

## **Parapatellar Semi-Extended and Flexed Knee Tibial Nailing Technique are Equivalent in Regards to Knee Pain: A Randomized Controlled Trial**

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**Purpose:** Knee pain is a common complication of intramedullary tibial nailing with a reported incidence of 10-86% at 2-year follow-up. Four reasons are commonly offered for knee pain after tibial nailing: skin incision location, approach in reference to the patellar tendon, nail insertion site, and nail prominence. Semi-extended nailing techniques have been gaining popularity outside of traditional indications (proximal third tibial shaft fractures) due to ease in imaging, fracture reduction, and leg positioning. The purpose of this study was to determine if the semi-extended, parapatellar tibial nailing technique (SEK) imparts any undue risk of knee pain compared to the traditional flexed knee, parapatellar tibial nailing technique (FK).

**Methods:** A single-center randomized controlled trial (RCT) was conducted at an academic Level I regional trauma center comparing the SEK technique to the FK technique. 60 patients with OTA 42A-C tibial shaft fractures were consented and enrolled. Exclusion criteria included prior operations around the knee, neurovascular compromise, a nonambulatory status, ipsilateral femur fractures, other tibia fractures not allowing tibial nailing, age <18, and non-English speakers. We collected age, sex, and injury-related variables including mechanism of injury, OTA fracture, Henley, Tschern, Gustilo-Anderson, and Kellgren-Lawrence classifications; and surgery-related variables including additional fixation (such as fixation of ipsilateral rotational ankle fracture), nonunion, malunion, hardware prominence, need for hardware removal, and additional complications. The primary outcome was the symptoms subset of the International Knee Documentation Committee score (SS-IKDC) at 1-year follow-up as this focused on knee pain. An a priori power analysis to test equivalence as defined by a  $\pm 5$ -point margin was performed assuming a standard deviation of 5 points or a 13% change in the SS-IKDC. With 23 evaluable patients per group we would have 80% power at a 0.05 significance level. Statistical analysis was performed using linear regression to estimate a 90% confidence interval (CI) for the group differences to ensure a 0.05 level of statistical significance using a two one-sided tests (TOST) procedure. Equivalence was defined if the 90% CI was within a  $\pm 5$  points window.

**Results:** 60 patients were enrolled, and final follow-up collected at 1 year for 24 SEK and 23 FK patients. No significant differences were found between the groups in regards to demographics, injury, or surgery-related variables except for the need for additional fixation (12% in SEK and 43% in FK,  $P = 0.02$ ). All additional fixation was for rotational ankle fractures in the ipsilateral tibia. The two techniques did not have equivalent SS-IKDCs when adjusting for additional fixation (90% CI: 1.89 [-2.8, 6.6]) but did have equivalent scores when not adjusting for additional fixation (90% CI: 0.3 [-4.2, 4.8]). The adjusted mean SEK subset score was 27.2 (standard error [SE] = 2.2) and the adjusted mean FK subset score was 25.3 (SE = 1.9,  $P = 0.12$ ). The nonadjusted mean SEK subset score was 25.3 (SE = 1.9) and the mean FK subset score was 26.0 (SE = 1.9,  $P = 0.50$ ). When comparing demographic and injury-related

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variables to the SS-IKDC, only age was statistically significant ( $P = 0.05$ ) where increasing age was associated with lower scores.

**Conclusion:** The results of this single-center RCT show that SEK and FK techniques for tibial nailing are equivalent in regards to knee pain (defined as  $\pm 5$  points on the SS-IKDC) when not adjusting for additional fixation in the ankle. While rotational ankle fractures in association with tibial shaft fractures may indicate increasing energy of injury or differing mechanism they are unlikely to affect knee pain in the context of understood causes. SS-IKDCs have a slightly higher but nonsignificant mean for the SEK technique when adjusting for fixation differences between the techniques. This study demonstrates that the use of the semi-extended technique for tibial nailing should not be associated with any higher likelihood of knee pain than the flexed knee technique.