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Effect of random variation of input and various daily activities on wear in a hip joint simulator

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Abstract

The ISO 14242-1 standard specifies fixed, simplified, sinusoidal motion and double-peak load cycles for wear testing of total hip prostheses. In order to make the wear simulation more realistic, random variation was added for the first time to the motion and load control signals of a hip joint simulator. For this purpose and for the simulation of various daily activities, computer-controlled, servo-electric drives were mounted on a biaxial hip simulator frame and successfully introduced. Random variation did not result in a statistically significant difference in the wear factor of large diameter VEXLPE liners compared with fixed sinusoidal waveforms. However, level walking according to biomechanical literature surprisingly resulted in a 134 per cent higher, and jogging in a 57 per cent lower wear factor compared with the fixed sinusoidal waveforms. These wear phenomena were likely to be caused by a variation in the lubrication conditions and frictional heating. Simplified motion waveforms may result in an underestimation of wear in walking.

Keywords: orthopedic biomechanics; wear of artificial joints; computer-controlled hip simulator; servo-drive; extensively cross-linked UHMWPE

1. Introduction

Wear studies of prosthetic joints are prompted by the fact that wear debris in large amounts has adverse effects that may limit the service life of the prosthesis (Harris, 2001; Langton et al., 2011). With improved bearing materials, wear can be reduced and the service life can be significantly extended (Scemama et al., 2017; de Steiger et al., 2018). Wear testing for prosthetic hips is usually carried out with fixed motion and load cycles of normal level walking obtained from biomechanical literature (Ramakrishnan and Kadaba, 1991; Viceconti et al., 1996; Bergmann et al., 2001; Besier et al., 2003; Stansfield et al., 2003; Tsai et al., 2014; Valente et al., 2015; ISO 14242-1, 2014/2018). Level walking is the principal activity responsible for wear because of the high number of cycles (Schmalzried et al., 2000; Silva et al., 2002). Still a fixed motion and load pattern may lead to a simplified picture of the wear characteristics of the implant design (Fialho et al., 2007; Fabry et al., 2013). The range of everyday activities is naturally wide, and even the variation of the walking speed changes the motions and loading of the hip (Bergmann et al., 1993; Morlock et al., 2001; Chatterji et al., 2004; Bergmann et al., 2010; Vissers et al., 2011; Vogel et al., 2011; Halilaj et al., 2018). The effect of the variation on wear remains unknown if only fixed conditions are included in the test programme. To shed light on this issue, computer-controlled servo-electric drives were mounted on a hip joint simulator and random variation was added to the motion and load input. The novel test system also enabled wear tests with different daily activities. Hence, the versatility of the simulator increased considerably. It was hypothesized that statistically significant differences in the mean wear factors between fixed simplified waveforms, added random variation, and various daily activities can be distinguished and established with the new hip simulator design.

2. Materials and methods

The present acetabular and femoral specimens were used in a recent study in which a wear rate of 8.5 ± 0.6 mg/10^6 cycles was obtained for the extensively cross-linked, vitamin E stabilized, ultra-high molecular weight polyethylene (VEXLPE) liners of 4.0 mm thickness against 54 mm diameter, polished CoCr heads (n = 3) using the HUT-4 hip simulator (Saikko, 2019). The acetabular abduction angle was 45°, the peak load was 2.5 kN, the lubricant was HyClone Alpha Calf serum diluted 1:1 with deionized water, and the tests were run at room temperature of 23 °C. 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, no stabilizers or processing aids, compression moulded, post-consolidation irradiated, no post-irradiation thermal treatment). Such novel VEXLPE bearing materials are expected to provide a long-lasting resistance to oxidation and good wear characteristics (Oral et al., 2005; Bracco and Oral, 2011; Rowell and Muratoglu, 2016). The experimental implant design reflected the resurged interest in hip resurfacing after it became apparent that CoCr-on-CoCr designs often show excessive metal release (Langton et al., 2011; Saikko et al., 1998). The wear factor that corresponded with the above wear rate, $1.08 \pm 0.08 \times 10^{-7}$ mm^3/Nm, was used as a reference for the present tests.

The 12-station, anatomic HUT-4 hip simulator has been described in detail elsewhere (Saikko, 2005; Saikko and Shen, 2010). The motion was implemented by an electro-mechanical crank drive so that the biaxial motion of the femoral head resulted in a multidirectional relative motion. The sinusoidal flexion-extension (FE, range 46°) and abduction-adduction (AA, range 12°) had a phase shift of $\pi/2$. These simplified waveforms were close to those specified in (ISO 14242-1, 2014/2018). The cycle time T was 0.94 s. The direction of the load was vertical and it was fixed relative to the anatomically positioned acetabular component that was self-centering on the femoral head. The heel strike occurred at maximum flexion. In the present study, the crank drive was replaced with two computer-controlled, servo-electric drives, one for the FE and the other for the AA (Fig. 1). The pneumatic loading system that produced a double-peak load waveform was not changed, with the exception that the load control signal was computer generated. The duration of each of the present tests was 300 h, and the wear was measured gravimetrically at intervals of 100 h, as described in (Saikko, 2019). For the calculation of the wear factor, the product of the instantaneous load value and the incremental sliding distance along the theoretical track of the point of load application on the femoral head, 'force track' (Calonius and Saikko, 2003) was numerically integrated throughout the test at 200 Hz frequency. In all of the present tests, the same specimens were used (n = 3). The Student's *t* test was used to determine a possible statistical significance of a difference in the mean wear factors with a threshold p value of 0.05. The four tests with the new servo drives were as follows.

Phase I. Continuation of the earlier electro-mechanically driven test (Saikko, 2019) so that all test conditions were kept as similar as possible (Fig. 2). The idea was to check that the change of the type of drive from electro-mechanical to servo-electric does not result in a statistically significant difference in the mean wear factors due to, e.g., a difference in vibrations induced by the motors and gears.

Phase II. Random variation was added to the cycle time T (0.8 s to 1.2 s) and to the amplitudes of FE (30° to 46°), AA (8° to 12°) and load L peak value (2 kN to 3 kN). For every cycle, starting at the maximum flexion, T was first computed by a random number generator using a continuous uniform distribution. The next FE, AA and L maxima were then computed so that they were inversely proportional to T. In other words, the lower the gait cycle time (faster walking), the larger the amplitudes, and vice versa (Fig. 3). The motion waveforms were computed so that the derivatives of the angular accelerations were continuous, and therefore the motion was always smooth. As in Phase I, FE and AA had a phase shift of $\pi/2$ and the 'heel strike' (the start of the rise of L) occurred at the maximum flexion.

Phase III. Level walking according to (Besier et al., 2003; Bergmann et al., 2001). The FE (range 46°) and AA (range 16°) waveforms were more complex than in Phase I, the peak load was 2 kN and the cycle time *T* was 1.1 s (Fig. 4). The heel strike occurred at 12 per cent of the cycle time after the maximum flexion. According to (Bergmann et al., 2001), the hip peak load in normal level walking is 2.38 times the body weight with an average bogy weight of 836 N. This results in 2 kN, which is one third lower than the ISO 14242-1 recommendation of 3 kN.

Phase IV. Jogging according to (Bergmann et al., 1993). The sinusoidal FE (range 46°) and AA (range 12°) were as in Phase I but the peak load was increased to 4 kN and the cycle time *T* was reduced to 0.8 s (Fig. 5).

3. Results

The test results are summarized in Table 1 and in Fig. 6. The mean wear factor in Phase I was 6 per cent lower than that in the reference test, but the difference was not statistically significant ($p = 0.57$). The mean wear factor in Phase II was 13 per cent lower than that in Phase I, but the difference was not statistically significant ($p = 0.36$). The mean wear factor in Phase III was 134 per cent higher than that in Phase I, and the difference was statistically significant ($p = 0.004$). The mean wear factor in Phase IV was 57 per cent lower than that in Phase I, and the difference was statistically significant ($p = 0.01$).

4. Discussion

For the first time, random variation was added to the input of a joint simulator wear test. It was found that statistical variation decreased the mean wear factor of thin, large-diameter VEXLPE liners by 13 per cent compared with fixed cycles. However, the difference was not statistically significant. Note that the test conditions in Phases I and II were not fundamentally different in the sense that the change of the sliding direction along the force track was 360°/cycle in both. Hence the multidirectionality in the two phases was basically the same. The accumulated change of the direction of sliding per unit sliding distance has been shown to have a strong effect on the wear factor (Calonius and Saikko, 2003). The addition of the random variation required computer-controlled servo drives. These were mounted and successfully introduced. Although the present preliminary observations regarding the effect of random variation on wear were not very dramatic, the tests nevertheless proved the usefulness of the new, computer-controlled wear test system for prosthetic hips. The servo drives substantially increased the versatility of the simulator.

While the hypothesis was not supported in Phase II, it was supported in Phases III and IV. The result of the jogging test (Phase IV) was surprising, as the increased intensity of the simulation resulted in a statistically significant decrease of the wear factor. This may have been attributable to improved lubrication caused by a higher mean sliding speed and to a higher temperature. The walking test (Phase III) on the other hand resulted in a surprisingly high wear factor which may have been attributable to the combination of poorer lubrication caused by a slower mean sliding speed, lower temperature, and increased multidirectionality due to the extra 'bend' in the force track. The wear rate of conventional UHMWPE strongly decreases with increasing temperature (Lu, 1999). The temperature here refers to the measured serum bulk temperature that reflects the changes in the unknown contact temperatures that vary with the load, sliding speed, friction, and location on the bearing surface. The wear rate of conventional UHMWPE increases with increasing multidirectionality (Saikko, 1993; Calonius and Saikko, 2003; Korduba and Wang, 2011). Whether these dependences regarding the temperature and multidirectionality apply to VEXLPE is yet to be shown. The wear behavior of VEXLPE in walking vs. jogging was opposite to that of conventional, moderately cross-linked (50 kGy) UHMWPE (Bowsher and Shelton, 2001). With large-diameter CoCr-on-CoCr, jogging resulted in a seven-fold increase of wear compared with walking (Bowsher et al., 2006). Hence, the present result appeared promising regarding the wear behavior of large-diameter VEXLPE liners under the conditions of intense activity. More importantly, since walking is the primary activity responsible for wear (Schmalzried et al., 2000; Morlock et al., 2001; Silva et al., 2002; Vissers et al., 2011; Vogel et al., 2011), the comparison of Phases I and III indicated that simplified motion waveforms specified in the ISO 14242-1 may lead to an underestimation of the wear rate in the simulation of level walking.

The relatively short test duration, 300 h, could be mentioned as a limitation of the study. However, the liners were from an earlier 700 h study, in which the wear proved to be highly linear. Moreover, since the liners were already worn, there was no running in effect in the present tests.

In summary, computer-controlled servo drives were mounted on a biaxial hip simulator frame in order to add random variation to the input. With this novel test system, different daily activities could also be readily implemented. Random variation added to gait cycles did not result in a statistically significant change of the wear factor compared with fixed, simplified motion waveforms. Surprisingly, walking according to biomechanical literature resulted in a statistically significant increase and jogging in a statistically significant decrease of the mean wear factor. Such a wear behavior may have been attributable to lubrication conditions and frictional heating. Simplified motion waveforms specified in the ISO 14242-1 may lead to an underestimation of wear in level walking.

Conflict of interest statement

The authors have nothing to declare.

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Table 1. Summary of test results.

Test phase	Test length* (km)	Total $\int L ds$* (10^6 Nm)	$\int L ds$/cycle* (Nm)	Average sliding speed* (mm/s)	Wear rate (mg/10^6 cycles)	Wear rate (mg/km)	Lubricant bulk temperature (°C)
I	53.9	96.9	84	49.9	8.0 ± 1.3	0.17 ± 0.03	31 to 32
II	41.9	75.4	70	38.8	5.8 ± 1.0	0.15 ± 0.03	31 to 34
III	46.7	59.0	61	43.6	13.5 ± 0.2	0.28 ± 0.004	27 to 29
IV	63.4	173	128	58.6	5.2 ± 1.7	0.11 ± 0.04	36 to 40
Ref.**	125	225	84	49.9	8.5 ± 0.6	0.18 ± 0.01	31 to 33

*Along ‘force track’ (Calonius and Saikko, 2003)

**(Saikko, 2019)

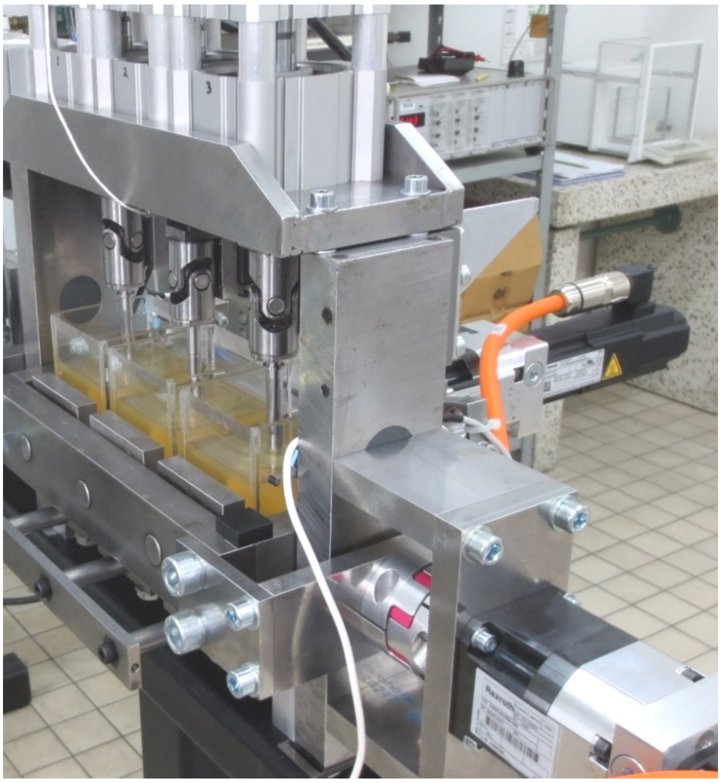
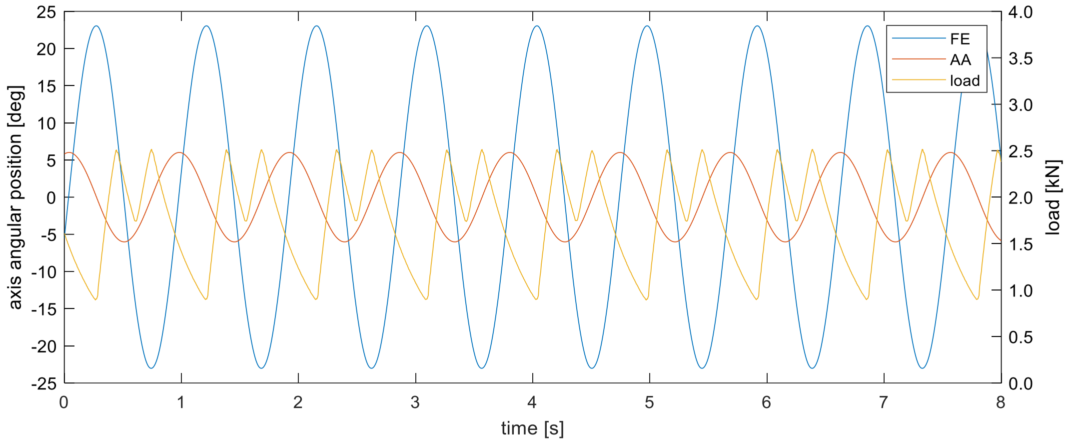


Figure 1. Servo-electric drives mounted on biaxial hip joint simulator frame.



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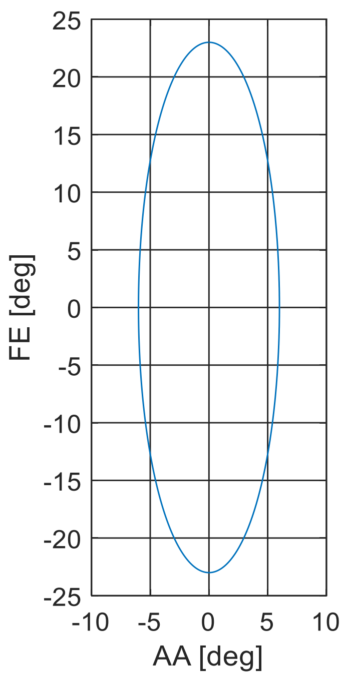
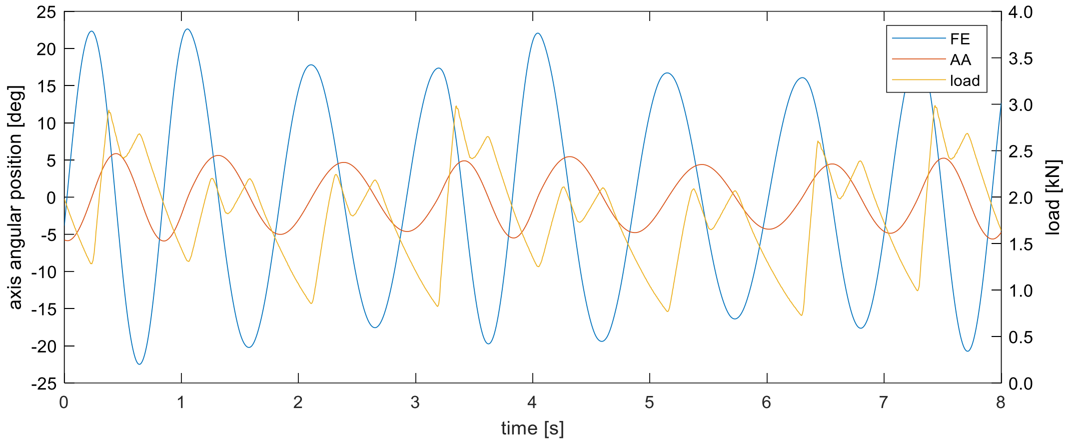


(b)

Figure 2. (a) Phase I motion and load, and (b) force track.



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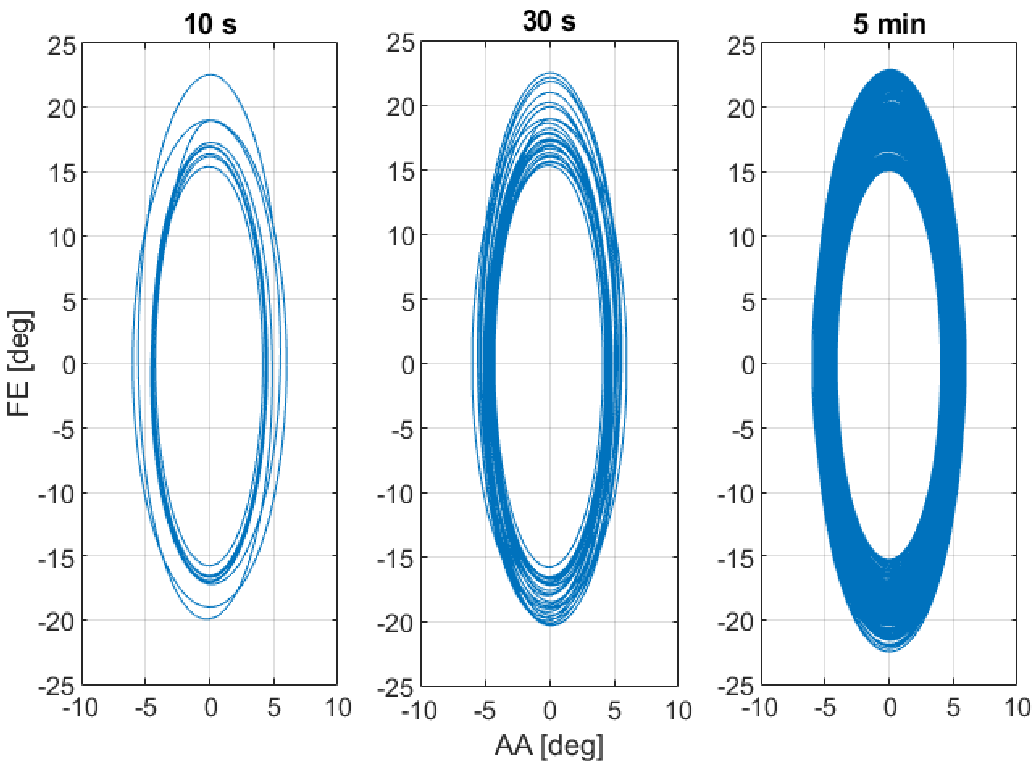
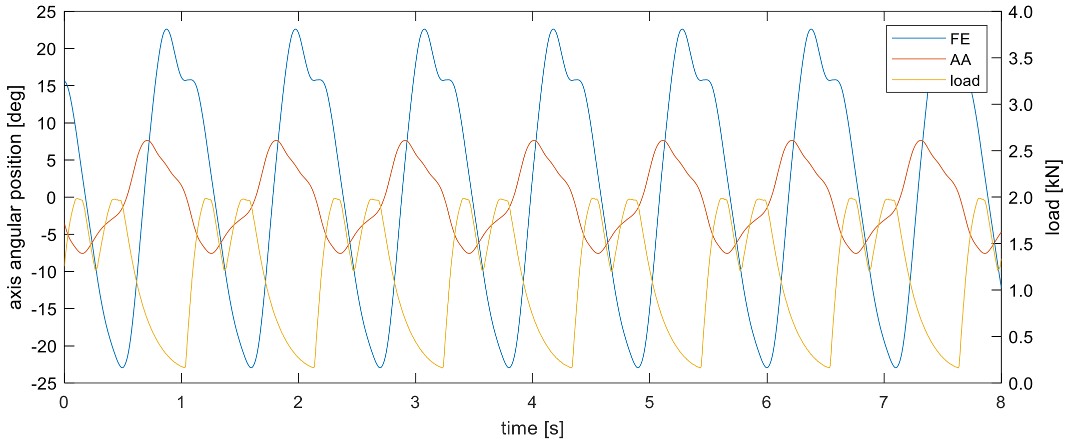


(b)

Figure 3. (a) Example of Phase II motion and load, and (b) force track.



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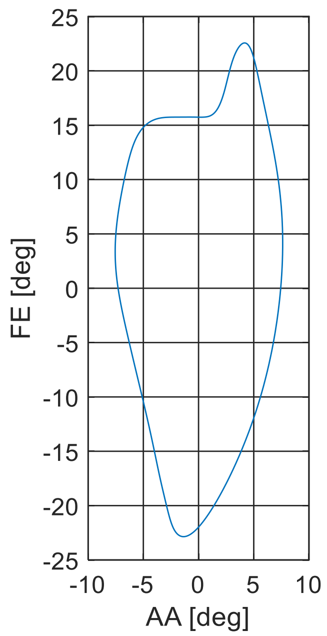

(b)

Figure 4. (a) Phase III motion and load, and (b) force track.

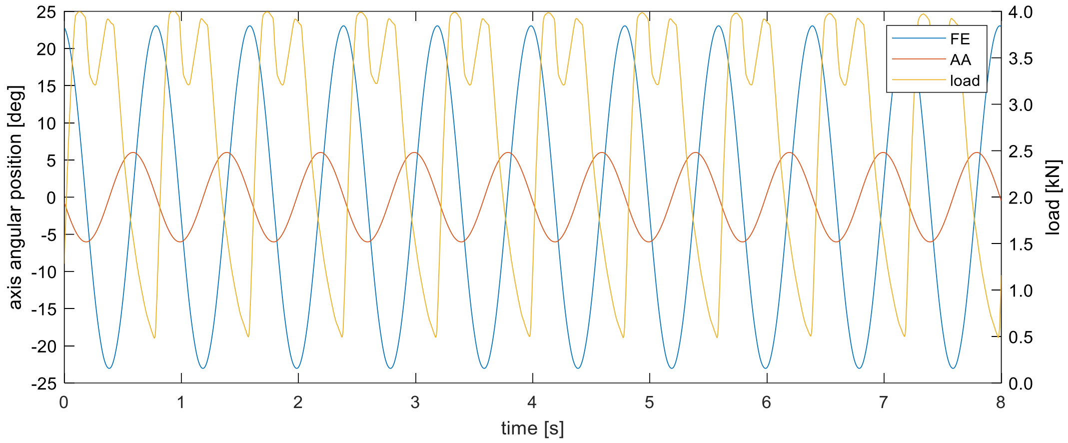

Figure 5. Phase IV motion and load. Force track as in Fig. 2 (b).

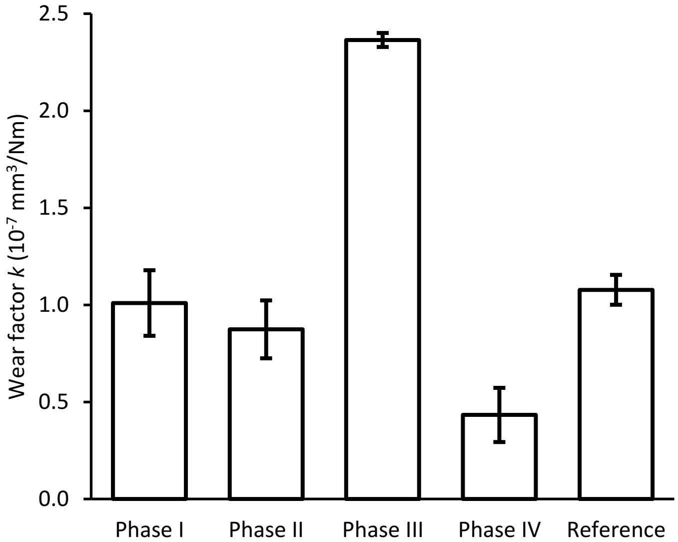

Figure 6. VEXLPE liner wear factors under various test conditions, mean and SD.