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# Effect of inward-outward rotation on hip wear simulation

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# Abstract

The ISO 14242-1 standard specifies a three-axis motion for the wear testing of prosthetic hips. Multidirectionality of the relative motion and serum-based lubrication are known to be necessary for the reproduction of clinical wear mechanisms. For multidirectionality however, biaxial motion has been shown to be sufficient. To a biaxial hip joint simulator that incorporated flexion-extension (FE, range 46°) and abduction-adduction (AA, range 12°), a third motion component, inward-outward rotation (IOR, range 12°) was added according to the ISO 14242-1 standard. Due to the addition of the IOR, the wear rate of vitamin E stabilized, extensively cross-linked polyethylene (VEXLPE) liners decreased by 50 per cent. This was probably attributable to the increased linearity of the relative motion in the stance phase, caused by the simplified motion waveforms and their relative phases specified in the standard. In order not to underestimate the wear rate, the established biaxial motion is preferred.

Keywords: orthopedic biomechanics; wear of natural and artificial joints; hip kinematics; inward-outward rotation; extensively cross-linked UHMWPE

# 1. Introduction

Wear testing of prosthetic hips is motivated by the fact that wear debris in large amounts may cause tissue damage leading to a need for reoperations (Harris, 2001; Langton et al., 2011). With improved bearing materials, such as extensively cross-linked ultra-high molecular weight polyethylene (UHMWPE), the need for reoperations can be significantly reduced (de Steiger et al., 2018). Hip simulator testing has recently been expanded to the study of the taper connection of the modular femoral head (Bhalekar et al., 2019) that presently poses substantial problems clinically (Langton et al., 2018). Wear testing is usually performed with fixed motion and load cycles for normal level walking, obtained from biomechanical literature (Ramakrishnan and Kadaba, 1991; Bergmann et al., 2001; Besier et al., 2003; Stansfield et al., 2003; ISO 14242-1, 2014/2018). Multidirectionality of the relative motion between the femoral and acetabular components has been shown to be a prerequisite for realistic wear mechanisms, together with serum lubrication (McKellop et al., 1995; Bragdon et al., 1996; Wang et al., 1996). Multidirectionality is a wide concept, though, and many different biaxial and three-axis motion combinations are being used by orthopaedic tribology laboratories around the world (Calonius and Saikko, 2002a). Clinically, multidirectionality varies substantially (Bennett et al., 2008), which is likely to affect the wear rate (Kang, et al., 2009). Another important factor in the clinical wear rate is the contact pressure distribution that has been shown to be highly patient-specific, depending on the abduction angle of the acetabular component and on the geometry of the musculoskeletal system (Daniel, et al., 2001; Daniel, et al., 2008; Wan, et al., 2008; Košak, et al., 2011; Daniel, et al., 2016).

It has been shown that the combination of flexion-extension (FE) and abduction-adduction (AA) with a phase shift of $\pi/2$ is sufficient to produce multidirectional conditions under which highly realistic wear has been produced in the 12-station, anatomic 'HUT-4' hip joint simulator (Saikko, 2005; Saikko and Shen, 2010). With UHMWPE acetabular components, this is manifested as wear particles in the 0.1 to 1 μm size range and a burnished appearance of the acetabular bearing surface, both of which are typical findings clinically (McKellop et al., 1995; Jasty et al., 1997; Edidin et al., 2001; Mabrey et al., 2002; Calonius and Saikko, 2002b). In an earlier hip joint simulator design, 'HUT-3', that incorporated also the third motion component, inward-outward rotation (IOR), the effect of the IOR on wear appeared minimal (Saikko, 1996). Nevertheless, the IOR is included and specified in the ISO 14242-1 standard together with the FE and AA.

To elucidate the issue, the IOR was added to the HUT-4 simulator and comparative wear tests were run. The objective was to complement the HUT-4 design by the IOR according to ISO 14242-1. However, it was hypothesized that since the addition of the IOR does not increase the multidirectionality of the relative motion (because the standard specifies that the FE and IOR have an opposite phase, i.e., a phase shift of $\pi$), the addition will not lead to a statistically significant difference in the mean wear rate of the polyethylene acetabular liners.

Novel vitamin E blended, extensively cross-linked ultra-high molecular weight polyethylene (VEXLPE) bearing materials are expected to provide a superior combination of oxidation and wear resistance (Bracco and Oral, 2011). In a recent study with the HUT-4 simulator using the biaxial motion, a wear rate of $8.5 \pm 0.6$ mg/$10^6$ cycles was obtained in a 700 h test for VEXLPE liners of 4.0 mm thickness against 54 mm diameter, polished CoCr heads ($n = 3$) (Saikko, 2019). The wear was highly linear. The liner abduction angle was 45°, the peak load was 2.5 kN, and the lubricant was HyClone Alpha Calf serum diluted 1:1 with deionized water. The VEXLPE was 100 kGy gamma-irradiated GUR 1020-E (ASTM F648, ISO 5834-1,2, ASTM F2695, ASTM F2565, 0.1% blended alpha tocopherol, post-consolidation irradiated, no post-irradiation thermal treatment). These three VEXLPE/CoCr specimens were used in the present study, and the above wear rate was used as the reference

## 2. Materials and methods

The HUT-4 hip joint simulator has been described in detail elsewhere (Saikko, 2005). The motion was implemented by an electromechanical drive so that the biaxial motion of the femoral head resulted in a multidirectional relative motion. The sinusoidal flexion-extension (FE, range 46°) and the sinusoidal abduction-adduction (AA, range 12°) had a phase shift of $\pi/2$. The cycle frequency was 1.06 Hz that fits in the ISO 14242-1 recommendation of $1.0 \pm 0.1$ Hz. The proportional-pneumatic loading system produced a double-peak load waveform. The loading direction was vertical and fixed relative to the anatomically positioned acetabular component that was self-centering on top of the femoral head, according to the ISO 14242-1. The heel strike, i.e., the start of the rapid increase of load, occurred at the maximum flexion, as recommended by the ISO 14242-1. The standard recommends a peak load of 3.0 kN, but according to (Bergmann et al., 2001), the peak load is 2.5 times the body weight, and so 2.0 kN appears more realistic. An intermediate value of 2.5 kN was used.

IOR was added to the simulator as follows. A bearing housing for the IOR shaft was fixed to a widened base plate of the inner (AA) cradle (Fig. 1). The upper end of the IOR shaft was similar to the adjustment disk of the original HUT-4 design and so the existing femoral head holder could be used as such. The IOR was implemented by a lever mechanism that turned the IOR shafts according to the FE of the outer cradle. Hence, all 3 motions were applied to the femoral head in an Euler sequence of FE→AA→IOR. Their combined effect on the track of the theoretical point of load application on the head, the so-called force track, was computed and verified according to (Calonius and Saikko, 2003). As required by the standard, the IOR was sinusoidal, its range was 12°, and the minimum outward rotation coincided with the maximum flexion (Fig. 2). Note that in Fig. 2, the IOR waveform was positioned in the y direction so that max. = -min. = 6° (for uniformity), unlike the IOR waveform in the ISO 14242-1, but the different positioning was tribologically insignificant in the case of a spherical joint, especially since the IOR was the last rotation in the Euler sequence. The deviations of the HUT-4 simulator's FE (max. 23°, min. -23°) and AA (max. 6°, min. -6°) waveforms from those of ISO 14242-1 (max. 25°, min. -18° and max. 7°, min. -4°, all with a ±3° tolerance) were minor and also likely to be tribologically unimportant. In the HUT-4 and in the ISO 14242-1, the maximum adduction occurred at 25 per cent vs. 21 per cent of the gait cycle after the maximum flexion (heel strike). This phase shift (π/2 or close to it) between the FE and AA is the most important requirement with respect to the multidirectionality of the relative motion that makes it possible to reproduce clinical wear mechanisms (McKellop et al., 1995; Bragdon et al., 1996; Wang et al., 1996; Calonius and Saikko, 2002a; Saikko, 2005).

The test length in the present study was 300 h (running in of the liners had already taken place in the 700 h reference test), and the wear was gravimetrically measured every 100 h using a balance with a resolution of 0.01 mg as described in (Saikko, 2019). There was a loaded soak control cup with which the amount of fluid absorption was estimated. The only intentional difference in the test conditions between the reference and present tests was the addition of the IOR. It was considered an advantage to use the same specimens in the tests because the possible observed difference in the wear rate would be more likely to be caused mostly by the difference in the simulator conditions (IOR). The Student's t-test was used to determine a possible statistical difference in the mean wear rates with a threshold p value of 0.05.

A lubricant chamber with a heat exchanger is available for the HUT-4. With this chamber, the lubricant bulk temperature can be kept at 37 °C, as recommended by the ISO 14242-1 standard. However, since the reference test (Saikko, 2019) was run at room temperature in order to retard microbial growth and protein precipitation, the present test was also run at the room temperature of 23 °C and the lubricant bulk temperature was monitored. Enclosing the test chamber, as recommended by the standard, can readily be done, but it was left out because it has been observed that free evaporation effectively prevents overheating of the lubricant

(Saikko, 2005; Saikko and Shen, 2010).

In order to estimate the maximum contact pressure $p_{max}$, the observation that the contact diameter was c. 40 mm (contact area ≈ 1 200 $mm^2$) was utilized (Saikko, 2019). Assuming a cosine contact pressure distribution, it can be shown that $p_{max} = 3L_{peak}/2\pi a^2$ (Saikko and Calonius, 2003), where $L_{peak}$ = load peak value = 2.5 kN and $a$ = contact half width = 20 mm.

## 3. Results

The addition of the IOR (Fig. 2) caused a bending of the earlier elliptical force track so that the sliding in the stance phase became more linear (Calonius and Saikko, 2003; Saikko, 2005) (Figs. 3 and 4). The wear of the 3 VEXLPE liners was linear, as indicated by the correlation coefficients $R^2$ of the linear regression, 0.9892, 0.9990 and 0.9773. The wear rate was 4.3 ± 0.15 mg/$10^6$ cycles. Compared with the reference value, 8.5 ± 0.6 mg/$10^6$ cycles, the 50 per cent decrease of the mean value was statistically significant (p = 0.005). The VEXLPE bearing surfaces were burnished. The lubricant bulk temperature varied from 31 °C to 34 °C. The maximum contact pressure at the peak load of 2.5 kN was calculated to be 3 MPa.

## 4. Discussion

Inward-outward rotation was added to an established biaxial hip simulator according to the ISO 14242-1 standard. This was the first study to evaluate the tribological significance of the IOR added to a biaxial hip joint simulator. Surprisingly, the addition resulted in a decrease of the mean wear rate of VEXLPE liners by 50 per cent. Therefore, the hypothesis was not supported. Figs. 3 and 4 show that the third motion component, IOR, did not increase the multidirectionality of the relative motion. On the contrary, the motion in the stance phase became more linear as the effects of the AA and IOR on the track curvature tended to neutralize each other due to their phase shift of π/2. This makes the decrease of the wear rate logical. The limitations of linear motion are well known (Saikko, 1993; Bragdon et al., 1996; Wang et al., 1996), that is, the UHMWPE wear rate is too low compared with clinical findings due to strain hardening. The increased linearity is mostly due to the simplified motion waveforms and their relative phases specified in the standard. It is not likely to directly reflect the clinical reality as the waveforms observed in gait analyses are more complex (Ramakrishnan and Kadaba, 1991; Wu et al., 2002; Besier et al., 2003; van Arkel and Jeffers, 2016).

The first two hip joint simulators designed according to the ISO 14242-1 standard specifications were the 'EndoLab' and 'E-SIM' designs (Kaddick and Wimmer, 2001; Reinisch et al., 2001). With the latter however, little research work seems to have been done. The 'EndoLab' design is similar to the present one with respect to the fact that in both designs the direction of the vertical load is fixed relative to the stationary acetabular component that is anatomically positioned above the femoral head. The 3 motions are applied to the femoral head in an Euler sequence of AA→FE→IOR. The 'bent elliptical' shape of the computed slide tracks is similar to the present one (Figs. 3 and 4). With the EndoLab simulator, a test similar to the present one has been carried out (Grupp et al., 2014). The wear rate of VEXLPE (0.1% blended, 80 kGy electron-beam-irradiated) liners against 36 mm alumina heads was 2.5 ± 0.5 mg/$10^6$ cycles.

Another established three-axis hip simulator, 'AMTI' (Bragdon et al., 1996), differs from the HUT-4 and EndoLab designs so that the direction of load is fixed relative to the femoral component, a structural characteristic recently added to the ISO 14242-1 standard as Amendment 1. The choice of the fixation of the loading direction may affect wear. This is because the contact stress field is either stationary (HUT-4, EndoLab), or it moves relative to the acetabular component (AMTI). In the AMTI simulator, the IOR is applied to the femoral component and the FE and AA to the acetabular component. The vertical IOR axis is also the load axis and the femoral component is located below the acetabular component. The Euler sequence is AA→FE→IOR. Vitamin E blended (> 0.1%), electron-beam-irradiated (> 100 kGy) VEXLPE ('Vivacit-E') liners showed a wear rate of 1.8 ± 0.2 mg/$10^6$ cycles in an AMTI simulator study against 40 mm diameter CoCr heads (Popoola et al., 2018). The test was exceptionally long, 100 million cycles. The wear was still linear throughout the course of the test, which may justify considerably shorter test durations with VEXLPE. Note that in the present 300 h tests the wear was highly linear and the variation of the wear rate was low. The calculated maximum contact pressure value of 3 MPa is considered moderate for VEXLPE with respect to its typical mechanical properties (Bracco and Oral, 2011). The relatively low value was mainly attributable to the large head diameter. For example, a value of 13 MPa was reported by (Hua et al., 2014) in a finite element computational study for a UHMWPE liner at 45° abduction against a 36 mm diameter head with 0.6 mm diametral clearance and 2.5 kN load.

In the widely used orbital bearing machine ('OBM') hip simulator (ISO 14242-3, 2009/2019), the contact stress field also moves relative to the acetabular component if the cup is located below the head in an inverted position. With the anatomic position, the OBM is highly similar to the HUT-4, the principal difference being the range of the AA (46° vs. 12°). The absence or presence of the IOR in the OBM simulator depends on the location of the rotation-control lever (Calonius and Saikko, 2002a). In the anatomic position, all motions are applied to the femoral component and the load is applied vertically to the stationary acetabular component, and vice versa in the inverted position. The Euler sequence is FE→AA→IOR in the anatomic position, and IOR→AA→FE in the inverted position (as in the HUT-3, Saikko, 1996). In an anatomic position OBM study with 44 mm diameter CoCr heads, the wear rate of unspecified VEXLPE liners was 7.6 ± 0.7 mg/$10^6$ cycles (Herrera et al., 2010).

## 5. Conclusions

The biaxial HUT-4 hip joint simulator was made three-axial by adding a third motion component, IOR, according to the ISO 14242-1 standard. Due to the addition, the wear rate of VEXLPE liners decreased by 50 per cent. This was probably attributable to the increased linearity of the relative motion in the stance phase caused by the simplified motion waveforms and their relative phases specified in the standard, which may lead to an underestimation of the wear rate. Therefore, the established biaxial motion is preferred.


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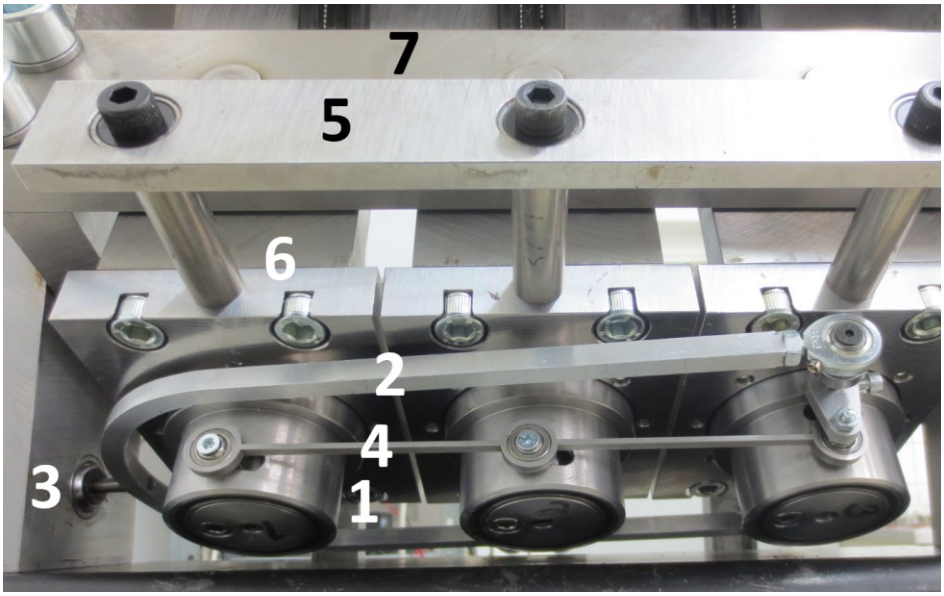


Fig. 1. IOR mechanism added to HUT-4 hip joint simulator, beneath FE and AA cradles, shown in positions of maximum FE (23°), neutral AA (0°), and minimum IOR (-6°), 'heel strike'. 1 bearing housing for IOR shaft, 2 IOR lever, 3 ball joint with slide bushing, 4 IOR transfer bar with ball joints, 5 AA transfer bar, 6 AA cradle, 7 FE cradle.

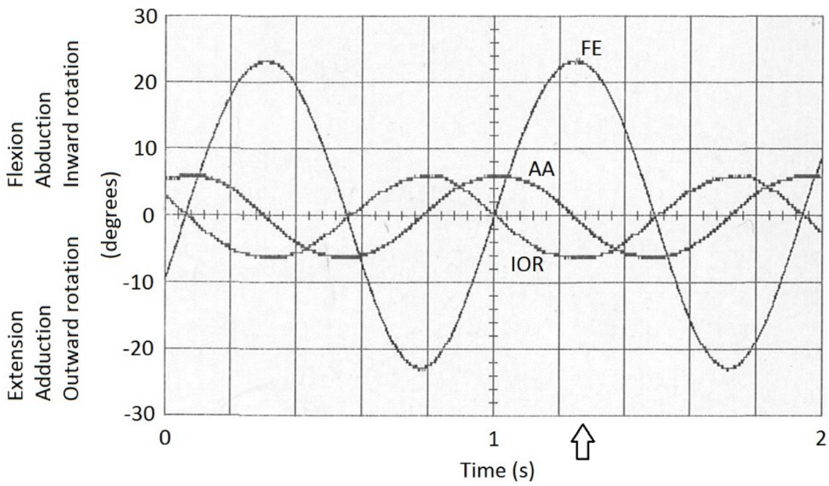


Fig. 2. FE, AA, and IOR of HUT-4 hip joint simulator, measured with angle transducers and oscilloscope. Cycle time = 0.94 s. Arrow indicates simulator position in Fig. 1, 'heel strike'.

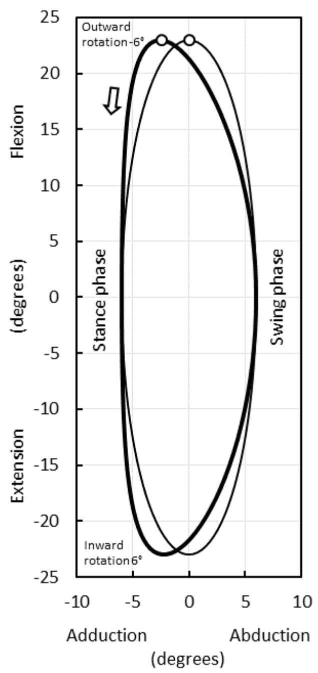


Fig. 3. Flattened tracks of theoretical point of load application on femoral head ('force track') produced by HUT-4 hip joint simulator with combinations of FE and AA (thin line), and FE, AA and IOR from ISO 14242-1 (thick line), computed according to (Calonius and Saikko, 2003). Circles indicate heel strike and arrow indicates direction of sliding.

Fig. 4. Verification of force track in HUT-4 hip joint simulator using stationary pen on 54 mm diameter femoral head with three-axis motion according to ISO 14242-1. Simulator position as in Fig. 1.