Preliminary Report: A Prospective, Multicenter Cohort Study to Compare SIGN Nail and Skeletal Traction for Femoral Shaft Fractures in Malawi

Hao-Hua Wu, BA[1]*; Brian C. Lau, MD*[2]*; David Shearer, MD, MPH*[2]*; Linda Chokotho, MBBS*[3]
[1]*Perelman School of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, USA*
[2]*Department of Orthopaedic Surgery, University of California, San Francisco, California, USA*
[3]*Department of Orthopaedics, Beit CURE International Hospital, Blantyre, MALAWI*

Purpose: The purpose of this study is to assess the quality of life of femoral shaft fracture patients treated by skeletal traction and Surgical Implant Generation Network (SIGN) IM nail in a resource-constrained environment.

Methods: Enrollment for this multicenter, prospective cohort study began in February 2016. Consecutive adult patients with femoral shaft fractures (AO/OTA 32) treated by skeletal traction or SIGN IM nail were enrolled at 6 hospitals in southern and central Malawi. Patients with polytrauma, surgical site infection, open fractures, and pathologic fractures were excluded. Primary outcome was the quality of life assessed by EQ-5D index (Zimbabwe) and EQ-5D visual analog scale (VAS). Secondary outcomes included patient-reported functional status using Short Musculoskeletal Function Assessment (SMFA), reoperation rate, complication rate, RUST score (Radiographic Union Score for Tibial Fractures), and objective clinical measures including Squat and Smile, Timed Up and Go, and Chair Stand Test. Patients were administered the EQ-5D and SMFA at baseline, then all subjective and objective tests at 6 weeks, 3 months, 6 months, and 1 year postoperatively.

Results: 260 patients with femoral shaft fractures were screened at 6 hospitals and 125 meeting eligibility criteria were consented (100% enrollment rate). There were 70 (56%) treated definitively by skeletal traction and 55 (44%) treated by IM nail. The most common mechanism of injury was road traffic injury (84%). At the time of this preliminary report, 62 patients reached 6-week follow-up, 43 reached 3-month follow-up, and 18 reached 6-month follow-up. No patients are yet eligible for 1-year follow-up. Patients treated with IM nail reported higher scores on the EQ-5D index, EQ-5D VAS, SMFA Functional Index, and SMFA Bothersome Index at 6 weeks, 3 months, and 6 months postoperatively ($P < 0.05$) compared to those treated with skeletal traction.

Conclusion: The high screening, enrollment, and preliminary follow-up rate demonstrate the feasibility of implementing a multicenter, prospective study in a resource-limited setting. The preliminary data suggest that up to 6 months postoperatively, patients with femoral shaft fractures report higher quality of life and functional outcome if treated with image-unassisted IM nail as compared to skeletal traction.

See pages 401 - 442 for financial disclosure information.