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RandomPOD — a new method and device for advanced wear simulation of orthopaedic biomaterials

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Abstract

A 16-station wear simulator of the pin-on-disc type, called RandomPOD, was designed, built and validated. The primary area of application of the RandomPOD is wear studies of orthopaedic biomaterials. The type of relative motion between the bearing surfaces, generally illustrated as shapes of slide tracks, has been found to have a strong effect on the type and amount of wear produced. The computer-controlled RandomPOD can be programmed to produce virtually any slide track shape and load profile. In the present study, the focus is on the biomechanically realistic random variation in the track shape and load. In the reference test, the established combination of circular translation and static load was used. In addition, the combinations of random motion/static load, and circular translation/random load were included. The pins were conventional ultra-high molecular weight polyethylene (UHMWPE), the discs were polished CoCr, and the lubricant was diluted calf serum. Random motion increased the UHMWPE wear factor significantly compared with circular translation. This was probably caused by the fact that in the random motion the direction of sliding changed more than in circular translation with the same sliding distance. The type of load, random vs. static, was unimportant with respect to the wear factor produced. The principal advantage of using the present random track is that possible unrealistic wear phenomena related to the use of fixed track shapes can be avoided.

1. Introduction

Contemporary wear simulators for prosthetic hip and knee joints repeat the same synchronized motion tracks and load profiles again and again, usually simulating level walking. In reality, there naturally are not only numerous different daily activities that may not even be recurring, but there is also variation in the track shape in the recurring activities (Isacson et al., 1986, Kadaba et al., 1990). It is possible that there is an important random characteristic in the joint kinematics, which has not been included in wear testing so far. If this characteristic is correctly incorporated in the set value signals of the test devices, the wear simulation may be further improved.

It is known that the shape of the slide track is of fundamental importance with respect to the wear rate (Bennett et al., 2002; Saikko and Ahlroos, 1999; Saikko et al., 2004; Wang 2001; Wang et al., 1996). For instance, the wear factor of conventional ultra-high molecular weight polyethylene (UHMWPE) with reciprocating sliding in serum has been found to be 2 to 3 orders of magnitude lower compared with multidirectional sliding. In order to produce wear factors that are in agreement with clinical findings (Atkinson et al., 1985b; Hall et al., 1996), multidirectional sliding is a necessity. On the other hand, multidirectional motion is a broad concept. Specific knowledge about the dependence of wear on different types of multidirectional motion will undoubtedly be useful for the progress of wear simulation.

A new computer-controlled 16-station pin-on-disc (POD) device, called RandomPOD, was designed and built. The RandomPOD device is based on the 12-station CTPOD and 100-station SuperCTPOD hip wear simulators (Saikko and Ahlroos, 1999; Saikko, 2005). While the CTPOD performs circular translation with static load, the RandomPOD can be programmed to produce virtually any track shape and load profile. In the present study, the focus is on the random variation in the slide track and in the load profile. The random signals for motion and load control were programmed, and then implemented with the system in wear tests using established prosthetic joint materials, UHMWPE against polished CoCr in serum. Based on biomechanical literature, limits

were set for velocities, accelerations, contact pressure, and rate of change for direction of sliding and contact pressure (Bennett et al., 2002; Bennett et al., 2008; Bergmann et al., 2001; Kadaba et al., 1990; Saikko and Calonius, 2002).

The reference test that was performed with the new device was circular translation with static load (Saikko, 2005). To test the hypothesis that random motion and random load, or one of them, may result in a significant change in the wear factor of UHMWPE, the wear produced by the new device in the reference test was compared with that produced with random motion/random load, random motion/static load, and circular translation/random load.

2. Methods

The 16-station RandomPOD design (Figs. 1 and 2) has biaxial motion, that is, horizontal x and y translations, and vertical loading. The motions are implemented servo-electrically, and the load proportional-pneumatically. The motions and the load are computer-controlled. The range of both motions is 10 mm, and the range of load is from zero to 150 N per station. The structure of the device is such that the test discs move with an x-y-table, and the stationary test pins are loaded by pneumatic cylinders through pin-guiding shafts, the lower end of which has a recess for the pin.

In the wear tests, 4 different conditions regarding the combination of motion (random and circular) and load (random and static) were included. The reference condition was the established combination of circular translation and static load, 71 N (Saikko, 2005; Saikko and Ahlroos, 1999). In circular translation, the pin translated along a circular track of 10 mm diameter relative to the disc with constant sliding velocity of 31.4 mm/s, and so the direction of sliding relative to the pin changed at a constant rate, 2π /s. The random motion was programmed so that the slide track of the pin remained inside a circle of 10 mm diameter, and the track covered the area within a few minutes (Fig. 3). The sliding velocity varied from zero to 32 mm/s so that the average velocity was half of that of circular translation, 15.7 mm/s. The acceleration varied from zero to 300 mm/s². The radius

of curvature of the track varied from zero to infinity. The track was smooth except for the occasional reversals that were similar to those of a reciprocator. The reversals were due to the random nature of the track and occurred when the curvature of the track was very high. With the above values, there were no jerky movements. The random load varied from zero to 142 N with an average close to 71 N. The load set value was a smoothened 5 Hz random step signal (Fig. 4). The maximum load change rate of the set value signal was limited to 300 N/s. The value of the integral $\int L ds$, where L is the load and s is the sliding distance, was updated at a frequency of 100 Hz. The accumulated total value was needed in the calculation of the wear factor, in which the gravimetric wear was divided by this value and by the density of polyethylene, 0.93 mg/mm³. In the present random track, the change of direction of sliding was 2.8 times that of the circular track with the same sliding distance. With the same test duration, however, the total sliding distance with circular translation was twice that with random motion.

The pins (9.0 mm dia.) were conventional, non-irradiated, calciumstearat-free GUR 1020 UHMWPE (ISO 5834-1/-2). The discs were polished CoCrMo wrought alloy Protasul-20 (Zimmer GmbH, Switzerland) with a surface roughness R_a value of 0.01 µm. The lubricant was HyClone (Logan, Utah, USA) Alpha Calf Fraction non-iron supplemented serum SH30212.03, diluted 1:1 with Milli-Q-grade distilled water. The RandomPOD has a separate lubricant chamber for each test station, containing 18 ml of lubricant.

Two sets of tests were done. In the first set, four test stations were employed. Four different conditions were compared in consecutive tests, i.e., circular translation/static load, circular translation/random load, random motion/static load, and random motion/random load. These tests were done at room temperature which was 25 °C on the average. The test length with each motion/load combination was 5 days. For the second set, the device was complemented with a temperature control system based on circulating water that surrounded the test chambers. Using this system, the serum temperature was maintained at 22 to 23 °C. All 16 stations were employed, and

the test length was 18 days. The test was stopped every 6 days for the weighing of the pins. In this way, 3 points were obtained for the determination of the wear rate using linear regression. From this, the wear factor was calculated. Two different conditions were compared in consecutive tests, i.e., circular translation/static load and random motion/random load. The unit used for the wear rate was mg/km instead of the typical $mg/10^6$ cycles, because of the non-cyclic random motion.

The wear factors produced in different conditions were compared with a t-test.

3. Results

Under all 4 test conditions, the wear surface of the pins became flat and highly polished. On the discs there was no damage, such as transfer layers, depositions or scratches. The wear factor resulting from random motion was 1.8 times that resulting from circular translation (Table 1). This was the case both with random load (p = 0.0004) and static load (p = 0.0008). The wear factor resulting from random load was not different from that resulting from static load, irrespective of the type of motion, random (p = 0.46) or circular translation (p = 0.43). During the first set of tests, the lubricant temperature was c. 2 degrees above the environment temperature 25 °C. In the second set of tests, the wear factors were higher (Table 2) but random motion/random load again resulted in a wear factor 1.6 times that resulting from circular translation/static load ($p = 1.26 \times 10^{-12}$).

4. Discussion

The present first test results produced by the new RandomPOD device confirmed the earlier findings that multidirectional motion is of primary importance in the wear simulation of orthopaedic biomaterials (Bennett et al., 2002; Davey et al., 2005; Saikko and Ahlroos, 1999; Saikko et al., 2004; Wang, 2001; Wang et al., 1996; Wang et al., 1997), and that the type of load, static vs. dynamic, is of secondary importance (Saikko et al., 2003). Random motion increased the wear factor significantly, which was probably due to the fact that in the random motion, the change of

direction of sliding was 2.8 times higher than that in the circular translation with the same sliding distance. The dynamic random load resulted in a mean wear factor that was close to that with static load, irrespective of the type of motion. This indicates that in wear tests of orthopaedic biomaterials, static load can be used provided that the nominal contact pressure does not exceed a critical level, which is about 2 to 3 MPa for UHMWPE (Saikko, 2006).

The wear mechanisms were similar with all 4 test conditions. The UHMWPE wear surface was burnished and the CoCr counterface was undamaged. These observations agree with clinical findings (Atkinson et al., 1985a; McKellop, 2007; McKellop et al., 1995). Burnishing is an indication of a common, specific wear mechanism resulting primarily from multidirectional motion and protein-containing lubrication. This generates wear particles that are mostly in the 0.1 μ m to 1 μ m size range, which is unfortunate since this size range is biologically the most active and harmful. In severe cases the biological reaction can lead to osteolysis and loosening of the fixation of the prosthesis, necessitating a reoperation.

In the RandomPOD, expertise in biotribology, machine design, control engineering and mechatronics was combined. Random motion and load were applied for the first time in wear testing of orthopaedic biomaterials. Biomechanically realistic limits were used for the velocity, acceleration, and angular rate of change of the relative motion, and for the nominal contact pressure. Charnley used separate electric motors in his POD device to produce three motions, x and y translations, and rotation of the disc (Charnley, 1976). The resulting relative motion was complex, but not truly random. Regarding the objective of avoiding track repetition, Charnley's POD device can be considered the nearest predecessor of the RandomPOD. The above study from the mid 70's treated the highly important subject of multidirectional motion that did not receive wider attention until two decades later. At present it is generally accepted that the motion must be multidirectional to reproduce the clinical wear phenomena (ASTM F 732, 2006). There is however no consensus on the specific type of multidirectional motion to be used (Affatato et al., 2008). The RandomPOD is

expected to be a useful tool in wear studies with different slide track shapes. The present first test series with the highly complex random track not only serves as a proof of the performance of new test system, but also gives an idea of its many possibilities. The principal advantage of the present random track is that all relevant track shapes (Bennett et al., 2002; Bennett et al., 2008; Saikko and Calonius, 2002; Wang et al., 1997) are included in it. This represents an advanced wear simulation principle compared with a sequential repetition of a few different activity cycles.

In an earlier study (Saikko, 2005), the mean wear factor produced for GUR 1020 UHMWPE with circular translation and static load was 1.63×10^{-6} mm³/Nm. The material, Sulene-PE (Zimmer GmbH, Switzerland) was gamma-irradiated by 25–40 kGy in nitrogen. In the present study, the material was otherwise similar, but it was left non-irradiated, and the wear factor was almost three times higher, 4.34×10^{-6} mm³/Nm (Table 2). A similar three-fold difference was observed in biaxial rocking motion hip simulator tests (Wang, 1996). Even the relatively low dose of gamma-irradiation used in the sterilization of UHMWPE components (25–40 kGy) apparently improves the wear resistance by crosslinking. Higher doses have been shown to improve the wear resistance by an order of magnitude (Saikko, 2010). The shorter tests showed lower wear factors than the longer ones, which was probably due to the different temperature.

The RandomPOD has potential, for example, in the study of advanced, crosslinked UHMWPE materials, which are highly topical and promising orthopaedic bearing materials. Presently, many different methods are used for crosslinking and for the elimination of the free radicals that are generated in the process of crosslinking. Free radicals may lead to oxidation and reduction of mechanical and wear properties years after the manufacture of the component.

The new device can be used for the study of hard-on-hard couples as well. This has earlier been shown with the CTPOD principle using ceramic-on-ceramic (Saikko and Keränen, 2002) and metal-on-metal, with and without coating (Joyce and Grigg, 2009). A ball-on-flat contact is preferred. The practical problem is in the manufacture of a sufficiently large radius for the spherical wear surface

of the pin in order to avoid excessive contact pressures even with low loads. A fact to be remembered is that during the test, the wear changes the contact into flat-on-flat, and so the contact area increases and the nominal contact pressure decreases in the course of the test.

It has been shown that a standard deviation value as low as 4 per cent of the mean wear factor is attainable in wear tests (Saikko, 2010). With such an SD value, the sample size being 4 and the difference in the mean wear factors between two materials being at least 6 per cent, the p value in the t-test is below 0.05, i.e., the observed difference is unlikely to be a mere chance. Hence, 4 different materials, or conditions, could be run simultaneously. Similarly, the sample size being 8, a difference of 4 per cent in the mean wear factors between two materials would be sufficient for a p value below 0.05.

In addition to wear studies of orthopaedic biomaterials, the programmable track shape and load profile can be useful in many other areas of tribology. An ordinary tribometer with a rotating disc is often useless because the wear mechanisms that are produced do not reflect the real multidirectional tribocontact that is to be simulated.

Conflict of interest statement

The authors do not have any conflicts of interest to disclose.

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Table 1. Wear factor mean \pm SD under different test conditions. First set of tests, n = 4, room temperature, test duration 120 hours.

Motion	Load	Wear factor (10 ⁻⁶ mm ³ /Nm)	
Circular	Static	2.55 ± 0.31	
Circular	Random	2.49 ± 0.51	
Random	Static	4.57 ± 0.37	
Random	Random	4.59 ± 0.30	

Table 2. Wear in the second set of tests, n = 16, controlled temperature, test duration 432 hours. Mean \pm SD values.

Motion	Load	Wear rate (mg/km)	Correlation coefficient R ²	y-axis intercept (mg)	Wear factor (10 ⁻⁶ mm ³ /Nm)
Circular	Static	0.29 ± 0.04	0.9967 ± 0.0050		4.34 ± 0.56
Random	Random	0.46 ± 0.05	0.9953 ± 0.0058		6.84 ± 0.68

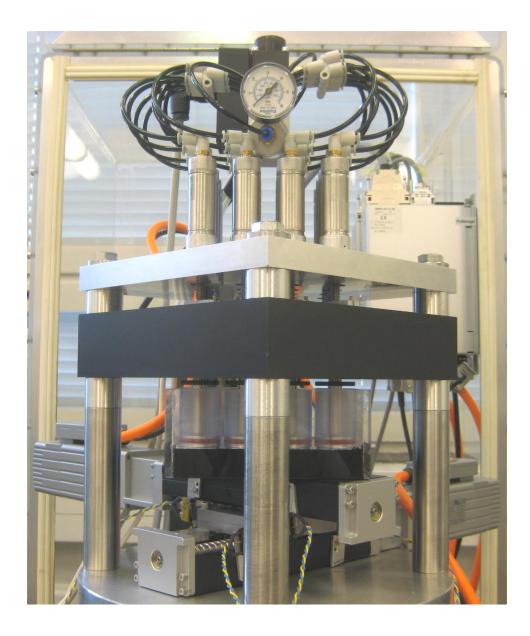
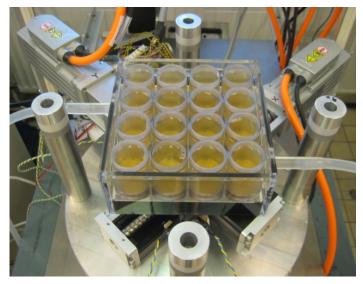


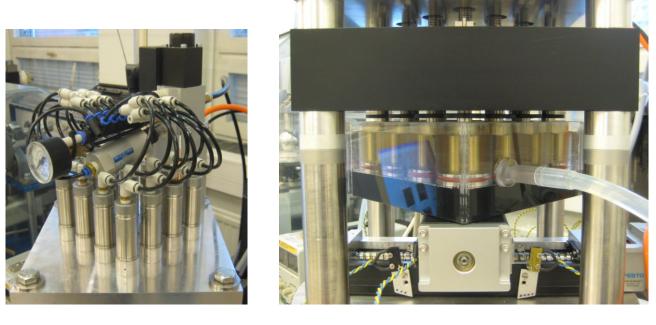
Figure 1. RandomPOD wear simulator with 16 test stations.







(b)



(c)

(d)

Figure 2. Close-ups of RandomPOD's modules. (a) Motion module. Motion plate is moved by servo-electric x-y-cross-slide. Note 16 separate test chambers filled with serum-based lubricant and surrounded by circulating water for temperature control. Test discs are attached to motion plate and they form bottoms of test chambers sealed with o-rings. (b) Pin-guiding module with 16 pin-guiding shafts holding test pins. (c) Loading module with proportional pressure controller and 16 pneumatic loading cylinders. (d) Motion module, above which pin-guiding and loading modules have been mounted. Test is ready for start.

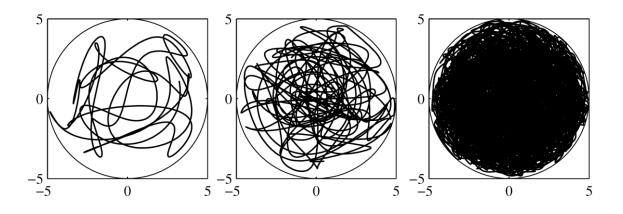


Figure 3. Example of random slide track after 10 s, 30 s, and 5 min of sliding. Circle diameter is 10 mm. Servo-electric motion is so accurate that set value and measured true value cannot be distinguished from each other with present line thickness.

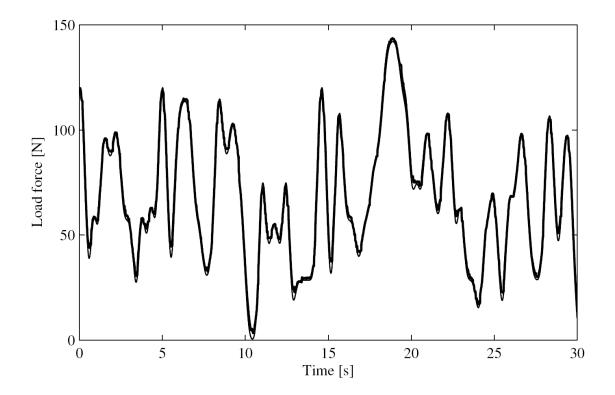


Figure 4. Example of random load profile during 30 s. Thin line is set value, thick line is measured true value. Note accuracy of proportional-pneumatic control.