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Effect of Lubrication Conditions on the Wear of UHMWPE with Noncyclic Motion and Load

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Abstract

In orthopaedic tribology, one of the most debated issues is the optimal lubricant. Many different types, concentrations, additives and temperatures of serum-based lubricants are in use. With the multidirectional RandomPOD wear test device, several different lubrication conditions were studied for conventional, gamma-sterilized ultrahigh molecular weight polyethylene (UHMWPE) against polished CoCr. The conditions included dry, deionized water, phosphate buffered saline (PBS) and Alpha calf serum. Only with serum, wear was similar to that known to occur clinically. It was highly linear and of substantial magnitude. Polyethylene surface was burnished and no macroscopic wear debris was produced. The absence of polyethylene transfer, however, was not limited to serum lubrication only. With PBS, no transfer occurred and the same held true occasionally with dry sliding. An increased temperature, 37 °C, as opposed to 20 °C, of 1:1 diluted serum was found to increase the standard deviation of wear factor 2.7 to 4.4-fold, depending on whether an antimicrobial additive, NaN_3, was absent or present (0.2 %). In the absense of NaN_3, the mean wear factor at 20 °C was 2.9-fold higher than at 37 °C. In the presence of NaN_3, the corresponding difference was 1.8-fold. A one-day vs. a 6-day serum change interval resulted in wear factors not statistically different from each other. The same held true for the wear factors with undiluted serum vs. serum diluted 1:1. The lubrication conditions appear to have significant effects in wear studies of orthopaedic implant materials and so they need to be carefully chosen.

Keywords: Biomedical devices; Lubrication environment; UHMWPE; Noncyclic pin-on-disk

Introduction

In the wear testing of prosthetic joints and of their materials, the most commonly used lubricant is bovine serum diluted with deionized water (Kurtz *(1)*). The protein concentration of the diluted serum is usually 20 to 30 g/l, close to that of synovial fluid in prosthetic joints (Yao, et al. *(2)*). Proteins and a multidirectional motion are prerequisites for the reproduction of realistic wear mechanisms and wear rates (Wang, et al. *(3)*; Saikko *(4)*; Burroughs and Blanchet *(5)*; Brown and Clarke *(6)*; Hua, et al. *(7)*). One contemporary problem with hard-on-hard hip bearings is squeaking (Mai, et al. *(8)*; Hua, et al., *(9)*), which may indicate that the in vivo articulation is sometimes poorly lubricated. Recently, clinical evidence was published showing that from 7 of 17 patients with a metal-on-polyethylene prosthetic hip no synovial fluid was found when aspirated (Eltit, et al. *(10)*). Moreover, some patients may have poorly lubricating synovial fluid (Mazzucco and Spector *(11)*). Retrieval studies show that in the metal-on-polyethylene bearings, the femoral head never has polyethylene transfer (McKellop, et al. *(12)*). This has generally been taken as an indication that the prosthetic joints are always lubricated by a synovial fluid. It is still possible that the absence of polyethylene transfer is not a proof of a well-functioning, protein-based biologic lubrication. It is logical to think that if the articulation was well lubricated, squeak would be unlikely to take place with any bearing material combination. Therefore, in addition to serum lubricated tests, dry, and water and saline lubricated pin-on-disk tests were run in the present study with conventional ultrahigh molecular weight polyethylene (UHMWPE). This was done to see whether polyethylene transfer is prevented by protein-based lubrication only, and to study the UHMWPE wear and friction behavior under these conditions. Heavy polyethylene transfer has been observed with distilled water and saline in reciprocating pin-on-disk tests (McKellop, et al. *(13)*) whereas dry conditions have seldom been studied.

In long-term wear testing, microbial growth inevitably takes place in serum. If the serum bulk temperature is 37 °C, the microbial growth is likely to be faster compared with room temperature. Microbial growth may affect the lubrication and consequently wear. In the ASTM F732 standard (*(14)*, sections 5.2.4 and 7.2) and ISO 14242-1 standard (*(15)*, sections 5.1 and 7.6), a test temperature of 37 °C and the addition of an antimicrobial agent, sodium azide (NaN_3) are recommended. However, scientific publications in which the necessity of the 37 °C temperature and the addition of NaN_3 have been shown are lacking. In fact, NaN_3 has been shown to be ineffective in the retardation of microbial growth, and an antibiotic-antimycotic has been recommended instead (Brandt, et al. *(16)*; Brandt, et al. *(17)*). It is even possible that NaN_3 itself affects the wear of UHMWPE. In tests run at 20 °C with 1:1 diluted Alpha calf serum, highly realistic UHMWPE wear has been produced without additives (Saikko *(18)*). Alpha calf serum is commonly used as a lubricant in orthopaedic tribology and it was originally introduced due to its slower protein precipitation compared with sera of different origins (Wang, et al. *(3)*). To gain more insight into these issues and to see whether justifications for the recommendations of the standards regarding the temperature of 37 °C and the addition of NaN_3 can be found, comparative pin-on-disk tests were run in diluted Alpha calf serum both at 20 °C and at 37 °C with and without NaN_3.

Biological lubricants unavoidably degrade in vitro by protein denaturation (Heuberger, et al. *(19)*). The lubricant change interval used by researchers varies (Kurtz *(1)*). With 1 Hz testing frequency, it is common to change the lubricant every half a million cycles (6 days) or so, but it is possible that a more frequent change interval affects the wear behavior of UHMWPE. In one test, the serum was changed daily, and the wear was compared with that obtained using a 6-day lubricant change interval. Since the standards do not specify the protein concentration (ISO 14242-1, section 5.1 only recommends a minimum value of 17 g/l despite the fact that a typical concentration found in the synovial fluid of prosthetic joints is 30 g/l (Yao, et al. *(2)*)), undiluted serum was included in the tests as well.

It was hypothesized that (a) the absence of polyethylene transfer is not limited to protein-based lubrication only, (b) the increase of temperature from 20 °C to 37 °C and the addition of NaN_3 and (c) the lubricant change interval and the protein concentration have measurable and significant effects on the UHMWPE wear behavior.

Materials and methods

The computer-controlled, 16-station RandomPOD wear test system has been described in detail elsewhere (Saikko and Kostamo *(20)*; Saikko and Kostamo *(21)*; Saikko, et al. *(22)*). Briefly, the pin translated biaxially and noncyclically relative to the disk so that the slide track remained within a circle of 10 mm diameter. The sliding velocity varied between zero and 31.4 mm/s, with a mean of 15.5 mm/s. The acceleration varied from zero to 300 mm/s^2. Its derivative was continuous, and therefore the motion was smooth even in reversals. The direction of sliding changed continually (mean 500°/s) relative to the pin, which has been shown to be important in the simulation of UHMWPE wear mechanisms with respect to implant applications (Wang, et al. *(3)*; Saikko *(4)*). The load varied noncyclically between zero and 142 N, with a mean of 74 N. Hence the nominal contact pressure varied between zero and 2.2 MPa. The lubricant bulk temperature was controlled by circulating water that surrounded the test chambers, each of which contained 18 ml of lubricant.

The type of conventional UHMWPE studied was gamma-N_2-sterilized GUR 1020 (ISO 5834-1/-2). The diameter of the cylindrical UHMWPE pins was 9.0 mm, and their length was 14.0 mm. The counterfaces were polished, CoCr alloy (ISO 5832-12) Protasul-20 disks. Their arithmetical mean surface roughness S_a was 0.009 µm ± 0.001 µm, measured with a white light interferometry profilometer. Their diameter was 28 mm and thickness 10 mm. The contact geometry was flat-on-flat with a nominal contact area of 63.6 mm^2.

The following lubrication conditions were covered by the tests. n = number of pins, serum was HyClone Alpha Calf Fraction SH30212.03, and deionized water was ultrapure, Milli-Q grade.

1. Dry (n = 4).

2. Deionized water at 20 °C (n = 4).

3. Phosphate buffered saline (PBS), HyClone SH30256.02 at 20 °C (n = 4).

4. Undiluted serum at 20 °C (n = 4).

5. Serum diluted 1:1 with deionized water at 20 °C, changed daily (n = 4).

6. Serum diluted 1:1 with deionized water at 37 °C (n = 8).

7. Serum diluted 1:1 with deionized water at 37 °C, containing 0.2 % NaN_3 (n = 8).

8. Serum diluted 1:1 with deionized water at 20 °C, containing 0.2 % NaN_3 (n = 8).

9. Serum diluted 1:1 with deionized water at 20 °C (n = 16), reference data from (Saikko and Kostamo *(21)*).

The total protein concentration of the undiluted serum was 40 g/l. The test duration was 679 to 884 hours. The test was stopped once a week for a gravimetric wear measurement of the pins (Saikko *(18)*) and the replacement of the used lubricant. The wear rate (mg/km) was obtained by linear regression for those pins that showed steady, uniform wear. The first wear measurement was preceded by a running-in phase of 5 to 6 days, which was omitted in the regression. The wear factor k (mm^3/Nm) was obtained by multiplying the wear rate $\dot{w}$ by the sliding distance between the first and the last measurement points s, and by dividing by the density (ρ = 0.935 mg/mm^3) and by the integral of the product of the instantaneous load L and the incremental sliding distance ds between the first and the last measurement points: $k = \dot{w}s/(\rho \int L\mathrm{d}s)$. The product was numerically integrated at a frequency of 100 Hz. When the wear was not linear, the mean wear factor and its standard deviation were calculated from the increment wear values between consecutive wear measurement points, to allow comparison. The *t*-test was used to assess whether differences in mean wear factors were statistically significant. A p-value of 0.05 was used as the threshold.

After optical microscopy, friction tests were run for the worn specimens with the multidirectional, circular translation pin-on-disk (CTPOD) device (Saikko *(23)*), as the RandomPOD has no friction measurement. The lubricants and temperatures were as in the wear tests. The pin translated, without rotation, along a circular track of 10 mm diameter on the disk at a constant sliding velocity of 31.4 mm/s. The disk was supported by low-friction ball bearings. The rotation of the disk was prevented by a load cell, from the signal of which the frictional force was calculated. The load was constant, 74 N, which was the mean value of the wear tests. Each friction test was run for 2 hours after which the steady state frictional force value was recorded.

Results

In the dry and water lubricated sliding, the wear was irregular (Figs. 1a and 2). The weight change between two consecutive mesurements often did not exceed 0.01 mg, which was the resolution of the balance, but sometimes a steep increase of the wear rate occurred. The UHMWPE transfer to the CoCr counterface was usually mild in dry sliding (Fig. 3a), and moderate with water lubrication (Fig. 3b). One disk of the dry tests showed no transfer. In the dry sliding, the wear debris was powder-like and in water lubrication, large shreds formed. Abrasive criss-cross wear marks were observed on the pins (Figs. 4a and 4b). With PBS, no transfer took place and the wear was virtually unmeasurable. The total weight changes of the pins were of the order of 0.01 mg. The original machining marks were still visible after the tests (Fig. 4c).

In all serum lubricated tests, wear was highly linear (Figs. 1b to 1g). Macroscopic wear debris was absent. No polyethylene transfer, scratches or any other type of damage were observed on the CoCr counterfaces in any test with serum (Fig. 3c). ‘Outlier’ polyethylene wear rates were still sometimes observed (Figs. 1b to 1g). All serum lubricated pins were burnished (Fig. 4d). In addition, formation of some protuberances with a typical height of 20 μm, measured by optical microscopy, was observed on the edge of pins lubricated by diluted serum (Fig. 4e). All serum-based lubricants visually turned opaque and light yellow-brown in color during testing.

At 37 °C, the mean wear factor k with NaN_3 was 2.4-fold compared with that obtained without additives (Fig. 2, conditions 6 vs. 7). The SD values were 29 per cent and 18 per cent of the mean. Despite the large SD values, the difference was statistically significant ($p = 0.0006$). At 20 °C, the corresponding difference was 1.5-fold (conditions 8 vs. 9), and the difference was statistically significant ($p = 0.003$). The SD at 20 °C with NaN_3 was 21 per cent of the mean. In the absence of NaN_3 the mean wear factor at 20 °C was 2.9-fold compared with that obtained at 37 °C (conditions 6 vs. 9) and the difference was statistically significant ($p = 5 \times 10^{-13}$). In the presence of NaN_3 the corresponding difference was 1.8-fold (conditions 7 vs. 8) and the difference was statistically significant ($p = 0.0002$). The difference in k between 37 °C with NaN_3 and 20 °C without NaN_3 (conditions 7 vs. 9) was not statistically significant ($p = 0.14$).

The difference in k between undiluted and 1:1 diluted serum (conditions 4 vs. 9) was not statistically significant ($p = 0.27$). The same held true in the comparison of k between diluted calf serum changed daily and that changed every 6 days (conditions 5 vs. 9) ($p = 0.30$).

The coefficient of friction μ varied widely (Fig. 5). One dry couple with virtually unworn topography on the pin had an exceptionally high μ, 0.45. With another dry couple, the mild transfer on the disk was removed during the 2 h friction test. The PBS lubricated tests with virtually unworn pin topography showed the lowest average μ, 0.03, and the second lowest was that obtained with water, 0.04. With all serum-based lubricants, μ was on a substantially higher level, from 0.07 to 0.27. Typically, the presence of protuberances reduced μ. The least protuberances were observed under condition 4 and the most under condition 5 (Fig. 5). The observed large difference in μ was not reflected on wear though, see previous paragraph.

Discussion

The RandomPOD has earlier been shown to produce a realistic wear simulation for the prosthetic hip with UHMWPE against CoCr (Saikko and Kostamo *(21)*), including the wear particle size (Saikko, et al. *(22)*), despite the seeming limitation of the flat-on-flat contact that may affect the lubricant ingress. Hence with its high testing capacity, 16 stations, the RandomPOD proved to be an efficient, useful tool in the study of lubricants for orthopaedic tribology. A mean clinical wear factor, 2.1×10^{-6} mm^3/Nm (range as wide as 1×10^{-7} mm^3/Nm to 1×10^{-5} mm^3/Nm), for Charnley total hip prostheses with a conventional UHMWPE acetabular cup has been obtained (Hall, et al., *(24)*). The present mean wear factors with serum-based lubricants were not far from the clinical mean. However, the limitation of the study by (Hall, et al., *(24)*) in the present comparison is that the Charnley design used exceptionally small femoral heads (22 mm diameter) and types of UHMWPE that are no longer available on today's market. The measurement methods for retrieved cups have improved considerably in the recent years (Langton, et al. *(25)*; Uddin *(26)*; Ranuša, et al. *(27)*). A problem still remains that the motion and loading history of the prostheses is unknown and would need to be estimated. Probably for this reason clinical wear factors for contemporary designs unfortunately cannot be found from literature for comparison with pin-on-disk results. Clinical wear rates expressed as mm^3/year are not helpful in this sense.

It may be speculated that the lack of boundary lubrication leads to the adhesion of polyethylene to the harder counterface which is typical of adhesive wear. The difference between deionized water and PBS in this sense was striking and quite unexpected. It was also interesting to note that the water lubricated tests resulted in more transfer than the dry conditions (Figs. 3a and 3b). After all, the true contact temperatures on the polyethylene pin must have been considerably higher in dry tests. One limitation of the study therefore needs to be discussed. The lubricant bulk temperature was controlled by the circulating cooling water, but the actual contact temperatures were unknown. Especially in the dry sliding, frictional heating of the contact may have been substantial, because only the bottom of the CoCr disk effectively transferred heat to the cooling water and to the motion plate (Lewicki and Van Citters *(28)*). Frictional heating may change the properties of UHMWPE in a way not similarly possible clinically. In dry tests, the increased temperature may have been the reason for the fact that transfer was so mild compared with water lubrication, despite the fact that μ was so high. The surprising observation that PBS prevented wear was particularly interesting in light of the recent finding by (Guenther, et al. *(29)*). They found in cyclic multidirectional pin-on-disk tests that the wear of moderately crosslinked polyethylene reduced manyfold when Alpha calf serum was diluted by PBS instead of deionized water as recommended in the ASTM F732 *(14)* and ISO 14242-1 *(15)* standards.

With serum lubrication, polyethylene transfer and macroscopic wear debris were absent. Only with serum lubrication, the wear was highly linear (Figs. 1b to 1g). The correlation coefficient of linear regression R^2 was 0.9963 ± 0.0052 (n = 48). Paradoxically, although the presence of proteins in the lubricant prevented the polyethylene transfer, apparently by a boundary lubrication mechanism, their presence led to considerable wear, and to a substantially higher μ, compared with that measured with deionized water and PBS. A similar large difference was also found in a reciprocator study (McKellop, et al. *(13)*). The present finding was also in agreement with unidirectional tribometer studies by (Yao, et al. *(30)*; Fang, et al. *(31)*; Safari, et al. *(32)*). The presence of proburances probably facilitated lubricant ingress and reduced μ. This was conspicuous especially in the comparison of conditions 4 vs. 5 that showed a large difference in μ (Fig. 5), but surprisingly not in k (Fig.

2). The limitation of the present friction measurements was that they were not done with the same device that was used in the wear tests. Hence the friction values may not closely represent conditions that prevailed during the wear tests. However, both devices were multidirectional and all other test conditions were kept as similar as possible, including the lubricant temperature.

The wear in the presence of a biologic lubricant is manifested as the release of numerous microscopic wear particles that unfortunately are biologically most active and cause bone resorption (Harris *(33)*). Hence boundary lubrication by a biologic lubricant is not necessarily advantageous with UHMWPE. Nevertheless, the absence of transfer (Fig. 3c) and of macroscopic wear debris, and the burnishing of the UHMWPE bearing surface (Fig. 4d) are important validation criteria for the wear simulation of the clinical wear of total hip prostheses (McKellop, et al. *(12)*; Jasty, et al. *(34)*; Edidin, et al. *(35)*; Pourzal, et al. *(36)*). It should be noted that the successful use of serum in biotribology testing is solely based on empiric experience, through trial and error, during the past few decades (Kurtz *(1)*). The biochemistry of serum as a boundary lubricant with various prosthetic joint materials is still largely unknown due to lack of research.

The basic observations of the present study that the wear rate decreased with increasing temperature and increased by the addition of NaN_3 indicate that the microbial growth tends to decrease wear. This was based on the assumption that NaN_3 was effective in retarding microbial growth, which however was not found to be the case in the tests run by another research group (Brandt, et al. *(16)*; Brandt, et al. *(17)*). The effect of NaN_3 on the increase of wear in the present tests was so strong both at 20 °C and 37 °C (Fig. 2) that undoubtedly NaN_3 had a role of some kind. It is also possible that the presence of NaN_3 itself increases the UHMWPE wear. On the other hand, the lower wear at 37 °C may be related to thermal degradation of proteins, as suggested by Liao, et al. *(37)*, and later corroborated by an albumin cleavage study by Dwivedi, et al. *(38)*. They found the lowest wear and highest μ with cleavaged albumin, which is in agreement with the present results regarding conditions 6 vs. 9 (Figs. 2 and 5). Brandt, et al. *(16)* found that the UHMWPE wear rate with NaN_3 was significantly higher than with an antibiotic-antimycotic additive. Their conclusion was that this was due to the better ability of the antibiotic-antimycotic to retard microbial growth, as bacteria harmfully affect the boudary lubrication by proteins. It should still be noted that the role of proteins may not only be a boundary lubricant, preventing polyethylene transfer. They may also be the primary cause of wear (by an unknown mechanism), as compared with the PBS lubrication that prevented wear altogether, and also prevented transfer. Hence the role of proteins appears ambiguous. The significantly higher friction with proteins in general compared with PBS (Fig. 5) may provide one explanation for the fundamental difference in the wear behavior. Dwivedi, et al. *(38)* discussed the effect of uncleaved albumin so that the albumin bonding increases the shear forces on the contact increasing polyethylene wear. The salt concentration of serum is close to that of PBS, and so it may actually be the osmolality that explains the absence of transfer with serum, not proteins. Deionized water with no dissolved salts could not prevent the transfer. The fact that substantial but erratic wear took place with deionized water was apparently caused by the rough transfer layer. After the transfer layer was formed, the wear became abrasive and of a type that does not occur clinically as the wear debris was macroscopic, consisting of large shreds. The standard recommendation that serum should be diluted by deionized water, which reduces the osmolality of the lubricant, is likely to warrant further attention in orthopaedic wear testing (Guenther, et al. *(29)*).

The difference in the wear factor k obtained with diluted calf serum changed daily vs. every 6 days was not statistically significant ($p = 0.30$). This indicates that the daily change of the lubricant is unnecessary. A 6-day lubricant change interval may bring substantial cost savings in joint simulator tests which require large quantities of serum, since a high-quality serum, such as that used in the present study (triple 0.1 µm sterile filtered Alpha Calf Fraction), is fairly expensive. In a knee simulator study, shortening of the replacement interval from 500 000 to 150 000 cycles nearly doubled the wear rate with n = 3 (Reinders, et al. *(39)*). In their tests NaN_3 was however present in the lubricant (diluted calf serum, protein concentration 20 mg/ml) which may partly explain the difference in the results. Secondly, the nonconforming contact with a moving contact stress field relative to the polyethylene component of a prothetic knee differs from the flat-on-flat contact used in the present tests.

Similarly, the difference in k between undiluted serum and 1:1 diluted serum was not statistically significant ($p = 0.27$). Hence, the protein concentration of 20 mg/ml appears to be sufficient, and the dilution brings cost savings as well. It exceeds the minimum value recommended by the ISO 14242-1 standard, 17 mg/ml *(15)*. In a hip simulator study with two tests for each condition, the wear rate decreased by 20 per cent as the protein concentration of the Alpha calf serum lubricant increased from 20 mg/ml to 40 mg/ml (Wang et al., *(40)*). The lubricant bulk temperature was not reported though.

The present results only partly resembled those obtained by (McKellop, et al. *(13)*). In their classic paper, the motion was linear reciprocation (average sliding velocity 83 mm/s), the wear surface area of the pin was 64 mm^2 and the nominal contact pressure was 3.45 MPa. The UHMWPE wear with serum was unrealistically low. The wear factor was approximately 9×10^{-9} mm^3/Nm. No transfer occurred with serum whereas heavy transfer occurred with both distilled water and saline. Compared with the transfer in (McKellop, et al. *(13)*), the present transfer in ion-exchanged water was however moderate, and no transfer occurred in the PBS. The type of saline was not specified. The present PBS was prepared with ion-exchanged water (similar to Milli-Q) with no calcium or magnesium. If calcium is not ion-exchanged, a calcium carbonate deposition may form, and this may visually be mistaken for polyethylene transfer. In the late 1970s it was not yet known that the discrepancy between the laboratory and clinical wear factor was not due to the pin-on-disk configuration itself, but due to the lack of multidirectional motion. It was later found that with multidirectional motion, a realistic wear simulation can be produced even with a simple pin-on-disk configuration, provided that serum is used as a lubricant (Wang, et al. *(3)*; Saikko *(4)*). It is possible that a transfer film reduces polyethylene wear by limiting polyethylene/metal interaction (Blanchet and Kennedy *(41)*) which may explain why the wear was usually lower in deionized water compared with dry sliding in the present study, even though more transfer occurred with water.

The circularly translating pin-on-disk (CTPOD) device (Saikko *(4)*; Saikko *(18)*) was a development from the reciprocator and the predecessor of the present RandomPOD. In the CTPOD, the resultant friction vector rotates about the loading axis at a constant angular velocity, 360°/s, relative to the UHMWPE specimen, thus making it multidirectional. In serum lubricated tests, this results in the burnishing of the polyethylene surface, production of microscopic wear particles, and wear factors that agree with clinical findings (Hall, et al., *(24)*). Pending the development of a synthetic, chemically stable replacement, serum is still the only lubricant, the use of which will lead to a clinically realistic wear simulation (Harsha and Joyce *(42)*; Scholes and Joyce *(43)*). Presently, the consensus of opinion in orthopaedic tribology is, on a general level, that the two principal prerequisites for a realistic wear simulation with prosthetic joint materials are (1) multidirectional motion and (2) serum-based lubrication. Regarding the type of multidirectional motion and the type of serum-based lubricant there are still many different views and practices. Undoubtedly, a substantial amount of more research is needed before consensus at a more detailed level will possibly be reached.

An advanced development from the CTPOD is the present noncyclic, computer-controlled RandomPOD with increased multidirectionality (Saikko and Kostamo *(20)*). The RandomPOD is the first biotribological test device with which the cyclic features in the relative motion and load are completely avoided. Hence the wear simulation is likely to be closer to the clinical reality as the numerous daily activities vary widely and thus they are not strictly repetitious (Fabry, et al. *(44)*; Valente, et al. *(45)*). The RandomPOD test is not related to any single daily activity, as joint simulator tests usually are. Instead, it was designed to be a general wear screening test intended to reproduce wear mechanisms of the prosthetic hip in a holistic manner. The flat-on-flat test configuration is naturally a limitation of the method, but simplifications are unavoidable in pin-on-disk testing. Although in the RandomPOD, the ranges of motion, velocity, acceleration and its derivative, and of load and its change rate are strictly limited, based on biomechanical literature, it is not possible to predict their values in a specific point of time by computational methods. Therefore, the motion and load of the RandomPOD, although they are not composed of white noise, can be considered *random with biomechanical relevance*.

In the earlier RandomPOD tests at 20 °C without additives, the standard deviation of the wear factor was 6.6 per cent of the mean (Saikko and Kostamo *(21)*). Some of the present SDs were surprisingly manyfold, 29 per cent at 37 °C with NaN_3, 21 per cent at 20 °C with NaN_3, and 18 per cent at 37 °C without NaN_3. The percentage refers to the height of the SD line relative to the height of the average bar in Fig. 2. In this sense, the results suggest that the test temperature of 37 °C and the addition of NaN_3 are not beneficial. The large variation may partly be due to the fact that at elevated temperatures, the biologic lubricant becomes unstable due to microbial growth and protein denaturation (Brandt, et al., *(16)*). If small differences, say, 5 per cent or less, in the mean wear factors between materials are to be determined using a *t*-test at a significance level of 0.05 with small n values (4 to 6), the SD should rather be 5 per cent of the mean at most, and by no means 10 per cent or higher as was common in the present study. In the SuperCTPOD validation study with gamma-sterilized UHMWPE (n = 100), the SD was 5.4 per cent of the mean in 1:1 diluted Alpha calf serum at 20 °C (Saikko *(18)*). The wear factor for the first time was shown to be normally distributed, which is a basic requirement for the use of the *t*-test.

Regarding the test temperatures, the RandomPOD results did not agree with those by (Cowie, et al. *(46)*). They found in a cyclic multidirectional pin-on-disk study that the UHMWPE wear at 20 °C was similar to that at 36 °C against CoCr. In the noncyclic RandomPOD tests, the wear factor at 20 °C was 2.9 times higher than that at 37 °C in the absence of NaN_3, and 1.8 times higher in the presence of NaN_3 (Fig. 2). Wimmer, et al. *(46)* used a cyclic multidirectional pin-on-disk device and different types of bactericide and fungicide (not NaN_3) in the newborn calf serum at 37 °C and found that the UHMWPE wear rate was six-fold lower compared with that in the serum with no additives. In the present study, the opposite was observed. The wear rate at 37 °C with NaN_3 was 2.4-fold higher than without it. These discrepancies may be attributable to the type of test, cyclic vs. noncyclic. Obviously, the effects of different serum additives on wear warrant further extensive studies, including joint simulator tests, in the field of orthopaedic tribology. Important trends currently are to find an effective replacement for NaN_3 (Wimmer, et al. *(47);* Brandt, et al. *(48)*), and to more accurately define the most clinically relevant lubricant for orthopaedic wear testing than is done in the current standards (Dwivedi, et al. *(38)*; Harsha and Joyce, *(42)*; Guenther, et al. *(49)*; Bortel, et al. *(50)*).

Conclusions

Polyethylene transfer and macroscopic wear debris, neither of which are seen clinically, were observed in dry and water lubricated sliding. The polyethylene transfer was absent not only with serum lubrication but also with PBS, the osmolality of which is close to that of serum. With PBS, no measurable wear took place, whereas in all serum-lubricated tests, i.e., in the presence of proteins, substantial and highly linear wear took place, the polyethylene bearing surface was burnished and macroscopic wear debris was absent. The observations regarding serum lubrication were in agreement with clinical findings. The wear factor decreased with increasing temperature and increased by the addition of NaN_3. The changes were statistically significant. The wear factor at 37 °C showed large variation, with and without NaN_3, and so did the wear factor at 20 °C with NaN_3, compared with the wear factor observed at 20 °C without NaN_3. Hence the temperature of 37 °C and the use of NaN_3 did not appear beneficial. The mean wear factors with undiluted serum vs. 1:1 diluted serum were not statistically different. The same held true for the daily change of diluted serum vs. a 6-day lubricant change interval.

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Figure captions

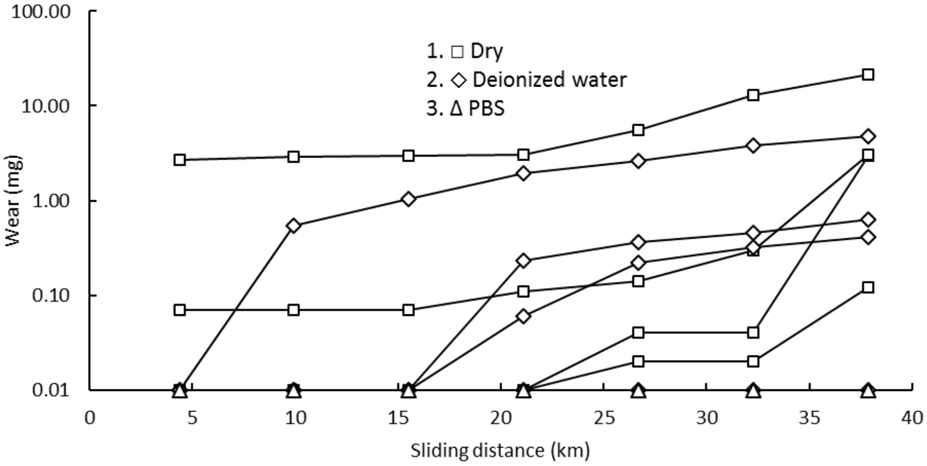
Figure 1. Variation of UHMWPE pin wear with sliding distance in RandomPOD tests, (a) □ dry, ◇ deionized water, and ∆ PBS, (b) undiluted serum at 20 °C, (c) serum diluted 1:1 at 20 °C, changed daily, (d) serum diluted 1:1 at 37 °C, (e) serum diluted 1:1 at 37 °C, with 0.2 % NaN_3, (f) serum diluted 1:1 at 20 °C with 0.2 % NaN_3, (g) serum diluted 1:1 at 20 °C. Note different y-axis scales. In (a), linear regression was not used due to erratic wear behavior or unmeasurable wear, and a minimum value of 0.01 mg was used in logarithmic y-axis as it was the resolution of the balance. Serum was HyClone Alpha Calf Fraction SH30212.03. Lubrication condition numbering as in Materials and methods.

Figure 2. UHMWPE wear factor, mean and standard deviation, in different lubrication conditions in RandomPOD tests. Serum was HyClone Alpha Calf Fraction SH30212.03.

Figure 3. Optical micrographs from centre of CoCr disks after (a) dry test, and tests lubricated by (b) deionized water and (c) diluted calf serum. (a) and (b) show mild and moderate polyethylene transfer, respectively, and (c) shows unchanged, polished surface with no transfer or wear marks, such as scratching or other damage, from test, which was similar to that observed with PBS.

Figure 4. Optical micrographs from worn UHMWPE pins after (a) dry test and test lubricated by (b) deionized water, both showing random criss-cross scratches due to multidirectional random motion, and lubricated by (c) PBS, showing original machining marks, and (d,e) diluted calf serum, on which burnishing is predominant feature together with occasional protuberances, (d) is from centre of pin and (e) from edge.

Figure 5. Coefficient of friction, mean and standard deviation, between UHMWPE and polished CoCr measured with multidirectional CTPOD device. Serum was HyClone Alpha Calf Fraction SH30212.03.



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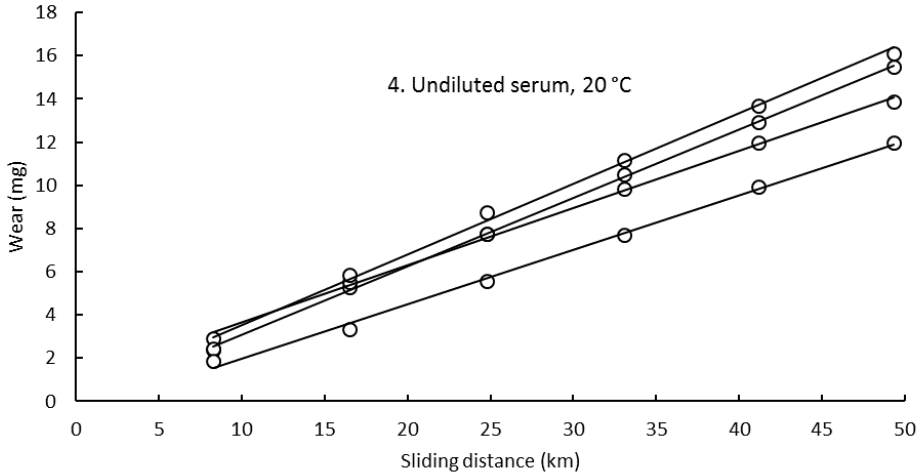

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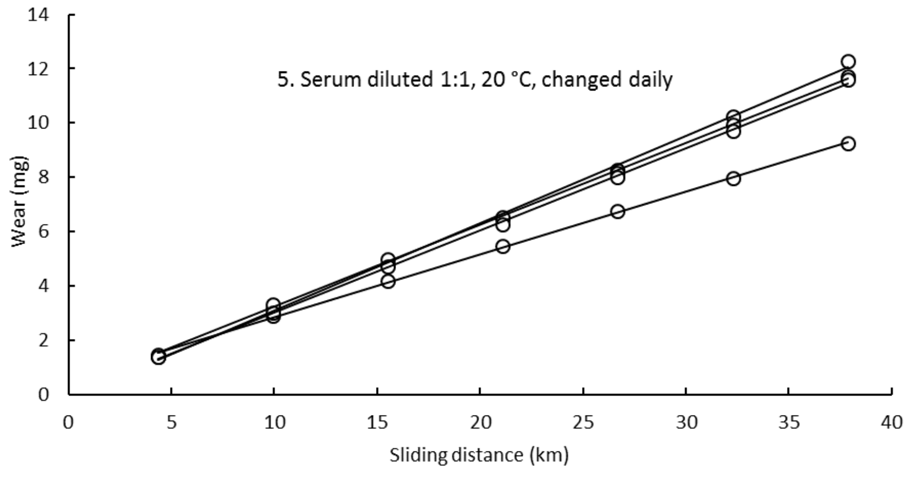

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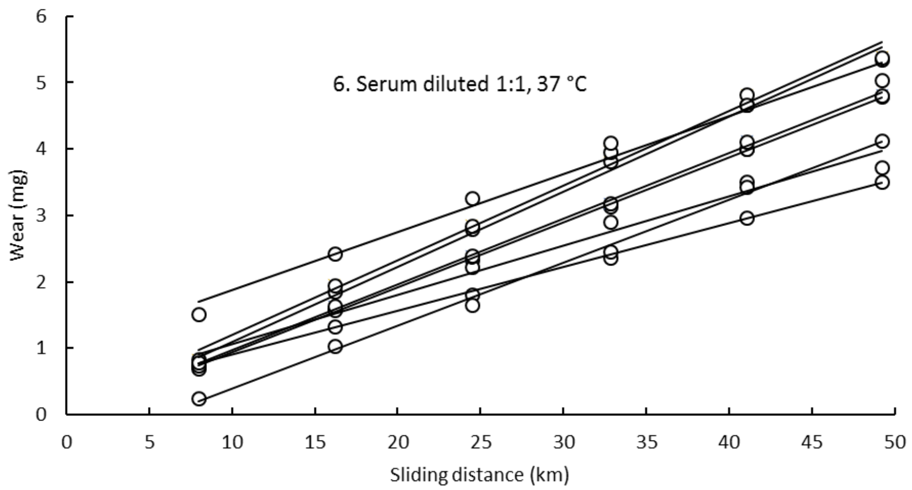

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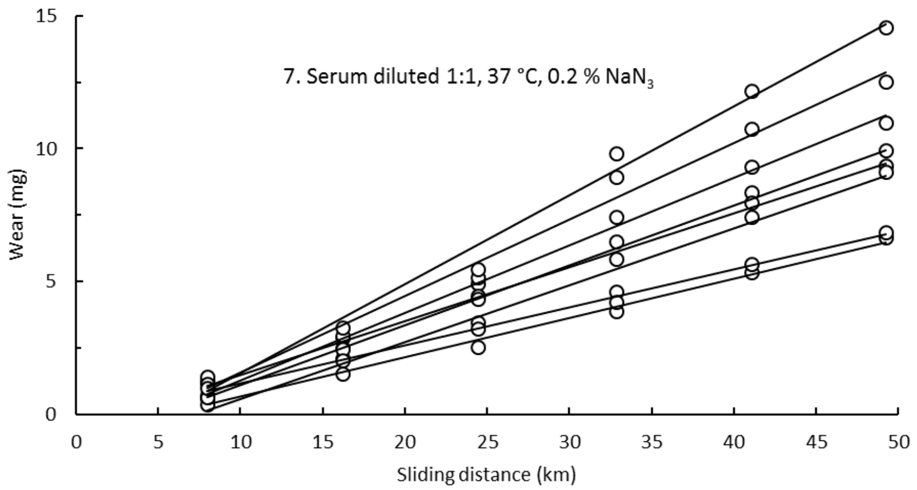

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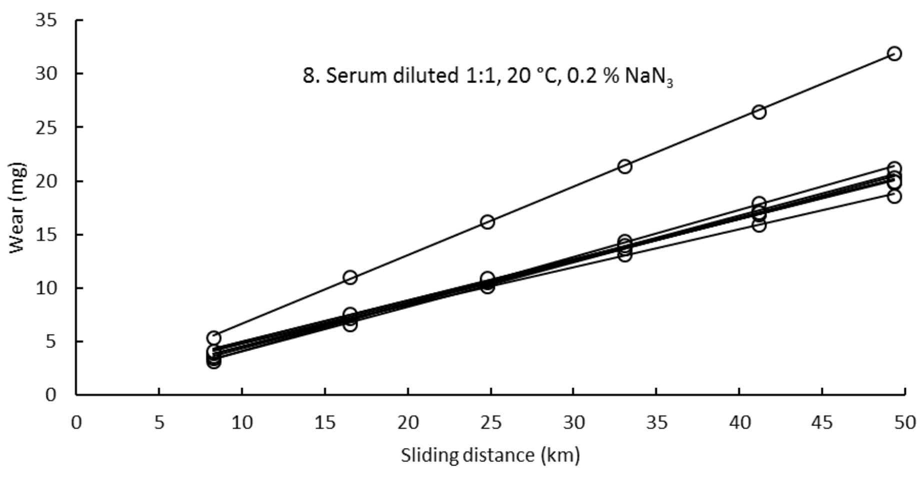

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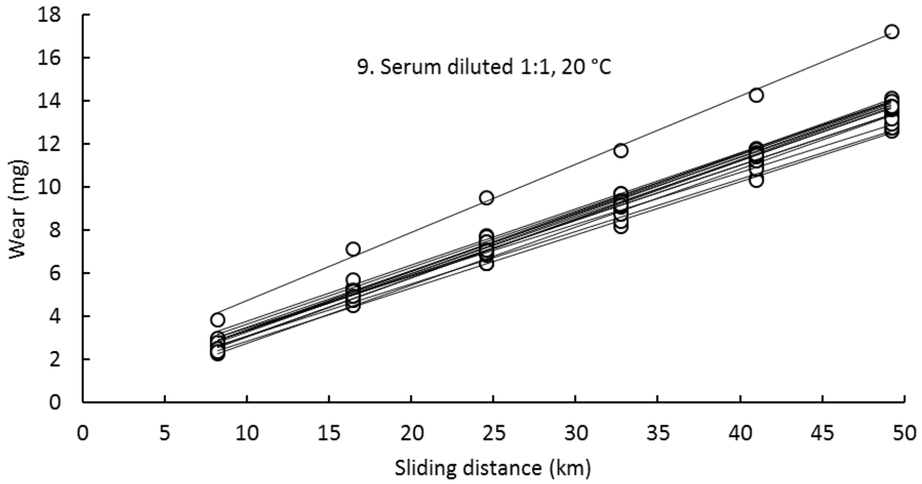

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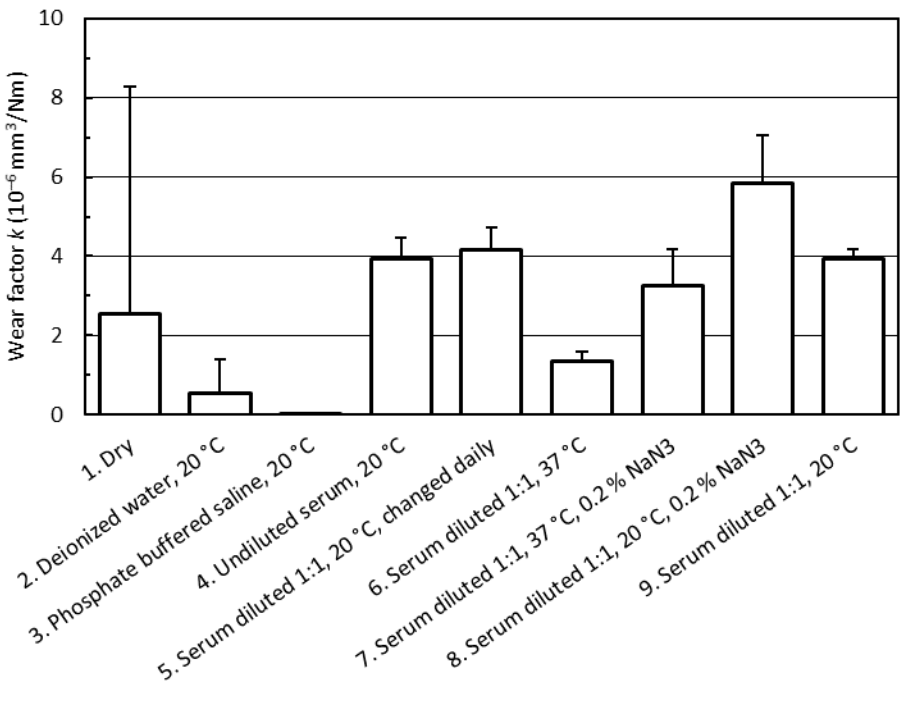

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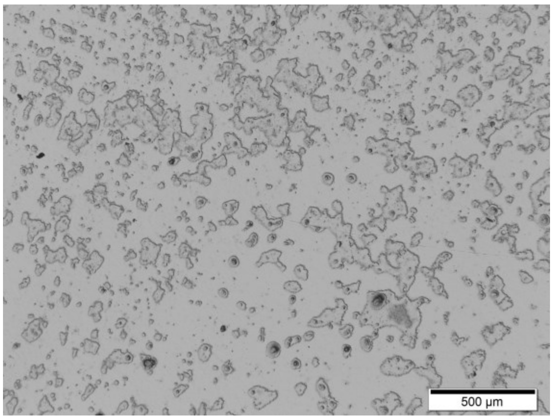

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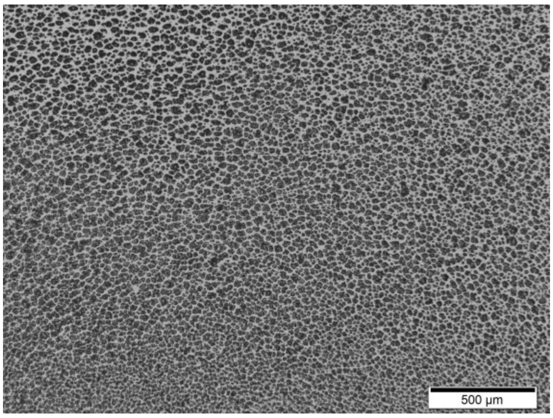

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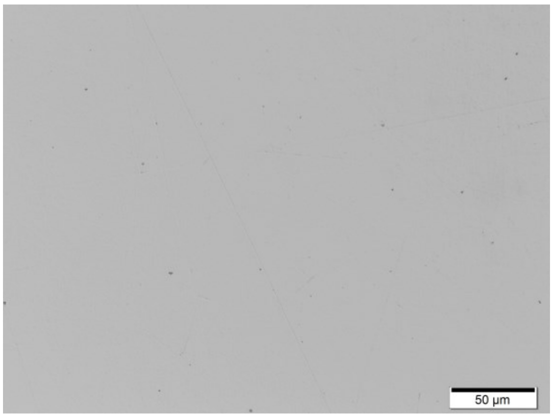

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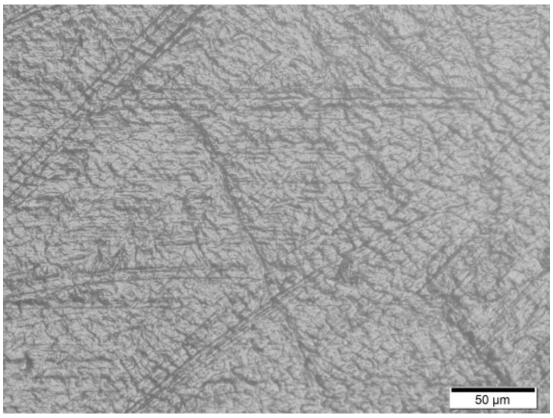

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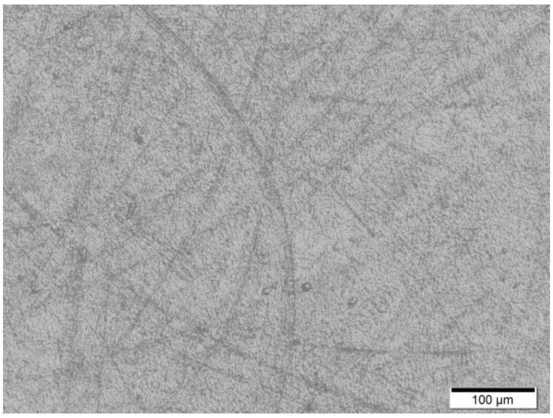

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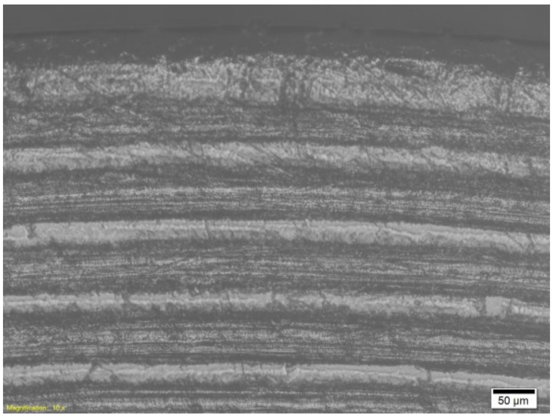

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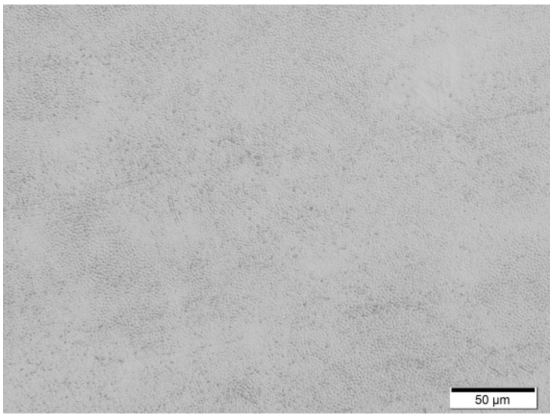

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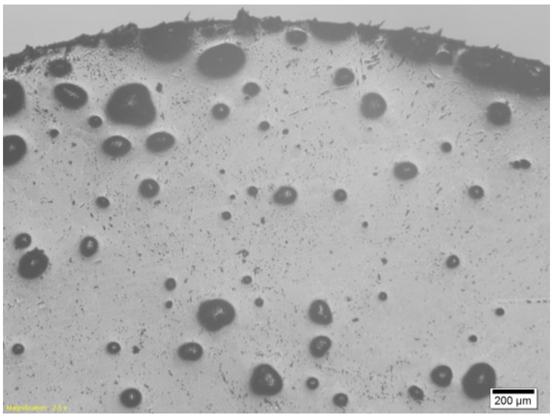

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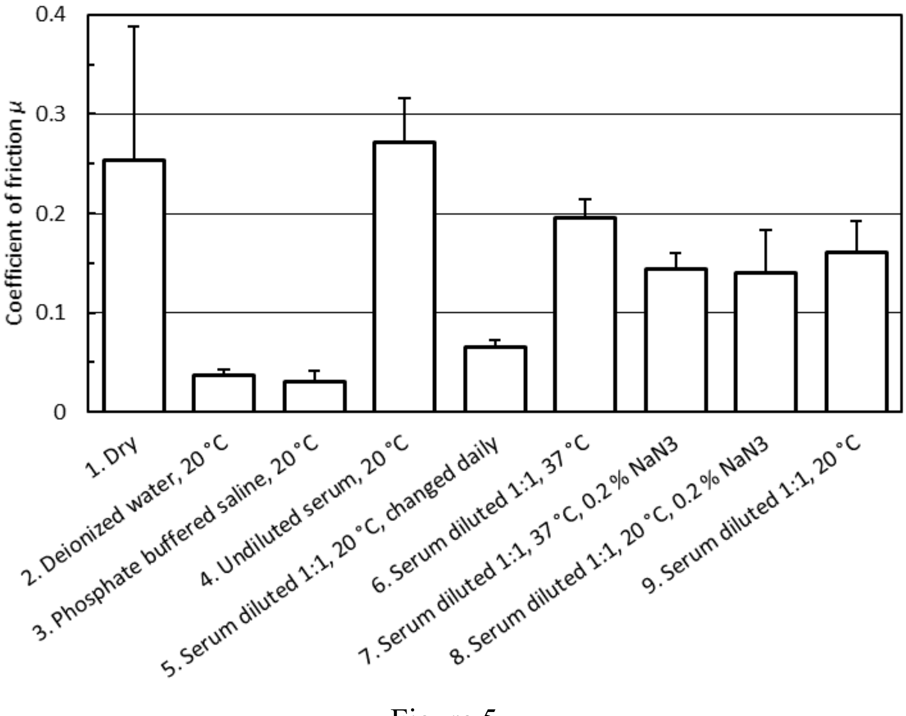

Figure 5.