ICD-10-PCS Coordination and Maintenance Meeting

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Agenda

I. Introduction/disclaimer

II. Description of the issue

III. Background on limb length discrepancy

IV. Description of a limb lengthening procedure and the PRECICE device

V. Clinical benefits/case studies

VI. Rationale for a new ICD-10-PCS code

Introduction

- Claire E Shannon MD, Assistant Professor of Orthopaedic Surgery, Johns Hopkins

- No Disclaimer

Description of the Issue

Limb lengthening procedures, including the tibia, femur and humerus, are performed for a variety of indications (congenital or acquired limb shortening, fracture malunion, fracture nonunion, etc.). Until recently, these procedures was performed using external fixation devices that require manual lengthening.

In 2011, the FDA approved the PRECICE nail. The device is implanted like a standard orthopaedic intramedullary nail. Once the nail is inside the bone, the limb can be lengthened via a non-invasive external remote control by activating the magnetic driver within the device.

Under the current ICD-10-PCS system, **there are no Device Characters that describe a limb lengthening intramedullary internal fixation device.** The Device Characters that describe standard orthopedic "intramedullary internal fixation device" are not adequate.

Limb Lengthening

Background:

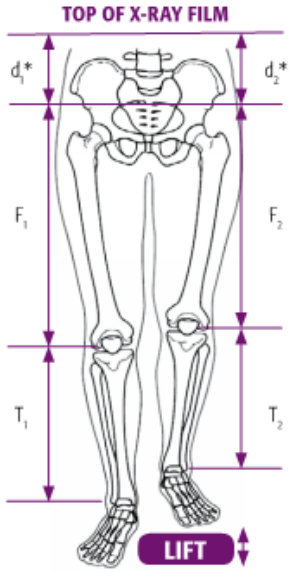
- Limb length discrepancy may be diagnosed as an infant, in childhood, or later in life, depending on the cause. Currently, treatment is recommended for leg length discrepancy greater than 1.5 to 2.0 cm (5/8 inch).
- Biomechanical, gait analysis and population based studies have shown that limb length inequality alters the pressure forces across the joints of the lower body during ambulatory activity. Over time, this increases the risk of developing knee, hip, and back pain, as well as arthritis.
- In the pediatric population, we can limit growth to equalize small differences, but this is undesirable for significant limb length differences due to limb proportion asymmetry and overall loss of height. In adults, there is no ability to modulate growth, and shortening of a bone is not ideal due to involvement of the normal limb and the extensive recovery required.

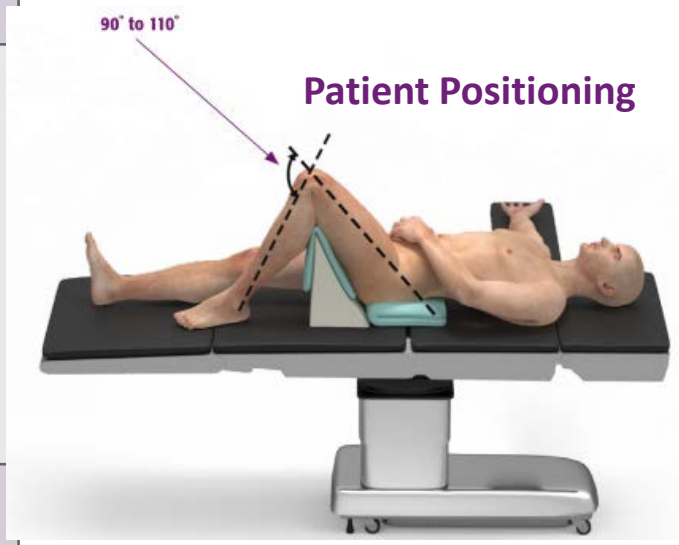
Tibial Lengthening Procedure

Step	Procedure
Pre-operative Planning	• Determination of limb length discrepancy • Implant templating • Osteotomy location, deformity correction planning • Soft tissue assessment
Patient Positioning	• Supine on radiolucent table • Fluoroscopy required
Osteotomy of Fibula	• Essential step with tibial lengthening

Soft Tissue and Nerve Release	• Based on individual patient requirements and surgeon preference:
	  • Gastrocnemius lengthening
	  • Proximal peroneal nerve release
	  • Prophylactic percutaneous anterior and lateral compartment fasciotomy
	  • Distal tibial nerve release

Venting of Tibial Canal	• Drill holes in tibia at the planned osteotomy site prior to reaming to decrease intramedullary pressure





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Tibial Lengthening Procedure Cont.

Step	Procedure
Entry Point and Reaming	• Knee is flexed and a guide wire is used to identify the start point in the proximal tibia • The intramedullary canal is reamed to create a space for the PRECICE nail
Osteotomy of the Tibia	• The PRECICE implant is carefully inserted into the bone up to the level of the planned osteotomy site. • The osteotomy is completed percutaneously and the nail inserted the rest of the way into the bone.
Insertion of Locking Screws	• Interlocking screws are inserted through the PRECICE implant at the top and bottom to fix the implant in place
Placement of Syndesmotic Screws	• To enable the fibula to lengthen with the tibia and provide stabilization, proximal and distal bone screws are used to secure the fibula to the tibia.

Tibial Lengthening Procedure Cont.

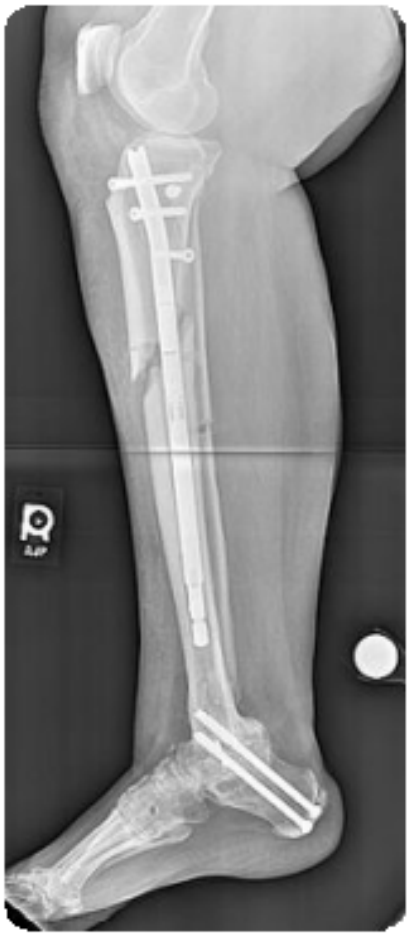
Step	Procedure
Intraoperative Distraction	• The location of the magnetic actuator is marked on the skin using xray. • The remote is then placed on the leg and activated to distract the PRECICE implant 1.0 to 2.0 mm to confirm proper functioning
Final Closure	• Surgical incisions are irrigated and closed in standard fashion. • Apply sterile dressings
Postoperative Management	• Postoperative pain control and mobility training. • Limited weight bearing during the lengthening and consolidation phase.

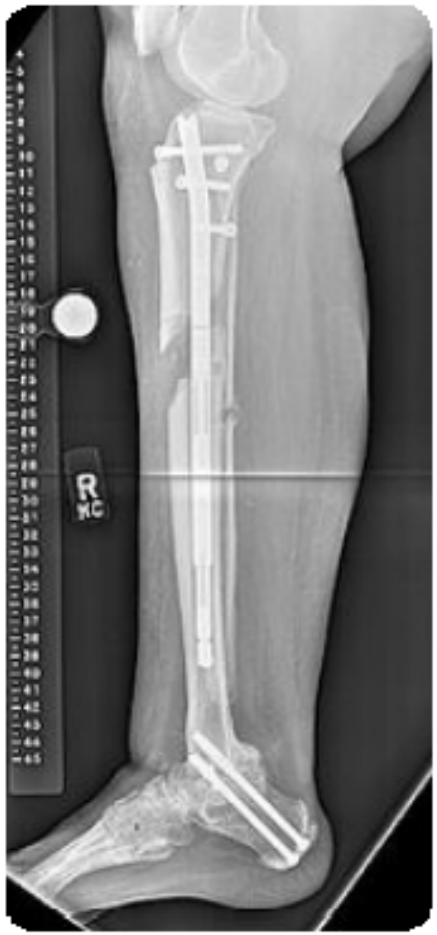
Images

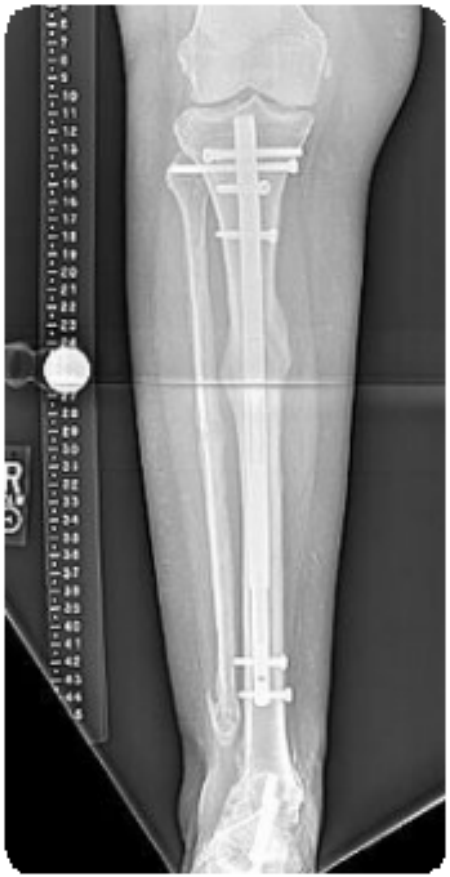
Post-Op Day 7

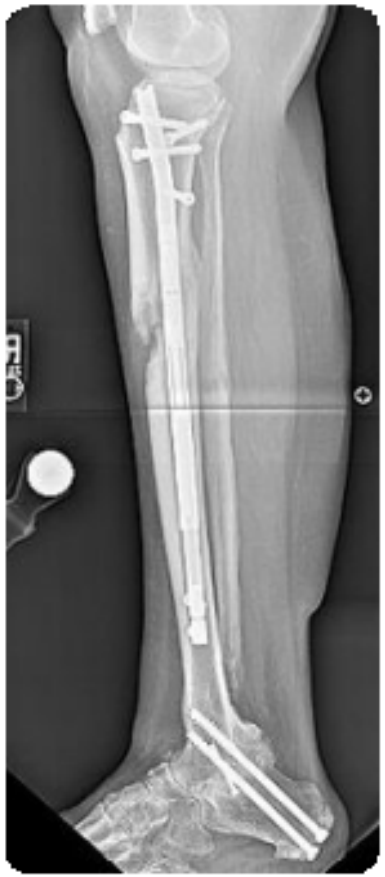
Post-Op Day 49,
41 mm

Consolidation and full weight bearing









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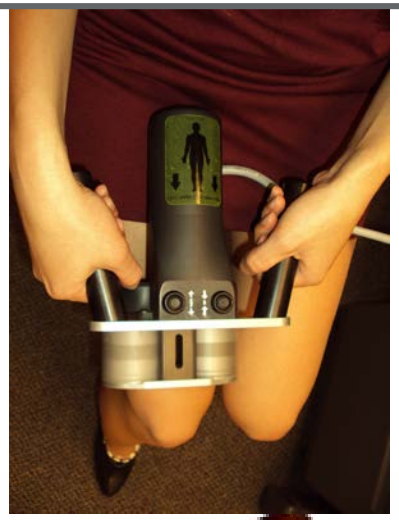
Current Standard of Care vs. PRECICE

Average time in frame – 41.5 weeks! (range 10-82 weeks)

Note pin tract



3 to 4 times a day for lengthening.

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Post Procedure-Limb Lengthening

- The External Remote Controller (ERC) is programmed by the surgeon for a patient-specific lengthening program.
- The patient is trained on using the non-invasive ERC, which is a hand held device that makes use of strong rare earth magnets. The magnet in the implant turns when the ERC is placed on the limb at the location of the implant actuator and turned on.
- In general, limbs are lengthened at a rate of 0.75mm/day to allow bone to form in the distraction gap. Once the desired length is achieved, it takes approximately double the lengthening time to consolidate the new bone.
    - 30mm lengthening = 40 days
    - Consolidation time = 80 days
    - Total time to lengthen = 120 days

Clinical Benefits of the PRECICE System

- There have been 18 peer-reviewed publications published, with a combined total of 510 patients, showing the clinical benefit of PRECICE

- Key benefits shown in these studies include faster healing time, lower pain scores during the distraction phase and consolidation phase, and higher patient quality of life measures, when compared to lengthening with external fixation devices (standard of care for limb lengthening prior to the PRECICE).

- Eradication of pin site infections due to all internal fixation.
    - External fixation devices have pin site infection rates as high as 50% in some studies

- Overall better quality of life with PRECICE intramedullary limb lengthening

Rationale for new ICD-10-PCS Code

- There is no device character that describes “Internal Fixation Device, Intramedullary, **“Limb Lengthening”**

- This new procedure/device offers a significant clinical benefit to the patient and there should be a way to differentiate this implant from non-limb lengthening intramedullary implants.

Thank you

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