

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

*METRC; Michael J. Bosse, MD*

*Carolinas Medical Center, Charlotte, North Carolina, UNITED STATES*

**Purpose:** The optimal technique for a transtibial amputation following severe lower extremity trauma remains 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, purporting that patients will have less pain and improved prosthetic fit and residual limb function. Surgeons who do not use this technique argue that the additional steps of the 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 the more commonly used Burgess technique. We hypothesized that complication rates would be lower among patients treated with a Burgess compared with Ertl procedure, but patient reported function would be better for patients receiving an Ertl.

**Methods:** The TAOS study is a prospective, multi-center randomized clinical 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 for at least one of five predefined complications: revision to the residual limb, infection, exostosis or heterotopic ossification, neuroma, or implant revision or removal; or diagnosis of complex regional pain syndrome; and (2) Short Musculoskeletal Function Assessment scores. Kaplan-Meier was used to estimate the treatment-specific probability of at least one complication within 18 months 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 106 patients (Burgess: n=52, Ertl: n=54) enrolled at 23 centers over 5 years. Ninety-two percent of individuals had at least 547 days of follow-up. The probability of at least one complication within that period was higher for the Ertl group (42% vs. 24%; Difference 18%, 95% CI: 0.35% to 36%, p-value = 0.046). SMFA scores were available for 80% of patients. The average observed dysfunction score was 26.1 and 27.2 for Ertl and Burgess groups, respectively (Adjusted Difference -3.4, 95% CI: -12.3 to 5.6). The average observed bothersome score was 27.7 and 27.4 for Ertl and Burgess groups, respectively (Adjusted Difference -2.2, 95% CI: -13.7 to 9.2).

**Conclusion:** This RCT supported our hypothesis of fewer complications with a Burgess compared with Ertl procedure, but we found insufficient evidence to conclude that Ertl patients have better function.