Saikko, Vesa

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Effect of increased load on the wear of a large diameter metal-on-metal modular hip prosthesis with a high inclination angle of the acetabular cup

Vesa Saikko

Aalto University School of Engineering

Finland

Correspondence:

Vesa Saikko, PhD

Aalto University School of Engineering

Department of Engineering Design and Production

PO Box 14300

FI-00076 Aalto

Finland

Tel. +358 50 355 1757

E-mail: vesa.saikko@aalto.fi

Abstract

In some earlier hip simulator studies of large-diameter metal-on-metal (MoM) hip prostheses high, unexplained variation in wear has been observed. In the present study it was found that high variation occurs when the tribological endurance limit of the MoM device in question is being approached. When the limit is exceeded, high wear takes place uniformly, and the variation is low. Below the limit, both the wear and its variation are low. The endurance limit was exceeded by increasing the peak load from 2 kN to 3 kN, to simulate obesity. The acetabular cup inclination angle was high, 70°. Potential clinical wear problems can be predicted by hip simulator studies provided that relevant adverse test conditions are included.

Keywords: Metal-on-metal; Acetabular cup position; Edge loading; Squeak

1. Introduction

In a metal-on-metal (MoM) hip prosthesis, a femoral head made from CoCr alloy slides against an acetabular cup made from the same alloy. They form a ball-in-socket joint. Under normal hip simulator test conditions simulating level walking of a typical patient, with optimal position of the acetabular cup (abduction 45°, anteversion 20°), the large-diameter metal-on-metal prostheses show low wear, typically of the order of 1 mg/10^6 cycles [1–6]. In some hip simulator studies on large-diameter MoMs, the wear was usually reasonable but sometimes high wear occurred in a minority of the prostheses [7,8]. Presently, the poor clinical wear performance of the large-diameter MoMs [9,10] is considered the largest disaster in the history of not only arthroplasty but of the entire orthopaedics. The situation may be partly due to the fact that adverse condition testing was not performed (no published adverse condition hip simulator studies exist from the time of the wide introduction of the large-diameter MoMs, the late 1990s and early 2000s). Although the MoMs are no longer implanted in large numbers it is important to thoroughly unravel the causes of their tribological failure, so that the mistakes will not be repeated in the future. It is quite possible that someday, perhaps a decade or two from now, the MoM will make a comeback once again, in one form or another.

A high inclination angle of the acetabular cup (> 60°) is known to be detrimental for the wear behaviour of the MoMs [9,11–15], due to the edge contact and the consequent failure of the fluid film lubrication [3,16]. In the present study, an extreme inclination angle of 70° was used. It was hypothesized that the high variation in MoM wear is due to the fact that the conditions approach the tribological endurance limit of the MoM device in question. Regarding the tribological behaviour of prosthetic joints, the endurance limit is defined here as a combination of (a) device-related parametrs such as diameter, clearance, sphericity of bearing surfaces, and the arc of cup coverage, and (b) operation conditions, such as load, inclination angle of cup and type of relative motion. Above the limit the tribological behaviour of the device is unacceptable, i.e., wear and friction will inevitably – not only occasionally – be so high that serious damage to the patient and early failure of the arthroplasty would result. Well below the limit, the wear and its variation are low [1–3]. In the present study, the limit was being approached with a combination of 2 kN peak load and 70° inclination angle. Variation of wear was high. The limit was clearly exceeded when the peak load was increased to 3 kN. This value simulated obesity [17]. Wear was high and linear and its variation was low. In other words the tribological endurance limit of the MoM device in question was exceeded under the test conditions used

2. Materials and Methods

The 12-station HUT-4 hip joint simulator, the fixation and alignment of the specimens, the test procedure and the method of MoM wear measurement have been described elsewhere [1–3]. Test 1 was run with three similar 52 mm diameter Metasul (Protasul-21WF, wrought-forged, high-carbon CoCr alloy, ISO 5832-12) MoM bearings with a diametral clearance of 0.16 mm. They were manufactured in the early 2000s by Centerpulse Orthopedics Ltd (Switzerland). The type of cup was Durom, introduced in 2001, and it was sub-hemispherical (165°). The cup inclination angle in the test was 70° (abduction 66°, anteversion 32°, Fig. 1). According to the definitions by Murray [18], these three angles corresponded to the anatomical inclination, operative inclination, and operative anteversion, respectively. The motion of the modular femoral head was biaxial consisting of sinusoidal flexion-extension (range 46°) and sinusoidal abduction-adduction (range 12°) that had a phase difference of $\pi/2$ [19] in order to produce a multidirectional relative motion [20]. The absolute value of the relative angular velocity during a gait cycle varied between 0.7 rad/s (heel strike and toe-off) and 2.7 rad/s (middle of stance and swing phases).

The loading direction was vertical, and so the load vector was at an angle of only 20° to the plane of the cup rim. An inclination angle higher than 70° would make the joint unstable, as the friction caused by the abduction of the head during the second (toe-off) load peak moves the contact point even closer to the cup edge [1]. The maximum value of the double-peak load cycle was 2.0 kN (minimum 0.3 kN, average 1.2 kN). The cycle frequency was 1.06 Hz, and the test length was 3 million cycles. The lubricant was HyClone Alpha Calf serum SH30212.03 diluted 1:1 with Milli-Q grade distilled water, so its protein concentration was 20 mg/ml. No additives were used. The amount of lubricant in the test chamber was 500 ml. The taper fixation surfaces of the femoral heads were isolated from the lubricant by silicone sealant. The test was run at room temperature 25 °C. In test 2, the maximum value of the double-peak load cycle was increased to 3.0 kN (minimum 0.4 kN, average 1.9 kN). Otherwise, the test conditions were as in test 1. Test 2 was run with three similar 50 mm diameter Metasul MoM bearings (52 mm diameter was unavailable as the components were no longer on the market).

The wear was evaluated from the Co and Cr concentrations of the used lubricant analysed by atomic absorption spectroscopy (AAS) and inductively coupled plasma atomic emission spectroscopy (ICP-AES) as described elsewhere [1–3,21]. At intervals of 0.375 million cycles on the average the test was stopped, and the test chambers and the specimens were removed. The lubricant was thoroughly mixed, its volume was measured and two 20 ml samples were taken. After this the specimens and their holders were cleaned and the test was continued with fresh lubricant. The first 375 000 cycles was considered running-in.

The roundness of the components was measured with a Talyrond 31c apparatus. Maximum inscribed method was used with the cups, and minimum circumscribed method with the heads. Hence the out of roundness values obtained reflected the magnitude of linear wear (depth of the wear pit). The cups were measured near the rim and on a plane parallel to the rim. Considering the arc of coverage of Metasul cups, 165°, and the rounding of the edge, the measurement took place approximately along the 10° latitude. Since the direction of load was at an angle of 20° to this plane, it was estimated that the linear wear was 94 % (cos20°) of the out-of-roundness value. The heads were measured approximately along the 45° latitude so that the stylus traversed the centre of the wear mark. Since the direction of load was at an angle of 45° to this plane, it was estimated that the linear wear was 71 % (cos45°) of the out-of-roundness value.

The surface roughness R_a of the components was evaluated with a Mitutoyo Formtracer SV-C3100 contact stylus instrument using an evaluation length of 0.4 mm and a sampling length of 0.08 mm. The R_a values were measured on the centre of load bearing surface in the direction of abduction-adduction after the wear tests.

3. Results

Squeak did not occur in test 1 but it was common in all three stations in test 2, in which the darkening of the serum was conspicuous (Fig. 2). In test 1, the serum temperature was on the average 5 °C, and in test 2, 16 °C above the room temperature due to frictional heating. In both tests, the contact on the cup was bordered by the edge. High variation and non-linearity in wear was observed in test 1 (Fig. 3a). A general trend was that the wear rate decreased with increasing number of cycles. The highest wear rate was 100 mg/10^6 cycles in station 1 between 0.39 and 0.78 million cycles. The lowest value was 1.9 mg/10^6 cycles, measured for the same prosthesis between 2.25 and 2.63 million cycles. In test 2, wear was uniform, linear and higher than that in test 1 (Fig. 3b). The mean wear rate ± SD was 167 mg/10^6 cycles ± 15.7 mg/10^6 cycles.

The roundness measurements showed that the cups wore more than the heads (Table 1). On the heads, the highest values were measured when the stylus traversed the centre of worn surface (Fig. 4). On the cups, however, the highest values were not measured on the centre of worn surface, but near the rim which indicates that the stability of the joints further decreased with increasing wear. The lateral motion of the cups at maximum extension (toe-off) was indeed conspicuous towards the end of test 2. The roundness profiles showed a distinct wear pit (Fig. 5). When the cup and the head wear were combined, the mean linear wear rate ± SD in test 2 was 139 $\mu m/10^6$ cycles ± 9.38 $\mu m/10^6$ cycles. There was a strong linear relationship (R^2 = 0.9544) between the linear wear and the wear evaluated from the Co and Cr ion concentrations of the used lubricant (Fig. 6). The original out-of-roundnesses, measured along latitudes, were of the order of 1 µm on the heads and below 10 µm on the cups.

In visual and microscopical examination of the bearing surfaces multidirectional scratching was typical on the heads (Fig. 7). The main load bearing surface of the cups near the rim where the highest contact pressures and wear took place was mostly highly polished, even in test 2, with the exception of occasional scratches (Fig. 8).

The original surface roughness R_a values of the bearing surfaces varied from 0.006 µm to 0.010 µm. Despite the high wear in test 2 the increases of the R_a values on the load bearing surfaces due to wear were small (Table 2). Even so-called self-polishing was observed (cup 1 of test 2).

4. Discussion

The present test results produced with the HUT-4 hip joint simulator supported the hypothesis that high variation in MoM tests is due to the fact that the tribological endurance limit is being approached. When this limit is exceeded, the wear rate will be high and its variation low. In the present study, the limit was exceeded by increasing the load by 50 %. At 70° inclination, 2 kN peak load resulted in high variation, whereas 3 kN produced uniform, high wear. When the conditions are well below the limit, wear and its variation are low. With 50 mm diameter Metasul MoMs (n = 3), 2 kN peak load and 48 degrees inclination, the steady-state wear rate was 0.89 ± 0.13 mg/10^6 cycles only [1].

The mean wear rate value observed in test 2, 167 mg/10^6 cycles was still only half of the highest value measured by Essner et al. [7], 332 mg/10^6 cycles for one exceptional MoM prosthesis. They ran eight similar 40 mm diameter MoMs (as-cast, high-carbon CoCr alloy, ASTM F-75) with 0.1 to 0.18 mm diametral clearance in the MTS simulator at c. 20° inclination angle (estimated from Fig.1 of the paper; edge loading therefore was not possible), with 2.45 kN peak load, and in diluted serum lubricant similar to that used in the present study. While five of the prostheses showed mild wear with a steady-state wear rate below 8.3 mg/10^6 cycles, three of them showed erratic behaviour and excessive wear. The critical parameter in that study from the point of view of the tribological endurance limit may have been the diameter, 40 mm. This value is relatively low in the category of large-diameter MoMs. Had they tested 28 mm diameter, high wear may have been common. The possibility for fluid film lubrication naturally decreases with decreasing diameter [22]. The clinical studies of resurfacing MoMs indicate that small (≤ 51 mm) joints show significantly higher wear than large (≥ 53 mm) joints [13].

In the hip simulator study by Vassiliou et al. [8], one of the five 50 mm diameter BHR MoMs showed exceptionally high wear under test conditions simulating gait (peak load 3 kN, inclination angle 33°). Its total wear at five million cycles was 160 mg, contrasted with 14 mg to 51 mg of the other four. In this study the critical parameter from the point of view of the tribological endurance limit may have been the type of relative motion. The motion in the Durham simulator is sinusoidal flexion-extension of the head (range 45°) and sinusoidal internal-external rotation of the cup (range 10°) with a phase difference of π/2. Hence the shape of the slide tracks on the load-bearing surface (which is small under normal test conditions) is a straight line on the head and a very narrow figure of eight on the cup [23]. Hence the relative motion is rather uniaxial reciprocating than truly multidirectional. At reversals of flexion-extension the angular velocity is close to zero and so the possible fluid film may fail. Had they disconnected the internal-external rotation, high wear may have been common. The aspect ratio of the slide track on the main load-bearing surface near the point of load application should not be above 5.5 in order to produce a truly multidirectional, 'polishing' relative motion which is a prerequisite for reproducing clinical wear mechanisms [24]. In the MTS simulator [4], the aspect ratio of the 'force track' is 1 (circular), and in the present HUT-4 simulator, it is 3.8 (elliptical). According to a biomechanical study, only 13 % of the patients showed an average aspect ratio higher than 5.5 [25]. While a more linear, reciprocating type of motion is beneficial for the wear of ultrahigh molecular weight polyethylene (UHMWPE), it is likely to be harmful for the MoM because of uniaxial grooving.

In an earlier study, high variation in wear was observed in the 52 mm diameter Metasul MoM (n = 3) with an optimal inclination of the cup, 48°, and a very high peak load of 4 kN [3]. Loud squeak was produced by the prosthesis with the highest wear rate of 116 mg/10^6 cycles. With a 48° inclination and 3 kN peak load, the wear rate was 1.3 mg/10^6 cycles, that is, almost as low as with 2 kN. In earlier tests with 2 kN peak load, the wear rate of the 52 mm MoM was 13 mg/10^6 cycles with 63° inclination, and 88 mg/10^6 cycles with 66°

inclination [2]. The wear in these two tests was highly linear for 3 million cycles, which is in disagreement with the results of test 1 of the present study. The above variations and discrepancies appear to be caused by the fact that the endurance limit regarding the combination of load and inclination was only being approached.

In the optimal position of the cup, fluid film lubrication apparently takes place in large-diameter MoMs up to the peak load of 3 kN, at least for a part of the gait cycle [22]. After the running-in wear of c. 5 mg, the steady-state wear rate under these conditions, 1 mg/10^6 cycles [1,2] can be estimated to correspond to 1 mg per year clinically. Since measurable wear nevertheless does take place, the principal lubrication mechanism is mixed lubrication. When the inclination angle is increased to 70°, the contact is bordered by the edge of the cup. The contact becomes asymmetric, due to which the fluid film is lost [2,3,16]. Metal-metal contact and an increase of wear rate by more than two orders of magnitude may result. This effect is exacerbated by a shallow cup design. The lower the arc of cover is, the poorer the lubrication is with high inclination angles. The squeak heard in test 2 certainly was indicative of poor lubrication [3]. The observation agreed with clinical findings, according to which squeaking is associated with high inclination angles [26]. Although denatured proteins are present, they are unable to provide an efficient boundary lubrication, that is, to prevent high friction and wear. Friction is not measured directly in the HUT-4 simulator but the average lubricant temperature increase of 16 °C in test 2 is an indirect evidence of high friction. This was the highest temperature increase ever measured in the HUT-4 simulator. Still, paradoxically, the proteins do play an important role which can be understood by running water-lubricated MoM tests for comparison [3]. Despite the fact that the linear wear in the present tests could be as high as 0.4 mm on the cups, the worn surfaces were surprisingly smooth (Table 2, Fig. 8), as are those of explanted components [27,28], apparently due to the presence of proteins and to the multidirectional motion. This phenomenon has been called self-polishing. There were no signs of galling that occurs in water lubrication [3].

Contrary to what has often been wrongly argued from commercial viewpoints, the wear behaviour in the absence of the fluid film has little to do with the CoCr metallurgy, that is, the wear and friction will be excessive irrespective of the manufacture method or composition of the CoCr alloy (high carbon, low carbon, as-cast, heat treated, hot isostatically pressed, wrought, etc.). Instead, the important parameters are, according to the fluid film lubrication theory, the position of the cup, diameter, clearance, sphericity of bearing surfaces, load and angular velocity [22]. With polished surfaces and in the presence of the pseudosynovial fluid, these parameters determine whether fluid film lubrication prevails or not. If it does, the wear rate is of the order of 1 mg per year which is likely to be well tolerated. If it does not due to, e.g., the combination of high inclination angle and increased load, the wear rate may increase by two orders of magnitude or more which is likely to cause serious problems to the patient and lead to an early failure of the arthroplasty [6], irrespective of the type of CoCr.

It seems to be characteristic of the tribological behaviour of the MoM that unlike UHMWPE against a polished metallic or ceramic head, MoM is not forgiving [3]. For example, seizure takes place in MoM within minutes if the lubricant does not contain proteins [3]. On the other hand, UHMWPE tests could be run even dry, without any lubricant, and still no damage to the components occurred despite considerable frictional heating [3]. Moreover, edge loading does not increase the wear of UHMWPE cups [29–31].

As a summary it could be stated that under ideal conditions the contemporary large-diameter MoM is a hydrodynamic bearing with negligible wear. However, it has to operate in an environment where circumstances for hydrodynamic lubrication cannot be guaranteed, which may result in excessive wear and friction. Essner et al. [7] concluded that the MoM wear is intrinsically unpredictable. The conclusion of the present study is that the wear of the large diameter MoM is unpredictable when the tribological endurance limit is being approached. Well below the limit, the tribological behaviour is excellent, but above the limit, the behaviour is disastrous. UHMWPE does not show such a split, unforgiving behaviour.

As a limitation of the present study the low number of components tested could be mentioned. The n values (3) and the slightly different diameter used in the two tests were due to the fact that the present Metasul design with the Durom cup is no longer commercially available. This is however not related to its tribological behaviour clinically, but to the problems in the fixation of the Durom cup [32]. With normal test conditions (48° cup inclination, 2 kN peak load), both the 50 mm (n = 3) and 52 mm diameter Metasul (n = 2) show a steady-state wear rate of the order of 1 mg/10^6 cycles [1,2]. Therefore it is reasonable to assume that the wear behaviour with a high inclination angle does not change significantly due to the 4 per cent difference in the diameter. When the load was increased by 50 per cent for test 2, the difference in wear could be assumed to be mainly attributable to the peak load, 2 kN vs. 3 kN. On the other hand, the standard deviation does not depend on n. The difference in the wear behaviour between the two tests was so obvious that it is unlikely that higher n values would have changed the outcome of the comparison.

5. Conclusions

The large diameter metal-on-metal hip prostheses have sometimes shown erratic, unpredictable wear behaviour in hip simulator tests. It was shown in the present study that high variation in wear is due to the fact that the conditions approach the tribological endurance limit of the MoM device in question. When the limit is exceeded wear is high and linear, and its variation is low. Below the limit under ‘normal’ test conditions, both the wear and its variation are low. Potential clinical wear problems can be predicted by hip simulator studies provided that relevant adverse test conditions are included.

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Table 1. Roundness of Metasul components after 3 million cycle HUT-4 hip simulator tests at 70° inclination angle of cup. Cups were measured along 10° latitude and heads along 45° latitude. Maximum inscribed method was used with cups and minimum circumscribed method with heads. Typical standard deviation was 2 %. In linear wear calculations, direction of measurement was corrected for.

Test no.	Peak load (kN)	Diameter (mm)	Component	Out of roundness (µm)	Linear wear (µm)
1	2.0	52	Cup 1	46	43
			Head 1	5	4
			Cup 2	75	70
			Head 2	3	2
			Cup 3	34	32
			Head 3	6	4
2	3.0	50	Cup 1	381	358
			Head 1	63	45
			Cup 2	392	368
			Head 2	115	81
			Cup 3	383	360
			Head 3	56	40

Table 2. Surface roughness R_a values, mean ± standard deviation, of Metasul components after 3 million cycle HUT-4 hip simulator tests at 70° inclination angle of cup, measured on centre of load bearing surface in the direction of abduction-adduction.

Test no.	Component	Surface roughness R_a (μm)
1	Cup 1	0.008 ± 0.001
	Head 1	0.015 ± 0.001
	Cup 2	0.007 ± 0.0003
	Head 2	0.026 ± 0.011
	Cup 3	0.010 ± 0.002
	Head 3	0.012 ± 0.001
2	Cup 1	0.005 ± 0.001
	Head 1	0.017 ± 0.001
	Cup 2	0.018 ± 0.008
	Head 2	0.011 ± 0.002
	Cup 3	0.015 ± 0.002
	Head 3	0.008 ± 0.001

Figure captions

Figure 1. Close-up of test station no. 2 of HUT-4 hip joint simulator showing 50 mm diameter Metasul MoM hip installed, without lubricant chamber. Gait of right hip is simulated. Durom acetabular cup is cemented to a position of 70° inclination (66° abduction, 32° anteversion). At this moment, i.e., maximum extension (outer cradle) and neutral abduction-adduction (inner cradle) of the femoral head, and maximum load of the second (toe-off) load peak (vertical loading bar above the joint), high friction almost dislocates the joint as the motion is momentarily purely abduction of head. Hence, 70° proved to be close to the highest possible inclination angle that could be run with.

Figure 2. Test stations 1 to 3 of HUT-4 hip simulator after 3 million cycle test with three 50 mm Metasul MoMs, 70 degrees inclination of cup, and 3 kN peak load. Note pneumatic double-piston loading system capable of increased loads up to 6 kN per station, load cell in station 2, universal joints making acetabular cups self-centring on femoral heads, and uniform darkening of serum lubricant due to high wear.

Figure 3. Wear of Metasul couples with 70° inclination of cup, (a) test 1, diameter 52 mm, peak load 2 kN, (b) test 2, diameter 50 mm, peak load 3 kN. Square, diamond and triangle markers refer to test stations 1, 2 and 3, respectively. Note different scale in y axes.

Figure 4. Roundness of head 1 of test 2 being measured with Talyrond apparatus so that stylus traversed the centre of worn surface. Dark-coloured protein residue from serum indicates extent of contact.

Figure 5. Roundness profile of cup 1 of test 2 on 10° latitude. Out-of-roundness was 392 μm (maximum inscribed method), and linear wear was 368 μm. Wear pit is directed upward.

Figure 6. Relationship between linear wear and wear evaluated from Co and Cr concentrations of used serum lubricant. Total wear of head and cup are combined. Markers are as in Fig. 3.

Figure 7. Optical micrographs from load-bearing surface of head 1 of test 2 showing (a) mild and (b) deep scratching. Shape of these scratches ensues from elliptical slide tracks (see Fig. 4 of [1]). The curvature of these scratches is due to the fact that maximum angular velocity of abduction-adduction, 0.7 rad/s, coincides with reversal of flexion-extension (see Fig. 1). Deep scratches shown in (b) are caused by contact with cup edge.

Figure 8. Superior edge of cup 1 of test 2. Load bearing surface is shiny although linear wear was as high as 0.36 mm.

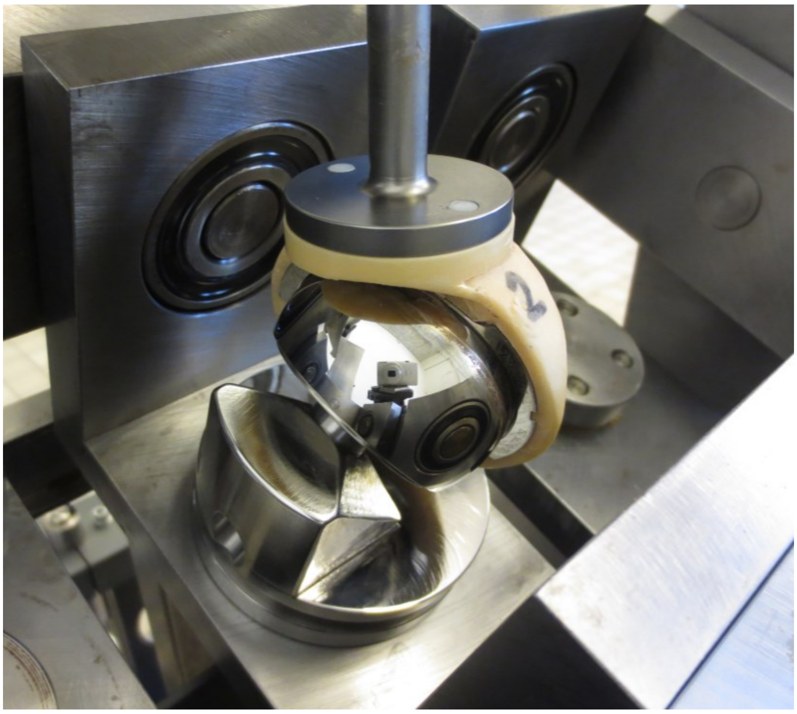

Figure 1.

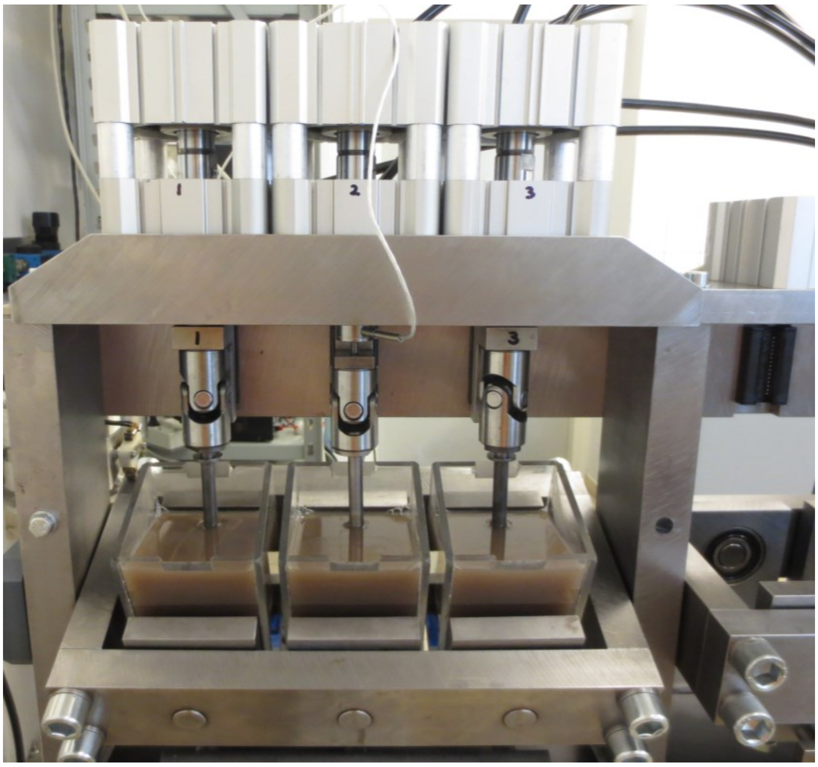

Figure 2.

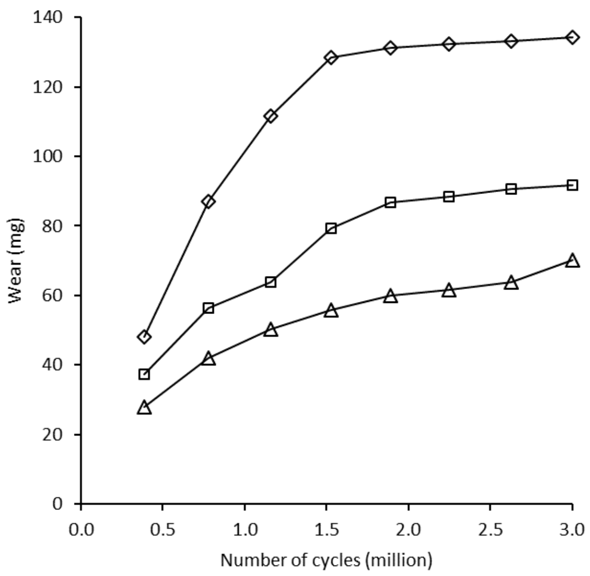

Figure 3a.

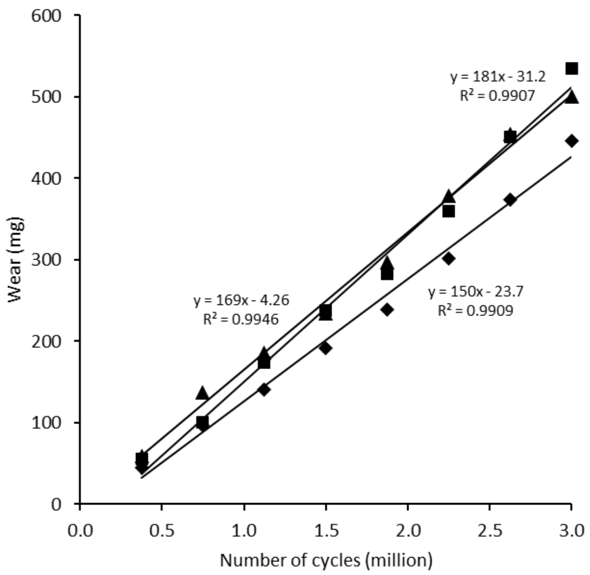

Figure 3b.

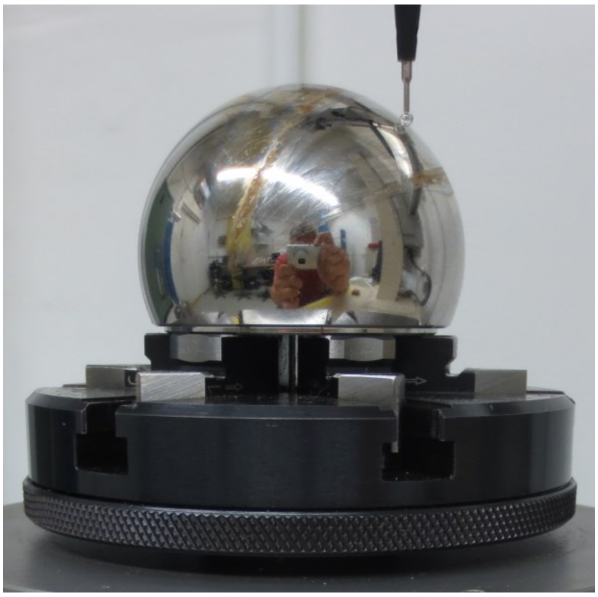

Figure 4.

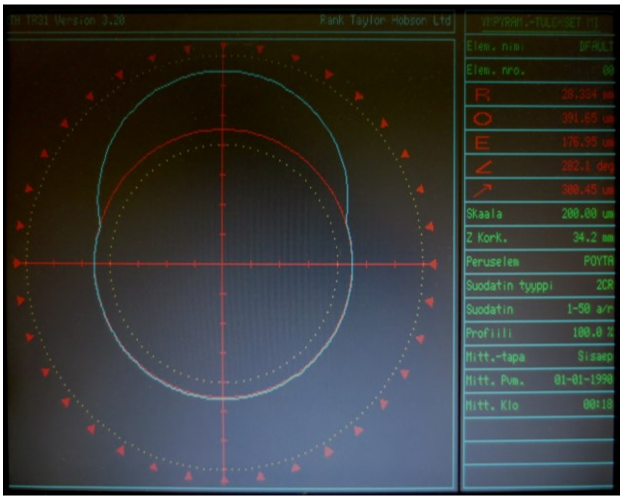

Figure 5.

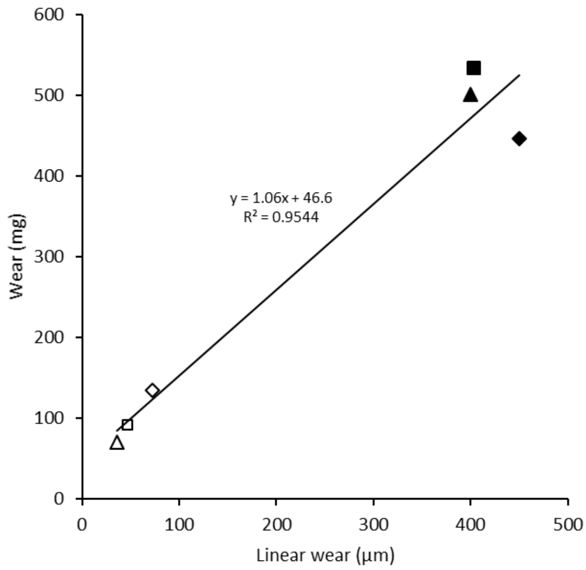
600
500
400
300
200
100
0
Wear (mg)
y = 1.06x + 46.6
R² = 0.9544
0
100
200
300
400
500
Linear wear (μm)

Figure 6.

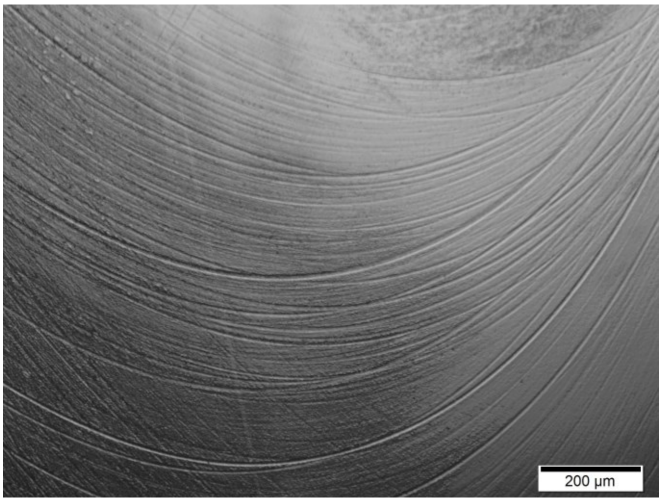

Figure 7a.

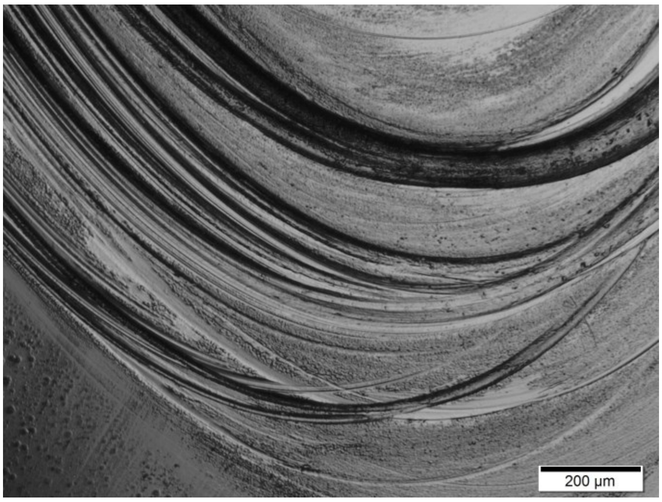

Figure 7b.

Figure 8.