Evaluating the Validity of a Novel Open Fracture Classification (OFC3) Using Post-Fixation Adverse Events in Open Tibia Fractures

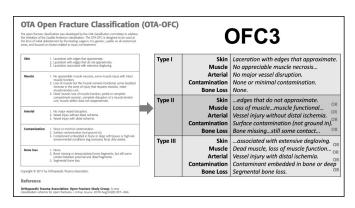
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Purpose: The Orthopaedic Trauma Association-Open Fracture Classification (OTA-OFC) was developed in 2010 to replace the Gustilo-Anderson (GA) Classification for open fractures, which lacks consideration for wound contamination, bone loss, and muscle injury. However, the OTA-OFC classification is seldom used by clinicians due to concerns about its complexity. A modification to OTA-OFC has since been proposed, coined "OFC3". OFC3 uses the highest severity levels across the 5 OTA-OFC domains to classify a fracture into 3 categories (Figure 1). However, to our knowledge no studies have attempted to validate OFC3. This study assesses OFC3 validity by examining the association between fracture classification and post-surgical adverse events in open tibia fractures.

Methods: Data from patients with open tibia fractures in 2 studies conducted in Tanzania (Pilot GO-Tibia Randomized Controlled Trial [RCT], External Fixator vs Intramedullary Nail RCT) were pooled. An adverse event was noted if patients suffered: deep/superficial surgical site infection, delayed wound healing, or malunion/nonunion. Multivariate logistic regression analyses were conducted to compare summation of all domain scores (OTA-OFC Sum), domain-specific scores (OTA-OFC domains), and OFC3. All statistics were performed using STATA version 15.0.

Results: For OTA-OFC Sum score, our model demonstrated that a higher score had higher odds of adverse events (odds ratio [OR], 1.41 [95% confidence interval [CI], 1.08-1.82]). OFC3 type III had higher odds of an adverse event compared to OFC3 type I (OR, 5.06 [95%CI, 1.27-20.16]) and OFC3 type II (OR, 3.03 [95%CI, 1.04-17.24]). OTA-OFC muscle score of 2 had higher odds to have an adverse event in comparison to OTA-OFC muscle score of 1 (OR 7.5, [95%CI, 2.04-37.89]). All other OTA-OFC domain-specific comparisons were not significant. GA classification was available for analysis in a subgroup but did not show a correlation to the rate of adverse events (OR, 1.62 [95% CI, .52-5.22]) for adverse event GA Type III relative to GA Type II).

Conclusion: OTA-OFC Sum, OFC3, and OTA-OFC muscle domain were predictive of adverse events. This study supports the OTA-OFC classification's validity and the need to score all classification domains when using it. The suggested OFC3 modification may serve as the 'best of both worlds' as it retains the OTA-OFC predictive abilities while communicating as efficiently as the GA classification.



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.