Is It Safe to Prep the External Fixator In Situ During Staged Open Reduction and Internal Fixation of Pilon Fractures? A Retrospective Comparative Cohort Study

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Purpose: Our objective was to compare the risk of fracture-related infection (FRI) and unplanned re-peration after staged open reduction and internal fixation (ORIF) of pilon fractures between cases in which components of the temporizing external fixator (ex-fix) were prepped into the surgical field and cases in which it was completely removed prior to definitive fixation.

Methods: This was a multisurgeon retrospective comparative cohort study on patients 18 years and older with pilon fractures who underwent operative treatment over a 10-year period between January 1, 2010 and January 1, 2020 at an academicl Level I trauma center. Medical records and radiographic images were reviewed for each patient to assess demographics, clinical characteristics and surgical outcomes. The primary outcome measures were FRI and unplanned reoperation, including arthrodesis and amputation. All analyses were completed using JMP Software and $\alpha = 0.05$ was used for statistical significance.

Results: 133 patients were treated with staged ORIF, including 47 fractures that had retained components of the original ex-fix prepped in situ during surgery for ORIF and 86 that had the ex-fix entirely removed prior to prepping and draping. The overall rate of fracture-related infection was 23.3% while the overall rate of unplanned reoperation was 11.3% with a 4.5% rate of arthrodesis and 6.8% rate of amputation. There was no difference in FRI between the group in which ex-fix was prepped in situ and the group in which it was completely removed (23.4% vs 23.3%, P = 0.985) and no difference in the overall rate of unplanned reoperation (10.6% vs 11.6%, P = 0.863). Looking at the subset of patients with FRI, those with the ex-fix prepped in situ had a higher prevalence of infection with methicillin-resistant Staphyloccus aureus (MRSA) and methicillin-sensitive S. aureus (MSSA) (81.8% vs 40%, P = 0.021). Using $\alpha = 0.05$, and power = 0.8, a sample size of 42 patients with FRI post-ORIF (27 with ex-fix prepped in situ, and 15 with ex-fix completely removed) would be needed to detect a difference in MRSA / MSSA bacteriology.

Conclusion: Although there were relatively high complication rates in this cohort of pilon fractures treated with staged ORIF, prepping in situ components of the external fixator did not lead to a significant increase in rates of FRI or unplanned reoperation, including arthrodesis and amputation. This study offers clinical guidance regarding maintaining and prepping in situ the existing external fixator during definitive fixation of pilon fractures.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device they wish to use in clinical practice.