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Δ Prognostic Factors for Predicting Reoperations after Operative Management of Open Fractures

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Purpose: Open fractures are often complicated by infections, wound healing problems, and failure of fracture healing—many of which necessitate operative management and result in delayed return to function. Identifying factors that are associated with these detrimental outcomes may help to optimize the care of these challenging injuries. The FLOW (Fluid Lavage of Open Wounds) trial recently evaluated the effects of irrigation solution and pressure in 2447 patients with open extremity fractures of whom 323 required a reoperation. Using the data from this multicenter trial, we investigated the association between key baseline and surgical factors and risk of reoperation within 1 year.

Methods: Based on biologic rationale and previous reports in the literature, we identified 23 potential prognostic factors from the baseline, fracture characteristics, and surgical data collected as part of the FLOW trial. Selected factors are summarized in Table 1. We used a multivariable Cox proportional hazards regression analysis to investigate their association with increased risk of reoperation within 1 year to treat an infection, wound healing problem, or fracture healing problem (ie, primary outcome of the FLOW trial). All tests were 2-tailed with $\alpha = 0.05$.

Results: We found the following fracture characteristics were associated with an increased risk of reoperation: lower extremity fractures (hazard ratio [HR] = 2.93, 95% CI 1.97-4.35),

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See pages 49 - 106 for financial disclosure information.

Gustilo-Anderson Type III fractures (HR = 1.49, 95% CI 1.14-1.96), and moderate to severe wound contamination (HR = 1.33, 95% CI 1.01-1.75). We also found that patients who received a surgical preparation solution in the emergency room and those who received an iodine-based preparation solution in the operating room had decreased risk of reoperation (HR = 0.66, 95% CI 0.48-0.91 and HR = 0.53, 95% CI 0.30-0.94, respectively). Delayed time to initial surgery (≥ 6 hours from injury) was not associated with an increased risk of reoperation.

Conclusion: As expected, Gustilo-Anderson Type III fractures, highly contaminated wounds, and fractures of the lower extremity were associated with an increased risk of reoperation. Results of this analysis also suggest that surgeons' choice of skin preparation solution and the use of a skin preparation solution in the emergency room may have an impact on rates of reoperation following an open fracture, warranting further investigation.

Table 1: Factors associated with re-operation within one year to treat an infection, wound healing problem or fracture healing problem in open fractures

Independent Variable	Frequency n (%)	Adjusted Hazard Ratio (95% CI)	p-value
Gender			
Male	1598 (69.48)	1.00	0.5111
Female	702 (30.52)	1.097 (0.833-1.443)	
Smoking status			
Current smoker	750 (32.61)	1.020 (0.803-1.296)	0.8696
Non-smoker	1550 (67.39)	1.00	
Mechanism of Injury			
High energy	2029 (88.22)	0.940 (0.605-1.463)	0.7849
Low energy	271 (11.78)	1.00	
Major Concomitant Trauma			
Yes	310 (13.48)	1.00	0.5080
No	1990 (86.52)	0.897 (0.650-1.237)	
Work-related Injury			
Yes	332 (14.43)	1.351 (0.996-1.833)	0.0533
No	1968 (85.57)	1.00	
OTA Fracture Class			
A	713 (31.00)	1.00	0.5778 0.1619
B	710 (30.87)	1.092 (0.802-1.487)	
C	877 (38.13)	1.235 (0.919-1.661)	
Location			
Lower extremity fracture	1582 (68.78)	2.927 (1.970-4.351)	<.0001
Upper extremity fracture	718 (31.22)	1.00	
Wound Contamination			
Mild	1765 (76.74)	1.00	0.0439
Moderate/Severe	535 (23.26)	1.329 (1.008-1.753)	
Wound Prep in ER			
Yes (Iodine, Chlorhex, Alcohol)	569 (24.74)	0.660 (0.481-0.906)	0.0100
No	1731 (75.26)	1.00	
Randomized Solution			
Saline	1144 (49.74)	1.00	0.0055
Soap	1156 (50.26)	1.382 (1.100-17.37)	
Randomized Pressure			
Very Low	770 (33.48)	1.056 (0.798-1.396)	0.7042 0.8596
Low	755 (32.83)	1.00	
High	775 (33.70)	1.026 (0.775-1.358)	
Time to Incision from Injury			
<6 hrs	458 (19.91)	1.00	0.7535
≥6 hrs	1842 (80.09)	1.044 (0.797-1.369)	
Iodine Prep Solution in OR			
Yes	1195 (51.96)	0.527 (0.296-0.935)	0.0287
No	1105 (48.04)	1.00	
Chlorhexidine Prep Solution in OR			
Yes	1019 (44.30)	0.651 (0.370-1.145)	0.1366
No	1281 (55.70)	1.0	
Alcohol Prep Solution in OR			
Yes	389 (16.91)	0.883 (0.640, 1.221)	0.4524
No	1911 (83.09)	1.0	
Other Prep Solution in OR			
Yes	137 (5.96)	1.067 (0.568-2.008)	0.8387
No	2163 (94.04)	1.0	

Initial Fixation Approach			
Plate	919 (39.96)	1.00	
Nail	714 (31.04)	1.091 (0.790-1.506)	0.5982
External fixation	354 (15.39)	1.322 (0.931-1.879)	0.1192
Other internal fixation	281 (12.22)	0.645 (0.403-1.034)	0.0683
No initial fixation	32 (1.39)	0.466 (0.114-1.908)	0.2882
Local Antibiotics at Wound			
Yes (beads)	73 (3.17)	1.433 (0.890-2.341)	0.1371
No	2227 (96.83)	1.00	
Amount of Muscle Debrided			
None/Small	2025 (88.04)	1.00	0.2462
Moderate/Large	275 (11.96)	1.233 (0.865-1.758)	
Amount of Skin Debrided			
None/Small	1979 (86.04)	1.00	0.8324
Moderate/Large	321 (13.96)	0.962 (0.678-1.366)	
Wound closed at initial procedure?			
Yes	1936 (84.17)	1.00	0.1371
No	364 (15.83)	1.260 (0.929-1.710)	
Fracture Severity (Gustilo Type-Post Op)			
Type I/II	1471 (63.96)	1.00	0.0036
Type III	829 (36.04)	1.49 (1.14-1.96)	
Post Op Fracture Gap			
<1cm	2067 (89.87)	1.00	0.4034
1cm or greater	233 (10.13)	0.856 (0.594-1.23)	

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