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Polyethylene Wear in Total Knees

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Abstract Knee arthroplasties in young and active patients place a substantial increase in the lifetime tribological demand and potential for wear-induced osteolysis. Polyethylene materials have advanced in recent years, reducing the potential for oxidative degradation and delamination failure. It is timely to consider tribological design variables and their potential to reduce surface wear and the long-term risk of osteolysis. The influence of reduced cross shear in rotating platform mobile-bearing knee designs and reduced surface wear area in low conforming fixed-bearing knees has been investigated. A reduction in cross shear substantially reduced wear in both multidirectional pin-on-plate studies and in rotating platform mobile-bearing designs in knee simulator studies. A reduction in bearing surface contact area substantially reduced surface wear in multidirectional pin-on-plate simulations and in low conforming fixed-bearing knee designs in knee simulator studies. This offers potential for a paradigm shift in knee design predicated by enhanced mechanical properties of new polymer materials. We

describe two distinct low-wearing tribological design solutions: (1) a rotating platform design solution with reduced cross shear provides reduced wear with conformity and intrinsic stability; and (2) a low conformity fixed bearing with reduced surface area, provides reduced wear, but has less intrinsic stability and requires good soft tissue function.

Introduction

Total knee replacement is increasing in younger and more active patients, with increased life expectancy. A 50-year-old patient, with life expectancy up to “50 more years after 50,” has a potential further lifetime tribological demand of 100 million cycles. In the longer term, wear debris-induced osteolysis will presumably be an increasing cause of failure [14, 15], as lifetimes and activity levels increase. The accumulation of polyethylene wear debris over time in periprosthetic tissue will lead to an increased incidence of osteolysis [16, 17].

Historically, the failure of gamma-in-air sterilization polyethylene in knees was due to oxidative degradation, causing a reduction in mechanical properties and fatigue failure, which has been described as delamination wear [5, 6, 8, 19]. Oxidative degradation also increases surface wear and osteolysis [7]. It is important to differentiate the delamination wear mechanisms, which produce fatigue failure [6, 19], from the surface wear mechanisms, which produce submicron- and nanometer-sized wear particles and result in long-term osteolysis [16, 17, 24]. Surface wear leading to the potential of osteolysis is considered the longer-term risk factor, particularly since increased kinematics with more active patients substantially increases

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wear rates and the total wear volume in fixed-bearing knees [4, 22].

Over the last decade, a range of new processing, sterilization, and cross-linking methods have been developed [21]. While stability and resistance to oxidative degradation have been substantially enhanced, this remains a concern with a few materials. In vivo oxidation can occur after 10 years in patients with polyethylene that had been gamma-irradiated in a vacuum and barrier packed [9]. Cross-linked polyethylene, which has been annealed below the melt temperature, leads to in vivo oxidation and reduction of mechanical properties [10, 21]. Cross-linking and heat treatment above the melt temperature are now widely used in an attempt to reduce free radicals and subsequent oxidative degradation [21, 23]. While cross-linking reduces surface wear, it also reduces the mechanical properties [21]. High levels of cross-linking used in the hip are rarely used in the knee due to the requirement for mechanical fatigue strength in the knee. Medium levels of cross-linking of 5 to 7.5 MRad are now more commonly used in the knee. Medium cross-linking (5 MRad) reduces surface wear by approximately 30% compared to gamma-irradiated in barrier pack polyethylene in the knee [22]. Given there is a limitation to the level of cross-linking that can be applied in the knee, it is important to consider other tribological design factors that may be used to reduce polyethylene surface wear. For example, surface wear of polyethylene is not only determined by sliding distance and load [1], but also by other variables including cross shear [3, 25] and the surface pressure and area [2] of the polyethylene being worn.

We therefore asked to what degree surface wear was reduced by (1) reduced levels of cross shear in rotating platform mobile-bearing knees, and (2) reduced bearing surface area in low conforming fixed-bearing knees.

Patients and Methods

We used laboratory wear simulations to determine the relationships between two design parameters (cross shear and contact surface area) and surface wear rates. Simple geometry multidirectional pin-on-plate studies [13] were used to investigate the fundamental material wear properties as a function of cross shear and contact area/pressure. Knee simulator studies [4] were used to investigate the effect of the two different design configurations, rotating platform mobile-bearing knees with small amplitude tangential curvilinear (rotation) motion on the lower tibial surface with zero cross shear and reduced cross shear on the upper femoral surface, and low conformity fixed-bearing knees with reduced surface area, on surface wear.

The material pin-on-plate wear studies were conducted to isolate and control the two independent variables, the amount of cross shear, and the contact area/pressure, and to determine their respective effects on wear. Standard wear testing methods were adopted that have been widely reported previously to determine the wear of polyethylene [13]. Material wear properties of GUR1050 polyethylene (taken from a single batch which was not irradiated to ensure time-independent properties) were determined using multidirectional pin-on-plate simulations [15, 20]. The angle of rotation of the pin was varied from $\pm 10^\circ$ to $\pm 55^\circ$, as the pin reciprocated with a stroke length between 10 mm and 38 mm. A continuous reciprocating movement forwards and backwards was applied, with cross shear introduced by rotation of the polymer pin. The cross shear ratio was defined as the frictional work transverse to the principal direction of motion divided by total frictional work [20], and the ratio had a range of values between 0 and 0.5 [13, 20]. Studies were carried out with cross shear ratios between 0 and 0.254, hence extending beyond the range of kinematics found in the knee, which are less than 0.2. Stress was varied by changing the load (80 to 200 N) and the contact face diameter of the pin (3 mm to 10 mm) giving nominal average stress values in the range 1 MPa to 10 MPa. This average contact stress range is representative of the normal contact stress averaged over the total contact area and the full gait cycle, and is lower than the peak stress in the center of the contact at peak loading in gait cycle for the total knee. Wear tests were run for approximately 0.5 million cycles. This minimum test duration was selected to allow all the different sets of variables to be studied within a 12-month period. At least three pin samples were studied for each set of the conditions. In total 14 combinations of cross shear and contact stress were studied. Wear studies were carried out in 25% (v/v) newborn calf serum. Wear volume was determined by gravimetric analysis and soak control pins were used to adjust for moisture uptake. A constant density of 0.934 mg/mm^3 was used to determine the volumetric wear.

Results were expressed as [1, 20]:

$$\text{Wear factor } K = \frac{\text{Wear volume } V}{\text{Load } P \times \text{Sliding distance } X}.$$

The wear factor is the wear volume divided by the load and divided by sliding distance. The average wear factor and 95% confidence limits were calculated for each set of the conditions. The wear factors were determined as a function of cross shear for stress levels of 1 and 3 MPa and as a function of stress for a single cross shear value of 0.254.

Knee simulation methodologies have been used consistently in our laboratories over a period of 10 years using standard operating procedures and carefully regulated

controls. Over 1 billion cycles of testing have been completed and published in the last decade in both pin-on-plate and knee simulator studies, providing a robust platform for standardized comparison of both materials and designs. Knee simulator studies were undertaken on the Prosim knee simulator (Simulation Solutions, Manchester, UK) [4, 11, 12, 22]. Two sets of tests were carried out: (1) comparison of fixed-bearing PFC sigma knee to the PFC sigma rotating platform knee (DePuy International) and (2) comparison of sigma fixed-bearing knee with low conforming fixed-bearing knee, where the curved tibial insert was replaced by a flat polymer insert.

In the first comparison, the PFC sigma knee had a shot-blast titanium tray and first-generation locking mechanism, which like many historical knee designs produces backside wear, while in the second comparison a current sigma knee design was used with a polished cobalt chrome tray and improved locking mechanism was used, so the effect of tray design on backside wear was also investigated. Cruciate-retaining designs of medium size 3 with 10-mm thick polyethylene were used in all cases. All bearings were manufactured from gamma irradiated in a vacuum polyethylene which was barrier packed until prior to the test. The irradiation level was between 2.5 and 4 MRad, indicating moderate levels of cross-linking, which was available for both types of knee design. Tests were carried out using the ISO loading profile 2.6 KN with a medial offset load and flexion extension waveform of 0° to 58° representing standard gait [22]. For high kinematic conditions displacement was controlled with internal external rotation set at $\pm 5^\circ$ as in the natural knee and anterior posterior displacement set at 0 to 10 mm [22]. Intermediate kinematic conditions with reduced anterior posterior translation of 0 to 5 mm and the same $\pm 5^\circ$ rotation as the high kinematics were also used [22]. Flexion extension, rotation, and anterior translation were controlled by displacement waveforms. For the rotating platform, the knee design constrained the AP motion; it was only studied with AP motion controlled by the force waveform defined by ISO 14243, with a displacement equivalent to that seen for the intermediate kinematic conditions. The rotating platform design allows rotation of the mobile tibial insert on a polished cobalt chrome tray, which leads to decoupling of motion, with flexion and extension on the upper femoral interface, and a small amplitude curvilinear rotation path on the lower tibial interface, resulting in decoupling of complex kinematics into two simpler motions each with very low cross shear at the two separate articulating interfaces. In contrast, the fixed-bearing knee has all three motions on the upper articulating interface resulting in cross shear of the polyethylene. For each set of conditions, six knee prostheses were tested for a minimum of 3 million cycles. Tests were carried out under high kinematics and

under intermediate kinematics, with AP force control for the rotating platform design. Wear was measured gravimetrically and soak controls were used to compensate for moisture uptake. All components were presoaked to stabilize prior to the tests. Simulations were carried out in 25% (v/v) newborn calf serum. For each set of six knees and each set of conditions the mean wear rate $\text{mm}^3/\text{million cycles}$ plus 95% confidence limits was calculated. Comparison of means was undertaken using one-way ANOVA. Wear areas on polyethylene were marked at the end of the tests, photographed, digitized, and calculated using Image-Pro Plus (Media Cybernetics, Bethesda, MD).

Results

A reduction in cross shear reduced the wear in both the pin-on-plate studies and in the rotating platform mobile-bearing knee in the knee simulator study. Reduced cross shear ratio reduced the wear factor in the pin-on-plate studies for the two different stress levels studied [13, 20] (Fig. 1). The rapid decrease in the wear factor as the cross shear ratio decreased from 0.1 to 0 is of particular note. The experimental data were curved fitted over the cross shear range 0 to 0.25, and the logarithmic curve [20] extrapolated to cover the full range of cross shear possible up to 0.5. These results also indicated that the values of the wear factor were dependent on the contact conditions, the load, contact area, and stress level. The reduction in cross shear inherent in the design of the rotating platform mobile-bearing knee [21] produced an 80% reduction ($p < 0.01$) in wear compared to the standard fixed-bearing knee under high kinematic conditions, and produced a 50% reduction in wear compared to standard fixed-bearing knee under

Fig. 1 Shown is the variation in wear factor as a function of cross shear ratio for two different stress conditions showing an increase in wear factor as the cross shear ratio increases. The 1 MPa data points correspond to a pin diameter of 10 mm and load of 80 N, while 3 MPa data point corresponds to pin diameter of 8 mm and load of 160 N. Data points represent mean values ($n = 3$) $\pm$ 95% confidence limits.

intermediate kinematic conditions (Fig. 2). The polyethylene insert in the rotating platform knee rotated on the inferior surface, thus producing linear flexion and posterior translation only on the femoral surface with very low cross shear. The small amplitude tangential curvilinear (rotation) motion on the lower tibial surface had zero cross shear (Fig. 3). The fixed-bearing knee under intermediate kinematics had a 100% increase in wear compared to the rotating platform mobile-bearing knee due to increased cross shear on its single femoral articulating surface. The fixed-bearing knee under high kinematic conditions had a further increase in wear associated with additional AP translation causing increased sliding distance, increased cross shear, an increased wear area, and additional back-side wear.

A reduction in the surface area of polyethylene being worn reduced the surface wear in both the pin-on-plate and in the low conforming fixed-bearing knee. An increase in the contact pressure in the pin-on-plate associated with either reduced surface area or increased load reduced the

Fig. 2 The wear rate of PFC sigma rotating platform mobile-bearing knee (with AP force control) is compared to the fixed-bearing PFC sigma knee under high and intermediate kinematics showing a reduction in wear in the rotating platform mobile-bearing knee with reduced cross shear. Mean ($n = 6$) $\pm$ 95% confidence limits.

Fig. 3 The linear low cross shear motions in rotating platform knee design shows AP and flexion extension as linear motion on the femoral interface, and rotation as a low amplitude curvilinear low cross shear motion on the tibial interface.

polyethylene wear factor (Fig. 4). The effect was more evident when the contact pressure was varied over a wider range of pressures associated with changes in both load and area (Fig. 4). Classical wear theory (Archard's Law [1]) assumes a constant wear factor that is assumed to be independent of contact stress or wear area (as shown by the constant wear factor line in Fig. 4). This is clearly not appropriate for polyethylene. The effect of contact pressure increased from 1 to 10 MPa produced an 83% reduction in wear factor, a similar level to the change seen with increased cross shear. The importance of reduced contact area producing reduced wear was confirmed in the knee simulation studies. The reduction in conformity and reduced surface area being worn for the fixed-bearing knee produced a remarkable reduction in surface wear (Fig. 5).

Fig. 4 The variation in the wear factor as a function of contact pressure (for changes in area and load) for a cross shear of 0.254, showing a reduction in wear factor with a reduction in surface area (and increase in contact pressure). Data points represent mean values ($n = 3$) $\pm$ 95% confidence limits. Contact conditions 1 MPa (10 mm diameter pin and 80 N load), 3 MPa (8 mm diameter pin and 160 N load), 6 MPa (5 mm diameter pin and 120 N load), and 10 MPa (5 mm diameter pin and 200 N load). The constant wear factor line $k = 4.5 \cdot 10^{-7} \text{ mm}^3/\text{Nm}$ is based on Archard's law assumption.

Fig. 5 Comparison in the wear rate in sigma fixed-bearing knee with standard curved insert design to low conforming flat tibial insert showing a reduction in wear rate with low conforming fixed bearing knees. Mean ($n = 6$) $\pm$ 95% confidence limits.

Fig. 6A–B Photographs comparing worn areas in (A) curved and (B) flat inserts of fixed bearing knees show smaller wear area in the low conforming flat insert.

The low conforming bearing knee produced a substantial 75% reduction ($p < 0.005$) in wear compared to the standard curved insert under high kinematic conditions and a 50% reduction ($p < 0.01$) in wear under intermediate kinematic conditions. The reduction in wear was associated with a 75% reduction in the apparent area of polyethylene being worn under high kinematics (Fig. 6A–B).

Discussion

Surface wear of polyethylene is not only determined by sliding distance and load [1], but also by other variables including cross shear [3, 25] and the surface area [2] of the polyethylene being worn. We therefore investigated to what degree surface wear was reduced by (1) reduced levels of cross shear in rotating platform mobile-bearing

knees, and (2) reduced bearing surface area in low conforming fixed-bearing knees.

We acknowledge several limitations. First, laboratory wear simulation studies can be criticized as only representing standard gait or ideal conditions and not determining wear under a wider range of conditions or accommodating variations in surgical technique and individual patient kinematics. While different kinematics such as lift off can accelerate wear [18], it is difficult to relate such data to the clinical situation when the rate of occurrence of these kinematics conditions is not known in the patient population. Similarly, while paradoxical AP motion for some cruciate retaining devices has been reported in some clinical studies, it is not currently recommended in the ISO standard, and has not been defined as a standard input waveform and was therefore not included in this study. However, simulation studies benefit from sets of standard conditions in a single laboratory, in which studies of individual variables can be undertaken. Laboratory wear simulation also allows wear to be determined gravimetrically, eliminating the difficulty in determining and eliminating creep deformation when using geometrical methods, but it does assume a constant density for polyethylene. Second, care must be taken not to compare the absolute values of wear rates between different simulators from different laboratories although similar trends may suggest important to observations. In this study 25% (v/v) newborn calf serum was used as recommended by the ISO standard. Third, for low wear rates of less than 5 mm³/million cycles it is difficult to differentiate the effect of the variables being studied from uncontrolled and random errors in the system. The methods we report here have been used in over 1 billion cycles of knee simulation during the last 10 years, and in sum we believe reflect the largest single laboratory experience.

The importance of cross shear in determining surface wear rates in the knee was demonstrated in both the pin-on-plate studies and the knee simulator studies, with decreased cross shear decreasing wear rate in the rotating platform mobile-bearing knee. In fixed-bearing knees increased cross shear and increased wear reportedly occurs with higher levels of activity, whether it be increased rotation [22] or increased lateral shift with lift off [18]. Increased cross shear also increases wear in the hip [3, 25]. The rotating platform mobile-bearing knee design, which accommodates rotation on the lower articulating surface, decouples complex motions to simple unidirectional motion and low cross shear on both articulating surfaces (Fig. 3), thus reducing cross shear and surface wear. However, the design does not accommodate any medial lateral shift arising from lift off, and lift off does result in increased cross shear and wear on the upper surface [18]. Additionally, if rotation does not occur at the lower tibial

surface, cross shear is increased on the top surface and for a conforming geometry this could also increase surface wear. The wear rates for the reference fixed bearing knees in this study, the PFC Sigma with gamma-irradiated polyethylene in a vacuum, were between 9 and 22 mm³/million cycles depending on kinematics and type of tray, with wear areas similar to those reported from retrievals [22]. Currently there are no volumetric wear studies of clinical wear rates with which to compare these simulator studies, which is a general deficiency in the research literature. Our method of using AP force control for the rotating platform design could be criticized as being different from the displacement control in the other fixed-bearing tests. However, it produces similar displacement to the intermediate kinematics conditions. It is justified on the basis that the rotating platform design controls anterior motion in this design. The rotating platform design gives low wear rates due to reduction in cross shear. Other studies have reported no difference in the size distribution of the wear particles between the fixed-bearing and mobile-bearing designs under conditions of surface wear [12], indicating the reduction in wear volume with rotating platform design will also lead to reduced functional osteolytic potential.

We also observed a reduction in wear with reduced surface area and increased contact pressure for both the pin-on-plate and fixed-bearing knee simulations. This was most evident in the low conforming fixed-bearing knee (Figs. 5, 6) which showed a fourfold reduction in wear rate compared to knees with a curved insert. The effect of contact pressure on wear has been previously reported for unidirectional motion pin-on-plate studies [2] and the effect of conformity on surface area on wear has also been reported in the hip [26]. This approach to reducing surface wear by reducing conformity and wear area contradicts the thinking of the 1980s and 1990s [5, 6, 8, 19] that led to more conforming designs in order to avoid the risk of delamination and fatigue following oxidative degradation. The conformity of fixed-bearing knee designs has generally increased over the last two decades, partly to address concerns over fatigue failure and delamination due to oxidative degradation of polyethylene. Our new results of decreased surface wear with reduced conformity and surface area offers the potential of a new paradigm in knee design. The pin-on-plate results can be extrapolated to predict the wear for fixed-bearing knee designs with high cross shear (Fig. 7), and illustrates very low surface wear at very low conformity and low surface area. This new concept of reduced surface area (increased contact pressure) is constrained when the fatigue limit of polyethylene is reached, when the surface area is reduced to extremely low levels (Fig. 7). As polyethylene technology has advanced with stabilization, cross-linking, and remelting, and use of antioxidants, the potential for extending the

Fig. 7 Prediction of wear rate in fixed bearing knee from pin-on-plate data as a function of wear area and conformity, showing a reduction in wear with reducing wear area. At very low-wear areas, the fatigue limit of the material is reached.

design envelope for less conforming design needs further exploration. Such approaches also bring the potential advantages for improved functionality, but are dependent on the soft tissues being intact to provide the necessary stability. Applications of low conforming fixed-bearing design are indicated in unicompartmental knees. The converse of this is that if soft tissue stability is not adequate, then a low conforming design is not appropriate and increased conformity is required in the design. Contrary to previous thinking, this will increase the surface area and surface wear in fixed-bearing designs. Under these circumstances if a low-wear solution is required then a rotating platform design that has conformity and stability, as well as low wear, is indicated.

Both reduction in cross shear, which is reduced in rotating platform mobile-bearing designs, and reduction in surface area, which is reduced in low conforming fixed-bearing designs, reduce surface wear and osteolytic potential. These two different tribological approaches to reducing surface wear generate two very distinctly different design solutions for low-wear knee designs. These should be considered alongside stability and soft tissue function in defining knee arthroplasties with low surface wear to meet the lifetime tribological demands of young and active patients.

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