

**Δ Health-Related Quality of Life Following Operative Management of Open Fractures**

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**Purpose:** Open fractures are common and debilitating injuries yet there are little data on the health-related quality of life and function following operative management. The recently completed FLOW (Fluid Lavage of Open Wounds) trial was a multicenter, blinded, randomized controlled trial, using a 2 × 3 factorial design that evaluated irrigation solution (soap vs normal saline) and irrigation pressure (very low vs low vs high) in patients with open fracture wounds. The FLOW primary analysis of 2447 patients found soap to have a significantly higher reoperation rate than saline and found no differences between the irrigation pressures evaluated. Using the FLOW data, we sought to describe health-related quality of life and function for patients in the year following their open fracture.

**Methods:** Patients enrolled in the FLOW study completed the Short Form-12 (SF-12) and the EuroQol-5 Dimensions (EQ-5D) at baseline (preinjury recall) and at 2 and 6 weeks, and 3, 6, 9, and 12 months postfracture. Using the standardized scoring method, we calculated the Physical Component Score (PCS) and the Mental Component Score (MCS) of the Short Form (SF)-12. The PCS and MCS are expressed on a scale from 0 to 100 with a minimally important difference of 5 points. EQ-5D results are expressed as a utility score on a scale from 0 to 1 with a minimally important difference of 0.03. The mean scores for the SF-12 PCS, SF-12 MCS, and EQ-5D were plotted over time for all patients and separately by treatment group. We conducted a multilevel Cox proportional hazards regression analysis with three levels (center, patient, and time of follow-up).

**Results:** We did not find any significant differences between soap and saline and between the three irrigation pressure groups on the SF-12 PCS, SF-12 MCS, and EQ-5D ( $P > 0.5$ ). Patients had not returned to their preinjury function at 12 months for any of the three functional outcomes ( $P < 0.001$ ). Patients' SF-12 PCS score at 12 months was 10.15 (95% CI 9.51-10.79) points lower than their preinjury score and their SF-12 MCS score was 2.66 (95% CI 2.01-3.31) points lower than their preinjury score. Patients' utility scores were 0.15 (95% CI 0.14-0.16) lower at 12 months than preinjury.

**Conclusion:** Similar to the findings of the FLOW primary analysis, there were no differences between irrigation pressures in the SF-12 and EQ-5D. The significant effect of irrigation solutions in our primary analysis was not found in the health-related quality of life and functional outcomes. This may be a result of generic instruments used not being sensitive

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See pages 49 - 106 for financial disclosure information.

enough to capture differences due to reoperation or this may be due to reoperations not having a large impact on general quality of life and physical function. Patients sustaining open fractures had not returned to their pr-injury status at 12 months postfracture, as demonstrated by the clinically significant lower SF-12 PCS and utility scores.

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.