

A Prospective Randomized Trial Comparing Transtibial Amputation With and Without a Tibia-Fibula Synostosis (Ertl) Procedure (TAOS Study)

Michael J Bosse, METRC TAOS Investigators

INTRODUCTION: The appropriate technique for a transtibial amputation following severe lower extremity trauma is controversial. Proponents of amputation with a tibia-fibula synostosis (Ertl procedure) argue that the synostosis provides stability, shape, and weight-bearing capability to the residual limb, claiming less pain and improved prosthetic fit and residual limb function. Surgeons who do not use this technique argue that the additional steps of synostosis procedure increase the surgical time, and complications without a notable improvement in function. However, no study has rigorously compared outcomes of the Ertl procedure with more commonly used Burgess technique. We hypothesized that complication rates would be lower among patients treated with a Burgess compared with Ertl procedure and functional outcomes would be similar.

METHODS: The TAOS study is a prospective, multicenter randomized trial (RCT) comparing eighteen-month outcomes following unilateral transtibial amputation among patients ages 18-60. Patients were randomly assigned to either Burgess or Ertl amputation. The primary outcomes were 1) operative treatment or rehospitalization for at least one of 5 predefined complications: revision to the residual limb, infection, exostosis or heterotopic ossification, neuroma, or hardware revision; or diagnosis of complex regional pain syndrome; and 2) Short Musculoskeletal Function Assessment (SMFA) scores. Kaplan-Meier was used to estimate the treatment-specific probability of at least one complication within 547 days of definitive amputation. Linear regression, accounting for age, BMI, pre-injury health and time of assessment, was used to estimate the effect of treatment assignment on SMFA.

RESULTS: The analysis included 107 patients (Burgess: n=52, Ertl: n=55) enrolled at 23 centers over 5 years. A total of 92% of individuals had at least 547 days of follow up. The probability of at least one complication within 547 days was 43% and 24% for the Ertl and Burgess groups, respectively (Difference 19%, 95% CI: 1% to 36%, p-value = 0.04). SMFA scores were available for 80% of patients. The average observed dysfunction score was 25.7 and 27.2 for Ertl and Burgess groups, respectively (Adjusted Difference -3.3, 95% CI: -12.2 to 5.5, p-value = 0.46). The average observed bothersome score was 27.1 and 27.4 for Ertl and Burgess groups, respectively (Adjusted Difference -2.4, 95% CI: -14.0 to 9.1, p-value = 0.68).

DISCUSSION AND CONCLUSION: This RCT supports our hypothesis of fewer complications with a Burgess compared with Ertl procedure with no difference in function. These results suggest no benefit of amputation involving a synostosis.