ABSTRACT

Aims: This investigation develops a predictive model for loss of alignment (LOA) following fixation of open tibia fractures. **Patients/methods**: An analysis was performed of adults with diaphyseal open tibia fractures randomized to intramedullary nailing (IMN) or external fixation (EF) followed at 6, 12, 24, and 52 weeks postoperatively. Demographic data were collected at baseline. Pre-injury and follow-up EuroQol 5-Dimensions (EQ-5D) and pain score were measured. Radiographs, taken postoperatively and in follow-up, were assessed for coronal and sagittal angulation, and used to calculate the modified Radiographic Union Scale for Tibia fractures (mRUST). LOA was defined as an increase in angulation >5° by one year follow-up. Fracture comminution was defined using AO/OTA classification. Putative risk factors were assessed for association with LOA using bivariate logistic regression. Adjusted associations with LOA were estimated using multivariable logistic regression and marginal analysis. Results: Analyses included 129 patients (70 IMN, 59 EF), majority male, of mean age 33 years (range 17.7-73) and body mass index (BMI) 25.2 (range 15.5-45.1), with 48% Type A, 41% Type B, and 11% Type C fractures (AO/OTA classification). The likelihood of LOA with EF increased with greater fracture comminution; 45.21% ($p<0.001$), 77.50% ($p<0.001$), and 100% LOA for Type A, B, and C fractures respectively. Relative risk of LOA for EF compared to IMN was 3.87 (95% CI 1.36, 11.02), 3.75 (95% CI 1.77, 7.92), and 5.76 for Type A, B, and C fractures, respectively. Compared to patients who lost alignment, patients without LOA had improved fracture healing ($p = 0.003$) and higher EQ-5D scores ($p = 0.03$) at one year. **Conclusion**: Increasing age and BMI are associated with LOA and segmental fracture amplifies the protective effect of IMN versus EF. The importance of LOA as a surrogate outcome after operative treatment of open tibial fractures is supported by its association with inferior radiographic and functional patient outcomes.

Keywords: Developing countries; External fixation; Intramedullary nail; Loss of alignment; Musculoskeletal trauma; SIGN nail; Tibial shaft fractures.