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The effect of acetabular cup position on wear of a large-diameter metal-on-metal prosthesis studied with a hip joint simulator

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Abstract

Clinically, malposition of the acetabular cup in large-diameter metal-on-metal prosthetic hip designs is associated with high wear, adverse reaction to metal debris and early failure. A steep angle of the cup (>60°) may lead to poor tribological performance. Large-diameter CoCr-on-CoCr prostheses were run in the HUT-4 hip joint simulator so that a steep angle was included. With a correct position, the tribological behaviour was excellent, the wear rate being 0.1 $mm^3/10^6$ cycles. In the steepest position, lubrication failed and the wear rate was two orders of magnitude higher. This study stresses the importance of rigorous pre-clinical testing.

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

1. Introduction

Several large-diameter metal-on-metal (MoM) prosthetic hip designs have been introduced since the early 2000s [1]. In the MoM articulation, both bearing surfaces are made from a CoCr alloy. The tribology of the MoM is very different from that of the most widely used and intensively studied metal-on-polyethylene articulation. For instance, MoM is highly sensitive to the presence of a sufficient amount of protein-containing lubricant [2], for which there actually are no guarantees. MoM designs differ from each other with respect to the clearance, sphericity, depth of the cup, and CoCr alloy used. The early failure rate of one of the widely used MoM resurfacing designs has recently proved to be unacceptable [3]. The failure appears to be related to inadequate tribological performance, especially to the high amounts of metal debris produced. The wear rates measured from retrieved components ranged from 0.51 to 95.5 mm^3/year [4]. If the abduction and anteversion angles of the cup are high, as they often are [3], the contact area may be bordered by the edge of the bearing surface leading to poor lubrication and high wear.

In the present study, the effect of cup position, ‘correct’ (angle $< 50°$) versus ‘steep’ (angle $> 60°$), on the wear of a 52 mm diameter MoM design was studied using the previously validated HUT-4 hip joint simulator [5]. In the wear test, level walking was simulated, the lubricant was diluted calf serum, and the wear was evaluated by measuring the Co concentration of the used lubricant by atomic absorption spectroscopy (AAS) and Cr concentration by inductively coupled plasma atomic emission spectroscopy (ICP-AES). The hypothesis was that in a MoM design that performs well in the correct position, a steep cup position causes substantially higher wear, the different amounts of wear and wear rates being quantifiable by the above methods, and being in agreement with clinical observations.

2. Materials and Methods

The 12-station HUT-4 hip joint simulator and the test method have been described in detail elsewhere [5]. In brief, the femoral head made biaxial rocking motion, flexion-extension (range 46°) and abduction-adduction (range 12°). The phase difference between the two motion waveforms of nearly sinusoidal shape was $\pi/2$, so the multidirectional 'polishing effect' that is necessary for the reproduction of clinical wear mechanisms was implemented. The load waveform was of a double-peak type with a maximum of 2 kN and a minimum of 0.4 kN. The direction of loading was vertical and fixed relative to the cup. The cycle frequency was 1 Hz. The prosthesis was surrounded by an acrylic chamber containing 500 ml of lubricant, which was HyClone (Logan, Utah, USA) Alpha Calf Fraction serum SH30212.03, diluted 1:1 with Milli-Q® grade distilled water (Fig. 1). The protein concentration of the lubricant was 20 g/l. No additives were used in the lubricant. The lubricant and environment temperatures were monitored.

The Metasul metal-on-metal prostheses that were studied were manufactured by Centerpulse Orthopedics Ltd, Switzerland. The head and the cup with 52 mm nominal diameter of articulation were made from wrought-forged, high-carbon CoCr alloy Protasul-21 WF, ISO 5832-12. The type of cup was Durom (product number 01.00214.058, code R) having a sub-hemispheric bearing surface of 165° and a rounded edge (radius 0.5 mm) connecting the bearing surface to the flat rim. A bone cement (acrylic) mantle of 4 mm thickness was cast around the cup. The mantle had a flat loading surface (40 mm diameter) with two recesses drilled for guide pins. The cementing was done in a mold designed so that the cup was to be in a required position in the simulator with respect to abduction and anteversion (flexion) angles, and the distance from the centre of the cup to the axis of symmetry of the loading surface was 0.1 mm at most. Besides the main function, i.e., providing a practical positioning/locking/loading interface with the simulator, the additional advantages of this cementing method was that (a) the porous titanium outer surface (Fig. 2), designed for fixation by bone ingrowth, was completely and tightly covered, and thus isolated from the test (there was no micromotion of the Ti coating against anything, and all surfaces were smooth and therefore easy to clean), and (b) it did not deform the cup (see below), the thickness of which was 4 mm only, in curing-shrinkage because the only deviation from the hemispheric form of 68 mm outer diameter was the flat loading surface. At the point of load application, the cement thickness was 3 mm.

The Large Head (product number 01.00181.520, code R) of the Metasul system was fixed to the femoral head holder using a 12/14-18/20 double-taper adapter (product number 01.00185.146, size M) and a double-taper pin, both made from CoCr by Centerpulse Orthopedics Ltd, Switzerland. The neck angle of the head holder made from stainless steel was 45°. All conical fixation surfaces were isolated from the test by silicone sealant. The head was carefully aligned with respect to the FE and AA axes by means of an adjustment disc of the inner cradle, to which the head holder was attached. The distance from the centre of the head to the axes was 0.02 mm at most, checked with a dial-gauge. The alignment was unaffected by the fact that the head holder together with the head was periodically removed for cleaning and inspection and then reattached for the continuation of the test. In any case, the cup was self-centring on the head so that possible misalignments had no tribological effects. The bearing surface of the head was similar to that of the corresponding resurfacing head of the Durom design.

The diameter of the heads was measured with a micrometer, and the radius of the bearing surface of the cups with a coordinate measuring machine. The roundness of the bearing surfaces was measured with a Talyrond 31c apparatus on several different planes, parallel to the equatorial plane, and inclined. The surface roughness of bearing surfaces was measured using a Mitutoyo Formtracer SV-C3100 diamond stylus apparatus with a sampling length of

0.08 mm.

Four bearing couples were available for the tests. First, a preliminary (P) test was run in station 2 of the simulator to check the viability of the setup. The cup was in the optimal, ‘correct’ position (Table 1). After that, three tests were simultaneously run in test stations 1, 2 and 3 of the simulator. Test 1 was a repetition of the preliminary test. In test 2, the acetabular cup was in a position 15° steeper than in test 1, and in test 3, an additional 3° steeper than in test 2 (Fig. 3). The test lengths were 3.3 million cycles. The tests were stopped every 6 days (550 000 cycles) for cleaning, inspection of bearing surfaces and change to fresh lubricant.

The Co concentration of samples of used lubricant was measured with AAS and Cr concentration with ICP-AES, as these are the optimal analytical methods for the two elements. In addition, Co was controlled with ICP-AES. Since the samples were digested before the analyses, the concentration values reflected the total metal removal from the bearing surfaces, that is, the metal ion release *and* wear particles. The amount of wear during each 6-day run could thus be calculated, as the volume of lubricant in the chamber was measured, and 90 per cent (weight) of the Protasul-21 WF alloy was known to consist of Co and Cr, the Co/Cr ratio being 2.1. Lubricant sampling was preceded by rinsing with Milli-Q® water of the components that were in contact with serum during the test, and thorough mixing. The basic assumption was that all removed metal was in the lubricant. With the above method, 6 points were obtained for the calculation of the wear rate using linear regression. In the calculation of the volumetric wear, the density of the Protasul-21 WF alloy was taken to be 8.29 mg/mm^3.

The digestion of the serum samples was done as follows. A sample of approximately 6 g was accurately weighed into a polytetrafluoroethylene (PTFE) pressure vessel. Four millilitres of concentrated nitric acid (HNO_3, E. Merck, suprapur) was added. The closed vessel was placed in a microwave-assisted digestion system (Milestone, Ethos) for 30 min at 200 °C. After cooling, the samples were diluted with Milli-Q® grade water (18.3 MOhm).

The cobalt measurements were obtained using a Varian AA-240 atomic absorption spectrometer equipped with an air-acetylene burner and a hollow cathode lamp. The AAS parameters were: wavelength 240.7 nm, slit 0.2 nm, lamp current 4 mA, acetylene flow 2 l/min and air flow 13 l/min.

A Perkin-Elmer 7100 DV ICP-AES instrument was used for the inductively coupled plasma atomic emission spectrometry analysis. A Scott type double-pass spray chamber and a cross-flow nebulizer were used throughout the study. The quantification of chromium was optimized using default software parameters for the instrument. The ICP-AES parameters were: Cr wavelength 267.716 nm, Cr control wavelength 283.563 nm, plasma gas flow 15 l/min, auxiliary gas flow 0.2 l/min, nebulizer gas flow 0.8 l/min, RF power 1300 W, and the plasma view was axial.

After the tests, the wear marks were examined with optical microscopy and with a field emission scanning electron microscope (FESEM) FEI Quanta 450 FEG.

3. Results

The mean radii of the heads and the cups before the wear tests were 25.99 mm and 26.07 mm, respectively. The diametral clearance of the joints was 156 μm ± 4 μm. All deviations from roundness were 10 μm at most. The cementing of the cups did not cause increase of deviations. According to a standard [6], published after the components were manufactured, the deviations from roundness should not exceed 5 μm. However, the deviations of the heads measured on any plane parallel to the equator were 1 μm at most. On planes inclined 45° relative to the equatorial plane, the values were close to 10 μm because the equatorial and polar zones were flatter than the intermediate zone. The surface roughness value Ra of the original bearing surfaces was 0.006 μm to 0.010 μm.

When the acetabular cup was in the correct position in the wear test, the wear rate was low, 0.1 $mm^3/10^6$ cycles on the average (Table 2). When it was in the steepest position, the wear rate was two orders of magnitude higher, 10.6 $mm^3/10^6$ cycles. In tests P and 1, the entire contact area was located at a distance from the edge of the cup (Fig. 4), the width of the contact area after the tests being c. 20 mm. In test 2, the contact area was bordered by the edge, and even more so in test 3, with severe consequences. The running-in wear was taken to be the amount of wear during the first 550 000 cycles. In tests P and 1, most of the wear occurred during the running-in phase. Altogether, the results of tests P and 1 were close to each other.

The average Co/Cr ratios of concentration in used lubricant samples were 2.4 (test P), 2.2 (test 1), 2.7 (test 2), and 3.0 (test 3). In the fresh serum, the Co and Cr concentrations were found with the ICP-AES to be below 0.02 mg/l.

The abrasive damage and surface roughness of the contact area increased with increasing cup angle (Fig. 5, Table 3). The increase of roughness in tests 2 and 3 was more pronounced in the heads than in the cups. Abrasion was nevertheless the most typical observation in the cups as well (Fig. 6). Cup 2 and 3 were the only specimens in the study for which Talyrond measurements showed deviations from roundness exceeding the initial maximum value of 10 μm. The maximum deviations were measured near the edge, parallel to the rim plane, and they had the form of distinct wear pits dug by the femoral heads. Their depths (linear wear) were 30 μm (cup 2) and 140 μm (cup 3), measured by using a maximum inscribed circle (MI mode).

In the four tests, P, 1, 2 and 3, the differences between the lubricant and environment temperatures, ΔT, were 0.1 °C ± 1.4 °C, 0.5 °C ± 1.0 °C, 1.8 °C ± 1.2 °C and 5.6 °C ± 1.3 °C, respectively. The environment temperature was 24.8 °C ± 1.0 °C. In tests P and 1, the friction was so low that ΔT was often negative due to evaporation, except for the running-in phase in which ΔT could be as high as 6 °C. The darkening of lubricant colour was in agreement with the severity of wear (Fig. 7). No squeaking occurred during the course of the tests in any of the prostheses.

4. Discussion

Despite the limited number of specimens available for the study (four), the striking difference in the tribological behaviour between the 'correct' and 'steep' positions of the acetabular cup became obvious. The present tests confirmed the earlier findings that when the cup is in a correct position, the steady-state wear rate of a Metasul large-diameter metal-on-metal prosthesis after the running-in phase is low, of the order of 0.1 $mm^3/10^6$ cycles [5]. The lubricant temperature was close to the environment temperature indicating that an efficient mixed lubrication mechanism prevailed. A full fluid film probably was not present, as the steady-state wear rate in tests P and 1 was still not negligible. The lubrication was remarkably good considering the relatively low velocity (48 mm/s on the average at the point of load application), water-like viscosity of the lubricant (1 mPas), and the fact that the joint was loaded during the entire gait cycle, the minimum load just before heel strike being 400 N. In the running-in phase, the higher ΔT values suggested that the lubrication mechanism was closer to boundary. The running-in wear was, after all, 0.6 mm^3 on the average. After the running-in phase, the lubrication mechanism turned closer to hydrodynamic, but apparently still was of the mixed type. Similar observations have been made in other hip simulators studies [7,8]. Clinically, the running-in phase and a lower wear rate after that seem to take place [9].

However, when the cup was in a steep position, the tribological behaviour of the articulation was very different. With the present methods and prostheses, the critical value of effective inclination angle appeared to be c. 60°. Above this value, the wear rate increased steeply with increasing angle. Apparently the lubrication failed because the contact area was bordered by the edge of the cup, which literally signified an edge of adverse tribological circumstances. An increase of inclination by only 3°, from 63° to 66°, resulted in a 7-fold increase in the wear rate. More tests would of course be needed to find out the exact angle dependence of wear rate, say between 60° and 70°. However, the knowledge that there is a critical angle, which categorically should not be exceeded if tribological problems are to be avoided, is much more valuable. For the present design, this angle appears to be c. 60°. The fact that the bearing surface of the cup was less than a hemisphere (165°) was important with respect to the critical angle. With a full hemisphere, the edge would have been 3.4 mm further from the point of load application.

Note that the high wear rates occurred without any deliberate separation (after toe-off), subluxation (during swing phase), and edge impact (at heel-strike) of the articulation, as is sometimes done to simulate a lax prosthetic hip [10]. The roughening of the cups (Table 3) was mild due to the multidirectional ‘polishing’ motion of the HUT-4 simulator [5]. According to the Talyrond measurements, the wear in tests 2 and 3 was mainly from the cups. Retrieval studies have not shown a distinct difference regarding which component has higher wear [4]. In the HUT-4 simulator, the load vector is fixed relative to the cup, and the head makes the biaxial rocking motion. Consequently, the major change of the heads was roughening, and the major change of the cups was loss of material. In MoM resurfacing prostheses (type ASR) removed because of tribological failure, wear rates even higher than that observed in test 3 have been measured [4], assuming that one million cycles in the simulator corresponds to one year in vivo. The mean value was 17.6 mm^3/year with a range of 3.11 mm^3/year to 87.7 mm^3/year. The result of test 3 is within this range and so it can be regarded to represent severe wear. Moreover, the maximum wear depth measured in the present study, 140 µm, is in agreement with values measured from explants [11]. On the other hand, it is difficult to find reference to the results of test P and 1 with a mean steady-state wear rate of 0.1 $mm^3/10^6$ cycles as the clinical wear rate of well-functioning large-diameter MoM prostheses is not known.

Multidirectional pin-on-disc (sphere-on-flat) tests with CoCr against CoCr produced wear factors of the order of 10^{-6} mm^3/Nm [12], substantially higher than that of test 3. It is possible that proteins are unable to provide an efficient boundary lubrication in a non-conforming contact, or even in a conforming contact with an asymmetric contact area as in tests 2 and 3. This means true metal-metal contact involving highly complex tribochemical mechanisms, in which the metallurgy of the alloy in question may be of importance [13,14]. In the normal position, the metallurgy is likely to be of secondary importance compared with the diameter, clearance, sphericity and surface roughness which dictate the lubrication mechanism. If lubrication is effective, metal-metal contact is mostly avoided. If it is not, there are hardly any metallurgical means to make a durable, low-wear joint.

Clinically, it has been observed that in the contemporary MoM hip resurfacing designs, the abduction angle of the cup varies from 23° to 78°, and the anteversion angle from -9° to 44° [3]. Especially a high anteversion angle appears to be associated with high wear, adverse reaction to metal debris and early joint failure. The present hip simulator results are in agreement with these findings. It has long been known that the in vivo position of polyethylene cups varies greatly [15]. Still no correlation between the cup position and wear has been observed [16], only between the cup position and propensity to dislocation [15]. It is possible that the experience with polyethylene cups led to an attitude of unconcern with respect to the position of the MoM cups. After all, the large head diameter as such could be expected to reduce the propensity to dislocation, so that a steep angle, which sometimes is difficult to avoid due to anatomical reasons, would be *less* of a concern.

Although the present study was admittedly motivated by the recent alarming news of clinically failing MoM prostheses, it still serves as an additional validation of the HUT-4 test method. Steep angle caused high MoM wear, which is known to occur clinically [3,17,18]. Another recent validation of the HUT-4 was the fact that a steep angle (60°) did not increase the wear of the polyethylene cup [19]. In the future, the available hip simulator capacity should definitely be utilized more systematically for thorough evaluations of new designs prior to clinical trials so that the likelihood of clinical disasters could be reduced. A true collaboration between university tribologists, orthopaedic industry, regulatory agencies and orthopedists would undoubtedly be worth pursuing.

The Durom cup has been disappointing in some clinics for reasons unrelated to the tribology of the Metasul MoM bearing couple, the use of which is not restricted to the Durom design. The high early revision rates of the Durom cups seem to be caused by a poor initial fixation, which prevents the desired bone ingrowth to the porous titanium surface [20]. The cup in question was a type sold in the USA and it was somewhat different from the present one, the universal type, with respect to the titanium coating. If there is relative motion at the cup-bone-interface, titanium and bone particles may be released and caught between the CoCr bearing surfaces damaging them. In such a case, the fixation failure causes increased friction and wear. The need for revision is inevitable, but in order to learn from the unfortunate cases for future improvements, it is important find out the causality of the events. In the present tests, the fixation surface was deliberately covered by bone cement as its behaviour was outside the scope of the study. Even the conical fixation surfaces of the head were isolated from the test by silicone sealant because the possible fretting corrosion at this interface [21–23], if considered important, would be a subject of a separate study.

5. Conclusions

The tribological behaviour of the large-diameter metal-on-metal hip prostheses appears to be strongly dependent on the position of the acetabular cup. The large-diameter Metasul CoCr-on-CoCr prosthesis, as studied with the HUT-4 hip joint simulator, shows excellent tribological behaviour, low friction and low steady-state wear rate, if the cup is in the correct position. However, a steep position of the cup exceeding a critical value of 60 degrees leads to an asymmetric contact area, boundary lubrication at best, and considerably higher wear rates. These findings are in agreement with clinical studies of contemporary large-diameter MoM prostheses, in which correct positioning of the cup is the key parameter to assure good clinical results.

Conflict of interest statement

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

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Table 1. Position of acetabular cups in hip simulator tests. Direction of load was vertical.

Test	Abduction angle (degrees)	Anteversion angle (degrees)	Angle of rim plane to horizontal plane, 'effective inclination' (degrees)	Distance from point of load application to edge of bearing surface of cup (mm)
P	45	20	48	15.7
1	45	20	48	15.7
2	55	35	63	8.8
3	58	38	66	7.5

Table 2. Wear of 52 mm Metasul prostheses in tests of 3.3 million cycle duration.

Test	Running-in wear (mm^3)	Steady-state wear rate ($mm^3/10^6$ cycles)	Correlation coefficient of linear regression R^2	Wear factor (mm^3/Nm)
P	0.75	0.08	0.9893	1.43×10^{-9}
1	0.45	0.11	0.9936	2.07×10^{-9}
2	3.75	1.58	0.9764	2.92×10^{-8}
3	7.69	10.6	0.9860	1.95×10^{-7}

Table 3. Surface roughness Ra (µm) of bearing surfaces, mean ± SD.

Test	Component	Original	After test, centre of contact area
P	Head	0.008 ± 0.001	0.010 ± 0.001
	Cup	0.010 ± 0.001	0.009 ± 0.001
1	Head	0.006 ± 0.0003	0.009 ± 0.001
	Cup	0.007 ± 0.001	0.010 ± 0.0004
2	Head	0.006 ± 0.0004	0.025 ± 0.001
	Cup	0.010 ± 0.001	0.013 ± 0.001
3	Head	0.006 ± 0.0002	0.077 ± 0.030
	Cup	0.006 ± 0.001	0.020 ± 0.002

Figure captions

Figure 1. Preliminary test ready for start. Lubricant chamber is filled with fresh, diluted calf serum lubricant. Cup position is 45° abduction and 20° anteversion. Direction of loading is vertical. Note load cell, linear bearing (‘loading guide’), and universal joint that makes cup self-centring on head.

Figure 2. Fixation surface of Durom cup. Porous Protasul-Ti coating, flattened pole, and flare with sharp fins.

Figure 3. From left to right, specimens of tests 1, 2 and 3 in HUT-4 simulator shown here without lubricant chambers. Note different cup positions implemented by cementing. Inclinations of rim plane relative to horizontal loading plane are 48°, 63° and 66°, respectively.

Figure 4. From left to right, cups 1, 2 and 3 after completion of test. Visible damage is in agreement with measured wear.

Figure 5. Optical micrographs from centre of contact area of femoral heads, taken after completion of test. Flexion-extension direction is horizontal. (a) Preliminary test, (b) test 1, (c) test 2, (d) test 3. General observation of criss-cross scratching is similar to that observed in clinical retrieval studies [24].

Figure 6. Scanning electron micrographs from contact area of acetabular cups, taken after completion of test. (a) cup 1, criss-cross scratching, (b) cup 1, close-up of scratch, (c) cup 2,

abrasive pitting, (d) cup 3, abrasive wear marks.

Figure 7. From left to right, lubricant chambers of tests 1, 2 and 3 after 6 days (550 000 cycles) of running, at completion of test, showing colour changes in lubricants. Pneumatic loading cylinders are visible on top.

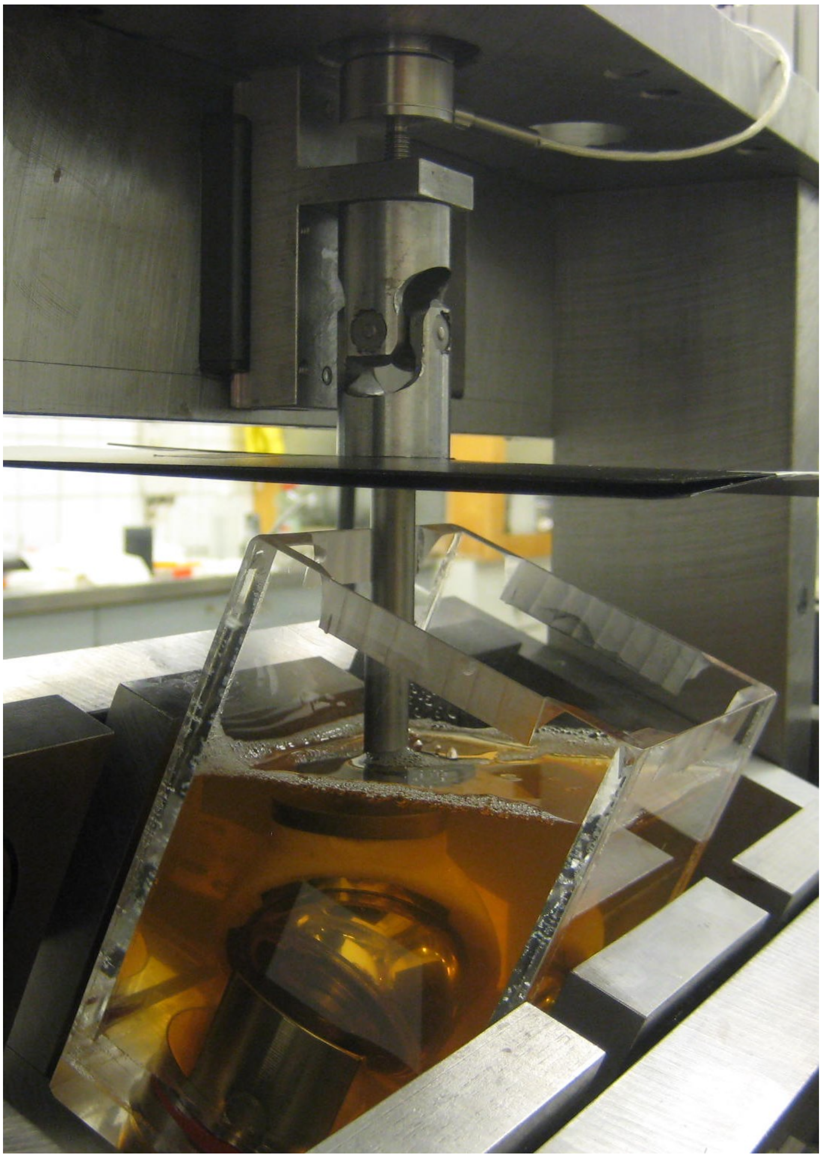

Fig. 1

Fig. 2

Fig. 3

Fig. 4

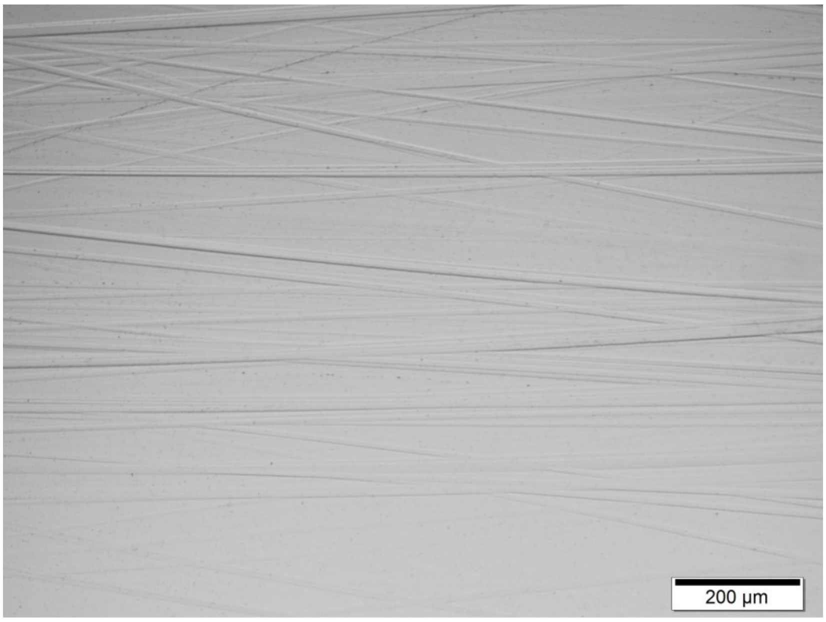

Fig. 5a

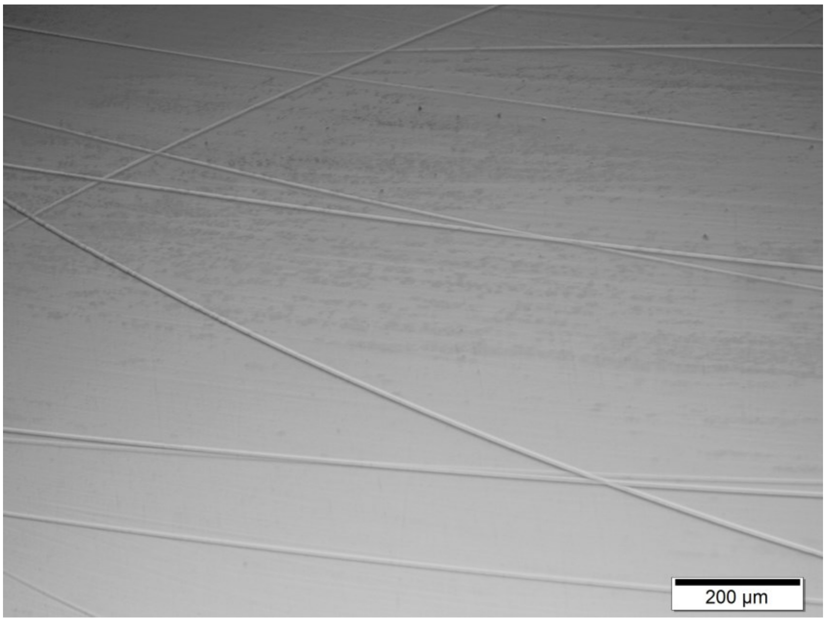

Fig. 5b

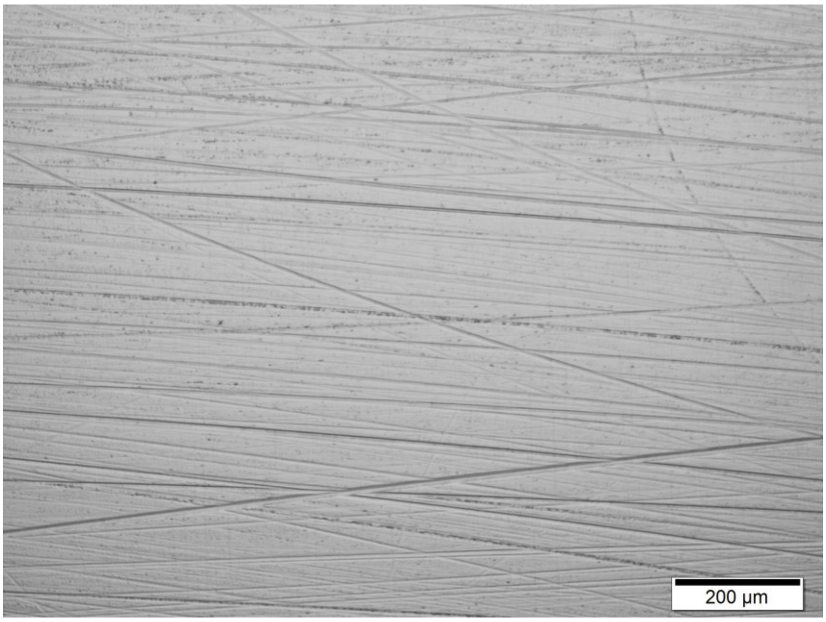

Fig. 5c

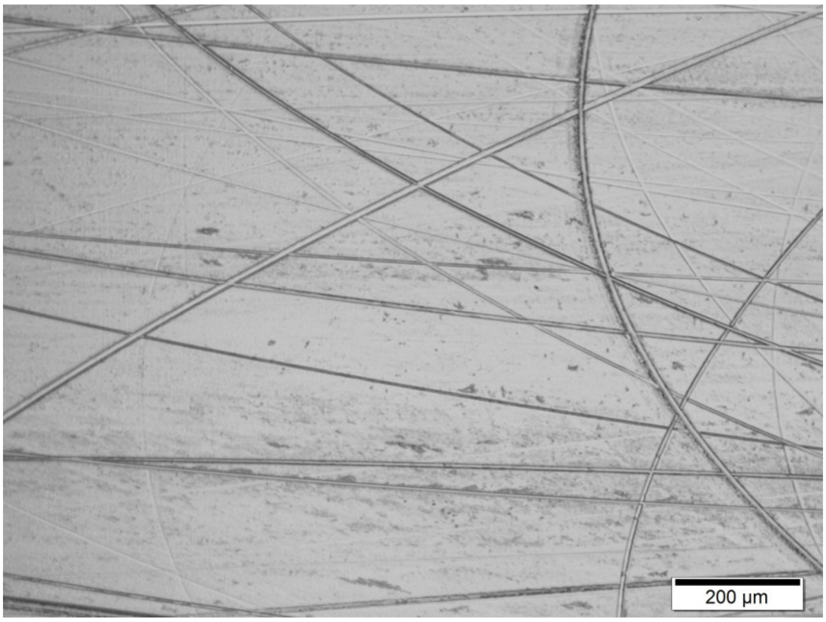

Fig. 5d

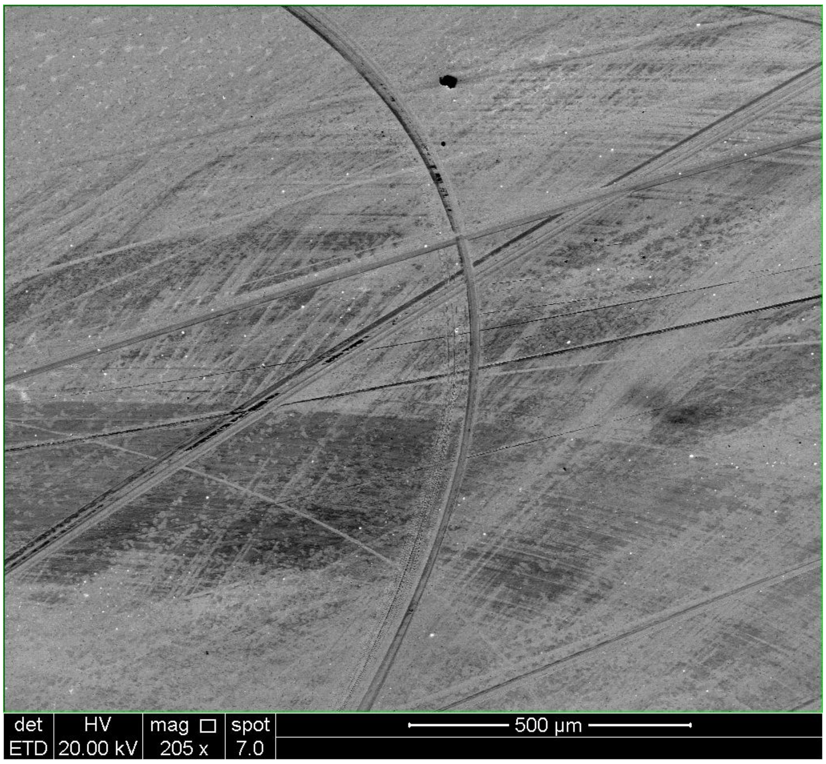
det
HV
mag ☐
spot
500 μm
ETD
20.00 kV
205 x
7.0

Fig. 6a

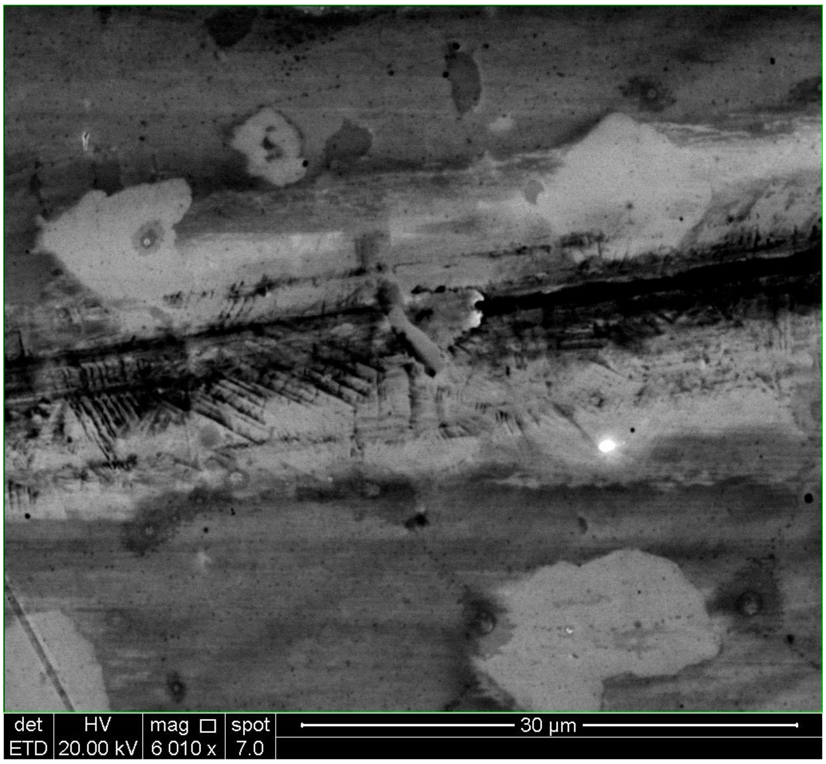
det
HV
mag ☐
spot
30 μm
ETD
20.00 kV
6 010 x
7.0

Fig. 6b

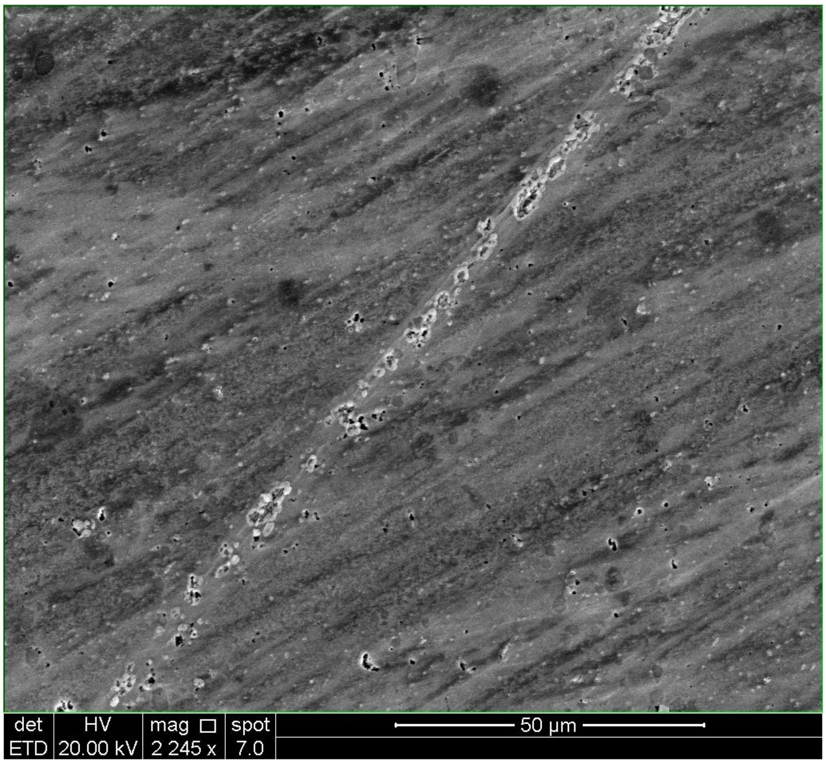
det
HV
mag ☐
spot
50 μm
ETD
20.00 kV
2 245 x
7.0

Fig. 6c

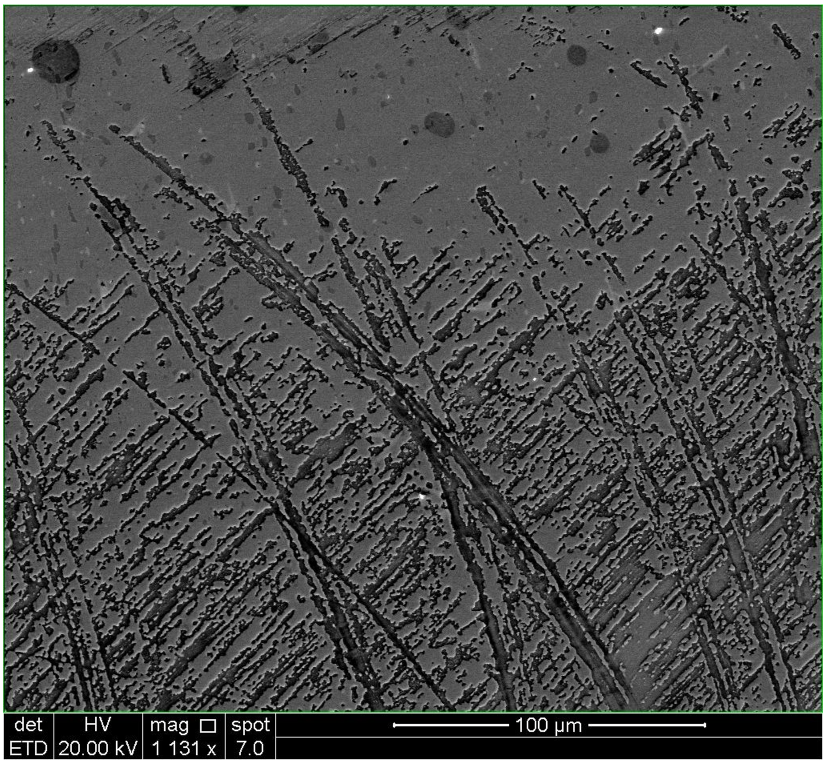
det
HV
mag ☐
spot
100 μm
ETD
20.00 kV
1 131 x
7.0

Fig. 6d

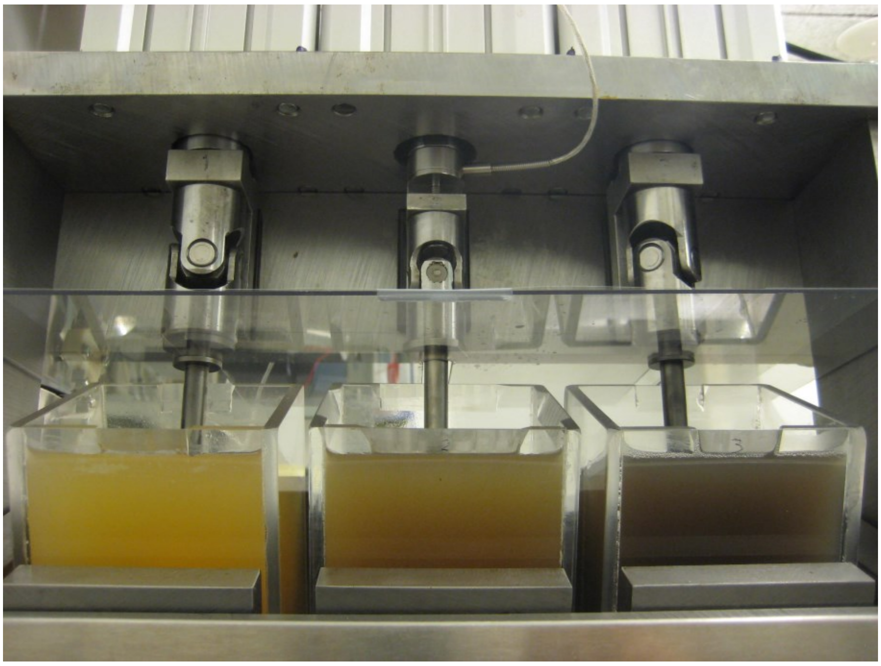

Fig. 7