



ORTHOPEDIC & SPINE INSTITUTE

at St. Mary's Medical Center

Dear Prospective Stature Lengthening Patient:

This document is intended to be an honest and practical guide to understanding Cosmetic Stature Lengthening. I continue to add to this comprehensive manual so as to make it a living document. If it has not answered all of your questions feel free to direct your questions to my staff or myself so we can better prepare you for this life changing process. Although this document switches from the first to the third person, it was entirely, written by me. All of the information contained herein is based on my more than 30 years of experience in the field of limb lengthening. I hope you find this useful and I hope to meet you in person should you choose to pursue this journey.

Sincerely,

Dror Paley, MD, FRCSC
Director, Paley Orthopedic and Spine Institute
dpaley@paleyinstitute.org
www.paleyinstitute.org

Cosmetic Stature Lengthening Frequently Asked Questions (FAQs)

(Please read this document carefully as it contains the answers to most of your questions)



Figure 1: Example of a 52-year-old physician who underwent femur and tibia lengthening for a height gain of 4½ inches (11cm). He is standing next to his wife for reference before (left) and after (right) the lengthening surgery. The lengthening was performed with the Precice method discussed below.



ORTHOPEDIC & SPINE INSTITUTE

at St. Mary's Medical Center

For further inquiries please contact:

Angelique Keller: International Patient Relations Manager — akeller@paleyinstitute.org
Angelique speaks and writes in Chinese

For financial inquiries please contact:

Craig Lawrence: Sr. Financial Analyst St. Mary's — clawrence@paleyinstitute.org

To book a consultation appointment please contact:

Angelique Keller: International Patient Coordinator — akeller@paleyinstitute.org

To book a surgery date please contact:

Angelique Keller: International Patient Coordinator — akeller@paleyinstitute.org

For Medical Questions please contact:

Vera Gray, PA-C: Physician Assistant — vgray@paleyinstitute.org

John Robb, PA-C: Physician Assistant — jrobb@paleyinstitute.org

Craig Robbins, MD: Orthopedic Surgeon — crobbins@paleyinstitute.org

Dror Paley, MD: Director Paley Institute — dpaley@paleyinstitute.org

Paley Orthopedic & Spine Institute
561 844-5255
901 45th St., Kimmel Building
West Palm Beach, 33407, Florida, USA

Frequently Asked Questions (FAQ's)

Who requests this operation?

The majority of people who seek this surgery are unhappy with their body image. Body image is the way we perceive ourselves. As it relates to height, it is the way we perceive our own height and our body proportions (limb length relative to trunk length).

Is there a name for this condition?

The psychologist that I worked with for over 20 years and who evaluated almost all of my patients with this condition between 1988 and 2008, Dr. Walter Windisch, called this condition *Height Dysphoria* (Dysphoria literally means unhappy, the opposite of euphoria). In other words unhappy with your height. Another term that has been used is the name Dr. Paley gave it: *Height Neurosis*.

Some patients also have Body Dysmorphic Disorder. They usually also need psychological support and medication but may be candidates for this surgery. Psychiatric consultation may be warranted in this group.

What is the relationship of height to Height Dysphoria?

While a person's actual height is related to the condition there is no height threshold under which you cannot suffer from height dysphoria. Most of us would assume that you could only suffer from Height Dysphoria if you are 'short'. The problem is that the perception of who is short varies from person to person. That threshold differs along racial, national and cultural lines: 5'10" (178cm) is tall in India but short in Holland.

The following anecdote illustrates the point: A man flew all the way from Holland to see me regarding stature lengthening. He was 5'11" (180cm) tall. He said that since he was a teenager he has suffered from feeling short. He is the shortest male in his family and even his sister is his height. All of his friends are much taller. He reminded me that the Dutch are the tallest people in the world. He is the same height as me. I have never perceived myself as short nor have any of my family or friends. I, therefore, had difficulty considering him for stature lengthening. I sent him for psychological evaluation. The psychologist report showed he suffered from the same body image problem as all of the other patients we had evaluated. Despite his seemingly tall height, he suffered from Height Dysphoria.

When we studied the relationship of starting height to the diagnosis of Height Dysphoria we found that patients starting height varied from 4'10" to 5'11" (147 - 180 cm) for males and 4'6" to 5'8" (137 - 173 cm) for women. While more of the patients were at the lower end of this spectrum, the fact that some were at the upper end clearly demonstrated that height is not the primary problem. The primary problem is the psyche's perception of height and proportion. We call this body image. Stature Dysphoria is a body image disorder. The patient perceives himself or herself as short irrespective of the actual height and irrespective of how others see them.

What is the normal range of adult height in the population?

When assessing the distribution of height in the population, we consider the normal bell curve. We divide people by distribution around the mean (average). Normal height is considered ± 3 standard deviations (SD) from the mean. Stature below 3 SD from the mean in persons without a medical condition such as dwarfism or growth hormone deficiency is considered constitutional short stature. A physician defines the normal range of height between the 5th and 95th percentiles. The lower limit of so-called *normal stature* for men is 5'5" (166 cm) and for women is 5'0" (153 cm).

Percentile	SD	Height Women (in)	Height Women (cm)	Height Men (in)	Height Men (cm)
95	+3	68.5	174	74	188
90	+2	67.5	171	73	185
75	+1	66	167	71.5	181
50	Mean	64.5	163	69.5	176
25	-1	63	160	68	172.5
10	-2	61.5	156	66.5	169
5	-3	60	153	65	166

Is there a height threshold above which stature lengthening is not appropriate?

Based on the above findings the answer should be no. I have learned to remove my personal bias regarding height from the evaluation. It is the patient's perception that counts. As regards risks of the procedure they are no greater if you are taller. In fact, they should theoretically be less since the percent increase in length of a longer bone is less.

What method do we use for stature lengthening (see figures 1,2,3)?

At the Paley Institute, we use the most cutting-edge technology available in the world today. We use implantable limb lengthening for stature lengthening. This involves inserting a telescopic intramedullary nail (tube-like device into the marrow cavity of the bone). The best device available today is the Precice-STRYDE nail from Nuvasive Specialized Orthopedics (NSO). The NSO products are currently the only FDA approved lengthening nails in the USA. The mechanism provides excellent rate control and patients claim the lengthening itself is painless. The mechanism can also go reverse. The ability to go reverse is a very important safety feature. We are currently using the latest technology Precice-STRYDE (PS) for stature lengthening. We have stopped using the Precice 2.2 (P2.2) for stature lengthening because the recover with Precice-STRYDE is so much better. The differences between these two is the P2.2 is made of titanium, which is more flexible and not as strong as the stainless steel PS nail. The P2.2 requires weight-bearing restrictions and therefore a walker or crutches for a prolonged period of time, while the PS does not require weight bearing restrictions or crutches.

Figure 2: Femur Lengthening with P2.2 or PS

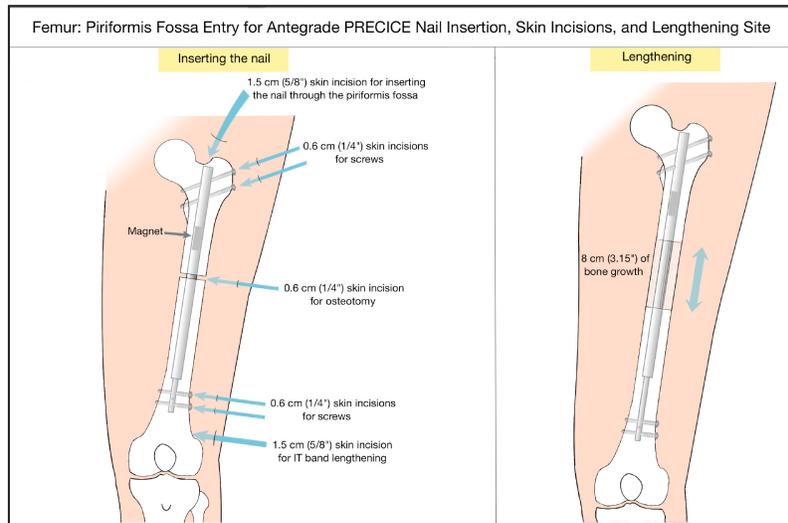
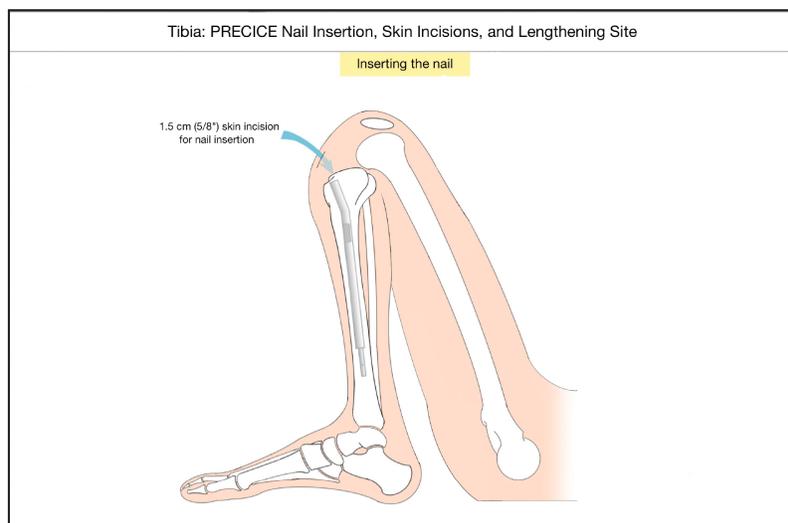
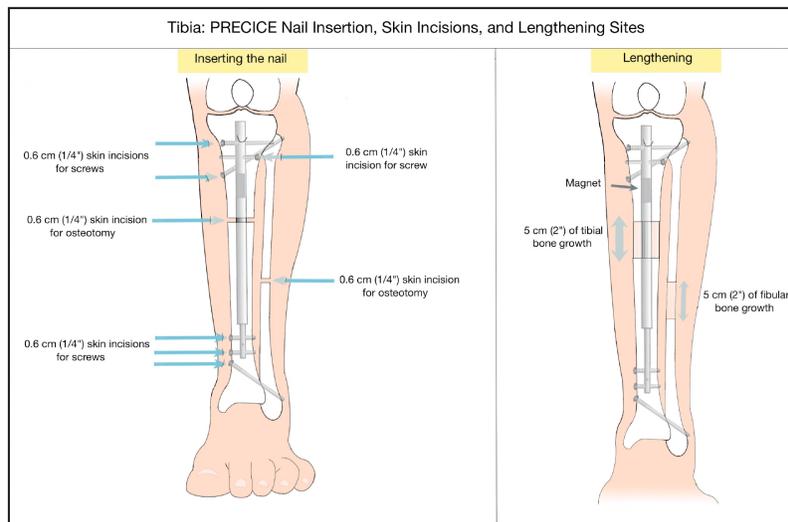


Figure 3: Tibia Lengthening with P2.2 or PS



How much height can I gain with the PS?

The maximum the Precice-STRYDE can lengthen is 8cm which is the same as P2.2. Patients who want more than this should consider a second lengthening of the other bone. The total height gain with two lengthenings is up to 13cm (8cm in the femurs and 5 cm in the tibias. (8cm is not well tolerated in the lower leg (tibia) and exceeding 5cm can lead to more serious complications such as equinus contracture [ballerina foot]). Most patients will not tolerate more than 5cm in the tibias. Of course the cost of two lengthenings is nearly twice that of one lengthening. Although the Precice can lengthen up to 8cm, not every patient can safely achieve this much even in the femurs. We will only allow lengthening to the tolerance of the patient's bone and soft tissues. SAFETY first. We will not risk a loss of function to gain one more cm. To get the full 8cm from both femurs and both tibias requires three lengthening surgeries (see option 5 below).

What is the difference between the P2.2 (Precice) and the PS(Precice-STRYDE) nails?

The difference between the two nails is strength due to material, diameter and the design of the nail. The mechanism for lengthening is the same for both nails. The P2.2 is made of titanium, which is a more flexible and brittle metal. It can therefore bend and break more easily. It is fine for unilateral use but requires significant weight bearing restrictions for bilateral use. The PS is made from Stainless Steel (Biodur 108 SST Alloy), which is stiffer and stronger. The mechanical testing of the SP show that its bending strength to failure (yield strength) is between 1.2 to 1.5 times higher than that of P2.2. The SP fatigue strength is between 2 to 2.5 times higher than P2.2.

PRECICE Stryde

Nail Features

Biodur 108 SST Alloy

- Housing Body
- Anti-Rotation Lug
- Distraction Rod



+5mm increase in magnet length
(18.6% increase in strength)



Additional 15mm overlap

Screws: new stronger design

<i>SST Partially Threaded Locking Screw (mm)</i>	<i>Fatigue Load (lbs)</i>	<i>Max Length Screw (mm)</i>
4.0	150	75
4.5	200	80
5.0	250	80

*Full body weight loading activities (walking). NUVASIVE

PRECICE 2 Nail	Yield Load (lbs)	Fatigue Load (lbs)
8.5	208	67
10.7	325	118
12.5	546	146
PRECICE Stryde Nail		
10.0	343	167
11.5	510*	244*
13.0	677	320

Is everyone a candidate for the Precice-STRYDE nail?

The only limitation on using the PS nail is length and diameter of the bone. The smallest diameter is 10mm and the shortest length is 265mm. Patients whose bones are too narrow or too short must use the P2.2 instead with its associated weight bearing restrictions of 50lbs (24kg) limitation for the 8.5 mm nail. Some smaller boned women are too small for the STRYDE and will still require P2.2 especially for the tibias.

Which lengthening strategies give what amount of length gain?

There are several lengthening strategies to get maximum height with each lengthening. Below are listed some of these strategies (please note that the cost increases from method 1 to 5):

1. Bilateral femur lengthening (up to 8cm; 3.25 in.)
2. Bilateral tibia lengthening (up to 5cm, 2in.)
3. Combined tibia (5cm) and femur (5cm) lengthening three weeks apart: total 10cm (4 in.)
4. Femur lengthening (8cm) followed by tibial lengthening (5cm) one year later; total 13cm (5.25 in.)
5. Combined tibia (4cm) and femur (4cm) lengthening three weeks apart: total 8cm followed by re-breaking of femur and tibia with same nails in place and repeating 4cm femur and 4cm tibia lengthening one year or more later: total 16cm (6.3 in) (do not need to replace nails for second lengthening)

What is the cost of each of these procedures? (all prices are for Precice-STRYDE nails)

1. Bilateral femur lengthening (up to 8cm; 3.25 in.) \$97,500
2. Bilateral tibia lengthening (up to 5cm, 2in.) \$109,000
3. Combined tibia (up to 5cm) and femur (up to 5cm) lengthening three weeks apart (up to total 10cm; 4 in.) \$196,500
4. Femur lengthening (up to 8cm) followed by tibial lengthening (up to 5cm) one year later (up to total 13cm; 5in.) \$206,500
5. Combined tibia (up to 4cm) and femur (up to 4cm) lengthening three weeks apart: total 8cm followed by re-breaking femur and tibia with same nail in place and repeating up to 4cm femur and up to 4cm tibia lengthening one year or more later (up to total 16cm; 6.3 in.) \$280,000

Femur plus tibia lengthening

Options 3,4 and 5 include both tibia and femur lengthening.

Lengthening of the femur and tibia allows for greater height gain and better proportions of the femurs and tibias. Lengthening both bones is much more involved and more expensive than lengthening only one pair of bones. There is also more pain involved if both are done at the same time. We do not insert the femur and tibia rods in the same surgery due to the **theoretical** increased risk of *fat embolism syndrome* from reaming the medullary canal of more than two bones at a time. To insert 4 rods at the same surgery would increase the chance of fat embolism and death. We have done this successfully without complication in two patients but do not recommend or even offer it as an option since it is less safe.

Option 3 reduces treatment time, since femur and tibia are done simultaneously. The tibia surgery is performed first and three weeks later, we do the femur surgery. The reason for this order is two fold: 1) slower healing of the tibia as compared to the femur, and 2) insertion of the tibial nail requires maximum knee flexion. Maximum knee flexion can be reduced during femur lengthening. To reduce pain and to increase the likelihood of reaching the maximum length with femur plus tibia lengthening, we do a peroneal nerve decompression at the time of the tibial lengthening. We do the fibular osteotomy through this same incision.

Option 4 allows maximum femur lengthening since the femur and tibia lengthening are done at different times. No nerve decompression is done since the lengthenings are a year apart.

Option 5 is a rather interesting one, since it allows one to achieve the maximum possible length in the safest possible way. Each Precice nail can lengthen up to 8cm. It is not possible to achieve 8cm in the tibia safely in one lengthening without compromising or lengthening the Achilles tendon (which leads to permanent weakness of push-off strength during gait). It is possible, however, to reach 8cm in the tibia safely if it is done one year apart through two independent tibial lengthenings. Therefore, to obtain the maximum of 16cm (6.3 in.) we need to lengthen the tibia and femur at the same time staggered three weeks apart, 4cm each bone. We then stop and allow the bones to heal. One year later, the femurs and the tibias and fibulas can be cut and the same nail used to restart the lengthening again. The remaining 4cm in each bone is then obtained. Since 4cm is considered a small lengthening, the risks from lengthening are much lower. This strategy is therefore very safe and minimizes the time of lengthening for each lengthening. The first time it takes 11 weeks to complete the femur and tibia 4+4cm lengthening. The second time, since all rods are already in place there is no need to do two surgeries. All the bones can be cut at one time through very small incisions. The biggest down side of this method is cost. Since it is three separate lengthening surgeries the total cost is higher than all of the other options.

How long will I be on crutches with the Precice-STRYDE nail?

I developed the STRYDE specifically for stature lengthening patients to allow full weight bearing soon after surgery. Because of the surgery there is pain immediately after surgery. Therefore most patients use crutches or a walker for two to three weeks. For longer distances a wheelchair can be used during these first few weeks. We do a weight bearing test in physical therapy and once the patient passes this test they can stop using crutches. We still recommend one cane when walking up or down stairs or on/off curbs.

What is the safe amount that can be lengthened and why can more length not be done?

The limits of lengthening are the soft tissues. The risk of complications from lengthening increases with increased length. A lot of research on this has been done by Dr. Paley. Up to 5cm is a low risk lengthening. Between 5-8cm is medium risk and over 8cm is high risk. For example to achieve 10cm of lengthening it is much safer to lengthen the femur and tibia each by 5cm than to lengthen either bone by 10cm.

Are there any additional unexpected costs from the initial surgery?

The pricing for the femur and tibia lengthening includes all additional ancillary procedures such as iliotibial band (ITB) release and biceps tendon lengthening for femur lengthening and blocking screws if needed for tibial lengthening, and peroneal nerve decompression for tibia followed by femur lengthening. These additional procedures are done to PREVENT complications.

At the first consultation, Dr. Paley performs four muscle length tests (Ober test, Popliteal Angle measurement, and Ely test for femur lengthening and Silverskiold test for tibial lengthening) to determine if the iliotibial band-fascia lata, hamstrings, and rectus femoris muscles (for femur lengthening) and the gastrosoleus muscles (for tibial lengthening) are tight. The greater the amount of lengthening, the more likely the need for such soft tissue releases. For most lengthenings between 5 to 8cm, an iliotibial band release is carried out. For tibial lengthening, if the Achilles tendon is too tight, as determined by the Silverskiold test (physical examination), then a gastro-soleus contracture could result. Gastrosoleus lengthening can be performed but can lead to permanent weakness of push-off strength. We, therefore, avoid this and prefer limiting the amount of tibial lengthening to 5cm maximum.

If the ITB is tight before surgery and not prophylactically lengthened, then more expensive surgery may be required (in the lay literature these are referred to as duck ass deformity for tight iliotibial band and fascia lata, and ballerina feet for tight Achilles tendon). Prophylactic anterior compartment release may be done at the time of tibial lengthening. This is done to prevent compartment syndrome. The normal cost of these releases is built into the global fee for the lengthening surgery.

Fortunately, complications that require surgery are uncommon. About 1% of patients experience complications that require unplanned surgery to fix. This leads to additional costs of about \$30,000 to fix the complication. We therefore advise to keep about \$30,000 in reserve even though the risk is quite small.

Will insurance pay for cosmetic stature lengthening surgery?

Cosmetic surgery of any kind is not covered by medical insurance. Cost is the number one limiting factor for most individuals seeking cosmetic stature lengthening. Not only will insurance not pay for the surgery, but if a complication arises that requires additional surgery, insurance will not pay for the costs associated with treating the complication since it is related to the uncovered cosmetic surgery. .

Can I get the surgery cheaper in other countries and is it safe?

The Paley Institute is the SAFEST most RELIABLE place in the world to have this surgery.

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 experience undergoing this surgery with bulky, painful external fixators, with all of their complications, including infections, joint stiffness, and scars, cannot be compared to having the procedure done with the newest, safest technology with few scars and little pain.

Many patients choose to go overseas for treatment only because of cost. There are many centers where you put yourself at risk of disaster and permanent disability. I have had to fix the complications of surgery of many patients that had lengthening done overseas. Since this surgery is very lucrative, it is open to abuse all over the world including in the United States. 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, it 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 United States 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 less expensive centers overseas. The cost to reconstruct and 'rescue' their limbs was as high or higher than the cost to undergo the procedure at the Paley Institute 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 surgery originally. Finally, the Precice-STRYDE is the most advanced and safest method for cosmetic lengthening, with less pain and lower complications than other methods. Ask yourself, is reduction in your function worth the cost savings.

How experienced is the Paley Institute at limb lengthening and who are the clinical team?

The Paley Institute is the most experienced place in the world to have this surgery.

Dr. Dror Paley is the most experienced limb-lengthening surgeon in the world for both stature lengthening and for lengthening for limb length discrepancy. He has performed over 20,000 limb-lengthening surgeries since 1986. He has the best track record of success with all types of limb lengthening. This is very important as regards safety. His protégé, Dr. Craig Robbins, has been working with him on Stature Lengthening for the past four years and helps Dr. Paley with almost every stature surgery and also helps with the follow up office visits. Together they have the largest and safest experience in the world with STATURE LENGTHENING.

The rest of the stature lengthening team includes physician assistants, nurse practitioners and one Nurse Coordinator. Our four physician assistants; John Robb, Vera Gray, Alan Loesch and Erica Boliek are very experienced in helping with the surgery and outpatient management. Our two nurse practitioners Marcia Haines and Osiris Ahuatzin are exceptional with the inpatient management. They are available all day on the inpatient surgical unit where the stature patients stay for three to four nights. The entire team approach is coordinated by, Angelique Keller, RN. Angelique who is also a nurse, is present at each stature consultation. She is the central point person who helps with all aspects of care including booking of consultation and surgery, patient housing, etc.

What is the most important consideration when choosing a limb lengthening surgeon and center?

SAFETY is number ONE.

EXPERIENCE is number TWO.

RELIABILITY is number THREE

REPRODUCIBILITY is number FOUR

Limb lengthening can lead to many complications. Unlike other cosmetic surgery, limb lengthening can lead to chronic pain and disability. Therefore the most important factor to consider is NOT COST, but rather SAFETY.

There are many centers around the world offering stature lengthening at cheaper prices than at the Paley Institute. There are no other centers offering limb lengthening as safely as at the Paley Institute. SAFETY is the most important consideration when choosing where to go. Safety comes from EXPERIENCE and organization. At the Paley Institute, we provide the most experienced limb lengthening team in the world with the best safety track record in the world. The multidisciplinary, organized team of surgeons, anesthesiologists, medical doctors, nurse practitioners, physician assistants, nurses, physical and occupational therapists, orthopedic technologists, and patient coordinators, etc. all of which are dedicated to the limb lengthening process makes it safe, secure and as streamlined as possible. The RELIABILITY of the team gives peace of mind knowing that 24 hours a day, 7 days a week, 356 days a year the team is there to provide care for all of our patients from around the world. Finally, we have achieved excellent results in all of our patients, demonstrating the REPRODUCIBILITY of the methods we use.

Can I get financing to help pay for the surgery?

We do not provide financing. If you need financing, you will need to obtain this privately on your own prior to surgery.

What is covered in the cost of surgery?

1. Hospital stay for up to 4 days. There is a surcharge for patients staying longer than this.
2. All hospital charges relating to the operating room and recovery room.
3. Implant costs: Two Precice-STRYDE lengthening rods.
4. Anesthesiologist fees.
5. Surgeon fees.
6. Surgery assistant fees.
7. Hospitalist fees (internal medicine doctor available during the entire hospital stay).
8. Radiologist fees (includes their reading fee of all the x-rays).
9. All hospital diagnostic tests during the admission are included.
10. All x-rays: up to 12 weeks (surcharge after 12 weeks).
11. All office visits: up to 12 weeks femurs; up to 14 weeks femurs plus tibias combined (surcharge after 14 weeks).
12. Transportation to and from the office and hospital (5 days per week) for office visits if you stay at one of the approved extended stay hotels (see list below).
13. Wheelchair, walker, crutches and bedside commode as needed for post surgery; provided as part of discharge from hospital.

What is covered in the physical therapy fees?

1. Daily (5 days per week) one hour of physical therapy at the Paley Institute outpatient rehab center (there is no PT on weekends); up to 12 weeks femurs and tibias (surcharge after 12weeks); femur plus tibia overlapped up to 14 (surcharge after 14weeks).
2. Transportation to and from the PT center to extended stay hotels on the approved list. PT is located next to our office and on the grounds of the hospital campus.

What is not covered?

1. Medications and pharmaceuticals (e.g. pain medicine, anticoagulants, supplements e.g. calcium, bone health now, Vitamin D, anti-inflammatory medications).
2. Accommodations in West Palm Beach.
3. Travel to and from West Palm Beach.
4. Travel to the hospital on weekends (although the hotel shuttles will usually provide this for free).
5. Food and other supplies during the stay in West Palm Beach.
6. Entertainment or Internet.
7. Home health aids (nurses, homemaker, etc.).
8. Additional PT beyond the one hour a day for 5 days a week. (patients may purchase more PT for a second hour a day or pool therapy).

When do I have to send the payment and do I need to leave a deposit to hold the surgery date?

Full payment is due two weeks before surgery or the surgery will be canceled. Payment can be made by wire transfer or certified check. If you want to use a credit card there will be a surcharge of 4%. A non-refundable deposit of \$10,000 is due at least two months before surgery. The deposit can be made by credit card on the phone or by wire transfer. We will not hold a surgery date for more than 3 days without a deposit. Cancellation, or change of surgery date by the patient or their family or representative with less than two months notice, will result in loss of the deposit. The deposit is fully refundable if changes or cancellation of surgery are more than two months before the booked surgery date. The deposit money is part of the total fee and will be credited to the total balance due unless it is forfeited. In the case of late cancellation, rebooking of the surgery will require a new deposit.

How are the scars from surgery?

We use a minimally invasive method to put the lengthening device into the bones. A 1 to 1.5cm incision is made at the hip area, and 4 or 5 less than one cm incisions are made on the side of the thigh. These scars are so small they are not very noticeable. Most look no bigger than a mosquito bite. For the tibia there are more incisions. The incision to cut the fibula is about 2-3cm long and the peroneal nerve decompression incision is about 5cm long. The nail insertion incision is again 1 to 1.5cm long and the rest of the incisions all less than one cm.

How painful is limb lengthening?

Immediately after surgery, there is post surgery pain. Most patients have epidural anesthesia or PCA (patient controlled analgesia). We often inject a long acting slow release local anesthetic into the wounds (Exparel), which lasts for 96 hours. These methods offer excellent post-operative pain control. Patients are switched to oral pain medication in preparation for discharge from the hospital. After discharge, all patients receive a prescription for oral pain medication. During the first two weeks after surgery most patients still feel some post-surgical pain. Once this is gone, the comfort level is greatly improved. The most painful times are during stretching exercises during physical therapy and when going to sleep. We often prescribe some medication to help with sleep. Most patients do not complain of much pain during the daytime. The actual lengthening process is usually painless. Most patients have little to no pain during the majority of the lengthening.

What can I do to prepare for surgery?

a) Education:

- (i) Read all printed materials we provide.
- (ii) Book a consultation and have your questions answered in person
- (iii) Email us any additional questions

b) Physical preparation:

Stretching exercises may help.

For femur lengthening:

- 1) iliotibial band; lie on your side, extend your hip so your thigh is in line with your body and flex your knee. In that position, try and bring the flexed knee towards the ground. Also, you can do cross-leg stretches with the hip straight. These stretch the IT band.
- 2) quadriceps and especially the rectus femoris muscle (bend knee with straightening of hip at the same time. Can be done standing while pulling foot behind butt and leaning back or kneeling with leaning back).
- 3) Hamstrings: knee straightening while flexing hip.

For tibial lengthening: Achilles tendon: heel cord; maximum dorsiflexion (foot up) with full knee extension (straight).

- c) Stop smoking and exposure to second hand smoke.
- d) Stop all anti-inflammatory medications, aspirin and fish oil supplements at least one month before surgery.
- e) Notify us if you are taking oral contraceptive medicines or estrogen/progesterone for any reason, as these increase the risk of blood clots (deep vein thrombosis and pulmonary embolus). If you wish to continue taking these you will have to be treated with an anticoagulant Xarelto during the entire distraction phase.
- e) Socio-economic preparation:

Organize your life so you can put it on hold for at least three months. You will need to stay in West Palm Beach for the duration of the distraction phase. This will vary according to which type of lengthening strategy you choose. Depending on your profession you may or may not be able to return immediately to work after completing the distraction. Prepare your finances so you can not only afford this surgery but also afford any possible complications from this surgery that can arise. These are not common but can be costly when they do occur.

Be prepared to be single-minded and not distracted during the process so you can devote all your energies and attention to the limb lengthening process and rehabilitation.

Visit West Palm Beach and check out where you will stay. Arrange for someone to come with you or be prepared to hire a home health aid to help you (see separate section on this).

Organize a leave of absence from your job so that you don't feel the pressure of the need to get back to work.

Do I need a psychological evaluation before surgery?

NO

For my first twenty-one years, I used 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 on patients with a body dysmorphic psychosis as well as to make sure that patients have realistic expectations and the proper support required to undergo this procedure.

Do I need to book a consultation before surgery?

HIGHLY RECOMMENDED

Although the information we provide via email is very educational, it is preferable to be assessed in person. This helps you become as prepared as possible for the surgery. We have found that patients who do not come for a consultation are not as prepared for the surgery and have much more difficulty when they undergo this procedure.

If you insist on having the consultation the week before surgery, please keep in mind you will not be as well prepared. Furthermore, you will have paid your deposit and it will be non-refundable at this stage should you change your mind. There is no problem if you change the strategy of lengthening and we will do everything to accommodate you. You will still need to pay separately for the consultation.

What is involved in the consultation and how much does it cost?

The consultation starts with a specialized standing x-ray called an EOS scan. This is a low radiation dose scan of your entire body from head to foot in a biplanar fashion (front and side at the same time). This may be done the night before the consultation if the consultation is first thing in the morning.

You will meet with one of our physician assistants as well as with Angelique Keller. After that you will see Dr. Paley. Dr. Craig Robbins will also try to meet with you. They will measure and evaluate you and your x-rays, including a physical examination of range of motion, muscle tightness, height, proportion, etc. They will measure your bone proportions from the EOS scan. The normal proportion of the tibia to femur lengths is 0.80 +/- 0.02. If the ratio is greater than 0.82, your tibias are relatively long compared to the femurs and femoral lengthening may be preferable, while if the ratios are less than 0.78 then tibial lengthening may be preferable. This must be tempered by the amount of lengthening desired since up to 8cm can safely be done in the femurs and usually only 5cm in the tibias.

Dr. Paley will then come in. He will discuss your goals and suggest the best lengthening strategy. He will advise the advantages and disadvantages of the various lengthening options. He will help you customize a lengthening strategy for you according to your specific height increase goals, proportions, level of affordability and time availability. Dr. Paley will go into these and other aspects of lengthening in detail and try and answer all your questions.

After the consultation with Dr. Paley, the PA or Dr. Robbins will stay to answer any additional questions that may remain. Angelique will then take you over to the physical therapy department for a tour. If possible, we will try and introduce you to other stature lengthening patients if they are around at the time. We cannot guarantee this as these other patients are scheduled for PT independently of our consultation schedule. We must also request permission from them. We respect and guarantee all patient privacy.

Can I take a tour of the Paley Institute in advance of the surgery?

Yes, a tour is part of every consultation.

How do I book a consultation?

Please email **Angelique Keller** (akeller@paleyinstitute.org) who will help you find a date for the consultation.

How do I book a surgery date?

Please email Angelique Keller (akeller@paleyinstitute.org) who will help you find a date for surgery. To secure a surgery date, you will have to make a deposit via wire transfer, check or credit card as explained in a previous section.

How do I protect my privacy regarding my consultation and surgery?

At the Paley Institute we are HIPPA compliant. We cannot and will not release your name or medical information to anyone unless you authorize it. The only exception to this is minor patients, in which we communicate private information to their parents or guardians. If you are over age 18, we cannot even speak to your significant other, parents or children without your permission.

Will I need to come in the day before surgery?

You will have a preoperative visit with the surgery team to go over the consent form and all of the paperwork. You will also have an appointment with our preoperative nurse and anesthesiologist. You can discuss your anesthesia and postoperative pain management in advance of the surgery. You will be given instructions for surgery. You should not eat or drink after midnight and you should come in two hours before your scheduled surgery time, to the preoperative area in the Kimmel building on the campus of St. Mary's Hospital, 901 45th St.

How long is the hospitalization?

The hospitalization is usually 3-4 nights. At St. Mary's Hospital, this is in a private room on the beautifully renovated surgical care unit in the Waters 3 Pavilion if you are over 18. If you are under 18 years, your private room will be on our newly renovated Pediatric Surgical Floor on the third floor of the Palm Beach Children's Hospital adjacent and connected to St. Mary's Medical Center.

What will happen during the hospitalization?

After surgery you will be taken to the recovery room for an hour or two before going to your room. You will receive an iron infusion which helps to replenish and blood lost and prevent a transfusion. If you have family or friends, our patient liaison will keep them informed during the surgery and then organize for Dr. Paley to speak to the family after the surgery. We will then bring the family or friends into the recovery room (PACU) after the surgery to be beside the patient. You will have an IV and a Foley catheter (bladder catheter). If an epidural catheter is used, the Foley will remain in place until the epidural catheter is removed. In most cases we don't use an epidural. If there is no epidural, then the Foley can be removed one or two days after surgery. While in the hospital, you will start on a blood thinner to prevent blood clots. The nurses will make sure you are comfortable and positioned in such a way as to prevent pressure sores. You will have blood test drawn to check your blood level. Even if your blood level is low we rarely need a transfusion. Each day our Nurse Practitioners will come by to check on you. You will also see the rest of the surgical team, as well as Drs. Paley and/or Robbins. The epidural or PCA will be discontinued usually after two days. A physical therapist will come each day to start teaching you to move around and to become more independent. You will learn skills such as transfers to and from the wheelchair and bedside commode, etc. Once you are mobile enough, you will be discharged from the hospital with instructions.

Will I require a blood transfusion?

We rarely transfuse patients after surgery. We do give intravenous Iron to all patients to increase their blood levels faster. Very few patients lose enough blood to require a blood transfusion before surgery. Auto-donation is an option but not required. We use blood from the blood bank if needed. The loss of blood occurs not only during surgery but also after surgery for a couple of days. The transfusion, if needed, almost always occurs one or two days after surgery. The risks from this are very minimal. Less than 10% of our patients require a transfusion.

Will I leave the hospital with a wheelchair, walker, and/or crutches?

Yes. You will be given a wheelchair and a walker to take with you. Our nurse case manager will organize all of this for you. Our inpatient physical therapists will teach you how to do transfers from bed to chair to toilet. You will start walking with a walker and later transition to crutches as an outpatient. With the PS nail you will be allowed weight bearing as tolerated right away. Due to pain you will not put full weight and will use your arms for about two to three weeks.

What medications will I take after discharge from the hospital?

Blood thinner to prevent blood clots: Since you have the PS nail and are allowed full weight bearing as tolerated we only use 81mg aspirin twice a day for prophylaxis. If you are on the birth control pill and do not wish to stop or if you have other known risk factors, then you will be started on Xarelto 10 mg daily (approximately \$313.99 per month). For P2.2 we use Xarelto.

Pain medicine (as needed): Percocet 5/325 # 90 pills an 7 day supply (approximately \$44.97); we refill this as needed during the lengthening. Due to the opioid crisis, the new law is that you must make an appointment with our Dr. or NP to have this refilled.

Muscle relaxant (optional): Valium 5 mg # 90 pills one-month supply (approximately \$24.00)

Vitamin D and anti-inflammatory medications are also part of the regimen.

Where will I stay after discharge from the hospital?

There are several options.

- 1) The most common place to stay is at one of our extended stay hotels on 45th Street. This is a few miles west of the hospital and the Paley Institute, on the same street. The cost of stay at these hotels varies with season and availability. High season is winter and low season is summer. Please book as far in advance as possible, especially for in-season. Always ask for the Paley rate.

(Shuttle service provided to the hospital)

Homewood Suites By Hilton - 561-682-9188

Residence Inn By Marriott - 561-687-4747

Springhill Suites By Marriott - 561-689-6814

(Near Airport, shuttle service not provided)

Doubletree By Hilton - 561-689-6888

- 2) Renting a condominium or house.

- 3) Staying at another hotel.

Is transportation available to and from the hospital to place of residence?

Wheelchair transportation vans are available to take you to and from the hotel to the hospital only if you stay at the extended stay hotels listed above.

How long do I need to stay in West Palm Beach?

You need to stay until the end of the distraction phase (lengthening). The distraction phase length for femur lengthening is one day for each millimeter of planned lengthening. E.g. 80mm = 80 days. We don't start lengthening for between 7 days. Therefore if we don't start lengthening until the 7th day, 80 days for 80mm plus 7 days = 87 days (12 weeks) for 80mm. Tibia lengthening is $\frac{3}{4}$ mm per day compared to 1mm/day for femur lengthening. For tibia lengthening, the distraction phase for 50mm is 10 weeks plus one week before we start lengthening for a total of 11 weeks.

Will I need help to look after myself?

Yes, you will need help for the first two to three weeks. You either need to come with someone who can help look after you or else you will need to hire a home health aid for the first two to three weeks. We can help you arrange for this. The hourly cost of this is approximately \$18/hr. In the first week after discharge from hospital, you will require more hours of help and less help as time goes on. You need to budget for this if you are coming alone. At the very least, everyone needs help for the first two weeks after discharge from the hospital. If you do not have anyone with you, this will cost you at least 16 hours a day of help at \$18 per hour (for two weeks the cost can be up to about \$4000).

How much weight bearing is allowed during lengthening?

With the Precice-STRYDE, you will start walking full weight bearing as tolerated with a walker or two crutches right away. This means you can put as much weight as you can tolerate. You will then be tested by our physical therapist with a special single leg standing test. This test has you step onto a scale and stand on one leg. If you can do this it shows that you have your balance back and it also shows peak single leg stance load which is higher than your weight. If the load is still within the fatigue strength limit of your nail diameter you may walk with no crutches. You will need to use a single cane for walking up and down stairs and for stepping one or off of a curb. If a patient exceeds certain weight limits related to the diameter of the PS nail, then we may ask you to walk with one or two crutches but full weight bearing. . This is quite uncommon.

Please ignore this next section if you are having the Precice-STRYDE nail:

For P2.2 users: During distraction, the bone ends are held separated by the implantable rod. This rod is secured to the bone by screws at either end. The diameter of the rod ranges from 8.5-10.7-12.5mm. The screws have a diameter ranging from 4-5mm. With enough repeated loading, the screws of any implant will bend or break. No implant of any make or design is immune to this. The heavier the patient, the greater this risk. This is true of any implantable lengthening nail no matter what the material it is made of and no matter what you are told by the manufacturer or the surgeon.

We permit full WB when we see complete bridging of the bone on the x-ray. At that point, the bone is taking the load and protecting the rod. During the lengthening, we allow WB using crutches or a walker and unweighting the legs using the arms. The amount of WB allowed depends on several factors: the weight of the patient, the diameter of the rod and the bone being lengthened. For the largest diameter Precice2, 12.5mm, we allow up to 75lbs (34kg) on each leg. This means that when a patient is standing on two legs with two crutches on the ground, they can take up to 150lbs (68kg). However, when walking and transferring load from one leg to the other, a patient **MUST USE TWO CRUTCHES** on the ground and unweight themselves to the 75lbs (34kg) weight with each step. Patients must **NEVER** walk with one crutch during the distraction phase no matter how much they weigh. During the consolidation phase, the same rules apply until the surgeon increases the WB quota. To know how much WB is being done, a patient can stand on a bathroom scale until it reaches the desired number (e.g. 75lbs). For the smaller diameter rods, 10.7mm and 8.5mm, no more than 50lbs (23kgs) is allowed per leg.

Am I allowed to drive?

Patients undergoing implantable limb lengthening can drive once they are not taking narcotics during the day. They do however need to be able to get in and out of the car on their own. Again we recommend the use of a single cane when getting in and out of a car.

How often will I have physical therapy?

Daily, 5 days a week for the entire distraction phase. (7 days a week may be available for an additional payment of \$220 per session-please inquire regarding this)

During the consolidation phase, the patient needs to continue with PT but less often (2-3 days per week). This

is usually done closer to home since most patients depart from West Palm Beach to return home. If you plan to stay locally for some time, we can arrange physical therapy at our center. The additional cost of this is as noted above and can be paid on a weekly basis.

Daily home exercises are required by the patient throughout both distraction and consolidation phases.

Who does the actual lengthening and where?

The patient or their helper at their place of residence does the lengthening during the lengthening phase. The lengthening is done in 0.25mm increments, 4 times a day for the femur and 3 times a day for the tibia. For simultaneous femur plus tibia lengthening, both bones are lengthened only 3 times a day. The lengthening is done using a special device called the ERC (External Remote Control) device. Our orthopedic technologist trains each patient to do this until they are comfortable using the ERC device. Each patient receives an ERC to take with them. The ERC must be returned at the end of the lengthening to avoid being billed by Ellipse Technologies for the device (\$10,000 cost). As long as it is returned, there is no charge for the ERC device.

How often am I seen by the doctor or physician assistant?

Every two weeks at the Paley Institute office.

When will I have x-rays done?

Every two weeks, x-rays of each bone being lengthened are taken. Again this is done at the office visit.

Once I am done lengthening how soon can I go home?

Immediately.

What is the follow-up after I go home?

Send monthly x-rays to Dr. Paley. The best way is to email these to dpaley@paleyinstitute.org. If you cannot figure out how to email x-rays, mail the disc to:

Paley Institute, Kimmel Building, 901 45th St. West Palm Beach, Florida 33407

When can I resume full weight bearing without crutches or a walker?

For the PS nail, a couple of weeks after surgery. For P2.2: After reviewing the x-rays, Dr. Paley will email you how they look and whether you can resume full WB. This usually happens after one or two months from the end of distraction. Most patients can return to full WB one month after a 5cm femur lengthening and two months after a 5cm tibial lengthening. Most patients can return to full WB two months after an 8cm femur lengthening.

When can I return to sports?

For both PS and P2.2, you have to regain your motion and then your muscle strength before returning to sports. If you work hard at this you can go back as early as six months after surgery. The doctor individualizes this for each patient. Most patients can start to run one month after being freed to stop using crutches. They can return to other sports after one month after starting to run.

What are the results from internal lengthening of the femur and tibia?

I have performed implantable lengthening of the femur for 17 years, and have used the Albizzia (1996 to 2000), the ISKD (2001-2010), the Precice1.0 (2011-2013) Precice 2.0 (2013), Precice 2.1 (2014), and Precice 2.2 (2015 to present). I have the world's largest experience with the ISKD (more than 300 cases) and the Precice (more than 900 cases) devices. To date, all of my patients have achieved the goals of treatment and have returned to full activities including sports. Articles of our published results are available upon request but are also posted online. I was the first surgeon to use the PS nail. The first one was implanted in May 2018.

Do I need to have the nails removed?

Yes. All of these nails should be removed. Removal timing is not critical, but most often is done one or two years after the original surgery. The reason to remove the nails is that they are made from metal have moving parts that generate metal ions over the course of many years. While they are inert and there is no urgency to remove them, it is recommended to remove them one or two years after insertion. The nail also has a rare earth magnet inside. This is sealed from the body inside a waterproof chamber. It is possible that after years this seal could leak and the rare earth magnet would be exposed to body fluids. As such, it is preferable to remove this device before this could happen. Finally, MRI is not permitted with the nails in place. Since you never know when you need an MRI it is better to remove these so that this does not become an issue.

What is the cost of removal of the Precice devices?

The cost of removal is separate and is not included in the treatment. The cost of removal is \$18,000 for bilateral femurs, \$22,500 for bilateral tibias (including tibio-fibular screws and blocking screws) and \$28,000 for simultaneous bilateral femur and tibial Precice removal. If you combine removal with a lengthening in another segment there is some reduction of cost.

How soon can I have another lengthening (e.g. both tibias)?

If you choose to have a second lengthening done, an interval of six to twelve months is recommended between lengthenings. It is possible to overlap the femur and tibia lengthenings and this option can be discussed with Dr. Paley.

What are the main risks and potential complications that can occur?

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 some of the potential complications:

Fat Embolism

This is a complication that is very rare and which can be prevented by venting the bone during the reaming (drilling) of the medullary canal of the bone. The way I vent the canal is to drill holes at the planned level of the osteotomy prior to the reaming process. As the pressure builds up in the canal, the reamings squirt out of the holes, preventing fat embolism. Fat embolism can make a patient very sick requiring stay in the ICU. Patients can even die from fat embolism. I have diagnosed fat embolism five times since 2011 when we started with the Precice nails. In all cases it resolved on its own and only needed to be treated with oxygen by mask for additional one or more days. No patient went to the intensive care unit and there have been no deaths or any serious sequella of this fat embolism complication

Deep Vein Thrombosis (DVT) and Pulmonary Embolism (PE)

DVT can occur after any orthopedic surgery or after any fracture. Fortunately, we have a very low rate of this complication. Prevention is key. We use anticoagulants after surgery in the hospital and each patient is sent home with a prescription for an anticoagulation drug to be taken until the end of the distraction phase. While I have seen very few cases of DVT, fortunately none of them resulted in pulmonary embolism (PE). PE occurs if the clot dislodges and wanders to the lungs. It can cause shortness of breath, chest pain and even death. This is why we are careful to protect against this. Taking oral contraceptives and smoking increases the risk of DVT. All of our patients are placed on an anticoagulant, either aspirin for PS patients or Xaralto for P2.2 patients or for high risk patients.

Premature consolidation

In this complication, the patient bone bridges the gap and prevents further lengthening. Premature consolidation (PC) can occur with any lengthening 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 a small outpatient surgery to re-break the bone through a tiny incision. The incidence of this complication is about 1%.

Delayed or failure of consolidation

Slow or failed bone healing can occur with any lengthening surgery. The best treatment is prevention. We start by identifying factors that may slow healing prior to surgery: low Vitamin D level, smoking including second hand smoke, anti-inflammatory medicine use, anti-convulsant medication use, menopause, and other medication use (e.g. acutane). We also recommend supplements to help the bone heal faster (Silical, Silical2 and Boost). If a patient's blood work shows a low Vitamin D level, then Vitamin D supplements are recommended. We try and identify these factors in advance of surgery.

Since 2011 when we started with the Precice nail, not one patient required surgery to treat delayed or failure of consolidation. All were successfully treated by nonoperative methods including Zolidronic Acid infusion, parathyroid hormone (Forteo), Vitamin D and other supplements and Exogen bone stimulator. If delayed healing occurs despite all of the above steps, we start using the accordion technique. Using an ERC device the bone is compressed one mm per day and distracted one mm per day. This cycle is repeated several times a day. This stimulates bone healing and avoids the need for surgery.

If surgery is necessary we know how to get the bone to heal with surgery. When we used the ISKD failure of bone healing occurred not infrequently. We therefore got very proficient at using bone and bone marrow grafting to get the bone to heal. While we hope not to ever need this with the Precice or STRYDE nails if we do need this as a fall back we are very experienced on managing this complication as needed..

Nerve injury

Nerve injury can occur with any lengthening surgery but is 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) occur, 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. With its excellent rate control with the Precice & STRYDE nails, nerve injury is very rare. Nerve irritation can also be treated medically using Neurontin or Lyrica.

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 his or her 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. The controlled rate of lengthening with the Precice makes the risk of muscle contractures and muscle spasm less. 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 associated expenses. 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 (e.g. iliotibial band). 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. 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 can 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 fix the fibula to the tibia and the method of cutting the fibula bone.

Axial Deviation

Axial Deviation or deformity secondary to lengthening is not an uncommon problem. It can usually be prevented. Varus deformity is more likely with the use a trochanteric nail. For this reason I prefer to use a piriformis entry nail. In proximal femur lengthenings if the osteotomy is done where the bone is tight around the nail the likelihood of varus angulation is unlikely. If a more proximal osteotomy of the femur needs to be performed, a medial blocking screw can prevent varus deviation.

Axial deviation is a more common problem in the tibia. The tibia tends to lengthen into valgus and procurvatum. To prevent this the nail should be inserted at the correct starting point, which is very high and as posterior as possible on the tibia on the lateral and centered on the knee in the frontal plane. If the nail has space between it and the lateral cortex above the osteotomy, a blocking screw should be inserted in this space. If the nail has space between it and the posterior cortex then another blocking screw is inserted there. I designed the STRYDE nail to resist axial deviation by also offering a third proximal locking screw (P2.2 only has two). If all these precautions are followed no flexion or valgus deformity develops with lengthening.

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 over 20,000 limb-lengthening surgeries. This is more than any other surgeon in the US or the entire world. The majority of these surgeries were for LLD. Over 1500 were for short stature related to dwarfism and cosmetic reasons.

Dr. Paley's history with cosmetic lengthening for stature is as follows:

Dr. Paley started with the *Ilizarov method* for lengthening of both tibiae in 1987 and soon after switched to the *lengthening over nail* method he had developed in 1990 and published in 1997. Although his results were excellent, the scars, the pain, the suffering, and the pin site infections were not conducive to a cosmetic procedure.

He sought a fully implantable lengthening solution. When the *Albizzia femoral nail*, developed by Guichet and Grammont, became available, he worked with the French company that made that nail to develop a tibial lengthening Albizzia for stature lengthening. He started using the femoral and tibial Albizzia 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, led him to stop using this non-FDA approved device. This device is still being used in Europe under the name Guichet nail and Betz-Bone. While they have modified this nail to a small extent, it is still the original Albizzia nail that Dr. Paley abandoned in the 1990's. There are much better devices now and the use of this older nail should be abandoned.

In 2001, when the *ISKD*, developed by Dr. Dean Cole, was approved by the FDA and marketed by Orthofix, became available, Dr. Paley was the first surgeon after Dr. Cole to implant this device. This device turned out not to be a great device for stature lengthening. Although he performed over 350 ISKD implantable limb lengthenings, more than anyone in the world, the lack of rate control with this device caused many complications. The ISKD either lengthened too quickly or failed to lengthen in the middle of the distraction phase. This led to increased numbers of procedures to treat complications. For stature patients this also meant increased costs. Despite this, Dr. Paley's final results were excellent in almost every patient with the ISKD. The ISKD, the Albizzia and the Fitbone are all contemporary devices. They can all be considered first-generation lengthening nails. They all suffer from significant mechanical and other problems. The Albizzia and ISKD have rate control issues and none of these three nails can go reverse.

The first second-generation device on the market was the Precice. On December 1, 2011, Dr. Paley implanted the first 3 Precice nails in the United States. By November 2013 when the improved model he helped develop the P2 was released, he had performed over 155 P1 cases. At present, he has implanted more than 900 Precice nails (more than any other surgeon worldwide). These cases include femoral, tibial and humeral lengthening with the Precice. The results with this device were excellent. The most serious shortcomings of the device were breakages of the nail or its lengthening mechanism that occurred mostly with the P1 and to a much lesser extent with the P2 and P2.1. There has not been any breakage with the P2.2 which was also designed in collaboration of Dr. Paley. Dr. Paley was the first to identify the problems and weaknesses of the P1 and together with Ellipse Technologies, set out to redesign the nail. The first improved device was the P2, with increased strength of the nail shell by up to 4X and of the mechanism by up to 3X. The P2 was launched in November 2013 and Dr. Paley again was the first to use this improved device. This eliminated the problems with the mechanism failures and reduced the breakages significantly. Dr. Paley then recognized a more minor problem in the P2 with fragmentation of a washer that helps connect the telescopic parts of the nail together. This led to further design changes and the emergence of the P2.1 in December 2014 and P2.2 in May 2015. Since then there have not been any further breakages. Ellipse was acquired by Nuvasive in 2015 and Nuvasive Specialized Orthopedics (NSO) was created to support and develop the Precice nail. NSO took up a project started between Dr. Paley and Ellipse; the creation of a full weight bearing nail to permit Stature Lengthening patients to walk without crutches. This project started by thickening the existing Precice nail. It then followed with development of a Cobalt Chrome Nail which was later abandoned in place of a Stainless Steel nail. After 4 years of work on this, the Precice-STRYDE was born and first implanted by Paley in May 2018.