Infrapatellar vs Suprapatellar Intramedullary Nailing for Fractures of the Tibia (INSURT Study): A Multi-Centered Randomized Controlled Trial

David Cinats, MD; Kelly L. Apostle, MD; Dory Boyer, MD; Alan Johnstone, MB, ChB; H. Michael Michael Lemke, MD; Farhad Moola, MD; Bert Perey, MD; Trevor Stone, MD; Darius Viskontas, MD; Canadian Orthopaedic Trauma Society Group; INSURT Study Group

Purpose: Several studies exist that compare infrapatellar nailing to suprapatellar nailing, but appropriately powered studies with objective outcomes are lacking. This international multicentered randomized controlled trial (RCT) aimed to determine if tibial nail insertion technique affects objective and patient-reported outcome measures (PROMs) regarding postoperative knee pain after intramedullary nailing of the tibia.

Methods: We randomized OTA type 42 and 43A fractures to receive infrapatellar or suprapatellar nailing and assessed patients at 6,16, 26, and 52 weeks postoperatively. The primary outcome was the visual analog scale (VAS) after kneeling; secondary outcomes included the patient-blinded Aberdeen Kneeling (AKT) and Aberdeen Standing (AST) weight distribution tests, Lysholm, Photographic Knee Pain Map (PKPM), EuroQol 5 Dimensions (EQ-5D), knee range of motion (ROM), Work Productivity and Activity Impairment Questionnaire (WPAI), fracture reduction, tibial alignment and union rates. The study was powered to detect a 16-point difference in the VAS kneeling test.

Results: A total of 245 patients were included in the final analysis; 128 patients were randomized to suprapatellar nailing and 117 patients to infrapatellar nailing. There were statistically and clinically significant lower VAS kneeling scores with suprapatellar nailing at all time points. The AKT demonstrated the ability to bear significantly more weight through the operative knee after suprapatellar nailing at all time points. PKPM demonstrated more pain in the patellar tendon after infrapatellar nailing and more quadriceps pain after suprapatellar nailing. There was no difference in EQ-5D, Lysholm, or WPAI. There was no difference in knee ROM between groups. Suprapatellar nailing demonstrated a significantly higher rate of anatomic fracture reduction with no differences in union rates or complication rates.

Conclusion: This is the largest and first appropriately-powered RCT comparing suprapatellar and infrapatellar nailing. The primary outcome demonstrated significantly less knee pain at every time point up to one year after suprapatellar nailing. The patient-blinded weight distribution test demonstrated that more weight was born during kneeling after suprapatellar nailing. There was a significantly higher rate of anatomic fracture reduction with suprapatellar nailing. Secondary PROMs did not demonstrate differences between treatments.

The FDA has stated that it is the responsibility of the physician to determine the FDA clearance status of each drug or medical device they wish to use in clinical practice.