Prominent locking bolts removed 11 months post nail insertion	None
2	19	F	R	Yes 20	10.7 × 275	Distal	0.9	CTEV	2.0/2.0/6.15%	Full	27	Broken syndesmosis screw after consolidation (removed with nail)	None
3	18	M	R	Yes 18	10.7 × 275	Distal	1.2	Fibular hemimelia	4.8/4.7/12.5%	Full	38.3	None	None
4	18	M	R	Yes 14	10.7 × 275	Distal	1.0	Congenital shortening	3.5/3.4/9.2%	Full	44.1	6° valgus but corrected preexisting tibia vara	None
5	18	M	R	No	8.5 × 305	Distal	0.4	Tibial pseudarthrosis	8.5/5.0/15.2%	Full	56	Lengthening stopped at 5 cm due to muscle tightness	None
6	**19**	**M**	**R**	**Yes 21**	**10.7 × 230**	**Distal**	**1.4**	**Short stature (LWD)**	**5.0/5.0/15.9%**	**Full**	**29.4**	**Prominent proximal locking bolts: revision bolts 4 months post nail insertion, muscle herniation (repaired RON),**	**None**
7	**21**	**F**	**R**	**Yes 8***	**8.5 × 230**	**Distal**	**1.3**	**Short Stature (Turner's)**	**5.0/5.0/17.9%**	**Full**	**37.8***	**valgus 16°: exchange nailing and CPN decompression 4 months after length achieved**	**Trigen: ×1 screw**
8	19	M	R	Yes 14	12.5 × 275	Distal	2.4	Post-traumatic	2.8/2.8/7.8%	Full	27.5	Proximal locking bolt backed out, removed with nail 14 months post insertion	Wires
9	**21**	**F**	**L**	**No**	**8.5 × 230**	**Proximal and distal**	**1.3**	**Short Stature (Turner's)**	**5.0/5.0/17.9%**	**Full**	**50.4**	**Broken diastasis screws proximal + distal, removed 8 months post insertion**	**Wires, Patellar splitting approach**
10	**19**	**M**	**L**	**Yes 17**	**10.7 × 215**	**Distal**	**1.7**	**Short stature (LWD)**	**5.0/5.5/17.5%**	**Full**	**44.5**	**Broken diastasis screw 11 months post insertion, removed, SPN paraesthesia spontaneously resolved**	**None**

Contd…

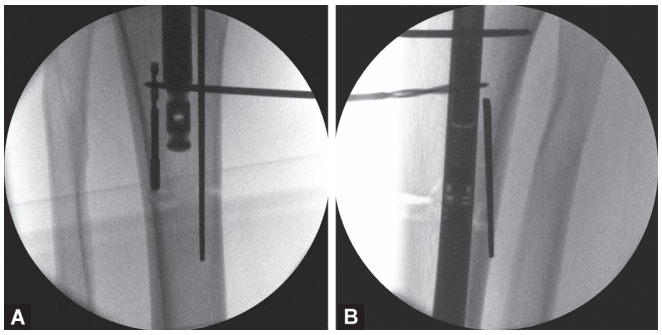
Contd…

Pt no	*Age*	*Sex*	*Side*	*RON Time in situ (months)*	*Nail size (mm)*	*Fibular fixation*	*Fibular migration (cm)*	*Diagnosis*	*Length Target (cm)/ Achieved/%*	*ROM knee and ankle*	*Healing Index (days/ cm)*	*Complication*	*Blocking method*
11	54	F	L	Yes 3**	8.5 × 245	None (old fracture NU)	N/a	Post traumatic	3.0/2.5/7.4%	Full	87.75**	12° valgus, had precice removed and TSF applied 3/12 post index	None
12	**19**	**M**	**R**	**Yes 4****	**10.7 × 245**	**Distal**	**1.1**	**Short stature (unknown)**	**5.0/5.0/17.7%**	**Full**	**46.2****	**Valgus (10°) had RON and TSF 3 months post nail insertion**	**None**
13	52	M	L	Yes 5*	10.7 × 245	Proximal	0	Post-traumatic	5.0/5.0/14.9%	Full knee, ankle fused	40.6*	Procurvatum (25°) and valgus (10°), had exchange nailing 4.5 months post Precice insertion	Precice: ×1 screw Trigen: ×2 screws
14	37	M	R	No	10.7 × 245	Distal	1.1	Short stature (PA)	4.5/4.5/12.2%	Equinus 10°	38.9	Valgus 6° (monitoring)	Screws ×3
15	**19**	**M**	**L**	**No**	**10.7 × 230**	**Distal**	**0.5**	**Short stature (unknown)**	**5.0/5.0/17.7%**	**Full**	**35.8**	**CPN exploration for foot drop**	**Screws ×3**
16	23	F	L	No	8.5 × 245	Distal	0.3	Short Stature (Turner's)	4.0/4.0/12.4%	Full	24.75		Screws ×3
17	40	M	R	No	10.7 × 275	None	1.0	Post traumatic (GSW)	22/22/7%	Full	50.9	None	Screws ×4

*Precice exchanged for Trigen trauma nail due to deformity during lengthening
**Precice exchanged for TSF due to deformity during lengthening
PMTB, posteromedial tibial bowing; CTEV, congenital talipes equino varus, CPN, common peroneal nerve; LWD, Leri Weil dyschondrosteosis; PA, pseudoachondroplasia; SPN, superficial peroneal nerve; N/A, not applicable
Bold entries = Bilateral cases



Figs 1A to C: Case 7: (A) Long leg radiograph with valgus postoperative mal-alignment; (B) Intraoperative AP intensifier view of CHAOS technique to acutely correct regenerate 4 months after Precice insertion; (C) AP radiograph of trauma nail *in situ* with corrected alignment immediately post-CHAOS



Figs 2A and B: Case 8. Use of temporary blocking wires intraoperatively: (A) AP intensifier view; (B) Lateral intensifier view

of regenerate consolidation was such that had an external fixator been used, removal at this point would have been appropriate.[16,19] Knee and ankle range of motion was recorded and was classified as full if within 5° of the preoperative range. Further operations and complications were documented. Removal of the Precice nail is recommended by the manufacturer following bone consolidation and remodelling and was not considered a reoperation.

No cases have been lost to follow-up. The median duration of follow-up was 17 months (range 7–39 months).

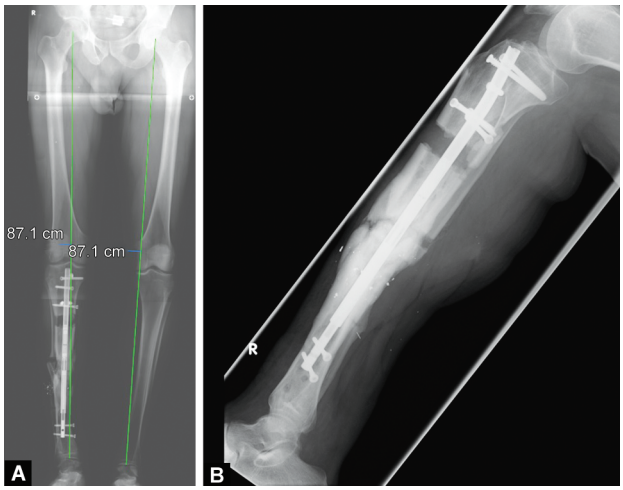
Results

All but one patient completed lengthening to within 5 mm of the preoperative plan. Target length ranged from 20 mm to 80 mm. Achieved lengths were 20–55 mm, with a median gain of 50 mm. The single failure occurred in case 5 with a diagnosis of tibial pseudarthrosis. The preoperative target was 80 mm, and lengthening was stopped at 50 mm due to muscle tightness and pain.

All patients formed regenerate and healed. Healing index ranged from 27 days/cm to 87.75 days/cm, with a median of 38.05 days/cm. There were no cases of premature consolidation or regenerate fracture.

Table 1 summarises the results from the cohort.

There were no implant failures. Three cases had problems with the proximal locking bolts backing out. In one case the prominent



Figs 3A and B: Case 17. Use of permanent blocking screws: (A) Long leg radiograph with AP blocking screws; (B) Lateral radiograph with sagittal blocking screws

bolt was revised 4 months post insertion. In the two other cases, the bolts were removed at the same time as nail extraction and was not considered additional surgery. In three cases a diastasis screw broke, two at the distal tibia-fibular joint, and 1 at the proximal tibia-fibular joint. This occurred after weight bearing had commenced. In two cases they were causing pain and, at 8 and 11 months post insertion, were removed. In the third case the screw was removed at the time of nail extraction.

In the cases that underwent proximal fibular fixation, two had no distal migration of the fibular head. One patient suffered breakage of the proximal fixation screw and the fibula migrated 13 mm. The median migration in all cases was 11 mm (range 0–24 mm). None of the patients were symptomatic from fibular migration.

Eleven nails have been removed successfully. Six nails remain *in situ*. There were no complications observed during the 11 nail extractions or since. The one patient (case 5) that had to stop lengthening at 50 mm due to muscle tightness is currently undergoing further lengthening of the same tibia following an

exchange of the Precice nail. The original Precice nail was exchanged due to concerns of device failure because of corrosion potential. In addition, in secondary lengthening, a longer nail with the same diameter may now be permissible and desirable.

Our surgical technique has evolved as complications were encountered. Deviations in the mechanical axis occurred in six cases.[22] The alignment was satisfactory intraoperatively in all these cases but the deviation occurred during lengthening. In two cases (4 and 14), a 6° valgus deformity developed, was monitored and has not require further intervention. Four cases developed a larger valgus deformity (10–16°). Two of these cases (7 and 13) underwent acute correction using the CHAOS technique (Computer-assisted Hexapod Orthopaedic System) and the Precice nail replaced by a trauma nail. A prophylactic peroneal nerve decompression was performed at the same sitting. The correction was done once lengthening was complete, but the regenerate still malleable, at approximately 4 months post Precice nail insertion. The Precice nail was used to achieve length before the CHAOS procedure. A trauma nail was used as this facilitated weight bearing whilst reducing risks of recurrent deformity or device failure. This nail did not need to be removed. Exchange nailing was performed with the use of multiple blocking screws, as described earlier with the evolution of this surgical technique.

In two cases (11 and 12), the Precice nail was removed and replaced with a Taylor Spatial Frame (TSF) for gradual correction of the deformity. With minimal distraction of the fibula osteotomy in both these cases it was felt that an acute correction of the valgus would result in too much lateral lengthening and place the common peroneal nerve at risk. In two of these cases requiring revision surgery, there was a procurvatum deformity in addition to the valgus. In all four cases, revision surgery was successful in restoring alignment without loss of length. The healing index within this group (the 4 tibial lengthenings which did not complete treatment with the Precice) ranged from 37.8 days/cm to 87.75 days/cm, with a median of 43.4 days/cm. By comparison, the remaining cases (13 tibias), had a healing index from 27 days/cm to 60 days/cm, with a median of 38.9 days/cm.

There were no cases of either superficial or deep infection.

One patient who had bilateral nails experienced a small muscle hernia at the site of the fibular osteotomy wound on the right side (case 6). This was repaired during nail removal. Two patients (cases 10 and 15) had neurapraxia, one of the superficial peroneal nerve and one of the common peroneal nerve. The superficial peroneal neuropraxia has fully recovered. Case 15 underwent exploration of the common peroneal nerve which revealed no abnormality. The common peroneal nerve patient has recovery of the peroneal compartment and sensation over the dorsum of the foot. At latest follow-up there is altered sensation within the first web-space and MRC grade power 2 out of 5 in the tibialis anterior, extensor hallucis and extensor digitorum muscles 7 months following nail insertion (3 months following completion of lengthening).

All but one patient regained the range of motion of the knee and ankle to within 5° of preoperative. Case 14 is for consideration of a gastrocnemius recession to treat calf muscle tightness that has resulted in 10° of equinus at the ankle with the knee extended and 20° of ankle dorsiflexion with the knee flexed. Of note, this patient previously had ipsilateral femoral lengthening using a Precice nail and does not want the proposed gastrocnemius recession at present.

Discussion

We have achieved successful lengthenings of the tibia using the Precice nail. There were no implant failures in this series and all nails lengthened at the programed rate. Using the first generation of Precice nails, Paley reported 3 nail breakages and 5 mechanism breakages in his series of 65 nails, including 8 tibial nails.[12] The breakages were largely due to weld failure in the femoral devices. Since using the second generation of Precice nails, Paley has reported no further incidences of device failure. The failure rate of other devices ranges from 1.2% in Fitbone nails,[10,11] up to 23% of ISKD nails,[8,9] with an average of approximately 6% in these large series.[23] With the Precice nail, locking bolts need to be seated with the threads engaged in the cortex firmly. This may avoid backing out of the bolts which was a complication, not widely documented by other groups, occurring in 3 of our 17 cases. It is likely to be underreported.

The healing index in the tibia is known to be longer than the femur.[24] We reported a femoral healing index of approximately 31.3 days/cm with the Precice nail.[19] Our median tibial healing index of 38.9 days/cm is comparable to 34–48 days/cm from other groups using the Precice tibial nail.[12,18] The Fitbone nail has generated a tibial healing index of 42 days/cm from the originator's group,[25] and 43.7–48 days/cm from other groups.[10,11] The ISKD tibial healing index is 36 days/cm[9] and with the Albizzia nail it is 35 days/cm.

There were no problems with use of the ERC to determine an expected rate of lengthening. The lengthening rate of 0.33 mm twice daily was chosen by the surgeon. It is less than the typical 1 mm daily divided into 0.25 mm steps as used in Ilizarov lengthening as we had concerns over gastrocnemius tightening; a more classic rhythm of 0.17 mm four times daily to promote regenerate formation will be considered for future cases.

Bone grafts were not needed for any patient in this series. Other groups have reported poor regenerate in the tibia with Kirane[14] grafting 2 out of 7 Precice tibial nails and Baumgart[25] grafting 3 out of 22 tibias when using the Fitbone nail. The longest healing index of 60 days in our cohort was in a patient who underwent a diaphyseal osteotomy due to simultaneous angular correction and CORA location. Paley has recommended a metaphyseal osteotomy due to improved regenerate formation and a lower likelihood of need to bone graft.[15]

The major complication seen in this series is valgus and procurvatum mal-alignment during lengthening. This has been documented by other authors in relation to tibial lengthening.[20,26] We have identified techniques to minimize this problem including care with an optimum entry point and the use of blocking screws. Blocking screws (sometimes referred as to as "Poller"–after the original German term–describing small metal poles on roads which act as guides to streetcars along their tracks) can prevent toggling of the nail in the proximal tibial metaphysis when a metaphyseal osteotomy site is used. The described surgical technique that accompanies the implant suggests the use of blocking screws only if doing an angular correction. Other authors, including Fragomen and Rozbruch, recommend also using blocking screws when doing an angular correction but not for routine lengthening. Paley does not mention the use of blocking screws in his account of the surgical technique.[15] Furmetz found that the use of blocking screws enabled for greater degrees of correction, with higher precision, in both the femur and the tibia.[26] Rozbruch recommended blocking screws whenever the diameter of the canal is larger than the nail at the osteotomy level and uses the "reverse rule of thumb" method

to identify the appropriate location of blocking screws.[20] In this series, the metaphyseal osteotomy will denote a level in the tibia where the canal diameter is always larger than the nail. Therefore, our experience indicates blocking screws should be a routine addition to the technique. In tibial lengthening, we recommend 2 lateral screws and 1 posterior screw in the proximal fragment to prevent valgus and procurvatum deformities, respectively. We advocate using 4.5–5.0 mm fully threaded titanium screws from any manufacturer, aiming for 1–2 mm of space between the screw and the nail. Titanium screws avoid contact reactions between metals and, being fully threaded screws, gain good purchase. These screws can be placed prior to reaming, and post reduction, to prevent an unwanted track for the nail being created. The screws need to be approximately 2 cm from the osteotomy site. Closer positioning risks propagation into the osteotomy whereas siting the screws further away is suboptimal for control of alignment. There were no problems with insertion of blocking screws in this series. Furmetz also utilised the concept of a "dummy nail", which matches the size of the nail to be implanted but is suitable for firm implantation to create the desired path, permitting easier solid nail insertion and a lower risk of damaging the lengthening mechanism.[26]

We compared the diameter of the intramedullary canal to the Precice nail at the osteotomy site to see if it was possible to predict those at risk of valgus and procurvatum mal-alignment. There was no correlation between the nails that migrated and the size of the canal nor the distance between the nail and the cortex at the osteotomy site, either in the sagittal or coronal planes. We hypothesise that the development of deformity in the regenerate is multifactorial. A wide canal diameter in relation to the nail at the osteotomy site, lack of good fixation with 2 proximal locking bolts, poor bone quality in some patients, and the strong muscular pull of the gastrocnemius, all play a part in the deformity as the lengthening proceeds.

The osteotomy site was chosen from the experience of lengthening with external fixators. Diaphyseal osteotomies tend to produce poor regenerate, as demonstrated by our case of delayed union. The metaphyseal-diaphyseal junction is our preferred osteotomy level. More proximal osteotomy sites lend themselves to a higher risk of deformity and further work is required to gain clarification on the variables leading to deformity from osteotomies at this level.

Nail length was determined by two factors: the lengthening that could be achieved by the device and the target lengthening required. The selection of the nail was conscious also of desire to have the wider portion of the segment within the regenerate upon completion of lengthening. Unlike the femur, the tibia is usually straight and without an anterior bow that limits straight nail insertion. The longest nail that fit was used.

We recommend distal tibia-fibula fixation only as none were symptomatic from a mean proximal fibular migration of 1.1 cm. It was thought that a normal fibular head position was worth preserving through transfixation but, if performed in cases with an abnormal fibular head position, this would risk damage to the peroneal nerve due to altered anatomy. In contrast, excessive fibular height that was identified in most of this cohort was normalized with the tibial lengthening. Despite some cases showing evidence of a distal positioning of the fibula head after lengthening, no patients described symptoms related to a tightening of the lateral collateral ligament. It is unclear if this is because of a good physiotherapy regimen that was implemented. As there were no noticeable ill effects clinically from omitting a proximal tibio-fibular screw, we do not believe it is required with this device. We conclude similarly on the need for a prophylactic peroneal nerve release as this was not done routinely for lengthening in this cohort.

For transfixation of the distal tibio-fibular joint, we chose a screw across 3 or 4 cortices to provide stability. The placement of the screw either from tibia to fibula, from fibula to tibia, or in an oblique or transverse orientation as seen in the coronal plane, was left to the surgeon's discretion, with no single consensus in this regard. The patient should be warned of the possibility of the screw breaking when weight bearing is commenced. The screw can be removed when the nail is removed.

All but one patient regained range of motion of the knee and ankle to within 5° of their preoperative range. None of the patients had prophylactic use of Botox, soft tissue releases, nor a temporary calcaneal-tibial posterior screw, as described in the device operative technique manual. Lower leg compartment releases, again recommended, were not performed in this cohort.

Although not carried out as a formal outcome measure, the cohort did not complain of anterior knee pain when asked at follow-up. This is a well-documented problem associated with infrapatellar nailing. The procedure can be performed using a semi-extended approach which is thought to reduce the incidence of the problem.

Both surgeons who performed the surgeries for this cohort still offer patients both internal and external lengthening methods. The development of the Stryde Precice nail which permits immediate weight bearing may offer a significant improvement to patient satisfaction, regenerate formation, and reduction in contractures. Lengthenings greater than 3 cm may need consideration of an external device when adjacent joints may benefit from neutral stabilisation to prevent contracture.

This cohort has demonstrated safe use of the Precice tibial lengthening nail. The technique requires careful planning and the use of blocking screws to prevent valgus and procurvatum deformity especially from a metaphyseal osteotomy site. The adjustments to the surgical technique described here will facilitate using this device safely and with good effect.

Compliance with Ethical Standards

This study was subject to an institutional Research and Development Department review (Research and Development registration number SE17.035). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

This work was performed in accordance with ethical guidelines, with conformity to the Declaration of Helsinki. A Research and Development number was obtained for this service evaluation: SE17.035.

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