

Unreamed Intramedullary Nailing Versus External Fixation for the Treatment of Open Tibial Shaft Fractures in Uganda: A Randomized Clinical Trial

Objective: To compare unreamed intramedullary nailing versus external fixation for the treatment of Gustilo-Anderson type II and IIIA open tibial fractures admitted to a hospital in rural Uganda.

Design: Randomized clinical trial.

Setting: Regional referral hospital in Uganda.

Patients: Fifty-five skeletally mature patients with a Gustilo-Anderson type II or IIIA open tibia shaft fracture treated within 24 hours of injury between May 2016 and December 2019.

Intervention: Unreamed intramedullary nailing (n = 31) versus external fixation (n = 24).

Main Outcome Measurements: The primary outcome was function within 12 months of injury, measured using the Function Index for Trauma (FIX-IT) score. Secondary outcomes included health-related quality of life (HRQoL) using the EQ-5D-3L, radiographic healing using the Radiographic Union Scale for Tibia (RUST) fractures score, and clinical complications.

Results: Treatment with an intramedullary nail resulted in a 1.0 point higher (95% CrI, 0.1 to 1.9) FIX-IT score compared to external fixation. Results were similar for the secondary patient-reported outcomes, EQ-5D-3L and EQ-VAS. RUST scores were not different between groups at any time point. Treatment with an intramedullary nail was associated with a 22.1% (95% CrI -42.6% to 1.7%) lower rate of malunion and a 20.8% (95% CrI -44.0% to 2.9%) lower rate of superficial infection.

Conclusion: In rural Uganda, treatment of open tibial shaft fractures with an unreamed intramedullary nail results in marginal clinically important improvements in functional outcomes, though there is likely an important reduction in malunion and superficial infection.

Table 1. Patient Characteristics

Characteristic	Intramedullary Nail N = 31	External Fixation N = 24
Age, years, mean (SD)	39 (11)	39 (13)
Male	21 (68%)	16 (67%)
Smoker	7 (23%)	4 (17%)
Alcohol use	21 (68%)	10 (42%)
Gustilo-Anderson type		
II	8 (26%)	5 (21%)
IIIA	23 (74%)	19 (79%)
OTA/AO classification		
42A	18 (58%)	15 (62%)
42B	9 (29%)	8 (33%)
42C	4 (13%)	1 (4%)
Mechanism of injury		
Car	3 (10%)	3 (12%)
Motorbike	20 (65%)	19 (79%)
Other	4 (13%)	1 (4%)
Pedestrian	4 (13%)	1 (4%)

Table 2. Primary and Secondary Outcomes, Treatment Differences, and Probability of Treatment Effect

Outcome	Intramedul lary Nail	External Fixation	Neutral Priors			Informative Priors ¹		Prob of Treatment Benefit Greater than Pre- Specified MCID ¹
			Difference (95% CrI)	Prob of Treatmen t Benefit Greater than 0	Prob of Treatmen t Benefit Greater than Pre- Specified MCID ¹	Difference (95% CrI)	Prob of Treatment Benefit Greater than 0	
<i>Primary</i>								
FIX-IT, overall mean ± SD	10.3 ± 2.7	8.9 ± 3.0	1.0 (0.1 to 1.9)	98%	16%	1.4 (0.7 to 2.1)	>99%	38%
1.5-month	7.6 ± 3.3	6.7 ± 2.1	-	-		-	-	
3-month	10.7 ± 1.8	7.9 ± 2.7	-	-		-	-	
6-month	11.8 ± 0.4	10.0 ± 3.3	-	-		-	-	
12-month	11.5 ± 1.1	11.4 ± 1.9	-	-		-	-	
<i>Secondary</i>								
EQ-5D-3L, overall mean ± SD	0.88 ± 0.13	0.83 ± 0.13	0.05 (0.00 to 0.10)	96%	44%	0.05 (0.00 to 0.10)	96%	45%
1.5-month	0.78 ± 0.09	0.78 ± 0.10	-	-		-	-	
3-month	0.86 ± 0.13	0.81 ± 0.15	-	-		-	-	

6-month	0.93 ± 0.13	0.82 ± 0.12	-	-		-	-	
12-month	0.98 ± 0.06	0.95 ± 0.11	-	-		-	-	
EQ-VAS, overall mean ± SD	80.5 ± 14.5	77.1 ± 14.3	3.2 (-5.7 to 12.0)	76%	34%	4.2 (-4.6 to 13.2)	83%	43%
1.5-month	70.4 ± 16.1	71.5 ± 12.8	-	-		-	-	
3-month	79.8 ± 12.3	79.1 ± 13.0	-	-		-	-	
6-month	83.8 ± 10.7	70.5 ± 13.5	-	-		-	-	
12-month	88.2 ± 12.3	88.9 ± 12.0	-	-		-	-	
RUST, mean ± SD	7.8 ± 3.0	7.4 ± 2.8	0.1 (-0.8 to 1.1)	59%	0%	0.9 (0.2 to 1.7)	>99%	6%
1.5-month	4.5 ± 0.8	4.4 ± 0.5	-	-		-	-	
3-month	7.3 ± 1.9	7.7 ± 0.8	-	-		-	-	
6-month	7.5 ± 2.6	7.5 ± 1.7	-	-		-	-	
12-month	10.7 ± 1.9	10.6 ± 2.7	-	-		-	-	
Malunion, no. (%)	3 (9.7%)	8 (33.3%)	-22.1% (-42.6% to -1.7%)	98%	87%	-15.7% (-30.2% to -1.5%)	98%	79%
Nonunion, no. (%)	3 (9.7%)	2 (8.3%)	0.0% (-16.4% to 15.5%)	47%	23%	-1.6% (-15.1% to 10.8%)	59%	29%
Deep infection, no. (%)	4 (12.9%)	3 (12.5%)	0.0% (-19.3% to 17.1%)	49%	30%	0.0% (-17.6% to 18.6%)	51%	37%
Superficial infection, no. (%)	6 (19.4%)	10 (41.7%)	-20.8% (-44.0% to 2.9%)	96%	82%	-11.6% (-26.3% to 3.4%)	93%	80%
Wound healing, no. (%)	3 (9.9%)	2 (8.3%)	0.8% (-16.3% to 17.4%)	48%	12%	-1.5% (-14.3% to 10.4%)	59%	28%

¹**Note:** The informative priors and pre-specified minimal clinically important difference (MCID) are based on an effect size of Cohen's $d = 0.5$ as observed in: Foote CJ, Guyatt GH, Vignesh KN, Mundi R, Chaudhry H, Heels-Ansdell D, Thabane L, Tornetta P 3rd, Bhandari M. Which Surgical

Treatment for Open Tibial Shaft Fractures Results in the Fewest Reoperations? A Network Meta-analysis. Clin Orthop Relat Res. 2015 Jul;473(7):2179-92.

The effect size values are scaled below for each study outcome.

FIX-IT = 1.5-point; EQ-5D-3L = 0.05-point; EQ-VAS = 5-point; RUST = 1.5-point; malunion = 10% absolute difference; nonunion = 5% absolute difference; deep surgical site infection = 5% absolute difference; superficial infection = 5% absolute difference; wound healing = 5% absolute difference.

Figure 1. Temporal trends in a) FIX-IT score, b) EQ-5D-3L, c) EQ-VAS, and d) RUST score by treatment arm.

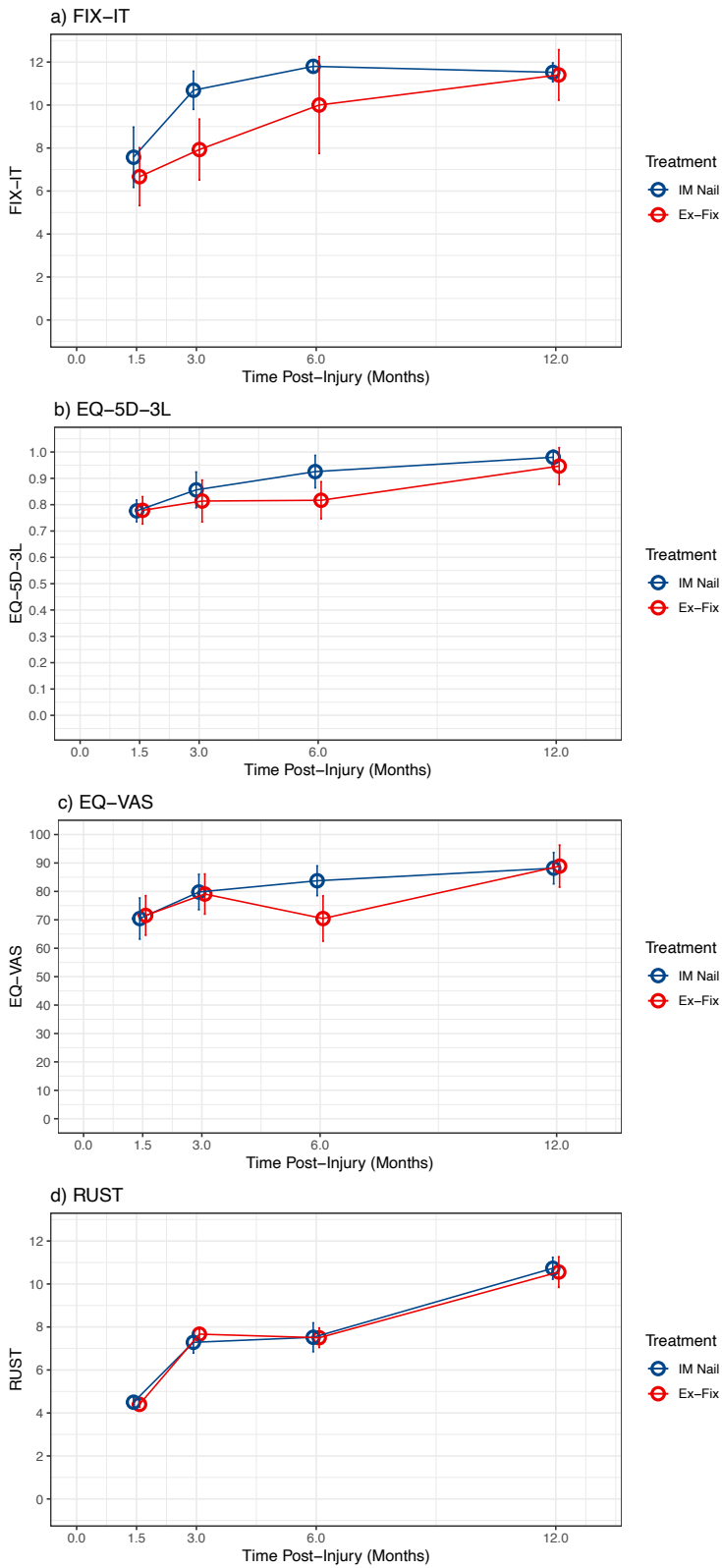


Figure 2. Probability of improved FIX-IT score within 12 months of injury with intramedullary nailing versus external fixation as estimated using a Bayesian analysis with neutral priors.

