

Efficacy of PRECICE Nail in Treatment of Adult Patients With Posttraumatic Femoral Leg Length Discrepancy

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Summary: Posttraumatic, limb length discrepancy in adults is a challenge to treat, and multiple treatment protocols over the years have shown varying levels of success and complications. Before the introduction of the PRECICE nail in 2011, our preferred method of limb lengthening used an Ilizarov or Taylor Spatial frame. To assess the PRECICE nail, we evaluated the accuracy and complications during treatment in a series of skeletally mature patients with posttraumatic femoral limb length discrepancy. The surgical technique along with a case series of 8 patients are described in detail. On average, the target lengthening for the PRECICE nail was 44 mm, and all patients achieved lengthening within 2 mm and complete bony consolidation. The only observed complication in our series was a broken screw 1 year after the patient started weight-bearing. The PRECICE nail demonstrated promising results and was useful for bone regeneration and consolidation without the need for additional procedures. The rate of complications was low compared with previous methods, making this device an excellent treatment option.

Key Words: posttraumatic, femoral LLD, PRECICE nail, distraction osteogenesis

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INTRODUCTION

Fracture of a long bone in skeletally mature patients can result in posttraumatic limb length discrepancy (LLD) due to bone loss at injury, loss of fixation, malreduction, malunion, and bone infection requiring debridement. Challenges in treating patients with posttraumatic LLD can arise from effects of multiple prior operative treatments, soft tissue scarring or contractures, nonunion or residual segmental bone defects, and retained implants.¹

Distraction osteogenesis (DO), traditionally applied using a ring or monolateral external fixator, is a successful method for treating leg length discrepancy. Use of external fixation for DO, however, is associated with a number of clinical problems and complications including pin tract infection,^{2–7} pain during distraction,² residual joint stiffness,^{2,3,5–7} and mechanical axis deviation.^{2–4,6,7} The risk of complications with external fixators increases with longer duration of treatment.

To reduce the treatment time and complications associated with external fixators, hybrid techniques using external fixation combined with intramedullary nailing were developed. Lengthening over nail (LON) reduces risk of external fixator complications but increases risk of other complications including osteomyelitis (up to 20%)^{3,8,9} and implant failure (up to 4%).^{3,8–10} Lengthening followed by intramedullary nailing was developed to reduce the complications of LON but does not reduce risk of external fixator complications. The first fully implantable devices for treating LLD were introduced in the 1980s, both using a mechanical ratcheting device in an intramedullary nail that required manual rotation of the distal limb segment to engage the ratchet.^{11,12} These devices were associated with substantial obstacles and complications during treatment, including pain during distraction that required general or epidural anesthesia to continue distraction,^{9,11,13} mechanical failure of the device,^{9,11,13} uncontrolled lengthening,^{9,14} failure to lengthen,^{9,11,13} and osteomyelitis.^{8,9,11}

The PRECICE nail (Nuvasive Specialized Orthopedics, San Diego, CA) was introduced in 2011, using 2 rotating magnets in an external controller to rotate a magnet within the nail, causing a controlled distraction of the bone. The PRECICE nail results in accurate lengthening, but some complications have been reported in 3 prior case series that included a variety of conditions, such as congenital deformity, tumor resection, and trauma, resulting in LLD in the upper and lower extremity.^{15–17} Complications may differ by anatomic location and the nature of the condition leading to the LLD. We describe the treatment protocol and evaluate the accuracy and complications associated with use of the PRECICE nail in a series of femoral LLD in skeletally mature patients.

SURGICAL TECHNIQUE

The use of an antegrade or retrograde nail was based on magnitude and location of deformities, mechanical axis deviation, and previous and planned joint surgeries such as

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hip or knee arthroplasty. The osteotomy site was determined per manufacturer recommendations by adding the distal distraction rod length (3 cm) to the target length with an extra 5 cm (total 8 cm) to maintain the stability of the distal segment of the bone. For the patient in our series with angular deformity and mechanical axis deviation, the osteotomy site was planned in the center of rotation of angulation.

On the day of surgery, patients received intravenous cefazolin or clindamycin. The osteotomy site was marked on the patient's skin based on preoperative measurements. A guide pin was inserted into the entry site through a small incision. For retrograde nails, a patella tendon splitting approach was performed. For antegrade nails, a percutaneous piriformis approach was performed. After confirming the pin position under fluoroscopic imaging, an opening reamer was used. Next, a guidewire was inserted into the femoral canal. To prevent high intramedullary pressure during reaming, the medullary canal was vented with a drill bit at the anticipated site of osteotomy and in the diaphysis at the furthest distance from the entry site of the femoral nail (for antegrade nails, a second vent hole is placed in the distal diaphysis; for retrograde nails, the second vent hole is placed in the proximal diaphysis). Reaming was performed until there was moderate chatter. The nail was then sized 2 mm smaller than the reaming as this technique allows distraction by providing a small space between nail and bone surface. After reaming, the osteotomy was made at the planned location with a 5-mm incision and scissors spreading down to bone, followed by multiple drill passes in different trajectories with intermittent drilling under constant irrigation. The osteotomy was completed using an osteotome. After completing the osteotomy, the guidewire was removed and the PRECICE nail was inserted and statically locked. Function of the PRECICE nail's magnetic distraction mechanism was verified under fluoroscope imaging. The center of the magnet location was marked on the skin using a nonabsorbable suture to aid in placing the external remote controller during the postoperative distraction phase.

PRECICE NAIL LENGTHENING

Immediately postoperatively, patients were non-weight-bearing to prevent nail or screw breakage. Physical therapy for passive and active range of motion exercises of the hip and knee was prescribed to prevent muscle contractures during the distraction phase. Patients were instructed how to use the external remote controller, which was programmed to distract 0.75–1.00 mm/d divided over 3 sessions/d beginning on postoperative day 7–10. During the distraction phase, patients returned to the clinic every 2 weeks to monitor lengthening and recovery and to adjust the distraction rate if needed based on the quality of their bony regenerate. The distraction rate was reduced if a patient had poor bone regeneration or substantial pain during distraction. The distraction rate was increased if radiographs indicated impending premature consolidation. Final leg length was confirmed by a bilateral lower extremity CT scan. Femoral length was measured from the superior aspect of the femoral head to the distal portion of the medial femoral condyle and the tibia

was measured from the medial tibial plateau to the tibial plafond.

After reaching the target distraction length by measuring both the regenerate length and the leg length, patients visited the office every 4 weeks to evaluate consolidation. If slow progression of bony consolidation was noted, the patient was referred to an endocrinologist for evaluation of metabolic/endocrine abnormalities.^{18,19} Once adequate consolidation of the bone regenerate was observed, patients started partial weight-bearing exercises. Patients were allowed to fully bear weight once their regenerate was felt to be adequate as observed on radiographs. Consistent with the preoperative staged plan, 2 patients had the PRECICE nail removed and received total knee arthroplasty for posttraumatic arthritis with intramedullary nailing 2 months after reaching the target length when regenerate showed signs of consolidation. Another patient who had undergone 35 prior procedures after the initial trauma on the affected limb wished to undergo removal of the PRECICE nail and femoral intramedullary nail insertion as soon as the regenerate showed signs of consolidation at 2 months postdistraction to allow him to start weight-bearing earlier. The remaining patients either had the PRECICE nail removed or are scheduled for removal at 1 year after consolidation.

Fig. 1 shows the progression of treatment for a 56-year-old woman presenting with a 30-mm LLD (case 6 in Table 1).

CLINICAL OUTCOMES

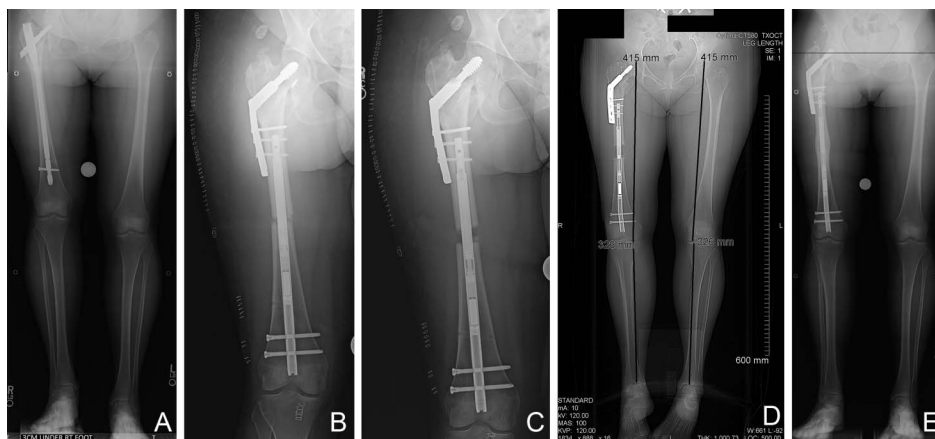
Between January 1, 2016 and September 31, 2018, the senior one of us (M.R.B.) treated 29 patients using the PRECICE nail: 20 femurs, 6 tibias, and 3 humeri. Eight of the 20 femoral cases were posttraumatic femoral LLD in patients who had been skeletally mature at injury. After receiving institutional review board approval at our institution, we reviewed the medical records of these 8 patients.

Data extracted from the medical records included date of injury, mechanism of injury, previous operative treatment and complications, smoking history, medication use, LLD, distraction plan, time from surgery to desired distraction length, time from surgery to consolidation of the regenerate, and treatment difficulties. The LLD was measured using weight-bearing anteroposterior 51-inch alignment radiographs with blocks of a known height placed under the foot of the shorter leg until the iliac crests appeared level. Treatment difficulties were categorized as described by Paley² as problems, obstacles, and complications. Efficacy of treatment was determined by calculating the accuracy and healing index of the PRECICE nail. PRECICE nail accuracy was calculated as²⁰: $100 - \frac{[ABS \text{ (final bone distraction - nail distraction)]}{\text{nail distraction}} \times 100$, where ABS is the absolute value operator.

The healing index was calculated as the postoperative days to full weight-bearing (healing period) divided by the final bone distraction length.

Eight patients (4 men and 4 women) with an average age of 55 ± 10 years were treated for posttraumatic femoral LLD with a PRECICE nail (Table 1). Initial mechanisms of injury included motor vehicle accidents (3 patients), fall (3

FIGURE 1. A–E (case 6): A 56-year-old woman presented 6.5 years after a right intertrochanteric femur fracture treated at an outside facility with a cephalomedullary nail. The patient complained of a LLD and resulting impaired activities of daily living. A, AP view alignment radiograph confirmed a 30-mm LLD involving the femur. Note: 3-cm block under right foot. B, The patient was taken to the operating room for removal of her cephalomedullary nail, prophylactic fixation of the proximal femur, and insertion of a retrograde PRECICE nail with a femoral corticotomy. C, The patient began lengthening on postoperative day 8 at a rate of 1/3 mm 3 times per day. Seen here, the patient has been lengthening for 12 days. D, The patient missed a few appointments related to a hospitalization and recovery for an unrelated gastrointestinal condition and returned at 2 months postoperatively having missed some days of lengthening. She was instructed to continue to lengthen for an additional week and returned with this CT scan, which revealed complete correction of her LLD. E, Final AP alignment view shows solid healing of her regenerate with equalization of her limb lengths. AP, anteroposterior.



patients; one resulting in periprosthetic fracture), and assault (2 patients). The cause of LLD included malreduction (4 patients), bayonet apposition (1), nonunion treated with compression technique (2), and resection of infected bone (1).

Antegrade nails (1 trochanteric entry and 4 piriformis entry) were used in 5 patients and retrograde nails were used in 3 patients. Two patients had concomitant deformities that were acutely corrected during surgery. One patient (case 1) with LLD of 22 mm underwent 8 mm acute correction via opening wedge osteotomy to correct 19 degrees varus with 17 degrees anterior angulation (27 degrees oblique plane angulation) deformity followed by 15 mm PRECICE nail distraction for a total of 23 mm of lengthening. The second patient (case 5) underwent

acute correction of a 40-degree external rotational deformity of the femur using an Ilizarov frame intraoperatively for precise correction before implantation of the PRECICE nail.²¹

All patients in our series healed completely with bone regenerated, consolidation complete, and started weight-bearing activities. The largest discrepancy between final and target length was 2 mm in 2 patients; the other 6 patients were within 1 mm of target length. The accuracy of the PRECICE nail was 98.5% with an average distraction period of 70 days (range, 26–189 days) to reach the mean target length of 44 mm (range, 20–80 mm).

Five problems occurred in 3 patients. One patient (case 2) had malfunction of the PRECICE controller that occurred

TABLE 1. Patient Demographics

Case	Sex	Age	LLD, mm	Angular Deformity	Mechanism of Injury	LLD Reason	Previous Surgeries	Latest Surgery
1	F	50	22	19 degrees varus 17 degrees anterior (27 degrees oblique)	MVA	Malreduction	2	Skeletal traction
2	F	46	81		MVA	Bone resection and compression technique	3	Plating with PICG
3	M	57	35		Fall, PPX FX	Malreduction	2	TKA
4	M	71	35		Fall	Compression technique	1	IM nail insertion
5	M	39	80	40 degrees external rotation	MVA	Infected malunion, I&D	35	IM nail insertion
6	F	56	30		Fall	Malreduction	0	
7	M	63	20		Assault	Malreduction	1	ORIF with IM nail
8	F	55	50		Assault	Bayonet apposition	2	Ilizarov
Total/mean ± SD	4 F 4 M	55 ± 10	44 ± 24					

CORA, center of rotation of angulation; I&D, incision and drainage; IM, intramedullary; MVA, motor-vehicle accident; ORIF, open reduction and internal fixation; PPX FX, periprosthetic fracture; TKA, total knee arthroplasty; PICG, posterior iliac crest graft.

14 days after starting distraction, which was resolved by replacing the controller at the next office visit on day 21. One patient (case 6) had substantial pain during distraction that was resolved by slowing the distraction rate from 0.75 mm/d over 3 sessions to 0.5 mm/d over 2 sessions and later to 0.25 mm/d. Later in the course of treatment, this same patient developed delayed consolidation that was resolved by starting the treatment of vitamin D deficiency. Another patient (case 5) had poor bone regenerate, which was successfully resolved by slowing down the distraction rate from 0.75 to 0.33 mm/d for a week followed by increasing the daily distraction by an additional 0.33 mm/d each week until reaching the distraction rate of 1 mm/d. Three weeks after distracting on 1 mm/d, the same patient had radiographic signs of premature consolidation, so distraction rate was increased to 2.0 mm/d for 1 week, followed by 1.5 mm/d for 2 weeks and then returning to 1.0 mm/d for the rest of distraction period.

Additionally, the patient who had malfunction of the controller (case 2) also had a broken distal locking screw (minor complication) 1 year after the start of weight-bearing (Fig. 2). The screw was partially removed in the same operative session as the PRECICE nail. No obstacles or major complications were reported.

DISCUSSION

All patients in the current investigation achieved the desired leg length with complete consolidation. Our mean distraction period of 70 days for target lengthening of 44 mm was similar to Tiefenboeck et al¹⁶ who reported an average distraction period of 57 days for the target length of 42 mm. Of the 7 reports we identified that included use of PRECICE nails for treatment of femoral LLD in adults,^{16,17,20,22–25} 3 studies (18 total patients) provided sufficient detail to identify patients who had posttraumatic etiology and skeletal maturity.^{16,17,22} Only one of those reports (8 patients) reported results by etiology and skeletal maturity, with a distraction accuracy of 100%²² similar to our mean accuracy of 98.5%.

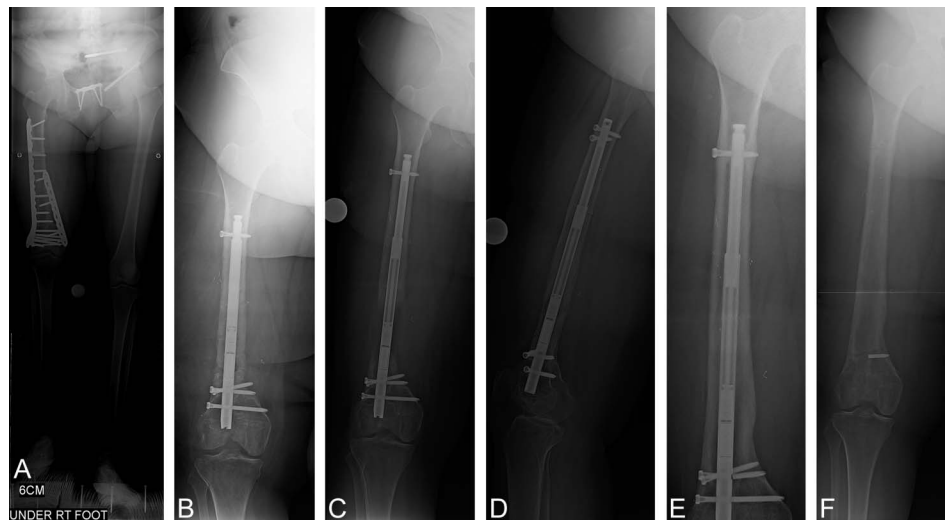
The other reports did not report results by etiology or skeletal maturity status, and 2 reports included patients treated for tibial LLD, so direct comparisons to our findings are difficult.

We observed only one complication, a broken distal locking screw in one patient, a year after the start of weight-bearing that had not been previously reported in femoral series. In our series, this complication occurred in a 46-year-old woman with an 81-mm LLD following nonunion treatment after sustaining an open femur fracture in a motor vehicle accident (Fig. 2). The broken distal locking screw occurred 1 year after the patient began weight-bearing and was partially removed when the PRECICE nail was removed. We did not observe complications that have reported in prior investigations, including nonunion (40%),¹⁶ soft tissue contracture requiring iliotibial band release (up to 15%),^{23,24} implant failure requiring exchange of the nail (4%–20%),^{16,23} and nail breakage (10%).⁶

In our series, 5 problems occurred in 3 patients. Poor bone regeneration and a premature bone consolidation later in the course of treatment of one of the patients, substantial pain during distraction period and delayed consolidation during the healing period in another patient, and the last problem encountered in our series was a malfunction of External Remote Controller (ERC) in another patient. Problems involving bone regeneration were easily resolved by altering the distraction rate on ERC without further need of additional procedures, a malfunctioned ERC was replaced on next office visit, and delayed consolidation was resolved by starting the osteoporosis treatment after referral of patient to endocrinologist and diagnosis of osteoporosis was made. Difficulties with bone consolidation are the most frequently reported problems in prior reports of treatment of posttraumatic femoral LLD using the PRECICE nail, with rates ranging from 6% to 14%.^{17,20,23} Our rate of 12.5% falls within the range of published studies.

Treatment of skeletally mature patients who have posttraumatic LLD using the PRECICE nail has high distraction accuracy (97.6%), with a reasonable treatment time and low complications rate relative to other treatment

FIGURE 2. A–F (case 2): A 46-year-old woman with a 81-mm LLD in her right femur after nonunion treatment. A, AP view alignment radiograph with 6-cm block under patient’s right leg. B, AP radiograph, a week after PRECICE nail insertion, and before initiating the distraction. C, AP view 80 mm length achieved at day 112. D, Lateral view showing signs of consolidation, allowing the patient to start weight-bearing. E, AP view at 1 year after weight-bearing started showing complete consolidation and a broken distal locking screw. F, AP view 3 weeks after removal of the PRECICE nail and the retained portion of the broken screw. AP, anteroposterior.



methods. Distraction rate is easily and accurately controlled and adjustable to adapt to the quality of regenerate formation and consolidation, without the need for an additional operative procedure. These features make the PRECICE nail an attractive treatment option for treatment of posttraumatic femoral LLD in skeletally mature patients.

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