The Effect of Malalignment on a Mobile Bearing Total Ankle Replacement

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INTRODUCTION

Total ankle replacement (TAR) is surgically complex; malalignment can arise due to surgical technique or failure to correct existing varus/valgus malalignment of the natural joint. In other joint replacements malalignment has been associated with pain, component edge loading, increased wear and higher failure rates. Good component alignment is considered instrumental for long term TAR success but to be deemed “clinically important misalignment” a deviation of at least 5° from the physiological alignment is needed. The conforming surface geometry of mobile bearing TARs leaves no freedom for coronal malalignment. The aim of this study was to investigate the biomechanical effect of coronal alignment on a mobile bearing TAR and how this affects the wear rate.

METHODS

Three TARs (Zenith, Corin Group) were tested under five equally spaced coronal alignment angles from 0-10° inverted in a single station electromechanical knee simulator applying an ankle gait profile of 30° plantar/dorsiflexion, 10° rotation, 4mm anterior/posterior displacement and peak load of 3.15kN. The swing load was varied to simulate the effects of different tissue tension. Tests were carried out for 600 cycles in 25% bovine serum. Under each condition, the version cradle was allowed to move freely and the profile under each alignment angle was recorded, averaged and interpreted in terms of change in angle, considered to be the equivalent degree of component lift off. Under similar conditions a tekscan pressure sensor was used to quantify pressure and contact areas under dynamic loading but no kinematics. The results informed the adverse conditions for the following wear test.

Six Zenith (Corin Group PLC) unconstrained TARs consisting of Titanium Nitride coated bulk titanium tibial and talar components separated by mobile bearing conventional polyethylene inserts were tested inverted in an adapted pneumatic knee simulator (Simulator Solutions, UK) under the same kinematic and lubrication conditions for 3 million cycles (Mc) with no coronal malalignment to ensure the inserts had bedded in (Smyth et al. 2016). The tibial components were then cemented into a 7.5° malaligned fixture, the first 0.6Mc were spent optimising the malalignment set up and once finalised the simulator underwent 2Mc in the malaligned condition. Across both conditions the wear rate was quantified gravimetrically every Mcs and a one way anova Tukey test was used to define the significance between the conditions. In order to visualise any changes an Alicona infinite focus microscope (10x mag; 300nm vertical resolution; 5µm lateral resolution) was used to measure the insert surface after testing under neutral alignment and 7.5° malaligned.

RESULTS

Biomechanical testing showed at higher swing phase loads of 300N and 500N the degree of lift off increased with the degree of malalignment for all TARs tested whereas a swing phase load of 100N resulted in peak lift off at 5° malalignment for two of the three tested devices (Figure 1). As the allotted wear simulator achieved a mean swing phase load of 370N, despite an input profile of 100N, results from the 300N swing were deemed the most relevant for the test. A malalignment of 7.5° was chosen as a balance between clinical relevance and severity of the degree of lift off. For the same loading conditions at 7.5° malalignment the Tekscan showed the contact area was reduced by a mean of 14.0% across the three TARs throughout the load profile and the mean contact pressure increased by 4.2% and the peak pressure to increased to ~18MPa, although this may vary with the addition of motion.

The first Mc with components neutrally aligned showed an initial wear rate of 31.2±5.4mm³/Mc (Figure 2) while the inserts bedded in, which reduced significantly to 18.9±2.4mm³/Mc over the next 2Mc (P=0.01). With the added coronal malalignment the wear rate reduced further to 11.9±1.8mm³/Mc (P=0.04). The centre of rotation (CoR) moved medially after 3Mc malaligned (Figure 3).

DISCUSSION

The simulator test has shown that in a controlled setting, the Zenith TAR is capable of facilitating a normal range of motion and transmitting high loads with the addition of a coronal malalignment despite the high surface conformity. With 7.5° malalignment there was a significant reduction in the wear rate, a result of reduced contact area. However, the peak contact pressures of ~18MPa encroach on the yield stress of polyethylene which over time may lead to failure. Simulator testing has limitations when replicating the in vivo conditions such as; the inverted set up of the TAR, standardised gait input, lack of ligament tension and absence of bony surroundings. A further limitation is the optimal translational positioning provided by the simulator setup, unlikely to be achieved clinically in combination with coronal malalignment. Therefore, the edge loading observed from retrievals is not achieved through this coronal malalignment alone. Further translational mismatch may needed to help simulate a more clinically relevant adverse condition.

SIGNIFICANCE

Biomechanical testing has shown that coronal malalignment of a total ankle replacement may cause component lift off. However implementing this malalignment alone results in a significant decrease in the wear rate, due the set-up and potential for compensatory alignment within the simulator. This outcome may not translate to reduced wear in a complex biological environment.

REFERENCES

Smyth, A. (2016) ‘Wear of a Total Ankle Replacement’. ORS Conference, Orlando, Florida. Available at: http://www.ors.org/abstract-search

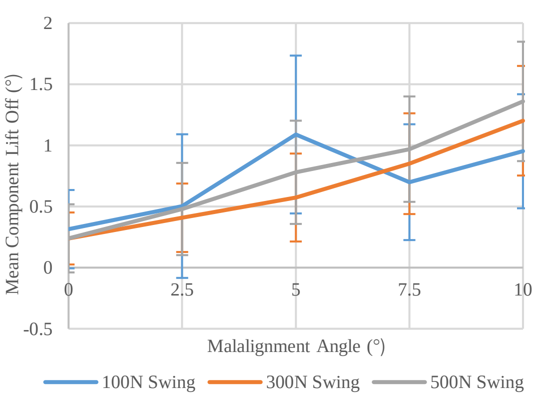

Figure 1. Effect of Malalignment Angle on the mean degree of component lift off and standard deviation for n=3 TARs under swing loads of 100, 300 and 500N

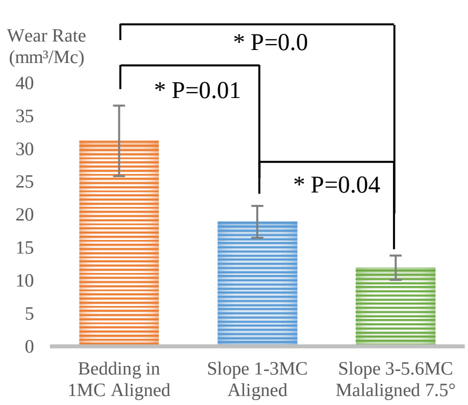

Figure 2. Wear Rate with 95% confidence limits for bedding in, neutrally aligned and malaligned tests

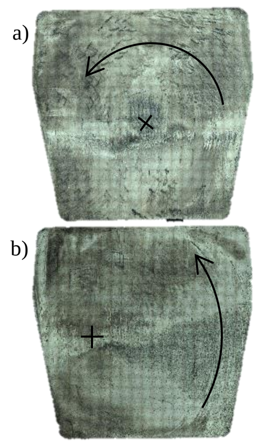

Figure 3. Example insert surfaces and CoRs after Mcs neutrally aligned (a) and malaligned (b)