

Pain Outcomes Following Modern External Ring Fixation versus Internal Fixation for Severe Open Tibial Fractures: A Secondary Analysis of a Prospective Randomized Trial (FIXIT)

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INTRODUCTION: It is unclear whether pain outcomes in patients with severe open tibial shaft fractures differ according to whether they are treated with modern external ring fixation versus internal fixation. Therefore, the purpose of this study was to report predefined outcomes of pain intensity and interference in a multicenter randomized clinical trial (FIXIT) of open tibial shaft fractures treated with ring fixation versus internal fixation. Our questions included: 1) Is the use of external fixation associated with better pain outcomes, including the Brief Pain Inventory (BPI) and numeric pain rating scale (NPRS), as compared to internal fixation at 6 months and 12 months?, 2) As pin-site infections are a known cause of pain in patients treated with external fixation, is the presence of pin-site infection a moderator for elevated pain?, and 3) What was the overall incidence of moderate-to-severe pain in this cohort?

METHODS: 260 patients between 18 to 64 years of age from 20 trauma centers were randomized to modern external ring fixation or internal fixation, of which 254 were included in final analysis (122 external fixation vs. 132 internal fixation) (**Figure 1 Consort diagram**). The primary outcome for this analysis was the Brief Pain Inventory (BPI) intensity and interference at 6 months and 12 months. Secondary outcomes included the numerical pain rating scale (NPRS) and the incidence of moderate-to-severe pain at 6 months and 12 months. Additionally, a post-hoc analysis of only external fixation patients was performed comparing those with and without pin-site infections to determine if these infections were a moderator for increased pain. Mann-Whitney U-tests were performed comparing BPI scores between groups at 6 and 12 months. Furthermore, a linear mixed-effects regression model was used to examine the effect of treatment on outcomes over 12 months.

RESULTS: When comparing just 6-month follow-up, patients with external fixation did not have different BPI intensity [median (interquartile range) 4.1 (2.2-5.5) vs. 3.0 (1.8-5.8), $P=0.11$], but had significantly greater BPI interference [6.0 (3.3-8.0) vs. 4.0 (1.9-7.4), $P=0.01$, **Table 1**]. However, when considering the entire 12-month follow-up period, the fixation method did not affect either BPI intensity [3.3 (1.3-5.3) vs. 3.5 (1.6-5.8), $P=0.27$, **Figure 2**] or BPI interference [4.6 (1.9-7.0) vs. 5.0 (2.1-7.4), $P=0.55$, **Figure 3**]. There was no significant treatment effect on NPRS scores when considering the entire 12-month follow-up period. Eleven (9%) patients had pin-site infections, at a mean of 98 ± 55 days from randomization. Patients with pin-site infections had greater pain intensity at 6 months [5.0 (5.0-7.0) vs. 4.0 (2.0-5.0), $P=0.009$], but not interference [7.0 (5.0-9.0) vs. 6.0 (3.0-8.0), $P=0.096$]. There was no significant difference in pain intensity [3.0 (2.0-5.0) vs. 3.0 (1.0-5.0), $P=0.795$] or interference [4.0 (4.0-9.0) vs. 5.0 (2.0-7.0), $P=0.696$] at 12 months between those with and without pin-site infections. The moderate-to-severe pain incidence was consistent over timepoints, with 33% at 6 months and 35% at 12 months.

DISCUSSION AND CONCLUSION: Modern external ring fixation was associated with greater pain interference at 6 months versus internal fixation, which may be partly attributable to pin-site infections. However, no differences in pain interference or intensity were seen at 12 months. Approximately one-third of patients in both treatment groups had moderate-to-severe pain at both timepoints, highlighting that persistent pain is common after these fractures. These findings argue against the routine use of definitive modern external ring fixation in patients with severe open tibial shaft fractures.

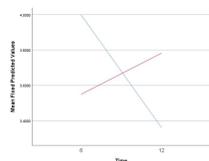
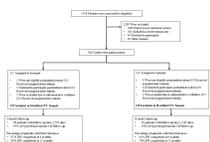


Figure 2. Mixed model linear regression of BPI Intensity pain scores at 6 and 12 months between External Fixation and Internal Fixation treatment groups: Effects of treatment ($F = 0.002$, $P = 0.962$) and time ($F = 1.556$, $P = 0.211$). Interaction between time and treatment effect was not significant ($F = 4.548$, $P = 0.030$).

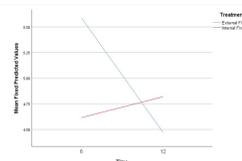


Figure 3. Mixed model linear regression of BPI Interference pain scores at 6 and 12 months between External Fixation and Internal Fixation treatment groups: Effects of treatment ($F = 0.757$, $P = 0.385$) and time ($F = 12.058$, $P = 0.001$). Interaction between time and treatment effect was not significant ($F = 12.096$, $P = 0.001$).

Table 1. Primary outcomes between external and internal fixation groups.

BPI Measure by Timepoint	No. of Cases with External/Internal Fixation	Median [interquartile range]	External Fixation	Internal Fixation	P-value
Pain intensity	6 Months	4.1 [2.2, 5.5]	3.0 [1.8, 5.8]	.11	
	12 Months	3.3 [1.3, 5.3]	3.5 [1.6, 5.8]	.27	
Pain interference	6 Months	6.0 [3.3, 8.0]	4.0 [1.9, 7.4]	.01	
	12 Months	4.6 [1.9, 7.0]	5.0 [2.1, 7.4]	.55	

BPI, Brief Pain Inventory.