

Cosmetic Stature Lengthening: A New Breakthrough

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In August 2011, a new implantable lengthening device, the **PRECICE**, was approved by the FDA. It was developed by Ellipse Technologies, out of California in conjunction with a team of orthopedic surgeon consultants, myself included. Ellipse used an internal lengthening mechanism that they had developed for use in the spine. The major advance of this device is that it has complete rate control and can even go reverse (shortening). Inside the lengthening nail there is magnet, which is connected to a gear box which in turn is connected to a screw shaft. Rotating the magnet, rotates the screw shaft and lengthens or shortens the telescopic nail. To rotate the internal magnet there is an external actuator that is held by hand and applied to the limb. The actuator has two magnets that are rotated by a motorized system while they are held against the leg at the level of the internal magnet in the nail. It takes hundreds of revolutions of the external magnet to effect a 1 mm change in length of the nail. The actuator lengthens the nail if it is facing one way and shortens it if it is facing the other way. It takes 7 minutes to achieve 1mm. The nail is designed to be able to lengthen against a force of 80kg (176 lbs). The forces that need to be resisted inside the limb have been reported to be up to 50 kg (110 lbs). Therefore this nail is more than strong enough to lengthen the limb.

Although each nail is for one time use, the actuator can be used for many patients. At present the FDA approved the use of the actuator only for the physicians office. This means that the patient must come in to the office daily to have the lengthening performed, including on weekends and holidays. The Precice can lengthen up to 6.5cms, although this amount may increase in future models. Our orthopedic technologist performs the lengthening for each patient daily. If there is any problem he alerts the clinical team, and the patient is seen by a physician assistant or doctor the same day. Since patients undergo daily physical therapy (PT) sessions at the Paley Institute, we coordinate the lengthening session with the physical therapy schedule. Patients have an x-ray every week to monitor the lengthening. The x-rays are measured to confirm that the amount of lengthening that the actuator did has in fact been achieved. After the x-ray they are seen by one of our doctors or PA's.

The Precice heralds in a new era for limb lengthening but especially for cosmetic limb lengthening. We now finally have a device that can be implanted with minimal incision surgery and which can perform lengthening by a remotely controlled mechanism without rate control problems. The safety factor with this device is excellent since it can be lengthened at any rate and can even be reversed to shorten

the limb. Rate control should eliminate most of the complications we saw with the ISKD. At present we are the only center in the US to implant this device but we expect other centers to start using it.

Despite the ease of insertion and use, the limb lengthening process remains the same and the risks associated with limb lengthening remain unchanged. For these reasons it is still essential that a surgeon experienced in limb lengthening and in the treatment of lengthening complications be the one performing the procedure and following the patient. (see complications section below)

Recovery from Implantable Limb Lengthening

The typical recovery from bilateral femoral or tibial lengthening is as follows:

- 1) surgery and hospitalization: 3-4 days
- 2) distraction phase (weight bearing (WB) for transfers only; daily PT) = one day for each mm of lengthening (65 mm = 65 days);
- 3) consolidation phase until full WB permitted = 1 month in most but can be longer. The end of this phase is when the bone on the x-ray appears to bridge the lengthening gap at least on one side. WB is progressed from transfers only to full WB.
- 4) Rehabilitation phase: full WB without crutches. Regaining of muscle strength and joint range of motion to normal. Usually 1-3 months.
- 5) Return to sports usually by 4-6 months after surgery.

Removal of Implant:

The implantable lengthening device should be removed. Although it is made of inert metal (either titanium or stainless steel), there are also other materials including rare earth magnets, etc. The moving parts also can lead to wear and even corrosion. For these reasons it is preferable to remove the device. The device can usually be removed as early as one year after surgery. There is no urgency in the timing of removal but it should be done. The removal is an outpatient procedure but does add some cost to the total costs of this surgery. It can be deferred for more than one year.

Historical perspective on implantable limb lengthening devices:

I have been performing Limb Lengthening Surgery since 1986. The two main indications for such surgery are limb length equalization for limb length discrepancy

(LLD) and stature lengthening for short stature. Since 1986 I have performed 13,000 limb lengthening surgeries. This is probably more than any other surgeon worldwide. The majority of these surgeries were for LLD. Over 1000 were for short stature related to dwarfism and about 300 for cosmetic reasons.

Many have asked me why over the course of the past 25 years I have not performed more cases for cosmetic reasons. The primary reason was that the magnitude of the procedure and its complications were out of proportion for a cosmetic procedure. I therefore was very selective and careful and worked out the safe parameters and methods for achieving stature increase for cosmetic reasons. That has all changed now with the Precise device. The rate control offered by this method finally makes the procedure more in proportion to a cosmetic height gain.

My history with cosmetic lengthening for stature is as follows:

I started with the Ilizarov method for lengthening of both tibiae in 1987 and soon after switched to the lengthening over nail method I had developed in 1990. Although my results were excellent, the scars, the pain, the suffering, the pin site infections were not conducive to a cosmetic procedure.

I sought a fully implantable lengthening solution. When the Albizzia nail, developed by Guichet became available I worked with the French company that made the nail to develop a tibial lengthening Albizzia for stature lengthening. I started using this in 1996. The severe pain experienced by patients from the 15° rotation of the thigh through the break in the bone, as well as several implant failures lead me to stop using this non-FDA approved device. In 2001, when the ISKD, developed by Cole was approved by the FDA and marketed by Orthofix became available, I was the first surgeon after Dr. Cole to implant this device. I thought that this was going to be the panacea for cosmetic lengthening. I have since performed over 350 ISKD implantable limb lengthenings, more than anyone in the world. Many of these patients were ISKD's for cosmetic stature lengthenings. The surgery was minimally invasive with few scars. The problem was rate control. The ISKD lengthening is dependent on movement. Therefore it can lengthen too quickly, too slowly or at the desired rate of 1mm per day. Over 50% of cases lengthened too quickly, 20% too slowly and only 30% at the desired rate. I was a consultant for Orthofix and advised them since 2001 that they need to redesign the mechanism to achieve rate control. Lack of rate control lead to most of the complications such as muscle contractures, nerve injury, poor bone formation, etc. Furthermore there were many malfunctions of the mechanism, which for unexplained reasons would fail to lengthen in the middle of the distraction phase. This lead to increased numbers of procedures to treat complications. For stature patients this also meant increased costs. I learned to work with the ISKD to minimize complications and became an expert at the treatment and prevention of these complications. My final results due to my diligence were excellent in almost every patient. The ISKD was the only FDA approved device and was the best implantable lengthening device that we had in the

USA. The ISKD, the Albizzia and the Fitbone are all what I call first generation lengthening nails. They all suffer from significant mechanical and other problems.

On December 1, 2011, I implanted the first 3 Precice nails. Although it is too early to tell the results, I can attest to the perfect rate control in these three cases and the complete lack of pain compared to the ISKD and Albizzia. While the procedure for implantation was the same with few and very short incisions (minimal scars) the postoperative course thus far has been much more comfortable for the patients. I think this difference is due to two factors: rate of lengthening control and no rotatory movement through the osteotomy site. I will continue to post up to date results for this new technology.

Cosmetic Stature Considerations and FAQs about Implantable Limb Lengthening

(The following represents the author's opinion based on his personal extensive experience with limb lengthening in general and with implantable limb lengthening)

Cost:

Cosmetic surgery of any kind is not covered by medical insurance. Therefore cost is probably the number one limiting factor for most individuals seeking cosmetic stature lengthening. Costs vary by country, center, surgeon and technique. The cost of the device contributes a lot to the cost of the procedure. External fixators while expensive when new can be reused. Therefore the cost of reused external fixators is very cheap. The remaining costs are related to the cost of healthcare in the hospital where the surgery is to be performed. For this reason many patients choose to go overseas for treatment. Although there are some credible and safe centers for stature lengthening in other countries, there are also many centers where you put yourself at risk of disaster and permanent disability. I have kept silent for many years while patients from many centers all over the world have made their way to me to fix the complications they developed in some of these international centers. Keep in mind that since this surgery is very lucrative it is open to abuse all over the world including in the US. It is very difficult for the consumer to discern where to go. All limb lengthening surgeons or centers are not the same. Just because it is cheaper does not mean that the patient will get the desired result. I have come to the conclusion that in many cases you get what you pay for. While the cost in the US is higher the safety factor is also proportionally higher. In the past 5 years I have seen and operated upon 20 American and foreign patients who went to have cosmetic stature lengthening at overseas less expensive centers. The cost to reconstruct and 'rescue' their limbs was as high or higher than the cost to undergo the procedure in the US in the first place. The final result although improved after I operated upon these patients is not as good as if I had done the original surgery.

Implant costs: The implant cost of the ISKD in the US costs is \$13,000 per unit. The Precice currently costs the same amount. That is subject to change. Therefore just the cost of the implants for bilateral implantable lengthening implants is \$26,000. Please note the cost quoted is not the cost of the surgery. It is the cost of the implants alone.

Surgery cost: The cost of a bilateral femoral or tibial lengthening at our center can be obtained by contacting us at www.PaleyInstitute.org or www.limblengtheningdoc.org

The medical costs of bilateral implantable limb lengthening surgery is broken up into inpatient costs, outpatient costs, and rehabilitation costs. Inpatient costs is the actual cost of surgery and hospitalization. This includes: the surgeon's fees based on the list of surgical procedures done; the surgical assistant fees; the hospital fees for the operating room, recovery room, and the number of days in hospital which also includes the implants used (including drugs such as Botox), the type and duration of postop analgesia (e.g. PCA or epidural), inpatient physical therapy and other miscellaneous charges. Outpatient costs include the number of clinic visits and the x-rays taken at each visit. Rehabilitation costs include the number of daily outpatient physical therapy sessions. These inpatient, outpatient and rehabilitation charges vary from patient to patient and from technique to technique.

For example: with the ISKD it is necessary to do additional procedures to prevent complications in case of a runaway nail; e.g. we routinely lengthen the fascia lata and the biceps tendon, decompress the peroneal nerve and injected Botox into the quadriceps muscles to prevent muscle spasm and pain. With the Precice we do not need to do any of these prophylactically, with the exception of lengthening the fascia lata in some cases.

Amount of stature gain:

Most patients desire 3 inches (7.5cms) of stature gain and some more than that. The Precice can lengthen up to 2.55 inches (6.5 cms) at present. This may change in the future. Patients who want more than this should consider a second lengthening of the other bone (femur 6.5cms and then tibia 6.5cms). The total height gain with this strategy is 5.1 inches. Of course the cost of two lengthenings is twice that of one lengthening. With the ISKD it was not safe to lengthen more than 5cms because of the risk of too rapid lengthening. The limits with the Precice will be the patients soft tissues. As long as patients can maintain good range of motion they can continue lengthening until the maximum of the nail (6.5cms). A major advantage of the Precice is that the lengthening can be stopped at any time without additional

surgery. With the ISKD the lengthening cannot be stopped without surgery until the total lengthening of the nail has been achieved.

Height requirements:

I used to restrict stature lengthening according to maximum height criteria. I currently don't have a maximum height threshold. The reason for this is that the risks and complications are independent of starting height. Furthermore the motivation to do this surgery, which in most people is called Height Neurosis or Height Dysphoria is also height independent. I have seen patients who are 5'10" just as bothered by their height as those who are 5' tall. Psychological profiles of such tall and short patients were the same and the final result was the same. Therefore I don't feel there is a reason to restrict this surgery by height.

Psychological Considerations:

I also used to use a psychologist to evaluate all my patients before surgery. After more than 20 years I have gotten fairly good at doing this evaluation myself. The purpose of this evaluation is to make sure we are not operating upon patients with a body dysmorphic psychosis as well as to make sure that patients have the proper support required to undergo this procedure. Research we did on the psychological evaluation before vs after lengthening, showed that patients were happier after the lengthening and that the body image problems they had before surgery went away. Based on these results I am now making this surgery more available to prospective patients.

Disability during lengthening:

Unlike other cosmetic procedures this stature lengthening is temporarily disabling to the patient. Furthermore the risks of this procedure can leave a patient with a permanent loss of function, range of motion and disability. During the lengthening the patient is in a wheelchair and dependent on others for many functions. Therefore cosmetic stature lengthening patients need support from friends or family or else need to hire a caregiver.

Weightbearing:

During the stature lengthening with an implantable device, the patient should not be full weightbearing (WB). The rod inside the bone needs to support the entire weight of the patient while allowing the bone to heal. Once the bone is healed there is no problem with WB. Irrespective of which implantable nail is used the consideration

regarding WB should be the same. All of the implantable nails are about the same strength. I have seen several nail failures as well as failure to heal related to premature WB. I permit WB with a walker for transfers from bed to chair and chair to toilet, etc. Once the lengthening is completed I do not allow full WB until the lengthening gap shows bony bridging on the x-ray. I hear all the time about other surgeons who permit full WB with crutches earlier. I also have seen the failures I described above sometimes because premature WB was permitted.

Unexpected problems, complications and costs:

No one wants unexpected problems, complications and costs. For these reasons I am very conservative regarding many aspects of the limb lengthening process. I try and anticipate problems and prevent complications. Many complications lead to additional surgery and therefore to additional costs. The following is a list of the more common complications:

Premature consolidation: in this complication the patient bone bridges the gap and prevents further lengthening. Premature consolidation (PC) can occur with any method if the patient is a very rapid bone healer. The patient in these cases is able to make bone faster than the speed at which the bone is being lengthened. The only way to prevent this is to speed up the lengthening intentionally for a week or two. The Precice nail with its rate control allows the surgeon to do this. If premature consolidation does occur it requires an outpatient small surgery to rebreak the bone through a tiny incision.

With the ISKD and Albizzia premature consolidation was a well recognized complication due to the lack of control of rate of lengthening. Since lengthening in both of these devices occurred by movement through the osteotomy site and since movement through the osteotomy site can cause pain and muscle spasm, the patients muscles sometimes would prevent the movement and therefore the lengthening from occurring. In other cases both the ISKD and the Albizzia have had broken mechanisms that fail to lengthen during the distraction phase leading to PC. The treatment in these cases was to not only rebreak the bone but also to change the device to a new device. Although in each such case the company provided a new device at no additional cost, the patient still had to bear the cost of an additional outpatient surgery.

Delayed or failure of consolidation: slow or failed bone healing can occur with any lengthening surgery. This complication can usually be prevented by making drill holes at the level of the planned osteotomy before reaming the bone. This is a technique I introduced in 1990 with the lengthening over nail method. Stable fixation is also important so the choice of nail length and diameter are important as well as the level of the osteotomy. Even the type of osteotomy affects the rate of bone healing. Cutting the bone with multiple drill holes and an osteotome is the most minimal invasive way while using an intramedullary saw or performing an

open osteotomy have higher failure rates. All of these are surgeon controlled parameters and are based on surgeon knowledge and experience. Choosing the wrong level or method of osteotomy or the wrong diameter or length of implant can significantly impact the result. Perhaps the most important parameter however is the rate of distraction. Lengthening too quickly can lead to delay or complete or partial failure of bone formation.

Too rapid distraction is the most common cause of poor bone formation with the ISKD. This is not a problem with the Precice since it has complete rate control. Poor bone healing can be recognized during the lengthening process. Once it is recognized the rate of distraction should be slowed. Slowing the distraction is difficult with the ISKD. It requires the patient to stop physical therapy, get into bed and decrease mobility and wear a brace from the hip to the ankle. With the Precice the lengthening can be reduced to any level or even stopped. If despite these changes the bone healing remains poor, the lengthening can be reversed until better bone formation is seen. The bone can then be relengthened. This can only be done with the Precice. Going reverse is not possible with the ISKD, Albizzia or the Fitbone. This is a huge advantage that was only possible before with external fixation.

Delay or failure of bone formation can delay weightbearing and increase the period of disability and recovery. Furthermore it can lead to the need for surgery to get the bone to heal. Such surgery requires a bone graft and is not a small operation and can be quite costly. Therefore having a device like the Precice that can prevent or treat the problem is a major advance.

Nerve injury: nerve injury can occur with any lengthening surgery but is usually uncommon if the rate of distraction does not exceed 1mm per day and if the amount of lengthening is restricted. Rate control is the most important factor to prevent nerve damage. Recognition of nerve symptoms is important. The lengthening should be stopped or slowed in such cases. If any motor symptoms (weakness or paralysis of muscles) occurs a nerve decompression should be done as soon as possible. This is a small outpatient surgery. In most cases it is the peroneal nerve that gets into trouble. It is important that the surgeon know how to decompress this nerve to prevent foot drop. Delay in decompression can lead to permanent foot drop.

The ISKD too rapid distraction has lead to nerve complications in some patients. For this reason I will not lengthen more than 5cms with the ISKD. With the Precice and complete rate control, nerve injury should be much less common.

Muscle contractures: muscles normally get tight with lengthening. A muscle contracture occurs when a muscle gets tight enough to prevent a joint from moving through its entire range of motion. To prevent muscle contractures physical therapy (PT) is essential. The patient should do daily stretches of the muscles and joints at risk. E.g. knee joint and quadriceps muscles for femur lengthening and ankle joint

and Achilles tendon for tibial lengthening. In addition to formal PT the patient should do their own stretches at home several times per day. PT is essential to the lengthening process. It is however expensive. I will not consider doing a lengthening if a patient is not willing to do PT. This is not an option for reducing cost. Too rapid distraction with the ISKD made PT even more difficult. We frequently had to suspend PT to slow the distraction. We also had to fight muscle spasm due to the constant bone movement with the ISKD. For this reason we started using Botox to prevent spasm with ISKD. Botox is very expensive. It is usually not necessary if the rate of distraction is controllable. Once again the controlled rate of lengthening with the Precice makes the risk of muscle contractures and muscle spasm less. I do not routinely use Botox with the Precice which is another cost savings. The Precice does not obviate the need for PT. Maintaining range of motion and preventing contractures during lengthening decreases the rehabilitation time to return to normal function after the lengthening is finished. A fixed contracture of the knee or ankle can lead to disability and the need for more prolonged PT and the expenses associated. If despite additional PT the contracture does not resolve additional surgery to lengthen muscles, tendons and fascia may be required. I try and anticipate this and prophylactically lengthen certain soft tissue structures to prevent contractures. If this is done at the initial surgery the additional cost is small. If soft tissue lengthening surgery is required at a later date the cost is much higher since one also has to pay for the hospital costs.

Fibular complications: with tibial lengthening the fibula has to be lengthened too. The implantable lengthening device only lengthens and fixes the tibia. The fibula has to be fixed to the tibia so that it lengthens together with it. If the fibula is not fixed or not fixed adequately it will not lengthen as much as the tibia and will lead to severe consequences including subluxation and arthritis of the ankle and flexion contracture of the knee. The method of fixation is critical. Many surgeons only fix the lower end of the fibula to the tibia. This can lead the fibula to prematurely consolidate and to pull down and dislocate from the tibia at its upper end. It is important to fix the fibula at both ends. With external fixation the fibula can be fixed with the wires of an external fixator. With implantable lengthening the fibula must be fixed with screws to the tibia; one screw at the upper end and one at the lower end. The angle, level, position, diameter, and type of screw are all important. E.g. a common mistake is to put the screw in horizontally between the two bones. This is not strong enough to prevent the fibula from pulling away from the tibia at the ankle. This is very subtle and even a few millimeters of difference in length of the fibula at the ankle lead to short term and/or long term consequences for the patient. Removing a segment of the fibula to prevent the fibula from not separating is another common method that should be abandoned. It leads to a nonunion of the fibula which can lead to a stress fracture at a later date in the tibia. Furthermore it usually does not prevent the fibula from pulling away from the tibia. Therefore fibular complications have nothing to do with the type of implantable lengthening

device but rather with the method the surgeon chooses to fixate the fibula to the tibia and the method of cutting the fibula bone.