2009 AOFAS Roger A. Mann Award

Prospective Controlled Trial of Scandinavian Total Ankle Replacement vs. Ankle Fusion: Initial Results

Presenting:
Charles L. Saltzman, MD
Salt Lake City, Utah

Additional Authors:
Michael J. Coughlin, MD – Corresponding Author
Roger A. Mann, MD
Jeanette E. Ahrens, PhD
Annunziato Amendola, MD
Robert B. Anderson, MD
Gregory C. Berlet, MD
James W. Brodsky, MD
Loretta B. Chou, MD
Thomas O. Clanton, MD
Jonathan Deland, MD
James K. DeOrio, MD
Greg A. Horton, MD
Thomas H. Lee, MD
Jeffrey A. Mann, MD
James A. Nunley, MD
David B. Thordarson, MD
Arthur K. Walling, MD
Keith L. Wapner, MD

ABSTRACT

Background: The safety and efficacy of ankle replacement vs. ankle fusion as treatment of end-stage ankle arthritis has not been previously studied. In the past decade, mobile bearing ankle replacements have been widely used outside the United States as they are conceived to allow more natural ankle motion with congruent component contact than current fixed bearing models. The United States Food and Drug Administration (FDA) considers mobile bearing designs as Class III "experimental" devices and permits the use of standard mobile bearing ankle replacements only with an approved Investigational Device Exemption (IDE). The goal of the present IDE study was to perform a prospective evaluation of the safety and efficacy of the mobile-bearing Scandinavian Total Ankle Replacement (STAR) prosthesis to treat end stage ankle arthritis.

Methods: The pivotal study design was a non-inferiority study using ankle fusion as the control. A non-randomized design with concurrent controls was employed from fifteen separate U.S. medical centers. After the pivotal study initial data collection was completed, a continued access arm was opened. We report the initial perioperative findings up to 24 months following surgery. For an individual patient to be considered an overall success, all of the following criteria needed to be met: a) 40 point improvement in total Buechel-Pappas ankle score, b) no device failures, revisions, or removals, c) radiographic success, and d) no major complications.

Results: In the pivotal study, 158 ankle replacement and 66 fusion patients were performed; in the continued access arm 448 ankle replacements were performed, of which 416 were at minimum 24 months post surgery at time of database closure. Complete data at 24 months was available for 96% of the pivotal ankle replacements, 79% of the pivotal ankle fusions and 66% of the continued access ankle replacements. Major complications and need for secondary surgical intervention were more common in the pivotal ankle replacement group than the ankle fusion group, although the incidence of secondary procedures was halved in the continued access ankle replacement subgroup compared to the pivotal ankle replacement subgroup, p=0.001. Treatment efficacy was higher for the ankle replacement group due to improvement in functional scores, and pain relief was equivalent between fusion and replacement treatments. The hypothesis of non-inferiority of ankle replacement was met for overall patient success. The criteria for overall success was met by 45% of the pivotal ankle replacement patients, 13% of the fusion patients and 62% of the continued access patients at 24 months post surgery.
Conclusions: By 24 months, ankles treated with the STAR ankle replacement had better function and equivalent pain relief as ankles treated with fusion. The criterion for overall success was achieved more frequently after ankle replacement. Use of the ankle replacement was associated with a higher rate of complications and secondary procedures. The rate of secondary procedures decreased by half during the study period with improved instrumentation and greater surgeon experience.

Level of Evidence: Level 1: Prospective controlled surgical trial