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Article

A Tribological Assessment of Ultra High Molecular Weight Polyethylene Types GUR 1020 and GUR 1050 for Orthopedic Applications

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Abstract: The wear properties of biomaterials have been demonstrated to have a high importance within orthopedic bearing surfaces. This study performed a comparison of the wear between the two main grades of Ultra High Molecular Weight Polyethylene types GUR 1020 and GUR 1050 articulating against Cobalt Chromium. Such a high capacity wear comparison has not been reported elsewhere in the scientific literature. Under an identical testing protocol it was found that GUR 1020 had a wear factor of $3.92 \pm 0.55 \times 10^{-6}$ (mm³/Nm) and GUR 1050 had a wear factor of $3.64 \pm 0.39 \times 10^{-6}$ (mm³/Nm), with a non-statistical significant difference of $p = 0.052$. These wear factors correlate closely with those observed from other screening wear studies and explant analysis.

Keywords: biopolymer; wear testing; Pin-on-Disc; GUR 1020; GUR 1050

1. Introduction

Osteoarthritis and Rheumatoid Arthritis are degenerative conditions that affect sufferers resulting in a diminishment of the joint's ability to function without pain. Often the ultimate result of these conditions is the need to replace the joint. In the UK, Osteoarthritis currently leads to the majority of hip replacement procedures at 93% [1]. According to the National Joint Registry for England, Wales, Northern Ireland and Isle of Man (NJR), there were approximately 100,000 completed hip procedures and 105,000 knee procedures in 2014 alone [2]. With an aging population, these figures are likely to rise.

The modern Metal-on-Polymer bearing surface was first introduced to Orthopedics in 1962 by Professor Sir John Charnley at Wrightington Hospital, UK, with this combination still considered the "gold standard" for joint replacement [3]. The polymer that has been used for the majority of these replacements is Ultra High Molecular Weight Polyethylene (UHMWPE) or, more recently, its crosslinked form.

Total joint replacement has been hailed as one of the great success stories in modern medicine. The National Institute for Health and Care Excellence (NICE) in the UK gives a guideline of no more than a 5% revision rate at 10 years after implantation of artificial hip joints [4]. From the, NJR's 2015 annual report it is clear that many hip replacements are not only meeting this target but exceeding it [1].

Wear induced osteolysis is considered to be the predominant cause of revision and the limiting factor for orthopedic implants which use UHMWPE as a bearing material. Aseptic loosening of hip implants was cited as the leading factor for revision from the NJR (4376) closely followed by pain (3870), then dislocation/subluxation (3027), adverse soft tissue reaction to particle debris (3019) and infection (2443) [1]. Polyethylene wear particles can cause a negative cascade of events within

the body that can often lead to osteolysis, bone resorption and aseptic loosening of the implant, thus requiring revision surgery [5,6].

It has been postulated that there is a threshold below which polyethylene wear will be reasonably tolerated within the body. A median threshold of 508 mm³ from retrieved hip explants at a median time of retrieval of 10.7 years (approximately 50 mm³/year) [7] has been offered. Another way of quantifying this threshold has been given as 10×10^9 particles/gramme of “wet interface” tissue [8] with both size and dose (i.e., volumetric concentration) having an effect [9]. Alternatively it has been suggested that a wear rate of below 0.05 mm/year would “eliminate osteolysis” [10]. Although this threshold concept has not been universally accepted [11] many studies have sensibly focused on reducing the amount of polyethylene wear debris generated by an implant.

Early wear testing of UHMWPE was conducted with reciprocating motion only, but this resulted in significantly lower wear factors than those of explanted hip prostheses. Later the importance of applying multidirectional motion in screening wear tests was found [12]. Similarly the effect of protein concentration has been observed to have a distinct effect on the wear of UHMWPE. While there are issues over the use of bovine serum in the wear testing of orthopedic biomaterials [13], it remains the lubricant recommended by international standards [14]. It has been suggested that a diluted bovine serum with a protein concentration no lower than 20 mg/mL [15] be used. This compares to a mean protein concentration of 34 mg/mL for a prosthetic and healthy joint [16].

The two most commonly used grades of UHMWPE in orthopedics are GUR 1020 and GUR 1050, defined as per BS ISO 5834-2 2011 [17]. A list of some of their properties is presented in Table 1.

Table 1. Specific material properties of GUR 1020 and GUR 1050 (Orthoplastics).

Mechanical Property	GUR 1020	GUR 1050
Charpy impact strength (kJ/m ²)	203	101
Tensile yield stress (kJ/m ²)	24.6	21.7
Ultimate tensile strength (MPa)	63	50
Density (kg/m ³)	937	932

As can be seen from Table 1, there are small differences between the two grades and their mechanical properties. The key difference between GUR 1020 and GUR 1050 is the difference in the molecular weight namely 3.5×10^6 (g/mol) and $5.5 - 6 \times 10^6$ (g/mol), respectively [18]. A direct wear comparison between the two grades of polymer under identical experimental conditions, including multidirectional motion and in a large batch quantity has not, to the authors’ best knowledge, been previously completed. Therefore, this investigation aimed to measure the differences, if any, in the wear factors of the two grades of polymer, GUR 1020 and GUR 1050.

2. Results

Wear tests ran to 2.5 million cycles, which was equivalent to 86 km. The wear rates of GUR 1020 and GUR 1050 are presented in Figures 1 and 2.

The R^2 values of the regression lines including the first 500,000 cycles (Figure 1) are $R^2 = 0.9979$ and $R^2 = 0.9926$ for GUR 1020 and GUR 1050, respectively. Without the first 500,000 cycles (Figure 2) this value increases to $R^2 = 1.0000$ and $R^2 = 0.9969$ suggesting there is a bedding in phase for both GUR 1050 and 1020. However, in the case of GUR 1020, the change from 0.9979 to 1.0000 is small.

The wear factors of UHMWPE were calculated to be $3.92 \pm 0.55 \times 10^{-6}$ (mm³/Nm) for GUR 1020 and $3.64 \pm 0.39 \times 10^{-6}$ (mm³/Nm) for GUR 1050. The wear results for the two grades of UHMWPE are summarized in Table 2, along with those for the CoCr discs.

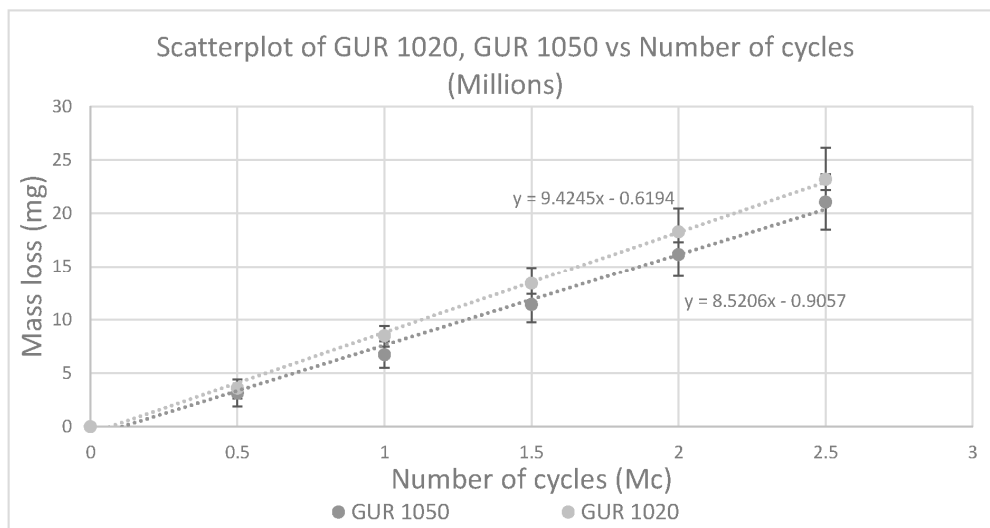


Figure 1. Comparative mean wear rate of GUR 1020 and GUR 1050 with the first 500,000 cycles.

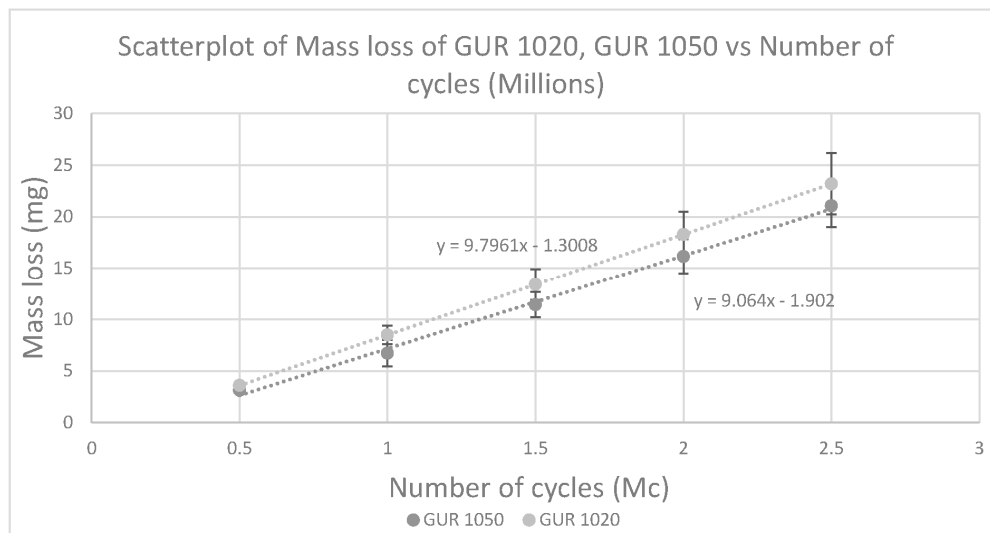


Figure 2. Comparative mean wear rate of GUR 1020 and GUR 1050 without the first 500,000 cycles.

Table 2. Summary of the wear test results.

Material	Mean Wear Rate (mg/Mc) (with Bedding in Phase)	Mean Wear Factor $\times 10^{-6}$ (mm ³ /Nm) (without Bedding in Phase)
GUR 1020 (pins)	9.4 ± 1.2	3.92 ± 0.55
GUR 1050 (pins)	8.5 ± 1.1	3.64 ± 0.39
CoCr discs	-0.029 ± 0.057	-0.0013 ± 0.0026

2.1. Statistical Analysis

A two sample *t*-test was used to analyze the significance between the wear factors of the materials at the 95% confidence level. It was found that the wear factors of the materials did not demonstrate a statistically significant difference. This analysis gave a *p*-value of 0.052 when comparing the two grades of polymer and is demonstrated by Figure 3. As indicated by Figure 3 there was one outlier for GUR 1050 and GUR 1020, respectively.

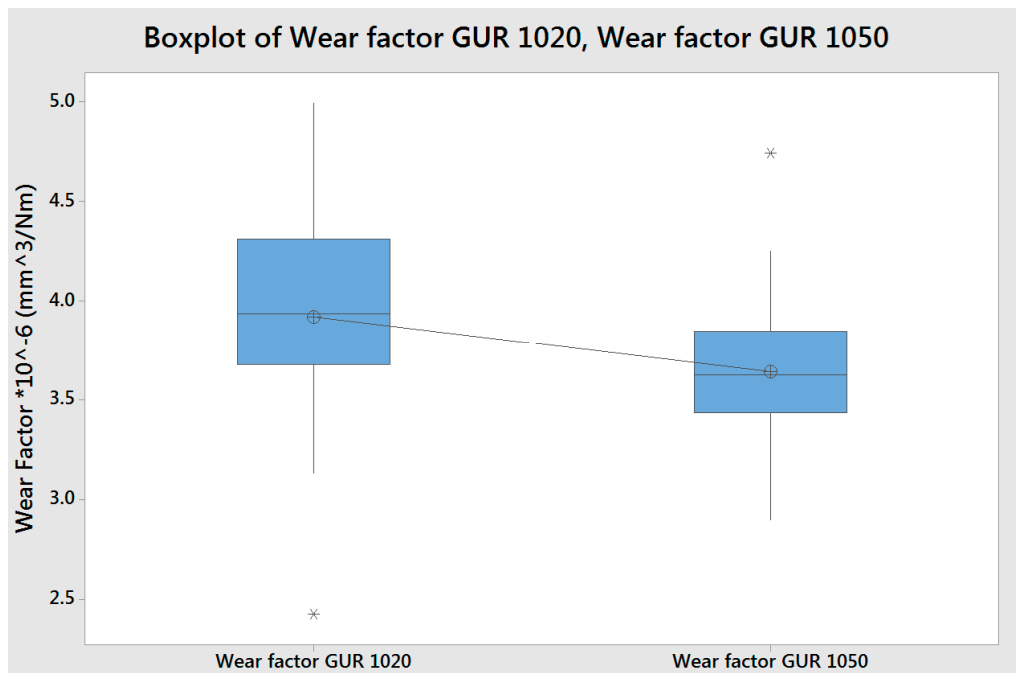


Figure 3. Box plot of the wear factors of GUR 1020 and GUR 1050 with mean values of $3.92 \times 10^{-6} \text{ mm}^3/\text{Nm}$ and $3.64 \times 10^{-6} \text{ mm}^3/\text{Nm}$, respectively.

2.2. Surface Profile

The surface roughness parameter S_a is one of the more commonly quoted topography descriptors hence will be presented for ease of comparison. There was a high standard deviation in the roughness values of the polymeric pins at the beginning of testing as shown in Table 3 and Figure 4. The initial machining marks on the polymeric pins were observed, through visual inspection, to have been removed by the first 500,000 cycles weighing point with the resultant surface burnished. By the end of testing, pin surface roughness values had fallen significantly ($p = 0.000$ for 1020 and $p = 0.011$ for GUR 1050). The surface roughness values of the CoCr discs showed little difference between the beginning and the end of the testing as shown in Table 3. Additionally, this lack of change was observed through visual inspection of the surfaces.

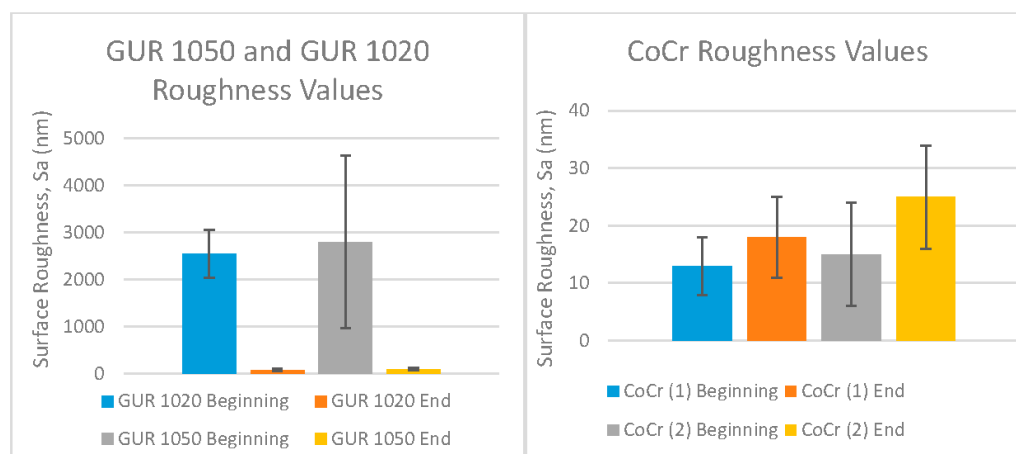


Figure 4. Change in roughness of the materials used. (left) Ultra High Molecular Weight Polyethylene (UHMWPE pins), (right) CoCr discs.

Table 3. Summary of surface topography measurements. Note, CoCr discs (1) were used with the GUR 1020 pins and CoCr discs (2) with the GUR 1050 pins.

Material	Mean Initial Roughness S_a (nm)	Mean Final Roughness S_a (nm)
GUR 1020	2540 ± 511	79 ± 23
GUR 1050	2793 ± 1835	96 ± 23
CoCr disc (1)	13 ± 5	18 ± 7
CoCr disc (2)	15 ± 9	25 ± 9

Both the GUR 1020 and GUR 1050 pins had a reduction in their roughness values to 79 ± 23 (nm) and 96 ± 23 (nm) respectively. The difference between the final roughness values of the two grades of polymer was not statistically significant ($p = 0.214$).

2.3. Controls

The control pins for GUR 1020 and GUR 1050 had a mean mass loss of 2×10^{-5} (g) and -4×10^{-5} (g), respectively. This compares to the mean test pin mass loss of 2110×10^{-5} (g) for GUR 1050 and 2320×10^{-5} (g) for GUR 1020. The CoCr control discs had a mean mass loss of 29×10^{-5} (g) compared to a mean mass loss of the CoCr test discs of 23×10^{-5} (g).

3. Discussion

The results showed that there was not a statistically significant difference in the wear factors between type GUR 1020 and GUR 1050 (p -value 0.052) UHMWPE. However, the authors acknowledge that the significance of $p = 0.052$ is borderline at the 0.05 threshold for a 95% confidence level.

Table 4 compares the wear rates and wear factors reported in this paper with other literature for in vitro wear testing of GUR 1050 and GUR 1020 UHMWPE. Additionally, included in the table is information on the dosage of gamma irradiation, as it is recognized that this can influence wear resistance. Other issues that can influence wear rates and wear factors of UHMWPE include the different test equipment, different types of UHMWPE and different test conditions. These differences likely explain the various wear factors and wear rates shown in Table 4. For example, consider the two studies [19,20], which have compared the two grades of UHMWPE in the forms of GUR 1020 and GUR 1050. There are important differences between these two studies and the present study. For example, the authors of [19] firstly had a sample size of 2 compared with 24 in the present study. Secondly, the authors used spherically ended pins (and, thus, a high, likely variable, contact stress as opposed to the constant contact stress in the current study). Thirdly, they compared compression molded GUR 1020 with ram extruded GUR 1050. In other words, they tested UHMWPE produced from different manufacturing methods. In the present study, the manufacturing method was kept constant, with both materials being compression molded. Fourthly, the test ran to only 500,000 cycles as opposed to 2,500,000 cycles in the current study. Arguably even greater differences were seen with Reference [20] as here a hip simulator, rather than a wear screening rig, was used. The loading and motion conditions applied in a hip simulator would be substantially different to those in a wear screening rig. Other differences include different manufacturing methods and an unspecified protein content in the lubricant. The different experimental conditions in References [19,20] therefore help to explain the different wear rates seen in Table 4 compared with the present study.

Table 4. A comparison of the in vitro wear results of this study and those found elsewhere for UHMWPE grades 1020 and 1050 (Mean \pm Standard Deviation).

Authors	Material (Gamma Irradiation (kGy))	Wear Rate \pm Standard Deviation (mg/Mc)	Wear Factor \pm Standard Deviation $\times 10^{-6}$ (mm ³ Nm)
This study	GUR 1020 (0)	9.4 \pm 1.2	3.92 \pm 0.55
	GUR 1050 (0)	8.5 \pm 1.1	3.64 \pm 0.39
[21]	GUR 1020 (0)	7.86 \pm 0.6	3.14 \pm 0.24
[22]	Various types of UHMWPE (NA)	0.52 \pm 0.04 – 77.1 \pm 5.51	0.25 \pm 0.02 – 37.3 \pm 2.67
[23]	GUR 1020 (25–40)	3.40 \pm 0.18	1.63 \pm 0.09
[24]	GUR 1020 (0)	1.70 \pm 0.63	1.2 \pm 0.45
[25]	GUR 1050 (0)	7.87 \pm 2.86	2.2 \pm 0.8
[26]	GUR 1050 (0)	8.23 \pm 0.36	2.3 \pm 0.1
[19]	GUR 1020 (0)	0.56 \pm 0.14	1.99 \pm 0.50
	GUR 1050 (0)	0.65 \pm 0.16	2.31 \pm 0.58
[20]	GUR 1020 (0)	45.91 \pm 6.62	NA
	GUR 1050 (0)	42.50 \pm 1.15	NA

The wear factors reported in the present study relate well with those measured from explanted UHMWPE acetabular cups of 2.1×10^{-6} (mm³/Nm) [7], $1.93 \pm 0.29 \times 10^{-6}$ (mm³/Nm) [27] and 2.9×10^{-6} (mm³/Nm) [28].

A reduction from a mean initial roughness of 2540 ± 511 (nm) and 2517 ± 2464 (nm), for GUR 1020 and GUR 1050 pins respectively, to 79 ± 23 (nm) and 96 ± 23 (nm) was found. This compares well to a mean roughness of 60 ± 17 (nm) for the final reading of GUR 1020 pins that were articulated against CoCr discs, tested to 2.5 million cycles, using the SuperCTPOD; employing similar test conditions [21]. Table 5 depicts the magnitude of the roughness value changes reported in this and other studies for GUR 1020 and GUR 1050 pins along with the associated counterface where available.

Table 5. A comparison of the mean roughness values (S_a unless shown otherwise) from multiple studies.

Authors	Material	Initial Roughness (nm)	Final Roughness (nm)
This study	1020	2540 \pm 511	79 \pm 23
	1050	2517 \pm 2464	96 \pm 23
	CoCr (1)	13 \pm 5	18 \pm 7
	CoCr (2)	15 \pm 9	25 \pm 9
[21]	1020	900 \pm 200	60 \pm 17
	CoCr	15 \pm 5	“unchanged”
[29]	SS 316L	4.5 \pm 0.5	“no damage whatsoever on the plates”
[20]	CoCr	$R_a \leq 20$	“no change in the surface roughness detected for the Cobalt chromium”
BS ISO 7206-2: 2011 [30]	CoCr	$R_a \leq 50$	NA

The CoCr discs had a roughness change of 13 ± 5 (nm) to 18 ± 7 (nm) for the discs used with GUR 1020 and 15 ± 9 (nm) to 25 ± 9 (nm) for the discs used with GUR 1050. It is interesting to note that the GUR 1050 had a lower wear factor articulating against a rougher counterface when compared to GUR 1020. The change in roughness was statistically significant for the discs that articulated against GUR 1050 though it is below the threshold of 50 nm recommended by BS ISO 7206-2: 2011 [30]. It is worth considering that, although the roughness measurements were taken in corresponding

locations, this minor yet statistically significant difference could be due to the measurement not being in exactly the same location. It should be noted that all discs were measured to obtain their roughness. However, only a subset of pins were measured. This was primarily because the discs were much harder than the pins and so their roughness was expected to have a greater effect. Clearly the roughness of the pins fell dramatically compared with their initial values whereas that of the discs remained relatively unchanged by testing (Table 5). As an aside, it is interesting to note how few studies have measured the roughness of polyethylene pins, as indicated in Table 5. All of the pins were turned. This appears to have resulted in high initial standard deviations. However, the influence of this initial roughness does not appear to have been great, as shown by the linearity of the wear results in Figures 1 and 2, and the similar final pin roughness values as shown in Table 5.

The control discs had a mean increase in weight of 29×10^{-5} g from the start to the end of testing. This compared with a value of 23×10^{-5} g for the test discs, thus resulting in an overall increase in weight of 6×10^{-5} g. However, this apparent increase in weight can be explained by the precision of the balance which was measured to be 10×10^{-5} g. The authors acknowledge a limitation of this study being that wear particle analysis has not been conducted, however a strength of this study is the number of samples that were used increasing the confidence in the results of the direct comparison between GUR 1020 and GUR 1050.

4. Methods and Materials

A high capacity, clinically validated [23], 50-station Circular Translational Pin-on-Disc device (SuperCTPOD) (TE 87, Phoenix Tribology Ltd., Newbury, UK) was used for the wear tests (Figure 5a). A schematic of the Pin-on-Disc setup is shown in Figure 5b.

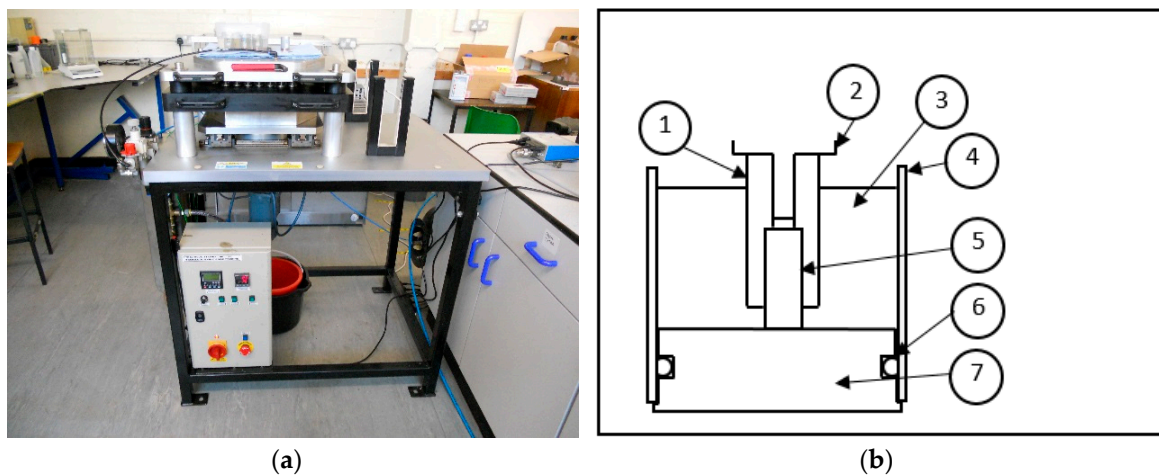


Figure 5. (a) General view of the SuperCTPOD; (b) Pin-on-Disc schematic (1) Polyacetal Pin Holder (2) Load application module (3) Lubricant (4) Lubricant container (5) Pin sample (6) Silicone O-ring (7) Disc sample.

Each flat ended UHMWPE pin, of 9 mm in diameter (5), was articulated against a polished Cobalt Chromium (CoCr) disc counterface of 28 mm in diameter (7). Both GUR 1020 and GUR 1050 materials, both compression molded conventional grades without Vitamin E doping or crosslinking, were purchased from the same supplier (Orthoplastics, Bacup, UK) and machined into pins of size 9 mm in diameter \times 12 mm tall. All pins were tested as machined with no sterilization. A load of 70.7 N was applied to each test pin resulting in a nominal contact stress of 1.1 MPa. The pins were articulated at a frequency of 1 Hz on a 12×10 mm elliptical wear path [21]. The test chambers were kept at a temperature of approximately 22 °C, as it has been seen with higher temperatures that protein precipitation occurs which reduces wear [31] whereas temperatures around 22 °C produced

clinically relevant wear [23]. The new born calf serum was diluted with deionized water resulting in a lubricant with a protein concentration of 22 g/L; no additives were used with the lubricant, and there was approximately 14 mL of lubricant in each test chamber. The lubricant was replaced at 250,000 cycle intervals and the mass of the pins and discs, including the controls, recorded at 0 cycles and then at 500,000 cycle intervals. Lubricant was always present throughout testing as has been seen previously [23]. In conformity with other studies, no pre-soaking was performed on the test and control samples [21–23]. Pre-soaking was not considered to be a critical factor as: test and control samples were subject to the same lubricant over the same timescale; and results showed that the weight change of the UHMWPE controls was minimal compared to the worn test samples. Gravimetric weight change of the pins and discs were recorded using a Denver TB-215D balance with a precision of 10×10^{-5} g. There were 24 test pins of UHMWPE GUR 1020 and 24 of UHMWPE GUR 1050. Three control pins and discs were used to account for any mass change caused by lubricant uptake. The control disc assemblies were immersed in a water bath with the control pins inserted into polyacetal sleeves, with 14 mL of diluted bovine serum used per chamber with pin assemblies inside, to closely represent the testing conditions, but with no motion or load applied. At 250,000 cycle intervals the test samples were immersed in Virkon disinfectant, rinsed with water and then with Isopropanol alcohol and allowed to air dry. The same procedure was applied to the control pins and discs.

The initial surface roughness values of discs and pins were recorded using a ZYGO NewView 5000 non-contacting interferometer with a vertical resolution of better than 1 nm [32]. Each disc had 13 roughness measurements, the S_a S_q S_k K and PV , taken of the articulating surface. These parameters are defined as: S_a the 3 dimensional surface average roughness, S_q the 3 dimensional root mean square roughness, S_k the surface skewness, K the kurtosis and PV the Peak-to-Valley measurement. A sample of 5 pins, each had 5 roughness measurements taken, including the S_a S_q S_k K and PV . For the discs and the pins, these measurements were taken at the beginning and end of testing, with all measurements being taken at corresponding locations.

From the weight changes, corrected for the control samples, volumetric wear was calculated, knowing the density of the materials (Table 1). Additionally, from the weight changes, corrected for the control samples, the wear rates (mg/Million cycles) and wear factors, from Archard theory [33], were determined for individual pins and discs. The mean wear rates and wear factors were then calculated. The wear factor (k) is defined as the volume loss V (mm^3) divided by the product of the load L (N) and the sliding distance d (m) with units of (mm^3/Nm):

$$k = \frac{V}{Ld} = \frac{m}{\rho} \cdot \frac{1}{Ld} = \frac{m}{d} \cdot \frac{1}{\rho L} \quad (1)$$

Linear regression analysis was performed on each of the pins to determine the wear factor of the two sets of UHMWPE materials by dividing the gradient of the regression graph (m/d) by the product of the density and the load. The mean of the wear factors was calculated as well as a standard deviation. A two sample t -test was implemented to determine the significance of the difference between the two polymers at the 95% confidence level using Minitab software. This method compares the means of two independent groups for the degree of significance between their differences.

5. Conclusions

This study found that there was not a statistically significant difference of the wear factors between the two main grades of UHMWPE used in orthopedics. GUR 1050 and GUR 1020 were calculated to have wear factors of $3.64 \pm 0.39 \times 10^{-6}$ (mm^3/Nm) and $3.92 \pm 0.55 \times 10^{-6}$ (mm^3/Nm), respectively. These wear factors correspond well with those from explanted Metal-on-Polymer hip replacements, as well as from wear screening tests, which apply multi-directional motion to the test specimens in the presence of a lubricant of dilute bovine serum.

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Author Contributions: Benjamin Hunt and Thomas Joyce conceived and designed the experiment, Benjamin Hunt performed the experiment and topographical measurements, Benjamin Hunt and Thomas Joyce analyzed the data and Benjamin Hunt wrote the paper. Thomas Joyce reviewed the paper.

Conflicts of Interest: The authors declare no conflicts of interest.

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