Tribological performance of various CoCr microstructures in metal-on-metal bearings

THE DEVELOPMENT OF A MORE PHYSIOLOGICAL PROTOCOL *IN VITRO*

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Hip simulators have been used for ten years to determine the tribological performance of large-head metal-on-metal devices using traditional test conditions. However, the hip simulator protocols were originally developed to test metal-on-polyethylene devices. We have used patient activity data to develop a more physiologically relevant test protocol for metal-on-metal devices. This includes stop/start motion, a more appropriate walking frequency, and alternating kinetic and kinematic profiles.

There has been considerable discussion about the effect of heat treatments on the wear of metal-on-metal cobalt chromium molybdenum (CoCrMo) devices. Clinical studies have shown a higher rate of wear, levels of metal ions and rates of failure for the heat-treated metal compared to the as-cast metal CoCrMo devices. However, hip simulator studies in vitro under traditional testing conditions have thus far not been able to demonstrate a difference between the wear performance of these implants.

Using a physiologically relevant test protocol, we have shown that heat treatment of metal-on-metal CoCrMo devices adversely affects their wear performance and generates significantly higher wear rates and levels of metal ions than in as-cast metal implants.

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The high incidence of long-term failure from osteolysis induced by wear debris in conventional metal-on-polyethylene hip replacements has led to revived interest in metal-on-metal (MoM) bearings. The first generation of MoM bearing total hip replacements (THRs) were made of high-carbon as-cast cobalt chromium molybdenum (CoCrMo) alloy, and performed well. Many of these implants lasted over 30 years, with no evidence of osteolysis.[1,2] In an attempt to optimise bearing design, some manufacturers developed MoM bearings with a different CoCrMo microstructure from that of the successful first generation as-cast MoM metallurgy, by varying the carbon content and/or changing the processing methods. Thermal treatments are commonly used to alter the metallurgy of as-cast CoCrMo.

The high-carbon as-cast CoCrMo alloy has a biphasic structure consisting of the matrix of the material supporting a second metallurgical phase of chromium carbide. This carbide phase has a coarse blocky morphology within the grains and at the grain boundaries. These blocky carbides are mechanically stable within the matrix of the material (Fig. 1). The most common heat treatment process used is hot isostatic pressing followed by solution annealing. This process is referred to as double heat treatments. For hot isostatic pressing cast CoCrMo alloy is exposed to 1200°C for four hours in an inert atmosphere, followed by a gas fan quench at a slow cooling rate. This thermal treatment is carried out at a high pressure of 103 MPa. The aim of this process is to reduce the microporosities within the microstructure and to improve some of the mechanical properties of the material. This also has a marked effect on the carbides, reducing the overall size from the blocky form to smaller, fine and agglomerate carbides that have a lower mechanical stability in the supporting matrix.[3] The subsequent solution annealing process takes place at 1200°C for four hours in a vacuum, followed by a gas fan quench in an inert atmosphere to homogenise the structure of the material. This process can further reduce the size and quantity of the already modified carbides (Fig. 2). Thus a material which starts off as a high-carbon cobalt chrome alloy can be changed to a low-carbide microstructure with a reduction in wear properties, as will be discussed later.

Pin-on-disc/plate and hip simulator studies have been carried out to determine the effect of carbides on the wear of high-carbon MoM components.[3-11] The effect of material microstructure on wear is apparent only when the

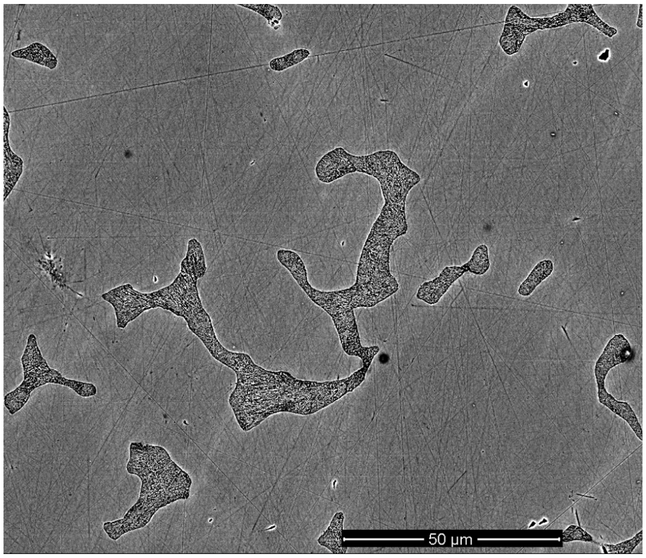

Fig. 1

Scanning electron micrograph of as cast high-carbon CoCrMo microstructure with blocky carbides.

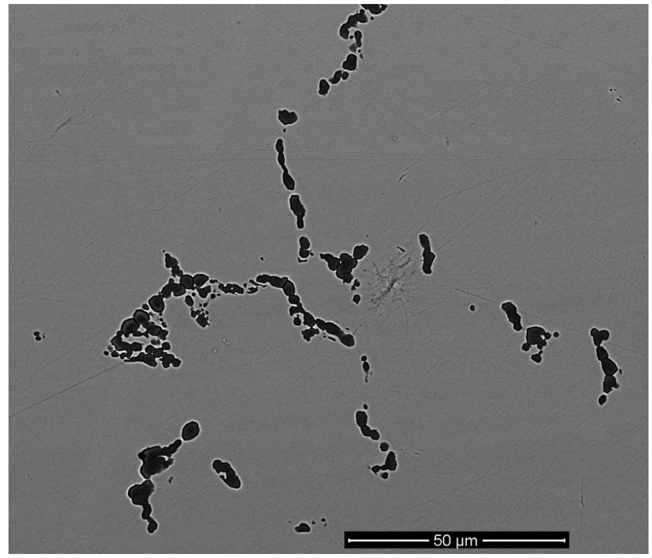

Fig. 2

Scanning electron micrograph of hot isostatic pressed and solution annealed microstructure of high-carbon CoCrMo with particulate carbides.

lubricant in the test is not separating the two articulating surfaces, as in pin-on-disc/plate studies. A number of studies using these machines have shown that the as-cast high-carbon CoCrMo alloy microstructure is superior to other CoCrMo alloy microstructure in terms of wear resistance.[3-10]

Concerns were raised by McMinn and Daniel[12] in a clinical study in which they noted high wear and osteolytic loosening in a cohort of high-carbon CoCrMo MoM hip resurfacing devices which had been subjected to post-casting heat treatment. The authors suggested that carbide depletion of the alloy from the heat treatment processes led to loss of wear resistance, leading to a high incidence of wear-induced osteolysis. The pin-on-disc/plate results confirmed their concerns. However, others have shown in studies using a hip simulator that there is no difference between the wear of high-carbon CoCrMo components with differing microstructures induced by various heat treatments.[8,11]

Hip simulators have been used extensively to determine the wear of implants under conditions considered to be relatively close to the normal walking cycle. However, these *in vitro* studies have consistently described wear rates lower than those observed in *in vivo* studies.[13] The fast, uninterrupted and identical movements per cycle in hip simulators allow the joints to operate in exaggerated conditions of lubrication which protect the bearing surfaces. However, *in vivo* there is an extensive range of movement, including stop/start activity, high forces and microseparation between the articulating surfaces. These factors may break down the fluid film, and consequently the bearings will operate in a less favourable lubrication regime, resulting in higher wear than *in vitro*. Hence, in order to determine the effect of microstructure on wear of high-carbon CoCrMo MoM hip devices, it is necessary to test the samples under physiologically relevant conditions. We have therefore assessed the daily activity of MoM Birmingham Hip Resurfacing patients using step activity monitoring devices and used the data to develop a physiologically relevant protocol for testing with a hip simulator to investigate the effect of heat treatment on the wear and generation of metal ions in CoCrMo MoM devices.

Development of a more physiological protocol for hip simulator testing

The use of the ISO standard (ISO 14242-1)[14] has been justified in testing conventional metal-on-ultrahigh-molecular-weight polyethylene (UHMWPE) joints. It is known that these devices operate under a boundary lubrication regime due to bearing characteristics such as modulus of elasticity and surface roughness. The lubrication conditions and hence the wear of this bearing combination may be less sensitive to stop/start motion and varying speeds of movement. However, MoM bearings depend on mixed and fluid film regimes of lubrication to generate low wear. Under the ISO test conditions with walking cycles of 1 Hz (60 cycles/min) with uninterrupted and identical movements, MoM devices would generate an exaggerated lubrication regime, resulting in extremely low wear during the steady state phase *in vitro*. Another predominant factor that can affect the thickness of the lubrication film is the sliding velocity between the articulating surfaces, as shown in equation 1:[15]

$$\frac{h_{\min}}{R} = 2.8\left(\frac{n\mu}{E'R}\right)^{0.65}\left(\frac{w}{E'R^2}\right)^{-0.21}$$

Where h_{min}= minimum film thickness, R = equivalent radius of the combined components, η = viscosity, μ = entraining velocity, E' = equivalent elastic modulus of the combined surfaces, and w = applied load.

It is clear from equation 1 that as the sliding (entraining) velocity increases so does the thickness of the fluid film, protecting the bearing surfaces and reducing wear. It is therefore crucial that physiologically relevant frequency and sliding velocity are used in the *in vitro* wear tests on the MoM hip. These should be based on actual walking speeds and patterns of daily activity observed in subjects implanted with MoM bearings. In order to investigate this a step activity monitoring study was carried out to measure the step counts of patients during their daily activities.

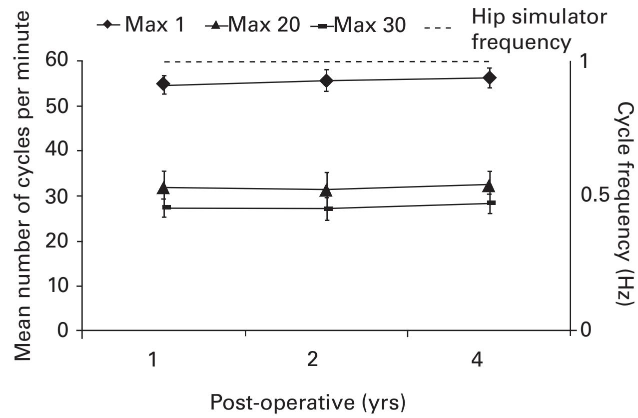

Fig. 3

Step activity monitor data of Max 1, 20- and 30-minute windows compared to hip simulator testing cycle frequency (± 95% confidence limit).

The step activity monitor

The step activity monitor (Cymatech, Seattle, Washington) is a small, unobtrusive instrument that continuously measures an individual's step count during daily activity, providing a continuous quantitative measure of activity over a period of time. The sensor consists of an acclerometer which is sensitive to the types of movement associated with a wide range of gait styles, and an electronic filter, which is designed to reject extraneous signals.

Two studies were carried out. The first was an ongoing prospective study for which we recruited 25 consecutive men with a mean age of 56 years (45 to 68) who had received a Birmingham Hip Resurfacing with a femoral head size of 50 mm between 2005 and 2008. Their step activities were recorded at follow-up at one, two and four years. The second was a cross-sectional study in which we assessed 28 patients before operation and 183 with a unilateral hip resurfacing arthroplasty at different stages of follow-up between one and ten years. The mean age of the cross-sectional study at the time of follow-up was 54.5 years (32 to 65).

All patients were asked to wear a step activity monitor device just above the lateral malleolus of the right leg or the medial malleolus of the left leg over a period of five to seven days throughout their waking hours. The temporal trend in change of step activity in these patients was recorded.

The step activity monitor records cycles per day, where each cycle corresponds to two steps. The device processes the raw data into different measures of step activity, defined by the developers. The peak index of step activity has been defined as the average of the 60 one-minute windows with most walking cycles throughout the day.[16] The maximum sustained activity over different designated time 'windows' of 1, 20 and 30 minutes is given as Max 1, 20 and 30, respectively, i.e., the maximum number of cycles of step activity over periods of one, 20 and 30 minutes of continuous measurement.

The statistical significance of mean differences were assessed using the 95% confidence intervals (CI) and a p-value of < 0.05.

Results: step activity monitor

Ongoing prospective study. It was observed that the 25 consecutive patients had a mean Max 1 of slightly fewer than 60 cycles per minute (1 Hz) (Fig. 3). This indicates that these patients, on average, do not walk at a pace of 1 Hz even over a short duration of one minute. Hip simulator studies are currently carried out at a frequency of 1 Hz (60 cycles/min), which is faster than the mean maximum number of cycles taken over a period of one minute by the patients in this study. This period constitutes a small fraction of the total walking period. The Max 30 gave an average cycle rate of fewer than 30 cycles per minute, and Max 20 gave an average of just over 30 cycles per minute (Fig. 3). The mean peak index also showed a clear difference from that of the frequency used in hip simulator studies (Fig. 4).

Currently, hip simulator studies are being carried out at a frequency of 1 Hz. The increase in sliding speed improves the lubrication between the articulating surfaces in MoM bearings. Hence, this fast walking speed of 1 Hz and the exaggerated lubrication conditions generated in hip simulators would protect the bearing surfaces of the implants and may mask the effect of changes in the microstructure of MoM bearings on wear.

These results are in agreement with the step activity monitor data generated by Silva et al,[17] who reported that patients stopped and started walking on average every 81 cycles. Hence, in order to bring the *in vitro* test conditions closer to that of those *in vivo*, stop/start motion every 100 cycles and a frequency of 0.5 Hz were introduced to the *in vitro* protocol.

Studies with the hip simulator have shown a much shorter running-in phase than that generated *in vivo*.[18-20] *In vitro*, the ISO kinematics and kinetics are identical in every single cycle, resulting in articulation over the same area throughout the test. However, *in vivo* the joints are subjected to a variety of kinematics and kinetics. Based on these findings, two different profiles with alternating

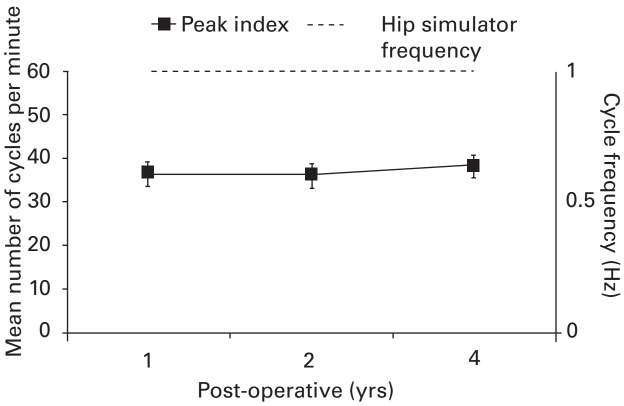

Fig. 4

Step activity monitor data of peak index compared to hip simulator testing cycle frequency (± 95% confidence limit).

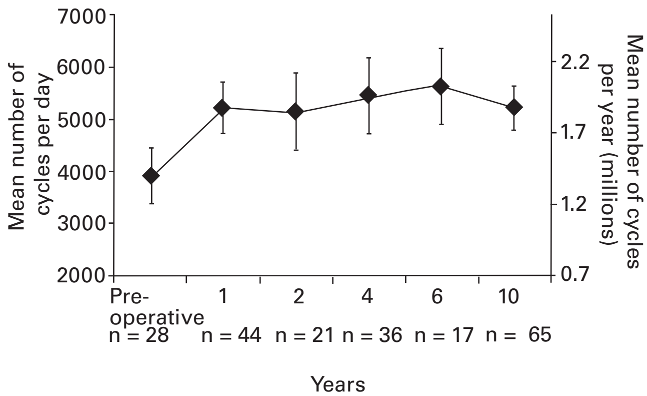

Fig. 5

Step activity monitor data of patient activity per day and per year (± 95% confidence limit).

Table I. The size, out of roundness and clearance of the components

	Femoral head			Acetabular component		
	Size (mm)	Diameter (mm)	Out of roundness (μm)	Diameter (mm)	Out of roundness (μm)	Clearance (mm)
As-cast						
1	50	49.800	0.59	50.035	1.82	0.235
2	50	49.810	0.55	50.039	1.38	0.229
3	50	49.797	0.81	50.036	1.85	0.239
Double heat-treatment						
1	50	49.784	0.65	50.023	1.78	0.239
2	50	49.785	1.20	50.026	1.76	0.241
3	50	49.787	1.07	50.028	1.99	0.241
4	50	49.788	1.67	50.029	1.36	0.241

kinematics and kinetics were developed to improve the physiological relevance of *in vitro* testing. We then used these regimes to test high-carbon case CoCr alloy devices with different microstructures derived from different post-casting conditions.

Cross-sectional study. In the cross-sectional group, the pre-operative patients had a mean step activity rate of 3926 cycles per day, equivalent to 1.4 million cycles (Mc) per year, compared to those seen at follow-up, whose mean was 5295 cycles per day, equivalent to 1.9 Mc per year (Fig. 5). Each of the individual stage groups at follow-up was also higher than the pre-operative cohort. There were no differences between the individual groups at follow-up (comparing first to second years ($p = 0.776$), second to fourth year ($p = 0.485$), fourth to sixth year ($p = 0.727$) and sixth to tenth year ($p = 0.343$).

Hip wear simulator: materials and methods

Wear. Three pairs of 50 mm high-carbon as-cast and four pairs of high-carbon double heat-treated CoCrMo MoM devices were tested in a ProSim hip wear simulator (SimSol, Stockport, United Kingdom) under the physiologically relevant conditions described below. The surface roughness measurements, including R_a (average surface roughness), R_p (maximum profile peak height) and R_{sk} (measure of the asymmetry of the profile about a mean line), were carried out using a surface profilometer (Mitutoyo, SV-3000, Andover, United Kingdom). Out of roundness (the maximum deviation from the best fitted circle) and clearance measurements (the difference between the diameter of the head and the inner diameter of the acetabular component) were measured using a Talyrond 290 (Taylor Hobson, Leicester, United Kingdom) and Coordinate measuring machine (Crysta Apex C 544, Miutoyo, Andover, United Kingdom). The values of the two groups were similar (Tables I and II).

The frequency in the simulator was 0.5 Hz, based on the step activity monitor data reported in this study and also those recorded by Silva et al.[17] Stop/start motion was implemented every 100 cycles.[17] Two sets of kinetics and kinematics were used, alternating every 100 cycles throughout the test, to simulate variations in patient activity. In the

Table II. The mean surface roughness (R_a), the mean skewness (R_{sk}) and mean peak (R_p) values of the components

	Femoral head (SD)			**Acetabular cup (SD)**		
	Surface roughness measurements			**Surface roughness measurements**		
	R_a (μm)	**R_{sk} (μm)**	**R_p (μm)**	**R_a (μm)**	**R_{sk} (μm)**	**R_p (μm)**
As-cast (average ± SD)	0.012 ± 0.001	-0.378 ± 0.143	0.011 ± 0.034	0.010 ± 0.002	-1.512 ± 0.101	0.029 ± 0.006
Double heat treated (average ± SD)	0.014 ± 0.003	-0.826 ± 0.277	0.029 ± 0.004	0.014 ± 0.004	-1.958 ± 0.503	0.028 ± 0.005

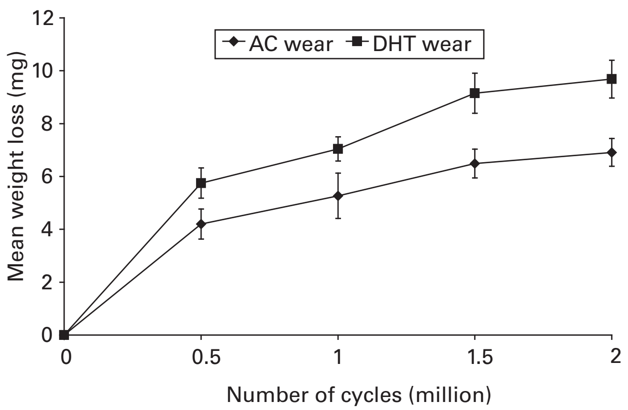

Fig. 6

Average cumulative weight loss of as-cast (AC) and double heat-treated (DHT) devices under more physiological testing conditions (± 95% confidence limit).

first, a flexion/extension range of 30°/15° and internal/external rotation of ± 10° were used. Paul-type stance phase loading was used, with a maximum load of 3 kN and a standard ISO swing phase load of 0.3 kN.[21] In the second, the flexion/extension was ± 22°. The internal/external rotation was ± 8°.[22,23] The force was a maximum stance phase load of 2.2 kN and a swing phase load of 0.24 kN.[24]

The lubricant used in this study was newborn calf serum with 0.2% (w/v) sodium azide concentration diluted with de-ionised water to achieve an average protein concentration of 20 g/l. The lubricant was changed every 125 thousand cycles. Gravimetric wear was assessed at 0.5, 1.0, 1.5 and 2 Mc following ISO standard (ISO 14242-20)[25] using an analytical balance (Toledo xp504, Mettler, Leicester, United Kingdom) with an accuracy of 0.1 mg.

Metal ions. Samples of the lubricant from each hip simulator test station were spun for an hour before 1.5 ml of serum was collected. The serum samples (0.5 ml) were then diluted in 9.5 ml (0.14 M) of nitric acid prior to analysis. The diluted samples (5 ml) were then used for analysis. The concentrations of CoCrMo ions were analysed (Analytica AB Laboratories, Luleå, Sweden) using a high-resolution inductively coupled plasma mass spectrometer (ELEMENT, ThermoFinnigan MAT, Bremen, Germany) under clean-room conditions. The detection limits were 0.05 mg/l for cobalt, 0.2 mg/l for chromium and 0.3 mg/l for molybdenum. The ion concentrations for all three were added together and converted into weight in milligrammes using equation 2.

$$\text{Mass} = \text{Volume} \times \text{Concentration}$$

Results: hip wear simulator

Wear. A biphasic wear pattern was observed similar to that observed *in vivo*,[17] showing the running-in (0 Mc to 0.5 Mc) and steady state (0.5 Mc to 2 Mc) phases (Fig. 6).

The mean gravimetric wear rates during the running-in phase (0 Mc to 0.5 Mc) of the double heat-treated and as-cast devices were 11.5 mg/Mc and 8.4 mg/Mc, respectively (Table III). The difference during the running-in phase of the two groups was statistically significant ($p = 0.014$). During the steady-state phase (0.5 Mc to 2 Mc), the mean gravimetric wear rate of 2.8 mg/Mc generated by the double heat-treated devices was significantly higher than that of 1.9 mg/Mc generated by the as-cast devices. This difference was also statistically significant ($p = 0.002$). The difference between the two groups continued to increase up to 1.5 Mc. Both groups were well into their steady-state phase at 2 Mc.

During the steady-state phase, between 1 Mc and 1.5 Mc, the double heat-treated devices showed a significant increase in wear ($p = 0.005$), but none was observed in the as-cast group ($p = 0.055$). Scanning electron microscopy showed that some unstable carbides had been pulled out of the matrix of the material for the double heat-treated devices, resulting in the generation of third-body particles (Fig. 7). This may have caused the increase in wear for these implants.

Levels of metal ions. The combined levels of CoCrMo ions showed a similar biphasic trend to that of the gravimetric weight loss (Fig. 8). Figures 6 and 8 show that there is a correlation between the ion levels and measurements of gravimetric weight loss. Other studies have also shown a similar correlation between volume loss and ion levels.[6]

Although the trends are similar in Figures 6 and 8, the loss of mass calculated from the ion levels is lower than the gravimetric mass loss. This may be due to incomplete ionisation of all the particles in the serum during high-resolution inductively coupled plasma mass spectrometry.

The mean rate of release of metal ions during the running-in phase (0 Mc to 0.5 Mc) for the double heat-treated devices was 8.2 mg/Mc (Table IV). Although the as-cast devices generated a lower mean rate of metal ions of 6.3 mg/Mc during the same period, this difference was not statistically significant ($p = 0.159$). During the steady-state

Table III. Mean wear rate of the as-cast *versus* the double heat-treated devices during running-in and steady-state phases (summary of Figure 6)

	Mean wear rate (mg/Mc) (± 95% confidence interval)	
Devices	**Running-in phase**	**Steady-state phase**
As-cast	8.4 ± (1.14)	1.9 ± (0.15)
Double heat-treated	11.5 ± (1.14)	2.8 ± (0.23)

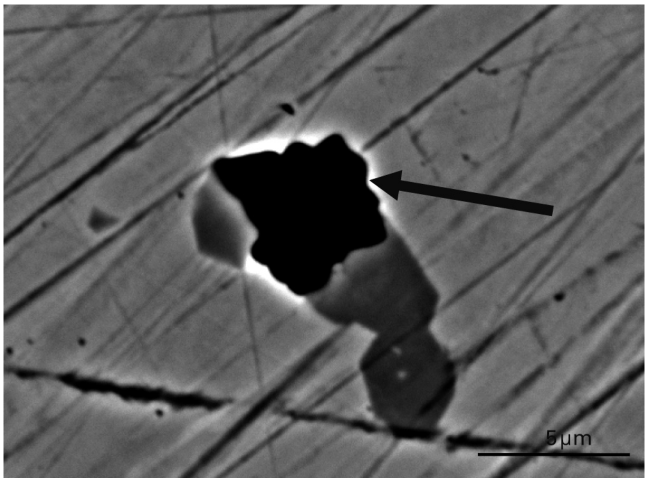

Fig. 7

Fragmentation and pull-out of carbides in the worn area of a double heat-treatment part after hip simulation test.

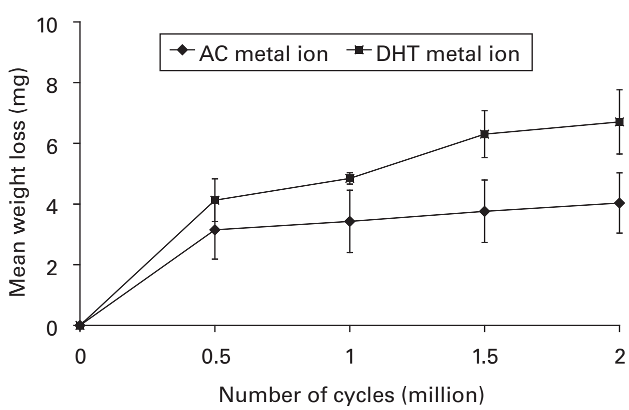

Fig. 8

Mean cumulative metal ion levels of as-cast (AC) and double heat-treated (DHT) devices under more physiological testing conditions (± 95% confidence limit).

phase (0.5 Mc to 2 Mc) the difference in the mean levels of metal ions in the as-cast and double heat-treated devices continued to increase. During this phase, the double heat-treated devices generated a mean of 1.8 mg/Mc of metal ions, compared to 0.6 mg/Mc for the as-cast devices. This threefold increase was statistically significant ($p = 0.024$).

Discussion

This study investigated the tribological performance of as-cast and double heat-treated CoCrMo metal-on-metal hip resurfacing devices. In contrast to previous studies with a hip simulator, it employed a more physiologically relevant use of the hip simulator, as obtained from objective measurement of activities in a prospective investigation of a cohort study of patients implanted with the device.

Hip simulators have been used for decades to assess the performance and longevity of hip implants. In 2002, in order to be able to compare the results the technical committee of the ISO (International Organisation for Standardisation) Implants for Surgery developed an international standard.[14] This standard (ISO 14242-1 Wear of total hip-joint prostheses) specifies the relative angular movement between articulating surfaces, the applied force profile, the articulating speed, the duration of the test, the sample configuration and the test environment.[14]

Conventional metal-on-UHMWPE joints operate predominantly under boundary lubrication.[26,27] They would not operate under fluid lubrication owing to bearing characteristics such as the elastic modulus and the surface roughness of UHMWPE. The wear of this bearing combination is less sensitive to stop/start motion and various articulating speeds which might cause breakdown of the lubrication regime. Hence, the ISO standard has been used effectively for the comparison of wear of combinations of metal-on-polyethylene bearing.

However, MoM bearings depend on mixed and fluid film lubrication to generate low wear. Under the ISO test conditions with walking cycles of 1 Hz with uninterrupted and identical movements, the metal-on-metal devices would generate an exaggerated lubrication regime between their articulating surfaces, and consequently generate extremely low wear. Physiological conditions have consistently shown higher values than that of the *in vitro* wear,[13] which could be attributed to daily activities of the patients resulting in the breakdown of the lubrication regimes *in vivo*. The extensive range of articulation, stop/start motion, high forces and micro-separation between the articulating surfaces would break down the lubrication regime in MoM bearings and may increase wear.

The entraining velocity between the articulating surfaces has also been shown to have a significant effect on the thickness of the lubrication film. An increase in entraining velocity would result in an increase in the thickness of the fluid film. Hence, it is important to consider walking speeds

Table IV. Mean rate of release of metal ions from as-cast *versus* double heat-treated devices during running-in and steady-state phases (summary of Figure 8)

	Mean metal ion rate (mg/Mc)(± 95% confidence interval)	
Devices	**Running-in phase**	**Steady-state phase**
As-cast	6.3 ± (1.9)	0.6 ± (0.1)
Double heat-treated	8.2 ± (1.4)	1.8 ± (0.6)

that correspond closely to our daily activites in studies of MoM bearings in a hip wear simulator. In this study, the step activity monitoring of 25 consecutive Birmingham hip resurfacing patients were collected. The results clearly showed that even Max 1, which is the mean of the maximum number of cycles during any minute, was not as high as that recommended by the ISO standard for hip simulator testing, i.e., 60 cycles/min or 1 Hz (Fig. 3). The maximum 20- and 30-minute windows (Fig. 3) showed mean walking cycles of between 27 and 32 cycles/min (approximately 0.5 Hz). Similarly, the mean of the maximum 60 one-minute windows with the most cycles (peak index) was found to be 36 cycles/min to 38 cycles/min. These results are in agreement with the step activity monitor data generated by Silva et al.[17] These authors also found that patients stopped and started walking at a mean of every 81 cycles.[17] Hence, in order to bring the *in vitro* test conditions closer to those *in vivo*, stop/start motion every 100 cycles and a frequency of 0.5 Hz were introduced to the test protocol.

Studies with hip simulators have shown high wear in the running-in phase during the first 0.1 Mc to 0.5 Mc, which corresponds to approximately 20 to 100 days *in vivo*, followed by almost negligible wear in the steady state.[28] However, *in vivo* high rate of wear has been noted during the running-in phase in the first six to 12 months, followed by relatively lower wear during the steady-state phase.[19] The reduction in steady-state wear *in vivo* is never as dramatic as that observed *in vitro*. This difference could be attributed to the ISO kinematics and kinetics that are identical in every cycle *in vitro*, resulting in articulation over the same area throughout the test whereas *in vivo* the joints go through various kinematics and kinetics. Hence, two different profiles with alternating kinematics and kinetics were used in this study to improve the physiological relevance of the test.

The as-cast devices generated significantly lower wear during both the running-in and the steady-state phases compared to the double heat-treated devices throughout the test (running-in ($p = 0.014$), steady state ($p = 0.002$)). The mean wear rate during the running-in phase was 36% higher with the double heat-treated devices than with the as-cast implants. During the steady-state phase the difference was increased further to 45%.

An increase in wear was observed during the steady state of the double heat-treated devices compared to that of the as-cast devices. This may have been due to pull-out of the mechanically unstable particulate carbides throughout the matrix of the material. These would become third-body particles and increase the wear. Similar features have been observed by Heisel et al,[18] who tested MoM hip resurfacing devices which consisted of as-cast femoral heads articulating against heat-treated acetabular components. These authors showed that carbides pulled fully or partially out of the matrix of the material on the acetabular components that were heat treated. Significant scratches were observed on the articulating surfaces, which had been originated by the pulled-out carbides, resulting in third-body wear. However, this phenomenon was not observed on the femoral heads which were as-cast CoCrMo.[18]

The difference in wear between the as-cast and the double heat-treated MoM CoCrMo devices may be due to the mechanical stability of carbides in the as-cast CoCrMo microstructure. These blocky carbides have been shown to resist abrasive wear owing to their extremely hard structure, terminating the scratches when they meet the carbides in the matrix, as shown in Figure 9. Similar features have also been observed by others.[18]

The combined levels of CoCrMo metal ions clearly show biphasic trends similar to those of the gravimetric wear for both the as-cast and the double-heat treated joints. The double heat-treated devices generated 30% higher mean cumulative release of ions during the running-in phase (0 Mc to 0.5 Mc) than the as-cast devices. This difference was not statistically significant ($p = 0.159$). However, as the test progressed this difference continued to increase, and during the steady-state phase (0.5 Mc to 2 Mc) a significant threefold increase was recorded ($p = 0.024$). Overall, at 2 Mc the level of metal ions for the double heat-treated devices was 67% higher than that generated by the as-cast implants. These results are in agreement with the clinical data reported by Clarke et al,[29] and Khan et al.[30] Clarke et al[29] compared the levels of metal ions of the double heat-treated Cormet 2000 (Corin Group PLC, Cirencester, United Kingdom) to that of the as-cast Birmingham hip resurfacing (Smith & Nephew Orthopaedics PLC, Memphis, Tennessee). They reported that the median levels of plasma ions of Co and Cr obtained from patients with double heat-treated resurfacing implants were respectively 44% and 60% higher than those obtained from those with as-cast resurfacing implants.[29] Khan et al[30] also compared the levels of metal ions for the as-cast BHR and double heat-treated Cormet 2000 patients, pre- and post-exercise. The authors reported that the mean pre-exercise levels of plasma ions for Co was 33% higher in patients with double heat-treated devices compared to the as-cast

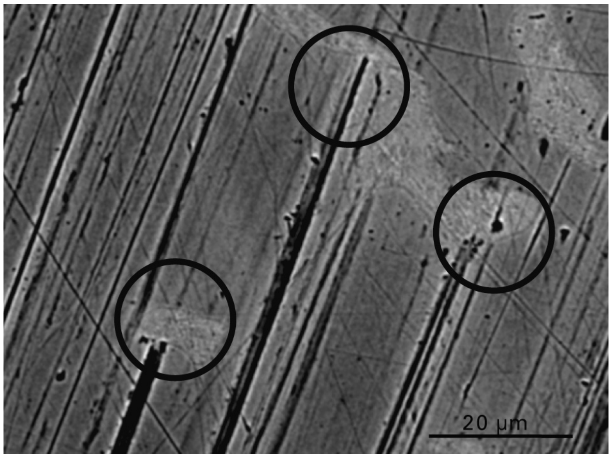

Fig. 9

Scanning electron micrograph of blocky carbides terminating scratches.

devices. They also reported that the mean increase in post-exercise Co ion levels was 76% higher for the patients with double heat treated compared to the patients with as-cast devices.[30]

The gravimetric wear measurements at 2 Mc showed 40% higher wear for the double heat-treated CoCrMo devices than for the as-cast CoCrMo implants (Fig. 6). However, the levels of ions showed an increase of 67% (Fig. 7). It has been stated that the double heat-treated devices generate smaller particles and in much greater numbers than those generated by the as-cast implants.[31,32] This would contribute to a larger net surface area of particles exposed to corrosion, thereby explaining the comparatively higher elevation of levels of metal ions with the double heat-treated devices compared to the as-cast devices. Hence the greater increase in levels of metal ions between the former and the latter devices compared to the increase in gravimetric wear may be attributed to the larger numbers of smaller wear particles generated by the double heat-treated implants. Further investigations should be carried out to determine the sizes of the particles generated by the as-cast and double heat-treated devices. Our understanding of the biological reactions to these fine particles is limited, and should be investigated further.

This study has shown that a test protocol for a hip simulator for MoM hip devices with 0.5 Hz walking frequency, stop/start motion and alternating kinetic and kinematic profiles is more physiologically relevant than traditional protocols. However, this method doubles the time taken and the cost of testing compared to the standard ISO protocol. Furthermore, at a measured activity of approximately 2 million cycles/year (Fig. 5), 20 million cycles of data from the hip simulator would be required under standard ISO test protocols to reach a clinical equivalent of ten years of use. In order to carry out the test under the more physiologically relevant test protocol presented here, the time and cost would be similar to performing at least 40 million cycles under the ISO test protocol. This would increase the test time for one device to approximately two to three years, which would not be feasible. The rates of wear of well-positioned MoM devices *in vivo* and *in vitro* do not change significantly after the bedding-in period.[8,11,33-36] Hence, when both test groups have gone through the running-in period and are well into the steady-state the test can be stopped to save time and reduce costs without losing or missing any meaningful data.

The effect of double heat treatments on the tribological performance of CoCrMo MoM hip resurfacing devices has been investigated under a novel and more physiologically relevant protocol for testing with a hip simulator. Both gravimetric and metal ion measurements showed that double heat-treated CoCrMo hip resurfacing devices had a significantly higher wear rate than as-cast CoCrMo devices. These *in vitro* results correlate well with the *in vivo* results, where higher wear, metal ion levels and failure rates were observed with double heat-treated MoM devices compared to the as-cast MoM devices.

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