ΔRandomized Clinical Trial of Supra- Versus Infrapatellar Tibial Nailing: A Pilot Study

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Purpose: The standard treatment for tibial shaft fractures is intramedullary nailing. This procedure has been described to include two approaches: infrapatellar (IP) and suprapatellar (SP). To our knowledge, no study has directly compared these two techniques. The purpose of this study is through a randomized clinical trial to compare the clinical outcomes and functional status of the knee after IP versus SP tibial nailing.

Methods: After IRB approval, skeletally mature patients with middle 3/5 tibial shaft fractures were randomized into the IP or SP nailing groups after informed consent was obtained. Patients with intra-articular involvement, ipsilateral concomitant injuries, prior knee surgery, or history of gout, rheumatoid, or osteoarthritis were excluded. Standard surgical techniques were employed which included a medial parapatellar IP approach, and a longitudinal quadriceps tendon split SP approach. SP patients also underwent a pre- and post-nailing knee arthroscopy to obtain a visual description of the patellofemoral joint (reviewed by a fellowship-trained sports medicine orthopaedic surgeon). Patients underwent routine follow-up (6 weeks; 3, 6, and 12-months) with standard tibia and knee radiographs, as well as visual analog scale (VAS) and pain diagram documentation. At the 6- and 12-month visits, a complete knee function questionnaire (Lysholm knee scale) and Short Form-36 (SF-36v2) were completed. Additionally, MRI of the affected knee was obtained at 12 months and independently reviewed by a board-certified, fellowship-trained musculoskeletal radiologist. As a pilot study, formal sample size calculations were not performed, and the information obtained from this investigation would enable a proper power analysis for the future larger prospective study. Therefore, 20 patients in each group were planned, with consideration for patient attrition across 12 months of follow-up.

Results: 41 total patients were enrolled, and 26 patients (13 IP, 13 SP) completed 12 months of follow-up. The average ages were 40 and 41 years for IP and SP, respectively. Similarly, each group was comprised of 9 males in IP, 8 in SP. At 12 months, all 26 patients had proceeded to successful union, and functional VAS and Lysholm knee scores showed no significant differences between groups ($P > 0.05$). The SF-36v2 comparison also revealed no significant differences in the overall score, all 4 mental components, and 3 of 4 physical components ($P > 0.05$). The bodily pain component score was superior in the SP group (46 vs. 36, $P = 0.022$) suggesting less pain and disability. Clinically, the differences between the affected and unaffected knee in extension and flexion were both near zero (extension: 0° IP, 1° SP, $P = 0.5$; flexion 1° IP, –3° SP, $P = 1.0$). 11 of 13 SP patients obtained MRI at 1 year. Four of the interpretations included chondromalacia patellae; however, in three of these patients chondromalacia can be noted in their pre-nailing arthroscopy assessment. The fourth patient's pre- and post-nailing arthroscopy documented no appreciable changes in the patellofemoral articular surfaces.

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See pages 99 - 147 for financial disclosure information.

Conclusion: Overall, there are no significant differences in pain, disability, or knee range of motion between these two tibial intramedullary nailing techniques after 12 months of follow-up. The suprapatellar approach can be performed safely with comparable clinical and functional outcomes to the infrapatellar method. A larger prospective trial with long-term follow-up is needed to improve statistical power and establish if any late sequelae exist.