Early Clinical Results of a Multi-centre Trial of a Novel Ankle Prosthesis (BOX Ankle)

Presenting:

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Results of a multi-centre clinical trial on a new design of total ankle replacement are very encouraging.

Design.
A linkage-based mathematical model was used to design a ligament-compatible prosthesis to keep certain ligament fibres isometric during passive motion. The sagittal plane talar component radius is about 50% longer than that of the normal talus, the tibial component is spherically convex. A fully conforming meniscal bearing is interposed between them. Experiments in cadaver specimens confirmed the mathematical prediction that the bearing moves forwards on both metal components during dorsiflexion and backwards during plantarflexion.

Clinical Trial.
Between July 2003 and July 2008, the prosthesis was implanted into 250 patients at 9 hospitals in Northern Italy. By November 2007, 158 in 156 patients were seen at least 6 months post-operatively. Mean age was 60.5 years. The diagnosis was post-traumatic osteoarthritis in 127, primary and other osteoarthritis in 21, rheumatoid arthritis in 10.

Results.
The mean follow-up was 17.7 months. The pre-operative AOFAS score of 36.2 rose to 74.6, 78.6, 76.4, and 79.0 respectively at 12, 24, 36, 48 months. At one hospital, dorsi-flexion intra-operatively increased from 0.1° to 9.7°, plantarflexion from 15.1° to 24.6° in 100 patients; in 30 of these patients, the range of postoperative motion, 14° - 53°, was significantly correlated to the range of bearing movement on the tibial component, 2mm-11mm, measured radiologically, (r2 = 0.37, p < 0.0005).
Revisions and Survival.
By December 2007, 2 revision operations had been performed at 24 months, one for unexplained pain not relieved by a successful arthrodesis, one in a patient with Charcot-Marie-Tooth disease. There were no device-related revisions (loosening, fracture, dislocation). The Kaplan-Meier survival rate (component-removal as end-point) at 4 years was 96.1% (Confidence interval 90-100%).

Discussion
Early clinical results have demonstrated safety and efficacy. The survival rate at four years compares well with multi-centre 5-year rates published by the Swedish (531 cases, survival 78% ), Norwegian (257, 89% ) and New Zealand (202, 86%) registries.