

The History of the STAR Ankle in the United States

The history of the Scandinavian Total Ankle Replacement in the United States dates back to 1998. At that time Roger A. Mann, M.D., Oakland, California went to a total ankle arthroplasty conference in Denmark where he heard lectures from Dr. Hocum Kofoed M.D., the designer of the Scandinavian Total Ankle Replacement. Dr. Mann was actually talking about an ankle arthrodesis at this meeting. When Dr. Mann returned he called his first Fellow, Michael J. Coughlin, M.D. in Boise Idaho and said this really merited investigation and this was probably the best ankle he had seen available and they should look to see whether it might be possible to introduce this to the United States.

The history of total ankle arthroplasties date back to the 1970s with a rise in popularity of total hip and total knee replacement. A total ankle replacement was felt to be an easy thing and several different designs were released. These were cemented prostheses, in general two-part components that were very nonanatomic. With short-term follow-up some of these ankles did well but in intermediate follow-up of even four or five years they began to fail. By the mid 1980s total ankle replacement in the United States was not being done. Many of these ankles were later fused as a salvage procedure. Thus over a fifteen to twenty year period ankle fusion was really the only choice for patients with severe arthritis of the ankle.

Once Dr. Mann returned, he and Dr. Coughlin contacted LINK Inc. who manufactured the ankle and sold it in Europe and other countries. Thus began an experience with the total ankle that culminated in an FDA approved Pre-market Approval (PMA) Study. Drs. Mann and Coughlin were appointed the medical directors of the study and designed the pivotal study. Given the rocky history of total ankle replacement in the United States, it was felt that careful patient

selection and reporting of adverse outcomes was important to protect patients in the study. Dr. Coughlin said "Based on the bad experience with total ankles in the past, we wanted to insure that we listed any adverse event and kept track of them meticulously for the safety of patients".

In 1999, Dr. Coughlin and Dr. Mann went before the FDA with the LINK Company and presented the proposed study. The initial study (pilot study) was designed for 158 total ankle patients and 69 arthrodesis patients. Total ankle replacements were performed by one group of physicians and fusions were performed by another group of physicians and their results were compared.

They chose an illustrious group of investigators for the total ankle implant group (Mayo Clinic, University of Kansas, Duke University, University of Texas, University of Iowa, Ohio State University, as well as the Boise and Oakland sites). For the fusion group Stanford University, University of Southern California Hospital for Special Surgery, Pennsylvania Hospital and Charlotte Medical Center were chosen.

The study patients were enrolled for the ankle arthroplasty group over a period of about eighteen months. At the culmination of the study these numbers were collected for both groups and analyzed.

After the initial pilot study of 158 patients, the FDA granted permission for three series of 150 patients each to be implanted during the years 2002 to 2008. Thus in the United States over 600 STAR ankles have been implanted by the original physicians involved in the study.

In 2007, some seven years after the study was initiated, Drs. Coughlin and Mann, accompanied by Dr. Saltzman (University of Utah), and Dr. Clanton (University of Texas) addressed the FDA panel

that was held to review the data. They received a positive vote. Another two years were required to finish the requirements necessary for the FDA and in June 2009 the STAR ankle was released with the proviso of specific teaching courses for physicians who would implant the ankle, a request for continued information on those patients who had received the STAR ankle and information from new physicians implanting the STAR ankle as to their successes and failures.

The FDA and Ankle Replacements in the United States

After the mid 1980s when almost all total ankle arthroplasty implants were removed from the market, Dr. Frank Alvine, Sioux Falls, South Dakota, continued to work with one model. This was an early two-part model that had initially been cemented. Dr. Alvine changed the design over a period of time and placed a noncemented porous coat on the back of the prosthesis. Alvine's model, the Agility Ankle, was the only option in America for approximately twelve to fifteen years. It was authorized by the FDA under the program called 510 K which allows an implant that is similar to something already authorized in the past to be authorized for use. It is this method, the 510 K pathway that has allowed the introduction of several other two-part total ankles during the last few years. While the STAR study was in process, the Salto Talaris Ankle (Tornier Inc.) was authorized. The only experience with the Salto ankle in Europe was with the three-part design. It was altered to a two-part design and thus was authorized by the FDA through the 510 K program. At this time there are several other three-part ankles in Europe that are being considered for a change to a two-part ankle so they may be authorized in the United

States. At this time, however, the Scandinavian Total Ankle is the only three-part uncemented ankle authorized by the FDA.

As a further note, the lengthy period of this study for the STAR ankle and the cost to the LINK Company (estimates exceed \$25 million) make it likely that no other three-part ankle will be authorized in the near future. It would take a lengthy comprehensive study that would be relatively expensive. Thus, for the foreseeable future the STAR ankle will be the only total ankle replacement in which a three-part uncemented component is utilized in the United States.