NuVasive
Specialized Orthopedics™

Precice® and Precice Stryde™ Limb Lengthening Systems Patient Management Guide

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This document offers guidance but, as with any such technique each surgeon must consider the particular needs of each patient and make appropriate clinical decisions as required. The topics and tips/tricks are for consideration rather than guidelines for treatment.

Contents

Introduction

Intramedullary lengthening nails have revolutionized the field of limb lengthening. Compared to external fixator lengthening patients, intramedullary lengthening patients are more comfortable, maintain their range of motion better, and have higher overall satisfaction. However, surgeons should be careful to avoid thinking that intramedullary lengthening is effortless and that all patients will automatically do well simply because the device is elegant and relatively easy to insert. The same pitfalls and potential complications of limb lengthening with external fixators are still present with intramedullary lengthening nails. In some cases, such as patients with joint instability, these concerns may be magnified with intramedullary nails compared to external fixators. This guide is designed to help you navigate the postoperative management of a routine intramedullary lengthening patient and will try to address the most frequently asked questions involving their use.[1]

Patient Selection

All limb lengthenings should be viewed as a journey shared by the surgeon and the patient. Every patient and surgeon wants to have a successful end to this journey. However, there is a big difference between a turbulent postoperative course that eventually reaches a successful outcome after repeated trials and tribulations and a postoperative course that sails smoothly into a successful conclusion. Sailing smoothly through the postoperative period starts with choosing the right patient for this procedure. At a minimum, the following criteria should be considered prior to agreeing to start this journey:

1) **A strong family/friend support system must be present.**
   The recovery process will take months. The patient will need assistance with daily tasks, daily ERC and stretching treatments, and transportation to and from multiple clinic/therapy appointments. If the patient does not have a strong support system, this may not be the right surgery for them. Have your clinic team screen the patient for any potential concerns regarding the patient's support system.

2) **The patient needs to be reliable.**
   The limb lengthening journey will require the surgeon to trust that the patient is genuinely going to follow the postoperative treatment regimen. The patient will be expected to adhere to specific weight bearing restrictions and perform daily range of motion exercises for an extended period of time. The patient will need to return to the clinic at regular intervals of time to ensure an optimized outcome.

3) **Bone and implant compatibility.**
   Before offering an intramedullary lengthening device as a surgical option, double check that the bone canal diameter and bone length will accept the implant. Determine your potential osteotomy site and make sure you are comfortable with its location. If deformity correction

1. Herzenberg JH, Standard SC, Specht SC. Limb lengthening in children with a new, controllable internal device. European Paediatric Orthopaedic Society (EPOS); April 17-20, 2013; Athens, Greece.

is planned, make sure the implant and osteotomy site will allow adequate re-alignment. If there are any obstructions in the bone canal make plans for how to manage them ahead of time.

4) **Soft tissue envelope**
Make sure the distance between the skin and the center of the bone will allow acceptable communication between the magnets. Review the published guidelines for the maximum allowable distance for each nail diameter. For potential femoral lengthening patients with large thighs, a retrograde nail may place the magnet in a thinner portion of the thigh than an antegrade nail.

5) **Patient anxiety/depression**.
An assessment of the patient's psychological health is important. Patients with pre-existing depression and/or anxiety may be at a higher risk for a more difficult postoperative course. If behavioral health concerns are identified preoperatively, get psychological services involved in the patient's care. In some cases, postponing the surgery until this component is sufficiently addressed is recommended.

6) **Narcotic dependency**
Similar to the above discussion, patients with narcotic dependence should be evaluated by a pain clinic prior to surgery. Multi-modal pain management strategies that include non-narcotic options should be employed with these patients. Direct communication with their pain health care team is also advised.

Preoperative Recommendations

1) **Previous external fixator**
Many patients have had previous limb reconstruction involving external fixators. There is a small risk of developing an intramedullary infection around the nail from a previously colonized pin site. Try to determine the extent of any previous pin site infections and obtain a preoperative MRI to evaluate the pin sites if there is concern. Be sure to have this discussion with your patient prior to starting the intramedullary limb lengthening.

2) **Knee extension brace**
Unlike lengthening with an external fixator, intramedullary nails cannot be modified to span the knee joint during the lengthening process. Therefore, it is extremely important that the patient maintain full knee extension during the postoperative phase. A custom dynamic knee extension brace should be ordered and fitted preoperatively. It can be placed directly on the patient at the completion of surgery and should be worn daily. It is recommended that the patient sleep in the brace and wear it during the day whenever he/she is recumbent. Use of the brace should be non-negotiable and it should be utilized 12-16 hours

per day at a minimum. This device is considered mandatory for all femoral lengthening patients and congenital tibial lengthening patients.

3) **Solid Ankle Foot Orthosis (AFO)**
For tibial lengthening patients, a solid AFO should be ordered prior to surgery as prophylaxis against the development of equinus contractures. It should be used in the same manner as the knee extension brace.

4) **Physical Therapy Evaluation (Refer to Pg. 19 for Additional Information)**
Physical therapy is such a critical component to the success of each patient that the process should start before surgery. The therapist can familiarize the patient with the daily strengthening and range of motion program that will be required after surgery. Gait training and other concerns can be addressed more effectively before the patient is distracted with postoperative pain, anxiety, and medication.

Suggested preoperative physical therapy program to address impairments detected during exam:

- Hip abduction and extension strengthening
- Quad strengthening
- Ankle AROM, particularly dorsiflexion
- Core strengthening
- Balance/proprioceptive training for lower extremities
- Gait training and recommend postoperative assistive device
- Prescribe HEP for first postoperative week before clinic follow up
    - Isometrics: quad and glute sets
    - AROM: Hip abduction, ankle in all directions, heel slides
    - Stretching: Hamstrings and gastrocnemius

5) **Psychology**
This is an underappreciated but integral part of the management of limb lengthening patients. Having a psychologist available to see the patient on a regular basis will help address the anxiety, stress, frustration, and depression that can arise during the months long postoperative journey. The psychologist can also reinforce alternative pain coping strategies to minimize the need for narcotic pain medications.

6) **Meet previous/active patient**
A patient advocate can be extremely helpful to future lengthening patients. Having the opportunity to meet and talk to a patient currently undergoing lengthening or a patient that has completed the process allows the exchange of information that only a patient could convey. Potential patients find these candid question and answer sessions with real patients priceless.

7) **Education**
Develop an information packet or website with videos (or references to videos) that will instruct the patient on the expected inpatient and postoperative course. The more you can prepare the patient beforehand the smoother the journey will be.

8) **Preparatory surgery**
The preoperative physical and radiographic examinations must determine whether the soft tissues and adjacent joints are adequately primed for limb lengthening. If an unstable joint is discovered, it is prudent to postpone the lengthening until the joint has been stabilized. If there are tight soft tissues, releases or fractional lengthenings; they need to be incorporated into the surgical plan. Remember, tight muscles will only get tighter during the lengthening process.

Intraoperative concerns (specific surgical technique details are covered in other available guides)

1) **Anticipate and address any roadblocks to successful lengthening**
Nothing is more embarrassing than to find out later that the patient left the operating room with an incomplete osteotomy. Spend a few extra moments to ensure the bone is truly separated (translation proves the cut is complete). Consider releasing the IT band in femoral lengthening patients. Perform any necessary additional soft tissue releases as determined by the preoperative examination.

2) **Do not hit the implant during insertion**
The implant should be inserted by hand without straining. If the nail does not pass easily, continue reaming until it can be passed by hand. Hitting the implant forcefully with a mallet to overcome a tight canal risks damaging the internal components and causing the nail to malfunction.

3) **Distraction confirmation**
Before leaving the operating room, test the nail with a one-millimeter lengthening. Any nail issue can then be addressed with the patient still under anesthesia rather than bringing the patient back to the operating room at a later date. If it is unclear whether the nail is distracting after testing with one millimeter, an additional millimeter lengthening should be performed. This can be reversed once the nail function is confirmed, if necessary.
(Tip: If using a laser guided C-arm, mark the position of the laser on the skin after an acceptable pre-lengthening image has been acquired. This will allow the technician to produce an exact replica of the image after the one-millimeter lengthening has been completed.)

4) **Mark the skin**
Do not forget to draw the location of the magnet on the skin before leaving the operating room. Since the first real lengthening will not happen for at least several days, it is easy to forget where to place the ERC on the limb. If you do forget to mark the skin, use the osteotomy incision as a guide to find the magnet based on the osteotomy/magnet location on the radiograph.

5) **Program the ERC**
Take a moment before leaving the operating room while the patient's parameters are fresh in your mind to program the ERC for the patient. It takes just a few seconds and it forces you to review the patient's lengthening plan. It also minimizes inadvertent programming errors by having others do it for you.

6) **Determine the latency period**
Based on your intraoperative experience with the patient, determine the latency period. For the femur, a typical latency period is 5 to 10 days. For the tibia, a typical latency is 7 to 14 days. Factors that will adjust this number up or down include:
a) Patient age (pediatric patients have shorter latency)
b) Osteoplasty location (metaphyseal has shorter latency than diaphyseal)
c) Additional acute deformity correction (increase the latency)
d) Health of bone at osteoplasty site (unhealthy bone require longer latency)
e) Difficult osteotomy (extend the latency period)
f) Patient medical co-morbidities (extend the latency)

7) **Determine the initial rate and rhythm**
The rate and rhythm of the distraction should also be based on the intraoperative conditions. It is better to start more conservative and then speed up later than to create poor regenerate from the beginning. Go especially slowly in tibial lengthening patients. Examples of common rate and rhythm settings:
- Distal femoral metaphyseal osteotomy = 0.25 mm X 4/day
- Femoral diaphyseal osteotomy 0.25 mm X 3/day
- Tibia: 0.11 mm X 6/day or 0.15 mm X 4/day

Inpatient Concerns

1) **Pain management**
Most patients do not have substantial pain after the nail insertion and should be able to go home the day after surgery. The patient should quickly become comfortable with only oral pain medication and valium (if necessary for muscle spasm). A few days' supply is usually all that is necessary to send home with the patient. If your hospital has a regional anesthesia team, peripheral nerve catheters work well and can minimize the amount of narcotics needed.

2) **Inpatient physical therapy (Refer to Pg. 20 for Additional Information)**
Primarily reinforces what was taught to the patient preoperatively. The patient should be touch down weight bearing only with the appropriate assistive device. A wheelchair may be necessary in the early recovery phase for traveling long distances. The home exercise program for first postoperative week before clinic follow up will include:

- Isometrics: quad and glute sets
- AROM: Hip abduction, ankle in all directions, heel slides
- Stretching: Hamstrings and gastrocnemius

3) **Deep Venous Thrombosis (DVT) prophylaxis**
There is no one set recommended therapy but most agree that all adult patients should receive something for DVT prophylaxis. Common strategies are:
a) Tranexamic acid (TXA) 1g IV at time out and another one 3 hours later. Start Aspirin (ASA) 325mg BID POD 1 in the morning X 4 weeks.
b) Xeralto until patient is weight bearing / after consolidation
c) Fragmin for 14 days

4) **Knee extension**
Maintain full knee extension with the use of the dynamic knee extension brace. Using the brace in the immediate postoperative period starts the process of enforcing the importance of wearing it throughout the postoperative period. If a dynamic knee extension brace is not available immediately, a knee immobilizer can be used as a temporary substitute. Avoid resting with the knee in flexion, which occurs when pillows are placed behind the knee. Pillows or blankets behind the ankle will help keep the knee extended.

Distraction Phase

1) **Weekly postoperative clinic visits**
There are many details to monitor during the distraction phase. Weekly visits allow you to evaluate the regenerate formation and joint range of motion and respond in a timely manner. Sometimes modifications need to be made quickly to the treatment plan to avert complications which visits every 14 days may not allow.

2) **Assign a contact person for the patient**
Patients will often have questions or concerns at home once their treatment begins. Having a reliable way to communicate with your team is important to the patient. Make sure they have a contact person's phone number or email address that is monitored every day. Good customer service will be appreciated by your patients.

3) **Weekly physical examination**
The following items should be included in your weekly patient interaction during the distraction phase at a minimum:

- **Assess pain level**
  Intramedullary limb lengthening should involve minimal discomfort. If the patient is continuing to have substantial pain after surgery look for a source (incomplete osteotomy, hardware malfunction, fracture etc.). If the patient was pain-free and begins to have pain this is a clue that something is not right. Stop and search for a reason, don't ignore it. (Premature consolidation, soft tissue stretch limit, hardware failure, fracture, etc.)

- **Assess range of motion**
  Every visit needs careful examination of the joint range of motion above and below the lengthening segment. Subtle loss of knee extension can be the first indication of an impending joint subluxation. Keep a weekly record of the amount of each motion to use a comparison. Guidelines for each joint:

  - Hip – maintain full extension and hip abduction to 45°
  - Knee – maintain full extension at all times, flexion should remain between 60-90°
  - Ankle – maintain dorsiflexion to neutral

  If your patient is losing range of motion, then this needs to be immediately addressed. Determine if the patient is diligently performing the home exercise program or not. Increasing the number of formal physical therapy visits may be necessary combined with slowing or stopping the lengthening until the range of motion returns.

- **Assess wound healing**
  The surgical incision sites should be healed within 7-10 days. Although infection is rare, make a habit of glancing at every incision site each week. Patients with previous external fixators have a small chance to develop a deep infection from a previous pin site.

4) **Weekly radiographs**
   There are multiple details to examine on each set of the weekly radiographs. Develop a mental checklist to ensure that you do not overlook any of these items.
   - **Implant integrity**
     Check that the nail is intact and not deforming. It is possible for the nail to bend if it is not properly protected. Check that the interlocking pegs/screws have not changed position or broken. Patients that are weight bearing too early have been known to break the pegs/screws.
   - **Expected distraction amount**
     Measure the distraction length at the osteotomy site in both views and determine if it represents the expected amount compared to the previous radiograph. This is

usually easier to analyze on the lateral radiograph. The implant is very accurate – a 1 mm per day lengthening should have 7 mm of distraction each week. Magnification/calibration markers should be used on the radiograph to increase the accuracy of your measurements. The distraction within the nail can also be measured and should match the distraction at the osteotomy.

- **Health of regenerate bone formation**
  There should be a continuous visible column of regenerate bone forming from one edge of the osteoplasty to the other (best seen on the lateral radiograph). Osteoid should be visible by the third week after surgery. If you do not have a smooth, continuous column of bone slow the lengthening rate or stop for a week and re-check it. Do not keep lengthening in the presence of a "black hole". On the other hand, if thickened bone with a cortical appearance is developing, you may need to speed up your lengthening rate.
- **Joint alignment above and below**
  It is natural to focus on the regenerate bone and the distraction gap when reviewing the weekly radiographs. Train your eye to also evaluate the joint alignment above and below, especially on the lateral knee radiograph. You do not want to miss the earliest signs of joint subluxation. The center of the tibial plateau and the femoral condyles should always be in alignment.

5) **Physical therapy (Refer to Pg. 21 for Additional Information)**
During the distraction phase, physical therapy is critical. The patient should have weekly sessions with the therapist, at a minimum, to monitor his/her range of motion. A daily home program is also mandatory. Here is a suggested therapy protocol:

Distraction phase therapy recipe

- Continue TDWB on affected LE for all ambulation and functional mobility
  - Can progress from walker to crutches if deemed safe by PT and desired by patient
- Continue manual therapy to improve lower extremity ROM
  - PROM of hips, knees, and ankles
  - Grades I-IV mobilization of knees and ankles
  - Patellar mobilization
  - Soft tissue release of quadriceps, hamstrings, gastrocnemius, anterior tibialis
- Continue to progress therapeutic exercise
  - A/AAROM of hips, knees, ankles within weight bearing restrictions
  - Recumbent bike/upright bike with TDWB on affected LE
  - Core strengthening
  - Continue to use electric stimulation if needed for quad contraction

- Goals for this phase of therapy
    - Full knee extension
    - Knee flexion to 90 degrees or more
    - SLR without lag
    - Ankle dorsiflexion to 0 degrees
    - Independence with assistive device (if appropriate for age)
        - Independence in stair negotiation, based on age and cognitive status
    - Independence in bed mobility without limitations by pain
    - Attending school with either assistive device or wheelchair, based on school's policy

6) Rate and rhythm

The initial rate and rhythm is just a starting point. It is purposefully conservative to promote the early formation of healthy regenerate bone. However, it is only a guide and not meant to be universal or inflexible. Every week you should determine whether the rate needs to be increased or decreased depending on the type of regenerate bone you see on the radiograph. The goal is to keep a smooth, continuous column of bone each week. If the regenerate is thickening and developing cortices, then you may want to increase the rate slightly. If there is wispy bone formation, then slow (or stop) the rate until it recovers.
If the rate is producing adequate bone but the pain is getting uncomfortable with each treatment, adjust the rhythm by breaking the total daily lengthening goal into smaller, more frequent increments.

7) Have the patient bring the ERC to every visit

Because the lengthening rate and rhythm can change from week to week, request that the patient brings the ERC each week. This will also give you the chance to troubleshoot any issues the patient may be having with their lengthening sessions at home.

8) Review and reinforce the weight-bearing status

Perhaps the most frustrating aspect of this procedure is the need to maintain weight bearing limits for long periods of time. With the standard Precice nails, touch down weight bearing only during the entire distraction phase is recommended. Early, aggressive weight bearing can cause the nail to bend at the regenerate bone level or the interlocking pegs/screws to break. Reinforce the importance of obeying the weight bearing restrictions with your patient each week. Demonstrating the large gap in the bone that is supported by just two interlocking elements on the radiograph usually helps the patient to understand why it is important to be careful.

(For patients that are using the Stryde implant, up to 150 lbs. of weight bearing are allowed with the smallest diameter implant. These patients can start with partial weight bearing rather than only touch-down weight bearing.)

9) **Psychologist Visit**
During the long road of limb lengthening, the patient will probably become frustrated or depressed at some point along the way. Monitoring the patient's mental health is just as important as their physical health. Having regular sessions with the psychologist can help to keep the patient motivated and keep you alerted to any problems the patient is having.

Determining End of Distraction

As you approach your target lengthening goal, it is not always clear how to determine when to stop the lengthening process. As a rule of thumb, it is always better to leave the "short" limb, a few millimeters shorter than the "long" limb. Inadvertent over-lengthening of the "short" limb (unless part of the preoperative plan) usually creates an unpleasant outcome for the patient.

1) **Radiographs**
   a) **Segment radiographs**
   The dedicated segment AP and Lateral radiographs are measured each week and give the best indication that the lengthening goal has been reached. Cross-check your measurement of the distraction gap with the amount of lengthening in the nail and with the ERC report. All three of these data points should correlate. It is important to have calibration markers on each radiograph to obtain accurate length measurements.
   b) **Standing lower extremity radiographs**
   The standing AP bilateral lower extremity radiograph is the ideal method to determine the leg lengths. However, the patient must stand with the weight evenly distributed between both limbs, keep the operative knee fully extended and have the foot flat on the floor. If any of these criteria are not met, the radiograph will not give an accurate representation of the limb length.

2) **Examination Pitfalls**
Have the patient stand will both legs balanced and both knees fully extended. The pelvis should be level and the posterior sacral dimples should be aligned. Because subtle contractures may have developed during the lengthening, standing or lying supine with both legs fully extended on the table may not accurately represent the leg lengths. If your measurements indicate that you have achieved the goal length, but the standing or supine exam doesn't seem to match, try having the patient sit on the exam table. The upright sitting position with the hips and knees flexed 90° may alleviate the contractures and allow for a better evaluation of the segment lengths. The prone position with the knees flexed 90° can also allow an evaluation of each segment's length.

Consolidation Phase

Once the distraction phase is deemed complete, the patient will enter the consolidation phase. Weekly visits are now replaced by monthly visits. The primary concerns during consolidation are the safe advancement of weight bearing and the maintenance of range of motion.

Monthly Clinic Visit

At each monthly clinic visit the following routine should be followed:

1) **Assess pain**
   The patient should remain pain free during this phase of treatment. New onset of pain should be a cause for concern. At this stage, peri-prosthetic fracture, implant failure, or infection are the primary potential causes of discomfort.

2) **Range of motion**
   Even though the distraction has stopped, it is still possible for the patient to develop a joint contracture/subluxation. A thorough range of motion exam should be part of each visit. The patient should still be using their braces at nighttime. If a loss of joint motion is detected, it should be aggressively addressed with additional therapy, bracing or soft tissue release.

3) **Radiographs**
   The evaluation of the monthly radiographs is essentially the same as the weekly radiographs with the following suggestions:

   a) **Assess implant integrity**
      Continue to monitor the implant for any signs of bending or breakage. In addition, look for any signs of stress at the junction where the implant ends and the empty bone canal begins. (Peri-prosthetic region)
   b) **Evaluate the regenerate bone healing**
      Intramedullary lengthening bone matures from the outside to the inside. Each month should demonstrate further consolidation and thickening of the regenerate bone edges. There should be an easily visible continuous column of bone across the entire distraction gap. The central portion of the regenerate bone should be gradually ossifying each month.
   c) **Joint alignment above and below**
      Even though the distraction phase has ended, it is still important to monitor the radiographic health of the joints at each visit. Joint subluxation has been known to occur in the consolidation phase.
   d) **Measure regenerate length**
      Double check at each visit that the regenerate bone length has been maintained. In rare instances of implant failure, the regenerate can become compressed. Finding a different distraction length compared to a previous one can be the first indication that there is an issue with the implant.

4) Determine weight-bearing status

This is the most vital step of the consolidation process. Once you have examined the patient and the radiographs, you can make a recommendation about the weight bearing status. The typical pattern is:

a) Continue touch down weight bearing for the first month of the consolidation phase
b) Gradually advance the weight bearing at each consecutive monthly visit from partial, to full with support, to full without support

Although the patient will try to persuade you to move faster, this conservative approach will keep you out of trouble. Moving forward with weight bearing too aggressively risks damage to the implant or the regenerate. As long as the radiographs demonstrate progressive thickening of the cortices each month, then the patient can progress with the weight bearing accordingly. If the patient experiences pain when the new weight bearing status starts, it is an indication that the patient is not ready for that amount of weight and should return to the previous level.

Using this weight bearing protocol, the consolidation phase will take four months. You can use this as a reliable estimate for the duration of time required to safely return the patient to full weight bearing without assistance. When discussing the total treatment time with the patient preoperatively, simply calculate the necessary amount of time needed for distraction and add 4 months.

For Stryde patients, this is an accelerated program since they are already starting with partial weight bearing. They will plug into the above formula at the partial weight bearing level. Stryde patients will be progressing at essentially two months ahead of the Precice patient pace. If the patient is struggling or having pain, however, slow down the weight bearing as necessary.

5) Psychology

During the consolidation phase is when the patient may really start to get frustrated. They do not have the weekly gain in length as positive feedback and they are tired of having restricted weight bearing. In this phase, the psychologist can help guide the patient through this difficult time and keep the patient motivated.

6) Physical therapy (Refer to Pg. 22 for Additional Information)

As the corollary to #2 above, even though the patient is seeing the surgeon monthly at this stage, the patient still needs to continue with their weekly monitoring by the physical therapist. In addition to continuing the strengthening and range of motion protocol, the therapist can also educate the patient and monitor their progress during the advancing stages of weight bearing. A suggested therapy protocol for the consolidation phase:

Weeks 1-4

- Continue TDWB
- Continue manual therapy to improve lower extremity ROM
    - PROM of hips, knees, and ankles
    - Grades I-IV mobilization of knees and ankles
    - Patellar mobilization
    - Soft tissue release of quadriceps, hamstrings, gastrocnemius, anterior tibialis
- Continue to progress therapeutic exercise
    - AROM/AAROM of hips, knees, ankles within weight bearing restrictions
    - Recumbent bike/upright bike with TDWB on affected LE
    - Core strengthening
- Goals for this phase of therapy
    - AROM
        - Hip: 75% of preoperative measurements
            - May see deficits in rotation and flexion d/t presence of nail
        - Knee: 0-120 degrees
        - Ankle: 75% of preoperative measurements
    - Strength
        - SLR in flexion, abduction, and extension for sets of 15 against gravity without quad lag
    - Mobility
        - Independence in bed mobility without limitations by pain
        - Independence in stair negotiation, based on age and cognitive status
        - Attending school with either assistive device or wheelchair, based on school's policy
- If patient has met the goals above, s/he can be released to HEP until next appointment with surgeon
    - HEP directed at maintaining and improving parameters addressed above

Weeks 5-8

- Progress to PWB on affected lower extremity as deemed safe by surgeon via x-ray during follow up
    - Time interval is variable based on rate of bone consolidation and size of length discrepancy
- Gait training
    - Continue use of assistive devices
    - Heel strike at initial contact
    - Reciprocal, step-through pattern

- Therapeutic exercise
    - Standing exercises in PWB
        - STS with elevating surface under foot on affected side
        - TKE with PWB (using assistive device)
    - Balance/weight shifting
        - AP and ML within PWB restrictions
    - Continue to progress hip, knee, and ankle strengthening and AROM

- Manual therapy
    - Continue to improve AROM of affected hip, knee, and ankle
        - Focus on knee flexion and ankle dorsiflexion
- Goals
    - Normal gait pattern with PWB and assistive device
    - Nearly full AROM of affected LE
    - Minimal pain and swelling with all activities

Weeks 9-12

- Progress to WBAT then FWB once consolidation determined completed by surgeon, via x-ray
    - Wean from assistive device
    - Address impairments present upon removal of devices
    - Symmetrical weight bearing between BLEs
- Progress strengthening exercises
- Progress balance and proprioceptive exercises
    - Promote FWB or bias weight bearing to affected LE
- Goals
    - Patient ambulating without AD
    - Walk without limp
    - Full AROM of affected LE
- Patient to continue to refrain from running, jumping, or other high impact activities
- Cleared for swimming, biking, walking

Consolidation to Removal Phase

Once the patient has graduated to pain-free full weight bearing, the clinic visits can be extended to approximately once every 3 months. During this phase, you are primarily monitoring the consolidation of the regenerate bone to determine when the patient might be ready for nail removal.

3 month visitation list:

1) **Assess pain**
   Patient should be pain free. Any new onset pain at this point is unusual and should be investigated.

2) **Range of motion**
   The patient should have regained any lost motion by now. The current range of motion should match the preoperative range.

3) **Radiographs**
   a) **Assess implant integrity**
      Examine the entire implant for any signs of bending, interlocking screw/peg position change or breakage.
   b) **Maturation of regenerate**
      This is the key element of the visit. You are working towards deciding when to remove the implant. The regenerate bone should continue to show progressive consolidation and strengthening.
   c) **Length and alignment maintained**
      Measure the distraction gap length and compare to previous radiographs to ensure the length has been maintained.

Determining When/If to Remove Nail

There are no definitive criteria for deciding when it is the proper time to remove the implant. In general, 9-12 months after insertion is the appropriate time to start thinking about the removal. Determining the extent of the radiographic healing is a personal judgement call. The following considerations may help guide your evaluation:

1) Patient should be have returned to full, pain-free participation in his/her normal preoperative activities.
2) Duration of time – at 9-12 months after insertion, the healing should be sufficient.
3) Radiographic evidence of 4 fully developed cortices on the AP and Lateral views
4) The regenerate bone blends into the host bone so well that it is hard to distinguish the old bone from the new bone.

Although the above criteria help determine when it is appropriate to remove the implant, a separate discussion needs to occur with your patient about whether implant removal is necessary. The manufacturer's guidelines recommend removal of all implants. There are theoretical concerns regarding the long term effects of leaving a rare earth magnet inside a patient. In addition, there are concerns about any future MRI studies that the patient may require. While some of the MRI concerns have been addressed (Gomez et al. *JPO* 2018), this aspect of the postoperative care needs to be reviewed with your patients. As a general rule, all implants should be removed from pediatric patients with nail removal from adult patients decided on a case by case basis.

Nail Removal

As discussed above, nail removal is recommended once the regenerate bone is sufficiently healed. Nail removal can be performed as an outpatient surgery. Nail removal is simplified by anticipating it during the nail insertion process. Leaving the interlocking screws/pegs slightly proud at the near cortex will make them easier to find and remove. Since the nail is generally removed at approximately one year after insertion, it is not necessary to add an end cap. The patient may be weight -bearing as tolerated but should avoid strenuous activities for at least six weeks. There are two further discussion points regarding nail removal:

1) **Exchange nailing**
   There are several situations where exchanging the Precice nail for a trauma nail may be a consideration:
   a) There is a defect in the regenerate bone that requires protection
   b) The anterior cortex at the end of the nail has been thinned by the reaming process and needs to be spanned for protection
   c) Maintaining intramedullary fixation in certain patient types (osteogenesis imperfecta, rickets, oncology, etc.)

2) **Future lengthenings**
   In some cases, the patient will require additional lengthening in the future. You must determine whether to leave the implant in situ until the next lengthening or to remove it as a separate procedure. The patient should help guide this decision.

Post Nail Removal Phase

1) **Activity level**
   For routine patients where the nail removal represents the final step in the limb lengthening journey, they are allowed to be weight bearing as tolerated in the immediate postoperative period. The patient should avoid strenuous activities or contact sports for at least six weeks. If there is any concern about the health or strength of the regenerate bone, exchange nailing should be considered (see above). If the patient needs to return to a contact sport, exchange nailing is an option.

2) **Follow up schedule**
   For routine patients, a two week visit to check the nail removal incisions is recommended. A follow-up at six weeks after nail removal with radiographs is used to evaluate the bone healing. Depending on your comfort level with the outcome, this can be the final visit. If you are not comfortable, continue with periodic visits until you determine it is safe to discharge the patient. If the patient requires further lengthening, a return to the normal every six month monitoring is appropriate.

Poor Regenerate Formation

It may sound clichéd, but the best way to manage poor regenerate formation is to prevent it from happening in the first place. Based on the patient's medical co-morbidities, the health of the bone and the surrounding soft tissue envelope, and the intraoperative findings, develop an appropriate latency period and initial lengthening rate and rhythm. It is always better to start more conservatively and speed up later than the reverse. Do not keep lengthening in the presence of a "black hole". Stopping the lengthening for a week to see if the regenerate improves will not create a premature consolidation. If you are faced with unhealthy regenerate, there are a few suggestions:

1) If it is still early in the distraction phase, run the nail in reverse to the starting point, re-institute the latency period and start the lengthening process again. The new lengthening rate and rhythm should be slower than the initial rate until good regenerate bone formation is noted.

2) If it is late in the distraction phase, stop lengthening immediately. There are several options:
   a) Stop and wait to see if the regenerate bone will gradually improve
   b) Reverse the nail until good regenerate is visible then slowly re-start the lengthening
   c) Stimulate the healing response with autogenous bone graft
   d) At this time, there is no published evidence regarding bone marrow aspirate injection, bone stimulators, or the use of the "accordion" method to rescue poor regenerate. If you are unsure what to do, have your Precice representative put you in contact with an experienced lengthening surgeon to review your case and provide possible solutions.

3) If you have reached the end of distraction and have minimal regenerate:
   a) Consider options 2a,2b, or 2c
   b) Exchange the Precice nail for a trauma nail. This will allow the patient to advance the weight bearing status more quickly which will promote bone healing. The reaming of the regenerate bone during the exchange process may also help to stimulate healing. A temporary fixator may be necessary to hold the bone length during the nail exchange process.

Joint Contractures

The best way to deal with joint contractures is to anticipate and prepare for them before they happen. At a minimum, train yourself to check the lateral knee radiograph at every visit in order to catch the first signs of joint subluxation. The appearance of a ski-slope knee indicates that joint subluxation is already underway.

1) The preoperative examination should identify any tight or unstable joints. Tight muscles will only get tighter during the lengthening process. Preparatory surgery to address these findings may be necessary before the lengthening surgery commences.

2) Femoral lengthening patients will need to use a dynamic knee extension brace for 12-16 hours daily. Tibial lengthening patients will need a solid ankle foot orthosis (AFO). These orthoses should be ordered preoperatively so they are available for immediate use after surgery.

3) Weekly postoperative visits should evaluate the range of motion of each joint. Any loss of motion should be addressed with increased physical therapy and slowing or stopping the lengthening rate.

4) If you have substantial concerns preoperatively about the stability of a patient's joint, surgical stabilization can be performed at the time of nail insertion. Submuscular locked plating of the knee or placement of an extra-articular tibio-calcaneal screw will hold each respective joint in the desired position during the distraction phase and early consolidation phase.

5) Congenital limb lengthening patients have soft tissue envelopes that are more resistant to lengthening than patients with developmental limb length discrepancies. In these patients, an open release of the ilio-tibial band at the level of the proximal patella is recommended for all femoral lengthenings. For developmental patients, the ilio-tibial band release should be performed if the preoperative physical examination reveals tightness.

6) Fractional lengthening of the hamstrings or gastrocsoleus muscles can be performed simultaneously with nail insertion if there is evidence that these muscles are mildly tight preoperatively. If moderate or severe tightness is identified preoperatively, this will need to be addressed separately prior to any lengthening surgery.

7) If joint contracture develops during the lengthening:

a) Immediately stop lengthening. Depending on the severity of the contracture, the lengthening may need to be reversed to shorten the femur/tibia until the contracture is resolved. Do not hesitate to sacrifice length in order to regain knee/ankle function.

b) Aggressively increase the number of weekly formal physical therapy sessions. If the patient has difficulty attending additional sessions, consider admitting the patient to the hospital for daily therapy until the contracture is corrected.

c) A custom knee device for knee contractures after intramedullary femoral lengthening has been described (Bhave et al. *Orthopedics* 2015)

d) If the above non-operative methods do not succeed and soft tissue releases were not previously performed, then soft tissue releases may be necessary. For femoral lengthening beware of postero-lateral joint subluxation. If this is occurring, the biceps femoris and ilio-tibial band need to be lengthened/released. For tibial lengthening, the typical equinus contracture can be addressed with a gastrocsoleus recession or Achilles tendon lengthening.

e) As a last resort, an external fixator can be applied to gradually restore the joint to normal alignment.

External Remote Controller (ERC)

Somehow this device doesn't seem to get the attention it deserves, but it is literally the engine that drives the success of the entire process.

1) Familiarize yourself with how to program and operate the ERC. There may be occasions where you need to adjust the program in clinic or troubleshoot patient issues. Having knowledge about the inner workings of the ERC will save time by avoiding a call to your Precice representative every time something needs to be changed on the ERC.

2) It is recommended to provide the ERC teaching to the patient/family at the first postoperative visit. Usually, there are too many distractions during the inpatient stay to add this extra layer of complexity to the patient or their family. Have the patient record a video of the in-office teaching session on their phone so they can refer to it later if there is a question.

3) Don't forget to mark the location of the magnet on the skin prior to leaving the operating room.

4) The goal is to find the thinnest portion of the soft tissue envelope at the level of the magnet when performing the lengthening sessions. This will allow the optimal magnet to magnet communication between the ERC and the implant. Sometimes the side of the thigh will work better than placing the ERC directly anteriorly.

5) Keep cell phones, credit cards and metal devices away from the ERC when it is in use.

6) Tell your patient to bring the ERC to each visit during the distraction phase in case you need to change the rate/rhythm.

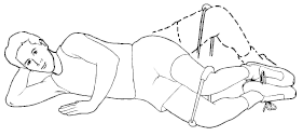
Physical Therapy and Regimen w/ Exercises

Preoperative Plan (performed daily from evaluation until day before surgery)

Routine For:
Created By: Claire Kopko

05-13-2019
Limb Lengthening: Pre-op and Week1 Post Op

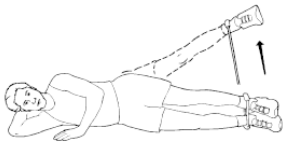
REHAB: LOWER EXTREMITY - 6 Hip Abduction: Side-Lying (Single Leg)



Lie on side with knees bent, tubing around thighs just above knees. Raise top leg, keeping knee bent. Hold for 60 seconds.

Repeat 3 times per set. X Repeat on other side.
Do 1 sets per session. Do 1 sessions per day.

TUBING LOOP - 35 Hip Abduction: Side-Lying (Single Leg)



Side-lying, tubing around ankles, raise top leg, keeping knee straight. Hold for 60 seconds.

Repeat 3 times per set. Repeat with other leg.
Do 1 sets per session. Do 1 sessions per day.

TRUNK STABILITY - 9 Bridging

Slowly raise buttocks from floor, keeping stomach tight.

Repeat 15 times per set. Do 3 sets per session.
Do 1 sessions per day.

BACK - 10 Arm / Leg Extension: Alternate (All-Fours)

Raise right arm and opposite leg. Do not arch neck.

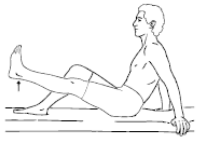
Repeat 20 times per set. Do 2 sets per session.
Do 1 sessions per day.

HIP / KNEE - 77 Functional Quadriceps: Sit to Stand

Sit on edge of chair, feet flat on floor. Stand upright, extending knees fully.

Repeat 15 times per set.
Do 3 sets per session.
Do 1 sessions per day.

HIP / KNEE - 19 Strengthening: Straight Leg Raise (Phase 3)



Resting on hands, tighten muscles on front of right thigh, then lift leg 6 inches from surface, keeping knee locked. Perform on both sides.

Repeat 15 times per set. Do 2 sets per session.
Do 1 sessions per day.

HAMSTRINGS - 4 Pull Back Toes, Double Leg

With hands on toes, pull torso forward and bend head toward knees until stretch is felt. Hold 60 seconds. For more stretch, put hands on ankles.

Repeat 2 times. Do 1 sessions per day.

ANKLE / FOOT - 14 Gastroc Stretch

Stand with right foot back, leg straight, forward leg bent. Keeping heel on floor, turned slightly out, lean into wall until stretch is felt in calf. Hold 60 seconds.

Repeat 2 times per set.
Do 1 sets per session.
Do 1 sessions per day.

Immediate Postoperative Protocol (from day after surgery until first clinic visit)

Routine For:
Created By: Claire Kopko

05-13-2019
Limb Lengthening: Pre-op and Week1 Post Op

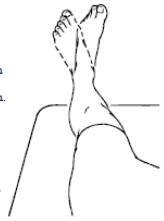
ANKLE / FOOT - 18 ROM: Plantar / Dorsiflexion

With right leg relaxed, gently flex and extend ankle. Move through full range of motion. Avoid pain. Perform on both sides.

Repeat 30 times per set. Do 1 sets per session.
Do 4-5 sessions per day.

ANKLE / FOOT - 19 ROM: Inversion / Eversion

With right leg relaxed, gently turn ankle and foot in and out. Move through full range of motion. Avoid pain. Perform on both sides.



Repeat 30 times per set.
Do 1 sets per session.
Do 4-5 sessions per day.

HIP / KNEE - 11 Strengthening: Quadriceps Set

Tighten muscles on top of thighs by pushing knees down into surface. Hold 5 seconds.

Repeat 10 times per set. Do 1 sets per session.
Do 4-5 sessions per day.

HIP / KNEE - 46 PROM: Knee Flexion

With towel around right heel, gently pull knee up with towel until stretch is felt. Hold 5 seconds.

Repeat 10 times per set.
Do 2 sets per session.
Do 4-5 sessions per day.

BACK - 7 Gluteal Sets

Tighten buttocks while pressing pelvis to floor. Perform in sitting or lying on back if you cannot get onto your stomach. Hold 5 seconds.

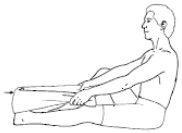
Repeat 10 times per set. Do 1 sets per session.
Do 4-5 sessions per day.

HIP / KNEE - 50 Hip Abduction / Adduction: with Extended Knee (Supine)

Bring right leg out to side and return. Keep knee straight. Perform on both sides.

Repeat 10 times per set. Do 2 sets per session.
Do 4-5 sessions per day.

HIP / KNEE - 63 Stretching: Calf – Towel



Sit with knee straight and towel looped around right foot. Gently pull on towel until stretch is felt in calf. Perform on both sides.
Hold 30 seconds.

Repeat 4 times per set. Do 1 sets per session.
Do 4-5 sessions per day.

HAMSTRINGS - 4 Pull Back Toes, Double Leg

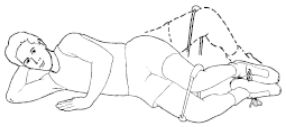
With hands on toes, pull torso forward and bend head toward knees until stretch is felt. Hold 60 seconds. For more stretch, put hands on ankles.

Repeat 2 times. Do 4-5 sessions per day.

Distraction and First Month of Consolidation Phase (still TDWB)

Routine For: 05-13-2019
Created By: Claire Kopko LLDupdate

REHAB: LOWER EXTREMITY - 6 Hip Abduction: Side-Lying (Single Leg)

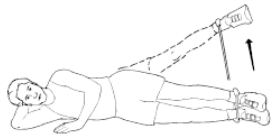


Lie on side with knees bent, tubing around thighs just above knees. Raise top leg, keeping knee bent. Hold for 60 seconds.
Repeat 3 times per set. X Repeat on other side.
Do 1 sets per session. Do 1 sessions per day.

TRUNK STABILITY - 9 Bridging

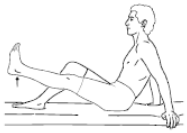
Slowly raise buttocks from floor, keeping stomach tight. May progress to single leg bridges if able.
Repeat 15 times per set. Do 3 sets per session.
Do 1 sessions per day.

TUBING LOOP - 35 Hip Abduction: Side-Lying (Single Leg)



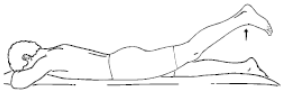
Side-lying, tubing around ankles, raise top leg, keeping knee straight. Hold for 60 seconds.
Repeat 3 times per set. Repeat with other leg.
Do 1 sets per session. Do 1 sessions per day.

HIP / KNEE - 19 Strengthening: Straight Leg Raise (Phase 3)



Resting on hands, tighten muscles on front of right thigh, then lift leg 6 inches from surface, keeping knee locked. Perform on both sides.
Repeat 15 times per set. Do 2 sets per session.
Do 1 sessions per day.

HIP / KNEE - 20 Strengthening: Hip Extension (Prone)



Tighten muscles on front of left thigh, then lift leg 6 inches from surface, keeping knee locked.
Repeat 15 times per set. Do 3 sets per session.
Do 1-2 sessions per day.

SPINAL MOBILIZATION - 31 Pelvic Rotation (Supine)

With right leg hanging off side of bench, relax leg as much as possible. Hold 60 seconds. Relax.
Repeat 2 times per set. Do 1 sets per session.
Do 1-2 sessions per day.

HAMSTRINGS - 4 Pull Back Toes, Double Leg

With hands on toes, pull torso forward and bend head toward knees until stretch is felt. Hold 60 seconds. For more stretch, put hands on ankles.
Repeat 2 times. Do 1-2 sessions per day.

UPPER LEG - 1 Quadriceps

Lying on stomach with thighs together, gently pull ankle toward buttocks until stretch is felt. Hold 60 seconds. Repeat with other ankle.
Repeat 2 times. Do 1-2 sessions per day.

HIP / KNEE - 63 Stretching: Calf – Towel

Sit with knee straight and towel looped around right foot. Gently pull on towel until stretch is felt in calf. Perform on both sides.
Hold 60 seconds.
Repeat 1 times per set. Do 1 sets per session.
Do 1-2 sessions per day.

Consolidation Phase (added to previous consolidation program once they start to advance their weight-bearing, with graded WB on the affected side, by placing a lift under the foot).

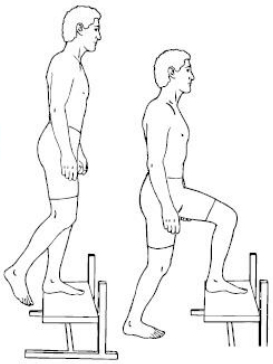
HIP / KNEE - 77 Functional Quadriceps: Sit to Stand

Sit on edge of chair, feet flat on floor. Stand upright, extending knees fully.

Repeat 15 times per set.
Do 3 sets per session.
Do 1 sessions per day.

HIP / KNEE - 52 Step-Down / Step-Up

Stand on stair step or 8 inch stool. Slowly bend left leg, lowering other foot to floor. Return by straightening front leg and lifting right leg in front, as if marching.



Repeat 15 times per set.
Do 2 sets per session.
Do 1 sessions per day.

Resisted Side Stepping

With band around ankles, maintain a partial squat and repeatedly step sideways. Perform each direction. 4x30 feet, once a day.

HIP / KNEE - 34 Stretching: Hip Flexor

Kneeling on left knee, slowly push pelvis down while slightly arching back until stretch is felt on front of hip. Hold 60 seconds.

Repeat 2 times per set. Do 1 sets per session.
Do 1 sessions per day.

Weight Bearing

Precice Limb Lengthening System

Diameter (mm)	Actual Weight Applied (lbs)
8.5	25
10.7	50
12.5	50

Stryde Limb Lengthening System

Diameter (mm)	Actual Weight Applied (lbs)
10.0	150
11.5	200
13.0	250

Rx Only.
The Precice® Intramedullary Limb Lengthening (IMLL) System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The PRECICE nail is a sterile single use device that is surgically implanted using the instruments and locking screws. The ERC is used daily after implantation to non-invasively lengthen or shorten the implant to a prescribed length. The PRECICE System is intended for limb lengthening of the femur and tibia. Contraindications include infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device, metal allergies and sensitivities, patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 51 mm for the 10.7 and 12.5 mm diameter implants or greater than 38 mm for the 8.5 mm diameter implant, patients with an irregular bone diameter that would prevent insertion of the PRECICE nail, patients in which the PRECICE nail would cross joint spaces or open epiphyseal growth plates, patients in which there is an obliterated medullary canal or other conditions that tend to retard healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity, patients unwilling or incapable of following postoperative care instructions, patients weighing in excess of 114 kg for the 10.7 and 12.5 mm diameter implants for models H, J, K, and U or weighing in excess of 57 kg for the 8.5 and 10.7 mm diameter implants for models N, M ,P, and Q. The implantable device is only to be used by a trained licensed physician. Please refer to the PRECICE IMLL System instructions for use for complete Important Safety Information. Caution: Federal law restricts this device to sale by or on the order of a physician.

Rx Only.
The Precice Stryde™ System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The Stryde nail is a sterile single use device that is surgically implanted using the instruments and locking screws. The ERC is used daily after implantation to non-invasively lengthen or shorten the implant to a prescribed length. The Precice Stryde System is intended for limb lengthening of the femur and tibia. Contraindications include infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device, metal allergies and sensitivities, patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 80mm for the 13.0mm diameter implant, 65 mm for the 11.5 mm implant and 50mm for the 10.0mm diameter implant, patients with an irregular bone diameter that would prevent insertion of the Stryde nail, patients in which the Stryde nail would cross joint spaces or open epiphyseal growth plates, patients in which there are conditions that tend to retard healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity, patients unwilling or incapable of following postoperative care instructions, 150lbs for the 10.0mm diameter implant, 200lbs for the 11.5mm diameter implant and 250lbs for the 13.0 mm implant. The implantable device is only to be used by a trained licensed physician. Please refer to the Precice Stryde System instructions for use for complete Important Safety Information.

Important Safety Information

The Precice and Precice Stryde System is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

This document offers guidance but, as with any such technique each surgeon must consider the particular needs of each patient and make appropriate clinical decisions as required. The topics and tips/tricks are for consideration rather than guidelines for treatment.

All non-sterile devices must be cleaned and sterilized before use. Multi-component instrument assemblies must be disassembled prior to cleaning. Please refer to the corresponding Instructions For Use (IFU). It is the surgeon's responsibility to discuss all relevant risks with the patient prior to surgery.

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