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ORIGINAL ARTICLE

## A Trial of Wound Irrigation in the Initial Management of Open Fracture Wounds

The FLOW Investigators

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### BACKGROUND

The management of open fractures requires wound irrigation and débridement to remove contaminants, but the effectiveness of various pressures and solutions for irrigation remains controversial. We investigated the effects of castile soap versus normal saline irrigation delivered by means of high, low, or very low irrigation pressure.

### METHODS

In this study with a 2-by-3 factorial design, conducted at 41 clinical centers, we randomly assigned patients who had an open fracture of an extremity to undergo irrigation with one of three irrigation pressures (high pressure [ $>20$  psi], low pressure [5 to 10 psi], or very low pressure [1 to 2 psi]) and one of two irrigation solutions (castile soap or normal saline). The primary end point was reoperation within 12 months after the index surgery for promotion of wound or bone healing or treatment of a wound infection.

### RESULTS

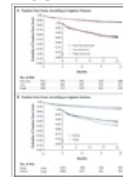
A total of 2551 patients underwent randomization, of whom 2447 were deemed eligible and included in the final analyses. Reoperation occurred in 109 of 826 patients (13.2%) in the high-pressure group, 103 of 809 (12.7%) in the low-pressure group, and 111 of 812 (13.7%) in the very-low-pressure group. Hazard ratios for the three pairwise comparisons were as follows: for low versus high pressure, 0.92 (95% confidence interval [CI], 0.70 to 1.20;  $P=0.53$ ), for high versus very low pressure, 1.02 (95% CI, 0.78 to 1.33;  $P=0.89$ ), and for low versus very low pressure, 0.93 (95% CI, 0.71 to 1.23;  $P=0.62$ ). Reoperation occurred in 182 of 1229 patients (14.8%) in the soap group and in 141 of 1218 (11.6%) in the saline group (hazard ratio, 1.32, 95% CI, 1.06 to 1.66;  $P=0.01$ ).

### CONCLUSIONS

The rates of reoperation were similar regardless of irrigation pressure, a finding that indicates that very low pressure is an acceptable, low-cost alternative for the irrigation of open fractures. The reoperation rate was higher in the soap group than in the saline group. (Funded by the Canadian Institutes of Health Research and others; FLOW ClinicalTrials.gov number, [NCT00788398](#).)

#### MEDIA IN THIS ARTICLE

##### FIGURE 1



Kaplan-Meier Estimates of Freedom from the Primary End Point.

##### FIGURE 2



Subgroup Analyses of the Primary End Point, According to Irrigation Solution.

#### ARTICLE ACTIVITY

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[Disclosure forms](#) provided by the authors are available with the full text of this article at NEJM.org.

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A complete list of the Fluid Lavage of Open Wounds (FLOW) Investigators is provided in the [Supplementary Appendix](#), available at NEJM.org.

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