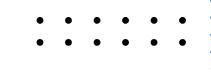
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RIMN COORDINATOR LAUNCH PRESENTATION

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Introductions



- Tell us your name
- · Site
- · Role
- · One of your favorite hobbies



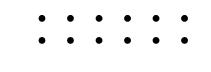


Ideally, we would like to have all of the Beta Test data entered into REDCap by **February 1st, 2025**

Please make sure to amend your site IRB's to include patients up until June 2024. Needs to be done before the first data pull.

Please make sure the PI in charge of measurements completes the App training before they identify open physes.

Study Overview



Primary Aim:

Quantify proximal tibial iatrogenic deformity at skeletal maturity in adolescents with diaphyseal tibial shaft fractures treated with antegrade rigid intramedullary nailing through an open proximal tibial physis

Hypothesis:

Antegrade rigid intramedullary nail fixation through open proximal tibia physis in adolescents nearing skeletal maturity will not cause clinically significant proximal tibial deformity (Mechanic axis deviation > 5mm, Leg length difference > 1 cm).

Study Overview Cont.





Flexible Nail

Study Overview Cont.

2:22

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TIB-Q- Lateral Tibial Physis Fusion

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Open

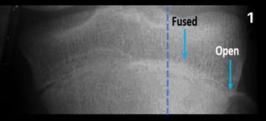
Grade 0 (Absent Fusion):

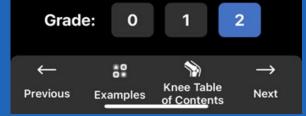
Radiolucent gap between epiphysis and metaphysis visible through entire lateral proximal tibia

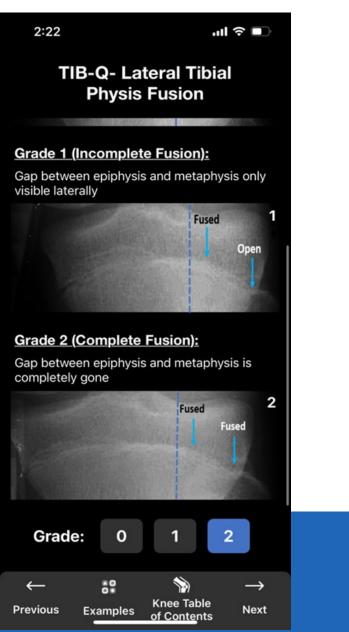
> Line delineates lateral Open 1/3rd of physis. Middle 1/3rd of physis not evaluated due to tibial tubercle overlap

Grade 1 (Incomplete Fusion):

Gap between epiphysis and metaphysis only visible laterally







Phase I

CPT/ICD9/ICD10 Codes Search Query

CPT 27759: Treatment of tibial shaft fracture (with or without fibular fracture) by intramedullary implant, with or without interlocking screws and/or cerclage

CPT procedural codes are the same for flexible and rigid, so must look in OP report or x-ray to specify that we are finding patients who had surgery with a rigid intramedullary nail (IMN)

Although we know that CPT codes work for BCH and WashU we want to ensure that we collect all the patients that we have please also check the following diagnostic codes:

ICD codes:

ICD-10: S82.20

ICD-9: 78.57 and 0QHG06Z

S52.222A	S82.222B	S82.242B	S82.291C	S82.402A	Y24.9XXA
S82.192B	S82.231A	S82.251A	S82.292A	S82.402B	S82.451A
S82.201A	S82.231B	S82.251B	S82.292B	S82.422B	S82.451B
S82.201B	S82.232A	S82.251C	S82.302A	S82.431A	S82.452A
S82.201C	S82.232B	S82.252A	S82.841A	S82.432A	S82.452B
S82.202A	S82.235A	S82.252B	S82.492B	S82.432B	S82.491A
S82.202B	S82.241A	S82.262A	S89.121A	S82.441A	
S82.222A	S82.242A	S82.291A	S82.401B	S82.492A	

- Go through all potentially eligible patient charts
- Include the rigid nails
- Exclude flexible
- nails

<u>Implants:</u> Implant Name	Туре	Inv. Item	Serial No.	Manufacturer	Lot No.	LRB	No. Used	Action
SMITH & NEPHEW/RICHCO /ORTHO TRIGEN META-NAIL 10MM 36CM TIBIAL NAIL INTRAMEDULLAR Y TITANIUM 71655136 - LOG11588750	Nail	SMITH & NEPHEW/RIC HCO/ORTHO Trigen Meta- nail 10mm 36cm Tibial Nail Intramedullary Titanium 71655136		Smith & Nephew/Richco/ Ortho	22CT6 1140	Right	1	Implanted



Rigid Nail



Flexible Nail

Phase I -> Phase II

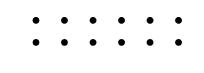
									Was skeletal immaturity reached by last Post-op													
MRN	NAME	X-Ray/Surgery DATE	Tib Q	DATE of XRAY	1: Post Op	:AP and Lat	eral X-ray 2	to 4 month		2: Post Op	:If you saw	skeletal m	aturity bein	3: Post Op	: Was there	a standing AP 2-4 m	onths post op	o If yes fill o	ut the follo	4: Post Op:	Was there a	a standing.
					MPTA:	LDTA:	PPTA:	ADTA:		MPTA:	LDTA:	PPTA:	ADTA:	MPTA Left:	MPTA:Righ	LDTA Left: LDTA Rig	ht AP Standir	Leg length	MAD (mec	MPTA Left:	MPTA:Righ	LDTA Left:
123456	Marino, Josh	11/11/2024																			i	
123457	Marino, Josh	11/12/2024																				
123458	Marino, Josh	11/13/2024																			i .	
123459	Marino, Josh	11/14/2024																				
123460	Marino, Josh	11/15/2024																			i	
123461	Marino, Josh	11/16/2024																				
123462	Marino, Josh	11/17/2024																			i la	
123463	Marino, Josh	11/18/2024																				
123464	Marino, Josh	11/19/2024																				
123465	Marino, Josh	11/20/2024																				
123466	Marino, Josh	11/21/2024																				

- • RC's will fill out the highlighted section of the Physician Excel Sheet
- •
 - • Once all patients with rigid nails have been identified and entered into this sheet, send this to your PI
- •
- • Pl's will be responsible for the other columns
- •

									Was skeletal immaturity reached by last Post-op														
MRN	NAME	X-Ray/Surgery DATE	Tib Q	DATE of XRAY	1: Post O	p:AP and La	ateral X-ray	/ 2 to 4 month Date of la	sx-ray?	2: Post Op	lf you saw:	skeletal m	aturity bein	3: Post Op	: Was there	a standing	AP 2-4 mor	nths post op	p If yes fill o	ut the follo	4: Post Op	: Was there	a standing.
					MPTA:	LDTA:	PPTA:	ADTA:		MPTA:	LDTA:	PPTA:	ADTA:	MPTA Left	MPTA:Righ	LDTA Left:	LDTA Right	t AP Standir	Leg length	MAD (mec	MPTA Left	MPTA:Righ	LDTA Left:
123456	Marino, Josh	11/11/2024																					
123457	Marino, Josh	11/12/2024																					
123458	Marino, Josh	11/13/2024																					
123459	Marino, Josh	11/14/2024																					
123460	Marino, Josh	11/15/2024																					
123461	Marino, Josh	11/16/2024																					
123462	Marino, Josh	11/17/2024																					
123463	Marino, Josh	11/18/2024																					
123464	Marino, Josh	11/19/2024																					
123465	Marino, Josh	11/20/2024																					
123466	Marino, Josh	11/21/2024																					

- • The remaining columns involve all of the radiographic measurements and follow up data
- • RC's will eventually enter this data into REDCap once the PI's finish their measurements
- • Please make sure that Pl's know to send this back to you (only applicable if you do not share the sheet
- with them on a shared drive site like WUSTL Box)
- •
- •

REDCap Accounts



New users

- Email mjoshua@wustl.edu with your Name, Site email, and Site name
- Will need Google Authenticator or Microsoft Authenticator

Returning Users

- Email the BCH REDCap team at <u>crit.request@childrens.harvard.edu</u> and fill out the email as shown below
- Project link: <u>https://redcap.tch.harvard.edu/redcap_edc/redcap_v14.0.43/index.php?pid=5140</u>
- For email input your site email that was used in the initial REDCap

▷ Send ~									
To crit.request@childrens.harvard.edu ×	_								
Cc									
[REDCap question] PID 5140	_								
Email: Project title: "Tibia Nail: CORTICES" Project Link: <u>https://redcap.tch.harvard.edu/redcap_edc/redcap_v14.0.43/index.php?pid=5140</u>									
Dear REDCap administrator,									
I would like to reactivate my account for the above project, in the external BCH External redcap.									
Sincerely									

Phase III

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Data Collection Instrument	Status
Eligibility	
Demographics	
Injury Characteristics	\bigcirc
Radiographic Measurements	0

Once PI's have identified all patients with open or partially open physes, data collection can begin for the first three sections

Pl's will most likely identify eligible patients before finishing the measurements, so you can get a head start on data collection

Do not worry about until PI's complete the excel sheet

Phase III

📕 Eligibility

Record ID * Choose an existing Study ID *Please refer to the Data Entry Guide for instructions about Study ID creation.		test	
Inclusion Cr	iteria		
Participant younger than 18 years at presentation	$\bigcirc M$	○ Yes ○ No	n
Diagnosed with tibial shaft fracture, open physes, and treated with rigid tibial intramedullary nail	\odot M	○ Yes ○ No	n
Presented at a CORTICES institution between January 2010 and June 2024	$\supset M$	○ Yes ○ No	n
Exclusion Cr	iteria		
Is the participant skeletally mature at presentation	۶M	○ Yes ○ No	n
Treated with anything other than rigid tibial intramedullary nail	$\supset M$	○ Yes ○ No	n
Only treatment was a nail removal at a CORTICES institution	$\bigcirc M$	○ Yes ○ No	n
Eligibilit	y		
If you answered NO for any of the inclusion questions or YES fo eligible for data o			nt is no longe
Is the participant eligible for data collection	$\sim M$	○ Yes ○ No	r
Form Status			
Complete?	P	Incomplete 🗸	
Lock this instrument?			

Most important note for this section: If you mark **NO** on any of the Inclusion criteria or mark **YES** on any Exclusion criteria, that patient is **NOT** eligible

••

Do not enter any data for that patient

• • • • • • • • • • • •

Adding new Record ID * Choose an existing Study ID *Please refer to the Data Entry Guide for instructions about Study ID creation. test.

Record ID * Choose an existing Study ID *Please refer to the Data Entry Guide for instructions about Study ID creation.

Site	M	~
Demograph	nics	
Sex	۶M	○ Male ○ Female
Patient date of birth	Ø	Today M-D-Y
Date of injury	\sim M	Today M-D-Y
Age at time of injury	P	View equation
Height	Ø	[150 (cm)
Weight		62 (kg)
вмі	>	27.6 View equation
Form Status		
Complete?	P	Incomplete 🖌
Lock this instrument? If locked, no user will be able to modify this instrument for this record until someone with Instrument Level Lock/Unlock privileges unlocks it.		🗌 🔂 Lock

When entering your patient data, you will be asked to enter a new or existing Record ID. Please use your 2-digit Unique Site Number (shown below) for your site's data.

SITE #	SITE	SITE #	SITE
20	Boston Children's	30	Le Bonheur Children's/Campbell Clinic
21	Levine Children's	31	Lurie Children's
22	Children's Atlanta	32	Nationwide Children's
23	Children's Colorado	33	Rady Children's
24	Scottish Rite for Children	34	Seattle Children's
25	Children's LA USC	35	St. Louis Children's
26	Children's Philadelphia	36	Texas Children's
27	Cincinnati Children's	37	Vanderbilt Children's
28	CS Mott Children's	38	UCSF Benioff Children's Hospital
29	Gillette Children's		

To generate your REDCap Record IDs, please use the following format (below), where 'S' is the 2-digit site code and 'P' is the 3-digit record ID. The IDs should be sequentially recorded.

<u>SS-PPP</u>

2-digit Unique **Site** Number

3-digit Sequential Patient ID Number

For example, BCH's first patient would have a <u>REDCap</u> ID of "20-001". BCH's twentieth patient would have a <u>REDCap</u> ID of '20-020'. It is crucial that sites use the correct site ID to avoid duplicate <u>REDCap</u> IDs.



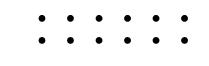
MVA/MCA/ATV: MVA: Motor Vehicle Accident High impact, MCA: Motorcycles and moped Accident, All Terrain Vehicle Accident.

Auto-ped: Automatic vehicle vs. pedestrian, includes nonmotorized bicycle vs. car, and children struck on skateboards and non-motorized scooters.

Sports

Fall from height: fall from greater than the height of the person

Other: Any mechanism not otherwise included



Was there a Left hand xray obtained within 3 months of injury?	\sim M	O Yes ○ No re	eset
Was there an ipsilateral or contralateral knee radiograph obtained within 3 months of injury?	\sim M	O Yes ○ No	eset

Will be calculated by the PI's when finding Tib Q using the skeletal bone age app

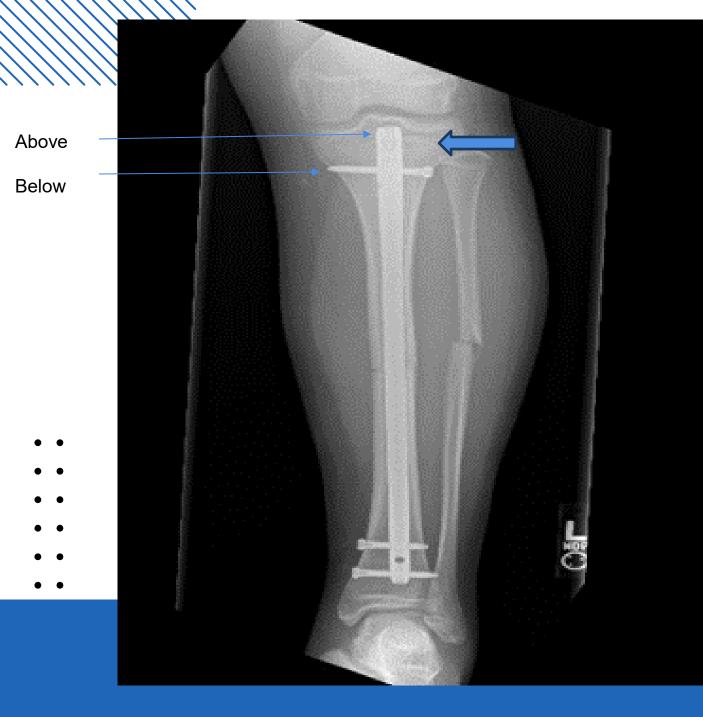
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Fracture location	O Distal 1/3 of shaft Middle 1/3 of shaft Proximal 1/3 of shaft	reset	Fracture open (not open or closed reduction)	
Fracture characteristics	 Transverse Spiral Oblique Comminuted 	reset	ΟΤΑ	Tibia
Fracture open	O Yes ∽ M O No	reset		41 Proximal end segment 40. Extransional 404. Addata 404. Addata 409. Verbin 409. Verbin 419. Verbin 418. Verbin 418. Verbin 418. Verbin 418. Verbin 418. Verbin
Fibula fracture	O Yes ☞M O No	reset	4IAI 4IA2 4IA3 4IBI 4IB2 4IB3 4ICI 4IC2 4IC3	Gompleta articular Gompleta articular GCI Simple articular articular articular simple metaphyseal AICS Simple articular wedge or multilingmentary metaphyseal AICS Fragmentary or multilingmentary metaphyseal Gompleta segment
OTA Classification Attachment: Attachment: ota.jpg (259.6 kB) *Use the link provided above to identify the OTA Classification*			42M 42A2 42A3 42E2 42E3 42C2 42C3	423. Simple 423.7. Sprail 424.7. Sprail 424.7. Transmerse (c. 37) 424.7. Transmerse (c. 37) 425.7. Transmerse (c. 37) 426.7. Transmerse (c. 37) 427.7. Transmerse (c. 37) 428.7. Transmerse (c. 37) 420.7. Transmerse (c. 37) 420.2. Transmerse (c. 37) 420.2. Transmerse (c. 37) 420.2. Transmerse (c. 38) 420.7. Transmer
 • • • • • • • • • 			434 4342 4343 438 4382 4383 4301 4502 4503	AC: The and trady was a constraining a first and a degree. A degree of the analysis of the an

Nail technique	 Suprapatellar Infrapatellar Extraarticular lateral Other: 		Implants: Implant Name	Туре	Inv. Item	Serial No.	Manufacturer	Lot No.		No. Used	Action
Nail Diameter	₽ M	reset	SMITH & Nail NEPHEW/RICHCO /ORTHO TRIGEN	SMITH & NEPHEW/RIC HCO/ORTHO Trigen Meta- nail 10mm 36cm Tibial Nail Intramedullary	Smith & Nephew/Richco/ Ortho	22CT6 1140	Right	1	Implanted		
Nail Length	₽® cm		META-NAIL 10MM 36CM TIBIAL NAIL INTRAMEDULLAR								
Nail Manufacturer	~M		Y TITANIUM 71655136 -								
Nail location	 Above physis At physis Below physis 	reset	LOG11588750	-	Titanium 71655136		A A		.		· · · ·

- In the op notes on the date of surgery you can find all of the specific nail
 information
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Date of x-ray depicting radiographic healing	→ M Today M-D-Y
Time for radiographic healing	View equation
Post-op immobilization	Cast/splint Boot Other:
Date patient regained full weight bearing without assistance	₩ Today M-D-Y
Time to full weight bearing without assistance	View equation
Complications?	● Yes
Complications	 Infection VTE (Venous thrombosis) Nerve or vessel injury Physeal arrest Delayed/nonunion Unplanned return to OR (i.e. other than HWR) Ipsilateral extremity injury Other:
Return to OR for HWR	O Yes ∽ M O No reset
Full return to normal activities and sports?	○ Yes
Last date of follow-up after injury	General M-D-Y

Healing

The date at which the physician has indicated that there is radiographic healing.

Complications

Only list complications that are **POST TREATMENT**. Both deep and superficial infections are included. Do not include Compartment syndrome or hardware removal as complications.

Feedback

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Please reach out with any questions, comments, concerns!

- Data entry guide unclear
- REDCap errors, typos, access, etc.
- Unable to find certain data points

Customer Support 24/7: mjoshua@wustl.edu

