



Comparative gravimetric wear analysis in mobile versus fixed-bearing posterior stabilized total knee prostheses

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Polyethylene (PE) wear is the limiting factor for the longevity of a conventional total knee arthroplasty (TKA). Excessive wear leads to loosening and eventual implant failure. The aim of our *in vitro* study was to investigate wear of a PE tibial insert on a rotating platform as compared to the same insert fixed to the tibial baseplate and articulating with a similar femoral component. All tests were performed at Endolab Laboratories, Rosenheim, Germany using a knee joint simulator following ISO 14243-1. Three specific configurations were tested and compared to a loaded soak control : (1) the rotating platform using machined polyethylene (PE), (2) fixed bearing using machined PE, (3) fixed bearing using compression-moulded PE.

Calf serum with a high protein concentration of 30 g/l was chosen as test lubricant. PE wear was measured gravimetrically using the ISO 14243-2 protocol.

The total wear rates found for all systems tested were low. The mean wear rate was 1.40 mg per million cycles for the moulded fixed bearing, 4.07 mg per million cycles for the machined fixed bearing type and 0.82 mg per million cycles for the machined rotating platform bearing type. We conclude that the TKA system we tested (Performance®, Biomet, Warsaw, IND, USA) demonstrated very low gravimetric wear. The wear rate of the same implant in the fixed mode compared to the rotating platform mode was four times higher.

Keywords : polyethylene wear ; posterior-stabilized TKA ; fixed insert or rotating platform.

INTRODUCTION

As aging baby-boomers develop progressive osteoarthritis and remain active, the need for knee replacements offering longevity will rise dramatically.

Wear of the polyethylene tibial insert is the main cause for long-term failure in TKA. In contemporary modular inserts, wear occurs on both the articulating side and on the backside or inferior surface of the insert. The resulting wear particles activate a specific cascade of events which may lead to implant loosening.

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In an effort to reduce polyethylene wear, one can improve the quality of the material or reduce the contact stresses. Therefore changing manufacturing techniques or sterilization methods are potential ways to improve the longevity of polyethylene. Insert moulding for example is a proven method to increase the wear resistance of polyethylene (3). It is also known that contact stress is inversely proportional to the contact area and therefore a large contact surface and high conformity will reduce contact stress and the wear rate. Larger contact area without inducing major constraint can be achieved using mobile bearing inserts. In a study by Delpport *et al* mobile-bearing knee designs indeed displayed better kinematics (5) and lower contact stresses. There is however no consensus on this, as other *in vivo* kinematic analyses failed to show any advantages of mobile-bearings with respect to rollback and axial rotation patterns, range of motion and condylar lift-off (6,20,24). A potential disadvantage of mobile-bearings is higher wear because of larger contact areas (28), owing to their double articulating interface. However, wear is expected to be reduced at the femorotibial interface in mobile-bearing knees prostheses featuring a high conformity of the articular surfaces in the coronal and sagittal planes ; this results in a large contact area (up to 800-1000 mm²), with contact stress under 21 MPa on the polyethylene bearing (13,23).

On the other hand, the value of highly cross-linked PE in knee arthroplasty is still controversial (7,18) and needs more investigation. Bourne *et al* (4) demonstrated increased backside wear in mobile-bearing inserts which allow rotation only or rotation and translation. On the contrary several studies have shown that PE inserts with mobility only in rotation are less exposed to wear than fixed bearings (9,11,12). Mobile bearing knee systems also demonstrate reduced contact stresses (14,18,19,25,26) and thereby suggest less generation of abrasive wear debris compared to contemporary posterior stabilized fixed-bearing knee designs (PS-FB). These features of the PS-Rotating Platform (PS-RP) insert should contribute to the clinical longevity of these implants (27).

This study analyses the *in vitro* gravimetric wear of a TKA system in which the femoral component

is designed to articulate with either a PS-RP or a PS-FB tibial plateau. It was our hypothesis that mobile-bearing PS TKA shows less PE wear than fixed-bearing PS TKA.

MATERIALS AND METHODS

We tested 4 pairs of femoral and tibial knee arthroplasty components using the same prosthetic design for the femoral component but with two different configurations : fixed Posterior Stabilized and mobile Posterior Stabilized with a Rotating Platform (Performance®, Biomet Inc., Warsaw, IND, USA). The mobile PS bearing is more dished both in the sagittal and coronal planes than the other configuration.

The femoral component was identical in all tests, left, medium size P/S, and made of Co-Cr-Mo alloy.

The tibial component in the fixed configuration had a polyethylene insert that was fixed to the baseplate with a screw ; in this configuration, a machined PE insert and a moulded PE insert (Arcom® is the trademark for the moulded polyethylene from Biomet) were studied in separate tests. In the mobile configuration a rotating platform with a machined PE insert was used. The inserts tested were 10 mm thick, medium P/S (fig 1).

All tests were carried out in a force controlled knee joint simulator using ISO standards (Implants for surgery – Wear of total joint prostheses – Part 1 : Loading and displacement parameters for wear testing machines with load control and corresponding environmental conditions for test).

The test procedure followed was ISO/F DIS 14243 (table I). The implant was fixed in neutral position at 0° flexion. A cyclic variation of the flexion/extension angle as well as of the contact force replicating normal human walking was simulated. The applied contact force actions was axial, AP and tibial rotation.

The contact surfaces of the femoral and tibial component were immersed in a fluid test medium simulating human synovial fluid as described by Alberts *et al* (1). Calf serum was used as the test medium to simulate human synovial fluid (a protein concentration of 30 g/l was used for this test). (Composition of the lubricant (250 ml) : serum 116 ml, Partricin 2.5 ml, EDTA 0.86 g, aqua dest. rest to 250 ml. Calf serum (Biochrom KG, Berlin, Germany, Lot 866EE) with a resulting protein content of 30 g/l.)

The test was interrupted every 500 000 cycles and the specimens were removed and cleaned to determine the weight loss : rinse in distilled water-vibrate in ultrasonic

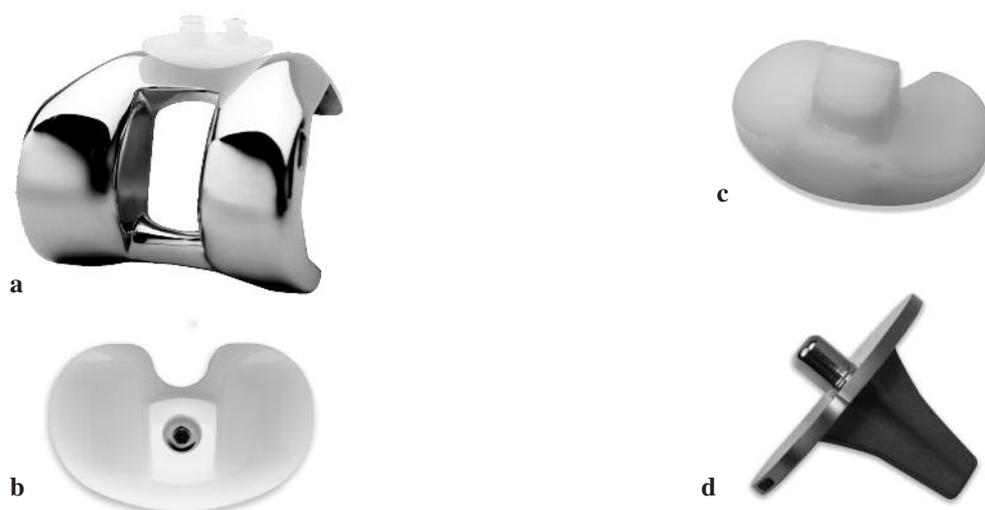


Fig. 1. — Total knee arthroplasty components used in this study : the same prosthetic design for the femoral component (a) was used with two different configurations of the tibial component : fixed Posterior Stabilized (b) and mobile Posterior Stabilized with a rotating platform (c & d).

Table I. — Test parameters

Value ROM	Flexion/Extension 0 to 58°
Axial force	166 to 2600 N
AP force	-265 to 110 N
Torque	-1 to 6 Nm
Frequency	1 Hz
Test fluid	Calf serum
AP – motion restraint	30 N/mm
Tibial rotation restraint	0.6 Nm/°

cleaner for 10 min in distilled water-rinse in distilled water-vibrate in ultrasonic cleaner for 10 min in a mixture of 2% cleaning detergent (31/8 Alsa-Chemie, Bad Friedrichshall, Germany) and distilled water-rinse in distilled water- vibrate in ultrasonic cleaner for 10 min in distilled water- dry in a jet of nitrogen (quality 4.6)-soak in propan-2-ol for 5 min \pm 15 s, dry in vacuum chamber (better than 13.33 Pa – 0.13 Pa) for 30 min- weight each specimen in rotation until the last two readings were within 1 mg and the sign of the mass change had alternated at least once. A loaded soak test, in which the components were subjected to the same cyclic load profile without motion, was used to normalize the wear data. The gravimetric changes in a loaded soak insert were used to correct for fluid absorption.

Table II. — Wear data In [mg/million cycles]

UHMPE 1	Molded + fixed	1.40 (0.78)
UHMPE 2	Machined + fixed	4.07 (0.97)
UHMPE 3	Machined + rotating	0.82 (0.95)
UHMPE Soak	Control	-0.30 (0.89)

According to data presented by Noordin *et al* (20), the protein concentration was set to 30 g/l rather than diluting the serum to 25% as indicated by ISO 14243-1 (table II). As shown by Wang *et al* (29), low protein concentrations may cause unphysiological wear. All tests were performed simultaneously together with a soak control.

RESULTS

The total wear rate for all systems tested was low (table II). A mean wear rate of 1.40 mg per million cycles was measured for the moulded fixed bearing type and of 4.07 mg per million cycles for the machined fixed bearing type. A mean wear rate of 0.82 mg per million cycles was measured for the machined rotating platform bearing type. The regression coefficient (fig 2) of the linear wear interpolation of the wear results was 0.78 for the

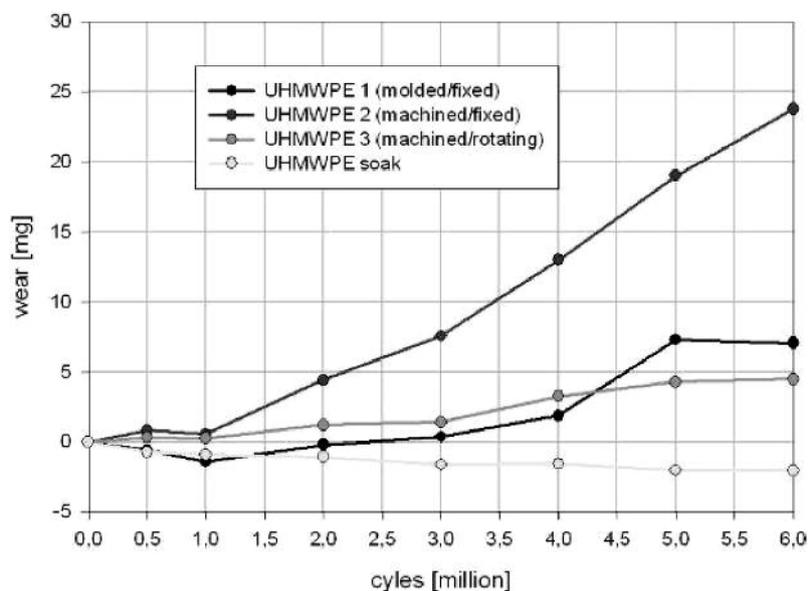


Fig. 2. — Wear vs number of cycles

moulded fixed bearing type, 0.97 for the machined fixed bearing type and 0.95 for the machined rotating platform bearing type. A linear regression model not including the zero wear measurements at zero cycles (since there is per definition no variability in wear at zero cycles) indicates that there is a significant difference in the wear rate between the different bearing types (including the control), $p < 0.0001$ (table IV). All bearings had a higher wear rate than the control ($p < 0.0001$ for moulded/fixed and machined/fixed vs control, $p = 0.002$ for machined/rotating vs control). More importantly, the wear rate for the machined/fixed bearing was significantly higher than for the moulded/fixed bearing ($p < 0.0001$) and than for the machined/rotating bearing ($p < 0.0001$). Finally, the wear rate for the moulded/fixed bearing was significantly higher than for the machined/rotating bearing ($p = 0.025$). However, evidence for the latter difference disappears when a correction for multiple testing is applied.

DISCUSSION

Several authors have previously reported on the *in vitro* wear rate of contemporary TKA designs using

a knee simulator. Walker *et al* (27) reported a mean wear rate of 26 mg per million cycles for the Insall Burstein II® system (Zimmer, Warsaw, IND, USA) and 16 mg per million cycles for the Kinematic® TKR (Stryker, Mahwah, New Jersey, USA). Both tests were performed using a Stanmore knee simulator ISO 14243-1. Schmidig *et al* (22) reported a mean wear rate of 12 mg per million cycles for the Duracom® TKR (Stryker, Mahwah, New Jersey, USA), also using a Stanmore knee simulator. Alberts *et al* (1) reported a mean wear rate of 12 mg per million cycles for the Foundation® Total Knee system (DJO Surgical, Austin, TX, USA).

The lowest wear rates for a fixed bearing type TKR were reported by Furman *et al* (8). Direct moulding of UHMWPE did result in a mean wear rate of 2 mg per million cycles when testing the Optetrak® TKR (Exactech, Inc., Gainesville, FL, USA)).

In our test a very low mean wear rate, compared to the literature, of 0.82 mg per million cycles was measured for the machined rotating platform bearing type TKR (table II).

There is only scarce literature data indicating wear rates of rotating-platform type TKRs. None of the current references indicates wear tests per-

Table III. — Estimates of intercepts and slopes in each condition. Estimates of differences between the slopes

Parameter	Estimate	Standard Error	t Value	Pr > t
intercept UHMWPE 1 (molded/fixed)	-2.96991501	0.81268361	-3.65	0.0016
intercept UHMWPE 2 (machined/fixed)	-3.50536827	0.81268361	-4.31	0.0003
intercept UHMWPE 3 (machined/rotating)	-0.46334278	0.81268361	-0.57	0.5749
intercept soak	-0.66742210	0.81268361	-0.82	0.4212
slope UHMWPE 1 (molded/fixed)	1.63439093	0.22508890	7.26	< .0001
slope UHMWPE 2 (machined/fixed)	4.35430595	0.22508890	19.34	< .0001
slope UHMWPE 3 (machined/rotating)	0.86062323	0.22508890	3.82	0.0011
slope soak	-0.25014164	0.22508890	-1.11	0.2796
slope UHMWPE 1 vs soak	1.88453258	0.31832378	5.92	< .0001
slope UHMWPE 2 vs soak	4.60444759	0.31832378	14.46	< .0001
slope UHMWPE 3 vs soak	1.11076487	0.31832378	3.49	0.0023
slope UHMWPE 1 vs UHMWPE 2	-2.71991501	0.31832378	-8.54	< .0001
slope UHMWPE 1 vs UHMWPE 3	0.77376771	0.31832378	2.43	0.0246
slope UHMWPE 2 vs UHMWPE 3	3.49368272	0.31832378	10.98	< .0001

formed according to ISO 14243-1. A direct comparison between the fixed and rotating bearings in our study demonstrates an increased wear of 3.25 mg per million cycles for the fixed bearing. One study by Bourne *et al* (4) directly comparing fixed-bearing type TKR and mobile-bearing TKR noted higher wear rates for the mobile system. We postulate that these findings are likely due to the small motions measured for the rotating platform.

In a previous study, we demonstrated that decoupling occurs *in vivo* in patients with mobile bearing PS knees (5,18). Compared to the fixed-bearing PS knees, where complex translation and rotational motions occur on the proximal bearing surface, the decoupling of translation and rotation may have important theoretical benefits with regard to polyethylene wear (15). McEwen *et al* reported in a number of publications that ultrahigh molecular weight polyethylene (UHMWPE) becomes molecularly oriented in the principal direction of sliding (antero-posterior), producing a strain hardening effect which increases the wear resistance (14). Concurrently the polyethylene softens along the axis transverse to the sliding motion and exhibits less wear resistance in that direction. Introducing a motion such as internal-external rotation produces a frictional force in the direction transverse to sliding and therefore increases the wear rate (21). This concept

has been confirmed in knee simulator studies, comparing the *in vitro* wear between the rotating platform LCS knee and the fixed bearing Sigma® TKR (DePuy Orthopaedics, Warsaw, IND, USA.). It was demonstrated that decoupling knee motions, by allowing unidirectional rotation at the baseplate-insert articulation and unidirectional translation at the femoral-insert surface, reduces UHMWPE wear by molecular orientation and decreasing cross shear on the polyethylene (15). The motion of the bearing on the tibial tray also minimizes the implant-bone interface stress (22).

A limitation of this study is that for each condition, only one single specimen has been tested. This implies that the variability due to differences between specimens is ignored in the current statistical analysis (table III). However, the large differences in wear rate suggest that similar conclusions with respect to differences between the machined/fixed condition will be obtained in a further study including multiple specimens.

Another weakness in our study is the fact that wear is only assessed gravimetrically. In our study we did not take into account the issue of the size or form of particulate wear debris. Data from literature suggests that these appear to be smaller in very congruous knees, especially in mobile-bearing design (10), although Minoda *et al* found that

mobile-bearing TKR generated larger particles (16,17). Smaller particles are potentially more biologically reactive.

In our study the machined mobile insert produced the same volume of wear as the fixed moulded insert. A compression moulded insert was shown to produce far less wear compared to a machined insert (3). This means that the results of the wear test are also affected by the polyethylene quality and manufacturing method.

CONCLUSION

In this *in vitro* study, the polyethylene wear rate in a mobile bearing posterior stabilized knee design was found to be lower than in an identical fixed-bearing PS design. Long term clinical studies are needed to confirm this finding *in vivo*.

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