Title of the Study: Using Ultrasound as an Alternative to Radiography in Measuring Magnetically Controlled Growing Rods (MCGR) in Tibia and Femur Lengthening Patients

IRB# 2169786

9/8/2025

2. Objective (purpose) / Hypothesis:

a. Objective: The purpose of this study is to evaluate the efficacy of ultrasound imaging as an alternative to radiographs in assessing the bone lengthening measurements in a pediatric cohort.

b. Hypothesis: We hypothesize that ultrasound will obtain the same measurements as radiographs during tibia and femur lengthening procedures in pediatric patients.

3. Background / Literature Review:

Limb lengthening with expanding intramedullary rods has become the standard of care for limb lengthening procedures [1]. The procedure entails performing an osteotomy of the short bone and placing a mechanical expanding intramedullary nail (**Fig. 1**).

Figure 1: Femur and Tibia Lengthening intramedullary nail.

The bone is then allowed to rest for 5-7 days to develop a callus, The callus is then stretched by using an external device to active the intramedullary rod. The lengthening is performed at home by the family at a rate of 0.75 to 1 cm per day. Patients undergoing lengthening have frequent follow ups in the orthopedic clinic for x-rays and

clinic exam to evaluate for complications such as joint contracture, hardware failure, or early consolidation. The average cumulative radiation dose from a lengthening procedure is estimated at 3.1 mSv or 1.1 mSv/cm [2]. Radiation exposure is cumulative and can cause cancers and diseases. Ultrasound is a non-invasive imaging modality that has been used in multiple aspects of medicine to measure the musculoskeletal system and help diagnosis disorders. Ultrasound has been used recently to assess magnetically controlled growth rod (MCGR) length in scoliosis treatment reveals promising results [3]. A prospective investigation by Yoon et al. highlights ultrasound as a reliable and non-invasive alternative to radiography, showing high agreement in MCGR length measurements [4]. However, studies by Cobanoglu et al. and Stokes et al. point out potential limitations, such as lower measurement values and underestimation of length compared to traditional X-rays, and the inability to assess certain complications or fusion blocks [5, 6]. Overall, these findings underscore the potential of ultrasound in reducing radiation exposure during pediatric scoliosis treatment. The aim of our study is to explore the role of ultrasound to measure tibia and femur lengthening procedures and compare the accuracy to standard radiographs.

4. Methods:

a. Study design: Prospective, Pilot Study

b. Patient cohort: All patients who were treated at Nemours Children's Hospital Florida for leg length discrepancy treated with a magnetically controlled growth rod in the tibia or femur (CPT 27715 Tibia lengthening and CPT 27466 femoral lengthening)

c. Sample size

5 tibias
5 femurs
About 10 pediatric patients

d. Inclusion and Exclusion Criteria:

Inclusion:

- All patients 8 to 21 years old
- Patients undergoing tibia or femur lengthening with an intramedullary mechanical rod.

Exclusion:

- Patients who underwent lengthening procedure with any other device such as external fixator.
- Patients under 8 years old and over 21 years of age

e. Data to be Collected:

i. Primary outcome variable:
    - Tibia and femur lengthening measured via ultrasound
    - Tibia and femur lengthening measured via x-ray

ii. Secondary variables:
    - Discomfort during imaging
    - Cost
    - Number of x-rays
    - Dose of Radiation 0.001 per x-ray
    - Patient Age

- Gender
- Laterality (Left vs Right limb)
- Limb segment being measured.
- Complications
- Rate of lengthening
- Final lengthening goal
- Length achieved.

f. Procedures:

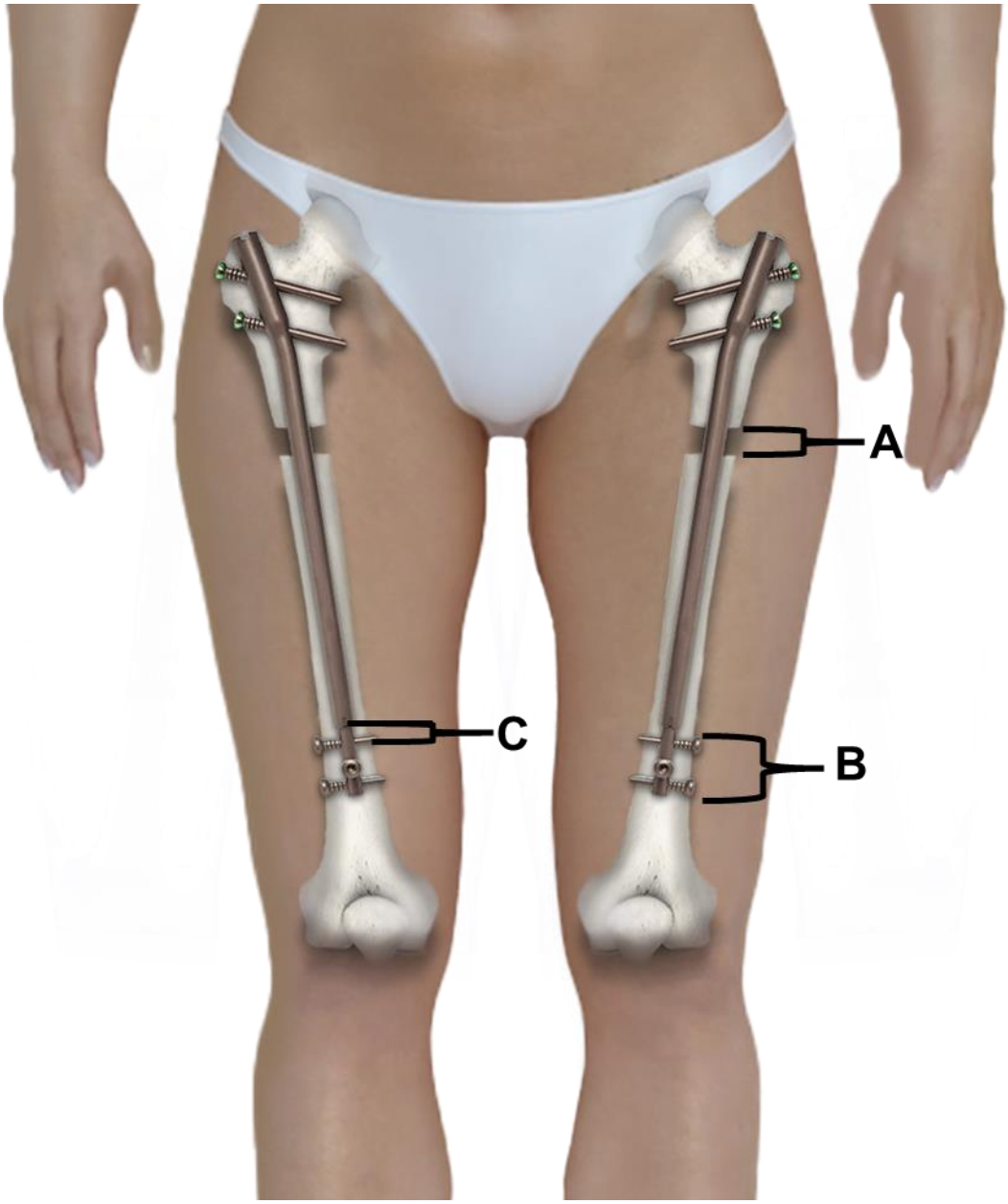

Figure 2: Femur areas of measuring on x-rays and ultrasound during lengthening

1. Patient will be recruited by Dr Malone in the orthopedic clinic

2. Consent will be obtained by Dr Malone
3. All patients will follow up weekly for clinical exam and imaging with no change to current workflow or standard of care.
4. All patients will obtain standard AP and Lateral x-rays
    a. Measurements will be obtained in three locations through the picture archiving and communication system (PACS) **(Fig. 2 and 3 for femur and tibia, respectively)**
        A. The end of the proximal bone segment to the proximal end of the distal bone segment
        B. The distal end of the female aspect of the rod to the distal end of the male aspect of the rod
        C. The distal end of the female aspect of the rod to the proximal screw in the male aspect of the rod

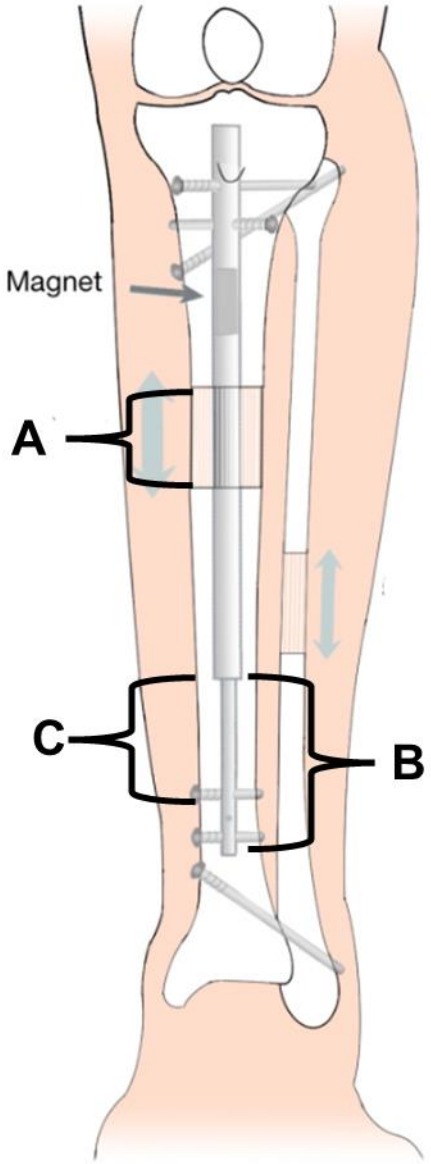

Figure 3: Tibia areas of measuring on x-rays and ultrasound during lengthening

5. All enrolled patients will have ultrasound imaging and measurements will be obtained in three locations and measured in millimeters (**Fig. 2 and 3 for femur and tibia, respectively**)
    A. The end of the proximal bone segment to the proximal end of the distal bone segment
    B. The distal end of the female aspect of the rod to the distal end of the male aspect of the rod
    C. The distal end of the female aspect of the rod to the proximal screw in the male aspect of the rod

6. Ultrasound measurements will be performed using a Point of Care Ultrasound (PoCUS), Butterfly iQ+
7. All PoCUS measurements will be performed by an ultrasound trained physician
    a. Dr. Cassidy Foley
    b. Dr. Amit Patel
    c. Dr Julia Fink
    d. Kaitlin Maher PA-C
8. Enrolled patients' information will be placed and stored on a password protected excel file and given a patient number.
9. All measurements will be stored on a password protected excel file with no patient identifiers except a patient number.
10. Patient demographic will be obtained from the electronic medical record (EMR)
11. Dose of Radiation will be estimated at 0.001 microseverts per x-ray [7].
12. Cost of x-rays will be estimated from the Nemours Children's Hospital, Florida posted chargemaster.
    a. The charge will not include the radiology read.
    b. The charge for a femur x-ray is $276.
    c. The charge for a tibia x-ray is $462.
    d. No charge will be made for PoCUS.
13. Patients will be asked about pain from the PoCUS
    a. Pain score will be obtained using Wong Baker FACES Pain Rating Scale (**Fig. 4**).

Figure 4: Wong-Baker Faces Pain Rating Scale

g. Statistical Analyses:

Means will be compared using T-test. Pearson correlation coefficient and the Bland-Altman method will be used to compare the measurements between ultrasound to x-ray measurements.

5. References:

1. Laubscher, M., et al., *Outcomes following femoral lengthening: An initial comparison of the Precice intramedullary lengthening nail and the LRS external fixator monorail system.* Bone Joint J, 2016. **98-b**(10): p. 1382-1388.
2. Schiedel, F.M., T.C. Buller, and R. Rödl, *Estimation of patient dose and associated radiogenic risks from limb lengthening.* Clin Orthop Relat Res, 2009. **467**(4): p. 1023-7.
3. Cheung, J.P., et al., *Clinical utility of ultrasound to prospectively monitor distraction of magnetically controlled growing rods.* Spine J, 2016. **16**(2): p. 204-9.
4. Yoon, W.W., et al., *The use of ultrasound in comparison to radiography in magnetically controlled growth rod lengthening measurement: a prospective study.* Eur Spine J, 2015. **24**(7): p. 1422-6.
5. Çobanoğlu, M., et al., *Comparison of Intended Lengthening of Magnetically Controlled Growing Rods: Ultrasound Versus X-Ray.* Journal of Pediatric Orthopaedics, 2017. **39**: p. e141–e146.
6. Stokes, O.M., et al., *Reducing radiation exposure in early-onset scoliosis surgery patients: novel use of ultrasonography to measure lengthening in magnetically-controlled growing rods.* Spine J, 2014. **14**(10): p. 2397-404.
7. Mettler, F.A., et al., *Effective Doses in Radiology and Diagnostic Nuclear Medicine: A Catalog.* Radiology, 2008. **248**(1): p. 254-263.