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In vitro wear simulation on the RandomPOD wear testing system as a screening method for bearing materials intended for total knee arthroplasty

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Abstract

The 16-station RandomPOD wear test system, previously validated for prosthetic hip wear, was used in the simulation of knee wear mechanisms with a ball-on-flat test configuration. This consisted of a CoCr pin with a ground and polished spherical bearing surface (radius 28 mm) against a conventional, gamma-sterilized UHMWPE disk in serum lubrication. The biaxial motion, consisting of x and y translations, and the load were non-cyclic. Relative to the disk, the center of contact wandered within a circle of 10 mm diameter, and the average sliding velocity was 15.5 mm/s (range 0 to 31 mm/s). The load varied non-cyclically between 0 and 142 N (average 73 N). In the 60-day test with 16 similar wear couples, moderate adhesive wear, the principal wear mechanism of a well-functioning prosthetic knee, dominated. This showed as a burnished, circular wear mark (diameter 13.2 mm, area 137 mm^2). The wear factor was $2.04 \pm 0.03 \times 10^{-6}$ mm^3/Nm (mean ± 95 per cent confidence limit). For the first time a truly multidirectional, realistic and uniform, large capacity pin-on-disk simulation of knee wear mechanisms was implemented.

Keywords: Non-cyclic; Wear simulation; Polyethylene; Total knee replacement; Contact mechanics

1. Introduction

Randomness of the relative motion and load in laboratory wear studies of prosthetic joint materials was recently introduced [Saikko and Kostamo, 2011]. The variations of motion and load in daily activities are large [Kutzner et al., 2010; Li et al., 2008] and not readily reproduced by specific cyclic inputs [Laz et al, 2006; Walker et al., 1997]. It is possible that by applying strictly cyclic motion and load only, the prediction of the clinical wear rate is somewhat on the optimistic side [Saikko and Kostamo, 2013]. Therefore, non-cyclic motion and load have interesting possibilities in critical studies on orthopaedic tribology. Until recently, only cyclic input has been used [Kurtz, 2009]. At most, a few different activities have been included in a study [Franta et al., 2011; Muratoglu et al., 2002; Schwiesau et al., 2013; Wang et al., 2008]. Instead of including a few high demand activities in the wear test in addition to walking, the non-cyclic motion and load inputs are designed so that they can be considered to contain, within biomechanically realistic limits, all relevant activities at once [Saikko and Kostamo, 2011]. Certain limits are set to the range of motion, velocity, acceleration and contact pressure. Within these limits, the motion and load produced by the test system are random. Consequently, the wear processes are free from cyclic features.

The ball-on-flat contact geometry has been found to be suitable for the simulation of prosthetic knee wear mechanisms [Saikko et al, 2001; Saikko and Calonius, 2002a; Saikko, 2014], similarly as the flat-on-flat contact is suitable for the pin-on-disk simulation of prosthetic hip wear mechanisms [Saikko 2005; Saikko and Kostamo, 2013], provided that the relative motion is multidirectional in both cases. CoCr pins with a ground and polished, spherical bearing surface (radius 28 mm) and conventional UHMWPE wear test disks were designed and manufactured for the 16-station RandomPOD device. A knee wear validation test was run with 16 similar wear couples. The hypothesis of the present study was that the RandomPOD principle is suitable not only for hip but also for knee wear screening tests.

2. Materials and methods

The 16-station RandomPOD wear test system (Fig. 1) has been described in detail elsewhere [Saikko and Kostamo, 2011; Saikko and Kostamo, 2013]. It was derived from the 100-station SuperCTPOD wear test system [Saikko 2005; Saikko 2010]. Both were designed primarily for wear studies of orthopaedic biomaterials. In earlier tests, flat-ended cylindrical (diameter 9.0 mm) UHMWPE pins slid against polished CoCr disks (flat-on-flat contact), and the wear simulation was that of the prosthetic hip. In the present study, the configuration was reversed so that the pin was made from CoCr and the disk from UHMWPE (Fig. 2). The spherical bearing surface of the 9.0 mm diameter CoCr (ISO 5832-12) pin was ground (radius 27.86 mm ± 0.36 mm; mean ± SD of 16 pins; Fig. 3) and polished (R_a = 0.010 μm ± 0.002 μm; measured with a Mitutoyo Formtracer SV-C3100 diamond stylus apparatus with a sampling length of 0.08 mm). The pin was fixed to the pin holder/pin guiding shaft via a press-fit polyacetal sleeve. The diameter of the disk holder made from UHMWPE was 28 mm and thickness 10 mm. A recess of 5 mm depth was machined into it for a press-fit fixation of the UHMWPE test disk (GUR 1020, ISO 5834-1/-2; preforms were sawn from a compression molded sheet and packed and gamma-irradiated by 25 kGy in nitrogen) of 14.2 mm diameter and 5.0 mm thickness. Thus the thickness of polyethylene in the vertical loading direction was 10 mm. The disks were manufactured by machining and their surface roughness value R_a was 2 μm. The disks were not subjected to accelerated aging or treated in any other way besides the gamma sterilization in nitrogen. Simultaneously, 16 similar pin-disk couples were run in order to find out how uniform the wear produced by the system is. This was the first ball-on-flat (BOF) study with the RandomPOD, the principal idea being to reproduce wear mechanisms of the prosthetic knee.

The motion and load were non-cyclic within specified limits, as follows. The motion consisted of x and y translations of the disk, implemented by two computer-controlled, servo-electric drives. The random slide track generated by a computer algorithm remained within a circle of 10 mm diameter. The sliding velocity varied between zero and 31 mm/s (average 15.5 mm/s), and the maximum acceleration was 300 mm/s^2. The motion was free from jerks, as the derivate of the acceleration was continuous and smooth. The average change of direction of sliding (accumulated absolute value) was 500 degrees per second. The load, applied by computer-controlled proportional-pneumatics, randomly varied between zero and 142 N. Its mean value was 73 N, and maximum change rate 300 N/s. The specimen size taken account of, the above limit values were considered realistic for prosthetic joints in normal daily activities, based on biomechanical studies [Kutzner et al., 2010; Li et al., 2008]. The lubricant was HyClone Alpha Calf serum SH30212.03 without any additives, diluted 1:1 with Milli-Q distilled water. The protein concentration of the lubricant was 21 mg/ml. To reduce microbial degradation, the temperature of the lubricant was kept at 20.0 ºC ± 0.5 ºC during the testing using a circulating cooling water system.The duration of the test was 60 days. The wear of the UHMWPE disks was evaluated by a gravimetric method [Saikko, 2005] at intervals of 6 days. For each disk, a wear rate (mg/km) was calculated by linear regression using the 10 measurement points. The wear factor was calculated so that the wear rate was multiplied by the sliding distance, and divided by the density (0.94 mg/mm^3) and by the numerically computed integral of the product of the instantaneous load and the incremental sliding distance. The first 6 days of the test was excluded from the calculations as it was considered a running-in phase. In reassembly, the specimen location and position was randomized [Saikko and Kostamo, 2013].

3. Results

The wear rate of the UHMWPE disks was 0.149 mg/km ± 0.004 mg/km (mean ± standard deviation, $n = 16$, $R^2 = 0.9956 \pm 0.0014$, Fig. 4), range 0.142 mg/km to 0.154 mg/km. The 95 per cent confidence interval was 0.149 mg/km ± 0.002 mg/km. The integral of the product of instantaneous load and incremental sliding distance after the total of 78.1 km (1 403 h) of sliding was 5.729×10^6 Nm, and the total wear was 10.89 mg ± 0.28 mg. The wear factor was $2.04 \pm 0.06 \times 10^{-6}$ mm^3/Nm (mean ± SD). The width of its 95 per cent confidence interval was 0.06×10^{-6} mm^3/Nm, that is, 2.8 per cent of the mean. A burnished, circular wear mark formed on the test disk (Fig. 5). Its diameter at the end of the test was 13.2 mm ± 0.05 mm (area 137 mm^2 ± 1 mm^2). From this can be deduced that the maximum width of the ball-on-flat contact was 3.2 mm (area 8.0 mm^2), and the maximum Hertzian contact pressure at the end of the test can be calculated to have been $p_{\max} = 3F_{\max}/2\pi a^2 = 3 \times 142\ \mathrm{N} / (2 \times \pi \times 1.6^2\ \mathrm{mm}^2) = 26\ \mathrm{MPa}$, where a is half the contact width. The elasticity assumption was corroborated by the observation that the volumetric wear (calculated from the profile, see Fig. 6) was in agreement with the gravimetric wear. The maximum size of the contact was confirmed by the microscopy of the pin. On the center, there was an area with a diameter of c. 3.2 mm from where the original polishing marks were removed by further polishing attributable to the test. The pins were not damaged in any way by the tests. The wear test caused a reduction of the central thickness of the disks by 0.18 ± 0.01 mm (Fig. 6), but no increase of edge thickness. The upper edge diameter increased by 0.05 mm.

4. Discussion

The RandomPOD wear test system with a ball-on-flat test configuration reproduced the principal UHMWPE wear mechanism of a well-functioning prosthetic knee, the moderate adhesive wear, manifested as burnishing [Kurtz, 2009; Muratoglu et al., 2002]. Although the specimen size was minimized in the radial direction (the inner diameter of the test chamber was 28 mm only), the burnished wear mark was of real size, 137 mm^2, which is attributable to the random motion algorithm of the test device. The CoCr/UHMWPE contact that was below 8.0 mm^2 in size most of the time, visited every location on the burnished surface in an unpredictable manner, the direction of sliding, track curvature, velocity, acceleration, size of contact and contact stresses, including friction, changing continually. In other words, the non-cyclic motion and load made the simulation of the moderate adhesive wear mechanism possible with the simple ball-on-flat test configuration.

It is known from earlier ball-on-flat knee wear studies [Saikko et al., 2001; Saikko and Calonius, 2002a] that if the UHMWPE disk has no subsurface white band indicative of oxidative damage and embrittlement, the most serious wear mechanism, delamination, is absent despite the fact that the contact stress field continually moves relative to the disk. Instead, the moderate adhesive wear mechanism dominates. This was the case in the present study. The wear factor value of 2.0×10^{-6} $\mathrm{mm}^3/\mathrm{Nm}$ can be considered moderate. Compared with this, wear factor values up to three orders of magnitude higher were obtained with shelf aged, delaminating disks [Saikko, 2014]. Gamma-sterilized disks subjected to accelerated aging using established methods showed no delamination [Saikko et al., 2001].

The radius of the spherical CoCr bearing surface, 28 mm, was of the same order magnitude as the radii measured from the femoral components of prosthetic knees [DesJardins et al., 2000; Walker et al., 1997]. The development of the manufacture method for these pins with a bearing surface diameter of only 9.0 mm was arduous, but it was considered necessary from the point of view of progress in the large capacity ball-on-flat simulation of knee wear mechanisms. The challenges stemmed from the fact that the ‘calotte’ that was ground, polished, and measured (Fig. 3) was small relative to the computational sphere of c. 56 mm diameter. The range of the diameter of the best-fit sphere, computed for 25 points measured on a 5 mm × 5 mm grid, of the 16 pins was 54.7 mm to 56.8 mm, but the highly uniform wear (Fig. 4) showed that this was eventually unimportant. If real prosthetic components were used, large capacity testing would be difficult. The maximum load in the RandomPOD is limited by the control software to 142 N per test station which is based on the load carrying capacity of the x-y-stage. It was found that with the spherical CoCr bearing surface of 28 mm radius and the peak load of 142 N, the peak contact pressure at the end of the test was 26 MPa, which is close to the peak contact pressures of prosthetic knees obtained by computational and experimental methods [Fregly et al., 2003; Godest et al., 2002; Halloran et al., 2005; Rawlinson and Bartel, 2002; Villa et al., 2004]. Compared with the disk of the preliminary tests (Fig. 2), the UHMWPE ‘minidisk’ design of 14.2 mm diameter and 5.0 mm possesses the advantages that it is not in contact with the cooling water nor with the motion plate of the machine, and its surface area is minimal so the absorption of fluid is minimized. The weight gain of the two soak control disks was only 0.14 mg in 2 months. The disk weighs about 740 mg. From the point of view of deformations caused by the CoCr counterface, it is important that the disk is radially surrounded by a holder of similar material, and beneath the disk there is another 5 mm of UHMWPE. A thickness of 10 mm is considered sufficient regarding the strength of the component.

The wear that was simultaneously produced with the 16 test stations was highly uniform. The standard deviation of wear factor was only 2.9 per cent of the mean value. An SD value of 5.4 per cent of the mean value (n = 100) was obtained earlier with the SuperCTPOD using a flat-on-flat contact simulating the prosthetic hip wear [Saikko, 2005], and in a subsequent study with n-values of 4 to 6 the standard deviation was as low as 1.0 per cent (mean 4.2 per cent) of the mean wear factor [Saikko, 2010]. The wear was highly linear as well (Fig. 4). In the wear vs. sliding distance, the correlation coefficient R^2 of linear regression of individual disks was 0.9956 ± 0.0014. The width of the 95 per cent confidence interval of the wear factor was as narrow as 2.8 per cent, that is, 0.06×10^{-6} mm^3/Nm, of the mean value, 2.04×10^{-6} mm^3/Nm, whereas widths of the 95 per cent confidence interval as wide as 50 to 150 per cent of the mean wear rate have been published from knee simulator tests by other researchers [Galvin et al., 2009; McEwen et al., 2005]. In the wear testing of actual prosthetic knees, a controversial issue arises from the geometry of each design which governs the kinematics especially if motions are implemented via springs by force control [DesJardins et al., 2000; Laz et al., 2006; Sathasivam and Walker, 1997; Walker et al., 1997; Willing and Kim, 2009].

In earlier ball-on-flat tests using 54 mm diameter CoCr femoral heads, three-axial cyclic motion consisting of flexion-extension, anterior-posterior translation and internal-external rotation was used, and the load was 2.0 kN [Saikko et al, 2001; Saikko and Calonius, 2002a; Saikko, 2014]. This resulted in a much larger contact area (150 mm^2) compared with that of the present study (max. 8.0 mm^2), but the burnished wear mark was no larger than 250 mm^2 (in the present study: 137 mm^2). The maximum contact pressures however in these two studies were of the same order of magnitude, 19 MPa vs. 26 MPa, due to the elastic-plastic deformation and wear of UHMWPE. The wear factor of gamma-sterilized GUR 1050 disks was $0.32 \pm 0.01 \times 10^{-6}$ mm^3/Nm ($n = 5$) [Saikko and Calonius, 2002a]. The shape of the slide track was a narrow figure of eight with a height of 10 mm and crossing angle of 10º. Compared with this, the present type of motion was characteristically much more multidirectional, which is the likely explanation for the higher wear factor. If the sliding is nearly unidirectional most of the time, the wear rate is substantially reduced [Gevaert et al., 2005; Saikko 2014]. The present motion may be considered to consist of two components, anterior-posterior translation and medial-lateral translation, which is sufficient for the two basic requirements, multidirectional sliding and a contact stress field that continually moves relative to the UHMWPE specimen, here specifically producing a circular, burnished wear mark. It was found out with the three-axis ball-on-flat simulator that the wear factor was insensitive to the removal of the flexion-extension so that no rolling took place and the remaining relative motion was biaxial sliding in the form of a figure of eight [Saikko, 2014]. Reciprocating ball-on-flat sliding, corresponding to mere anterior-posterior translation, is relevant only in the case of severely oxidized, delaminating UHMWPE [Saikko, 2014]. With the present knee wear specimens, the circular translation as a type of motion [Saikko, 2005] would not be relevant because with respect to the disk, the sliding would not be truly multidirectional.

The mean wear factor value obtained in the present study, 2.0×10^{-6} mm^3/Nm, is close to that obtained with another ball-on-flat (radius 22 mm, load 200 N) knee wear device using biaxial sliding in the form of a figure of eight, $2.4 \pm 0.08 \times 10^{-6}$ mm^3/Nm [Patten et al., 2013]. In an earlier RandomPOD study with a flat-on-flat contact (area 63.6 mm^2, maximum nominal contact pressure 2.2 MPa, UHMWPE pin, CoCr disk) simulating the hip wear, the wear factor with materials, motion and load input, and lubricant similar to those of the present study was $3.92 \pm 0.26 \times 10^{-6}$ mm^3/Nm (n = 16) [Saikko and Kostamo, 2013]. As for the different types of possible wear references, the following can be stated. First, in knee joint simulator tests, the wear is not or cannot be quantified as a wear factor, or as a wear depth [Knight et al., 2007], so a direct comparison is not possible. Nevertheless, the duration of the present test, 1 403 h, corresponds to 5 million cycles in a 1 Hz simulator. In knee joint simulator studies also, burnishing is a typical observation [Kurtz, 2009]. Second, retrieved tibial components, removed from patients, can be utilized in the damage type analysis, but not exactly in the measurement of the amount of wear [Blunn et al., 1997]. Third, in vivo wear measurements are inherently inaccurate [Short et al., 2005].

The wear factor of conventional UHMWPE is highly sensitive to the type of relative motion [Saikko et al., 2004; Saikko, 2014] and contact pressure [Saikko, 2006]. With decreasing multidirectionality and increasing contact pressure, the wear factor decreases significantly. At the early stages of the present test, the contact area was smaller, as deduced from the diameter of the burnished wear mark, and the contact pressure was higher, and therefore the wear rate was lower in the first 15 km than in the steady state after that (Fig. 4). In actual prosthetic joints, not only the contact pressure but also the size and shape of the slide track varies considerably on the contact surfaces [Saikko and Calonius, 2002b]. It may not be possible to determine a characteristic wear factor for every type of slide track. Therefore in computational wear models, a maximal wear factor for a truly multidirectional motion (accumulated change of direction of sliding 2π to 4π rad/s) in general would be most useful. The present wear factor, 2.0×10^{-6} mm^3/Nm, is independent of the slide track shape and contact pressure value because no specific shape or value was used. It can be considered to be a representative, maximum (regarding the multidirectionality of motion) knee wear factor for reasonable contact pressures, especially because it was obtained with the most popular material combination used in prosthetic knees, conventional gamma-sterilized GUR 1020 UHMWPE against polished CoCr. In a wear model, the wear factor value can be scaled down depending on the aspect ratio of the local slide track [Saikko et al., 2004]. It is especially emphasized that a wear model should not be based on the assumption that the local wear depth is some constant value of wear factor multiplied by the local contact pressure and the local sliding distance [Knight et al., 2007].

The present study was limited to the simulation of moderate adhesive wear, which is the principal wear mechanism of the well-functioning prosthetic knee. Abrasion of the femoral components does occur in vivo [Scholes et al., 2013] which is likely to increase the

UHMWPE wear rate. The abrasive wear mechanism however was outside the scope of the study. It was considered an exceptional condition which should be avoided. The same holds true for oxidative damage of UHMWPE. The present disks were not subjected to accelerated aging, and so the possible delamination wear mechanism was excluded. The tests were run so that the lubricant temperature was kept at 20 ºC in order to retard the microbial degradation that is likely to adversely affect the lubrication properties of serum [Saikko, 2005]. This was considered to outweigh the effect of temperature, 20 ºC vs. 37 ºC, on the elastic modulus [Kurtz et al., 2002] and therefore on the contact stresses and contact area. The elastic modulus of gamma-nitrogen-sterilized UHMWPE at 20 ºC is known to be 25 per cent higher compared with that at 37 ºC [Kurtz et al., 2002]. Finally it may be noted that pin-on-disk wear simulations are inherently limited to the basic mechanisms of wear occurring in prosthetic joints and so features and phenomena that are specific to the implant design cannot be studied directly. For the latter purpose, various knee simulators have been built [DesJardins et al., 2000; Franta et al., 2011; McEwen et al., 2005; Muratoglu et al., 2002; Wang et al., 2008].

In conclusion, the principal wear mechanism of the well-functioning prosthetic knee, moderate adhesive wear, was successfully simulated with the RandomPOD system using the ball-on-flat test configuration, polished CoCr against conventional, gamma-sterilized UHMWPE. This creates exciting methodological prospects for large capacity pin-on-disk wear testing of prosthetic knee materials. For example, (a) efficient wear screening of the latest developments in prosthetic knee materials is now possible, (b) the effect of the accelerated aging time in the so-called oxygen bomb on knee wear properties of gamma-irradiated UHMWPE, which was recently brought under scrutiny [Saikko, 2014], could be effectively studied, and (c) the eccentric drive of the 100-station SuperCTPOD [Saikko, 2005] could be replaced by computer-controlled servo-electric drives with random input to further increase the knee wear testing capacity.

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Figure captions

Fig. 1. Ball-on-flat test ongoing in 16-station RandomPOD. Note servo-electric x-y-stage and circulating cooling water surrounding test chambers that contain serum lubricant. Size of motion plate is 135 mm × 135 mm. On top is proportional-pneumatic loading module.

Fig. 2. UHMWPE and CoCr specimens and holders. (A) Single-piece (diameter 28 mm, thickness 10 mm) UHMWPE disk and CoCr pin of preliminary test; UHMWPE test disk (diameter 14.2 mm, thickness 5.0 mm) and its UHMWPE holder, CoCr pin, its polyacetal fixation sleeve, and pin guide shaft; alternative, single-piece CoCr specimen/shaft. (B) Close-up of pin and disk after test. Preliminary tests showed that diameter of burnished wear mark does not reach 14 mm within reasonable testing times. In CoCr specimens, bearing surface is ground and polished ($R_a = 0.01$ μm), spherical (radius 28 mm).

Fig. 3. Measurement of spherical bearing surface of CoCr pin in coordinate-measuring machine. Best-fit sphere was computed for 25 points measured on 5 mm × 5 mm grid.

Fig. 4. Variation of UHMWPE wear with sliding distance in 60-day RandomPOD ball-on-flat test (n = 16); mean ± standard deviation at each measurement point, and best fit line.

Fig. 5. Optical micrographs from (A) edge of UHMWPE disk showing original machining marks and fringe of burnished wear mark on left, and (B) burnished UHMWPE surface showing no orientation.

Fig. 6. Profile of wear mark of UHMWPE disk, obtained with coordinate-measuring machine.

Figure 1.

(A) (B)

Figure 2.

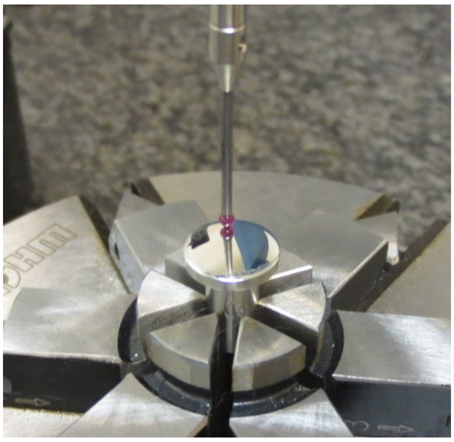


Figure 3.

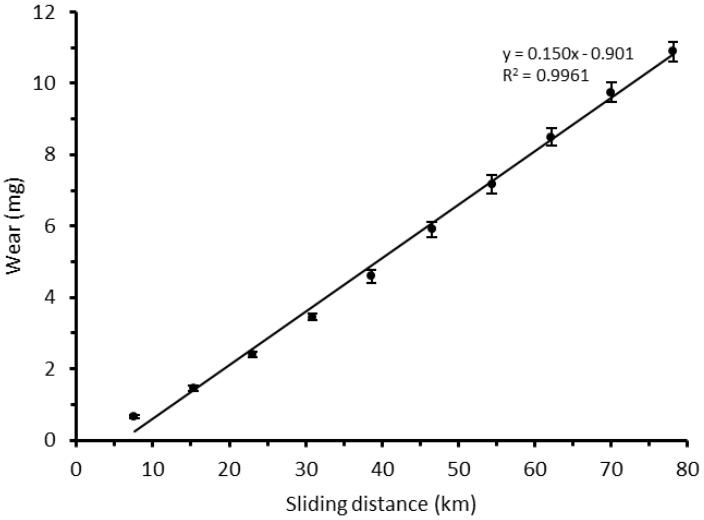
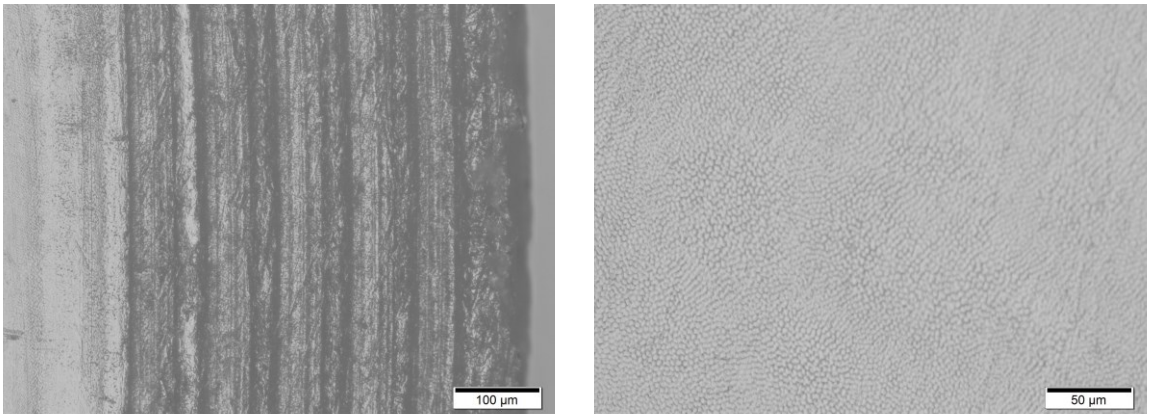


Figure 4.



(A) (B)

Figure 5.

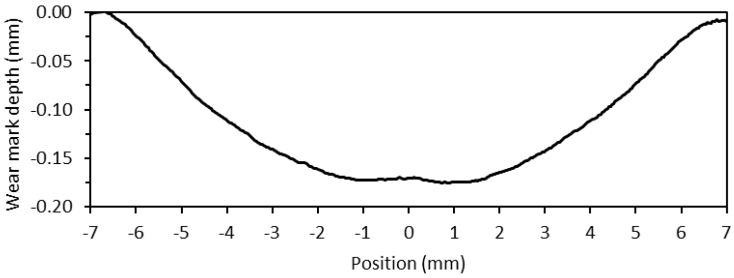


Figure 6.