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Influence of kinematics on the wear of a total ankle replacement

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ABSTRACT

Total ankle replacement (TAR) is an alternative to fusion, replacing the degenerated joint with a mechanical motion-preserving alternative. Minimal pre-clinical testing has been reported to date and existing wear testing standards lack definition. Ankle gait is complex, therefore the aim of this study was to investigate the effect on wear of a range of different ankle gait kinematic inputs. Five Zenith (Corin Group) TARs were tested in a modified knee simulator for twelve million cycles (Mc). Different combinations of IR rotation and AP displacement were applied every 2Mc to understand the effects of the individual kinematics. Wear was assessed gravimetrically every Mc and surface profilometry undertaken after each condition. With the initial unidirectional input with no AP displacement the wear rate measured 1.2 ± 0.6 mm^3/Mc. The addition of 11° rotation and 9 mm of AP displacement caused a statistically significant increase in the wear rate to 25.8 ± 3.1 mm^3/Mc. These inputs seen a significant decrease in the surface roughness at the tibial articulation. Following polishing three displacement values were tested; 0, 4 and 9 mm with no significant difference in wear rate ranging 11.8–15.2 mm^3/Mc. TAR wear rates were shown to be highly dependent on the addition of internal/external rotation within the gait profile with multidirectional kinematics proving vital in the accurate wear testing of TARs. Prior to surface polishing wear rates were significantly higher but once in a steady state the AP displacement had no significant effect on the wear.

1. Introduction

The natural ankle is a highly complex joint. Like other articulating joints, it is prone to arthritis, most commonly post-traumatic arthritis, a painful and debilitating problem (Bragdon et al., 1996; Jones et al., 1999). When conservative treatments fail, a choice has to be made between immobilisation of the joint through ankle arthrodesis (AA) and preserving motion with total ankle replacements (TAR). TARs have been implanted since the 1970s evolving from cemented, highly constrained designs to three component, cementless, mobile bearings. The more recent generations have become a much debated alternative to AA (Jones et al., 1999; Flavin et al., 2013). Despite restoring gait and range of motion which protects the adjacent joints from contracting the same arthritic problems when the joint has been fused, TARs are not the preferred solution for many surgeons (Bragdon et al., 1996). Current TARs can be subdivided into two categories; semi-constrained two component designs and unconstrained TARs with 3 components. The two component designs provide greater stability but at the increased risk of higher shear forces at the tibial-bone interface whereas the unconstrained designs rely on the addition of a mobile insert to facilitate rotation and reduce the shear forces but with that comes a dislocation risk (Gaudot et al., 2014). The choice of implant can spark debate as both have advantages and disadvantages. Unconstrained designs are believed to be biomechanically and kinematically superior (Gundapaneni et al., 2015) but the free moving insert introduces cross shear which will dictate the wear volume (McEwen et al., 2005).

Compared with hip and knee replacements, ankles are implanted in small numbers with less than 500 per year recorded by the national joint registry for England and Wales (Registry, 2015) although the actual number is believed to be closer to 1200 (Arthritis Research UK, 2014), while in the USA the New York Times estimated the annual number of TARs to be just 4400 (Parker-Pope, 2010). The small numbers are an inevitable result of surgical complexity, historically low mid-term survival rates, as well as extensive contra-indications for surgery. The 5 year failure rate varies across the marketed devices and centres implanting them with a range of 0% to 32% (Gougoulias et al., 2010), however looking at the wider picture, a recent systematic review analysing the published results from 7942 TARs suggested a survivorship of 89% at ten years, better than previous generations as papers reporting on TARs no longer on the market were excluded from the review (Jones et al., 1999). Infection and aseptic loosening are

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the most common failure mechanisms for TARs (Hopgood et al., 2006; Michael et al., 2008). Historically, in hip and knee replacements the polyethylene wear debris has been associated with an immune response which triggers osteolysis and aseptic loosening (Ingham and Fisher, 2000; Gupta et al., 2010). As the survival rates of modern mobile TARs are improving, there is a risk that wear mediated osteolysis may become more prevalent.

TAR devices are a lower classification of medical devices compared to hip and knee replacements, therefore pre-clinical testing has not typically been undertaken for pre-clinical approval and there is limited studies published. As the longevity of new TAR devices improves it is important to understand the wear effects of this mobile bearing. Thus far displacement controlled wear testing on TARs has been limited mostly to a set of conditions defined by Bell and Fisher (2007) and in 2014, an ASTM standard was updated to highlight the need for wear testing on new bearing materials but without specific conditions (ASTM, 2014). Under this gait condition, Bell and Fisher (2007) tested the DePuy Mobility and the Buechel-Pappas (BP), three component mobile bearing cobalt chromium and titanium nitride TARs, respectively. The wear rates measured without anterior/posterior (AP) displacement 10.36 ± 11.8 mm^3/Mc for the BP and 3.38 ± 10.0 mm^3/Mc for the Mobility. These wear rates increased to 16.4 ± 17.4 mm^3/Mc and 10.4 ± 14.7 mm^3/Mc, respectively, with the addition of displacement for a final Mcs. At the same time Affatato et al. (2007) also applied similar gait conditions to the BOX Ankle (Finsbury Orthopaedics Ltd., Leatherhead, UK), although with lower forces and higher AP simulated in deionised water to substantiate the use of a knee simulator for ankle wear simulation. Testing in de-ionised water is not relevant to the clinical situation and produces tribological artefact. Most recently Kincaid et al. (2013) used the Bell and Fisher (2007) gait conditions to quantify the wear of conventional ultra-high molecular weight polyethylene (UHMWPE) compared to that of highly cross-linked UHMWPE. For a semi constrained two component TAR, the wear rates were lower due to the rotational constraints measuring 7.4 ± 1.3 mg/Mc and 1.9 ± 0.3 mg/Mc for the respective polyethylene.

Clinical failure of TAR and limited studies into wear testing defined a need for further exploration into TAR wear to understand the effects of the kinematics on the mobile bearing design. Following trends which were discovered investigating total knee replacement wear, it was hypothesised that the magnitude of rotation and displacement occurring at the ankle would have a significant effect on the wear of a mobile bearing total ankle replacement.

2. Materials and methods

2.1. Materials

Five Zenith (Corin Group PLC., Cirencester, UK) unconstrained TARs were tested. The Zenith comprised of three components; a flat tibial component, a dual condyle talar and a mobile bearing insert which conformed to both of these surfaces (Fig. 1). The tibial and talar components consisted of bulk titanium coated with ceramic like

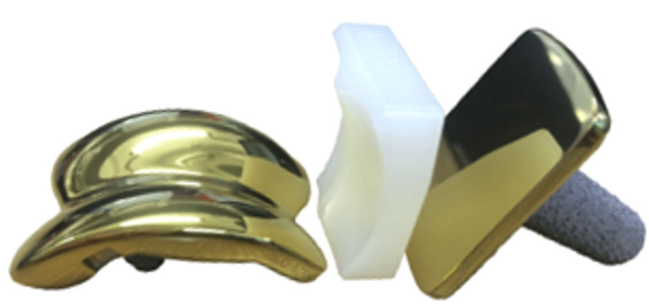

Fig. 1. Zenith total ankle replacement.

Titanium Nitride (TiN). The inserts were manufactured from conventional UHMWPE GUR1050 insert. A mid-range implant size was selected as this was the most frequently implanted. These were paired with the thinnest polyethylene insert with a minimum thickness of 5 mm. This is an example of a mobile bearing TAR which has a similar design philosophy to many other three components designs marketed worldwide.

2.2. Methods

Five TARs were tested and three inserts provided a non-weight bearing soak control. Wear testing was undertaken in an adapted displacement controlled knee simulator (Simulator Solutions, UK) to investigate the influence of kinematic inputs on the wear of a TAR design (Table 1). Different gait conditions were explored with each run for two Mc. Finally, stage 2, with rotation and high displacement, was repeated to understand any changes that may have occurred during the intermediate stages.

The peak axial load of 3.15 kN was taken from the historic talocrural force profile defined by Procter and Paul (1982), the equivalent to 4.5 times a body weight of a 70 kg individual. This was applied in phase with flexion, rotation and displacement profiles relative to the gait cycle. The loading range is similar to that applied previously (Bell and Fisher 2007; Kincaid et al., 2013). The flexion component ranged from 15 degrees plantarflexion (+) to 15 degrees dorsiflexion (−) (Stauffer et al., 1977; Ounpuu, 1994; Novacheck, 1998; Rao et al., 2006; Bell and Fisher, 2007; Nester et al., 2007; Ingrosso et al., 2009). The rotation, applied at the tibial component ranged from 2.3 degrees internal rotation (−) to 8 degrees external rotation (+) (Moseley et al., 1996; Smith et al., 2001; Bell and Fisher, 2007). The anterior/posterior displacement (AP) was taken from the maximum displacement profile for a natural ankle reported by Conti et al. (2006), this varied from approximately 7 mm anterior (+) to 2 mm posterior (−) throughout the gait cycle. In this instance the displacement is considered anterior when the joint contact lies anterior to the midline of the talus. These inputs are presented in Fig. 2. At stage 5 this displacement was reduced to a range between 3.1 mm anterior (+) and 0.9 mm posterior (−). With the pneumatic simulator there was a maximum mean phase lag of approximately 0.06 seconds for the displacement while the rotation and load were in phase relative to the demand profile.

Prior to the wear testing the polyethylene inserts were soaked in deionised water for a period exceeding four weeks in order to reduce the effects of fluid weight gain once the test was underway. Following this soak period the inserts were weighed before testing was started. Every Mc the wear was determined gravimetrically using an XP26 Analytical Balance (Mettler Toledo, Salford, UK) with a resolution of 1 μg. A mean of five weights within a range of $\pm$ 10 μg was calculated.

Each of the TARs were tested in secured chambers filled with 330 ml of lubricant consisting of 25% (v/v) bovine serum, 0.03% (w/v) Sodium Azide solution running at 30 °C. The testing was carried out at a frequency of 1 Hz. The components were rotated through the simulator stations every Mc to account for interstation variation. Gravimetric measurements of polyethylene wear were taken every Mc. The average insert weight loss was calculated taking into consideration the effects of fluid absorption from the weight change for the soak controls. The relevant volumetric wear was calculated with a polyethylene density value of 935.5 kg/m^3, the mid-point of the standard, ISO5834-2 (2011).

At the end of each two Mc stage, surface measurements were taken using a contacting profilometer (Talysurf, Taylor Hobson), with multiple medial/lateral traces on each of the articulating surfaces to give an average surface roughness value for each surface. A least squares line Gaussian filter was used for the tibial and superior insert surfaces and a least squares arc for the talar and inferior insert surfaces. In accordance with ISO 4288 (1997) and the Taylor Hobson guidelines a cut off value of 0.25 mm was used for the TiN surfaces whereas 0.8 mm was applied for the polyethylene surfaces both alongside a 100:1 bandwidth ratio. These parameters remained constant throughout to ensure comparability and a mean average surface roughness was calculated for each surface at the end of each stage.

It was important to understand what influence the gait motion inputs had on the local joint kinematics and the movement of the different interfaces; two of the TARs were run with Vaseline rather that serum for fifty cycles to allow visualisation of the components interaction during the test cycles. To quantify the observations, two 1 mm ball bearings were placed in both articulating surfaces of two polyethylene inserts and the simulator was run with rotation and 9 mm AP displacement for 50 cycles allowing the ball bearings to score the TiN surface showing the inserts motion.

A one way ANOVA with a post hoc Tukey test was used to determine the significance between the wear rates and surface roughness changes for the various stages. A null hypothesis stated the kinematics would have no effect on the wear rate or measured surface roughness. A significance level of 0.05 was defined.

3. Results

The wear of a TAR was assessed through several kinematic conditions. During the initial unidirectional input for stage one the wear

Table 1
Test conditions.

	Test Stages (2Mc/stage)					
	1	2	3	4	5	6
Force	✓	✓	✓	✓	✓	✓
Flexion	✓	✓	✓	✓	✓	✓
Rotation	✗	✓	✓	✗	✓	✓
AP Displacement	✗	✓9mm	✗	✓9mm	✓4mm	✓9mm

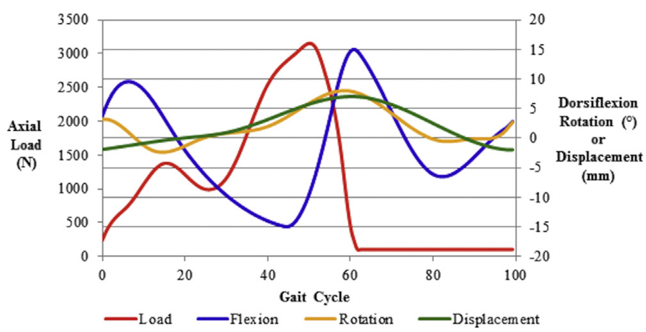

Fig. 2. Stage 2 Simulator Input Profile.

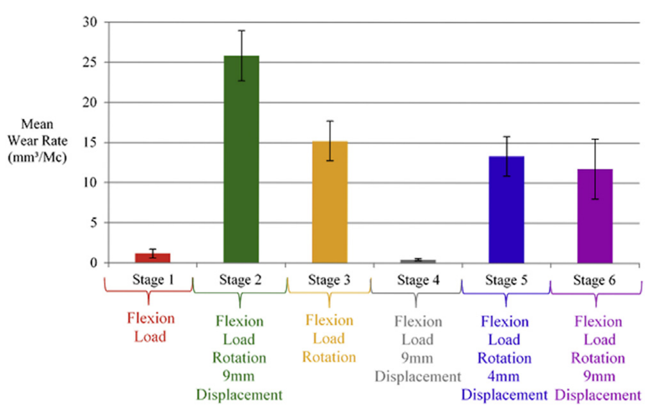

Fig. 3. Mean polyethylene wear rate for n=5 Zenith TARs with 95% confidence limits.

Table 2
Mean Ra values (μm) for the tibial-insert articulating surfaces where significant changes in surface roughness ($P < 0.05$) are highlighted in bold.

Stage	Mc	Mean Tibial Ra	Mean Superior Polyethylene Insert Ra	Mean Talar Ra	Mean Inferior Polyethylene Insert Ra
Pre-test	0	0.030	1.665	0.126	1.984
1	2	0.031	**1.343**	**0.155**	**1.379**
2	4	**0.035**	**0.140**	0.170	1.395
3	6	**0.023**	0.101	0.169	**1.277**
4	8	0.022	**0.189**	0.181	1.257
5	10	**0.017**	**0.080**	0.180	1.255
6	12	0.017	0.072	0.188	1.259

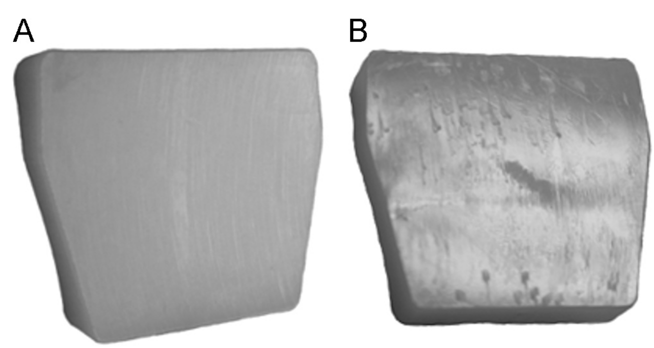

Fig. 4. (A) Pretest photograph of the machined surface of one insert (B) photograph of an insert surface after 4Mc where the machining lines are no longer visible accounting for the tenfold decrease in surface roughness.

rate was 1.2 ± 0.6 mm^3/Mc (Fig. 3). The addition of 11° rotation and 9 mm of AP displacement in stage two resulted in a statistically significant increase ($p=0.000$) in the wear rate to 25.8 ± 3.1 mm^3/Mc. At the end of this stage, two tibial components showed severe coating damage and were replaced with new tibial components for the subsequent stages to ensure the wear rates produced permit solely investigation of kinematic conditions. Further coating damage did not occur in the subsequent stages (stages 3–6).

During stage three, displacement was removed, but rotation retained, resulting in a wear rate of 15.2 ± 2.5 mm^3/Mc, statistically lower than stage two ($p=0.000$). The following condition (stage four) had no rotation, but 9 mm AP displacement, resulting in a very low wear rate of 0.4 ± 0.2 mm^3/Mc. There was no significant difference when compared with stage one ($p=0.998$). Stage five included rotation, with reduced AP (4 mm) resulting in a wear rate of 13.3 ± 2.5 mm^3/Mc. The reduction in AP displacement appeared to have little and no significant effect on wear, as this stage was not significantly different from stage 3 ($p=0.886$). The final stage of the study included 9 mm AP displacement and rotation (a repeat of stage two conditions) and produced a wear rate of 11.8 ± 3.7 mm^3/Mc, not statistically different to stage three ($p=0.428$) or five ($p=0.961$) but significantly lower than the first time this condition was tested, stage 2 ($p=0.000$), when deterioration of coating occurred.

The mean Ra value for each of the articulating surfaces at the end of each stage is presented in Table 2. The effects of each stage's gait inputs on roughness vary for each bearing surface, although no significant surface changes occurred in the last stage of testing. The most apparent change in roughness was seen on the superior polyethylene insert surface with a tenfold decrease in the surface roughness observed between stages one and two, highlighted in Table 2. The roughness generally continued to decrease but not by the same magnitude as during the initial wearing-in period. This polishing effect of the superior insert surface corresponds with the highest wear rate, this is not repeated at stage six despite identical gait conditions. The change in roughness of the other bearing

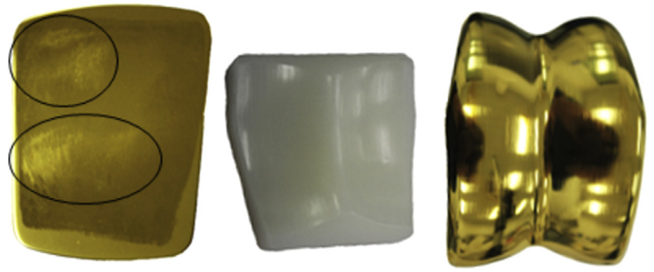

Fig. 5. Component surfaces after 4Mc with polyethylene transfer circled.

surfaces were typically small by comparison, however some were statistically significant.

The changes in the superior insert surface between the start of the test and the end of stage 2 were also visually apparent on all components. Although pretest (Fig. 4A) it looks less rough the finished machining lines were prominent increasing the measured roughness. In comparison, after 4Mc (Fig. 4B), there were obvious signs of pitting and abrasive wear alongside burnishing which is the main cause for the reduction in surface roughness.

Despite lesser changes in the roughness traces, there were visible changes in the metallic component surfaces at 4 Mc. The TiN coating degeneration on the tibial component within the area of polyethylene contact was identified (Fig. 5). There were also obvious signs of adhesive wear, the orientation of which suggests the flat articulation facilitates the rotation applied. By comparison the wear scars on the talar articular surface were all linear with fine scratches visible on the TiN but no obvious coating degeneration or polyethylene transfer.

3.1. *Wear track analysis*

During visual inspection of the TAR motion under the stage 2 (kinematics of rotation and 9 mm displacement), it was observed that the majority of the AP translation displacement occurred at the flat bearing articulation. In this simulation, the conformity of the talus retains the insert centrally allowing just flexion to occur at this surface. Importantly, only the flat tibial interface appears to experience rotational motion. At 9 mm displacement the insert undergoes edge contact due to the small clearance on the tibial. The addition of ball bearings confirmed these interactions. The scratches measured 10–11 mm in length on the tibial bearing, greater than the displacement input, suggesting effects of both displacement and some flexion were occurring at the tibial interface. There was a multidirectional element to the scratches on the tibial whereas the lighter scratches observed on the TiN talus were linear in the AP direction.

4. Discussion

The present investigation has shown TAR wear rates to vary depending on the gait inputs and kinematic conditions. The wear rate results can be divided into two phases, an initial bedding in period in stages one and two and the steady state which follows from stage three onwards, once the components have undergone some surface polishing.

In the steady state, the wear rate depends solely on the addition of rotation and the magnitude of AP displacement had no significant effect on the wear rate. It has been widely recognised that the wear of UHMWPE is dependent on whether articulations are occurring uni or multidirectionally. If all motions are applied in one direction, the polyethylene chains align and strain harden, improving the wear resistance. In comparison under multidirectional motion the shear forces cause the surface chain orientation to change continually which results in shearing of polyethylene particles from the surface, generating wear (Bragdon et al., 1996; Wang et al., 1996). It is proposed this strain hardening effect was responsible for the significantly lower wear in stage four which had no rotation included. Similarly, Johnson et al., (2001) removed all rotation in a total knee replacement wear test and found a decrease in wear greater than tenfold, which is a comparable magnitude to the results presented for this TAR. In knees, displacement was found to have an equivalent effect (Johnson et al., 2001; McEwen et al., 2005), however, this was not the case for the rotating platform mobile bearing TAR.

Rotating platform mobile bearing knee replacements aim to decouple the motions at each surface so that flexion and AP displacement occur on the top surface and rotation at the backside interface, making them unidirectional (Jones et al., 1999). Other designs of mobile bearing knees which allow rotation and translation on the flat tibial articulating surface have higher wear. Wear track analysis of the TAR showed that the AP displacement and rotation both happen at the tibial surface, this multidirectional motion results in higher wear on this surface. Only flexion appeared to occur at the talar articulation indicating low wear on this surface. The displacement scratches measured on the tibial component in wear track analysis were greater than that of the displacement input suggesting there may always be some displacement at this surface as a result of the flexion. If this is the case with rotation present there is always multidirectional motion present at the tibial interface surface causing the higher wear rates. Analysis of video footage of the bearing articulating with no displacement applied confirmed this was the case.

As part of the bedding in phase, stage one with just flexion applied produced low wear rates, not significantly different to stage four due to the similarly unidirectional motion inputs. Stage two, however, resulted in a polyethylene wear rate of 25 mm^3/Mc significantly higher than all of the other stages. It is hypothesised that this was not caused by the high kinematics including rotation and AP displacement alone but was also associated with the original surface roughness of the polyethylene and also the tibial surface coatings. After stage two, the superior polyethylene surface roughness reduced tenfold as the wavy machined surface of the polyethylene was polished and two of the tibial surfaces underwent some coating damage, however there was no significant difference in wear rate across the five TARs. It is not possible to be certain which factors caused increased wear in stage two. At the end of stage three, there was a significant reduction in the tibial surface roughness, the higher roughness present in stage two corresponded with the elevated wear rate. There was a significant reduction in wear between stage two and stage six under the same kinematic conditions, indicating an effect of change in surface roughnesses, while there was no difference in the wear between stages six, five or three when displacement was reduced from 9, to 4 to 0 mm, but with similar roughness measurements.

The coupled multidirectional motion at the tibial bearing surface may explain why the wear rate for the Zenith was comparable to the wear results for the DePuy Mobility and the Buechel-Pappas tested by Bell and Fisher (2007), and the Finsbury BOX by Affatato et al. (2007), whereas all were substantially greater than the results published by Kincaid et al. (2013) for the semi constrained Zimmer trabecular metal TAR with both conventional polyethylene and the cross-linked as this design limits rotation reducing the multidirectional wear. Care must be taken when comparing wear rates between different prostheses tested in different simulators.

Retrieval TARs have been collected and studied at the University of Leeds (Stratton-Powell et al., 2016). Although there are no Zenith, titanium nitride coated TARs in the collection at present

Table 3
Comparing the superior articulating surfaces of the in vitro wear tested Zenith to example AES and Hintegra retrievals.

	Tibial	Superior Insert
Biomet AES Retrieval		
Corin Zenith in vitro simulation		
Intergra Hintegra Retrieval		

these examples of other three component mobile bearing TARs show similar wear scars and damage modes to those simulated in vitro. There are prominent signs of abrasive and adhesive wear as well as burnishing across the three examples (Table 3).

This study had limitations. Gait inputs relied on historic force data calculated for healthy individuals but instrumented implants in knees have shown this to overestimate the axial loads (Zhao et al., 2007), however, in considering the wear rate relative to the kinematics this input parameter remains the same and thus is less critical. In order to use a conventional knee simulator the TAR had to be inverted which although a standard method in displacement controlled TAR wear tests may alter the biomechanics (Affatato et al., 2007; Bell and Fisher, 2007; Kincaid et al., 2013). The in vitro test method eliminated the presence of third body debris and effects from surrounding tissues and ensured optimal component alignment. In removing the two tibial components which experienced coating damage from the test it was ensure this had no effect on the relationship between the kinematic conditions and wear.

The polyethylene wear rates for the three component TAR under multidirectional kinematics are comparable to those associated with wear debris mediated osteolysis for hips and knees and have been found to be in a similar size range (Reinders et al., 2015). This study has established a method and furthered the understanding of the effects of the kinematic inputs in mobile bearing TAR devices which in future will allow us to test other device designs under a range of adverse conditions. Inputs which have the greatest influence on wear have been highlighted and therefore should aim to be the most physiologically relevant.

5. Conclusion

The addition of internal external rotation has proved very important to realistically simulate the polyethylene wear of a mobile bearing total ankle replacement. Without the inclusion of rotation, wear rates were significantly lower due to the strain hardening effects associated with linear wear conditions which are known to improve wear resistance in that direction. Wear track analysis showed the AP displacement and rotation to occur at the tibial interface for the mobile bearing ankle prosthesis, as well as an element of translation associated with the flexion motion. The majority of the flexion appeared to happen at the conforming talar bearing surface, creating one linear wear interface (talar) and one multidirectional cross shear interface (tibial) providing rotation was present. Once the mobile bearing TAR reached a steady state following the bedding in cycles where changes in surface roughness were significant there was no statistical difference between the wear rates depending on the magnitude of AP displacement alone.

Conflict of interest statement

Professor John Fisher acts a consultant to Invibio, DePuy-Synthes, Simulation Solutions and Tissue Regenix, Dr Silvia Suñer is a paid employee of Corin Group PLC and Alexandra Smyth's studentship is part funded by Corin Group PLC.

Data statement

The data associated with this paper (surface roughness and wear study data) are openly available from the University of Leeds Data Repository (Smyth et al., 2017).

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