

A Multicenter, Blinded, Randomized Trial Comparing Soap Versus Saline Lavage in Patients with Open Fractures

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Background/Purpose: Open fractures can have devastating complications, including infections, wound healing problems, and failure of fracture healing, many of which necessitate subsequent operations. The initial management of open fractures mandates a thorough wound irrigation and debridement to remove contaminants. A lack of consensus regarding the optimal approach to irrigating open fracture wounds fueled the design and execution of the FLOW multinational randomized controlled trial (RCT). Using a 2 x 3 factorial design, FLOW investigated the effects of irrigation solutions (soap vs normal saline) and irrigation pressure (low vs high; gravity flow vs high; low vs gravity flow) on reoperation within one year among patients with open fractures. Here, we present the effect of the type of irrigating solution on reoperation rates.

Methods: The FLOW RCT included patients with operatively managed open fractures of the extremity randomized to one of the two open wound irrigation arms (castile soap and normal saline). The primary outcome was reoperation within 12 months to promote wound or bone healing, or to treat an infection. Secondary outcomes included patient function and quality of life measured by the Short Form-12 (SF-12) and the EuroQol-5D (EQ-5D) at 1, 2, and 6 weeks, and 3, 6, 9, and 12 months, as well as rates of nonoperatively managed infections, wound healing problems, and fracture healing problems within 12 months. Patients, outcome adjudicators, and data analysts were blinded. The primary analysis will utilize log-rank test and Kaplan-Meier survival curve to compare the main effects of irrigation solution on time to the first reoperation after the initial surgery.

Results: 2549 patients were enrolled into the FLOW trial over a 4-year period from 2009 to 2013 at 42 clinical sites in the United States, Canada, Australia, Norway, and India. The final patients completed their 12-month follow-up in the fall of 2014, and data analysis is currently underway. We will complete the analysis and draft papers presenting the primary and secondary outcome results for the irrigating solution comparison in early 2015. Our rationale for submitting the abstract prior to data analysis is to ensure that the OTA is the inaugural venue in which the results of this benchmark trial are presented.

Conclusion: The FLOW trial is the largest randomized trial conducted to date in the field of orthopaedic surgery, and represents a major international effort to identify a simple, effective, and easily applicable strategy for the management of open fracture wounds. The results will determine whether the use of soap solution, at pennies per application, can reduce the risk of reoperation, and will have potentially important clinical and economic implications, in particular to patients in low and middle income countries where disability from traumatic injuries is substantial.

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.