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REVIEW

Retrograde magnetic internal lengthening nail for acute femoral deformity correction and limb lengthening

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ABSTRACT

Introduction: The Precice magnetic internal lengthening intramedullary nail is being used with great success in femur lengthening and deformity correction with a retrograde approach.

Areas Covered: Our personal history of limb lengthening and the Precice nail will be reviewed. Several technical aspects are discussed including design updates, pre operative planning, selection of nail length, the use of blocking screws and intra operative temporary external fixation, osteotomy practice, post operative management, and cost analysis.

Expert Commentary: The phenomenal bone healing ability for the retrograde Precice nail after femoral osteotomy for lengthening, even after acute deformity correction, is recognized throughout the growing body of scientific publications on this topic. The few failures that have occurred appear to be attributable to excessive loading of the femur and implant during a vulnerable time of bone healing. Further studies with more uniform outcome criteria need to be conducted to better standardize user's experiences. The higher one time cost of the implant is offset by the reduced number of surgeries needed when compared with the gold standard of lengthening-over-nail-technique, and we suspect that patients return to work sooner due to the ability to wear normal clothing and the reduction in pain throughout the entire lengthening process.

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KEYWORDS
Precice; retrograde; limb deformity; limb lengthening; femur; intramedullary lengthening nail

1. Introduction

History is most accurate when presented by primary sources, and the history of the internal lengthening nails (ILN) at our institute is no exception. A fantastic review of a broad history of ILN was published by one of the creators of the Precice (NuVasive, Paramus, NJ, USA) nail and merits careful study for anyone who will use this implant [1]. We can complement this publication with a brief recall of our experience in the ILN world which started with the intramedullary skeletal kinetic distractor (ISKD) (Orthofix, Austin, TX, USA) nail. Initially excited about this mechanical lengthening implant, we implanted several ISKD nails. With a 30% complication rate including 'run-away' nails, non-distracting nails, and prolonged bone healing our enthusiasm waned. A larger series of ISKD lengthenings confirmed our findings [2]. Careful study of our results using lengthening-over-nail (LON) [3] versus ISKD showed clear advantages of the LON method primarily due to improved control over distraction rate and rhythm [4]. LON took over the femur lengthening space, and innovations were aimed at improving this technique. These included custom nails with no bow (to match the straight rail distractor) and narrower proximal nail diameter (to make it easier to place two half pins posterior to the nail in the lesser trochanter). The Fitbone (Wittenstein, Igersheim, Germany) nail was released in 1997 which was the first motorized ILN offering tight control over distraction rate. This nail required specialized instrumentation including rigid reamers and cannulas, and a special training certification from its creator [5] was a prerequisite. To further stifle growth, the Fitbone was released in a highly limited fashion to only two centers in the United States.

Ellipse (Irvine, CA, USA) created the first motorized-magnetic ILN produced in the United States. The Precice became rapidly available and demonstrated excellent control with great ease of use. We quickly adopted this implant into our center focusing on femur lengthening. The Precice, which could be used with the standard instrumentation for any IM nail, displaced LON. The Precice demonstrated total control over lengthening rate, no cantilever bending with binding of the nail in the canal seen with LON, less knee stiffness, and greater patient comfort. We learned to use blocking screws implementing the 'reverse-rule-of-thumbs' [6], routinely corrected coronal plane deformity acutely [7], developed a successful distraction protocol, and orchestrated the effective use of perioperative tranexamic acid (TXA) and anticoagulation. Currently we use the Precice ILN for lengthening and deformity correction of the femur, tibia, and humerus. We have also used the pre-distracted Precice for compression of difficult fracture nonunions with great success.

The focus of this report is on the retrograde femoral ILN. Indications for a retrograde approach to the femur are numerous. The primary reason we use retrograde nailing is to correct periarticular knee deformity. Both varus and valgus of the distal femur can be realigned with osteotomy and IM nail insertion. The correction of rotational deformity through a

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distal femoral osteotomy is more controversial due to concerns over the impact of this soft tissue torsion on the patellofemoral tracking. Sagittal plane deformity can be corrected as well. The use of blocking screws greatly facilitates deformity correction in both planes. Retrograde nailing can be used in patients with no deformity. Some profess that lengthening along the anatomic axis of the femur, with the production of a lateral mechanical axis deviation, can only be compensated through a distal osteotomy by building a slight correction of valgus into the osteotomy site [8]. By that logic any femoral lengthening can be done through a retrograde approach. A person with a preoperative valgus alignment is also indicated for retrograde lengthening to correct the existing alignment and prevent further lateral axis deviation. A proximal femoral obstacle (such as a hip prosthesis or additional deformity) can also require the use of a retrograde approach. The retrograde approach to the femur is facile and minimally invasive. The trajectory of the insertion tools is under tight control making this method optimal for translating radiographic alignment planning to the patient's limb in the operating room. Patients are not complaining of any residual knee symptoms once healed.

2. Design considerations

The Precice ILN creates distraction of the thinner, telescoping section of the nail through a series of gears inside the nail that turn a central distraction rod. The gears are driven by an internal magnet that turns in response to an external stronger magnet. The closer the magnets are to each other the stronger their force. This can be an issue for patients with very large thighs; the distance between magnets is too great for the device to generate enough force to turn the gears. The amount of lengthening the Precice is capable of and the weight bearing load it can tolerate vary with the nail specifications.

The most significant change to the Precice nail occurred when it became a single piece housing. The first generation Precice (P1) was a modular nail with a separate distraction segment that was assembled in the OR and secured with a set screw. The screw head was subject to stripping during tightening and loosening after implantation. This seam was also a weak point where nail failure was reported [9]. The second-generation Precice (P2) was introduced as a single piece with the lengthening unit contained in one common casing. Although this did not eliminate the risk of failure, it limited the number of problems experienced with the two-piece system.

The external remote controller (ERC) magnet unit was recently updated to include a camera for the patient to visualize where to place the magnet on the skin for optimal magnetic connection. This ERC relies on locating a mark on the skin created with a marking pen and is not capable of identifying the actual location of the internal magnet in the femur. The new ERC is larger than the original unit and often collides with a tibial external fixator when both systems are used together. When performing an ipsilateral proximal tibial surgery with circular fixation, we use the older ERC to activate the retrograde femoral ILN. The newer ERC has attempted to make the programing of a lengthening schedule easier for the programmer and less likely to be erroneous. The older unit provides less structure for programming and as such has been our ERC of choice in cases of retrograde compression nails where the compression schedule is different from a typical distraction schedule (e.g. 1 mm of compression per session).

3. Preoperative planning

Preoperative planning for deformity correction and lengthening of the femur using a retrograde nail has been accomplished using two different techniques. The reverse planning method [8] described for the Fitbone ILN has been applied to the Precice by many users with great satisfaction. The technique describes the use of rigid reamers and specialized tubes for safe passage of these unforgiving reamers past the patella. The potential for notching of the anterior cortex of the femur at the tip of the nail has been raised with the solution of preferentially reaming the posterior cortex [10]. The reverse planning method can be used with flexible reamers as well; however, this was not the intent of its inventor. However, many Precice users prefer to use the standard planning methods for femoral deformity correction based on the anatomic axis of the femur as described by Paley [11] and the method described by Fabricant [12]. Adjustments can be made through an angular correction of the distal femur for the tendency of the mechanical axis to drift laterally during lengthening along the anatomic axis [13] (Figures 1 and 2) The standard technique utilizes readily available equipment including flexible reamers with the recommendation of over reaming by 2 mm greater than the diameter of the nail. Critics argue that the standard technique requires too much over-reaming with loss of control of alignment. A study by Hawi et al. [14] showed that a 'loose' nail (where the nail filled less than 85% of the canal) produced a *medial* mechanical axis deviation in antegrade internal lengthening. A careful review of all publications using both techniques revealed that the amount of over-reaming used was very poorly documented and that the accuracy of deformity correction of the distal femur was acceptable to all authors, the measurement of which was heterogeneous (Tables 1–3). There is no literature to support the superiority of either method and will likely continue to the debated with level V evidence at conferences.

3.1. *Nail length*

The ideal nail length to use for a retrograde ILN is an important topic to review since a straight nail is being inserted into a bowed tubular structure. A nail that is too short may not control the distal fragment during lengthening creating deformity, while a nail that is too long will impinge the anterior cortex of the proximal femur resulting in the bending of the nail with possible implant failure [26] or an inability to insert the nail fully. A full length lateral radiograph of the femur is required to identify the bow, plan the osteotomy site, and measure the ideal nail length. In addition to accommodating for the shape of the femur the surgeon also needs to consider the ideal location of the osteotomy. It is recommended that 5 cm of the thick portion of the nail remain in the proximal femur fragment at the completion of the lengthening. This has been recommended to reduce the risk of

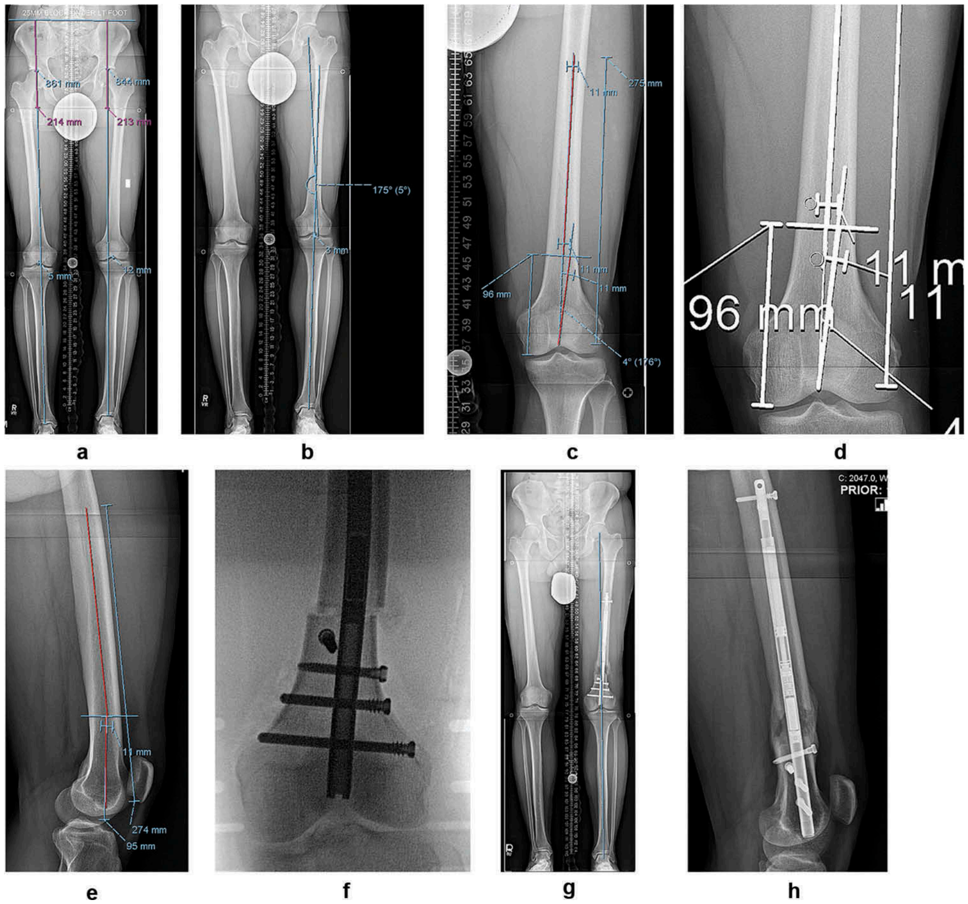

Figure 1. (a) This standing radiograph demonstrates a patient with a 24mm limb length discrepancy. The majority of the shortening stems from the left femur (17mm). There is also a 12mm medial mechanical axis deviation with visibly more varus of the left versus the right leg. Indications for lengthening surgery included non-compliance with a shoe lift, asymmetric coronal alignment, and a safe method for limb length equalization. (b) The tibial mechanical axis (MA) line (distal femur MA line) was placed 2.5mm medial to the knee center to undercorrect the varus. The proximal femur MA line was created normally. The intersection was the osteotomy site. This yielded a 5 deg correction of varus. Placing the distal MA through the center of the knee would have produced 6 deg varus correction. The under-correction of varus allows for the MA to slide laterally 2.5mm during lengthening. (The actual correction planned was reduced to 4 degrees to better match the other side.) (c) The translation of the MA planning to the actual method for nail insertion is demonstrated. The proximal portion of the nail is restricted to sitting straight in the femoral diaphysis (proximal red line). The distal portion needs to start in the center of the femoral notch and then extend along the desired angular correction toward the osteotomy site (distal red line). The osteotomy site needs to be moved distally in order to provide a 4 deg correction. The 11mm lines represent the width of the nail which helps to visualize its path. (d) The circles represent potential sites for blocking screws to assist in an accurate deformity correction. (e) The lateral radiograph of the entire femur is recommended to measure the maximum length of the nail to avoid the proximal femoral bow. In this case, there is minimal bowing in the femoral diaphysis and a 275mm nail will end short of the proximal bow. (f) This intra operative fluoro shot demonstrates the anterior blocking screw placed according to the pre operative planning. A posterior blocking screw has also been inserted. The reamings are seen spilling out of the lateral aspect of the osteotomy site. (g) After 24mm of length the mechanical axis is measured. (h) A final lateral radiograph shows the posterior blocking screw prevented lengthening induced flexion.

deformity occurring due to bending or fracture at the junction of telescopic and thick portions of the nail. This concern has not been formally studied. An osteotomy that is planned too proximally in the femur will leave an inadequate amount of the thick portion of the nail in the proximal fragment during lengthening. The osteotomy location may need to be pushed distally to ensure that enough of the thick portion is contained in the proximal bone segment. We have used a simple calculation to plan the shortest nail length required to meet these requirements (Figure 3(a,b)).

3.2. Blocking screws

Blocking screws were introduced for trauma in 1994 [30]. Their use has been applied to distraction osteogenesis with ILN with great success regardless of the nail or planning technique used (Table 2). The main difference between trauma and lengthening applications of blocking screws is the element of time. When a nail is used to stabilize a fracture, blocking screws are used to help obtain the reduction. When lengthening the femur, additional deformities will occur that do not exist at the time of osteotomy [6]. The femur will tend to flex and may veer into varus or valgus. Blocking screws help to obtain acute correction of angular deformity at the time of osteotomy and help prevent recurrence of deformity during distraction. Additional screws are often placed after insertion of the nail to prevent lengthening induced deformity. This is particularly true of the posterior blocking screw in the distal femur fragment (Figure 1(d,f,h)). Debate exists over when to place the blocking screws: prior to reaming or after nail insertion. When correcting coronal plane deformity, we recommend placing the blocking screws prior to reaming. If the screws are used solely for preventing deformity then, we recommend inserting the screws once the nail has been

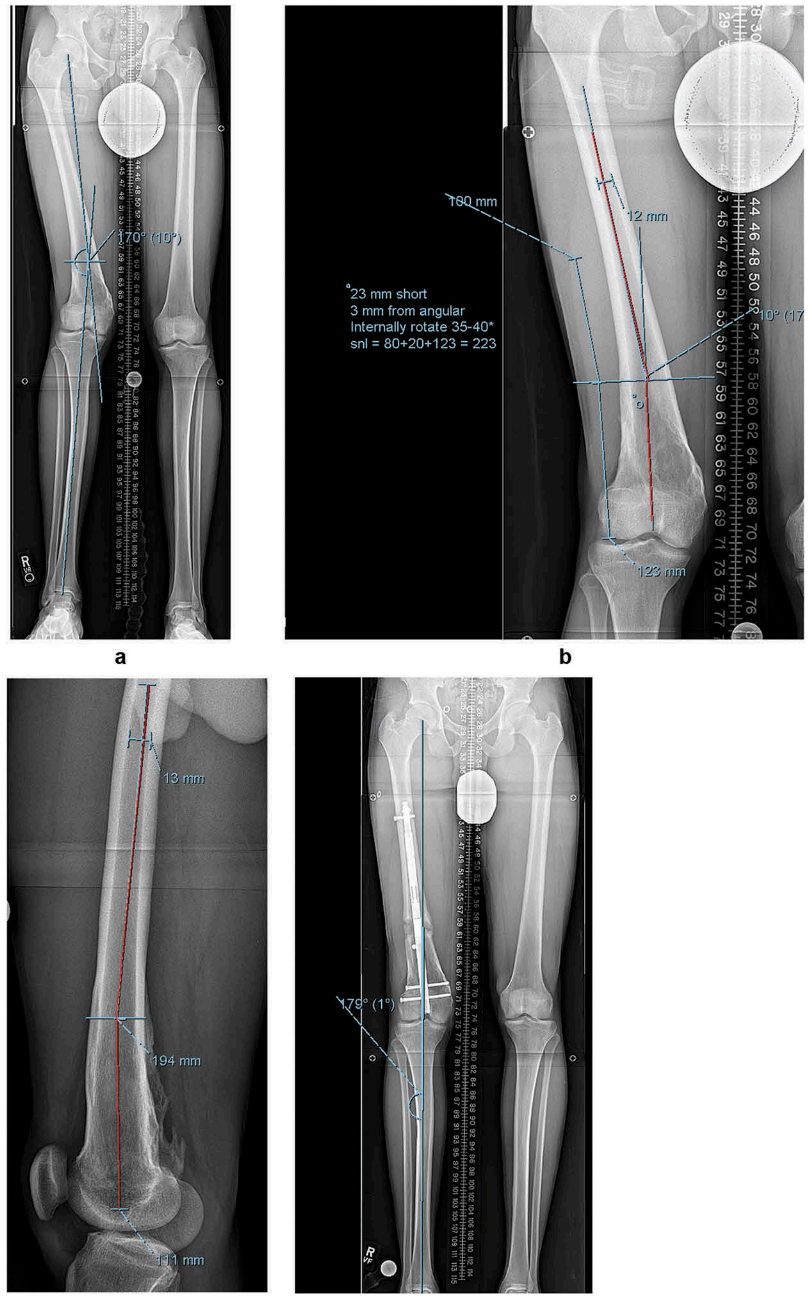

Figure 2. (a) This patient suffered from a post traumatic valgus deformity and LLD of 23mm. Indications for lengthening surgery included non-compliance with a shoe lift, asymmetric coronal alignment, and a safe method for limb length equalization. Mechanical axis planning of this valgus deformity, with the distal axis placed through the center of the knee, yields a quantity (10 degrees) and location for corrective osteotomy and lengthening of 23mm. (Alternatively, the distal axis could have been moved 2.3mm medially to compensate for the 2.3mm lateral shift during lengthening. (b) Translation of the MA planning is done by placing the proximal portion of the nail in the diaphysis (proximal red line) and then aligning the distal portion at an angle of 10 degrees staring from the notch (distal red line). Notations are also made of the desired rotational correction and the shortest nail length calculation. The 100mm line extending from the osteotomy site proximally is the most important aspect and is comprised of accounting for the 50mm of thick portion of the nail needed in the proximal fragment at the completion of lengthening, the 30mm thinner telescoping section of nail, and the desired length (rounded to 20mm in this case). This length of 100mm is added to distal portion (123mm) to yield the shortest nail that will accomplish the lengthening accurately (223mm). (c) The lateral radiograph then dictates the longest nail length possible as the nail tip needs to lie distal to the bow. This shows that a 305mm nail is the longest possible for this patient. (d) This post lengthening radiograph shows a 1 degree valgus (3mm lateral MAD) residual deformity. Because the lateral MA shift was not addressed in the planning the patient remained in slight valgus. An 11 degree correction would have been predicted by moving the distal MA 2.3mm medially during planning.

placed and locked. This allows the blocking screws to be inserted very closely to the nail and ensures they will not interfere with the locking screws. The ideal size of screw needed is not known. We use 5 mm, fully threaded, titanium, IMN locking screws with captured screw heads from various vendors for blocking screws.

3.3. Sagittal plane deformity correction

Procurvatum is the most common sagittal plane deformity we encounter and can vary from mild congenital to severe rachitic multi-apical types. While the correction of sagittal deformity near the knee joint is possible with an ILN, far-distal deformities (less

Table 1. Relevant literature on motorized ILN demographics.

Year	Lead author [ref]	Study design	Limbs (n)	Bone (n)	Age (years): mean (range)	Type ILN	Preop planning method
2006	Singh [15]	R IV	24	Femur (13), tibia (11)	32 (21–47)	Fitbone	Not Specified
2011	Krieg [16]	R IV	32	Femur (21), tibia (11)	16.9 (IQR 15–19)	Fitbone (Gen 1)	Rev planning
2011	Lenze [17]	R IV	11	Femur (10), tibia (1)	14–34	Fitbone	Standard
2012	Al-Sayyad [18]	R IV	14	Femur (9), tibia (5)	16 (11–18)	Fitbone	Rev planning
2014	Kirane [19]	R IV	25	Femur (17), tibia(8)	31 (13–67)	Precice	Standard
2014	Schiedel [9]	R IV	26	Femur (20), tibia (6)	19 (12–31)	Precice (P1)	Not Specified
2014	Thaller [20]	R IV	10	Femur (6), tibia (4)	25 (15–40)	Phenix	Custom Software
2015	Black [21]	R III	15	Femur (15)	18 (15–21)	Fitbone	Rev planning
2015	Kucukkaya [22]	R IV	25	Femur (25)	27 (13–35)	Fitbone	Rev planning
2015	Laubscher [23]	R III	33	Femur (33)	25 (15–57)	Precice (20 nails)	Not Specified
2016	Accadbled [24]	Pro	26	Femur (15), tibia (11)	22.5	Fitbone (Gen 2)	Rev planning
2016	Karakoyun [25]	R IV	27	Femur (21), tibia (6)	23 (14–38)	Precice	Standard
2016	Kucukkaya [10]	R IV	65	All femur (65): 45 retrograde, 20 antegrade	27 (11–42)	ISKD, Fitbone, Precice	Software
2016	Tiefenboeck [26]	R IV	10	Femur (5), tibia (5)	42 (12–74)	Precice (P2)	Standard
2016	Wiebking [27]	R IV	9	Femur (5), tibia (4)	32 (17–48)	Precice	Standard
2017	Furmetz [28]	R IV	5	Humerus (5)	29 (19–51)	Fitbone (3 nails), Precice (2 nails)	Not Specified
2017	Hammouda [29]	R IV	17	Femur (17)	30 (11–72)	Precice	Standard

Ref: reference; R: retrospective; ILN: internal lengthening nail; Gen: generation; P: Precice; Rev: reverse; ISKD: intramedullary skeletal kinetic distractor; IQR: interquartile range; BID: Twice Daily; IM: Intramedullary; TID: Three times daily; NR: Not reported; ITB: Iliotibial band; POD: post operative day; AP: Anteroposterior.

Table 2. Relevant literature on motorized ILN operative details.

Lead author	Reamers	Over-ream (mm)	Blocking screws	Osteotomy type	Latency (days)	Rate DO (mm/day)	Pre-op deformity: MAD or degrees (range)	Amt. lengthened (mm), mean (range)
Singh	Rigid	1–1.5	NR	IM saw	3 femur, 5 tibia	1.0	NR	40 (27–60)
Krieg	Rigid	NR	NR	PerQ Drill	5 femur, 7 tibia	1.3 femur 1.0 tibia	MAD 13 medial and MAD 13 lateral	37.3
Lenze	NR	NR	NR	NR	NR	NR	MAD 50 med and MAD 13 Lat	32 (21–43)
Al-Sayyad	Rigid	0.5	Yes	PerQ Drill	6 both	1.0 femur, 0.66 tibia	Varus 15 (6–30), IR 30°	46 (28–60) femur, 42 (38–48) tibia
Kirane	Flexible	2	Yes	PerQ Drill	5 femur, 7 tibia	1.0	Varus 6–20	35 (14–65)
Schiedel	NR	NR	NR	PerQ Drill	7 femur, 10 tibia	1.0 femur, 0.66 tibia	NR	37 (15–50)
Thaller	Rigid	0.5–1.0	NR	PerQ Drill	5–6 days	0.85	NR	46 (13–76)
Black	NR	NR	NR	NR	NR	NR	NR	44 (15–70)
Kucukkaya	Rigid	0.5	Yes	PerQ Drill	5 femur	1.0, TID	9 (5–22)	58 (20–140)
Laubscher	NR	NR	NR	PerQ Drill	6 both	1.0, TID	No deformity correction	59.7 (50–70)
Accadbled	Rigid	NR	Yes	PerQ Drill	7	1.0, TID	Valgus 8.7 (4–15), Varus 13 (4–20)	45 (20–80)
Karakoyun	Rigid	0.5	Yes	PerQ Drill	7	NR	15 (7–25)	48 (34–120)
Kucukkaya	Rigid		Yes	PerQ Drill	NR	NR	NR	59 (20–140)
Tiefenboeck	RIA or standard	2	Yes	Gigli/Drill	5	1.0 BID	Varus up to 10, valgus up to 16, rotation up to 26	47- Femur 42- Tibia
Wiebking	NR	2	NR	PerQ Drill	5–7	1.0 femur, 0.5 tibia	NR	35 (21–52)
Furmetz	NR	NR	NR	Mixed open or PerQ	NR	1.0	NR	55 (40–65)
Hammouda	NR	NR	NR	NR	5–7	1.0 QID	NR	38 (23–60)

PerQ: percutaneous, DO: distraction osteogenesis, MAD: mechanical axis deviation, RIA: reamer irrigator aspirator; ILN: internal lengthening nail.

Table 3. Relevant literature on motorized ILN results.

Lead author	Accuracy of deformity correction	BHI (days/cm)	Total comp (%)
Singh	NR	35 (19–71)	18
Krieg	Post MAD (var grp) = 4 med (range 38 med–11 lat); post MAD (val grp) = 0 (range 10 med–28 lat)	41.8	12.5
Lenze	MAD 1mm lateral (12 lat -12 med	Femur 35, tibia 48	27
Al-Sayyad	'Full correction', planned length achieved 96.9% of the time	24 (20–39)	0
Kirane	Length: accuracy 96%, precision 86%, angular deformity: 1 mm MAD (2–8)	NR	28
Schiedel	Length accuracy: 97%	NR	17
Thaller	Achieved length goals: 80%	27 (16–37)	30
Black	Planning length achieved in 73%	NR	73
Kucukkaya	NR	33.1 (22.5–48.6)	8
Laubscher	No deformity correction performed. 100% planned length achieved. MAD deviation <1mm/cm lengthening.	31.3	25
Accadbled	Post val 3° (range 0–5); post var 2° (range 0–5)	Femur 73, tibia 83	15
Karakoyun	NR	33	4
Kucukkaya	NR	31.5 (22.5–48.6)	NR
Tiefenboeck	NR	41.5 (25.5–53.7)	70
Wiebking	Length accuracy: 78%; precision 61%	NR	20
Furmetz	NR	33 (25–54)	60
Hammouda	16/17 achieved desired length	32 (16–51)	18

MAD: mechanical axis deviation, Var: varus, Val: valgus, med: medial, lat: lateral, BHI: bone healing index, Comp: complications, NR: not reported; ILN: internal lengthening nail.

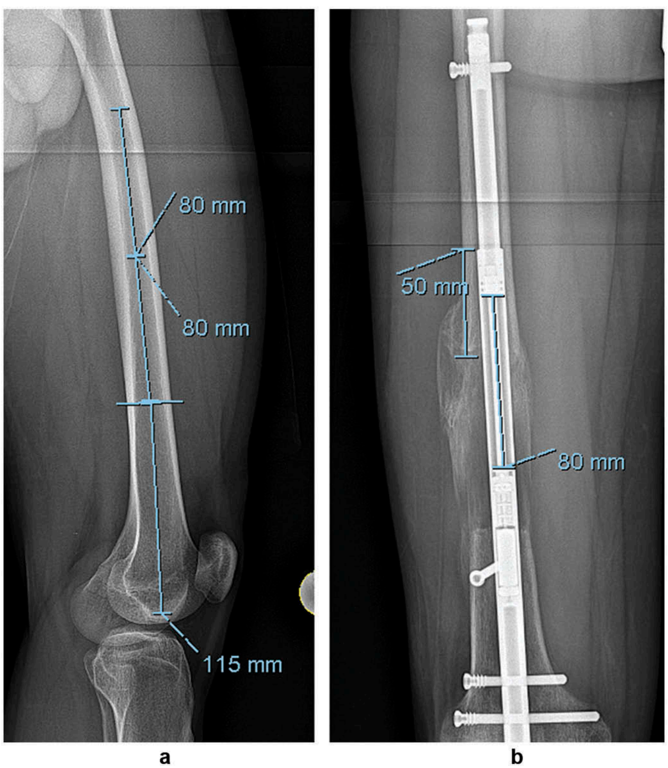

Figure 3. (a) This lateral radiograph shows the pre operative planning for an 80mm lengthening. In order to keep 50mm of the thick portion of the nail in the proximal fragment one needs to add 80mm (50mm + 30mm tip of the nail) to the 80mm planned distraction = 160mm. For the proposed osteotomy site, the distal length of the nail will be 115mm. The shortest nail length (SNL) is 160 + 115 = 275mm. This is also the longest nail length as the proximal tip will scrape the anterior femoral bow. The SNL could be lowered by moving the osteotomy site distally. (b) The 275mm nail was used and at end distraction of 80mm there was 50mm of the thick portion of the nail remaining in the proximal fragment. We believe this is important for nail integrity (prevention of fracture) and maintaining alignment.

than 7 cm from the knee joint line) are probably most reliably treated with a distal femoral plate. Lengthening can be addressed with an antegrade ILN simultaneously. Large procurvatum deformity correction will result in lengthening of the limb and stretching of the sciatic nerve. These straight nails require a complete correction of all femoral bowing for insertion, a concept that experienced external fixation surgeons are not used to. These high magnitude deformities may require prophylactic peroneal nerve release, and surgeons may consider nerve monitoring to ensure safety. One must be sure to use a posterior blocking screw to prevent recurrence of the flexion deformity during lengthening.

3.4. *Intraoperative temporary external fixation*

The use of an intraoperative external fixator has been advocated by some authors [22,27] but remains poorly documented in most series. By placing a Schantz pin into the distal femur, posterior to the path of the ILN, and another into the lesser trochanter the rotation of the femur can be marked (Figure 4). Connecting an external fixation bar between the pins helps to stabilize the osteotomy during distal locking ensuring that rotational deformity is not introduced. When the osteotomy is performed and deformity corrected prior to reaming, the external fixator is very helpful for holding the reduction during reaming. When reviewing our own cases of retrograde Precice surgeries, we found that the use of 6 mm Schantz pins resulted in more accurate final alignment than the use of 5 mm Schantz pins implying that not only was the fixator useful but that the stiffer the construct, the better the accuracy [31].

4. Osteotomy considerations

The percutaneous osteotomy of the femur has yielded a very low bone healing index (BHI) in most series using a motorized ILN (Table 3). In fact, the Precice has produced some of the lowest bone healing indices ever seen in femur lengthening surgery with an average of 32 days/cm of length [22,23,27,29]. Through a very small incision all the authors created drill holes for the osteotomy and then performed IM canal reaming which deposited the reamings at the osteotomy site (Figure 1(f)). One study on Precice was an outlier in that it yielded a longer average BHI and a high incidence of nonunion which may have been due to use of a reamer-aspirator followed by open grafting of the osteotomy site [26]. Ostensibly the lack of an essentially closed reaming technique or the more aggressive stripping of the osteotomy site impeded osteogenesis.

Figure 4. This lateral fluoro spot shot shows the half pin for the intra operative external fixator on-end placed posterior to the path of the ILN.

5. Postop care

The use of intraoperative TXA has been a welcomed addition to femur osteotomy in our practice. It is our observation that there has been less swelling, less pain, and less postoperative blood loss since introducing this remarkable medication one year ago. We administer 1 g IV at the start of surgery and another 1 g dose 3 h later. The incidence of venous thromboembolism (VTE) has not changed since adding TXA.

Anticoagulation medication (rivaroxaban or enoxaparin) are started postoperative day 2 after osteotomy. This has also been an evolution in postoperative management. These strong medications were causing excessive swelling after femur osteotomy when administered postoperative day 1. By starting day 2 we accomplished two goals: (1) we have seen much less swelling with no increase in VTE, and (2) we are able to use continuous spinal epidural anesthesia for pain control through postop day 1.

Weight-bearing restriction is a critical variable for successful treatment with the Precice ILN. Most, if not all, nail failures have occurred in cases where the patient bore too much weight on the operative leg (Tables 3 and 4). Most of these happened during the consolidation stage when patients felt ready to increase their mobility [9,25]. Early excessive weight bearing can cause the implant to collapse or recoil [27] without damaging the lengthening mechanism which is a far more subtle complication. The allowable weight bearing varies with the diameter of the nail and is well publicized by the company. The patient's ability to assess how much weight they are placing on the operative leg is an area that needs further innovation. The patients are currently instructed to place the foot on a scale and load the limb until the maximum weight is measured. This exercise helps to give the patient some proprioceptive guidance for appropriate weight bearing.

6. Distraction protocol

The lengthening protocol we have developed has been the result of several years of experience with this implant. For a

Table 4. Relevant literature on motorized ILN complications.

Lead author	Pre Mat Cnsldn	Breakage/ Mech Fail	Non-delayed-union	Joint Cntrct	Detailed description
Singh	0	2	3	0	1 tibia delayed union, 2 ant cortical tibia defect: authors recommend slow distraction 0.75 for tibia. 2 femurs stopped lengthening.
Krieg	0	1	2	2	Bolt loosening 3 tibia with loss of length, DVT-1-Tibia, motor failure 1 femur, delayed consolidation 2 tibias.
Lenze	0	1	0	1	1 motor failure, 1 DVT, 1 knee flexion contracture
Al-Sayyad	0	0	0	0	Painful antenna.
Kirane	1 femur	1 femur	2 tibia	3	Contracture treated with releases. Nail non-functioning and premature consolidation treated with repeat surgery.
Schiedel	1	4	0	0	2 non-distracting nails, 2 nail Fx, need for magnet readjustment due to poor efficiency.
Thaller	3	0	0	0	3 rods did not distract.
Black	1	2	0	2	Collapse ILN of 1.5 cm w/o failure(1); fall with nail breakage, Fx, and collapse loss of length (1); Quadsplasty (2), deep infection (1).
Kucukkaya	0	0	2	0	NU in smoker and in 13 year old (excessive reaming).
Laubscher	0	0	0	3	ITB release (2), ITB and hamstring lengthening (1), DVT (1).
Accadbled	0	1	0	4	Intercondylar Fx, nail dysfunction-no lengthening, Skin necrosis req flap, AV fistula in tibia req ebolization.
Karakoyun	0	1 Precice	0	0	Nail Fx after 6.5 cm in consolidation phase.
Kucukkaya	NR	NR	NR	NR	Emphasize that anterior cortical impingement of the tip of the nail is a risk factor for Fx, and posterior reaming will avoid this problem.
Tiefenboeck	0	3	4	0	Open bone grafted the osteotomy with RIA (3) or ICBG at index surgery. Nonunion with broken mechanism from MVA (1). Used very long retrograde nail – (broke nail from the femoral bow?).
Wiebking	0	2	1	0	Collapse of nail – loss of length – tibia (1), collapse nail femur (1) with NU eventual nail breakage (both: P1 nail, early WB, 50 mm lengthening).
Furmetz	1 Precice	1 Precice	0	1	P2 collar broke after 1 cm. Biceps lengthening needed.
Hammouda	2	0	0	0	Post Tib N Palsy req tarsal tunnel.

Pre Mat Cnsldn: premature consolidation, Mech Fail: mechanical failure, Cntrct: contracture, ant: anterior, DVT: deep vein thrombosis, Fx: fracture, NU: nonunion, RIA: reamer irrigator aspirator, ICBG: iliac crest bone graft, MVA: motor vehicle accident, WB: weight bearing, Post Tib N: posterior tibial nerve.

percutaneous distal femoral osteotomy treated with a retrograde magnetic ILN, distraction begins on POD 4. Adjustments are set for 0.33 mm per session. The patient applies four sessions for the first four days of lengthening (POD 4–8). Then the frequency is slowed to 0.33 mm three times per day. Patients are followed bimonthly and the rate is adjusted as needed based on the radiographic assessment of the regenerate bone quality. Part of the learning curve of this implant included premature consolidation of the osteotomy which we attributed to a slow start. By moving the start date from POD 5 to POD 4 and increasing the adjustment frequency from 0.33 mm TID to 0.33 mm QID for the first four days we have been able to eradicate premature consolidation and avoid nonunion. Other authors have reported premature consolidation of the femur osteotomy site in cases where the distraction started on POD 5–7 and proceeded at 1 mm/day [9,29].

7. Cost analysis

A cost comparison is a useful method to determine how a new technique compares to its predecessor and if it is worth the expense. The two most reliable lengthening nails are the Precice and Fitbone nails. Both are motorized, accurate, and well tolerated [9,18,19,24,27,32]. Of these two, the Precice is the only ILN that is readily available in the United States at this time for widespread use. The ILN is replacing the lengthening over nail (LON) technique [33] in the femur which was previously the most reliable method available in the United States [4]. When compared with ILN, LON requires an extra surgery to lock the nail and remove the external fixator. In a retrospective comparison of our LON and Precice patients, we found that the cost of both techniques was equal. This analysis included the total reimbursement to hospital and surgeon by the insurance carrier for all related surgeries. We found that the increased cost of the magnetic ILN implant was equaled by the cost of the extra surgery for the LON technique. These data were presented at the 2016 Annual Scientific Meeting of the Limb Lengthening and Reconstruction Society. As the cost of the implant declines over time, the procedure will become more economical than its predecessor.

8. Conclusion

The retrograde approach for the Precice ILN provides surgeons with a safe and routine method for femur lengthening with or without concomitant deformity correction. The current iteration of the implant is accurate and has a low complication rate. Preoperative planning (including appropriate nail length, osteotomy site, and blocking screw position) is essential for a good outcome. A percutaneous osteotomy with drill holes and an osteotome, the same as that used for external fixator-assisted lengthening, combined with the suggested lengthening protocol provides rapid bone healing. Postoperative care has evolved to improve safety and optimize the patient experience. The cost of treatment with this implant is no greater than that using the cheaper LON because of the reduced number of surgeries, while the improved patient experience is priceless. There is no data to support superiority of the retrograde technique over antegrade technique for femoral lengthening, and long-term effects of passage through the knee joint for this indication are not described. The retrograde method does uniquely allow for periarticular deformity correction and simultaneous lengthening.

9. Expert commentary and 5-year view

The research to date on the magnetic internal lengthening nail has produced two consistent findings worthy of discussion. The first is the rapid BHI seen with femoral lengthening using the magnetic ILN with an average hovering around 1 month per cm of lengthening. It is likely that the titanium alloy used possesses the ideal modulus of elasticity for femur bone growth, and the fine control over the rate and rhythm of distraction provides an optimal condition for osteogenesis. The second finding that resounds throughout the literature is that early excessive weight bearing can result in mechanical failure of the implant. Excessive means in excess of the prescribed amount of force allowable for the diameter nail inserted. This amount has improved with the newer generation Precice nails, and failure is less common now. The benefit of the retrograde approach is that a larger nail can often be used than would have been possible for the same patient with an antegrade nail. This is because the thinner telescoping portion of the retrograde nail occupies the isthmus. By using the larger nail more weight can be borne safely.

The literature on Precice leaves much to be desired. These are mostly retrospective case studies, level IV evidence (Table 1). There is much inconsistency in outcomes measured between studies making comparison difficult. The data collected varied greatly with omissions including the type of reamers used (flexible vs. rigid), the amount of over reaming, the generation of nail studied, the distance of the osteotomy from the joint, and the use of blocking screws or intraoperative external fixation. The accuracy of deformity correction was not well studied with large ranges of results and minimal commentary. Some papers reported that deformity was corrected while others looked at final mechanical axis after correction. This makes it impossible to measure the effectiveness of pre operative planning method for deformity correction on the actual final alignment. Most studies mixed data from antegrade femoral, retrograde femoral, and tibial lengthenings in the same outcome averages for bone healing and complications. The reader needs to carefully review data charts and the complication discussion section to comprehend the nuances that exist for each treatment. We have come to know that tibial bone healing indices are universally slower than the femoral counterpart and need to be either reported separately always or not included in the same study. The tendency to ‘throw in’ a few tibial lengthenings during data collection needs to be resisted for the good of the world community. There is a need for further cost analysis for the Precice. With greater control, faster healing times (and presumably less time out of work), less bulk compared with external fixators (making attending work more possible), and less surgery compared with integrated fixation methods (LON), the Precice provides benefits that offset and, perhaps, outweigh the cost of the implant.

Goals in the field of limb lengthening have been limited to the available technology. During the era of external fixator-assisted distraction osteogenesis, the goals were focused on reducing pin infections, reducing joint contractures from tethering pins, and devising techniques to integrate internal fixation to remove the frames faster. This goal led to the development of mechanical internal lengthening nails which strived for rate control and accuracy. The magnetic ILN has delivered these elements, and goals have shifted to improving the materials of the nail to allow for more weight bearing without compromising the regenerate bone biology. This would be particularly helpful for stature lengthening where both femurs are operated on simultaneously putting the lengthening sites at risk for collapse. The ultimate goals in limb lengthening have always been the same: grow new bone organically as fast as possible, provide a safe and relatively painless experience, and minimize joint contractures and complications in general. Any engineering feat that accomplishes these objectives will always be welcomed.

The compression ability of the pre-distracted Precice nail is an underutilized attribute of the Precice. This has been quite useful for healing at risk humeral fractures [34] and recalcitrant tibial nonunions [35]. Its potential is far greater with possible applications to knee and ankle fusion surgery, femoral shortening surgery, and other procedures that benefit from bone compression for healing. Unlike other 'compression' nails that provide a one-shot intraoperative compression, Precice can deliver multiple compressive sessions throughout the post-operative period as needed, functioning much like an external fixator. Much study is needed to determine the effectiveness of compression alone and with the addition of other treatment variables such as bone grafting and systemic biologics.

The dream of an internal implant that can produce a gradual angular correction has become a reality with Opty-Line from NuVasive. This implant can correct proximal tibia vara gradually using a clever IM technology and has enjoyed success in Europe anecdotally. The expansion of a similar implant into correction of malalignment through the distal femur is eminent.

Where the field will go next is limited only by our imagination and the support of a culture dedicated to financing innovation.

Deformity planning has been a two-dimensional activity done using AP and lateral radiographs with some input from physical exam or CT imaging particularly for rotational malalignment. This is not three-dimensional planning which would allow for assessment of hidden coronal plane deformities that lie within large rotational deformities only to be discovered after correcting the torsion for example. These 'new', or really, unseen deformities are revealed and may require additional surgery. There has been much progress with computer-generated 3D analysis of deformity based on CT scans of the extremity which allows for the production of a disposable custom plate and cutting guide [36]. An application of this technology to preoperative planning of osteotomy site and multiplanar deformity correction would be an asset. The addition of improved guidance for blocking screw placement would also improve the accuracy of acute deformity correction with IM nails.

Key issues

- Blocking screws are useful for achieving deformity correction with a retrograde IM nail and for preventing lengthening induced deformity.
- Percutaneous distal femoral osteotomy has yielded rapid healing times using the following sequence: multiple drill holes in the axial plane to perforate the cortex, reaming across these vent holes with extrusion of marrow contents through the holes, and percutaneous osteotome insertion for corticotomy.
- Early excessive weight bearing can be disastrous for any motorized ILN.
- Tranexamic acid administered IV in the operating room combined with anticoagulation starting POD 2 has reduced the post operative swelling and blood loss after femoral osteotomy and is part of our routine practice.
- Beware of using long retrograde nails as they do not accommodate for the bow in the proximal femur diaphysis.
- Since implementing a 'rapid sequence' nail distraction protocol (starting on POD 4 at a distance of 0.33mm and a frequency of 4-sessions/day for four days) followed by slowing to a standard rate (0.33mm 3-sessions/day starting POD 8) subject to adjustments based on bi-monthly radiographs, we have avoided both premature consolidation and delayed union.

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Declaration of interest

A Fragomen is a consultant for Smith & Nephew, Synthes, and NuVasive. SR Rozbruch is a consultant for Stryker, Smith & Nephew, and NuVasive. The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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