

## MINI-SYMPOSIUM: TOTAL KNEE REPLACEMENT— PRACTICAL CONSIDERATIONS

### (i) Wear of polyethylene in artificial knee joints

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#### INTRODUCTION

Increasing numbers of artificial knee joints are being implanted in patients worldwide. In particular, there is a growing demand in younger patients under the age of 60 who have a longer life expectancy, often beyond 20 years, and also undertake higher levels of activity with their prosthetic replacement. Currently, most knee replacements comprise a polished metallic femoral component articulating against an ultra-high molecular weight polyethylene (UHMWPE) tibial insert, which is often supported by a metallic tibial tray. The medium-term results of current generation knee replacements are good with less than 10% failure at 10 years in some series. However, this has not always been the case. Some knee designs from the 1980s failed in less than 10 years due to delamination and structural fatigue.<sup>1</sup> Improvements in designs, materials and sterilization techniques during the 1990s have led to the improved clinical performance currently recorded at 10 years. However, in the longer term, concern remains regarding the surface wear of these components as the generation and accumulation of micrometre and submicrometre size wear particles may lead to osteolysis and long-term failure mechanisms similar to those found in hip replacements.<sup>2</sup>

These concerns are supported by recent observations of micrometre and submicrometre size wear particles in tissues surrounding knee prostheses that were revised for infection in the early years of implantation.<sup>3</sup> The concentration of particles per gram of tissue was similar to that found in tissues surrounding early hip revisions. Although both the early failure knees and the early failure hips showed lower concentrations of particles than

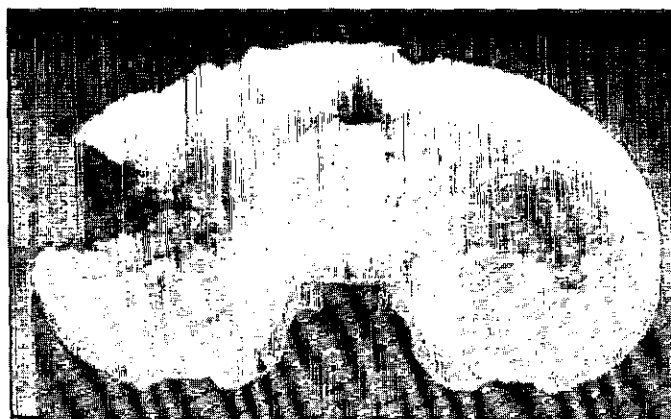
those found in tissues surrounding longer-term revisions in the hip due to osteolysis and loosening, the potential for accumulation of polyethylene wear particles in the knee, in a similar manner to the hip, is indicated.

In this paper, recent studies of the wear of polyethylene in knee prostheses by our research group are reviewed, key findings are presented and current and future research issues are considered. In the first section, delamination failure and structural fatigue is discussed and the recent improvements in materials for knee prostheses, which have led to a dramatic reduction and potential for elimination of this failure mode, are described. In the second section, surface wear and the generation of micrometre and submicrometre wear particles is discussed and the influences of design and material properties on the surface wear and osteolytic potential are considered.

#### DELAMINATION AND STRUCTURAL FAILURE IN KNEES

Repeated cyclic loading of the UHMWPE, which results in subsurface fatigue and failure of the UHMWPE tibial insert, causes delamination wear. The fatigue failure can occur with or without surface sliding and commonly results in gross structural failure of the UHMWPE insert (Fig. 1).<sup>1</sup> The factors that contribute to and accelerate delamination failure can be considered in two groups: biomechanical factors and material factors.

The biomechanical factors which contribute to delamination failure include implant conformity, UHMWPE thickness, implant alignment, and excessive gliding or translation of the contact zone on the tibial insert. The conformity of the knee prosthesis is dependent on the curvatures of the femoral component and its articulating UHMWPE insert in both the coronal and sagittal planes. The contact becomes more



**Figure 1** An example of delamination failure and structural fatigue in an explanted UHMWPE tibial insert.

conforming as the difference in radii of curvature of the two components is reduced. The experimental and theoretical studies of Stewart et al.<sup>4</sup> and Jin et al.<sup>5,6</sup> showed that as the geometries become less conforming the values of peak contact stress approach and exceed the yield stress of UHMWPE, making it prone to fatigue failure. The maximum shear stress in the contact occurs several millimetres below the surface in the centre of the contact and this peak stress, which is reached during each cycle of walking, is the initiator of subsurface fatigue failure. Whilst geometries can be made more conforming to reduce these stress levels, there are design contradictions as the more conforming geometries can result in less favourable kinematics. Jin et al.<sup>5,6</sup> demonstrated that the thickness of the UHMWPE also had a marked effect on the stress level, with a thickness of less than 6 mm causing a clear increase in contact stress. High contact stress can also occur in some knees if the components are not correctly aligned, as edge contact or loading is produced on areas of the geometry that are less conforming. If the knee prosthesis has low stability, possibly due to poor soft tissue constraint, and there is excessive gliding of the femur on the UHMWPE insert, the translation of the contact can produce high levels of cyclic stresses. These stresses may be close to the edge of the insert and this can further increase the potential for delamination failure.

The material factors that contribute to delamination failure include poor consolidation of the UHMWPE, fusion defects and oxidative degradation of the UHMWPE. Incomplete consolidation of the grains of the polyethylene powder during compression moulding or extrusion can result in defects in the microstructure of the material. These can act as sites for crack initiation and propagation, leading to fatigue failure. However, the single most important factor that contributes to delamination failure is oxidative degradation of the

UHMWPE following irradiation sterilization in the presence of air. Gamma irradiation causes scission of the long chains of polyethylene, creating free radicals that are long lived and lead to degradation of mechanical properties over time. In particular, the molecular weight of the polymer is reduced and the ductility and toughness are also markedly decreased. Clinical observations of delamination failure have been reported with UHMWPE that has been gamma irradiated in air and then aged.<sup>7,8</sup> Laboratory studies<sup>9</sup> were able to replicate delamination failure in sliding wear tests with UHMWPE which had been sterilized by gamma irradiation in air, aged and oxidized. Similarly, Bell et al.<sup>10</sup> reproduced delamination failure in a knee joint simulator with UHMWPE that had been gamma irradiated in air, oxidized and aged. Most importantly, neither study was able to produce delamination failure with UHMWPE that had not been oxidized and degraded. It is extremely unlikely that delamination of good quality standard UHMWPE will occur in the absence of oxidative degradation.

UHMWPE is currently stabilized against oxidative degradation either by sterilization without irradiation or by irradiation sterilization in an inert atmosphere, such as argon, nitrogen or vacuum, followed in some cases by heat treatment to quench free radicals. It is extremely unlikely that these stabilized materials will degrade substantially, hence, delamination failure is improbable in the future. However, it is important to note that some new materials use a high dose of radiation to elevate the crosslinking of the polymer with the aim of improving wear resistance. This also substantially reduces ductility and toughness.<sup>11,12</sup> Therefore, caution is required in applying these materials to highly stressed knees in case the reduction in mechanical properties, caused by high levels of crosslinking, leads to further delamination and structural fatigue.

## SURFACE WEAR

The introduction of stabilized UHMWPE with the potential to eliminate delamination failure indicates that surface wear is now the predominant concern and potential cause of long-term failure in knee prostheses. Surface wear produces micrometre and submicron size wear particles as a result of the metal and UHMWPE articulating surfaces sliding over each other. This can lead to osteolysis and loosening,<sup>2</sup> thus replicating long-term failure modes found in the hip joint. Recently, it has been shown that the volumetric concentration of polyethylene particles in the tissues surrounding knee prostheses is similar to that observed in hip prostheses.<sup>3</sup> UHMWPE wear debris may also be generated at fixation interfaces in knee prostheses, such as the interface between the UHMWPE insert and the titanium tibial tray in a fixed bearing knee. However, at present these volumes are thought to be small although no quantitative data exist to confirm this.

The generation of UHMWPE wear debris from the articulating surfaces in knee prostheses is controlled by a number of factors. These include oxidative degradation of the polymer, damage or scratching to the femoral counterface, kinematic input conditions (in particular, the amount of internal and external rotation) and the design of the knee.

The effect of oxidative degradation of polyethylene, which had been gamma irradiated in air, on surface wear was first shown in 1995.<sup>13</sup> Shelf ageing for 5 years produced a threefold increase in wear rate. More recently, it has been shown that ageing for longer periods further increases wear and that oxidative degradation produces smaller and more biologically active wear particles; thus, further increasing the osteolytic potential of the material.<sup>14</sup> The introduction of stabilized UHMWPE, either with gas plasma sterilization or with irradiation in inert atmospheres, has resulted in materials that no longer exhibit increased wear rates with ageing.<sup>9,15</sup> Oxidative degradation should not occur in the new stabilized polyethylenes and therefore accelerated surface wear will be prevented.

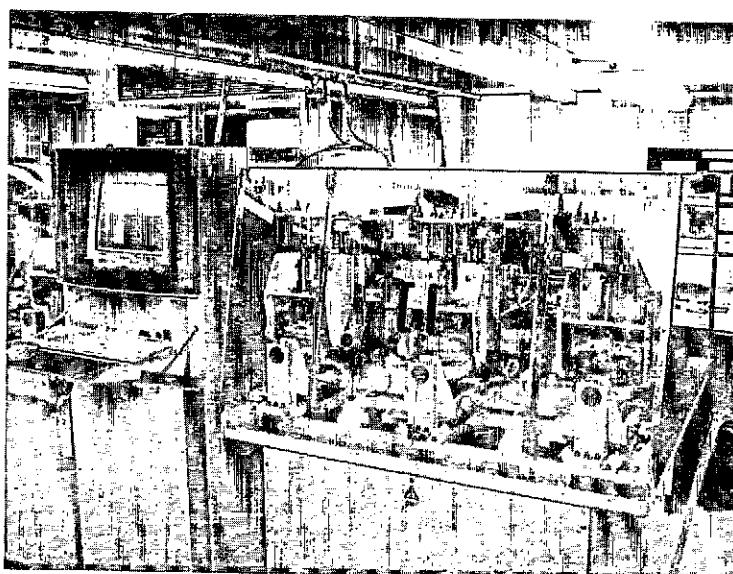
Damage to the polished metallic femoral counterface is a well-recognized factor that increases UHMWPE wear in the hip.<sup>16,17</sup> Discrete scratches on the femoral component, with height and depth in the range 1–2  $\mu\text{m}$ , can increase wear rates by two to three times. In laboratory tests, in which the discrete scratches are located perpendicular to the principal direction of sliding, the wear rate is also increased by up to a factor of three.<sup>16,15</sup> However, in vivo scratches on the knee primarily occur in the antero-posterior direction on the femoral component, which is parallel to the principal sliding direction.<sup>18</sup> It has been suggested that these may not have as large an effect on wear as scratches located perpendicular to the direction of sliding. Recent *in vitro*

simple configuration wear tests, with simulated scratches parallel to the principal direction of motion, have shown that wear is increased by up to a factor of two, provided there is also a small amount of multidirectional motion such as 10° of internal-external rotation. Whilst the primary direction of sliding in the knee is antero-posterior as a result of the flexion-extension motion, there is also a degree of multidirectional motion produced by the internal-external rotation. This will accelerate the wear of UHMWPE in the presence of scratched femoral components. Further work is needed to understand the interactions of femoral counterface damage, knee design and kinematics on the acceleration of UHMWPE surface wear.

The kinematics of the knee have a marked effect on the wear of UHMWPE, even in the absence of femoral condylar scratching. Early knee joint simulators produced simplified motion patterns and, whilst they replicated flexion-extension and in some cases antero-posterior translation, they failed to simulate the important internal-external rotation. As a result, the wear rates produced were generally very small and were in the range 1–2  $\text{mm}^3$  per million cycles. This has led to an inappropriate historical perception of the amount of surface wear that can occur in artificial knee joints. The cause of reduced wear rates with simplified motions such as flexion-extension and antero-posterior translation is that these produce a simple linear motion in the antero-posterior direction. Under these conditions, a linear polymer such as polyethylene becomes strain hardened and increases its wear resistance along the axis of the unidirectional motion. Consequently, the polyethylene becomes much weaker in its transverse direction. Introducing a motion such as internal-external rotation, which produces a frictional force in the transverse direction, increases the wear rate. During the late 1990s, standards were developed for knee joint simulator testing which specify the kinematic inputs required, namely axial force, flexion-extension motion, antero-posterior translation and internal-external rotation.<sup>19</sup>

The Leeds ProSim knee joint simulators are examples of machines that subject knee components to these forces and motions.<sup>20</sup> A photograph of one of the ProSim six station knee joint simulators is shown in Fig. 2 and the force and kinematic inputs that have been used in testing are illustrated in Fig. 3. Recent studies in our laboratories and in other centres have highlighted the importance of kinematic input conditions, particularly internal-external rotations, on the wear of UHMWPE in artificial knee joints. This has significant impact on the long-term osteolytic potential of knee prostheses, particularly in younger and more active patients.

The Leeds ProSim knee joint simulators have been used to study fixed bearing knees under different kinematic input conditions and to compare these with



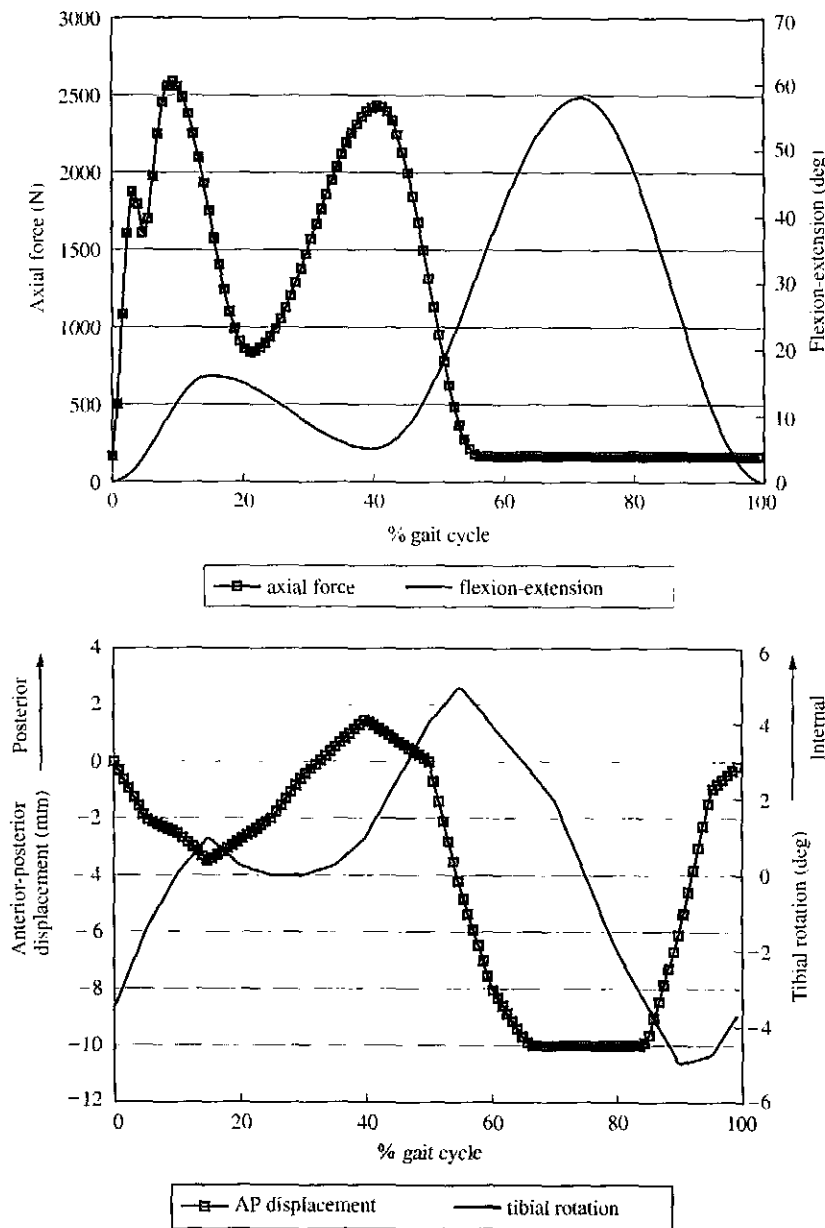
**Figure 2** A photograph of the Leeds ProSim six station knee joint simulator.

mobile bearing knees. The PFC Sigma (DePuy, Leeds, UK) fixed bearing knee has been studied on both machines using the kinematic inputs illustrated in Fig. 3 to assess both inter-station and inter-machine variability.<sup>20</sup> The mean wear rate and 95% confidence limits for the PFC Sigma knee for the 12 stations of the two machines was  $18.1 \pm 3 \text{ mm}^3$  per million cycles. There was no statistical difference between the two knee simulators. The effect of kinematic input conditions on the UHMWPE wear rate was compared using PFC (DePuy, Leeds, UK) fixed bearing knees. Initially the knees were studied for three million cycles under low kinematic input conditions, during which the internal-external rotation and anterior-posterior translation motions were reduced to half the values shown in Fig. 3. After three million cycles, the kinematic inputs were increased to the high input conditions illustrated in Fig. 3 and the wear rate was determined over a further three million cycle test. The wear rates for the low and high kinematic conditions are shown in Fig. 4.<sup>21</sup> For the low kinematic conditions the wear rate was  $7.7 \pm 2 \text{ mm}^2$  per million cycles but the wear rate increased to  $41 \pm 14 \text{ mm}^3$  per million cycles with the high kinematic input conditions. The greater wear is attributed to the increased amount of cross shear of the polyethylene, due to the increased internal-external rotation. The cross shear that is caused by increased rotation when subjected to high kinematic input conditions accelerates wear. The higher level of wear exhibited by the PFC knees compared with the PFC Sigma knees under high kinematic conditions is partly attributable to oxidation effects, as the PFC was irradiated in air and aged for up to 3 years, while the

modern design PFC Sigma is irradiated in a vacuum and foil packed to prevent oxidation.

In a second in vitro study, wear of the LCS Rotating Platform (DePuy, Leeds, UK) mobile bearing knee was compared with that of the PFC Sigma fixed bearing knee over six million cycles under high kinematic input conditions.<sup>22</sup> The LCS Rotating Platform had a significantly lower wear rate than the fixed bearing knee (Fig. 5). We postulate that the rotating platform design decouples the motions between the femoral-insert and tray-insert articulating surfaces. Most of the rotation will occur at the distal tibial articulating surface, which is simply a unidirectional rotation motion that produces low wear. Since most of the rotation occurs at the distal interface of the UHMWPE insert, the proximal femoral articulating interface has very low rotation. Therefore, at this articulation the motion is also preferably unidirectional and similarly has a low wear rate. Thus, a much lower overall wear rate is exhibited by the rotating platform design with high kinematic inputs than that observed for the fixed bearing PFC Sigma knee. It is interesting that reduction of the internal-external rotation kinematic inputs with the rotating platform knees produced little change in wear rate. This further supports the above explanation that the rotation is decoupled to the distal interface of the UHMWPE bearing where very little wear is produced.

It must be emphasized that the knee prostheses in these simulators are tested using standard, regular kinematic inputs and are correctly aligned in the machine. Prostheses will be subjected to a greater range of kinematic conditions in vivo due to different patient

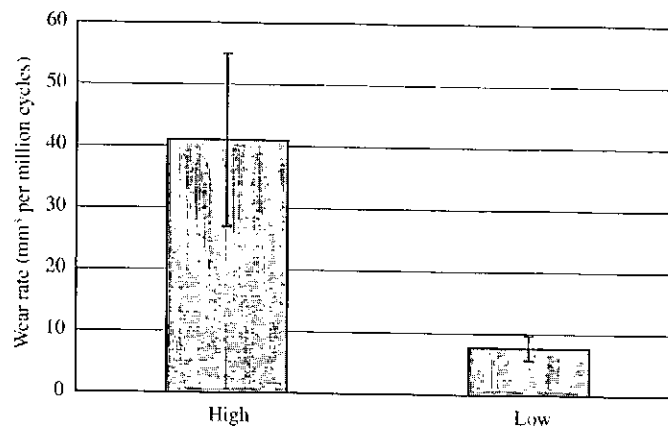


**Figure 3** A diagram of the inputs used for the knee joint simulator. (a) flexion-extension and axial force:<sup>19</sup> —□—, axial force; —, flexion-extension. (b) internal-external tibial rotation and anterior-posterior displacement:<sup>42</sup> —□—, AP displacement; —, tibial rotation.

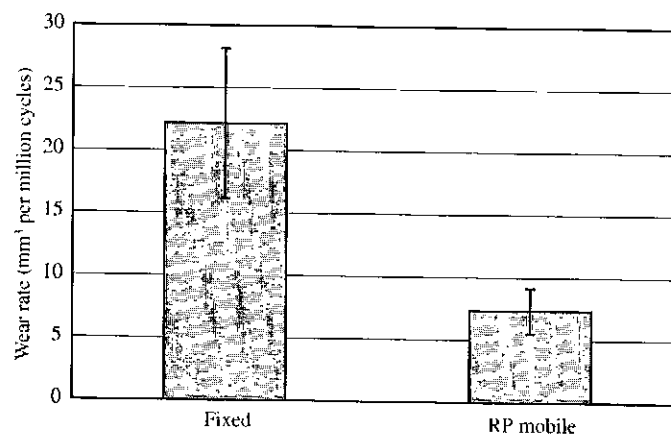
activities. Recent fluoroscopic studies have shown considerable variation in the kinematics experienced by individual patients and between different patients and designs of knees.<sup>23,24</sup> Further work is needed to understand the effect of different kinematic conditions, such as condylar lift-off on wear of knee prostheses.

There is a definite need to further reduce surface wear in polyethylene components of knee prostheses for implantation in younger, more active patients. This is generating interest in the use of highly crosslinked polyethylenes. While the wear rates of these materials

in the hip may be lower than non-crosslinked or moderately crosslinked and stabilized materials, similar wear reductions in the knee, which has different kinematics to the hip, remain to be demonstrated. In addition, the recognition that highly crosslinked materials produce smaller and more reactive polyethylene wear particles must be considered alongside any reductions in wear volume. Concerns about reduced toughness of the highly crosslinked materials also need to be addressed prior to widespread use in the knee. The increase in polyethylene wear due to femoral surface damage demands alternative biomaterial solutions in the knee.



**Figure 4** Comparison of the mean wear rates  $\pm 95\%$  C.L. for the PFC ligament retaining knee under low and high kinematic input conditions.<sup>21</sup>



**Figure 5** Comparison of the mean wear rates  $\pm 95\%$  C.L. for the LCS Rotating Platform mobile bearing knee with the PFC Sigma fixed bearing knee under high kinematic input conditions.<sup>22</sup>

Surface modifications and surface coatings such as titanium nitride are under consideration and have the potential to reduce the detrimental effects of third body damage on UHMWPE wear.

## CONCLUSIONS

The wear of UHMWPE in total knee replacements has been described in terms of delamination wear and surface wear. The advent of stabilized UHMWPE with the potential elimination of oxidative degradation indicates that delamination should not occur with current generation implant materials.

Surface wear remains a concern and the potential for long-term osteolysis necessitates the minimization of the number of wear particles generated. In addition to factors such as oxidation and femoral condyle scratching, which increase surface wear in both the hip and the knee,

the influences of reduced kinematic conditions and rotating platform mobile bearing knee design have been shown to be important in reducing UHMWPE wear rates.

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## MINI-SYMPOSIUM: TOTAL KNEE REPLACEMENT — PRACTICAL CONSIDERATIONS

### (ii) The role of unicompartmental knee replacement

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#### INTRODUCTION

The treatment options for medial compartment osteoarthritis of the knee, producing symptoms sufficient to warrant surgery include:

- High tibial osteotomy (HTO)
- Unicompartmental knee replacement (UKA)
- Total knee replacement (TKR)

When considering which to offer one must consider the outcome, in terms of symptomatic relief and function, the survival rate and the difficulty of revision in the event of failure of each method. Until recently UKA has remained a procedure for the enthusiast because of three perceived problems:

1. Inferior survival rates to TKR.
2. Limited indications and therefore a technique appropriate for only small numbers of patients.
3. Technical difficulty of the procedure.

The benefits, however, of UKA in terms of morbidity and mortality, function and the length of hospital stay are well known and the procedure should appeal to patients, surgeons and managers alike if the apparent problems can be overcome. Recently, there has been a rise in the popularity of this procedure and increasing numbers of reports of its success. To avoid repetition of the failures in the 1980s the principles, indications and techniques required for success must be understood and adhered to.

#### THE DEVELOPMENT OF OSTEOARTHRITIS IN THE KNEE.

In most cases, articular cartilage degeneration in the knee probably results from high impulse loading occurring at heel strike.<sup>1</sup> The area of contact in the knee at this phase of the gait cycle is in the anteromedial tibiofemoral compartment. Radiological studies in the 1960s and 1970s demonstrated that about 90% of patients with osteoarthritis of the knee showed initial wear in the medial compartment and that progression to the lateral com-

partment was uncommon.<sup>2,3</sup> This is reflected in clinical practice. Most arthritic knees have a varus deformity and predominantly medial tibiofemoral arthritis. In 1999, it was shown that progression of osteoarthritis to the lateral compartment is usually associated with rupture of the anterior cruciate ligament (ACL), probably due to impingement of osteophytes in the intercondylar space which abrade the synovial covering of the anterior cruciate ligament.<sup>4,5</sup> The resulting instability and abnormal kinematics lead to tri-compartmental osteoarthritis. Rupture of the ACL is also associated with the development of a fixed varus deformity.<sup>4</sup> Before rupture occurs the posterior parts of the medial tibial and femoral articular surfaces remain intact so that in flexion the medial collateral ligament is stretched to its normal length (Figs. 1–3). Once the ACL has ruptured the contact point in extension moves posteriorly causing damage to hitherto normal cartilage. The resulting loss of joint height in flexion allows the medial collateral ligament to remain shortened throughout the full range of knee movement and permanent contracture of the ligament then develops. This description of the progression of osteoarthritis explains both the association between an intact anterior cruciate ligament and preservation of the lateral compartment and the association between rupture of the ACL and the development of a fixed varus deformity. (Figs. 1 and 2). In TKR removal of an intact ACL and well-preserved lateral compartment is often the first step in the operation. In UKA these healthy structures are preserved allowing the restoration of normal kinematics.

In order to choose the best treatment for a patient with medial compartment osteoarthritis a comparison of the available options has to be made. This must compare their efficacy, long-term survival and options for revision in the event of failure.

#### UKA VS HTO

High tibial valgus osteotomy has long been an accepted treatment for medial osteoarthritis, particularly in young active men. Its continued use into the era of joint replacement can only be justified by comparison with uni- or total replacement but there are few good