Complications involving the patellofemoral joint, caused by malrotation of the femoral component during total knee replacement, are an important cause of persistent pain and failure leading to revision surgery. The aim of this study was to determine and quantify the influence of femoral component malrotation on patellofemoral wear, and to determine whether or not there is a difference in the rate of wear of the patellar component when articulated against oxidised zirconium (OxZr) and cobalt-chrome (CoCr) components. An in vitro method was used to simulate patellar maltracking for both materials. Both rates of wear and changes in height on the patellar articular surface were measured. The mean rates of wear measured were very small compared to standard tibiofemoral wear rates. When data for each femoral component material were pooled, the mean rate of wear was 0.19 mm²/Mcycle (SD 0.21) for OxZr and 0.34 mm²/Mcycle (SD 0.33) for CoCr. The largest change in height on each patella varied from -0.05 mm to -0.33 mm over the different configurations.

The results suggest that patellar maltracking due to an internally rotated femoral component leads to an increased mean patellar wear. Although not statistically significant, the mean wear production may be lower for OxZr than for CoCr components.

Materials and Methods
A total of 18 right Genesis II femoral components size 5 (Smith & Nephew, Memphis, Tennessee) were placed on specially designed metallic fixtures using bone cement (Versabond; Smith & Nephew). They were made of either OxZr (n = 9) or CoCr (n = 9). Matching 32 mm diameter polyethylene patellar components were clamped into the corresponding holders. The femoral and patellar components were then fitted into a six-station ProSim knee joint wear simulator (Simulation Solutions, Stockport, United Kingdom) which permitted six degrees of freedom (Figs 1 and 2). With regard to the three translational movements the patellofemoral contact force had a range from 0 N to 4000 N (coefficient of repeatability (CR) 46.7 N) and a distal-proximal (DP) displacement range of -10 mm to +10 mm (CR 0.02 mm), both of which were pneumatically driven; the mediolateral (ML) displacement ranged from -10 mm to +10 mm and was constrained by linear springs. With regard to the three rotational movements, patellar flexion was motor driven with a range from -10° to 130°.

Complications involving the patellofemoral joint may cause persistent pain after total knee replacement (TKR) leading to revision surgery. The clinical importance of patellofemoral wear should therefore not be underestimated.

In previous work Verlinden et al found that excessive internal or external malrotation of the femoral component in TKR had a significant influence on the mechanics of the patellofemoral joint, whose contact area decreased with progressive malrotation, resulting in a concomitant increase in contact pressure. This can result in the contact area being subjected to loads exceeding the yield stress of the patellar polyethylene as the maltracking increases. The authors concluded that in contemporary TKR designs the elevated pressures noted with malrotation could cause accelerated wear of the patellar component, even under relatively low loads such as during normal walking. Whether such malrotation does actually increase the wear of the patellar component has not yet been demonstrated.

This study was carried out to determine the influence of malrotation of the femoral component on patellofemoral wear, and whether there is a difference in the wear rate of the polyethylene patellar component when articulated against a cobalt-chromium (CoCr) or an oxidised zirconium (OxZr) femoral component.
to $+100^\circ$ (CR 3.4$^\circ$), patellar rotation was pneumatically controlled from -10$^\circ$ to +10$^\circ$ (CR 0.001$^\circ$) and patellar tilt was mechanically blocked, as rotation around this axis was defined by the endo-/exorotation of the femur.

The fixtures allowed positioning of the femoral component in different angles of axial rotation (Figs 1 and 2). Components were tested in neutral alignment with the posterior condylar line parallel to the epicondylar axis, and in 5$^\circ$ internal rotation and 5$^\circ$ external rotation. Each alignment was tested with three OxZr and three CoCr components during four million cycles each on the wear simulator.

Loads and displacements between the patella and the femur during the gait cycle were simulated by the computer-controlled knee joint simulator. Patellar flexion, patellar rotation and DP displacement were derived from the literature on patellofemoral kinematics as a function of the angle of flexion of the knee.$^{10,11}$ We began the investigation by applying the knee flexion curve from the international standard for wear-testing machines with displacement control (ISO 14243-3$^{12}$); the corresponding patellar flexion, patellar rotation and DP displacement were then calculated versus the cycle time. The contact force between the femoral and the patellar components were applied in accordance with the in vivo estimations derived from MRI data and instrumented gait analysis by Ward and Powers.$^{13}$ The mediolateral constraints on the patella were simulated by two linear compression springs with a constant load of 8 N/mm. Tilting of the patella was mechanically blocked. The input curves for the flexion

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**Fig. 1**

Diagrams showing lateral (left) and frontal (right) views of the experimental set-up with the femoral component mounting piece (top), which allowed correct and reproducible rotation of the femoral component, and the patellar component (below). All degrees of freedom are indicated; tilt was locked. Mediolateral (ML) soft-tissue restraints were mimicked by linear springs.

**Fig. 2**

Photograph showing side view of the experimental set-up in station 4 with the femoral component mounting fixture (top), which allowed correct and reproducible rotation of the femoral component, and the patellar component (below). For clarity, the surrounding rubber bags and bovine serum have been removed.

**Fig. 3**

Graph showing the input curves for the wear simulator.
angle, rotation and contact force as a function of the portion of the gait cycle are shown in Figure 3.

The contact surfaces of the femoral and patellar components were immersed in a fluid test medium simulating human synovial fluid. The lubricant was composed of 40% newborn calf bovine serum (HyClone, Logan, Utah) diluted with deionised water, with ethylenediaminetetraacetic acid (EDTA; 20 mM ratio) and sodium azide (0.2%) added as antimicrobial agents. Each station was filled with 350 ml fresh filtered serum solution (0.2 μm filter). All patellar components were pre-soaked for six weeks to allow for stabilisation of possible weight gain attributable to fluid absorption. During each of the three runs, a soak control was used. The cyclic frequency was 1 Hz and the test duration was four million cycles (Mcycle).

The measurements of weight were converted to volumetric wear loss using a density for ultra-high-molecular-weight polyethylene (UHMWPE) of 0.93 mg/mm³, based on manufacturer information and published literature. A linear regression model was used to calculate the wear rate of each patellar sample, from which a mean rate of wear was calculated with its standard deviation (SD). Additionally, height changes on the patellar articular surface were measured with the use of a coordinate-measuring machine (CMM; Mitutoyo, Andover, United Kingdom) at 0 Mcycle and 4 Mcycle.

**Statistical analysis.** Statistical significance was examined using a two-tailed Student's t-test with equal variance to compare two configurations. The test was considered statistically significant when p < 0.05. Post hoc analyses were used for the pairwise comparisons, as on occasion some of the data were pooled.

**Results**

For the OxZr components the mean wear rates for the neutral, 5° internal rotation and 5° external rotation alignment were 0.24 mm³/Mcycle (SD 0.18), 0.20 mm³/Mcycle (SD 0.09) and 0.15 mm³/Mcycle (SD 0.39), respectively (Fig. 4).

For the CoCr components the mean wear rates for the neutral, 5° internal rotation and 5° external rotation alignment were 0.25 mm³/Mcycle (SD 0.47), 0.54 mm³/Mcycle (SD 0.39) and 0.31 mm³/Mcycle (SD 0.27), respectively (Fig. 4). Although the mean wear rate for the CoCr components in malrotation was more than twice that for malrotated OxZr components, this did not reach statistical significance (internal rotation p = 0.21, power = 21%; external rotation p = 0.59, power = 7%).

When the data for each femoral component material were pooled the mean rate of wear was 0.19 mm³/Mcycle (SD 0.21) for OxZr and 0.34 mm³/Mcycle (SD 0.335) for CoCr (Fig. 5). There was a tendency for CoCr components to produce higher wear than OxZr components, although the difference was not statistically significant (p = 0.25, power = 20%).

When the data across both materials for each alignment were pooled the mean wear rate for neutral alignment, internal rotation and external rotation alignment was 0.23 mm³/Mcycle (SD 0.30), 0.35 mm³/Mcycle (SD 0.29) and 0.21 mm³/Mcycle (SD 0.29), respectively (Fig. 6). Internally rotated femoral components tended to generate more wear than neutrally aligned or externally rotated components, although the differences were not statistically significant (internal rotation vs neutral p = 0.50, power = 10%; internal vs external rotation p = 0.44, power = 11%).

Figures 7 to 9 show maps of mean wear for the patellar samples in neutral position, 5° internal and 5° external rotation of the femoral components.

For the neutral position the largest change in height on the patella after four million cycles was a mean of -0.15 mm (SD 0.08) for OxZr and -0.27 mm (SD 0.20) for CoCr when measured over three samples. For internal rotation, the largest change in height was a mean of -0.24 mm (SD 0.06)
Landmarks available for this assessment. Using all available component and the epicondylar axis are usually the only anatomical references makes correct alignment in revision surgery possible to avoid some patellofemoral complications. Lack of some of these landmarks is essential to ensure optimal patellar tracking in the trochlear groove and to avoid patellofemoral complications. When this is achieved, it seems logical to assume that it would result in a lower rate of wear.

Our data show a general tendency for an internally rotated femoral component to produce higher rates of wear than a neutral or externally rotated component (Fig. 6). Malalignment of the femoral component by 5° of internal or external rotation has been shown to increase the contact pressure in the patellofemoral joint by 25%, mainly due to a reduction in contact area. Although excessive internal rotation of the femoral is generally considered to be more harmful to the patellofemoral joint than excessive external rotation, this previous study could not find a statistically significant difference in contact values between the same amount of internal and external malalignment. Furthermore, the mean pressures measured did not exceed the yield strength of UHMWPE. However, large parts of the contact area experienced much higher loads than the mean, so that these parts were at risk for producing focal accelerated wear of the patellar component, leading ultimately to loosening or failure. Our study supports this hypothesis and provides much evidence that particularly excessive internal rotation is to be avoided. We found the highest mean rate of wear (0.54 mm³/Mcycle) and the highest individual sample rate of wear (0.86 mm³/Mcycle) in the group of internally rotated CoCr femoral components.

In general the mean patellofemoral rate of wear with a CoCr femoral component was higher than that seen with an OxZr femoral component (Fig. 5), as is often observed in simulations of tibiofemoral wear and hip wear, although in our study the difference was not statistically significant (p = 0.25). For both internal and external malrotation the mean wear rate was lower when using an OxZr component than when using a CoCr component (Fig. 4), but again these differences were not significant. The differences between the mean wear rates of the three alignments were smaller for OxZr femoral components than for CoCr components. This suggests that incorrect rotation of an OxZr femoral component is less harmful than the same degree of malrotation of a CoCr component. An OxZr femoral component therefore seems to be more forgiving in terms of wear with regard to malrotation of the femoral component. We also noted that the standard deviation of our results was higher when CoCr femoral components were used. In general, the mean rates of wear for the different rotational alignments and both materials tested were minimal compared with rates of tibiofemoral wear reported in the literature: Spector et al reported a wear rate of 0.69 mm³/Mcycle for OxZr and 4.68 mm³/Mcycle for CoCr; and Ezzet et al reported a wear rate of 12.52 mm³/Mcycle for OxZr and 21.49 mm³/Mcycle for CoCr. The maximum patellofemoral rate of wear observed in our study was 0.86 mm³/Mcycle for a sample in the group of the internally rotated CoCr femoral components, which is about 18% of the rate measured in published tibiofemoral wear tests using CoCr femoral components.

The mean patellofemoral wear rate (0.34 mm³/Mcycle) for the CoCr components in all three alignments was 7% of a typical tibiofemoral published wear rate for CoCr. The mean patellofemoral wear rate (0.19 mm³/Mcycle) for the OxZr components was 27% of a typical tibiofemoral wear rate for OxZr and 4% of a typical tibiofemoral wear rate for CoCr. The mean patellofemoral wear rates were:

![Bar chart showing the mean rate of wear of ultra-high-molecular-weight polyethylene in neutral, 5° internal and 5° external rotational alignments (error bars represent ± 1 SD)](image)
however, very low compared to the SD (the coefficient of variation ranged between 45% and 260%), which made it difficult to find any statistically significant difference between groups.

Nevertheless, the wear rates found in this study were minimal compared to standard tibiofemoral wear rates. Moreover, they were significantly lower than the patellofemoral wear rate first quantified by Ellison et al.\textsuperscript{23} who showed a mean wear rate of 3.13 mm\textsuperscript{3}/Mcycle (SD 1.78). Also, the maximum change in height after four million cycles was 65\% lower in our study than the maximum penetration found by Ellison et al.\textsuperscript{23} This can be explained by the fact that our maximum input load was less than half their maximum input load (55\% lower). Our test setting simulated normal level walking within lower ranges of flexion, which is one of the limitations of the study design. In the higher flexion range, seen in activities such as negotiating stairs and rising from sitting, the risk of failure of the UHMWPE, with contact pressures exceeding the yield strength, is more obvious and one might expect higher wear rates under these conditions. The difference in prosthesis design between the two studies might also have an influence on the wear rate and penetration.

The shape and orientation of the wear scars (Figs 7 to 9) is consistent with the contact pressure measurements in the different rotational alignments resulting from previous work by our group.\textsuperscript{9} Compared to the location of the wear scar reported by Ellison et al.,\textsuperscript{23} in our study it was located...
more proximally. Again, the shape and location of the wear scar depends on the design of the prosthesis, which was different in the two studies.

In our previous study, three positions of malrotation were tested: 2.5°, 5° and 7.5°. In clinical practice, malrotation of the femoral component is, however, not likely to exceed 5°.24,25 Higher degrees of malrotation are rather uncommon, and as the difference in wear between 2.5° malrotation and neutral alignment might have been too small, 5° of malrotation was chosen for this study.

Better efforts to control the different parameters influencing wear in a wear simulation set-up could narrow the relatively large spread of results observed in each test group. Our inability to do so was a weakness, as this is important when measuring small amounts of wear. Another limitation of this study was that for each combination of material and position only three specimens were tested. A post hoc power analysis for each comparison confirmed that the study was underpowered. A larger number of samples for each test condition, in combination with higher loads, as used by Ellison et al,23 might have provided a statistically significant result. However, these significant differences would be small (given the low wear values seen for patellofemoral wear compared with tibiofemoral wear) and it is uncertain that they would be clinically relevant.

In conclusion, our in vitro study showed that patellar maltracking due to an internally rotated femoral component may lead to increased patellar wear. Although not statistically significant, the wear rate may be lower for OxZr components than for CoCr components. This study highlights the need for a more comprehensive investigation in which more specimens are used in order to determine whether there is a statistically significant difference between the two groups. Optimal femoral rotation remains one of the most important factors in avoiding patellofemoral wear.

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References


