

## **History of Implantable Limb Lengthening**

## By Dror Paley, MD, FRCSC

Surgical limb lengthening dates back to the turn of the 20th century with the publication of Codivilla. Over the first half of the 20th century, the lengthening devices ranged from the traction Thomas splint device of Codivilla, to various bed mounted and semi-portable external fixation devices. The early limb lengtheners employed distraction osteogenesis to fill the distraction gap produced by their fixators. It was not however until the 1950's and 60's that the biology of distraction osteogenesis became understood. This was largely due to Ilizarov and his group in Kurgan, USSR. Despite their ability to predictably achieve desired length, external fixators are plagued by high complication rates secondary to pin tract infections, associated risk of deep infection, neurovascular injuries, prolonged treatment time until removal, muscular and soft tissue transfixation that lead to contractures and stiffness, pain and discomfort, refracture after removal of the fixators, as well as, psychosocial burden, requirement to perform daily pin cleaning and physical awkwardness.

Due to all of the above reasons many postulated and conceived of internal implants to achieve limb lengthening. Implantable Limb Lengthening using distraction osteogenesis also takes it origins in the Soviet Union. Alexander Bliskunov from Sinferopel, Ukraine first published his method in 1983. This was before most of the Western world had heard of Ilizarov. Bliskunov developed a telescopic lengthening nail that used a crankshaft connected to the pelvis to drive his mechanism and lengthen the femur. Rotational motion of the femur produced lengthening of the nail. The rotation was through the hip joint and not through the osteotomy. His technology was not available outside of the Soviet Union. Even today it is only used by a few in Ukraine.

Over the last three decades, other fully implantable lengthening nails have been developed. Baumgart and Betz from Germany developed a motorized nail in 1991 (now called Fitbone). The Fitbone (Wittenstein, Igersheim, Germany) is a fully implantable lengthening nail whose mechanism is driven by an internal motor that requires an external transmitter. An antenna comes out of one end of the nail and is implanted subcutaneously. It is powered and controlled by radiofrequency and the lengthening is performed at night when the patient is in bed to mimic natural growth. Data is limited, as there are only three studies in the English literature that have reviewed a total of 37 implants, although they report good overall results. The series by Singh et al. reported that 3/24 nails in 2 patients required later bone grafting. They also had 2 implants that needed to be removed and exchanged for large diameter implants because the gears in the original nails were not strong enough to achieve distraction. Baumgart et al. reported that 2/12 nails had faulty motors that required re-operation and only one patient required a later bone graft procedure. The Fitbone is the only motorized nail available. It is on

limited release. To obtain permission to use it one has to either receive agreement from Dr. Baumgart or the Wittenstein company.

Guichet and Grammont from France, developed a telescopic nail in 1994 using a ratchet mechanism which rotated the two segments of the nail through the osteotomy and callus of the distraction gap. The Gradual Lengthening Nail also known as Albizzia (Depuy, Villerbuane, France) was later modified and released as the Betzbone and the Guichet nail for use by its two namesakes respectively. It takes 20 degrees of rotation to move the ratchet one notch. Each notch is 1/15 of a millimeter. Many reports exist of patients suffering from severe pain and discomfort, which limit their ability to independently perform the lengthenings. In some cases, these patients required readmission to the hospital with general anesthesia and closed manipulation. In other reports, 12% of the lengthenings remained incomplete because the patients were simply unable to tolerate the pain of the manipulation.

Using the same concept of lengthening by rotation through the callus, Cole developed a double clutch mechanism to cause distraction. Only 3-9 degrees of rotation was required to cause the nail to lengthen. The intramedullary Skeletal Kinetic Distractor [ISKD] (Orthofix, Inc., McKinney, Texas) was FDA approved in 2001. It was recently removed from the market and is no longer available. Since the lengthening was so easy to activate, and since there was no 'governor' to the lengthening mechanism, the nail is free to lengthen at any rate. Too rapid distraction was a frequent complication. This was referred to as a 'runaway nail' or 'runaway lengthening'. Due to the uncontrolled lengthening rate and rhythm the ISKD had a very high complication rate. The nail would often lengthen at a rate that exceeded the ability for distraction osteogenesis of bone and histogenesis of soft tissues leading to many complications. Restriction of activities and bracing were required to try and prevent and control too rapid lengthening. Failure of bone formation required separate bone grafting procedure for deficient regenerate

Arnaud Soubieran from France developed the Phenix nail. The Phenix has a mechanism activated by a large external, hand held magnet. By rotating the magnet around the leg an internal crankshaft mechanism in the nail was rotated. This lead to traction on a wire pulley, which caused distraction of the nail. The mechanism for the Phenix was first used in a spinal distractor, and, in a lengthening prosthesis manufactured by the same company. Rotating the magnet one direction leads to lengthening while rotating it the other way leads to shortening. This device was self marketed by Soubieran until 2012 at the time of his accidental death. The Phenix produced excellent results in the small number of cases in which it was used. There were anecdotal reports that the nail was not able to lengthen against too much force. A version of his mechanism is contracted to Smith and Nephew and awaits FDA clearance and release.

Ellipse Technologies(Ellipse Technologies, Irvine, California) developed the Precice nail with a team of surgeons (Dr. Paley included) headed by Dr. Stuart Green. Ellipse used the same mechanism that they had developed for their spinal growing rod called "the MAGEC System". There is a magnetic metal spindle that is connected to a series of gears. The gears are connected to a coupling, which is connected to a threaded drive shaft. The mechanism is activated by an external remote control (ERC) device. The ERC employs two motor driven rotating magnets to magnetically couple to and rotate the magnetic metal spindle. The ERC performs 30 revolutions per minute. It takes 7 minutes and 210 revolutions to

achieve one mm of lengthening. Facing the ERC one direction causes the nail to lengthen, while facing it the other direction would go in the reverse (shortening) direction. The Precice is the second FDA cleared implantable lengthening nail device (July 2011) and the first one to have bidirectional control (lengthening and shortening). I had the privilege of implanting the first Precice nail in the US on Dec. 1, 2011. The initial experience with this device in the US and several countries around the world has been excellent. Nevertheless, there have been many lessons from the learning curve of this device.

Device evolution is part of progress. Dr. Paley had the privilege of being involved in the development of four of the implantable lengthening nails that are used today. He was a consultant to the Medinov of the Landinger group (Nancy, France) regarding the Albizzia nail and designed and first implanted their tibial nail (femoral nail developed by Guichet and Grammont). This non-FDA approved device was used as a compassionate use device in the US in the mid 1990's by Dr. Paley. This experience uncovered an essential design problem that led to frequent failure due to wear ratchet gear. Hardening the metal used for this part solved this problem. The current Albizzia has also been strengthened to use cobalt chrome instead of stainless steel to permit greater weight bearing in bilateral lengthening cases. It is currently marketed as either the Guichet nail or Betz bone device by these two surgeons respectively. Despite the increased strength of cobalt chrome there continue to be fatigue failures of the stainless steel screws due to excessive loading, as a reminder that unprotected weightbearing until distraction gap consolidation is not a good idea. Dr. Paley was also the first user of the ISKD device after its inventor Dean Cole, MD. As a consultant to Orthofix at that time, the company was advised in the first year of ISKD device use (2001-2002), that the lack of rate control was a major problem. Certainly many of the problems of not being able to get the nail going which plagued the Albizzia, were solved by the smaller degree of rotation required to actuate the lengthening. These were replaced by the 'runaway' phenomenon of too rapid distraction. While surgeons worked around this problem by decreasing patient activity, using bulky braces such as hip-knee-ankle-foot orthotics, no fix to the problem was offered by the company. The device was finally withdrawn from the market in 2011. It is unknown whether an ISKD2 with better rate control will be available in the future. Dr. Paley also worked with Arnaud Soubieran while he was developing the Phenix nail. There were many trials and tribulation with the initial mechanism. After Soubieran solved most of these, the Dr. Paley introduced this nail to Smith and Nephew and worked briefly as a consultant for them on this device. In 2010, Dr.Paley elected to leave the Smith and Nephew team and to become part of the Precice nail development team headed by Stuart Green, MD. In that capacity he worked with former company engineer Scott Pool to redesign the Precice, leading to the release and FDA clearance of the Precice 2 in Nov. 2013.

The future for non-invasively adjusted limb lengthening devices is very exciting. Future innovation will likely produce a bone transport nail to treat bone defects, limb lengthening plate for children with open growth plates, and gradual deformity correction plates. Miniaturization and new mechanisms will allow greater application of such technology. Adjustable nails could eventually replace simple locking nails for trauma, allowing adjustability of length postoperatively. The same technology as applied to prostheses will also find its way from growing prostheses for bone tumors in children to adjustable length joint replacement for the treatment of arthritis. Both children and adults with MHE have already benefited with Internal Precice limb lengthening.

#### Surgical Technique:

Preoperative planning is important before surgery to determine the ideal nail length, insertion point (e.g. trochanteric vs piriformis), osteotomy level and direction of the nail (antegrade vs retrograde). The nail length and osteotomy level are very inter-related. To avoid too much friction the osteotomy level is planned to leave one to three centimeters of the wider tube of the nail engaged in the opposite segment of the bone (this is explained in detail below). When there is a larger femoral bow we prefer to make the osteotomy at the level of the apex of the bow. Working backwards this can help calculate the ideal length of the nail to use. In most cases a relatively short nail is used compared to nailing for fixation of fractures. The femur can be reamed with flexible or straight rigid reamers. The latter are less available and less forgiving. However they conform to the shape of the nail better and are preferred if available. Piriformis start is preferred in most adult femurs unless there is a coxa breva or valga. In children with open proximal femoral physes, a trochanteric start point is preferred to minimize the risk of avascular necrosis. Retrograde nailing is used in the femur in conjunction with angular deformity correction of the distal femur or if there is a quadriceps lag that needs to be tightened (one case in the series below had retrograde nailing for the quadriceps lag). Retrograde tibial nailing is used in patients with pantalar arthrodesis.

### Dr. Paley's Surgical Technique Femur:

Step 1: The patient is positioned supine on a radiolucent operating table. A radiolucent bump (usually a folded towel or sheet) is placed underneath the ischium on the operative side. This allows good visualization of the hip on both AP and cross table lateral views.

Step 2: Using the image intensifier (fluoroscopy) the tip of the level of the greater trochanter is marked on the skin. Knowing the length of the nail to be used for the surgery, a ruler is used to mark the distal end of the nail.

Step 3: The level of the osteotomy is determined by knowing the amount of distraction planned. One must plan to end up with the larger diameter of the nail always engaged on both sides of the distraction gap at the end of lengthening. Assuming one wants to have 2cms of the larger diameter of the nail engaged, then add 2cms plus the 3cms of smaller diameter nail, which is exposed plus the distraction amount. This total measured from the distal end of the nail represents the level of the desired osteotomy that will leave at least two cms of the larger diameter of nail always engaged.

Step 4: Make a 1cm incision laterally at the level of the osteotomy. Drill holes using a 4.8mm drill bit. I prefer one entrance and three exit holes; anteromedial, anterolateral, and medial. Then make two more holes anterolateral and posterolateral at the level of the other holes. These holes will serve to vent the canal from fat emboli and to allow the reamings that spill out to help fertilize the bone formation at the distraction gap.

Step 5: Get your starting point using a Steinmann pin in the piriformis fossa for adults or children with closed growth plates. Enlarge this opening using an ACL reamer. For open growth plates insert the Steinmann pin into the tip of the greater trochanter.

- Step 6: Open the fossa or trochanter with an ACL reamer.
- Step 7: Insert a beaded guide rod down the femur.
- Step 8: Ream in one mm increments until there is chatter and then in ½ mm increments. Ream to 12.5 mm for the 10.7mm nail and to 14.5 for the 12.5mm nail.
- Step 9: Prepare the nail for insertion. Precice 2, the nail is not modular and one must choose the length of the entire nail in advance.
- Step 10: Apply the proximal targeting device and test its alignment to the screw holes by insertion the drill guides and bits.
- Step 11: Place the nail under the beam of the image intensifier to see if the mechanism is not predistracted. Save this image for reference.
- Step 12: Remove the initial beaded guide wire used for reaming, as the nail is not cannulated. Insert the nail into the canal up to the level of the planned osteotomy (drill holes).
- Step 13: Have one assistant lift the foot off the table. Have the other assistant lift the proximal end of the nail using the insertion guide. The two assistants are applying an extension moment to the femur to prevent displacement of the femur during the osteotomy.
- Step 14: Use a sharp osteotome to osteotomize the femur through the one cm lateral incision. The femur will easily break through the six drill holes. Listen for the break and once it occurs withdraw the osteotome. Test that the femur is fractured while maintaining the extension moment. Move the femur gently into varus and valgus and watch it move on the image intensifier.
- Step 15: Once the break is confirmed to be complete, advance the nail by gently hammering on the impactor until the upper end is at the level of the base of the piriformis fossa or just inside the greater trochanter for piriformis and trochanteric nails respectively.
- Step 16: Lock the nail proximally with two screws. For distal locking screws, my personal preference is to insert a long 1.8mm wire into the locking hole, followed by a 3.8mm cannulated drill for the distal 10.7 nails and a 4.8mm cannulated drill for the distal 12.5mm drills. In the 10.7 over drill with a solid 4.0 mm drill after removing the cannulated one.
- Step 17: Lock the nail distally with two screws. Avoid inserting the antero-posterior middle screw because it can act as a stress riser for fracture of the femur.
- Step 18: Insert the end cap into the proximal part of the nail.
- Step 20: Close all the incisions
- Step 21: Insert the ERC device into a sterile sleeve. Mark out the level of the magnet on the skin using fluoroscopy. Apply, the ERC directly over the magnetic spindle, using the image intensifier to mark out

the magnet. It takes 7 minutes to lengthen the femur 1mm. Remember to program the ERC for antegrade or retrograde use.

Step22: Check if the distraction gap is seen radiographically and compare it to the pre-distraction space. If an objective increase in space is seen the procedure is completed. If not do a second millimeter of distraction to confirm. In the rare case where the bone does not separate, the nail must be extracted and tested on the bench and if it does not distract then replaced with another nail. An incomplete osteotomy can cause a failure of distraction and can even lead to failure of the mechanism due to the high force of resistance.

Dr. Paley's Surgical Technique Tibia:

Step 1: Mark the proximal and distal end of the nail as before.

Step 2: Mark the level of the osteotomy as before.

Step 3: Make a single drill hole anteriorly at the level of the tibial osteotomy. Avoid getting into the anterior compartment. Additional holes can be made medially and postero-medially under the subcutaneous border.

Step 4: Insert temporary arthrodesis screws just proximal to the distal tibio-fibular joint. Start with a wire from the fibular side and make sure it passes relatively posteriorly into the tibia. This wire should be oriented distal on the fibula and proximal on the tibia. A second wire of equal length can be used to measure the appropriate length of the screw. Bring the wire out the tibial side and then antegrade drill it with a 3.2mm cannulated drill bit. Measure and insert a solid (non-cannulated) 4.5mm screw of the correct length antegrade.

Step 5: Make a 3cms incision posterolateral in the midlevel of the leg. Dissect between the peroneals and gastro-soleus muscles anterior to the intermuscular septum. Dissect down to the fibula. Incise and elevate the periosteum off of the lateral aspect of the fibula and insert a Hohmann elevator anterior and posterior to the fibula. Make multiple drill holes in the fibula with a 1.8mm wire. Use a narrow osteotome to break the fibula. Confirm that the osteotomy is complete by displacing the osteotomy.

Step 6: Insert a Steinmann pin into the proximal tibia at the level of the joint in line with the medial tibial spine, medial to the patellar tendon. Start as high and posterior as possible. Use an ACL reamer to open the starting point.

Step 7: Ream the tibia in one mm increments until there is chatter and then in half mm increments until 12.5 mms for the 10.7mms nail and 14.5mms for the 12.5mms nail.

Step 8: Osteotomize the tibia with a sharp osteotome.

Step 9: Insert the Precice tibial nail down the tibia.

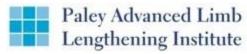
Step 10: Orient the upper end of the nail so that the upper medial locking screw is oriented towards the tibio-fibular joint. Drill this screw into the head of the fibula. Insert this screw to fix the tibia and fibula.

Lock the second proximal locking screw from the lateral side. If the first drill hole and screw misses the fibula, then lock the fibula separately with another 4.5mm screw in a retrograde fashion using a wire and cannulated drill first.

Step 11: Free hand lock two of the three distal screws leaving either the middle or distal one empty.

Step 12: Perform a distraction test of one mm using the ERC.

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