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Preliminary results of a biomechanics driven design of a total ankle prosthesis

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Introduction

A new design of total ankle replacement [1] was developed according to extensive prior biomechanical research [2-5]. A linkage-based mathematical model was used to design for the first time ligament-compatible shapes of the prosthesis components in the sagittal plane (Fig. 1). The radius of the metal talar component in the sagittal plane is about 50% longer than that of the normal talus, the metal tibial component is spherically convex. A fully conforming meniscal bearing is interposed between them and free to move. Experiments in cadaver specimens confirmed the mathematical prediction that the bearing moves forwards on both metal components during dorsi-flexion and backwards during plantarflexion. FEA models [6] and experiments with a wear simulator [7] confirmed that the risk of wear is minimised. Preliminary clinical results are here reported as support to the biomechanical claims.

Methods

Between July 2003 and May 2007, the prosthesis was implanted in 189 patients at 7 hospitals in Northern Italy. Mean age was 59.4 years. The diagnosis was post-traumatic OA in 79.3%, primary OA in 6.9%, RA in 8.0%. At one hospital, range of motion was measured in the operating theatre before and after implantation in 90 ankles, and meniscal motion in lateral radiograms at maximum plantar- and dorsi-flexion in 30 ankles.

Results

At September 2007, the mean follow-up was 21 months. The mean pre-operative AOFAS score of 41.1 rose to 80.2, 79.7, 77.9, and 79.0 respectively at 18, 24, 36, 48 months. Mean dorsi-flexion increased after implantation from 0.1° to 9.7°, plantar-flexion from 15.1° to 24.6°. From radiographic measurements, the range of full motion, 14° – 53°, was significantly correlated to the range of bearing movement on the tibial component, 2–11 mm ($r2 = 0.37$, $p < 0.0005$), as predicted. Two revision operations had been performed, respectively for obvious surgical and indication errors.

There were no device related revisions (loosening, fracture, dislocation). The Kaplan-Meier survival rate (components removal as end-point) at 4 years was 97% (Confidence interval 92–100).

Conclusion

The shapes of the three components are compatible with physiologic ankle mobility and with the natural role of the ligaments. 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 and with a recent meta-analysis [8]. The early clinical results have demonstrated safety and efficacy and encourage a widening of the clinical trial.

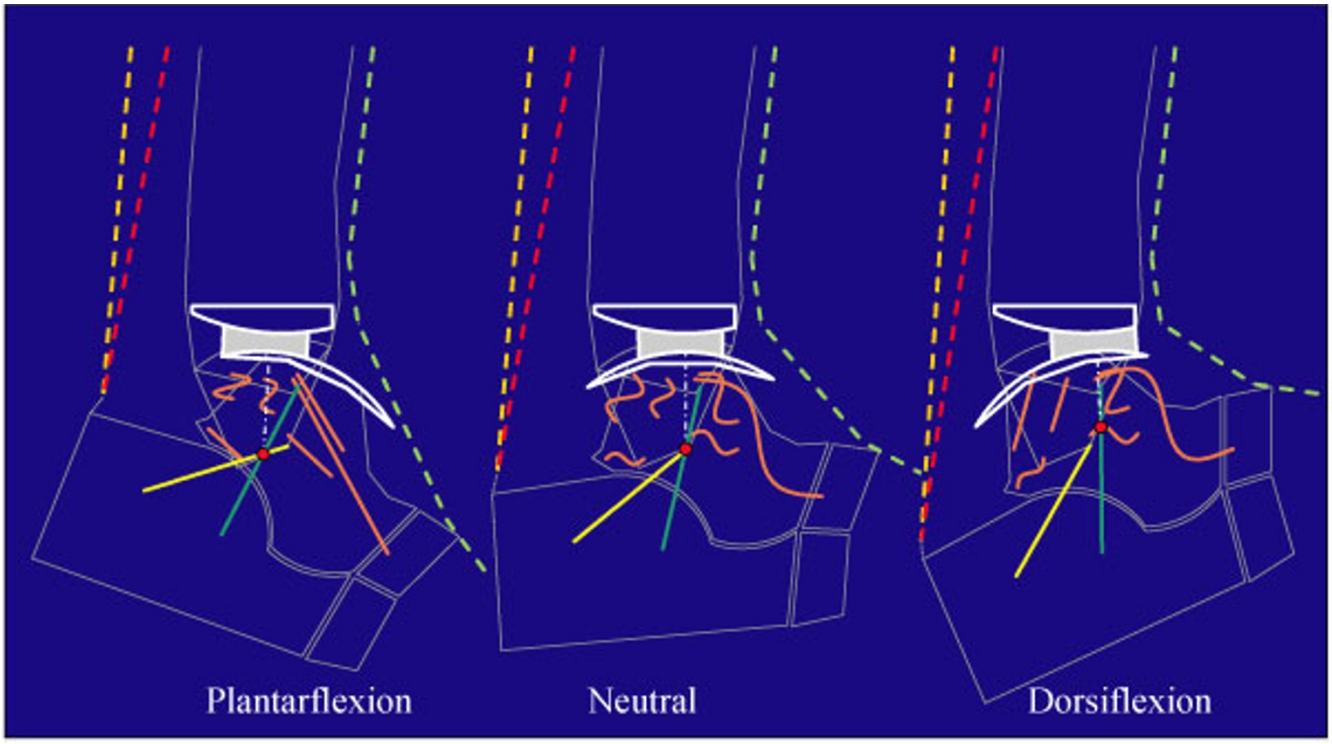

Figure 1
Model-based mobility of the replaced ankle in the sagittal plane.

References

1. Leardini A, *et al.*: *Clin Orth Rel Res* 2004, **424:**39-46.
2. Leardini A, *et al.*: *J Biomech* 1999, **32:**111-118.
3. Leardini A, *et al.*: *J Biomech* 1999, **32:**585-591.
4. Leardini A, *et al.*: *Med Biol Eng Comp* 2001, **39:**168-175.
5. Leardini A, *et al.*: *Gait Post* 2002, **15:**220-229.
6. Reggiani B, *et al.*: *J Biomech* 2006, **39:**1435-1443.
7. Affatato S, *et al.*: *J Biomech* 2007, **40(8):**1871-6.
8. Stengel D, *et al.*: *Arch Orth Trau Surg* 2005, **125:**109-119.