Rates of Surgical Site Infection After Open Fractures: Findings of the UK Wound Management of Open Lower Limb Fractures (WOLLF) Trial

*James Masters, MB BS*¹; Julie Bruce, PhD²; Nick Parsons; Matthew L. Costa, PhD¹ ¹University of Oxford, Oxford, Oxfordshire, UNITED KINGDOM ²Warwick University, Coventry, Warwickshire, UNITED KINGDOM

Purpose: Surgical site infection (SSI) remains a common and significant problem after open fracture. Rates of superficial and deep SSI are estimated between 13% and 26%, although rates vary by definition used. Given that deep infection can result in extensive treatment, including further surgery, it is an important and potentially modifiable outcome after open fractures. We sought to test the effect of different means of diagnosis in the context of the trial.

Methods: We investigated the rate of deep SSI within a multicenter randomized controlled clinical trial comparing negative pressure wound therapy (NPWT) to standard usual care in adults with open fractures of the lower limb. We assessed SSI rates using different criteria: (1) the Centers for Disease Control and Prevention (CDC) definition for superficial and deep SSI assessed at 6 weeks after surgery, (2) digital photographic images taken at 6 weeks, and (3) medical or surgical treatment for deep SSI within 12 months of surgery. At 6 weeks, wounds were assessed and photographed by an independent research assistant. Medical records and adverse event reports up to 12 months after initial surgery were reviewed by an independent surgeon.

Results: A total of 460 participants were randomized to trial interventions (NPWT, n = 226; standard care, n = 234). Median age was 42.5 years (interquartile range, 29-61). The CDC definition comprises multiple individual criteria. For superficial SSI, 68 participants (14.8%) had 1 or more wound symptoms present within 6 weeks of surgery (NPWT 15.5% vs standard care 14.1%). 35 (7.5%) had deep SSI (NPWT 7.1% vs standard care 8.1%). 6-week infection based on assessment of photographic images alone was 12.6% (58 of 460). Longer term follow-up using any medical or surgical treatment of infection within 12 months yielded a deep SSI rate of 17.1%. No differences were found by treatment group by any infection definition.

Conclusion: This is the first large-scale clinical trial to accurately capture infection rates over time after surgical repair of open lower limb fracture. Rates vary by definition used and duration of follow-up. Measurement of deep SSI in the acute postoperative period grossly underestimate longer-term rates. Future studies looking to assess interventions that affect infection should make careful assessment of how the diagnosis of infection is made.

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.