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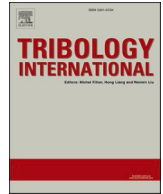
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Analysis of wear produced by a 100-station wear test device for UHMWPE with different contact pressures

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ABSTRACT

In orthopaedic tribology, a useful wear test device must produce clinically relevant wear with low variation and have a large capacity for adequate sample sizes and simultaneous testing of several samples. The present study emphasized statistical considerations that are often overlooked. The 100-station SuperCTPOD device was used to study the effect of contact pressure, 0.5–3.0 MPa, on UHMWPE wear with a sample size of 10. The mean wear rate varied from 2.00 to 5.06 mg/10⁶ cycles and the SDs from 0.18 to 0.54 mg/10⁶ cycles. The lowest difference between means was 0.56 mg/10⁶ cycles with $\geq 80\%$ power. The study provided corroborative evidence for the usefulness of the present large capacity wear test system.

1. Introduction

To complement wear testing with hip joint simulators, multidirectional pin-on-disk (POD) devices have been designed and validated [1]. POD devices are highly cost effective and useful in the basic research on orthopaedic tribology and in the selection of promising bearing materials for hip joint simulator studies. Clinically, the principal problem caused by the wear of ultra-high molecular weight polyethylene (UHMWPE) is the generation of a large number submicron wear particles that may cause osteolysis [2]. Cross-linking significantly reduces the wear rate [3], but the number of wear particles may still be large since cross-linking leads to a decrease of the particle size [4]. Macroscopically, the wear mechanism that generates submicron wear debris is manifested as burnishing of the bearing surface [2,5,6]. Hence it is called adhesive polishing, even though UHMWPE transfer to the metallic femoral head does not occur. Burnishing is caused by multidirectional relative motion and protein lubrication [2].

Burnishing, clinically relevant wear particle size distribution, and low variation of wear have been produced by the circular translation pin-on-disk (CTPOD) device [7–9]. It is multidirectional since the direction of sliding relative to the pin changes continually. In fact, it is a planar (flat-on-flat) modification of the orbital bearing type hip joint simulator [2]. Due to its structural simplicity, it was straightforward to increase the testing capacity from 12 to 100 test stations, which resulted in the ‘SuperCTPOD’ design [8]. This was necessitated by the test length, 6 weeks [8]. For statistical power, the sample size needs to be larger than

the traditional 3, dictated by the lack of adequate testing capacity. Still it must be possible to test many different conditions or materials simultaneously to reduce the time needed for the tests. The production of wear data is inherently laborious because of the several wear measurements needed in the determination of the wear rate.

The sample sizes in earlier SuperCTPOD tests for UHMWPE were 100 [8] and 4–6 [9]. In [9], 38 different polyethylenes were compared. The standard deviations (SD) were 5.4% [8] and 1.0–8.5% (average 4.2%) [9] of the mean wear rates. In 10 pairwise comparisons of samples, a difference between mean wear rates below 5% was detected with $\geq 80\%$ power [9]. The test temperature was 20 °C to retard protein denaturation and microbial growth in alpha calf serum [8,9]. In multidirectional, serum lubricated RandomPOD tests for UHMWPE, an increase of the test temperature from 20 °C to 37 °C resulted in a relative increase of the SD from 6.6% to 18% of the mean wear rate [10]. However, the SDs in the RandomPOD are typically larger than those in the SuperCTPOD. It was considered interesting to see if a corresponding increase of SD occurs in the SuperCTPOD as well.

Assuming that the SD would increase to 10% of the mean, detecting a 10% difference between means with 80% power would require a sample size of 14. However, a sample size of 10 was chosen for the present study. With the capacity of 100 test stations, 10 different conditions could be tested simultaneously, which was considered an adequate number. With a sample size of 10 and a difference between means of 12%, the null hypothesis would be correctly rejected with 80% power. This was considered still a reasonably low difference to be detected with

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80% power. The conditions chosen were 10 different nominal contact pressures for UHMWPE pins, from 0.5 MPa to 3.0 MPa. This covered the most relevant contact pressure range for UHMWPE [11]. Protuberance formation, not seen clinically [2,5,6], was observed above 2.0 MPa [11]. The present study intended to produce relevant wear, wear rates and SDs from which relatively low differences between means can be detected with 80% power. Using the test conditions specified above, the study intended to answer the following questions:

- (1) does increased test temperature lead to increased SDs in comparison with earlier studies?
- (2) what is the magnitude of the SDs?
- (3) how is wear rate correlated with contact pressure?
- (4) what is the lowest difference between means that can be detected with 80% power?
- (5) should contact pressure be limited to avoid protuberance formation in future tests?

2. Materials and methods

The pins (diameter 9.0 mm, length 12 mm) were made of conventional UHMWPE (GUR 1020, ISO 5834-2, ASTM F648-14). They were gamma irradiated by a dose of 30 kGy, which is used in the sterilization of acetabular liners and results in mild cross-linking [1]. Before irradiation, the pins were individually packed in nitrogen. The disks (diameter 28 mm, thickness 10 mm) were polished CoCr (ISO 5832-12) with a surface roughness $R_a = 0.01 \mu\text{m}$. The lubricant was alpha calf serum (HyClone SH30212, Cytiva, HyClone Laboratories, Logan, UT, USA), diluted 1:1 with ultrapure deionized water. The protein concentration of the lubricant was 20 mg/ml. Antibiotic/antimycotic solution (HyClone SV30079) was added to the lubricant (10 ml/1000 ml) to reduce microbial growth.

The 100-station SuperCTPOD wear test device (Fig. 1) has been described elsewhere [8]. Briefly, the pin translated without rotation on the disk along a circular track of 10 mm diameter at a velocity of 31.4 mm/s. One lap was called a cycle. The cycle frequency was 1 Hz. In the present tests, the pins were subjected to 10 different, constant nominal contact pressures p , from 0.5 MPa to 3.0 MPa. Therefore, the pneumatic loading system was modified. The pneumatic cylinders were connected to form groups of 10. Each group had a separate pressure controller to control the pneumatic pressure from 0.2 MPa to 1.0 MPa. The load produced by each pneumatic cylinder (from 32 N to 191 N) was checked

with weights, the loading module lying upside down. The test length was 3 million cycles (6 weeks). The gravimetric wear measurement was done at intervals of 0.5 million cycles (139 h). The wear rate was determined by linear regression from 6 wear values, the origin omitted. The first 0.5 million cycles was considered running in, that is, removal of the machining marks. In addition to the 100 wear test pins, there were 3 soak control pins for the correction of fluid absorption. After the wear measurement, the test was continued with fresh lubricant. At each restart, the locations of the disks were randomized. Hence, if a pin proved to be an outlier, it would be likely to be due to true material inhomogeneity. The lubricant temperature was maintained at $37.0 \pm 0.5^\circ\text{C}$ by the circulating water bath of the SuperCTPOD (Fig. 1) and a laboratory heater. The wear factor k was calculated by dividing the wear rate by the density (0.935 mg/mm^3), load (from 32 N to 191 N), and sliding distance (94.2 km).

3. Results

The correlation coefficient R^2 of the linear regression of wear, 0.9984 ± 0.0017 (mean \pm SD), indicated that the wear was linear (Fig. 2). The wear rate linearly increased with increasing p , whereas the wear factor decreased (Fig. 3). The mean wear rates varied from 2.00 to $5.06 \text{ mg}/10^6$ cycles and the SDs from 0.18 to $0.54 \text{ mg}/10^6$ cycles (Table 1). They were 7.5–15.9% (average 11.1%) of the mean wear rates with no correlation (Fig. 4). In pairwise comparisons of samples, the lowest difference between means (samples 8 vs. 10) that could be detected with 80% power was $0.56 \text{ mg}/10^6$ cycles which was 13.2% of the lower mean (Table 2). The UHMWPE bearing surface was burnished, but with $p = 2.06 \text{ MPa}$, protuberances were observed as an additional feature on some pins, and with $p \geq 2.38 \text{ MPa}$, protuberances were observed on the entire sample (Fig. 5). There was no polyethylene transfer to the disks.

4. Discussion

The present tests resulted in relevant wear data by which statistical considerations could be illustrated. Conventional UHMWPE is still widely used globally in hip and knee replacements, excluding the richest countries in which it has mostly been replaced by highly cross-linked UHMWPE (XLPE). Contact pressure was chosen to be the parameter because it is known that relevant differences in the wear rate can thus be produced [11]. Besides, the optimal p value is still disputed and therefore, additional tests were considered helpful to determine it. With the 4 lowest p values, the wear rate was not very sensitive to p . Therefore, the wear factor decreased steeply with increasing p because the load is in the denominator. Acknowledging the controversy of retrospective power analysis [12,13], it can be stated that the present study produced valuable information on the SDs with different contact pressures at the test temperature of 37°C for future considerations of the sample size. The SDs were 7.5–15.9% of the mean wear rates. The sample size was larger and the test was longer than in the earlier CTPOD contact pressure study [11].

The first SuperCTPOD study consisted of conventional UHMWPE (GUR 1020, gamma irradiated 25–40 kGy) against polished CoCr for 3 million cycles in 1:1 diluted alpha calf serum at 20°C with $p = 1.1 \text{ MPa}$ and with a sample size of 100 [8]. The pins were burnished and the wear particle size distribution was shown to be clinically relevant. The mean wear rate was $3.40 \text{ mg}/10^6$ cycles, and the SD was $0.18 \text{ mg}/10^6$ cycles, that is, 5.4% of the mean. R^2 of the linear regression was 0.9973 ± 0.0018 . It also proved that 6 wear measurement points, at intervals of 500 000 cycles, is sufficient for the determination of the wear rate. This was the first study to show that the wear rate data is normally distributed, which justifies the use of Student's t-test. Earlier, normality was merely assumed.

The following SuperCTPOD study consisted of 2 consecutive tests of 3 million cycles each with sample sizes of 4, 5 or 6 [9]. A total of 200

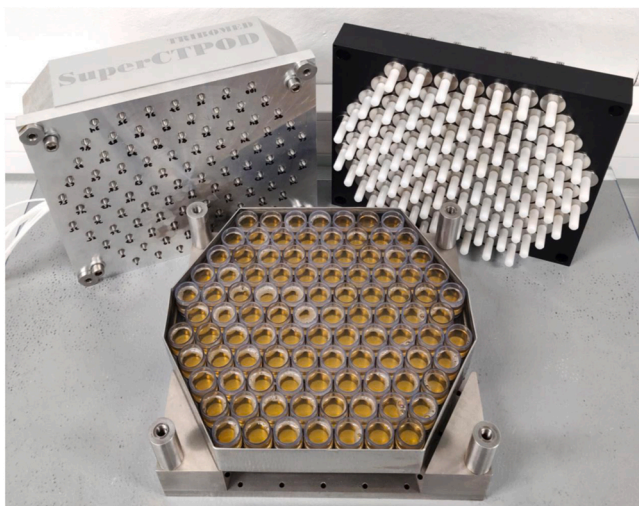


Fig. 1. SuperCTPOD wear test device, modules separated. Loading module (left), motion module (middle), and pin guiding module (right). Octagonal motion plate of motion module, on which 100 test chambers filled with serum-based lubricant are arranged, incorporates circulating water bath for temperature control.

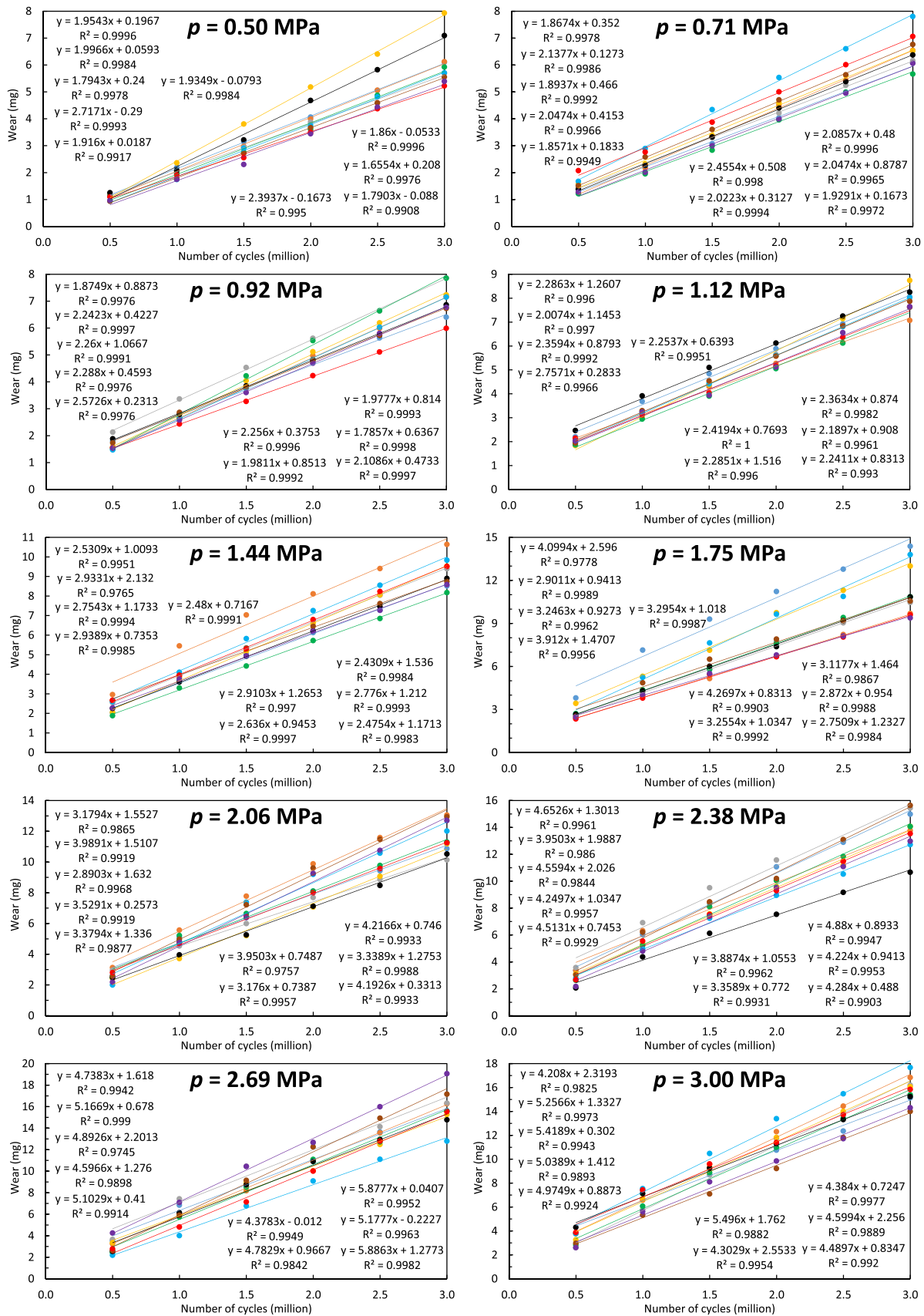


Fig. 2. Wear vs. number of cycles with different nominal contact pressures p . Linear regression is shown for each pin. Note differences in y-axes.

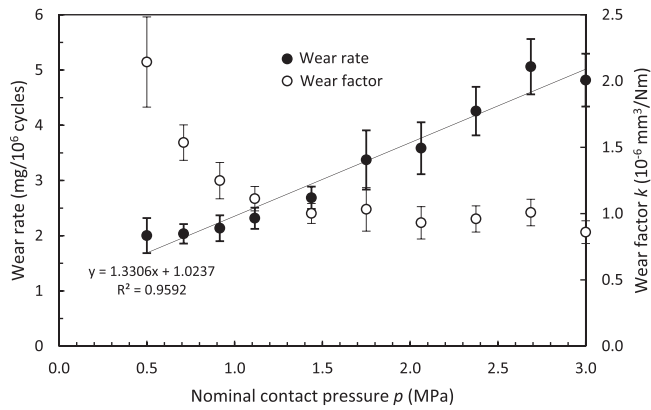


Fig. 3. Mean and SD of wear rate and wear factor vs. nominal contact pressure.

Table 1
Mean wear rates and standard deviations.

Sample #	<i>p</i> (MPa)	Mean wear rate (mg/10 ⁶ cycles)	SD (mg/10 ⁶ cycles)	SD % of mean wear rate
1	0.50	2.00	0.32	15.9
2	0.71	2.03	0.18	8.7
3	0.92	2.13	0.23	11.0
4	1.12	2.32	0.19	8.3
5	1.44	2.69	0.20	7.5
6	1.75	3.37	0.54	15.9
7	2.06	3.58	0.47	13.1
8	2.38	4.26	0.44	10.3
9	2.69	5.06	0.50	9.9
10	3.00	4.82	0.48	10.0

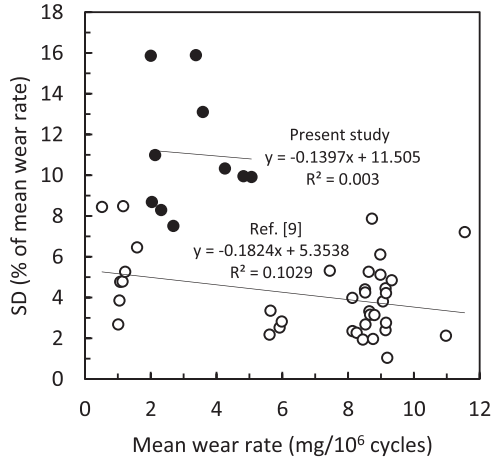


Fig. 4. SD vs. mean wear rate.

pins were tested in conditions similar to those of [8]. The pins were made of 37 different UHMWPEs and one high density polyethylene. The pins were burnished and the mean wear rate ranged from 0.52 to 77.1 mg/10⁶ cycles. R^2 of the linear regression was 0.9978 ± 0.0027 . The wear rate decreased with increasing gamma irradiation dose, that is, with increasing cross-link density. This was in agreement with clinical findings [3]. The SD ranged from 1.0% to 8.5% (average 4.2%) of the mean wear rate. In 10 pairwise comparisons, a difference between means below 5% was detected with $\geq 80\%$ power. The lowest difference between means was 3.6% with $\geq 80\%$ power (90.7%). In this comparison, the SDs were 1.9% and 2.0% of the means.

In RandomPOD tests for UHMWPE, the increase of the test temperature from 20 °C to 37 °C resulted in an increase of the SD from 6.6% to 18% of the mean wear rate [10]. The choice of the present sample size

Table 2
Statistical power for differences between mean wear rates below 20%.

Samples #	Difference between means (mg/10 ⁶ cycles)	(% of lower mean)	Power (%)
1, 2	0.03	1.7	8.3
2, 3	0.10	4.9	28.7
9, 10	0.24	5.0	29.1
6, 7	0.21	6.3	23.7
1, 3	0.13	6.7	27.4
3, 4	0.18	8.5	64.4
8, 10	0.56	13.2	85.9
2, 4	0.28	13.9	96.8
1, 4	0.32	15.7	85.9
4, 5	0.37	16.0	99.5
7, 8	0.67	18.7	95.5
8, 9	0.80	18.9	98.4

was based on this indicative finding and on the SDs produced by the SuperCTPOD at 20 °C [8,9]. The present SDs varied from 7.5–15.9% of the mean wear rates. They were larger than those at 20 °C [8,9], which corroborated the RandomPOD finding [10]. It can now be stated that using the SuperCTPOD device, test temperature of 37 °C and sample size of 10, a 13.2% difference between mean wear rates (samples 8 vs. 10) is detected with $> 80\%$ power (Table 2). A difference of 13.2% was reasonably close to the target value, 12%.

The increase of SD with increasing test temperature could be related to temperature dependent wear behavior of UHMWPE. The observed value of wear is affected by (1) the functional variation, i.e., the slope of wear vs. sliding distance and (2) the random variation caused by, e.g., uncertainties in the gravimetric method [14]. In [10], the wear factors were $3.92 \pm 0.26 \times 10^{-6} \text{ mm}^3/\text{Nm}$ at 20 °C and $1.34 \pm 0.24 \times 10^{-6} \text{ mm}^3/\text{Nm}$ at 37 °C. The decrease of the wear factor was 66%. The SDs were close to each other but their relative magnitudes were very different, i.e., 6.6% and 18% of the means. Obviously, the random variation did not depend on the test temperature whereas the functional variation did. If the present mean wear rate with $p = 1.12 \text{ MPa}$, $2.32 \pm 0.19 \text{ mg}/10^6 \text{ cycles}$, is compared with the value obtained with similar materials and contact pressure at 20 °C, $3.40 \pm 0.18 \text{ mg}/10^6 \text{ cycles}$ [8], the decrease of the wear rate was 32%. The SDs were close to each other. This was in agreement with the RandomPOD finding [10]. In the present study however, the SD had no correlation with the wear rate (Fig. 4), and in [9], there was a weak negative correlation only. The wear factors produced by the RandomPOD are typically larger than those produced by the SuperCTPOD, probably due to the increased multidirectionality (change of direction of sliding 500°/s vs. 360°/s), but the wear mechanisms are similar.

Protuberance formation on UHMWPE bearing surfaces has been observed in hip simulator tests as well [15], but not clinically [2,5,6]. The first POD observation of protuberances was in [11]. In the present study, they were observed with $p \geq 2.06 \text{ MPa}$ (Fig. 5). Therefore, it is recommended that $p \leq 2.0 \text{ MPa}$ in POD tests for UHMWPE when wear mechanisms of the acetabular bearing surface are to be simulated. The protuberances are likely to be produced by plastic deformation. The true contact area increases with increasing load which hampers mixed lubrication. On an individual contact patch, lubricated by a boundary mechanism by proteins (as evidenced by the absence of polyethylene transfer), material is plastically forced to the center of the patch because the friction vector changes its direction 360°/s. When the load is released for the wear measurement, the center rises above the surroundings and thus forms a perceptible protuberance. In the dynamic loading of the RandomPOD, the maximum load was limited to 142 N in order to avoid protuberance formation [10,11]. Indeed, protuberances were never observed with 9 mm diameter pins ($p_{\text{max}} = 2.2 \text{ MPa}$).

The studies published by the users of the commercial version of the SuperCTPOD (TE 87, Phoenix Tribology Ltd, UK) cover many pin and disk materials [16–25] (Table 3). The SDs vary from 4.3% to 155% of the

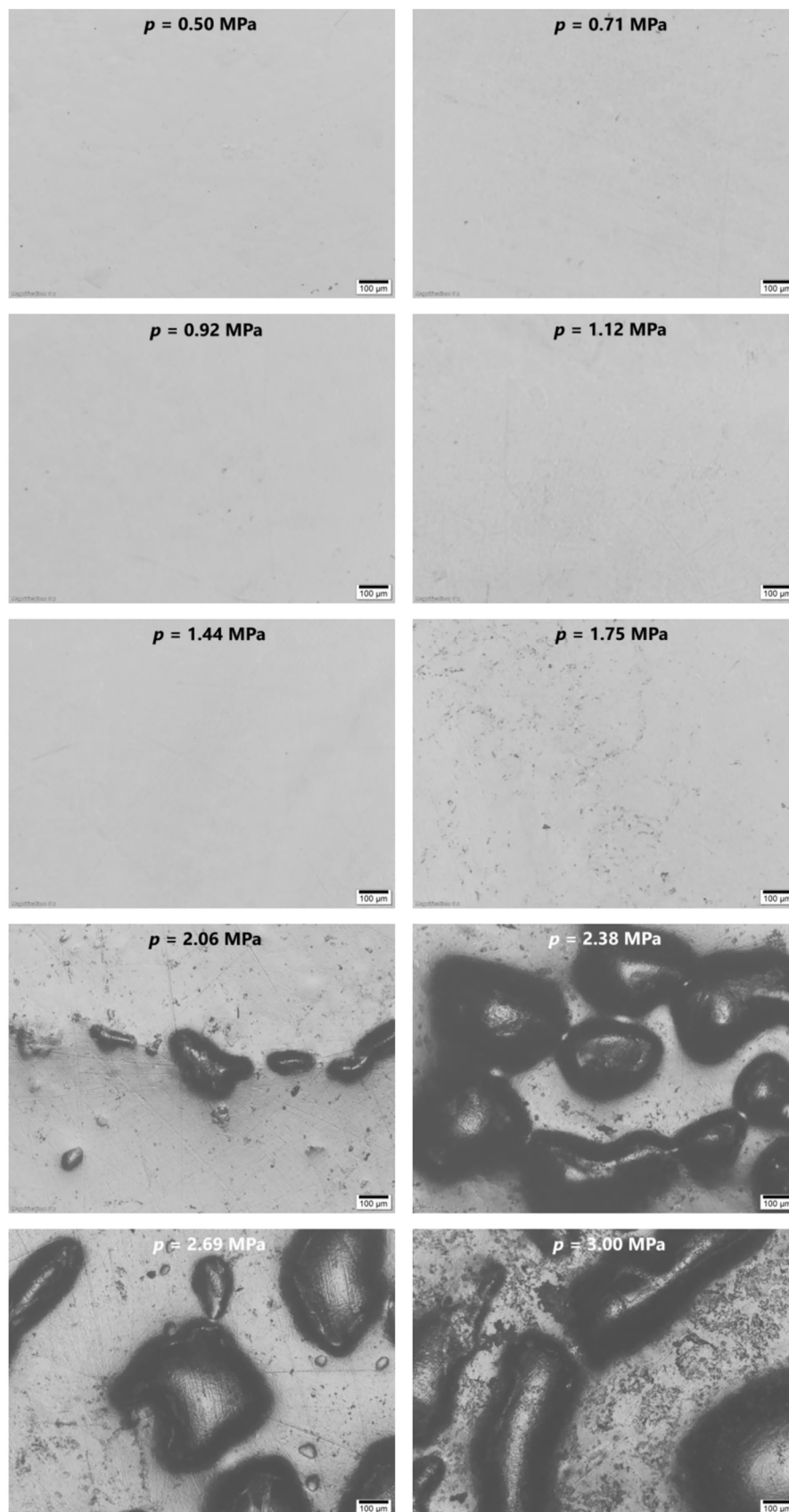


Fig. 5. Optical micrographs of wear faces of UHMWPE pins worn for 3 million cycles with different nominal contact pressures p .

Table 3
SuperCTPOD studies published by other research groups.

Study	Test	Temperature (°C)	Mean wear rate (mg/10 ⁶ cycles)	SD (% of mean)
[16]	UHMWPE/CoCr with 2 different slide tracks	22	7.86 and 9.21	7.6 and 4.3
	XLPE/CoCr with 2 different slide tracks		1.50 and 2.06	40 and 19
[17]	UHMWPE against CoCr in substitute lubricants	20	-0.02–27.4	4.8–155
[18]	GUR 1020 UHMWPE/CoCr	22	3.92	14
	GUR 1050 UHMWPE/CoCr	22	3.64	11
[19]	XLPE/CoCr with different contact pressures	22	0.28–1.05	31–47
[20]	CFR PEEK ^a /CoCr with different contact pressures	20	0.58–1.59 ^b	20–84
[21]	Vitamin E XLPE/CoCr in CMC ^d fluids	20	0.73–1.63 ^c 0.02–0.93	19–40 43–85
[22]	HALS antioxidant XLPE/CoCr	20	0.29	14
	Vitamin E XLPE/CoCr	20	0.83	18
[23]	UHMWPE/CoCr, shelf-aged, air, surface	37	39.9	21
	UHMWPE/CoCr, shelf-aged, air, subsurface	37	33.7	49
	UHMWPE/CoCr, shelf-aged, inert, surface	37	5.0	45
	UHMWPE/CoCr, shelf-aged, inert, subsurface	37	3.7	39
	UHMWPE/CoCr, retrieved, air, superior	37	6.5	121
	UHMWPE/CoCr, retrieved, air, inferior	37	7.0	66
	UHMWPE/CoCr, retrieved, inert, superior	37	6.5	102
	UHMWPE/CoCr, retrieved, inert, inferior	37	6.7	98
[24]	UHMWPE/CoCr	37	5.2	39
	Vitamin E UHMWPE/CoCr	37	4.9	38
	XLPE/CoCr	37	1.5	125
	Vitamin E UHMWPE/ BaSO ₄ -PEEK	37	7.1	26
	UHMWPE/PEEK	37	6.0	36
	Vitamin E UHMWPE/PEEK	37	7.4	35
	XLPE/PEEK	37	0.8	122
	UHMWPE/CFR-PEEK	37	20.5	83
	Vitamin E UHMWPE/CFR-PEEK	37	17.9	65
	XLPE/CFR-PEEK	37	2.4	77
[25]	UHMWPE, XLPE and retrieved XLPE/CoCr	37	n.a. ^e	n.a.

^aCarbon fiber reinforced polyether ether ketone^bPins^cDisks^dCarboxymethyl cellulose^eWear rate order was UHMWPE > retrieved XLPE > XLPE.

mean wear rates. Factors that appear to substantially increase the SD include very low wear rate [16,19,21,24], aberrant wear with alternative lubricants [17,21], abrasion [20,24], and, of course, inhomogeneity of the test material, especially retrieved UHMWPE and XLPE with various extent of oxidative damage [23,25]. TE 87 tests show manyfold lower wear for XLPE compared with UHMWPE [16,18,19,22,24], which is in agreement with clinical findings [3]. TE 87 tests also show that carbon fiber reinforced polyether ether ketone (CFR-PEEK) is an unacceptably poor bearing material due to its abrasiveness [20,24].

Regarding the capacity of existing multidirectional wear test devices, the second highest number of test stations after the SuperCTPOD is 16 of the Random POD [26], from which a 4-station friction measurement device, the Friction RandomPOD, has been developed [27]. The original CTPOD had 12 test stations [7]. The ‘OrthoPOD’ [28] and the POD

devices of University of Leeds [29] and Massachusetts General Hospital [30] have 6 test stations. If 6 test stations only are available, the execution of large wear test programmes takes a very long time.

5. Conclusions

The wear rate linearly increased with the nominal contact pressure p . A 6-fold increase of p , from 0.5 MPa to 3.0 MPa, resulted in a 2.4 fold increase of the mean wear rate, from 2.00 mg/10⁶ cycles to 4.82 mg/10⁶ cycles. The SDs were 7.5–15.9% (average 11.1%) of the mean wear rates. In pairwise comparisons of samples, a 13.2% difference between mean wear rates could be detected with 85.9% power. The present tests corroborated the RandomPOD finding that the increase of the test temperature from 20 °C to 37 °C leads to a relative increase of SDs due to the decrease of the wear rate. In multidirectional pin-on-disk tests for UHMWPE, p should not exceed 2.0 MPa to avoid the formation of protruberances that are not observed clinically.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Statement of originality

The work described has not been published previously, it is not under consideration for publication elsewhere, its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out, and, if accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder.

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