



FOR IMMEDIATE RELEASE:

CONTACT:

Judy Datz
Communications Manager
847-384-4379
jdatz@aofas.org

**Results of Controlled Clinical Study of STAR Total Ankle Replacement versus Ankle Fusion
Presented at AOFAS 2009 Annual Summer Meeting**

Better ankle function result of a TAR after two-year study published in *FAI*

(Rosemont, IL – August 25, 2009) – [Charles L. Saltzman, MD](#), newly-elected president of the [American Orthopaedic Foot & Ankle Society \(AOFAS\)](#), presented the results of a groundbreaking study at the recent AOFAS 2009 Annual Summer Meeting in Vancouver, British Columbia, Canada. This 24-month non-randomized clinical trial was conducted at 15 equivalent medical institutions offering a broad spectrum of surgical experience and is the first clinical study of its kind in the United States of the Scandinavian Total Ankle Replacement (STAR). After 24–months, the ankles treated with STAR ankle replacement had better function and equivalent pain relief as ankles treated with [ankle fusion](#) surgery. The study was published in the July 2009 issue of the [Foot & Ankle International \(FAI\)](#), the official journal of the AOFAS and also won the prestigious Roger A. Mann Award for best clinical paper presented at the meeting.

The STAR is unique because it is an uncemented, mobile-bearing [total ankle replacement \(TAR\)](#) device which is new in this country, although mobile-bearing ankle replacements have become popular outside the United States over the past decade. The goal of this study was to perform a prospective evaluation of the safety and efficacy of a mobile-bearing prosthesis to treat [end-stage ankle arthritis](#) and was approved as part of the investigational device exemption (IDE) by the Food and Drug Administration (FDA). According to the study, current US estimates for degenerative ankle disease suggests greater than 50,000 new cases reported each year. According to corresponding author, Michael J. Coughlin, MD, “This is the first prospective comparison between total ankle arthroplasty (replacement) and ankle arthrodesis (fusion) regarding function following surgery. The STAR ankle won hands down.”

The Pivotal study design was a non-inferiority study with ankle fusion as the control. In a non-inferiority study, the primary objective is to demonstrate that a new treatment is equivalent to a standard therapy with regard to a particular result while also having benefits for other clinical end points, thus making the new treatment an attractive option. Three groups of patients were used in the study: a group of 158 STAR total ankle patients and a control group of 66 ankle fusion patients (the Pivotal Study Groups) and a second group of 448 STAR patients (Continued Access Group), whose surgery was performed following the completion of enrollment in the Pivotal Study.

Results were reported up to 24 months following surgery. For a patient to be considered a success, four criteria had to be met:

- A 40-point improvement in total Buechel-Pappas ankle score
- No device failures, revisions, or removals
- Radiographic success
- No major complications

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. Complications and the need for follow-up surgery were more common in the pivotal ankle replacement group than the ankle fusion groups. However, the need for secondary surgery was cut by 50% in the continued access ankle replacement group compared to the pivotal ankle replacement group, likely due to increased experience by the surgeons involved and improved instrumentation. By the end of the 24 months, ankles treated with the STAR ankle replacement had better function and equivalent pain relief as ankles treated with fusion.

Dr. Coughlin said, "There is no question that the new design of total ankle replacements is a more anatomic design. It is not cemented and requires less bone resection demonstrating far more superior results than the ankle replacements implanted in the 1970's. We are continuing to follow the over 600 patients involved in the study and will speak to their experiences in future publications.

The STAR ankle is intended for use in patients with degenerative traumatic and/or rheumatoid arthritis for which conservative measures are no longer successful. Ankle replacement should be reserved for those patients with severe pain and loss of function for which conservative measures are no longer effective."

To learn more about AOFAS or to locate an AOFAS orthopaedic foot and ankle surgeon in your area, please visit its Web site at <http://www.aofas.org/>.

###

About AOFAS

The AOFAS promotes quality, ethical and cost-effective patient care through education, research and training of orthopaedic surgeons and other health care providers. It creates public awareness for the prevention and treatment of foot and ankle disorders, provides leadership, and serves as a resource for government, industry and the national and international health care community.

About Orthopaedic Foot and Ankle Surgeons

Orthopaedic foot and ankle surgeons are medical doctors (MD and DO) who specialize in the diagnosis, care, and treatment of patients with disorders of the musculoskeletal system of the foot and ankle. This includes the bones, joints, ligaments, muscles, tendons, nerves, and skin. Orthopaedic foot and ankle surgeons use medical, physical, and rehabilitative methods as well as surgery to treat patients of all ages. They perform reconstructive procedures, treat sports injuries, and manage and treat trauma of the foot and ankle.

Orthopaedic foot and ankle surgeons work with physicians of many other specialties, including internal medicine, pediatrics, vascular surgery, endocrinology, radiology, anesthesiology, and others. Medical school curriculum and post-graduate training provides the solid clinical background necessary to recognize medical problems, admit patients to a hospital when necessary, and contribute significantly to the coordination of care appropriate for each patient.

Education

- AOFAS members have the following credentials:
- Completed four years of medical school. The curriculum covers basic and clinical sciences, surgery, internal medicine, pediatrics, family medicine and all other medical specialties.
- Completed five years of accredited graduate medical education (residency training) in orthopaedic surgery.
- Many orthopaedic foot and ankle surgeons also complete advanced fellowship training in foot and ankle surgery.
- Satisfactory completion of the national medical licensing examination.
- Continuing medical education credits over a specific time period.
- Board certification: Certified by or eligible for examination and certification by the American Board of Orthopaedic Surgery or the American Osteopathic Board of Orthopedic Surgery.
- Each member must hold membership in the American Academy of Orthopaedic Surgeons (AAOS).

When selecting a medical provider to care for your feet and ankles, be sure to ask him/her about:

- Medical school education
- Accredited residency training
- Areas of practice specialization
- Experience in your prescribed treatment (surgical and/or non-surgical)

###