

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.

OTA Open Fracture Classification (OTA-OFC)		OFC3	
<p>Skin</p> <ol style="list-style-type: none"> 1. Laceration with edges that approximate. 2. Laceration with edges that do not approximate. 3. Laceration associated with retained debris. 	<p>→</p>	Type I	<p>Skin Muscle Arterial Contamination Bone Loss</p> <p>Laceration with edges that approximate. No appreciable muscle necrosis... No major vessel disruption. None or minimal contamination. None.</p>
<p>Muscle</p> <ol style="list-style-type: none"> 1. No appreciable muscle necrosis, some muscle injury with intact muscle function. 2. Loss of muscle but the muscle remains functional, some localized necrosis in the zone of injury that requires extensive, intact muscle-tendon unit. 3. Dead muscle, loss of muscle function, partial or complete non-repairment possible, complete disruption of a muscle-tendon unit, muscle defect does not approximate. 		Type II	<p>Skin Muscle Arterial Contamination Bone Loss</p> <p>...edges that do not approximate. Loss of muscle...muscle functional... Vessel injury without distal ischemia. Surface contamination (not ground in). Bone missing...still some contact...</p>
<p>Arterial</p> <ol style="list-style-type: none"> 1. No major vessel disruption. 2. Vessel injury without distal ischemia. 3. Contaminant embedded in bone or deep soft tissues or high-risk environmental conditions (eg, bayonet, frost, dirty water). 		Type III	<p>Skin Muscle Arterial Contamination Bone Loss</p> <p>...associated with extensive degloving. Dead muscle, loss of muscle function... Vessel injury with distal ischemia. Contaminant embedded in bone or deep soft tissues. Segmental bone loss.</p>
<p>Contamination</p> <ol style="list-style-type: none"> 1. None or minimal contamination. 2. Surface contamination (not ground in). 3. Contaminant embedded in bone or deep soft tissues or high-risk environmental conditions (eg, bayonet, frost, dirty water). 			
<p>Bone loss</p> <ol style="list-style-type: none"> 1. None. 2. Bone missing or disarticulated bone fragments, but still some contact between proximal and distal fragments. 3. Segmental bone loss. 			

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.