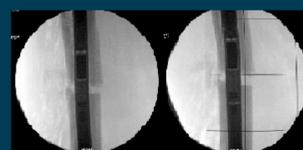


Introduction

Limb lengthening through the use of external fixators has many complications, and is inconvenient to the patient [1,2]. Implantable limb lengthening intramedullary nails (IMN) avoid many of these complications and is an attractive alternative. Previous devices such as the ISKD and Albizzia were fraught with problems, namely rate control. The PRECICE™ implant (Ellipse Technologies, Irvine, CA) is a new FDA approved lengthening IMN. It elongates by means of an internal magnet and gearbox, actuated using an external rotating magnet. It is the first implantable device to offer accurate bidirectional lengthening control.



Objectives

The purpose of this study is to report the early results of this emerging technology, based on the experience of three surgeons at a single center. We aim to present these early PRECICE™ results in order to establish a benchmark for its comparison to existing lengthening nails such as the ISKD, Albizzia and Fitbone in our future studies.

Materials & Methods

We reviewed the results of 48 consecutive patients (65 PRECICE™ nails) implanted between 12/1/2011 and 12/4/2012. Lengthenings were carried out in the femur (54 nails), tibia (8), humerus (1) and fibula (2). Indications were for congenital LLD (23 pts), post-traumatic LLD (8), developmental LLD (3) and cosmetic lengthening (14 pts). Mean age for all patients was 25.6 (10.3 - 58.4), and mean pre-op limb length discrepancy was 5.35cm (0.0 to 18.2cm).

Diagnosis	# of patients	Females	Males
Stature Lengthening	14	3	11
Post-traumatic LLD	8	2	6
Congenital LLD	23	14	9
Developmental LLD	3	1	2
Totals	48	20	28

Diameter	# of nails
10.7mm	25
12.5mm	40
Totals	65

Location	# of patients	# of nails
Piriformis	25	36
Trochanteric	11	12
Femoral Retrograde	5	6
Fibula	1	2
Tibial Antegrade	5	6
Tibial Retrograde	2	2
Humerus	1	1
Totals	N/A	65

Nails were initially available in two diameters, and three lengths, each capable of a maximum of 6.5cm distraction. Mean follow-up is 8.6 mos (4.0 - 16.0), and all patients included in this study have completed their treatment. Institutional Review Board approval was obtained for this ongoing study.

Results

Mean length gained was 4.41cm (0.5 - 6.5cm), with a mean distraction rate for all nail segments of 0.83mm/day (0.50 - 1.11mm/day). Three patients required a bone grafting procedure for failed regenerate. Three nails broke in two patients while they were full-weight-bearing and demonstrated healing on at least 3/4 cortices at the time of breakage. Each was exchanged for a locked standard IMN, and length was preserved in each case.



Four nails ceased to lengthen the full 6.5cm in three patients. The mean length achieved was 4.73cm (4.1 - 5.5cm) in these four nails. Operator error by lengthening two retrograde placed nails in an antegrade fashion caused the mechanism to malfunction, and these

needed to be replaced. Mean healing time, and return to full-weight-bearing was 125.3days (52 - 262 days). In total, there were 18 unplanned surgeries in 16 patients. The remaining patients successfully completed treatment without any complication.

Complications	# of events	# of Pts
Implant Breakage		
Nail Breakage/Fatigue Failure	3	2
Mechanism Fail to Lengthen	1	1
Premature Consolidation	2	1
Operator Error	0	0
Nail Failed to Distract	4	3
Dense Regenerate Resistance	2	2
Screw Dislodgment Hardware	1	1
Peri-prosthetic Fracture	1	1
Deep Infection/Implant Removal	3	3
Failed Regen / Bone Grafting	1	1
Hematoma requiring evacuation	1	1
Soft Tissue Contracture Release	1	1
Compartment Syndrome	1	1
Total Unplanned Surgeries	18	16
Superficial Infection	1	1
DVT	1	1
Patient Request to Stop Early	10	7
Joint Subluxation	1	1
Pain Preventing Final Goal	5	5



Conclusions

The PRECICE™ demonstrated excellent rate control and accuracy. The bidirectional feature proved useful in one pt who was acutely shortened 2cm, and later safely resumed gradual distraction. Two patients requiring bone grafting, had previously undergone external fixator lengthenings; one was complicated by infection. All nails that ceased to lengthen were in males with large muscular thighs, and abundant regenerate. This combination likely caused the distraction mechanism to fail. Each nail that broke fractured at the proximal weld, a site now identified as a failure point. These results have led to a redesign of the nail. A solid piece implant with a fortified distraction mechanism is currently being prepared for release.

References

- Green SA. Complications of external skeletal fixation. *CORR*. 1983;180:109-116.
- Paley D. Problems, obstacles, & complications of limb lengthening by the Ilizarov technique. *CORR*. 1990;250:81-104.