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5 Title: PEEK-OPTIMA™ as an Alternative to Cobalt Chrome in the Femoral Component of Total
6 Knee Replacement: A Preliminary Study

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8

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14

15

16 **Abstract**

17 PEEK-OPTIMA™ (Invibio Ltd., UK) has been considered as an alternative joint arthroplasty
18 bearing material due to its favourable mechanical properties and the biocompatibility of its wear
19 debris. In this study, the potential to use injection moulded PEEK-OPTIMA™ as an alternative
20 to cobalt chrome in the femoral component of a total knee replacement was investigated in terms
21 of its wear performance. Experimental wear simulation of three cobalt chrome and three PEEK-
22 OPTIMA™ femoral components articulating against all-polyethylene tibial components was
23 carried out under 2 kinematic conditions. 3 million cycles (MC) under intermediate kinematics
24 (maximum anterior-posterior (AP) displacement of 5 mm) followed by 3MC under high
25 kinematic conditions (AP displacement 10 mm). The wear of the GUR1020 UHMWPE tibial
26 components was assessed by gravimetric analysis and for both material combinations under each
27 kinematic condition, the mean wear rates were low, below 5 mm³/million cycles. Specifically,
28 under intermediate kinematic conditions, the wear rate of the UHMWPE tibial components was
29 0.96±2.26 mm³/MC and 2.44±0.78 mm³/MC against cobalt chrome and PEEK-OPTIMA™
30 implants respectively (p=0.06); under high kinematic conditions, the wear rates were 2.23±1.85

31 mm³/MC and 4.44±2.35 mm³/MC respectively (p=0.03). Following wear simulation, scratches
32 were apparent on the surface of the PEEK femoral components. The surface topography of the
33 femoral components was assessed using contacting profilometry and showed a statistically
34 significant increase in measured surface roughness of the PEEK femoral components compared to
35 the cobalt chrome implants. However, this did not appear to influence the wear rate, which
36 remained linear over the duration of the study. These preliminary findings showed that PEEK-
37 OPTIMA™ gives promise as an alternative bearing material to cobalt chrome alloy in the
38 femoral component of a total knee replacement with respect to wear performance.

39

40 **Keywords**

41 Joint Simulators, Knee Prostheses, Orthopaedic Tribology, Wear Analysis/Testing, Biomaterials,
42 PEEK-OPTIMA™, UHMWPE

43

44 **Word Count**

45 3347

46

47 **Introduction**

48 Polyether ether ketone (PEEK) is a thermoplastic polymer which has been used clinically in the
49 spine and investigated for use as a biomaterial in trauma and orthopaedics due to its favourable
50 mechanical properties and relative bioinertness.^{1,2} There has been growing interest in its use as
51 an arthroplasty bearing material either in its natural, unfilled form or reinforced with carbon
52 fibres (CFR-PEEK). Natural PEEK has been used in the spine in PEEK-on-PEEK articulations
53 where pre-clinical studies have demonstrated an equivalent wear rate for PEEK cervical (NuNec)³
54 and lumbar disc replacements (NuBac) compared to conventional materials,⁴ and although
55 clinical follow-up has been relatively short-term, the implants have shown promise.⁵ CFR-PEEK
56 has been considered for use as acetabular cups in total hip replacement, experimental wear
57 simulation under standard gait conditions has shown lower wear rates than cross-linked
58 UHMWPE against ceramic heads;⁶⁻⁸ although a 5 year follow-up from clinical trials of the Mitch
59 cup has yielded a revision rate of 4 in 25 due to loosening and squeaking.⁹ CFR-PEEK has
60 exhibited low wear experimentally in the tibial component of a highly conforming
61 unicompartmental knee replacement.¹⁰ However, despite promise from experimental wear
62 simulation in low contact stress situations, in high contact stress environments, there are
63 questions about the suitability of CFR-PEEK^{11, 12} and PEEK¹³ and to date there is minimal
64 clinical data.¹⁴

65

66 The material of interest in this study was unfilled PEEK-OPTIMA™ manufactured by Invibio
67 Biomaterials Solutions Ltd. (Thornton Cleveleys, UK)^{1, 15} and injection moulded to a geometry
68 for use as the femoral component in total knee replacement. There are several potential
69 advantages of using PEEK over cobalt chrome in this application. For example, the lower
70 stiffness of PEEK compared to cobalt chrome may reduce implant loosening caused by stress
71 shielding and bone resorption.¹⁶⁻¹⁸ Also, when coupled with an all polyethylene tibial component
72 as proposed in this study, the implant will be metal-free, which will be of particular benefit to
73 patients with metal sensitivity.¹⁹

74

75 Wear debris induced osteolysis leading to aseptic loosening^{20, 21} however remains one of the
76 primary failure mechanisms of total knee replacements²² therefore, there is continuing interest in
77 investigating novel material combinations for joint replacement. The wear performance of such
78 novel material combinations should be assessed under a wide envelope of clinically relevant

79 conditions to determine their efficacy, reliability and safety prior to implantation.²³ With the use
80 of implants in younger more active patients, the threshold for osteolysis^{24, 25} is reached sooner and
81 implant longevity diminishes. Hence, in this study wear rates were investigated in a knee joint
82 simulator under different kinematic conditions representative of different levels of patient
83 activity.

84

85 The aim of this study was to assess the suitability of PEEK-OPTIMA™ for use as an alternative
86 bearing material to cobalt chrome in the femoral component of total knee replacements in terms
87 of its wear performance. It was hypothesised that the wear rate of the UHMWPE tibial
88 components would be equivalent when articulating against cobalt chrome or PEEK-OPTIMA™
89 femoral components of similar initial surface topography and geometry.

90

91 **Materials and Methods**

92 Three injection moulded PEEK-OPTIMA™ femoral components (Invibio Knees Ltd, UK) with
93 initial mean surface roughness (Ra) of 0.02µm and three Co-Cr-Mo (cobalt chrome) femoral
94 components (Ra 0.02µm) (Maxx Medical Pte. Ltd., PA, USA) were tested against GUR1020
95 (conventional, unsterilised) all-polyethylene tibial components (Figure 1) (Maxx Medical Pte.
96 Ltd., PA, USA). The surface topography of the PEEK-OPTIMA™ femoral components was as-
97 moulded, there was no additional post-processing of the articulating surfaces of the implants and
98 the geometry of the PEEK-OPTIMA™ implant was based on the engineering drawing of the
99 cobalt chrome component.

100

101 All implants were right, mid-sized, cruciate retaining implants. Two additional UHMWPE tibial
102 components were used as unloaded soak controls to compensate for uptake of moisture during the
103 study.²⁶ Prior to the start of testing, the UHMWPE components were soaked in sterile water for a
104 minimum of 2 weeks to maximise their moisture uptake.

105

106 Experimental wear simulation was carried out on a 6 station ProSim electro pneumatic knee
107 simulator (Simulation Solutions, UK). Each station had six degrees-of-freedom with four
108 controlled axes of motion as shown in Figure 2 - axial force (AF), flexion/extension (FE), anterior
109 posterior displacement (AP) and tibial rotation (TR). The AF (maximum ~2800N) and FE (0 to

110 58°) were taken from the international standard for wear testing (ISO 14243-3) (Figure 3).²⁶ The
111 AP and TR were delivered through the tibial side of the implant and were displacement
112 controlled. Displacement control was selected as these prostheses did not have intrinsic
113 constraint within the design and relied on soft tissue constraints in vivo.²⁷ The TR was consistent
114 for all tests and set at $\pm 5^\circ$, two AP displacement conditions were used. Intermediate kinematics
115 applied an AP displacement of 0-5mm and under high kinematics, the AP displacement was
116 larger, 0-10mm (Figure 4). The shape of the input profiles were based on the natural kinematics
117 of the knee as described by Lafortune et al.²⁸ The magnitude of the displacement under
118 intermediate kinematics was similar to that detailed in the ISO standard,²⁶ and under high
119 kinematics, the magnitude of the displacement was based on gait analysis of the natural knee of
120 healthy subjects.²⁸ Abduction/adduction motion was passive and the AF was offset 7% of the
121 width of the implant in a medial direction from the tibial axis as described in the ISO standard.²⁶
122 The cycle frequency was 1Hz.

123

124 The femoral components were set up on the distal centre of rotation to facilitate femoral rollback
125 as per standard practice at Leeds²⁹ with the tibial components cemented with respect to the
126 position of the femoral components. The fixation of the tibial components was unique to each
127 implant which minimised micro motion between the implant and the cement mantle, and the tibial
128 components could be removed from the cement mantle for gravimetric analysis. The femoral and
129 tibial components remained paired for the duration of the study but to reduce interstation
130 variation, each million cycles, the implants were moved to the adjacent station. The tests were
131 carried out in 25% (v/v) new born calf serum diluted with 0.03% (v/v) sodium azide solution to
132 retard bacterial growth giving a final protein concentration of 15g/l. Approximately every 0.3
133 million cycles, the lubricant was replaced. The study was carried out at room temperature to
134 minimise potential artefacts due to protein deposition and denaturation at elevated temperature³⁰
135 and to investigate the potential for frictional heating of the lubricant to occur in the all-polymer
136 implant.

137

138 Prior to the start of the study, the simulator was calibrated and the tibial components were cleaned
139 for 10 minutes in 70 % propan-2-ol in an ultrasonic bath before drying in air and being left to
140 stabilise in a temperature ($20 \pm 1^\circ$) and humidity ($45 \pm 1\%$) controlled environment for 48 hours.
141 Gravimetric analysis of the UHMWPE tibial components was carried out using a Mettler Toledo
142 XP205 (Mettler Toledo, Leicester, UK) digital microbalance with a 0.01 mg resolution.

143 Measurements were repeated until 5 consecutive measurements fell within a range of ± 0.05 mg.
144 Surface roughness measurements of the articulating surfaces were taken using a Taylor Hobson
145 PGI800 contacting Form Talysurf (Taylor Hobson, Leicester, UK) with a $2\ \mu\text{m}$ conical tip stylus,
146 filtering and cutoffs were used appropriate to the material and to ISO 4288:1996.³¹ The surface
147 roughness parameters of interest were, the mean surface roughness (Ra), the maximum profile
148 height above the mean line (Rp) and the maximum profile depth below the mean line (Rv).

149

150 Three million cycles (MC) of wear simulation was carried out under intermediate kinematics, the
151 bulk lubricant temperature was monitored daily, close to the articulating surfaces using a Fluke
152 51 II thermocouple (Fluke, Washington, USA) and the wear of the UHMWPE tibial components
153 assessed at 1 and 3MC. At the conclusion of the study under intermediate kinematics, the surface
154 topography of the articulating surfaces was reassessed. The test was then resumed using the same
155 components but running a high kinematic profile with an increased AP displacement for an
156 additional 3MC. The wear of the UHMWPE tibial components was measured at 1 and 3MC
157 (minimum). The surface topography of the articulating surfaces was assessed at the completion
158 of the study. Three sets of implants were tested for each material combination.

159

160 For each set of three knees and each set of kinematic conditions the mean wear rate (mm^3/MC),
161 bulk lubricant temperature, Ra, Rp and Rv plus 95% confidence limits were calculated. The mean
162 wear rate was calculated using linear regression. Statistical analysis was carried out using a
163 students t-test³² comparing the PEEK implants with the cobalt chrome implants at each time point
164 with significance taken at $p < 0.05$.

165

166 The data associated with this paper are openly available from the University of Leeds Data
167 Repository.³³

168

169

170 **Results**

171 Following 3 MC of intermediate kinematics, the wear rate of cobalt chrome-on-UHMWPE was
172 $0.96 \pm 2.26\ \text{mm}^3/\text{MC}$ and the wear rate of PEEK-on-UHMWPE was $2.44 \pm 0.78\ \text{mm}^3/\text{MC}$ (Figure
173 5). There was no significant difference in the wear of the UHMWPE tibial components

174 articulating against the different materials ($p=0.06$). After 3MC of wear simulation under
175 intermediate kinematics, a polished region was apparent in the contact area of the tibial
176 components, the cobalt chrome implants had discrete scratches running in an anterior-posterior
177 direction on their surface and the PEEK-OPTIMA™ femoral components had a high density of
178 light scratches where there had been contact between the two surfaces. Table 1 shows the surface
179 topography of the articulating surfaces of the femoral components. Prior to the start of wear
180 simulation, there was no significant difference ($p>0.05$) between the measured Ra, Rp or Rv of
181 the PEEK-OPTIMA™ or cobalt chrome femoral components. After 3MC of wear simulation
182 under intermediate kinematics, there was a significant difference ($p<0.05$) in the Ra, Rp and Rv
183 of the PEEK-OPTIMA™ femoral components compared to the cobalt chrome implants. After
184 3MC wear simulation, the UHMWPE tibial components had a polished region in the wear area
185 where the machining marks had been removed (Table 2). For the tibial components articulating
186 against the PEEK-OPTIMA™ femoral components, within the burnished region, light, linear
187 scratching was apparent. As a result of this, the mean surface roughness (Ra) of the tibial
188 components articulating against PEEK-OPTIMA™ was significantly ($p<0.05$) higher than those
189 articulating against cobalt chrome after 3MC wear simulation under intermediate kinematic
190 conditions. Over the duration of the study, the wear rate was linear for both material
191 combinations as shown in Figure 6. Under intermediate kinematics, the R^2 value for the wear rate
192 of the all-polymer knee was 0.99 and 0.95 for the conventional materials. The change in surface
193 topography of the PEEK-OPTIMA™ femoral components did not appear to influence the wear
194 rate. The mean bulk lubricant temperature in the all-polymer knee was 29.5 °C which was
195 significantly ($p=0.01$) higher than that of the conventional metal-on-UHMWPE implant (28.0
196 °C).

197

198 The same implants were then tested for an additional 3MC under high kinematic conditions with
199 an increased AP displacement, reflecting a higher demand patient. The mean wear rate of the
200 conventional implant materials as shown in Figure 7 was 2.23 ± 1.85 mm³/MC and the wear of the
201 all-polymer knee was significantly higher than the conventional implant materials, $p=0.03$
202 (4.44 ± 2.35 mm³/MC). The wear rate under high kinematic conditions remained linear over the
203 duration of the study for both the all-polymer implant ($R^2 = 0.99$) and the conventional metal-on-
204 polyethylene implant ($R^2 = 0.99$). Analysis of the surface of the femoral components (Table 3)
205 showed a significant difference ($p<0.05$) between the surface roughness parameters (Ra, Rp and
206 Rv) of the PEEK and the cobalt chrome implants after 3MC intermediate and 3MC high

207 kinematics. The scratches evident on the surface of the PEEK implants after 3MC of wear
208 simulation under intermediate kinematics were still visible but following an additional 3MC
209 under high kinematics, the measured values for Ra, Rv and Rp for the PEEK components were
210 similar to those taken after 3MC of intermediate kinematics and there was no apparent further
211 deterioration of the surfaces. The surface roughness of the tibial components however, was
212 significantly higher ($p < 0.05$) for the implants articulating against PEEK-OPTIMA™ compared to
213 those articulating against cobalt chrome (Table 2) for all the surface roughness parameters of
214 interest. When tested under high kinematics, the mean bulk lubricant temperature of the all-
215 polymer implant was significantly higher (29.7 °C) ($p < 0.01$) than the lubricant temperature
216 measured in the conventional materials (27.6 °C).

217

218 **Discussion**

219 The aim of the study was to assess the suitability of PEEK-OPTIMA™ for use as an alternative
220 bearing material to cobalt chrome in the femoral component of total knee replacements in terms
221 of its wear performance. The wear of the all-polymer implant was directly compared to that of a
222 conventional metal-on-polyethylene implant of similar geometry and surface topography,
223 experimental wear simulation was carried out under different kinematic conditions indicative of
224 different patient activity levels.

225

226 After 3 MC of experimental wear simulation under intermediate kinematic conditions, the wear
227 performance of an all-polymer PEEK-OPTIMA™-on-UHMWPE total knee replacement was
228 comparable to a conventional metal-on-UHMWPE implant of similar initial geometry and surface
229 topography. To put these results into context, previous experimental wear simulation of fixed
230 bearing knee replacements under similar intermediate kinematic conditions have shown wear
231 rates of approximately 8.6 mm³/MC with stabilised UHMWPE³⁴ and 2.6 mm³/MC for moderately
232 cross-linked UHMWPE³⁵ against cobalt chrome femoral components; the moderately cross-
233 linked UHMWPE is considered to be low wearing (< 5 mm³/MC). Therefore the wear rate of
234 0.96 ± 2.26 mm³/MC for the metal-on-UHMWPE implants in this study with a conventional
235 UHMWPE tibial insert were also considered low wearing, possibly due to their low conforming
236 design.³⁴ Measuring low wear rates of UHMWPE (< 5 mm³/MC) by gravimetric analysis is
237 difficult and there is a loss of reliability in the measurement technique which makes the
238 differentiation between the effect of variables being studied and uncontrolled and random errors

239 in the system difficult. This, combined with the small sample size, may have contributed to the
240 high variability in the measured wear rates of the tibial components.²⁰ The low wear of the all-
241 polymer knee was consistent with previous simple geometry wear simulation of PEEK-on-
242 UHMWPE.³⁶

243

244 Damage on the PEEK-OPTIMA™ femoral components was observed in the form of scratching
245 parallel to the principal direction of sliding. Brown et al also reported damage to the articulating
246 surfaces of PEEK-on-PEEK cervical discs early in a spine simulator study however, despite the
247 initial change in surface topography, the wear rate remained constant as observed in our study.³
248 However, there was evidence that the linear scratching on the PEEK-OPTIMA™ femoral also
249 caused scratching in the wear scar on the UHMWPE tibial component. The bulk lubricant
250 temperature was higher in the all-polymer knee than in the conventional implant, this elevated
251 temperature could be attributed to frictional heating³⁷ due to the anticipated higher friction in this
252 material combination⁸ and poor dissipation of heat due to the low thermal conductivity of the
253 polymers.³⁸ Although higher friction bearing couples have exhibited frictional heating in vivo,³⁹
254 the clinical relevance of the elevated temperatures measured in our tests is unknown. The
255 continuous running of the simulator may have accentuated the frictional heating⁴⁰ and led to a test
256 artefact⁴¹ by creating differing environmental test conditions for the different materials. The
257 lubricant used was 25 % serum analogous to synovial fluid with the final protein concentration
258 (15 g/l) matched to that in vivo⁴² and tests were carried out at room temperature to minimise test
259 artefacts caused by denaturation of the protein-based lubricant. However, to minimise the
260 influence of frictional heating, rest periods could have been incorporated into the test protocol.

261

262 Having demonstrated a similar rate of wear of UHMWPE against the two femoral materials under
263 intermediate kinematics, the wear of the same implants under high kinematic conditions with an
264 increase in the anterior-posterior displacement was investigated. By using the same implants for
265 both kinematic conditions, the potential for variability in set up of the implants has been
266 minimised, the study has started to investigate the influence of longer-term testing on the wear of
267 the PEEK-OPTIMA™ implant and the study is more representative of changes in patients gait as
268 they perform different activities. Typical wear rates for fixed bearing knees under high kinematic
269 conditions tested on the same simulator as in this study were 15.9 mm³/MC³⁴ for stabilised
270 UHMWPE and 6.7 mm³/MC for moderately crosslinked UHMWPE.³⁵ It was anticipated that the

271 surface topography of the femoral component would influence the wear rate of the UHMWPE
272 tibials however, the wear rate remained low ($<5 \text{ mm}^3/\text{MC}$) and was linear over the duration of the
273 study, likely due to the orientation of the scratches in the principal direction of sliding. Surface
274 topography measurements of the femoral components following 3 MC of high kinematics showed
275 no further change to their surfaces compared to measurements taken after 3 MC of intermediate
276 kinematics. However, the wear rate of the PEEK-on-UHMWPE was statistically significantly
277 higher than metal-on-UHMWPE under these conditions. It was a limitation of this study that the
278 tests under the different kinematic conditions were not independent since the same samples were
279 tested first under intermediate kinematics before testing under high kinematics. Therefore, it is
280 possible that changes in the surface topography of the femoral components as a result of the
281 intermediate kinematic conditions test may have influenced the wear under high kinematics.
282 Although, this appears not to be the case, since the wear rate under both the intermediate and high
283 kinematic conditions remained linear over the duration of the study for both the all-polymer
284 implant and the conventional metal-on-polyethylene implant. Longer-term testing with a larger
285 set of samples will be necessary to fully assess whether the changes in surface topography of the
286 PEEK-OPTIMA™ femoral component influence the wear rate of UHMWPE tibial components.

287

288 This was a preliminary study focusing solely on the wear performance of the all-polymer knee
289 implant and therefore there were several other limitations, such as sample size. Three sets of
290 implants were studied for each material combination, restricted by the number of stations in the
291 simulator and the necessity to carry out control tests of conventional implants of similar geometry
292 in parallel. This is best practice and allowed the influence of the different femoral materials on
293 UHMWPE wear to be directly compared. However, a larger sample size may have reduced the
294 95% confidence limits, making the statistical analysis more robust and giving greater evidence on
295 which to draw conclusions. Another limitation was the use of unsterilised components. However,
296 the proposed sterilisation route of the UHMWPE by ethylene oxide has been shown not to
297 influence the mechanical properties or induce cross-linking and therefore the wear performance
298 of the UHMWPE is not anticipated to be influenced by such sterilisation.^{6, 43} In this study, the
299 wear of the UHMWPE tibial components were assessed. Previous work on metal-on-
300 polyethylene knees assumes all wear generated is from the UHMWPE. It is not known whether
301 there was wear of the PEEK-OPTIMA™ femoral component as the implants could not be
302 assessed by gravimetric analysis nor was a method available to assess potential wear
303 geometrically. Future work will assess the wear debris generated by the all-polymer knee implant

304 and compare its morphology and size distribution to that generated by a conventional metal-on-
305 polyethylene implant. Further, the tests conducted in this study were relatively short-term, longer
306 duration simulation will be necessary to fully assess the long term wear performance of the
307 implant.

308

309 In conclusion, under intermediate kinematic conditions, the wear rate of the UHMWPE tibial
310 components was independent of the femoral material as a similar rate of wear was shown against
311 cobalt chrome and PEEK-OPTIMA™ femoral components of similar geometry. Under higher
312 demand kinematics, the wear of the UHMWPE was significantly higher against PEEK than cobalt
313 chrome but the magnitude of the wear was considered to be low ($<5 \text{ mm}^3/\text{MC}$) against both
314 materials, and measuring low rates of wear gives potential for measurement errors especially in a
315 low sample size. Over the duration of this study, the surface of the PEEK-OPTIMA™ femoral
316 components did change but this did not influence the wear rate in this short term study. This study
317 showed that PEEK-OPTIMA™ has potential for use as an alternative bearing material to cobalt
318 chrome in total knee replacement however, the study should be considered as generation of
319 baseline data prior to further and longer term pre-clinical testing under a wider envelope of more
320 adverse and clinically relevant conditions.

321

322 **Declaration of conflicting interests**

323 Adam Briscoe is a paid employee of Invibio Ltd., John Fisher is a consultant to Invibio Ltd.

324

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333

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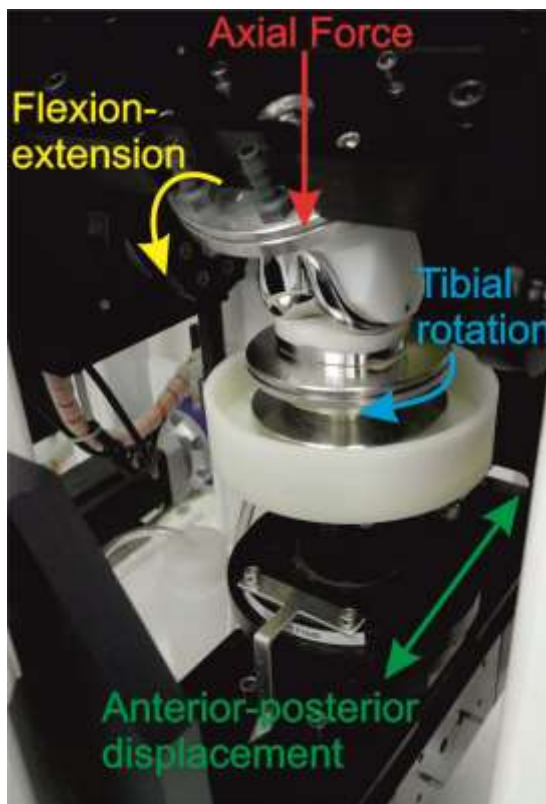
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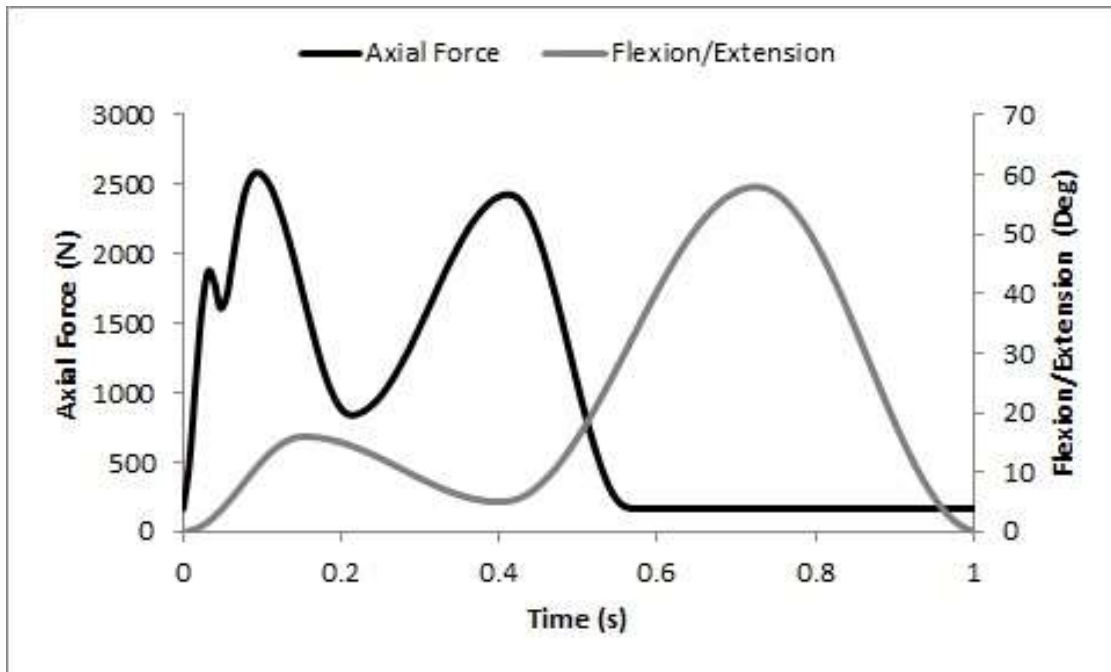
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458 Figure 1: Injection moulded PEEK-OPTIMA™ femoral component coupled with an all-
459 polyethylene tibial component.



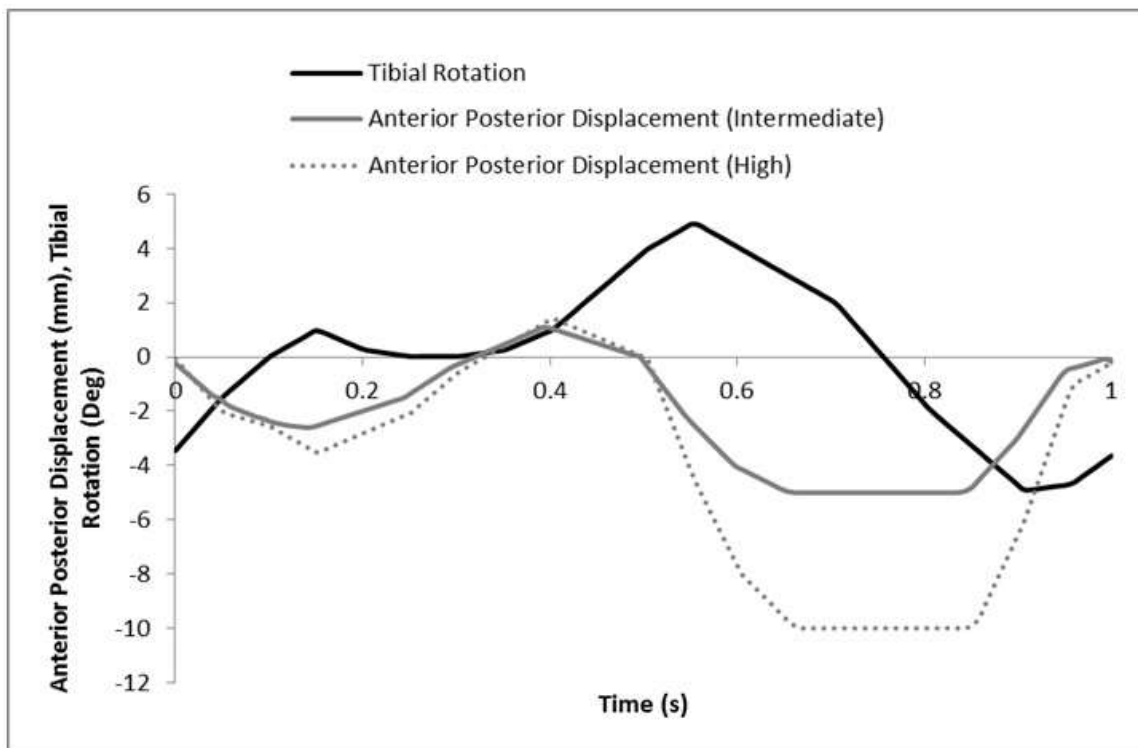
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461 Figure 2: The four controlled axes of motion in a knee wear simulator.



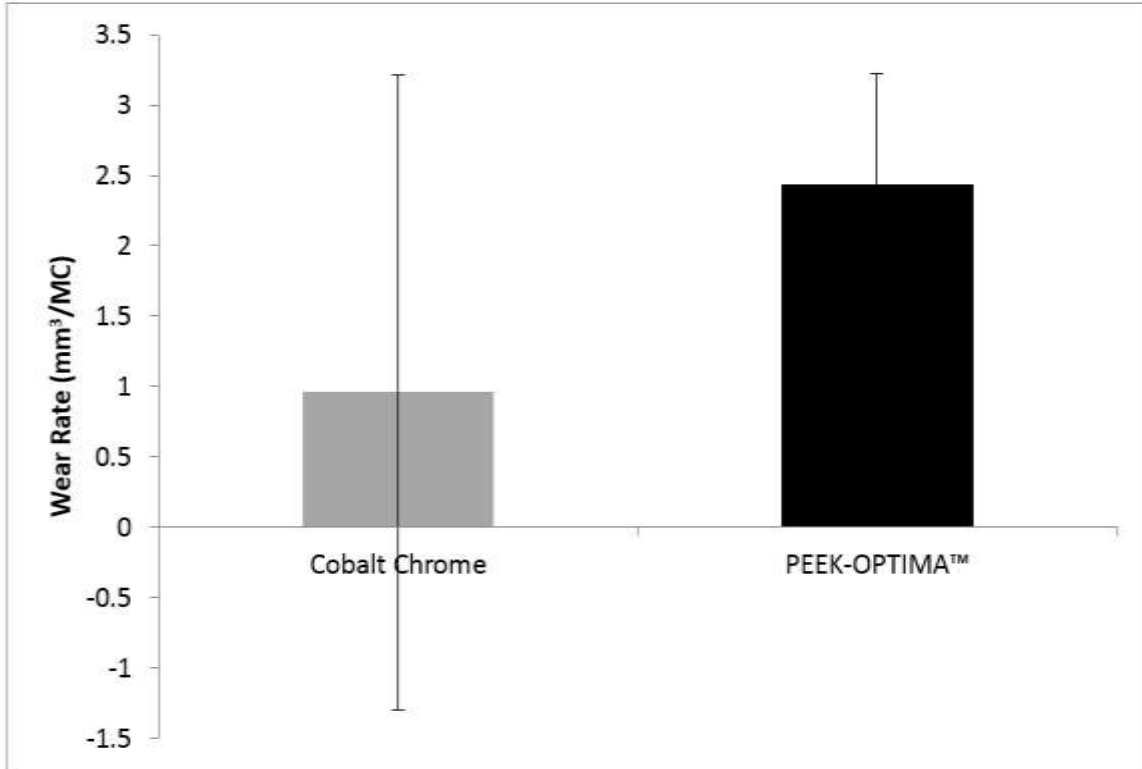
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Figure 3: Axial force (AF) and flexion/extension (FE) input profiles.



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Figure 4: Tibial rotation (TR) and anterior-posterior displacement (AP) input profiles for intermediate and high kinematic conditions.



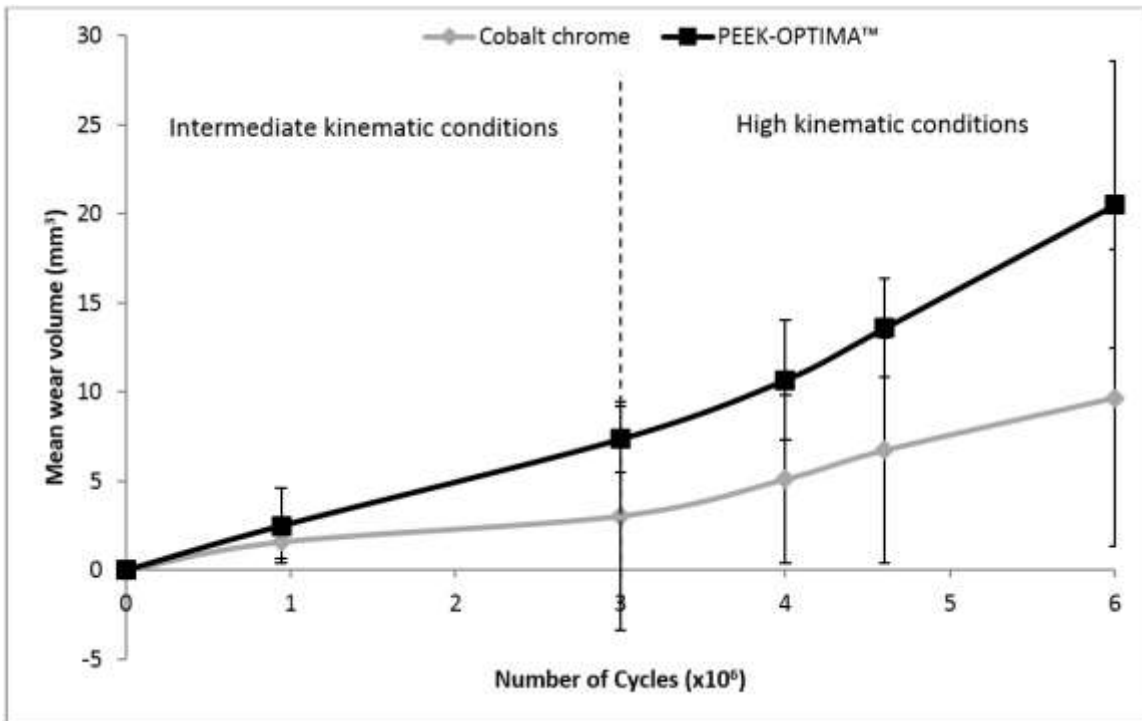
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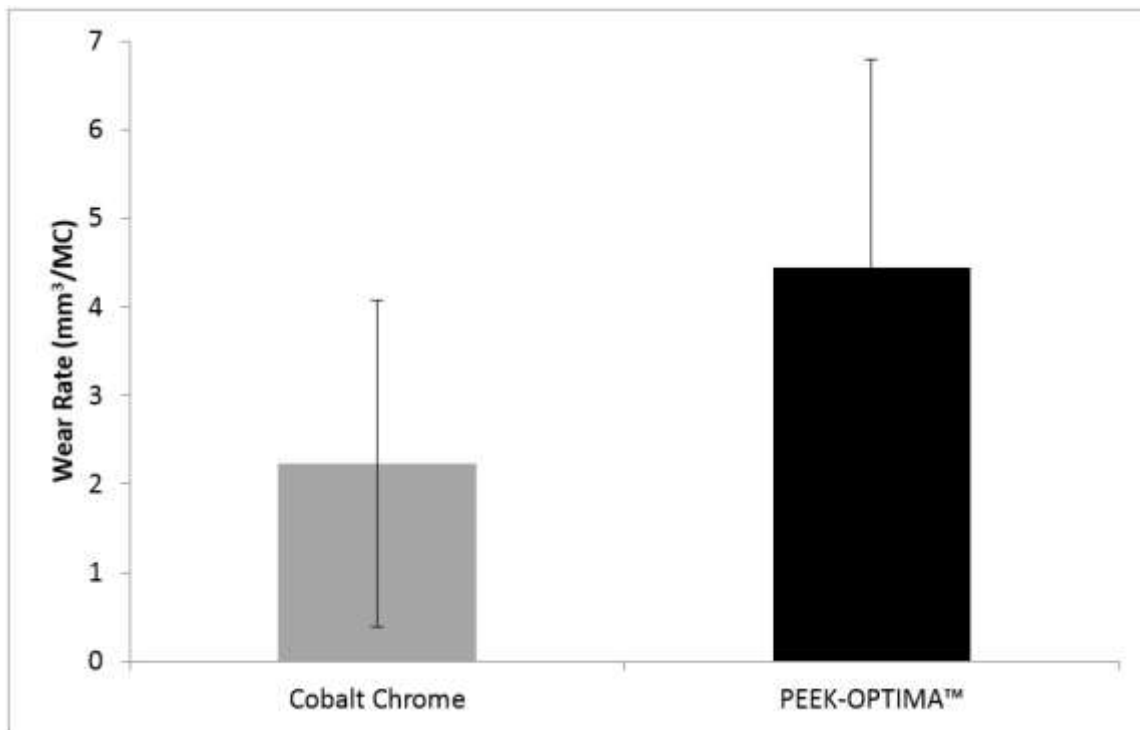
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Figure 5: Mean wear rate (mm³/MC) with 95% confidence limits of UHMWPE tibial components against cobalt chrome and PEEK-OPTIMA™ femoral components under intermediate kinematic conditions (n=3).



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472 Figure 6: Mean wear volume (mm^3) with 95% confidence limits of UHMWPE tibial
473 components against cobalt chrome and PEEK-OPTIMA™ femoral components under
474 intermediate and high kinematic conditions (n=3).



475 Figure 7: Mean wear rate (mm^3/MC) with 95% confidence limits of UHMWPE tibial
476 components against cobalt chrome and PEEK-OPTIMA™ femoral components under
477 high kinematic conditions (n=3).
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480 Table 1: Surface roughness measurements (mean \pm 95% confidence limits) of cobalt
 481 chrome and PEEK-OPTIMA™ femoral components. Measurements taken in a medial-
 482 lateral direction prior to testing and following 3MC wear simulation under intermediate
 483 kinematic conditions (n=3).

Parameter	Cobalt Chrome femoral components		PEEK-OPTIMA™ femoral components	
	Pre-test	Post-test	Pre-test	Post-test
Ra (μm)	0.02 \pm 0.00	0.03 \pm 0.04	0.02 \pm 0.01	0.23 \pm 0.18
Rp (μm)	0.08 \pm 0.00	0.10 \pm 0.07	0.08 \pm 0.01	0.52 \pm 0.49
Rv (μm)	0.06 \pm 0.01	0.09 \pm 0.09	0.07 \pm 0.01	1.29 \pm 0.56

484
 485 Table 2: Mean surface roughness (\pm 95% confidence limits) of UHMWPE tibial
 486 components articulating against PEEK-OPTIMA™ and cobalt chrome femoral
 487 components tested after 3MC intermediate kinematic conditions and 3MC high kinematic
 488 conditions (n=3).

Parameter	UHMWPE tibial components articulating against Cobalt chrome			UHMWPE tibial components articulating against PEEK-OPTIMA™		
	Pre-test	3MC intermediate	3MC high	Pre-test	3MC intermediate	3MC high
Ra (μm)	0.52 \pm 0.11	0.30 \pm 0.20	0.30 \pm 0.07	0.49 \pm 0.12	0.47 \pm 0.06	0.67 \pm 0.35
Rp (μm)	1.86 \pm 0.30	0.94 \pm 0.67	0.82 \pm 0.29	1.80 \pm 0.26	1.24 \pm 0.45	1.91 \pm 0.31
Rv (μm)	1.55 \pm 0.26	1.13 \pm 0.97	0.55 \pm 0.19	1.45 \pm 0.35	1.67 \pm 0.80	0.93 \pm 0.17

489

490 Table 3: Surface roughness measurements (mean \pm 95% confidence limits) of cobalt
 491 chrome and PEEK-OPTIMA™ femoral components. Measurements taken in a medial-
 492 lateral direction prior to testing and following 3MC wear simulation under high kinematic
 493 conditions (n=3).

Parameter	Cobalt Chrome femoral components		PEEK-OPTIMA™ femoral components	
	Pre-test	Post-test	Pre-test	Post-test
Ra (μm)	0.03 \pm 0.04	0.03 \pm 0.01	0.23 \pm 0.18	0.23 \pm 0.16
Rp (μm)	0.10 \pm 0.07	0.09 \pm 0.03	0.52 \pm 0.49	0.54 \pm 0.38
Rv (μm)	0.09 \pm 0.09	0.10 \pm 0.04	1.29 \pm 0.56	0.74 \pm 0.43

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