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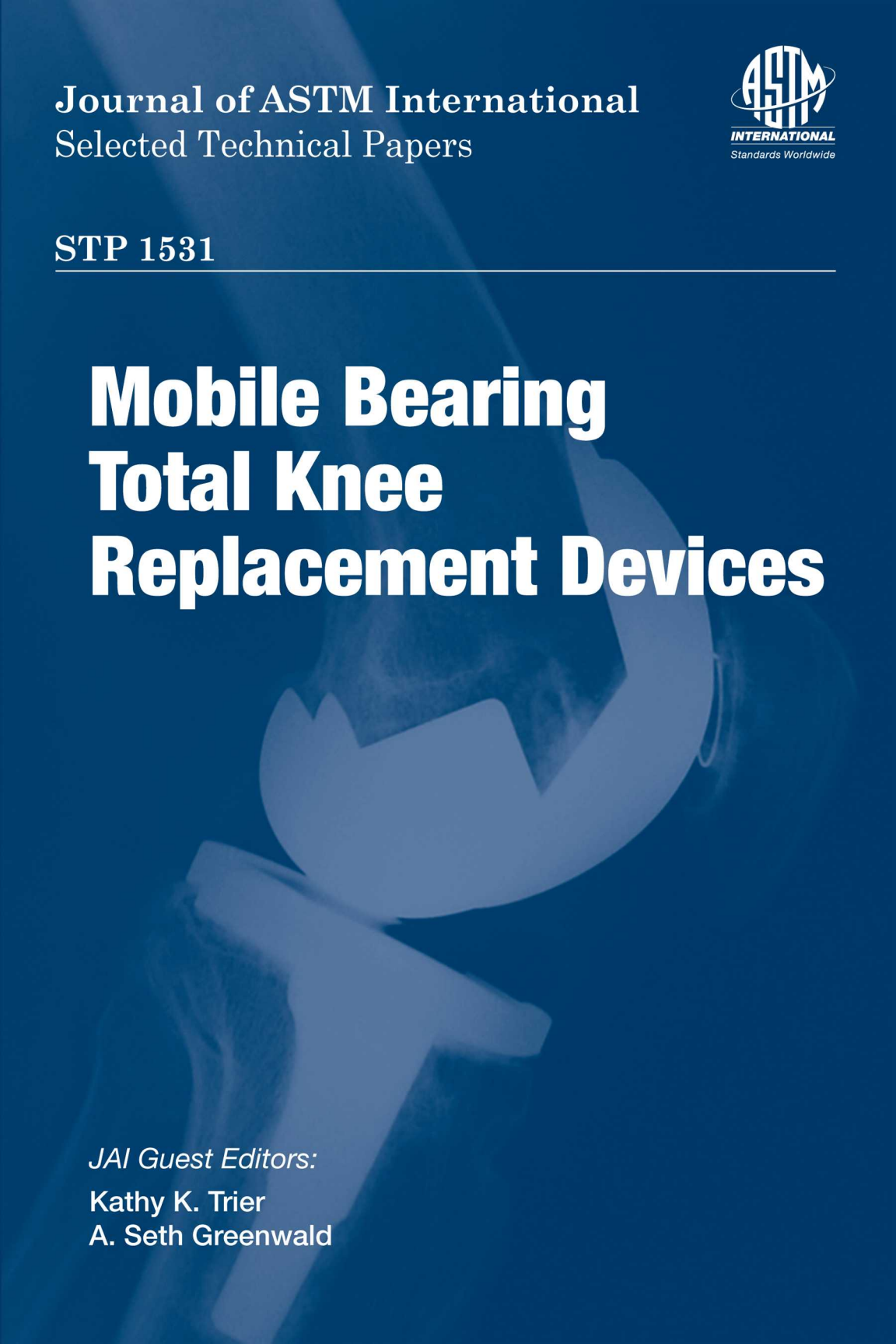
Mobile Bearing Total Knee Replacement Devices



JAI Guest Editors:
Kathy K. Trier
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The JAI is a multi-disciplinary forum to serve the international scientific and engineering community through the timely publication of the results of original research and critical review articles in the physical and life sciences and engineering technologies. These peer-reviewed papers cover diverse topics relevant to the science and research that establish the foundation for standards development within ASTM International.

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Foreword

THIS COMPILATION OF THE *JOURNAL OF ASTM INTERNATIONAL (JAI)*, STP1531, *Mobile Bearing Total Knee Replacement Devices*, contains only the papers published in JAI that were presented at a symposium in St. Louis, Missouri, on May 18, 2010 and sponsored by ASTM International Committee F04 on Medical and Surgical Materials and Devices.

The JAI Guest Editors are Kathy K. Trier, Corin USA, Clearwater, FL, USA and A. Seth Greenwald, Orthopaedic Research Laboratories, Cleveland, OH, USA.

Contents

Overview

Orthopedic knee replacement is a well accepted and clinically successful treatment procedure that provides pain relief and improved function for millions of people each year. Both fixed bearing and mobile bearing knee devices have well recognized success rates as a general category of device with the primary distinction between them characterized by whether the polyethylene tibial component is affixed in a stationary position in the metal tibial tray (fixed bearing) or whether the polyethylene tibial component is allowed to move on the tibial tray (mobile bearing).

While fixed bearing knee devices existed prior to the Medical Device Amendments of the Federal Food, Drug and Cosmetic Act of 1976, the mobile bearing knee devices were not in existence and thus, having no pre-amendment predicate device to support a Substantial Equivalence determination, were automatically classified as Class III devices.

The mobile bearing knee devices were first introduced in the late 1970s and since that time, several generations of mobile bearing knees have been developed and available on the international market. Designs include unicondylar and bicondylar, with either platform-style or meniscal bearing design of the polyethylene articulating surface, with variations in the mobility of the polyethylene, type of constraint of the polyethylene and treatment of the PCL.

In the U.S., the first mobile bearing knee cleared for marketing through the FDA was the Low Contact Stress (LCS) Meniscal Bearing, Cemented, Tricompartmental Knee (DePuy, Warsaw, IN) with PMA approval in 1985. The Rotating Platform version and cementless application gained PMA approval shortly thereafter. In comparison with the global market, the number of mobile bearing knee devices available in the U.S. has been limited in part as a result of the regulatory pathway to commercialization for a Class III device.

Reclassification of mobile bearing knee devices from Class III to Class II has been proposed since the late 1990's with petitions submitted by the Orthopaedic Surgical Manufacturers Association (OSMA) to the FDA. The 1997 reclassification petition was reviewed by the FDA Advisory Panel on July 25, 1997 with the panel determination that there was insufficient evidence to provide reasonable assurance of safety and efficacy for the entire class of mobile bearing knees to be reclassified and recommended that tricompartmental and unicompartmental mobile bearing knees remain Class III devices. A second reclassification petition was favorably reviewed by the FDA Advisory Panel on June 4, 2004 but subsequently denied by FDA on October 28, 2004. Communications with FDA focused on the need for special controls, particularly pre-clinical bench tests that would distinguish

between clinically successful and unsuccessful designs and also recommended working with ASTM to develop consensus standards to address this need.

A determination for reclassification of mobile bearing knee devices from Class III to Class II requires that general controls and special controls, recognized by FDA, can provide reasonable assurance of the safety and effectiveness of the devices and that testing will be able to differentiate between good and bad designs and that test outcomes should be predictive of clinical outcomes. In 2007, ASTM standards development was initiated to incorporate testing for mobile bearing knee designs into existing ASTM knee standards for fixed bearing knee designs and include F1223 Test Method for Determination of Total Knee Replacement Constraint, F1800 Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee joint Replacements, and F2083 Standard Specification for Total Knee Prosthesis. In addition, four (4) new standards have been developed specifically for mobile bearing knee designs and include F2722 Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops, F2723 Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation, F2724 Evaluating Mobile Bearing Knee Dislocation, and F2777 Evaluating Knee Bearing (Tibial Insert) Endurance and Deformation Under High Flexion. The goal of this work was to provide consensus standards that would address the required special controls to mitigate identified risks of all knee device designs. An added revision of F2083 is currently in process to provide a guidance document that covers all known clinical risks associated with the use of knee replacement devices and calls out relevant test methods across a wide range of generic knee designs, unicondylar and bicondylar, fixed and mobile bearings.

The purpose of the ASTM Symposium on Mobile Bearing Knee Devices, May 2010, and this compilation of the papers as presented (STP1531) are to provide a scientific discussion on mechanical testing with regards to their relevance to clinical outcomes and clinical failures. The call for papers requested discussion of clinical data that is relevant to bench performance on the following topics related to mobile bearing total knee replacement devices:

- Mobile bearing knee tibial baseplate/ bearing resistance to dynamic disassociation.
- Mobile bearing knee tibial baseplate rotational stops.
- Dislocation, spin out, spit out.
- Determination of constraint for mobile bearing total knee replacements
- Cyclic fatigue testing of metal tibial tray components for mobile bearing total knee joint replacements.

- Knee bearing (tibial insert) endurance and deformation under high flexion for mobile bearing knee replacements.
- Knee bearing (tibial insert) wear including backside wear.
- Contact area, contact pressure distribution for mobile bearing knee joint replacements.
- Range of motion testing for mobile bearing knee joint replacements.

All presenters were encouraged to submit their work for inclusion and were peer reviewed using independent qualified reviewers. Given the specific goal of the symposium, peer review criteria to meet editorial requirements were liberal.

Two papers serve to provide a context for the remaining papers presented here (STP1531). The first provides an overview of the standards development as described and the second provides an updated review of the literature on clinical outcomes of mobile bearing knee devices. The following symposium papers have been organized under four themes that address the above specified clinical risks. For obvious reasons, while papers are organized under the key themes, they may overlap across themes.

Component Disassociation

The intent of this section is to present clinical papers that address ASTM F2724 and F2723 test methods, mobile bearing knee dislocation and tibial tray/polyethylene bearing disassociation respectively. Papers describe clinical results related to spin out, polyethylene dislocation and subluxation related to differing implant designs. One paper describes implant design modifications which were implemented to address spin out. Other papers report results of the relationship of polyethylene dislocation on revisions and a comparison of crepitation and pain following TKA with posterior stabilized designs, both rotating platform and fixed bearing.

Mechanical Fracture

Test methods to evaluate rotational stop (F2722) and polyethylene bearing deformation/fracture (F2777) are newly developed standards while testing for tibial tray fatigue/fracture (F1800) has been used with regards to fixed bearing knee designs. The papers in this section include a discussion of validated computational models using finite element (FE) methods to visualize the magnitude and location of stresses on the polyethylene bearing and identify parameters that vary with in vivo movement. Results demonstrate that FE models successfully predict clinically observed results.

Functional Performance

Papers in this section look at clinical outcomes as they relate to alignment and range of motion, measuring intraoperative rotation (F1223 constraint) and postoperative revisions as a result of spinout and dislocation. Wear simulator and wear particle analysis, clinical and radiographic results, and evaluation of the impact of the tibio-femoral bearing on abrasive wear, tibio-femoral kinematics and particle release across different designs are discussed. The focus of these papers are on knee devices with rotational mobility (rotational and linear motion) between the polyethylene bearing and tibial tray with one paper suggesting that the benefit the mobile bearing devices offers is self alignment to accommodate small rotational misalignments.

Longevity and Wear

F2083 addresses the specification of test methods for knee replacement devices and covers known clinical risks associated with the use of knee replacement devices, both fixed and mobile bearings. Focus in this section is on contact area, backside wear and total wear. Two papers addressing backside wear in mobile bearing rotating platform total knee designs evaluate the distinction between bearing wear and bearing damage suggesting that damage is not a proxy for polyethylene wear and the rate of wear over time with a mobile bearing device compared to a fixed bearing knee device. Papers also discuss a conservative measurement of total wear penetration and penetration rate in one mobile bearing design and a method for simulation of wear in mobile bearing unicompartmental knee replacement. Comparisons of total wear for many different knee device designs, both fixed bearing and mobile bearing and total and unicompartmental in a wide range of sizes, are reported. Key questions address "Do mobile bearing knee devices produce less total wear than fixed bearing devices? Is the difference found across knee devices a result of materials and implant designs?"

Significant and Future Work

Central to the discussion during the symposium was the fundamental question – "Are the standards sufficient to differentiate across mobile bearing device designs and predict clinical outcomes?" It is clear that some mobile bearing knee designs have long successful clinical history. A number of papers provided test results specific to a particular device design while others covered a wider range of designs. A common thread throughout the papers and symposium discussions is that few knee devices (fixed and mobile) today experience clinical failures making it difficult to validate ASTM test methods by testing both "good" and "bad" device designs via round robin

testing. It is appropriate to suggest that testing completed on the currently successful mobile bearing devices can serve as a measure of validation for the knee device standards. It is important to remind that these knee standards have been developed by consensus of the members of the ASTM F04 Arthroplasty subcommittee and that the collective experience and knowledge of the breadth of knee device design is extensive.

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JAI Guest Editors

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Standard Testing Methods for Mobile Bearing Knees

ABSTRACT: From 1970 to 2000, many types of total knee arthroplasties were introduced, including mobile bearing knees. In order to mechanically evaluate the designs, tests were developed for factors such as strength, laxity and constraint, kinematics, and wear. A number of the testing methods became ASTM or ISO standards, which are generally required for market introduction. In the year 2000, attention was given to testing methods specifically for mobile bearing knees, because of their mechanical differences from the more widely used fixed-bearing designs. The process began with the identification of potential problems unique to the mobile bearings themselves. These problems included bearing dislocation and deformation of the bearings due to stops and pivots. Wear testing methodology was also seen as important because of the original claim that mobile bearings would have reduced wear compared with fixed bearings due to the lower contact stresses. In this paper, the theoretical framework for defining the tests was specified. Specific tests were then defined for the following potential failure modes: dislocation ('spin-out'), dynamic dissociation ('spit-out'), deformation (due to stops, etc.), and endurance and deformation (due to overhang). Existing tests for total knee arthroplasty, in general, were also cited: cyclic fatigue of tibial trays, constraint (upper bearing surface), and wear (with a recommendation for differentiating upper and lower bearing wear). In the future, it is recommended that laboratories and manufacturers use these new tests to gain experience in their use and evaluate the safety of future mobile bearing designs.

KEYWORDS: total knee arthroplasty, mobile bearing knees, artificial knee testing, knee replacement testing, mobile bearing knee testing

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Introduction

Since the early 1970s when condylar types of total knee replacements (TKRs) were introduced, various testing methods have been formulated in academic and company laboratories. The purposes of the tests were to evaluate potential failure modes, optimize design features, and improve materials performance. The test specifications were facilitated because data on the forces and moments acting across the knee in everyday activities had, by then, been calculated [1,2]. Only recently has such data been measured directly on instrumented total knees [3,4], which showed that the early data had produced similar values. One of the first problems clinically recognized was loosening at the implant-bone interface. To assess the durability of fixation, cyclic or static loading tests were carried out on candidate components, measuring interface micromotions, contact stresses, and surface bone strains. Stresses and strains in the whole construct were computed using finite element analysis (FEA). Realizing that cement penetration into trabecular bone was necessary, different fixation experiments were carried out to determine the effect of variables such as bone cleaning, pressure, and viscosity [5].

Polyethylene wear was a major concern, prompting some designers to opt for congruent bearings such as roller-in-trough and dual ball-in-sockets, on the assumption that low contact stresses would equate to low wear. Wear test machines of differing complexities were fabricated, while testing methodology evolved over several decades before a general consensus was reached. Even then, both force input and displacement input methods were specified, which are fundamentally different. Currently, unifying methods are under investigation by accounting for the effects of soft tissue restraints on the input forces and displacements. Computer models have been developed to predict wear, with the obvious advantage of being quicker and less expensive than the laborious knee simulation wear testing which can last for many months for each test sequence [6]. However, while models can be utilized in mapping contact areas and the progress of wear scars over time, they cannot replicate the complexities of the multi-mode wear mechanisms and the highly non-linear materials properties. Hence, physical wear testing will continue to be necessary. It is noted that both pin-on-disc and simulator testing have shown that contact stress cannot be used as a simple predictor of the wear and damage of polyethylene. However, there is evidence that the fatigue properties of polyethylene may be related to certain wear processes and hence fatigue testing, which is much more rapidly performed than wear testing, can be utilized for materials screening [7].

Fatigue testing has routinely been used for determining the overall structural strength of components. In some early TKR designs, the fracture of metal tibial trays occurred, which was found to be due to lack of bony support, usually on the medial side. To test for this, a cantilever test with cyclic loading was developed [8]. Similar tests were also carried out for femoral components where the lack of cement support under the posterior condyles was an observed problem. The fatigue strength of the central plastic posts of cam-post designs has been determined using cyclic load testing and by FEA [9]. Such testing methods were also applied to measure the contact areas on the plastic, especially at the extremes of flexion or in edge-loading simulations.

The requirement to predict the clinical performance of TKRs led to testing where different loading combinations including shear and torque were applied, and the displacements measured. The general interpretation of the results is that small displacements would imply that the components would provide most of the stability invivo, with large displacements implying that ligaments and muscle control would be required. Many such studies included implanting components into cadaveric knees to observe component-soft tissue interactions. However, the problem with using specimens in a standard testing context is the high variability between specimens and the practical inability to obtain arthritic specimens. Hence, some tests have included simulations of soft tissue using springs or are built into the software controlling the input forces. Regarding terminology, such testing has usually been referred to as constraint or laxity testing, where the displacements in response to input forces have been measured. The term stability has usually been applied to clinical situations, where the displacement of a component would be assessed as being within acceptable limits. The technologies for wear and constraint testing have borrowed from each other and have resulted in complex knee simulating machines with force or displacement inputs.

The patello-femoral joint has not escaped attention, initially addressing the clinical problems of wear, especially with metal-backed components, and dislocations or subluxation. Tests for these problems, and for contact areas, fixation, and tracking abnormalities, have been devised. However, considering the importance of the patello-femoral mechanism to knee function, it is surprising how little attention has been given to standard testing, compared with the femoral and tibial components as a whole.

The purpose of the various tests previously noted and other testing methods has been one or more of the following: to improve the designs or materials, to compare new designs or materials with those already in use, to try to ensure safety from various failure modes in service, to develop a standard testing method, or to develop a performance standard. As with any engineered product, some testing methods have been formulated as part of the design and testing process, while other tests have arisen in response to unforeseen problems encountered in clinical practice. As a result of the 40 years of clinical follow-up data, the innumerable practical tests carried out, and the steady pace of improvements in design and technique, total knee replacements are now highly reliable and are likely to have a durability of at least two decades in the large majority of patients. The most frequent problems encountered today, amounting to only a few percent, are the result of sub-optimal surgical technique, infection, or the poor musculature and soft tissues of certain patients.

Mobile bearing knees, introduced in the late 1970s, were included in the general overall testing milieu. This is not surprising, considering a major proposed advantage was low wear due to the high bearing conformity; the major initial focus was on wear testing, with wear being a major concern at that time. The existing partially-conforming fixed bearing condylar designs of the 1970s had already shown that delamination wear could result in early failure. This wear mechanism persisted until the 1990s when major improvements in sterilizing techniques and materials processing were introduced, reducing wear rates to extremely low values. Even though mobile bearing knees were distinctly

different in mechanics to fixed-bearing knees, tests specific to mobile bearings were slower to develop on the basis that the tests for TKRs were regarded as being generic to all types of designs. For example, tests of fixation, component strength, and patella tracking would be the same. Another reason for the lack of specific tests was that, apart from the dislocation and fractured bearing problems of the early meniscal bearing designs, where separate plastic bearings ran in tracks in the metal baseplate, there were few major mechanical problems clinically reported, while clinical performance itself was comparable to that of fixed-bearing designs.

However, this stance changed gradually during the 1990s when mobile bearing designs embodying mechanical features such as rotational stops, combinations of rotational and anterior-posterior freedom, and various methods for pivoting the plastic bearing on the metal baseplate were being introduced. As a result, responsible companies, academic laboratories, and more importantly, the regulatory bodies, began to recognize that specific mechanical tests needed to be devised and implemented to evaluate these various mechanical features associated with the mobility of the bearings. In addition, clinical problems such as spin-out, spit-out, and the deformation of plastic at stops and due to overhang, although relatively few in number, were being reported. As a result, in the early 2000s, a systematic evaluation of the mechanics of mobile bearings was undertaken by representatives from Orthopedic Surgical Manufactures Association, American Society for Testing and Materials, and the academic community. All known and foreseeable mechanical problems were defined and testing methods were formulated to address each of these problems. The general principle was that for a particular design of mobile bearing knee (MBK), the mechanical factors, in addition to those which applied to the TKRs in general, would be identified for testing. It was recognized, therefore, that a new design feature brought about in mobile bearings, without any prior history, potentially posed a previously unaddressed risk in testing. A total of four new tests, specific to MBKs were formulated, while considerations were given to modifications of existing tests for TKRs, for application to MBKs. All of these tests will now be described. Additionally, existing standard testing methods for TKRs which are also applicable to mobile bearing knees will be highlighted, to present a full battery of tests applicable to mobile bearing knee designs.

New Proposed Tests for Mobile Bearing Knees

The principle is that each test shall simulate the mechanical conditions in the human body, as it relates to the potential failure mode being investigated. In this way, the test conditions can be specified to represent the extremes of what might actually occur, while simplifying the test to address only that failure mode. There are many different test machines which could be used for the tests, ranging from simple fixtures for specific tests, to complex knee simulators which can be used for multiple tests. However, in all cases, appropriate constraints must be applied to the different components (femoral, tibial, and bearing), with particular attention given to reproducing the 'self-centering' characteristics of the knee, and therefore avoiding over-constraint.

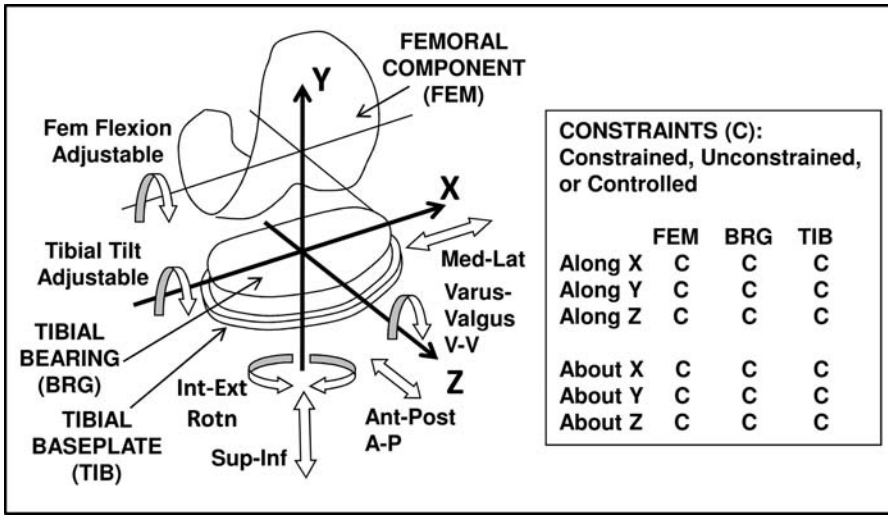

FIG. 1—*The general concept for the testing methods for mobile bearing TKR. In the test, each of the 3 components (FEM, BRG, TIB) is either constrained, unconstrained, or controlled along and about each axis. Controlled means that the input forces or displacements are applied. The outputs from each test are defined and recorded.*

A methodical approach to the constraints is shown in Fig. 1, where 6 degrees of freedom are defined from axes embedded in the femoral and tibial components. Each degree of freedom is either constrained, unconstrained, or controlled. The latter means that a force or displacement is applied along or about that axis. For example, in an anterior-posterior shear test, a cyclic shear force is applied to either the femoral or tibial component. To allow for relative vertical displacements between the components due to dishing of the bearing surfaces, the femoral displacement in the Y-direction needs to be unconstrained. To account for asymmetric medial-lateral dishing, rotation about the y-axis also needs to be unconstrained. These various constraint requirements do introduce a degree of complexity in the test equipment, with the additional requirement of safety stops in testing MBKs due to the lack of any inherent rotational constraint in many designs. In the following test descriptions, only the main points are described, with the details being expounded in the current ASTM documents themselves.

The dislocation test (Fig. 2) was configured to investigate the likelihood of the tibial bearing component rotating out from under the femur, which is called 'spin-out.' This failure mode has usually occurred due to excessive laxity on the lateral side of the joint at high flexion angles. It is related to the amount of dishing of the tibial surface, especially posteriorly. The test is 'worst-case' in the sense that due to the unconstrained varus-valgus rotation, there is no lateral ligamentous restraint, while 80% of the compressive load is applied on the medial side. The same test also addresses 'spit-out,' where a tibial bearing can be totally extruded from under the femoral component. Examples of this have occurred

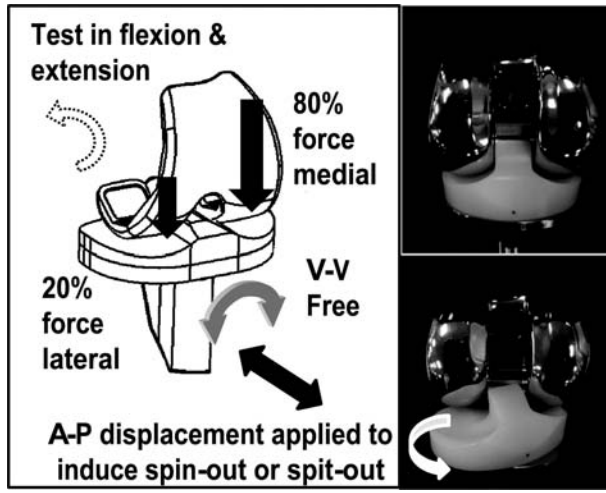

FIG. 2—*Evaluating Mobile Bearing Knee Dislocation (Spin-out and Spit-out), Designation F2724-08 [17]. The lower right view shows a typical anterior spin-out of the lateral side of the tibial bearing component.*

with separate lateral and medial tibial bearing components which ran in A-P tracks in the tibial baseplate. However, such a failure mode does not seem possible with typical rotating platform designs.

The next test is for dynamic disassociation (Fig. 3). This can occur if the tibial bearing is loaded on a short stud projecting from the tibial baseplate, or if the bearing is constrained only in a horizontal plane but can tilt about a medial-lateral axis. The test is carried out with a cyclic A-P shear force on the basis that there could be progressive deformation of the plastic bearing. This is monitored by measuring the tilt angle of the bearing at the start and end of the test. A major increase in the angle, together with deformation of the plastic, would be taken as a sign of impending failure, even if outright failure had not occurred. This should prompt a redesign at that stage. Testing at both high and low flexion angles is specified, because the femoral-tibial contact areas will be different, resulting in different forces being applied to the bearing restraints. While certain designs such as a rotating platform (see photo in Fig. 3) are unlikely to show disassociation, they might show local deformation where the plastic peg or stem enters the hole in the baseplate, therefore useful test data can be obtained in that regard.

Deformation of the plastic is a greater possibility where there are rotational stops or metal pegs in slots for motion guiding purposes. To test this possibility, a special test was formulated (Fig. 4). The test is similar to the disassociation test, except that a cyclic torque is substituted for a cyclic A-P shear force. While some designs have configured the stops to prevent extreme rotation from occurring, the malrotation of components at surgery could result in frequent activation. This justifies the action of the test, which applies a defined torque against the stops; again, a worst-case approach. Impact of the stops on the plastic can result in progressive deformation which could lead to local elevation of the

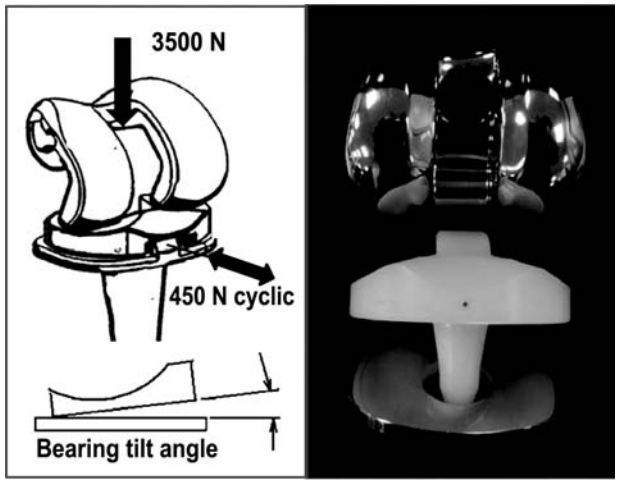

FIG. 3—*Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation, Designation F 2723-08 [18]. The photograph shows that disassociation would be geometrically unlikely for a standard rotating platform design.*

material and the prevention of complete bearing contact between the plastic bearing and the smooth surface of the tibial baseplate. Another possible phenomenon at a stop is plastic material failure, resulting in cracking and flaking, producing third-body debris on the flat bearing surface. Wear from third-body particles is a well-known problem in mobile bearing knees, increasing wear on both the metal and plastic surfaces [10]. As with the disassociation test, excessive deformation would indicate a redesign.

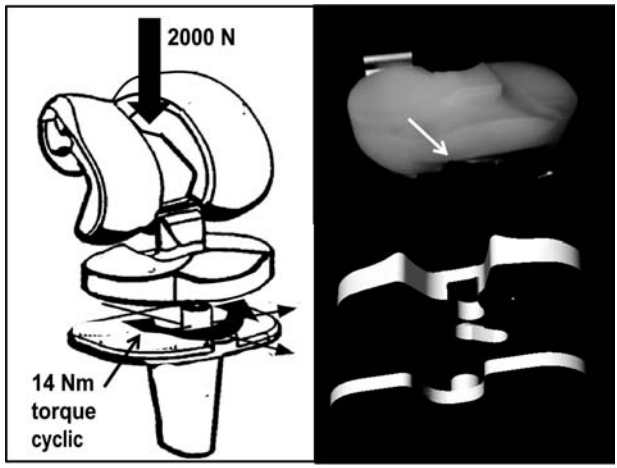

FIG. 4—*Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops, Designation F2722-08 [19]. The upper photo shows potential digging-in at the corner of a stop (arrow). The lower photo shows typical pins in slots where deformation could occur.*

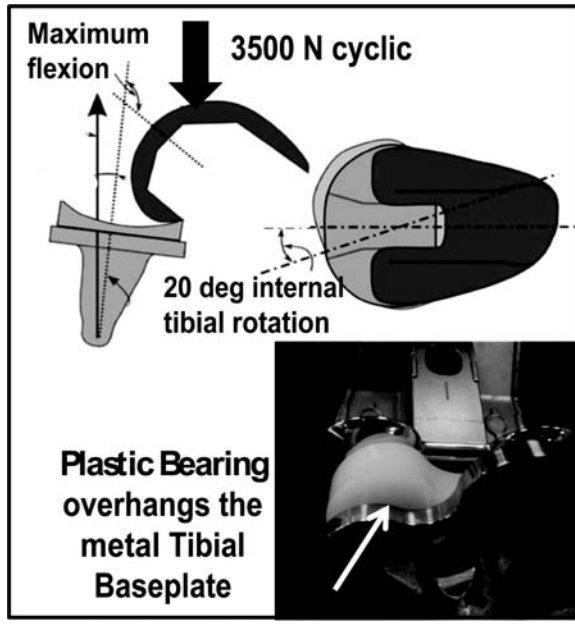

FIG. 5—*Evaluating tibial bearing component endurance and deformation under high flexion. The main issue is the overhang of the bearing with the load near the posterior, and potential damage initiated at the edge (arrow).*

The final test for MBKs is to evaluate the endurance and deformation of the tibial bearing in positions where the bearing overhangs the tibial baseplate (Fig. 5). In the design of MBKs, if the peripheral shape of the bearing matches that of the baseplate, any relative rotation or displacement will result in an overhang of the bearing, which could lead to loading on a cantilevered area of plastic or to soft tissue irritation. If the bearing is much smaller than the baseplate, that will reduce the contact areas, but more importantly, increase the possibility of bearing dislocation by spin-out or spit-out. In practice, there is usually a compromise resulting in some overhang at extreme rotational positions. The fracture of bearings due to cantilevering occurred with meniscal bearings in early designs, although this has seldom been reported with one-piece bearing components. Nevertheless, deformation of the lower surface of the bearing can occur due to overhanging on the edge of the tibial baseplate. This test assesses the effects of loading the area of overhang for both strength and deformation and, hence, involves cyclic load testing. The test specifies that when the sizes of components are interchangeable, the combinations with the largest overhangs should be tested.

Existing Tests Applicable to Mobile Bearing Knees

One existing test for TKRs which can be applied directly to MBKs is the Cyclic Fatigue Testing of Metal Tibial Tray Components, F1800-07 [11]. While finite element analysis is generally used in the design of tibial trays for both TKRs

and MBKs, fatigue testing is still required to account for possible material problems and the uncertain stress conditions at corners and edges. The flat upper surface of many MBKs avoids stress concentrations due to incomplete rims, however, usually requires extra thickness.

The test entitled Determination of Total Knee Replacement Constraint, F1223-08 [12], can also be carried out on MBK designs, but with some restrictions. The A-P test will be valid in rotating platform types of MBKs, however, in designs which allow unrestricted sliding of the bearing component on the baseplate, the femoral component to plastic bearing constraint is measured. For MBKs with unrestricted internal-external rotation, the constraint test needs to be carried out with the bearing component artificially clamped to the baseplate to measure femoral to plastic constraint. The experience of using this test on multiple designs has been discussed in detail [13]. Another approach to constraint testing of the anatomic knee, fixed-bearing, and mobile bearing designs, is shown in Fig. 6 [14]. Such a machine can be automated or configured in a servo hydraulic test machine [15].

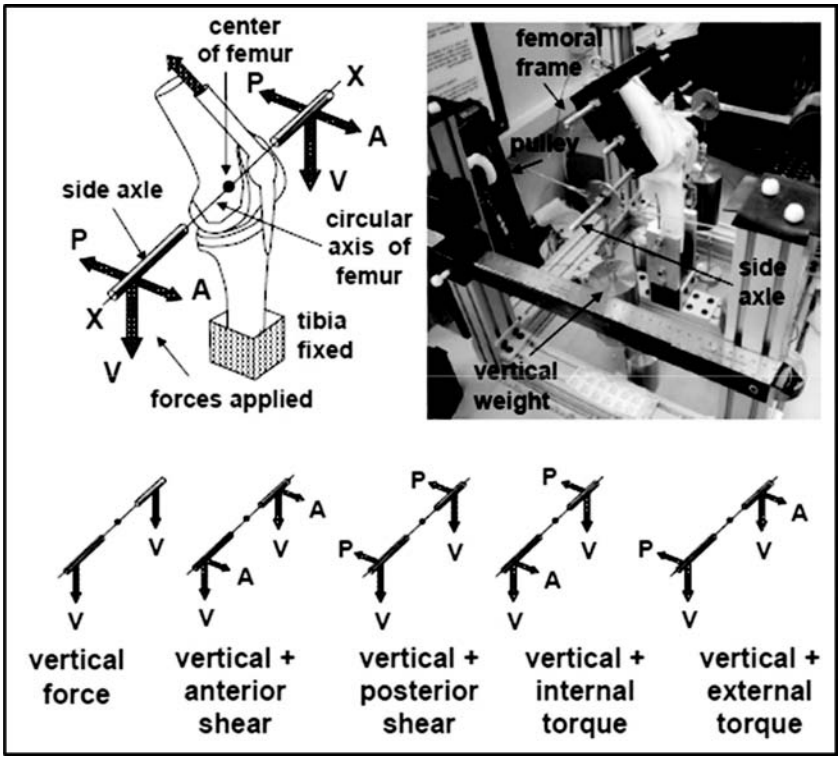

FIG. 6—*Concept for universal test machine for carrying out tests on TKRs including mobile bearing knees. The capability includes constraint testing, based on Designation F1223-08.*

The standard testing for wear (ISO 14|243:2009 [16], in 3 parts) can be carried out for MBKs, noting that when the force-input methodology is used, the spring or software restraints for axial rotation are mandatory, which would result in the full ±6 degrees of rotation occurring. Identifying the source of the wear has presented difficulties for both fixed and mobile bearing knees. In the former, wear occurs between the bearing and the baseplate, mainly due to small relative motions under the cyclic loading of activity. For mobile bearings, wear occurs due to the larger relative motions, but more especially due to starved lubrication and to the entrapment of third-body particles on the lower bearing surface [10]. While the total gravimetric wear and particle analysis can be determined on the combined wear products of the upper and lower bearing surfaces, no definitive method has been devised for measuring the wear separately, although methods are available for making reasonable estimates.

The previously discussed tests, including the existing tests for fixed bearing TKRs and the special tests for MBKs, represent a reasonable methodology for assessing the safety and efficacy of new or existing MBK designs. All of the tests have been introduced and have evolved over the past few decades to address the potential mechanical problems which can occur with knee replacements. These problems have been identified due to the very large numbers of designs and the experience from the millions of cases performed. It is suggested that the tests are adequate for MBKs and for TKRs, but that any new feature on any type of design without a known behavioral history may need a special test performed whether it is a TKR or an MBK.

Discussion

In this paper, testing methods for total knees, in general, and for mobile bearing knees, in particular, have been described. The methods represent existing ASTM and ISO standards, or those in progress. Apart from their value as being part of the design process, the tests are intended for use in submissions of new designs to the FDA. For any engineered product, the testing regimen needs to anticipate all operating conditions within reason. In the case of TKRs, whether fixed or mobile, the extensive clinical history with numerous design configurations allows for the anticipation of potential problem areas.

Some of the tests for MBKs are at the draft stage as ASTM standards; whether the methods have been sufficiently validated and the small number of published reports, has been pointed out. Some of the existing standards, such as for the loading conditions to determine the strength of tibial trays, were formulated after extensive laboratory tests of samples of different tibial component designs, some with and some without a known history of fatigue failure. This research enabled a performance standard, that is, with a pass-fail criteria, to be specified in the standard test method. At this time, the standards in progress for MBKs should be regarded as test methods only, or characterization tests. Each test is capable of demonstrating failure, but lack of failure would not, per se, predict that a clinical failure could not occur. To be specific, if a test design exhibited spin-out or spit-out, or dislocation, or fracture or excessive

deformation at a stop or on an overhung bearing component, that would be cause for a redesign. However, the implications as to whether the failure would be likely to occur clinically, would need further evidence by also testing a predicate device with a successful clinical history and comparing the data. Over time, and if funding is available, performance requirements could be added to the standards in the future. Thus far, no specific tests have been formulated for the patello-femoral joint. The patella could be more susceptible to subluxation if the plastic bearing were excessively rotated. However, on the basis that there has been no reported evidence of patella problems with mobile bearing knees, a special test may not be a priority at this time.

In this article, we have described the development of testing methods for mobile bearing knees as tests to be performed in addition to those for total knees in general. The tests were based on an extensive review of the clinical performance of numerous mobile bearing designs around the world. The standard tests are, therefore, considered suitable for testing a new mobile bearing design which, in general, resembles devices already used. For totally new concepts involving unknown features, it may be necessary for a manufacturer to formulate an additional test specific to that device if the existing tests would not be applicable.

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Comparison of Mobile Bearing and Fixed Bearing Total Knee Arthroplasty Outcomes: A Review of the Literature

ABSTRACT: To better compare the outcomes between fixed bearing (FB) and mobile bearing (MB) total knee arthroplasty (TKA) a review of the literature was carried out to determine any published differences. An extensive literature search utilizing PubMed was carried out to identify all publications concerning MB and FB TKA. Once studies were identified from set inclusion criteria the groups (27 studies in total) were categorically compared for differences in instability, persistent pain, loosening, radiolucencies, knee society pain and function scores as well as range of motion (ROM). ROM comparisons favored MB ($P = 0.03$, eight studies) statistically but not clinically (3° ROM difference), and the incidence of tibial radiolucent lines improved with the use of MB TKA ($P = 0.03$, eight studies) while all other categories were found not to be significantly different (p values of 0.1–0.72). This up to date comparison of the literature found MB and FB TKA outcomes to be comparable.

KEYWORDS: knee, arthroplasty, mobile bearing, outcomes

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Introduction

The number of total knee arthroplasty (TKA) cases performed per year continues to increase. Advances in TKA implant design and surgical technique have continued to improve TKA survivorship and a trend towards younger patients continues to be reported. Studies focusing on modern TKA implants have reported survivorship rates of >95 % at 10 years for aseptic loosening [1–3].

Modifications in implant design continue to evolve in an attempt to further increase the longevity of TKA implants. Despite these modifications polyethylene wear and component loosening continue to be modes of failure for TKA implants. With fixed bearing (FB) designs, contact stress is transferred to the polyethylene based on the amount of conformity between the insert and the femoral component [4,5]. While increasing conformity decreases contact stresses [4–6], the inability of the FB design to allow for rotation and translational motion transfers stress to the bone-cement interface, potentially leading to loosening of the tibial component.

Conversely, mobile bearing (MB) TKA implants utilize a polyethylene insert that is not rigidly fixed to the tibial component. Rotation and/or translation of the insert on the tibial baseplate attempts to achieve more intimate conformity between the femoral component and polyethylene insert, without subsequent tibial component loosening seen in highly conforming FB designs [6–8]. The increased conformity between the articulating surfaces has been shown to decrease contact stress between the components and transfer lower stresses to the bone implant interfaces [4–8]. MB implants, therefore, have the theoretical potential to decrease polyethylene wear, decrease stress at the bone-cement interface, and increase the longevity of the TKA components.

However, at this point in time, clinical studies comparing mobile bearing and FB TKA have not clearly borne out that theoretical advantage. Furthermore, unique complications exist exclusively with MB inserts that are not present with FB designs. The most worrisome complication is spinout or dislocation of the MB insert. Clearly, many variables exist that must be accounted for by the surgeon considering mobile bearing versus FB implants. While the increasing conformity and low contact stress seen with the mobile insert is attractive, the prospect of early failure due to bearing dislocation is not.

Meta-analyses comparing mobile bearing and FB TKA designs have been reported in the literature. Previous meta-analyses by Smith and Oh [9,10] as well as thorough literature reviews by Post and Van der Bracht [11,12] all concluded that no specific clinical or radiographic advantage could be found with MB implants. Nevertheless, continued study on this topic is ongoing to determine, with longer-term follow-up, whether MB inserts provide any advantage over fixed implants.

In this study, we report the most update meta-analysis of the current literature on this topic. To do so, we have selected studies with strict inclusion criteria to report pooled data from the highest quality studies on the topic. Specifically, this report focuses on clinical outcome parameters, along with selected radiographic indices, to elucidate which type of implant provides superior outcomes.

Materials and Methods

Candidate studies were identified through a search of PubMed using the terms "mobile bearing and total knee arthroplasty." Each abstract was reviewed for applicability prior to inclusion in the study. Studies published either online or in print before December 2009 were accepted into the analysis. In an effort to ensure completeness of the assembled articles, the reference sections of available review articles were searched for papers missed by the initial database search. These articles were then compiled for data extraction.

We reviewed all available studies on MB TKA and included all studies that directly compared mobile bearing and FB constructs. Only clinical studies were included, although some radiostereometric studies reported clinical outcomes and the clinical data from these papers were included. All case reports, cases series, reviews, meta-analyses, expert opinions or other non-comparative studies were excluded from this analysis.

Data were extracted from articles reporting clinical outcomes using standardized data extraction forms. All data were then entered into an Excel spreadsheet for statistical analysis. Extracted variables were limited to the follow-up outcomes reported by the included studies. The primary clinical outcomes analyzed included the American Knee Society (AKS) knee and function scores, the Oxford knee score, knee flexion, and total range of knee motion. We also recorded the incidence of various prosthesis-related mechanical complications such as bearing spinout or dislocation. Medical complications or other perioperative complications were not included in our analysis.

Clinical outcomes and complications that were reported in at least three studies were combined for analysis. All prosthesis-related mechanical complications were recorded as binary (yes/no) outcomes. For each of these binary outcomes, odds ratios (OR) (mobile versus fixed), along with corresponding 95 % confidence intervals, were calculated for each contributing study. The OR was used to measure whether the probability of the outcome for each variable was equal for fixed and mobile bearing total knees. These study results were then combined using the Mantle–Hanzel method in either a fixed or random-effect model to generate an overall pooled OR estimate and 95 % confidence interval. Similarly, mean differences of continuous clinical outcomes along with 95 % confidence intervals were calculated for each study and combined using the inverse-variance method into a pooled mean difference with corresponding 95 % confidence interval. Finally, for all outcomes, a test for overall effect was calculated to determine if there was a significant difference between the fixed and mobile bearing knee replacements.

Heterogeneity of the published results for each outcome was considered using both the I^2 statistic as well as the Chi^2 test for heterogeneity. An I^2 statistic >30 % or a p-value <0.10 from the Chi^2 test was considered indicative of at least moderate heterogeneity. In outcomes where heterogeneity was found to be important, random-effect models were used to combine the study results. If heterogeneity was found to be low, fixed-effect models were employed.

The sensitivity of the results to the model choice was considered by modeling the heterogeneous studies by both random and fixed models, and observing

the change in the pooled estimates as well as the test for overall effect. Of note, the selection of model did not alter the significant/non significant finding of any test for overall effect, for any of the outcomes analyzed.

Graphing and analysis were performed in RevMan5 (Version 5.0. Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2008). Forest Plots were utilized to display the data as these are typically utilized to illustrate graphically the outcomes of meta-analyses by showing the summary measures and confidence intervals of each study for the variable analyzed.

Results

Of the 295 studies identified by our search strategy, 68 reported clinical outcomes that were extracted for analysis and 27 [13–39] were comparative studies included in the meta-analysis. The 27 studies included 3665 patients (1851 FB and 1814 MB) and 3776 total knee replacements (1900 FB and 1876 MB). We analyzed the OR and mean differences of various mechanical complications and clinical outcomes. Two variables had significant inter-study heterogeneity so random-effect models were employed for post-operative AKS knee score and post-operative range of motion (ROM) ($I^2 = 37$ and 68 %, respectively). One paper [13] discussed clinical outcomes and complications for inclusion, but reported standard deviations that approximated the means of the study. This study was used in the analyses of complications but was excluded from clinical outcome analysis. Inclusion or exclusion of the study did not significantly alter the outcome (significant versus non-significant) of any of the analyzed variables.

Complications

Various complications were reported in the 27 analyzed papers, however, only five were mentioned in three or more papers. These complications include limited ROM, instability, persistent pain, bearing dislocation, and component loosening.

Eight studies [13–20] reported limited ROM as a post-operative complication. The OR for limited ROM did not favor either implant (OR = 1.12; 95 % CI 0.53 to 2.38; $P = 0.76$; Table 1). Instability was reported in six of the

TABLE 1—*Odds ratio characteristics for complicated rates.*

Complication	95% CI	P-value	I^2 value	x^2 P-value
Limited ROM	0.53, 2.38	0.76	0%	0.44
Instability	0.30, 2.50	0.79	0%	0.61
Persistent pain	0.32, 2.50	0.83	0%	0.56
Loosening	0.24, 3.01	0.81	0%	0.7
Tibial RLL	0.50, 0.96	0.03	7%	0.38
Femoral RLL	0.79, 2.91	0.27	0%	0.89
Overall RLL	0.70, 1.17	0.44	19%	0.27

Note: I^2 and x^2 P-value are measures of inter-group heterogeneity; Cl, confidence interval; ROM, range of motion; RLL, radiolucent line.

examined studies [19,21–25]. There was no statistical difference between mobile bearing or FB devices with regard to this outcome (OR = 0.86; 95 % CI 0.3 to 2.5; $P = 0.79$; Table 1). Persistent pain requiring revision showed no difference between the four groups [22,26–28] reporting this complication (OR = 0.89; 95 % CI 0.32 to 2.5; $P = 0.83$; Table 1). Bearing dislocation, spinout, or spitout was addressed in seven studies [13,27,29–33]. In studies reporting dislocation there was an incidence of 1.3 %, or 0.3 % of all MB knees analyzed.

Five of the studies reported significant loosening [20,24,26,30]. Of the papers reporting loosening of a FB prosthesis, two of the three reported had loosening before two years [20,26]. The third study had a final follow-up of 13.2 years and reported a case of radiolucent lines (RLL) greater than one millimeter in all zones surrounding the tibial implant but does not give a clear indication of when the loosening occurred [24]. One of the two studies that had loosening of a MB knee was in an active elderly patient with good knee scores [17] and the other had progressive radiolucencies on follow-up radiographs [30]. The OR for having loosening with a FB knee was not significantly different than with a MB construct (OR = 0.86; 95 % CI 0.24 to 3.01; $P = 0.86$; Table 1).

RLL were reported as the percent of knees showing RLLs at final follow-up. The OR for tibial radiolucenies was significant and favored MB knees (OR = 0.69; 95 % CI 0.5 to 0.96; $P = 0.03$; Fig. 1; Table 1). The eight studies [17,24,27,29,30,32,34,35] ranged in length from 2.6 years [35] to 13.2 years [24]. The type of prosthesis had no significant effect on the presence of femoral RLLs in six studies [24,25,27,32,34,35] as long as 13.2 years (OR = 1.51; 95 % CI 0.79 to 2.91; $P = 0.21$; Table 1). The OR of having any RLL (femoral or tibial) was also not statistically significant in eleven studies [17,24,25,27,29–32,34–36] up to 13.2 years (OR = 0.9; 95 % CI 0.7 to 1.17; $P = 0.44$; Table 1).

Clinical Outcomes and Scores

Several different clinical outcome measures were reported, the most popular being the AKS knee and function scores (Figs. 2–4). Ten studies [13,17,21,22,26,30,31,36–39] reported the AKS knee score. The mean difference was not statistically significant (mean difference = −0.34; 95 % CI −1.66 to 0.97; $P = 0.61$; Table 2) using a random-effect model. These studies reported AKS knee scores from 1 to 7 years. Knee Society functional score, reported in six studies [13,17,22,31,37–39], tended to favor MB knees, however, the difference was not statistically significant (mean difference = 3.27; 95 % CI −0.58 to 7.12; $P = 0.1$; Table 2). Studies ranged in length from 1 to 7 years. Five studies [16,21,22,31,37] reported the Oxford Knee score and had data up to 3.7 years. The mean difference did not favor mobile bearing or FB knees (mean difference = 0.33; 95 % CI −0.79 to 1.46; $P = 0.56$; Table 2).

Studies were also inconsistent in reporting of post-operative ROM, either as total arc of motion or post-operative flexion. These studies ranged in length of follow-up from one to 6 years with the majority reporting at 2 years. Eight of the examined studies [13,15,22,26,30,31,35,37,39] reported on ROM and the mean difference of these studies was statistically significant (mean difference = 3.2; 95 % CI 0.33 to 6.06; $P = 0.03$; Table 2) when using a random-effect model.

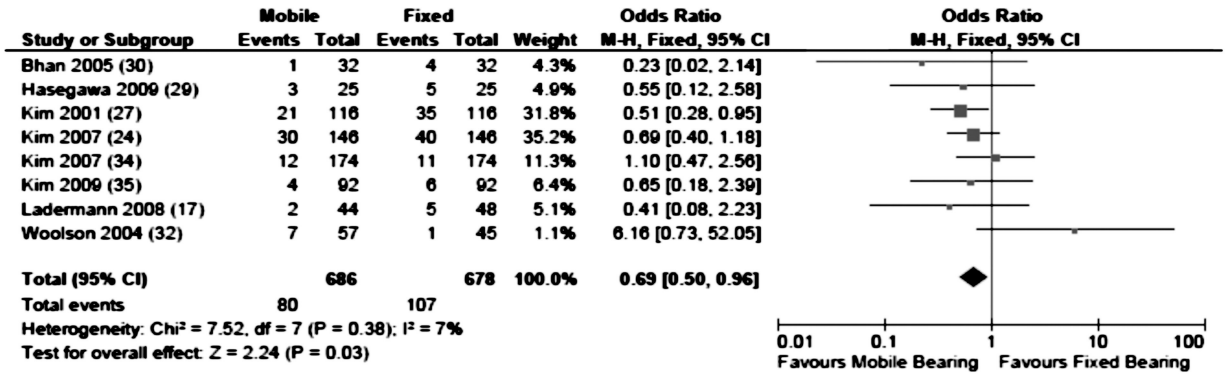

FIG. 1—*Forest plot of tibial RLL. Boxes indicate estimates of the OR for individual studies with horizontal lines showing the respective 95 % confidence interval. The width of each box represents the weight each study had in the pooled estimate. The diamond indicates the 95 % confidence interval of the pooled OR.*

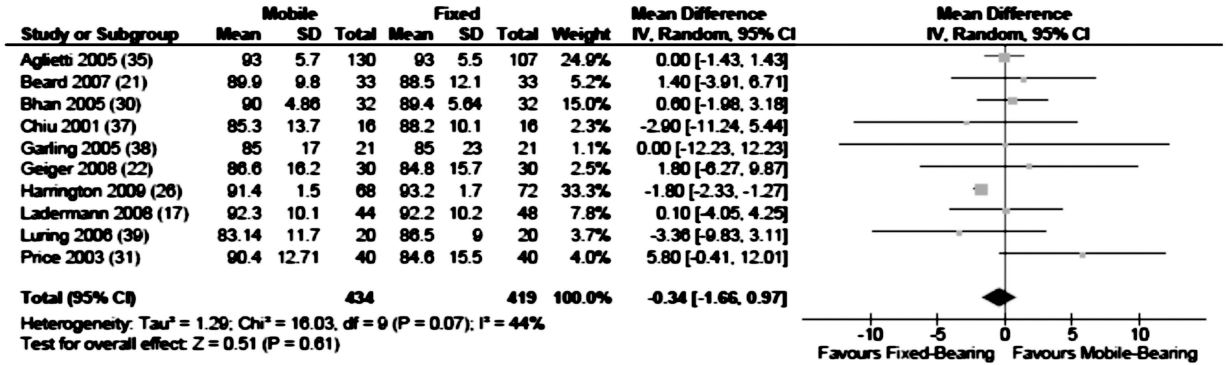

FIG. 2—*Forest plot of post-operative AKS knee score. Boxes indicate estimates of the OR for individual studies with horizontal lines showing the respective 95 % confidence interval. The width of each box represents the weight each study had in the pooled estimate. The diamond indicates the 95 % confidence interval of the pooled OR. The I^2 value was >30 % so a random effects model was used.*

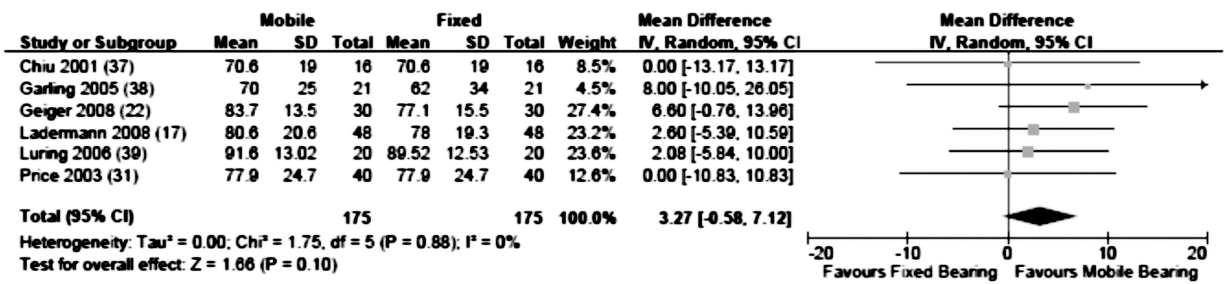

FIG. 3—*Forest plot of post-operative AKS function score. Boxes indicate estimates of the OR for individual studies with horizontal lines showing the respective 95 % confidence interval. The width of each box represents the weight each study had in the pooled estimate. The diamond indicates the 95 % confidence interval of the pooled OR.*

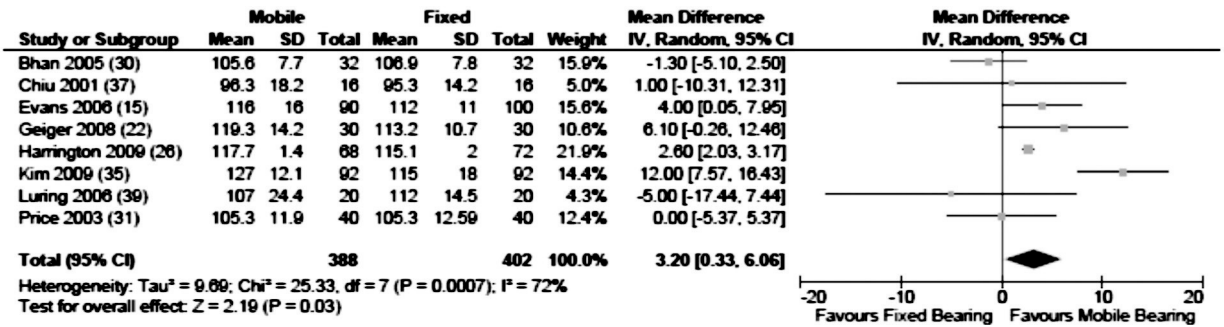

FIG. 4—*Forest plot of post-operative ROM. Boxes indicate estimates of the OR for individual studies with horizontal lines showing the respective 95 % confidence interval. The width of each box represents the weight each study had in the pooled estimate. The diamond indicates the 95 % confidence interval of the pooled OR. The* I^2 *value was >30 % so a random effects model was used.*

TABLE 2—*Mean difference characteristics for quantitative variables.*

Outcome	95% CI	P-value	I^2 value	x^2 P-value
Post-op AKS knee score	−1.66, 0.97	0.61	44%	0.07
Post-op AKS pain score	−0.87, 4.43	0.19	9%	0.33
Post-op AKS function score	−0.58, 7.12	0.10	0%	0.88
Oxford knee score	−0.79, 1.46	0.56	0%	0.43
Post-op ROM	0.33, 6.06	0.03	72%	0.03
Post-op flexion	−1.71, 2.96	0.60	0%	0.45

Note: I^2 and x^2 P-value are measures of inter-group heterogeneity; Cl, confidence interval; AKS, American Knee Society; ROM, range of motion.

Instead of complete arc of motion, five studies [15,17,25,37,38] reported flexion and flexion contracture separately. The mean difference of flexion did not significantly favor mobile bearing or FB knees (mean difference = 0.62; 95 % CI −1.71 to 2.96; $P = 0.6$; Table 2). Studies ranged from 2 to 7 years in length.

Discussion

Our meta-analysis of 27 comparative studies found a statistically significant benefit of MB knees on the percent of tibial RLLs and post-operative ROM. It should be pointed out that a 3° difference in ROM is not clinically significant and it may be within the clinically measurable error. All other radiologic and clinical outcomes and complication rates did not display a significant difference between mobile bearing and FB knees.

We should note some of the limitations of the present study. Regarding the available literature for review, there is a significant amount of heterogeneity in terms of the way data are reported. Several other studies were available for data extraction, however, the data were not reported in such a way that allows inclusion in a meta-analysis. Only studies that reported means with standard deviations or another statistic that could be converted to standard deviation could be used in analyzing quantitative variables. A standardized method of reporting, including means and standard deviations, would make interpretation of results easier. Several of the studies demonstrated methodological flaws at various points in study design. A paucity of studies used power calculations in determining sample size, therefore many of included papers may not have had sufficient sample size to detect differences in the variables analyzed (type II error). The method of blinding in many of the studies was poorly described. Few mentioned patient blinding, the method of prosthesis allocation was often poorly blinded, and clinical evaluators were not universally blinded. The lack of sufficient blinding exposes the included studies to bias and may thus affect the ability to detect meaningful differences between the prosthetic designs. Furthermore, there was much variation in the specific fixed bearing or MB implant chosen between each study.

Comparative studies available at the time of review had a variety of follow-up periods with only one longer than 10 years. Therefore, a meta-analysis of

these studies' results combines clinical parameters and complication rates at very different times in the post-operative period. Additionally, the relatively short-term follow-up limits the ability to detect many of the expected advantages of MB knees including improved wear characteristics [8,40] and the lower expected rates of loosening and osteolysis. Most of the studies included in the meta-analysis were 2 years in length, whereas, aseptic loosening may not show up until later in the life of the prosthesis, depending on the activity of the patient.

Instability, reported as either a subjective feeling [19,21] or laxity on exam [22–25] was reported in six of the examined studies. The events reported as instability were also different ranging from a subjective feeling to gross collateral deficiency requiring revision. Previous studies have emphasized the importance of good ligament balancing in MB knees especially in the setting of bearing dislocation [41,42]. Our analysis showed a low risk of bearing dislocation 0.3–1.3 % with MB implants and no incidence of bearing dislocation in FB devices. Of the four studies reporting dislocations Bhan and Hasegawa [29,30] reported severe preoperative deformity that would predispose patient's to bearing dislocation. Price et al. [31] reported one dislocation and noted that all surgeons in their study were relatively new to the MB design. The rate of bearing dislocation and the incidence of instability were not significantly different between prosthetic types in the present study (Table 1). It is extremely important to ensure proper balancing at the time of the index operation so as to avoid this complication. If there is doubt regarding the stability of the knee or severe preoperative deformity, a FB construct may be more appropriate.

Persistent pain not related to implant failure following TKA can result from a number of causes. It may result from the decision to resurface the patella, although some authors suggest that it makes no difference [43]. Other reasons may be related to implant design [44] or result from fat pad impingement [45] with MB knees. There was no difference between mobile bearing and FB knees with regard to continued complaints of knee pain (Table 1). In addition, the AKS pain score did not significantly favor one type of TKA over the other (Table 2).

Loosening following TKA can result from infection, excessive wear debris, motion at the bone-implant interface, or various other reasons. Mobile bearing implants are designed to minimize micromotion between the implant and the bone and also decrease wear debris because of the high congruency of the articular surfaces [8,40,46,47]. Our study showed a statistically significant advantage for MB TKAs over FB TKA for the incidence of tibial RLLs (Fig. 1, Table 1). There was not, however, a difference between the two prostheses in the overall incidence of RLL, incidence of femoral RLL, or component loosening (Table 1).

The AKS knee and function scores [48] are commonly used in reporting the clinical results of patients undergoing TKA. Many of the studies included in this analysis reported AKS scores; however, many did not report data capable of being incorporated into a meta-analysis due to the lack of standard deviations. More data on the variation within the population, beyond range, would be useful in data interpretation. We were unable to detect a statistically significant advantage of mobile bearing or FB knees on the final knee and function scores. The data tended to favor MB knees in the function score (Table 2, $P = 0.09$) but

did not reach statistical significance. Similarly, the Oxford knee score did not demonstrate a difference between the two TKAs (Table 2).

The MB design allows for increased articular conformity during knee motion. Better articular conformity and allowing for rotational alignment of the prosthesis has been proposed to lead to a more natural feeling knee that performs better in kinematic studies [49,50]. Despite these results, some studies report that there is no significant difference between fixed bearing and MB knees. In a post-mortem study, Most et al. [51] found no difference in restoration of the native knee's translation and rotation when tested using a robotic system. Still other authors suggest that there is no difference with regard to restoration of normal knee motion or improved ROM [51,52]. The present study found a statistically significant improvement in ROM of MB TKA over FB TKA (Table 2, $P = 0.03$), the studies reporting only knee flexion did not display any difference between the groups.

Conclusions

MB total knee replacement yields statistically improved ROM although not clinically significant and fewer tibial RLL than FB knees in the studies analyzed. All other clinical parameters and complication rates were not different between the groups. It is worth noting, however, that several studies had to be omitted from analysis because data were not presented in such a way that is conducive to inclusion in a meta-analysis. As several parameters appeared to favor mobile bearing knees but were not statistically significant (i.e., AKS functional score and component loosening), it may be that with longer follow-up MB knees will display further advantages over FB knees. At present, with limited follow-up and few rigorous comparisons of the prostheses, there is at least no significant difference and may be several advantages of MB TKA over FB TKA.

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31 Year Evolution of the Rotating-Platform Total Knee Replacment: Coping With "Spinout" and Wear

ABSTRACT: Low-contact-stress rotating-platform knee replacements were the original mobile-bearing knees developed by the senior authors in 1978 to improve fixation and minimize wear, however, 1-2 % experienced "spin-out" and wear resulting in the development of a third generation rotating platform (Buechel-Pappas, or B-P) in 1991. The purpose of this study is to evaluate design modifications incorporated into the B-P device based upon clinical outcomes. Clinical results of the initial 310 cementless B-P rotating platform total knee replacements in 257 patients were analyzed using a strict knee scoring scale. Of that group, 259 total knees in 206 patients were followed for 2–18 years (mean: 7.6 years). The titanium alloy metallic implants had a 10 μm thick titanium nitride (TiN) coating on all bearing and fixation surfaces and sintered-bead porous-coating, pore size of 350 microns, on all fixation surfaces. The rotating-platform bearing allowed 45° of internal and external rotation with further rotation limited by a stop pin on the tibial component to block complete rotary subluxation/dislocation of the bearing in the event of significant flexion instability or rotational trauma. The study showed 86.4 % excellent, 12.3 % good, 0.3 % fair, and 1.0 % poor results using a strict knee scoring scale. Complications requiring revision included tibial component

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loosening in 2 super-obese (BMI >50), osteoarthritic patients (0.6 %) and 1 late deep infection (0.3 %) in a rheumatoid patient after 3.3 years. There were no cases of bearing wear, subluxation, or dislocation seen. Radiographic analysis, using >2 mm lucency in any implant zone, demonstrated 0 % of radiolucencies around femoral components, 2.6 % around tibial components, and 0 % around patella components. Survivorship, using an end point of revision for wear or component loosening was 99.4 % at the 18-year interval.

KEYWORDS: total knee replacement (TKR), rotating-platform, mobile-bearing, spin-out, bearing wear

Introduction

Wear and loosening problems associated with knee joint replacements have been the major mechanical causes of failure since their early use in the 1970s [1–7]. The development of mobile-bearings reduced the risk associated with these problems by allowing needed mobility to minimize loosening torques on fixation while providing an increased surface contact area on the bearings to reduce wear [8–17].

Various types of mobile-bearing low-contact-stress (LCS) total knee replacements were developed to satisfy the requirements posed by existing pathologies and deformities. The bicruciate-retaining meniscal bearing total knee replacement was displaced by the posterior cruciate-retaining meniscal-bearing knee mainly because of tibial component loosening problems and surgical difficulty in retaining an intact anterior cruciate ligament, [9,18] even though good results were reported [19]. Wear problems of the meniscal-bearings negatively affected their long-term survivorship, [8,9] which in turn, led to the development of the A-P Glide type meniscal-bearing knee replacement that functioned extremely well in comparison to a rotating-platform type, [20] especially when the fat pad was resected during the surgical procedure [21]. However, when the patellar fat pad was retained, the bulky A-P Glide bearing would often translate anteriorly in flexion to make painful contact with this richly innervated tissue, causing severe anterior knee pain [21]. Because of this technical drawback, use of the A-P Glide type meniscal-bearing knee remains limited and has even been rejected by one group in favor of the rotating platform after a comparative analysis [22].

The rotating-platform type mobile-bearing was developed by the two senior authors (F.F.B., Sr. and M.J.P.) and initially used in 1978 as a revision prosthesis to salvage failed bicompartmental fixed-bearing knee replacements [23]. This versatile implant quickly became useful in primary and revision knee replacements, including pathological conditions with fixed-varus, fixed-valgus, and significant flexion deformities [8,9,24–30]. Wear problems were encountered in 1-2 % of cases after long term use [8] as a result of increased loading activities and gamma-in-air sterilized shelf-aged polyethylene, [31–33] which has also been incriminated in rapid fixed-bearing wear [2,31,34].

Subluxation or rotatory dislocation, sometimes referred to as “spin-out,” of rotating platform bearings have been observed in 1-2 % of cases by various

authors [35,36]. The cause for this "spin-out" appears to be flexion instability at the time of surgery [8,37,38].

Revision surgery can result in significantly higher dislocation rates of rotating platforms due to challenging flexion-extension gap-balance problems [37] and rates of 5.8% dislocation have been reported [25]. Despite these wear and dislocation problems, the rotating-platform type mobile-bearing knee replacement has demonstrated superior long-term survivorship in both cemented [26] and cementless [8,20,24,28,29,39,40] embodiments.

However, when an irreducible dislocation occurs, it usually requires revision surgery to implant a thicker bearing to control the flexion gap. Occasionally, even a thicker "deep-dish" bearing fails to solve the problem and recurrent dislocation can occur, requiring in some cases, revision to a more constrained-type of knee replacement or a custom rotating-platform with a rotational stop pin to limit excessive axial rotation [41].

Such rotating-platforms with rotational stop-pin bearings have been developed for use in primary and revision total knee replacement to eliminate or at least minimize the risk of "spin-out." This investigation examines the use of these advanced rotating-platform bearings in primary and multiply-operated knee replacements over an 18-year interval to evaluate potential improvements in wear and dislocation resistance.

Design Modifications

While the third generation B-P knee retains commonalities with specific variants of the LCS, key design features were added to the B-P, which is the subject of this clinical study, to address issues of wear and spin-out. The B-P knee design uses a generating curve around a series of parallel axes (Fig. 1) producing two spherical regions in the principal load bearing segment, which provides for 162° of flexion. The dimensions of the articulating surfaces of the B-P knee are such that fully congruent contact exists to about 50° of flexion, providing a greater degree of congruity in the most highly loaded phases of walking and stair climbing, and significantly reduces contact stresses compared to earlier generation LCS designs that provide quasi-congruent or area contact to about 35° flexion (Fig. 2). Full line contact occurs with the B-P knee at greater flexion angles while the LCS has quasi-line contact at these flexion angles.

The primary load bearing segment arc of the B-P femoral component is greater by 19°, thereby increasing the degree of congruent contact during flexion. A comparison of testing demonstrates that stresses in the B-P are substantially lower than the LCS knee at all flexion angles (Fig. 3).

The distal and posterior condylar thicknesses are the same so that the prosthetic gaps can be precisely reproduced. The fixation side of the sulcus is flat, providing contact with bone, and the medial anterior flange side wall angle is greater, eliminating overhang. The hard biocompatible TiN ceramic coating on the titanium substrate provides a less abrasive surface and reduces the potential for wear of the bearing surface [42].

The B-P tibial platform is anatomically shaped and contains a stop pin to limit bearing rotation and reduce the potential for spin-out. The stop pin on the

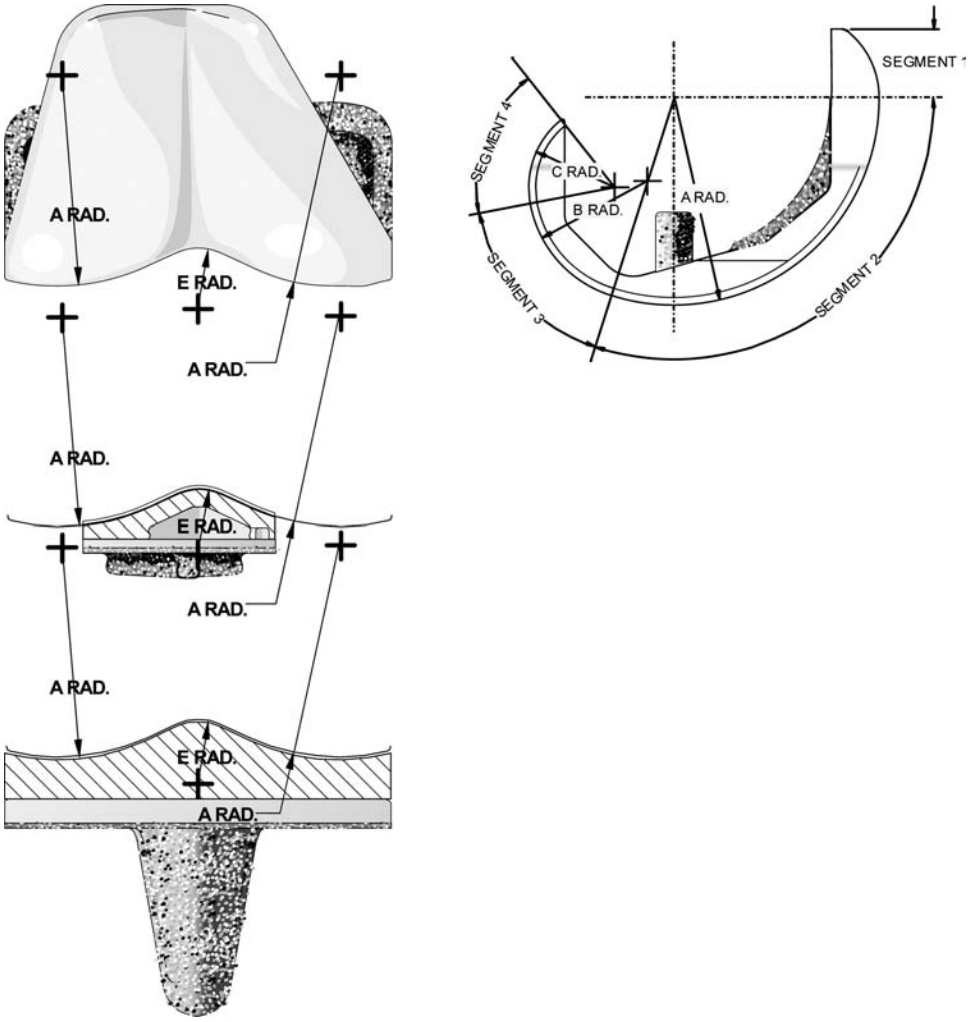


FIG. 1—*Use of common generating curve.*

superior surface of the tibial platform engages a slot in the inferior surface off of the bearing (Fig. 4) and provides ±45° axial rotation. The limits of the rotation are not encountered during any activity but are reached only in the event of subluxation of the bearing from the femoral component. This stop pin reduces the potential for spin-out as seen in the LCS where the combined effects of an A-P shearing load, distraction of one of the condylar compartments, and a lax collateral ligament associated with the distracted compartment, demonstrate that the rotating bearing can be forced to rotate to a dislocated position. With the LCS, only ligament tension sufficient to prevent the femoral condyle on the distracted side from climbing over the lip of the bearing can prevent such a dislocation.

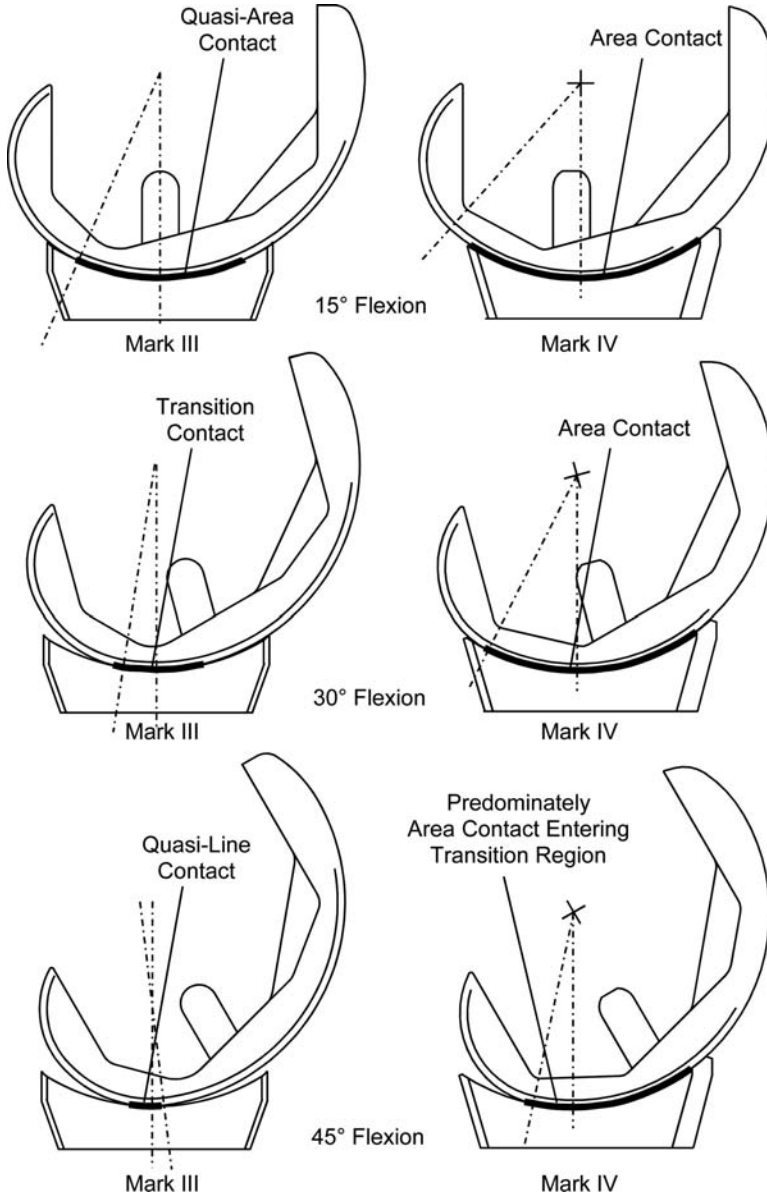


FIG. 2—*Contact in the first and third generation articulations.*

The generating curve is designed to provide congruent medial-lateral stability since the bony structures naturally providing this stability are resected (Fig. 5). As an LCS based knee, the B-P uses a natural femoral component sulcus cross sectional shape with a normal sulcus angle and a conforming patella with an anatomic articulating surface. The spherical shape of the femoral condyles

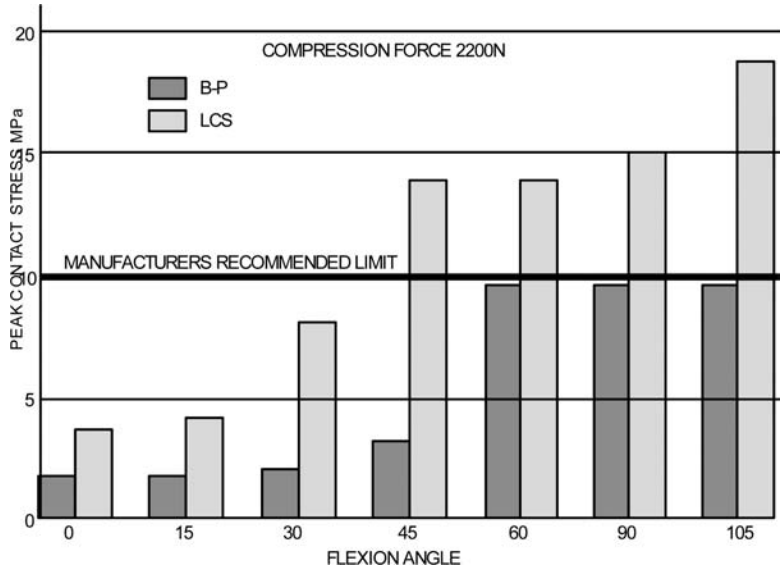


FIG. 3—*Contact stress comparison of B-P and LCS rotating platform knee replacements at a load of 2200 N using equations from Refs. [11] (B-P) and [16] (LCS).*

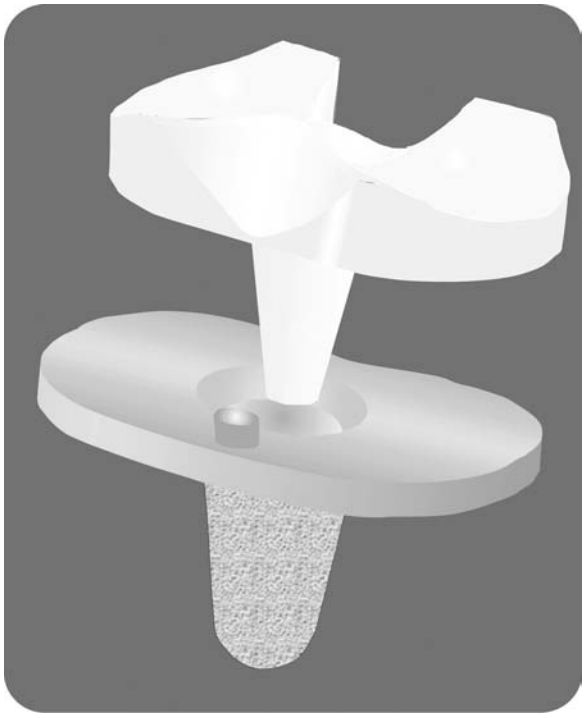


FIG. 4—*B-P tibial platform.*

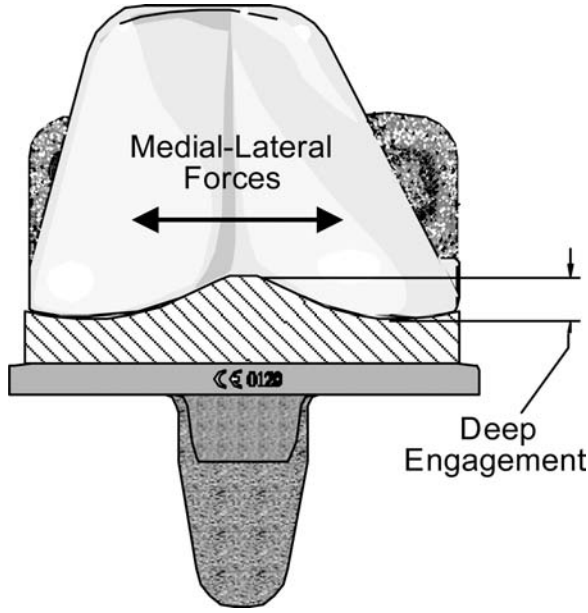


FIG. 5—*M-L stability provided by the articular surfaces.*

along with the lateral and middle patellar facets provide for patellar tilt without loss of congruency. The patella articulates over the primary load bearing segment for all of the range of motion (ROM) where there is significant compressive load and provides quasi-congruent contact on the lateral side where loads are heaviest throughout the patellofemoral motion range except near full extension. The femoral components use a common radius of curvature for most of the patellar articulation and part of the tibial articulation. A rotating patella bearing is used to accommodate the normal axial patellar rotation to the extent that it actually occurs. The femoral component, however, is designed to allow retention of the natural patella in many cases [43–46], based upon surgeon evaluation. The medial-lateral width of the femoral component has been developed for standard and narrow width patients regardless of gender [47–49].

Materials and Methods

Primary and multiply-operated Cementless B-P Rotating Platform Total Knee Replacements with Rotational Stop Pin (Endotec, Inc., Orlando, FL) were sequentially implanted from October 1991 to October 2009 and were prospectively evaluated, clinically and radiographically, in a cohort series [50] of 310 knees in 257 patients.

In the minimum 2-year interval (average follow-up 7.6 years: min 1.01 years; max 18.02 years), there were a total of 259 knees in 206 patients (53 patients had bilateral replacements). Knee system components used the same articulating geometry during the entire study period and included

ultra-high molecular weight polyethylene cruciate-sacrificing rotating platform bearings mated with TiN femoral and tibial components. The metallic implants were made of a titanium alloy with a 10 μm thick titanium nitride (TiN) ceramic coating [51] on all bearing and porous coated fixation surfaces. All polyethylene bearings were sterilized by ethylene oxide. A rotating bearing patella component was used for tricompartmental replacement in 127 knees (49.0%). The patella was rim-cauterized, debrided, and retained in 132 knees (51.0%).

In this minimum 2-year interval there were 86 males and 173 females ranging in age from 34 to 91 years (mean: 67 years). Diagnoses were osteoarthritis in 233, post-traumatic arthritis in 4 patients and rheumatoid arthritis in 22 patients. Their height ranged from 53 to 75 in. (135 to 190 cm) (mean: 66 in. (168 cm)), and their weight ranged from 93 to 410 pounds (42 to 185 kg) (mean 197 pounds (89 kg)).

Clinical evaluations using the validated New Jersey Orthopaedic Hospital Knee Scoring Scale [52] (100 points) were performed after knee replacement surgery along with radiographs at 3, 6, and 12 months and biannually thereafter, for as long as the patient lived.

Radiographic analysis using $\geq$2 mm lucency in any zone around the femoral, tibial, or patellar components was identified for all available x-rays.

Kaplan-Meier Survivorship Analysis [53] was used to document comparative knee system component results using the following three end points: (1) revision for any reason in primary TKRs; (2) revision for any mechanical reason, including component loosening, bearing wear, or bearing dislocation; and (3) a poor clinical knee score.

Exhaustive efforts were made to locate patients, in order to minimize patients that were lost-to-follow-up. These included Internet yellow page searches, social security death index searches, last known phone number/relative contacts, referring or covering physician contacts, and hospital/clinic contacts.

Results

The New Jersey Orthopaedic Hospital Knee Scoring Scale [52] ranged from 36 to 68 points out of a possible 100 points (mean: 52 points) pre-operatively, and 55 to 100 points (mean: 90 points) post-operatively. The pe-operative range of motion averaged a total arc of 100° (range 30° to 135°) and post-operatively increased to 116° (range 30° to 142°).

There were 37 deaths (42 knees) and 26 patients (31 knees) lost-to-follow-up (LTF). At the time of death, those patients had an average knee score of 86.4 points (excellent) (range: 71 to 96), while those patients LTF had an average of 87.9 points (excellent) (range: 70 to 96) at their last follow-up visit.

The study showed 86.4% excellent, 12.3% good, 0.3% fair, and 1.0% poor results. Radiographic zonal analysis for lucencies $\geq$2mm around the femoral, tibial, and patellar components are shown in Table 1, which demonstrates 0% of radiolucencies around femoral components, 2.6% around tibial components, and 0% around patella components.

Kaplan-Meier survivorship analysis of cementless total knee replacement components using an end point of revision for any reason in patients without

TABLE 1—*Complications requiring surgical management in 310 B-P total knee replacements in 257 patients.*

Complication	Number of Occurrences	Time of Occurrence, Years	Management
Supracondylar femur fracture	1	0.1	Fracture bracing
Femoral component loosening	0	…	…
Tibial component loosening	2	0.9, 1.5	Cemented revision with long-stem tibial component
Patellar component loosening	0	…	…
Bearing dislocation	0	…	…
Bearing wear	0	…	…
Patellar bearing wear	0	…	…
Ligamentous instability	2	1.0, 1.1	Thicker bearing and/or MCL repair
Deep infection	1	3.3	Exchange revision
Poor wound healing	4	0.1, 0.1, 0.1, 0.1	Wound revision and primary closure
Quadriceps rupture	2	0.1, 0.2	Quadriceps repair

previous knee surgery (PRIMARY) was 100 % at 18 years (95 % confidence interval [54] of 0.61 to 1.19).

Survivorship in all cementless B-P total knee replacements, including those with previous knee surgery using an end point of revision for any mechanical reason (including component loosening, bearing wear and bearing dislocation), was 99.4 % at 18 years (95 % confidence interval of 0.64 to 1.16). Survivorship for a poor knee score (including persistent pain, loosening, instability, and infection) was 97.6 % at 18 years (95 % confidence interval of 0.64 to 1.16).

Complications

Complications requiring implant revision or fracture management in 310 B-P cementless rotating platform total knee replacements in 257 patients are shown in Table 2.

Two tibial components subsided in two multiply-operated, super obese (BMI >50) (318 lb. and 300 lb.) osteoarthritic male patients; one into valgus and the other into varus after 18 months and 11 months, respectively. In both cases, the tibial component settled into the previous fixed-valgus and fixed-varus deformities, while cystic degeneration and evidence of avascular necrosis of the tibial plateau was noted under the tibial loading plates. Long-stemmed, modular revision tibial components, with screw-reinforced antibiotic cement were used to correct the deformities without removing the well-fixed femoral components.

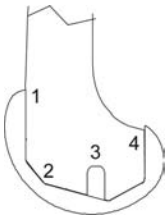
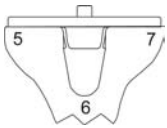
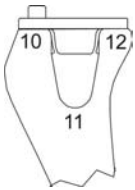
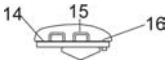
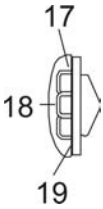
Two total knees in two obese multiply-operated patients developed traumatic medial collateral ligament (MCL) instability after they both fell, one year from their initial total knee surgery. In both cases, knee braces failed to satisfactorily control the instability after a trial of 6 months. Surgical exploration revealed an intact, healed, but attenuated, MCL in one knee, while the other knee demonstrated a complete disruption of the MCL with resorption from the femoral attachment, requiring repair and augmentation through femoral drill holes. Excellent stability was achieved in both knees by using a 5 mm thicker rotating-platform bearing without disrupting the well-fixed metallic components.

One late (3.3 years) deep infection (staph aureus) developed in a 48-year-old rheumatoid woman, which was managed by primary bearing exchange, 6 weeks of intravenous antibiotics and 6 months of oral antibiotics with retention of her well-fixed, cementless, metallic components. After initially doing well, she developed leg ulcers, an open ankle infection, and a secondary knee infection with *Pseudomonas* 2 years later that required significant medical and surgical management prior to her death from rheumatoid pulmonary problems.

Wound revisions were successfully performed in 4 patients with poor initial wound healing. The wounds were elliptically excised and primarily closed. One patient had a subcutaneous abcess (MRSA) that was drained in conjunction with wound revision and debridement. The deep cultures were negative and the patient's wound responded to Vancomycin and Bactrim management without opening the knee joint.

Two elderly female patients developed traumatic quadriceps ruptures in the early post-operative period; one from a fall and the other from over-

TABLE 2—*Radiographic zonal analysis results of patients with rotating platforms (RP) showing lucencies greater than or equal to 2 mm in B-P compared to LCS [8]knee replacements.*

		% Radiolucencies (>2 mm)	
		Cementless Rotating Platform	
	Zone	(259 knees) B-P	(40 knees) LCS
	1	0	0
	2	0	0
	3	0	0
	4	0	0
	5	2.6	7.5
	6	1.3	2.5
	7	2.6	5.0
	10	2.6	5.0
	11	2.6	5.0
	12	1.3	2.5
	14	0	0
	15	0	0
	16	0	0
	17	0	0
	18	0	0
	19	0	0

manipulation in physical therapy. Both patients underwent successful quadriceps repairs and regained terminal extension.

One supracondylar femur fracture in an osteoporotic woman, sustained during a rehabilitation session 2 weeks post-surgery, was successfully treated by closed reduction, cast immobilization, and fracture bracing over a 3 month interval.

Non-fatal pulmonary embolism was seen in 5 patients despite routine post-operative anti-coagulation. All patients responded to routine prolonged anti-coagulation and medical management without further complications.

No femoral component or patella component loosening was seen. Additionally, no rotating-platform bearing wear, osteolysis, or dislocation was seen in this study.

Case Reports

The following case reports provide clinical radiographic documentation of typical osteoarthritic and rheumatoid arthritic patients in this study.

Case #1—This 43 year old, 180 cm (71 in.) tall, 108 kg (240 lb.), osteoarthritic male patient underwent right cementless B-P TKR in 1993 for a 15° fixed varus deformity. He recovered uneventfully with a ROM of 0-125° and a knee score of 100 points (excellent) at 16 years post-op. Pre-operative and post-operative x-rays are shown in Fig. 6.

Case #2—This 64 year old, 168 cm (66 in.) tall, 81 (180 lb.) kg, rheumatoid arthritic female patient underwent left cementless B-P TKR in 1995, and a right B-P TKR in 1996. She recovered uneventfully with a ROM of 110° in her right knee and 118° in her left knee, and bilateral knee scores of 84 points (good) at 13 and 14 years post-op for her right and left knees, respectively. Pre-operative and post-operative x-rays are shown in Fig. 7.

Discussion

The long term clinical success of total knee replacement has been documented for both fix-bearing [55–57] and mobile-bearing [3,8–10,15,24–26,29,58–61] designs, making knee replacement an extremely worthwhile and dependable treatment for end-stage arthritis. Cemented all-polyethylene components for elderly patients (≥75 years) have shown superior survivorship and appear to be

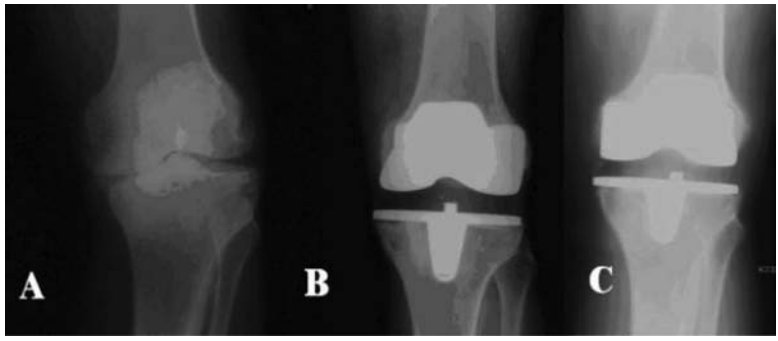


FIG. 6—*Anteroposterior radiographs shows: (A) pre-op; (B) 3 years post-op; and (C) 16 years post-op of the patient described in Case #1.*

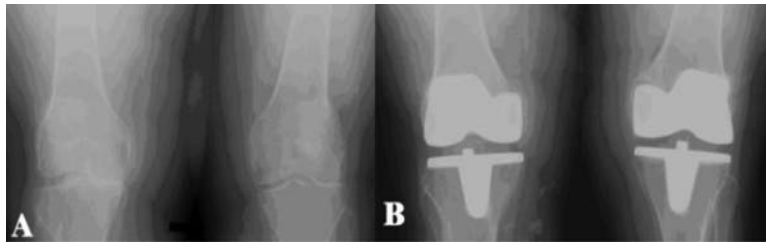


FIG. 7—*Anteroposterior radiographs shows: (A) pre-op; (B) bilaterally at 14 years and 13 years post-op of the patient described in Case #2.*

more cost effective than metal-backed modular components [62]. Some modular fixed-bearing components have produced inferior survivorship to their cemented all-polyethylene counterparts, [63] even though they were designed to improve performance and longevity.

The explanation of the poor performance has been placed on the sterilization methodology and locking mechanisms in the case of fixed-bearing designs [64] and rotational instability in the case of mobile bearing designs [41,65]. Gamma-radiation-in-air and shelf aging with accelerated wear in polyethylene bearings [31,33,34,48] has been documented, however, surface congruity seems to play an even larger role in the evolution of bearing wear [16,32,66].

Collier and associates have evaluated fixed and mobile bearings after mid term and long term use with similar sterilization methodology and consistently found dramatic improvements in wear resistance in more-congruent mobile bearings over less congruent fixed-bearings [32,33,67]. These findings have been confirmed in simulator studies that demonstrate a four-fold improvement in the wear resistance of a rotating-platform type bearing over a less congruent fixed-bearing of the same implant system [12].

As patients become more active and undergo joint replacement at an earlier age, this wear difference between bearing types becomes an important issue. Maximizing contact areas to reduce contact stress during major load-bearing phases of motion while restoring normal flexion of the knee remains an important goal for implants to meet. Additionally, modularity which can provide for ease of removal and replacement of worn bearings without disturbing well-fixed components, remains another essential goal.

The LCS rotating platform set the standard for modular metal-backed components. Long term cemented [26] and cementless [8,24,28,40] studies have documented durability, while the ease of reviseability in the event of wear-related failures has been demonstrated [68]. The major down-side of rotating platforms has been the occasional "spin-out" (1-2%) complication [8,35] that does not respond to a simple, increase-in-thickness, deep-dish bearing exchange. The B-P implant, which is the subject of this clinical report, was undertaken for design improvements (i.e., spin-out, contact stress and improved wear) in joint replacement systems [69].

The B-P rotating-platform system has incorporated an emergency stop-pin enhancement and contact stresses have been lowered in certain key load

bearing regions without dramatically altering the "tried-and-true" LCS design concepts. No intercondylar posts have been added that would increase contact stresses; [70,71] condylar lift-off [72] is expected to be essentially unaffected in varus or valgus and may be improved compared to some recent designs [73,74] (i.e., increased spherical congruity and without the intercondylar post inhibition) [71,75]. Most importantly, wear-related and "spin-out" failures, although unusual (1-2 %) in the LCS [8,35,36] have been essentially eliminated in the current improved design.

A TiN ceramic coating has been applied to reduce the allergy potential to Co-Cr metals, while maintaining excellent wear resistance, comparable to simulator evaluation [51] and long-term clinical studies of cementless hip [76] and ankle replacements [77] using the same material.

The current literature which reflects the discussion on resurfacing or not resurfacing the patella has been studied in multiple designs [78–81]. It appears that anatomically shaped or "patella friendly" trochlear designs allow for smooth articulation of the unresurfaced patella with few complications or the need for revisions. The LCS type femoral flange has been in use for over 30 years and has been viewed as "patella friendly" by multiple authors [28,43,44]. In fact, because of long-term rotating patella component failures [82], although generally less than 1 %, some surgeons have exclusively unresurfaced the patella with equally good results in the long term [44,81].

The current study reflects a common-ground with both schools of thought. There were 132 (51.0 %) unresurfaced patellae and 127 (49.0 %) resurfaced patellae using the rotating-patellar component followed for 2–18 years (mean: 7.6 years). No failures or complaints of severe anterior knee pain were seen in either group; thus demonstrating no patient preference of patella resurfacing or unresurfacing in this series of knee replacements.

The rate of device-related complications in this clinical series is low. One infection occurred late (3.3 years) in an immuno-compromised rheumatoid patient and the other major complications included tibial component loosening, ligamentous instability, and quadriceps rupture in the early post-operative period (0.1 to 1.5 years). No other late failures were encountered.

A potential drawback in this study is the relatively small number of knee replacements followed for more than 15 years (32 of 310 patients), although 102 knee replacements were followed for 10 years or more. This drawback is overshadowed by the relatively minor design changes incorporated into the B-P device design from the LCS design, which do not allow contact with mechanical stops (except in an emergency or traumatic rotary subluxation of the tibia) or introduce intercondylar posts, which necessitate increasing contact stresses and surface incongruity [70,71,73,83]. It is envisioned that these subtle design changes may increase bearing longevity beyond 30 years, while eliminating or, at least, substantially reducing rotating-platform "spin-outs."

In summary, the current study of cementless B-P rotating-platform knee replacements has identified and apparently reduced or solved two of the long-term problems of the clinically successful LCS rotating platform; namely, wear and tibial bearing "spin-out.. Although these two problems represent only a 1-2 % complication rate [8,35], it is certainly worthwhile to address the design

features that appear to be responsible for them. The improvement in bearing surface congruity, sterilization by ethylene oxide, and the addition of an emergency stop-pin to prevent rotary subluxation of the tibial bearing appear to have eliminated these problems without adding additional complexity or degrading the bearing surfaces. The 18 year survivorship of the cementless B-P knee replacement of 99.4 % compares most favorably to the 98.3 % 18 year survivorship of the cementless LCS device [8] while apparently reducing or solving two of its small but formidable problems. Future studies of extremely high-activity-level patients in an evidence-based approach [84] may be needed to discover the full potential of these design improvements.

Acknowledgments

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The Incidence of Anterior Knee Pain and Crepitation After Total Knee Replacement: A Matched Pair Analysis between Rotating Platform and Fixed Bearing Posterior Stabilized Designs

ABSTRACT: Persistent pain, especially anterior knee pain, with or without crepitation, has been a persistent complaint after total knee arthroplasty in both rotating platform posterior stabilized (RP-PS) and fixed bearing posterior stabilized (FB-PS) designs. Because PFC Sigma RP-PS and FB-PS designs have identical femoral components, we hypothesized that the incidence of post-operative pain, anterior knee pain, asymptomatic crepitation, painful crepitation, and painful crepitation requiring scar excision is similar in both designs. Between March 2000 and May 2004, 81 near-consecutive RP-PS Total Knee Replacements (TKRs) were matched to 81 FB-PS knees based on gender, age, and body mass index. Radiographic analysis included alignment, fixation, and patellar tilt. Clinical assessments were performed at the

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time of follow-up using the Knee Society Scores. The incidence of anterior knee pain and crepitation was investigated using a detailed patient administered questionnaire. The incidence of post-operative pain, anterior knee pain, asymptomatic crepitation, and painful crepitation was similar in both groups (20.9 %, 19.7 %, 1.2 %, and 8.6 % in the RP-PS; and 20.9 %, 18.5 %, 0 %, and 6.1 % in the FB-PS, respectively). The severity of painful crepitation was also similar in both groups. None was excruciating. The incidence of painful crepitation requiring scar excision was slightly higher in the RP-PS group (6.1 % versus 2.4 %) but it was not statistically significant. In conclusion, there is a trend of increased incidence of painful crepitation requiring scar excision in the RP-PS TKR, although it was not statistically significant in this study.

KEYWORDS: anterior knee pain, crepitation, total knee replacement, rotating platform, fixed bearing, posterior stabilized

Introduction

The primary indication for a Total Knee Replacement (TKR) is pain relief. Post-operative knee pain, especially anterior knee pain (AKP), has been a constant complaint after TKR [1–5], both in primary and revision surgeries [6]. In some cases, AKP is also associated with catching sensation and crepitation, which may require surgical intervention. Several reports have shown an increased incidence of anterior knee pain and crepitation with newer modern rotating platform designs [7,8] compared to fixed bearing TKR [9,10]. The reported incidence of persistent post-operative pain, AKP, and crepitation in the literature has been variable in both rotating platform (RP-PS) and fixed bearing (FB-PS) posterior stabilized (PS) TKRs [11,12]. Our hypothesis was that the RP-PS TKR has a higher incidence of anterior knee pain and crepitation compared to FB-PS TKR.

Materials and Methods

Between March 2000 and May 2004, 81 near-consecutive PFC Sigma RP-PS TKRs (Depuy Orthopaedics, Warsaw, IN) that had complete radiographic and clinical follow-up were matched to 81 PFC Sigma FB-PS TKRs, based on age, sex, body mass index (BMI), (Table 1) and pre-operative deformity. The RP-PS and the FB-PS Sigma designs have identical femoral components (Fig. 1).

All components were cemented and all patellae were resurfaced. The technique for patella replacement included excising the articular surface of the

TABLE 1—*Demographics.*

Parameter	RP-PS	FB-PS
Age (range)	66.5 ± 8.4 (44–84)	67.1 ± 8.3 (37–82)
BMI	28.6 ± 4.3	27.9 ± 4.8
Follow-Up (yr)	8.6 ± 1.6	
Gender M:F	39:42	

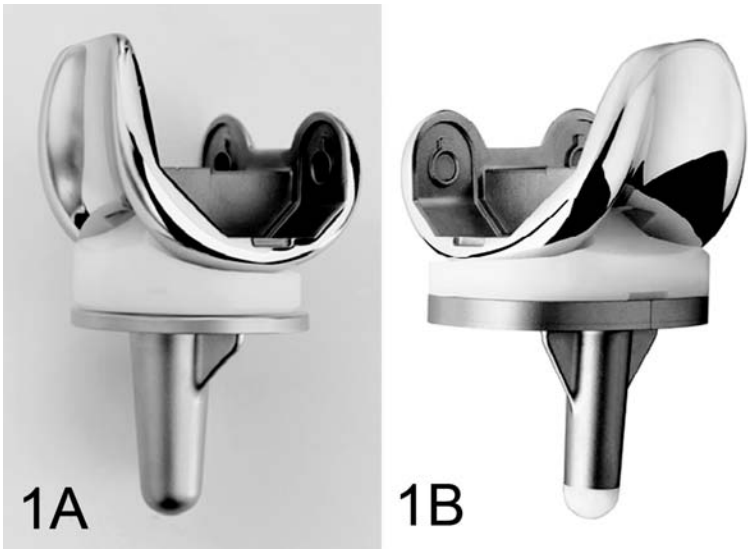

FIG. 1—*PFC Rotating-Platform (A) and Fixed-Bearing (A) demonstrating identical femoral components.*

patella to the depth of the hard subchondral plate of the lateral facet. All loose synovium and osteophytes were removed to minimize peri-patellar scar formation and subsequent crepitation or clunk. A round or oval patella is chosen to maximize bone coverage with medialization of the component without any overhang. Also the tibial and femoral components were lateralized to enhance patellofemoral tracking. All surgeries were performed by one of two surgeons at one institution using the standard medial parapatellar approach. All patients received the same peri-operative pain management [13] and post-operative rehabilitation protocol.

Radiographic analysis included alignment, fixation, component position and patellar tilt on final post-operative antero-posterior (AP), lateral and skyline radiographs. The incidence of any post-operative pain, anterior knee pain, asymptomatic crepitation, painful crepitation, and painful crepitation requiring scar excision was investigated using a detailed patient administered questionnaire (ROC-PAQ, Fig. 2). The Knee Society Score (KSS) was also used for clinical assessment. All descriptive statistics (mean, SD, and mean standard error) were performed with SPSS 16.0 (SPSS Inc., Chicago, IL). Student's *t*-test was used for statistical analysis. Two-tailed ρ values less than 0.05 were considered statistically significant.

Results

The mean ages in the RP-PS and FB-PS groups were 66.5 ± 8.4 (range 44–84) and 67.1 ± 8.3 (range 37–82), respectively. These matched pairs (162 knees, 18 bilaterals) included 144 patients (66 males and 78 females). The mean BMI in

ROC **PATIENT ADMINISTERED QUESTIONAIRE** **KNEE**

Name: _____ Date: _____ (Please circle responses)

1. Have you had pain recently (within the last 3 months) on the affected knee?

Right Knee:	**Yes / No**					
If yes,	**location:**	Inner	Outer	Front	Back	Allover
	Severity:	None	Mild	Moderate	Severe	Excruciating
	Frequency:	Never	Rarely	Occasionally	Frequently	Always
Left Knee:	**Yes / No**					
If yes,	**location:**	Inner	Outer	Front	Back	Allover
	Severity:	None	Mild	Moderate	Severe	Excruciating
	Frequency:	Never	Rarely	Occasionally	Frequently	Always

2. Do you hear any noises coming from your knee? No / Right knee / Left knee / Both knees
If yes, is it associated with pain? Yes / No

3. Do you have difficulty with:

a. putting on socks/shoes?	None	Slight	Moderate	Great	Unable
b. personal care (toilet, bathing, etc)	None	Slight	Moderate	Great	Unable
c. household activities (cleaning, etc)	None	Slight	Moderate	Great	Unable
d. getting in and out of a car?	None	Slight	Moderate	Great	Unable
e. kneeling?	None	Slight	Moderate	Great	Unable
f. squatting?	None	Slight	Moderate	Great	Unable

4. How much assistance do you need with going up and down stairs?
None cane/crutch/banister 2 crutches walker/someone's assistance Unable

5. How far can you walk? (before your pain limits you)
Unlimited 10+ blocks 4-10 blocks 1-3 blocks Housebound

6. Please select your favorite recreational activities and how often you would participate in them:

a. Walking (>1 mile)	Never	Rarely	Occasionally	Frequently	Always
b. Running	Never	Rarely	Occasionally	Frequently	Always
c. Swimming	Never	Rarely	Occasionally	Frequently	Always
d. Gym Workout	Never	Rarely	Occasionally	Frequently	Always
e. Tennis	Never	Rarely	Occasionally	Frequently	Always
f. Golf	Never	Rarely	Occasionally	Frequently	Always
g. Gardening	Never	Rarely	Occasionally	Frequently	Always
h. Other:_____	Never	Rarely	Occasionally	Frequently	Always

How often does your affected knee influence or prohibit the performance of these activities?
Never Rarely Occasionally Frequently Always

7. How often does your affected knee influence your social activities? (recreation, traveling)
Never Rarely Occasionally Frequently Always

8. How often does your knee pain influence your sense of well being? (emotionally, mentally)
Never Rarely Occasionally Frequently Always

9. Please rate your degree of satisfaction with your ability to use your knee.
Unsatisfied 0 1 2 3 4 5 6 7 8 9 10 Fully Satisfied

FIG. 2—*ROC-PAQ (Patient Administered Questionnaire), which has a specific section for location, severity, and frequency of knee pain.*

the RP-PS and FB-PS group was 28.6 ± 4.3 and 27.9 ± 4.8 respectively. The mean follow-up was 8.6 ± 1.6 years. The mean KSS improved from 56.7 ± 9.5 pre-operatively to 95.1 ± 9.5 at final follow-up. The majority of femoral components and polyethylene sizes used in both groups were 3.0 and 10mm respectively. There was no difference between the mean post-operative patellar tilt between the two groups ($0.8^\circ \pm 3.2^\circ$ in FB-PS versus $0.9^\circ \pm 4.1^\circ$ in RP-PS). There was no statistical difference between the two groups for any of the matching criteria.

TABLE 2—*Clinical results from the ROC-PAQ.*

Criterion	RP-PS	FB-PS	p Value
Any post-operative knee pain	17 (20.9 %)	17 (20.9 %)	1
Anterior Knee Pain	16 (19.7 %)	15 (18.5 %)	0.842
Asymptomatic Crepitation	1 (1.2 %)	0	1
Painful Crepitation	7 (8.6 %)	5 (6.1 %)	0.765
Painful Crepitation Requiring Scar Excision	5 (6.1 %)	2 (2.4 %)	0.442

The incidence of post-operative pain, anterior knee pain, asymptomatic crepitation, and painful crepitation was similar in both groups (Table 2). The severity of painful crepitation was also similar in both groups (Table 3). None were excruciating. The incidence of painful crepitation requiring scar excision was slightly higher in the RP-PS group but it was not statistically significant ($p = 0.44$, Fig. 3). In patients that underwent scar excision, intra-operative patellar tracking was found to be appropriate based on symmetric position of the patellar component on the trochlear groove during full range of motion (ROM).

Radiographic analysis showed no malalignment or osteolysis with appropriate cement mantle. There were no complications such as spinout, infection, patella fracture, avascular necrosis, subluxation, or dislocation (Fig. 4). There were 3 patients in each group that required manipulation for decreased range of motion at three to six months post-operatively (Table 4). One patient in the RP-PS group required revision of both components to fixed-bearing for severe stiffness and decreased ROM. Intra-operatively there was excessive scar formation without any evidence of loosening or patellar maltracking.

Discussion

Persistent pain, especially anterior knee pain, with or without crepitation, has been a persistent complaint after total knee arthroplasty. The common causes of pain after TKR include osteolysis, wear-induced synovitis, infection, instability, or fracture. However, a subgroup of patients complain of persistent post-operative knee pain that does not have a clear etiology based on traditional imaging techniques, physical exam, and laboratory evaluation. Our objective was to investigate the incidence of persistent post-operative pain, anterior knee pain, asymptomatic crepitation, painful crepitation, and painful crepitation

TABLE 3—*Severity of painful crepitation.*

Severity of Painful Crepitation	RP-PS	FB-PS
Mild	2 (2.5 %)	1 (1.2 %)
Moderate	3 (3.7 %)	4 (4.9 %)
Severe	2 (2.5 %)	0
Excruciating	0	0

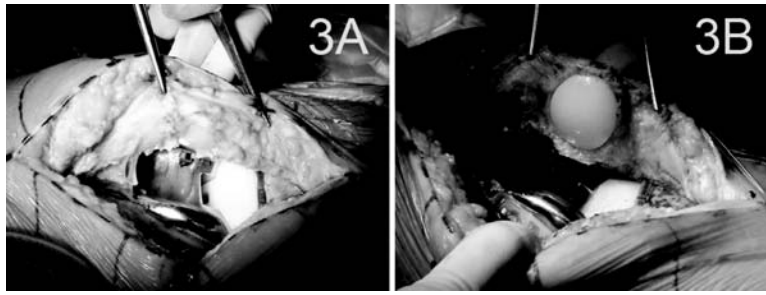

FIG. 3—*Intra-operative photo showing peri-patella scar formation (3A) and a after excision (3B) in a patient with painful patellar crepitation.*

requiring scar excision in a matched pair analysis between the Sigma RP-PS and FB-PS designs.

We found a similar rate of post-operative pain and anterior knee pain in both the RP-PS and FB-PS groups, without any statistical differences. Reported results of the incidence of anterior knee pain in mobile-bearing design compared to fixed-bearing designs have been variable [2,4–6]. Several studies have investigated component positioning, patellar mal-tracking, mild instability and subclinical synovitis, backside wear, and component trochlear design as

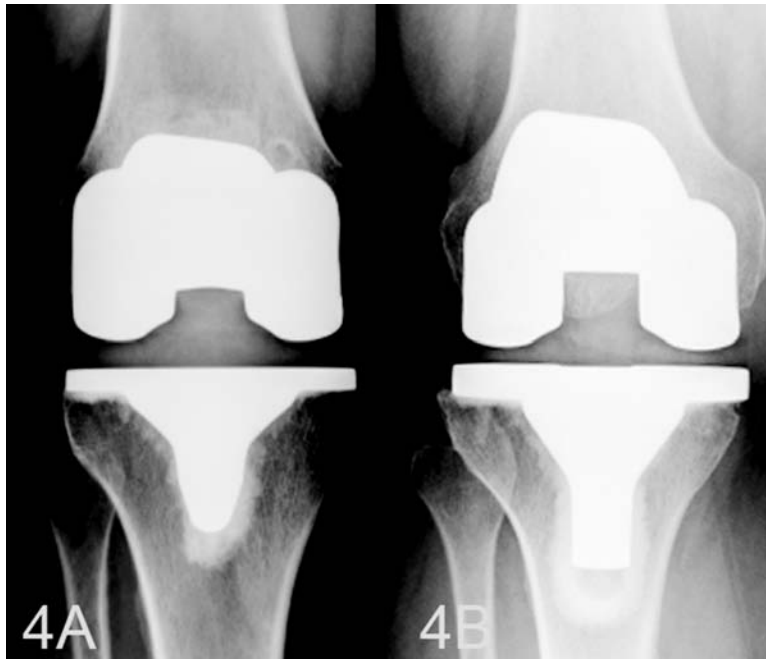

FIG. 4—*Sample anterior-posterior radiographs of two patients 5 years post-operatively, RP-PS (A) and FB-PS (B).*

TABLE 4—*Re-operations other than scar excision.*

Operation Type	RP-PS	FB-PS	p Value
Manipulation	3 (3.7 %)	3 (3.7 %)	1
Revision	1(1.2 %)	0	1
Total	4 (4.9 %)	3 (3.7 %)	1

possible etiologies of AKP [5–9,14–19]. Breugem et al. [11] in a recent prospective randomized study comparing mobile-bearing with a fixed-bearing prosthesis reported less incidence of anterior knee pain in mobile-bearing knees. Popovic et al. [5], on the other hand, reported more anterior knee pain in mobile-bearing than fixed-bearing knees, resulting from inappropriate trochlear design of the femoral implant. Several other studies report component positioning as a potential contributor to knee pain after TKR. Using CT scan for component positioning, Barrack et al. [3] showed that patients with combined component internal rotation are more than five times as likely to experience anterior knee pain compared with those with combined component external rotation in a fixed-bearing design. However, in RP-PS, the rotational freedom of the polyethylene inset may compensate for mild malrotation of the components.

The reported incidence of painful crepitation in the literature with fixed bearing compared to rotating platform design is lower, although not statistically significant, ranging between zero and 5 % [20–22]. The self-alignment feature of the RP-PS theoretically improves patellar tracking [23]; however, Pagnano et al. [8] in a prospective randomized study reported no differences in patellofemoral function between patients with RP-PS and fixed-bearing knee replacement. Ranawat et al [9]. in a study comparing fixed- and mobile-bearing design in two separate cohorts of patients showed an incidence of painful crepitation in 1.5 % and 1 % of patients, respectively, without any statistical significance.

In this study, there was no statistical difference between the RP-PS and FB-PS groups in terms of asymptomatic crepitation, painful crepitation, and painful crepitation requiring scar excision; however, there is a trend of increased scar excision in the RP-PS group. The incidence of painful crepitation requiring scar excision in the RP-PS study group was higher than the rate in our registry of over 800 RP-PS TKRs (6.1 % versus 2.8 %). This may be due to selection bias, as patients with symptomatic knees had more complete follow-up, which was a limitation to this study.

In conclusion, the results of this study show that the incidence of postoperative pain, anterior knee pain, asymptomatic crepitation, and painful crepitation in both RP-PS and FB-PS Sigma are similar. There is a trend of increased incidence of painful crepitation requiring scar excision in the RP-PS TKR.

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Early Instability with Mobile Bearing Total Knee Arthroplasty: A Series of Twenty-Five Cases

ABSTRACT: Between Dec. 1987 and Jan. 2002, twenty-five cases of clinical instability following mobile bearing total knee arthroplasty with meniscal bearings or rotating platforms presented for evaluation at our institution. These cases were retrospectively identified. All were performed at outside institutions by a variety of surgeons. All clinical examinations were performed by the authors. Nine cases were revised at our institution. All twenty-five cases had clinical evidence of severe coronal plane instability and pain. Eight cases had polyethylene dislocation or subluxation evident radiographically and clinically. Four cases had extensor mechanism dysfunction. Eighteen cases had symptoms immediately postoperatively. Twenty-three of the twenty-five cases had symptoms within two years postoperatively. Any potential long-term benefit of design innovations must be balanced with known problems leading to early failure. This paper is a review of a previously published manuscript by Dr.'s Moskal and Ridgeway [Ridgeway, S. R. and Moskal, J. T., "Early Instability with Mobile Bearing Total Knee Arthroplasty: A series of twenty-five cases," *J. Arthroplasty*, Vol. 19, No. 6, 2004, pp. 686–693]. The current manuscript has been updated with additional discussion and references covered in his planned presentation.

KEYWORDS: instability, total knee arthroplasty, mobile bearings, revision, dislocation

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Introduction

Mobile bearing knees were introduced in the mid to late 1970s in an effort to maximize congruity of the articular bearing surface in total knee arthroplasty (TKA) while allowing tibial motion relative to the polyethylene insert and thereby theoretically improving knee flexibility and kinematics [1,2]. It has been hoped that the increased congruity and concomitant decreased contact stress would decrease polyethylene wear and subsequently ensure a longer service life of the implant. Additionally, the "self-aligning" nature of the implants has been advocated as simplifying the surgical technique and making the procedure more forgiving.

The proposed long-term advantages in terms of polyethylene wear with mobile bearing knees, however, must be taken in context with any early complications affecting outcome. One such complication is instability with or without polyethylene insert dislocation. In several studies, the incidence of polyethylene dislocation has ranged from 0 to 9.3 %. One study indicated that these problems occurred midterm at 4 and 6 years post-operatively [3] and another found that these problems occurred within 6 months of the index procedure [4]. Most studies have concentrated on the incidence of the problem and have included relatively few cases [3–5]. Clinical presentation and the ultimate management of this type of complication in mobile bearing knees and its outcome have been minimally addressed in the literature.

The purpose of the current report is to present the largest series from a single institution of post-operative instability following mobile bearing TKA utilizing both menisical bearing and rotating platform implants—twenty-five cases.

Materials and Methods

A retrospective review was performed of all knees identified from a prospectively maintained database that presented at our institution for the evaluation of instability following mobile bearing TKA with menisical bearing or rotating platforms. From Dec. 1987 and Jan. 2002, a total of twenty-five knees (in 19 patients) met the criteria for inclusion in the study. All TKAs were performed elsewhere at outside institutions. All were community hospitals performing in excess of 100 total knee arthroplasties per year by a variety of surgeons. All available charts, radiographs, and subsequent operative notes were reviewed.

There were nineteen patients of which ten were women and nine were men. Six patients had symptomatic bilateral knee arthroplasties for a total of twenty-five cases, as shown in Table 1. The mean age at presentation (and standard deviation) was 70.80 ± 7.99 yr (range, 57 to 86 yr). The average height was 168.64 ± 9.29 cm (range, 158 to 183 cm) and the average weight was 84.88 $\pm$ 21.73 kg (range, 53 to138 kg). There were fourteen right knees and eleven left knees.

The diagnosis was osteoarthritis in twenty-two cases, rheumatoid arthritis in two cases, and post-traumatic arthritis in one case. Twenty-four cases were primary TKA and one was a conversion of a unicompartmental knee arthroplasty to a TKA.

TABLE 1—*Patient demographics.*

Case	Side	Age	Sex	Height, cm	Weight, kg	Initial Diagnosis	Initial Surgery Date	Knee Arthroplasty
JS-1	Right	73	Female	160	72	Osteoarthritis	3/92	MB
JS-2	Left	73	Female	160	72	Osteoarthritis	3/92	MB
RB-3	Right	86	Female	158	75	Osteoarthritis	4/96	RP
MP-4	Right	72	Female	163	96	Osteoarthritis	3/90	MB
MP-5	Left	72	Female	163	96	Osteoarthritis	3/90	MB
JU-6	Right	70	Female	158	82	Osteoarthritis	11/92	MB
GW-7	Left	57	Male	180	116	Osteoarthritis	4/92	Rev. of Uni to MB
RH-8	Right	70	Male	175	87	Osteoarthritis	8/90	MB
MG-9	Left	67	Female	158	71	Osteoarthritis	1/85	MB
JS-10	Right	61	Male	180	138	Osteoarthritis	1/98	RP
HD-11	Right	68	Female	165	64	Osteoarthritis	9/96	MB
HD-12	Left	68	Female	165	64	Osteoarthritis	9/96	MB
JJ-13	Right	65	Male	178	130	Posttraumatic	9/99	RP
JH-14	Right	59	Female	158	70	Osteoarthritis	6/95	MB
GJ-15	Left	66	Female	165	108	Osteoarthritis	8/92	MB
CF-16	Right	85	Female	175	53	Osteoarthritis	3/00	MB
CF-17	Left	85	Female	175	53	Osteoarthritis	3/00	MB
JW-18	Left	73	Male	170	70	Osteoarthritis	9/00	RP
ET-19	Right	65	Male	183	86	Rheumatoid	4/00	RP
ET-20	Left	65	Male	183	86	Rheumatoid	4/00	RP
JL-21	Right	63	Female	168	70	Osteoarthritis	2/01	RP
EP-22	Left	76	Male	180	77	Osteoarthritis	10/00	RP
LC-23	Right	69	Male	180	86	Osteoarthritis	1/92	MB
WD-24	Left	81	Male	158	100	Osteoarthritis	1/95	MB
WD-25	Right	81	Male	158	100	Osteoarthritis	1/95	MB

Note: Index Procedure: MB = Menisical Bearing; RP = Rotating Platform; Uni = Unicompartmental.

Seventeen cases were performed with a cruciate retaining Low Contact Stress TKA (Depuy, Warsaw, ID) with menisical bearings, and eight cases were cruciate sacrificing Low Contact Stress TKA (Depuy, Warsaw, ID) with a rotating platform tibial bearing.

The evaluation consisted of radiographs at the initial evaluation and at subsequent visits when appropriate. Axial alignment measurements and assessment of the joint line for each case was made from radiographs obtained at the time of initial presentation. The axial alignment was an anatomic axis measured on standing anterior-posterior radiographs, since long standing films were not available for all cases. The cases that were revised had identical post-operative

measurements made. Stress radiographs were occasionally obtained when deemed appropriate by the attending surgeon.

All clinical examinations were performed by the authors. All cases had Hospital for Special Surgery (HSS) knee scores determined at the initial presentation. Additionally, the nine cases revised at our institution had post-operative HSS knee scores obtained one year post-operatively. Those nine cases had examination under anesthesia, as well, and the operative findings were available for review.

Results

All twenty-five cases had clinical evidence of severe coronal plane instability and pain (see Table 2). In addition, eight cases had polyethylene dislocation or subluxation radiographically (Fig. 1) and clinically evident. Four cases had extensor mechanism dysfunction or frank patellofemoral instability (Fig. 2). Additionally, one proximal tibial stress fracture was felt to be secondary to severe coronal plane instability.

TABLE 2—*Presenting symptoms.*

Case	Side	Symptoms in Addition to Medial and Lateral Instability
JS-1	Right	pain
JS-2	Left	pain, PE dislocation
RB-3	Right	pain, multiple dislocations
MP-4	Right	pain
MP-5	Left	pain
JU-6	Right	tibial stress fracture, pain
GW-7	Left	pain, polyethylene dislocation
RH-8	Right	pain
MG-9	Left	pain
JS-10	Right	pain
HD-11	Right	pain
HD-12	Left	pain
JJ-13	Right	patellar instability, pain
JH-14	Right	A/P instability, pain, PE dislocation
GJ-15	Left	pain, PE dislocation and fracture, 15° extensor lag
CF-16	Right	pain, PE subluxation and fracture
CF-17	Left	pain, PE subluxation and fracture
JW-18	Left	pain, extensor mechanism rupture
ET-19	Right	pain
ET-20	Left	pain
JL-21	Right	pain, patellofemoral instability
EP-22	Left	pain, polyethylene subluxation
LC-23	Right	pain
WD-24	Left	pain
WD-25	Right	pain

Note: A/P = Anterior and Posterior; PE = Polyethylene.

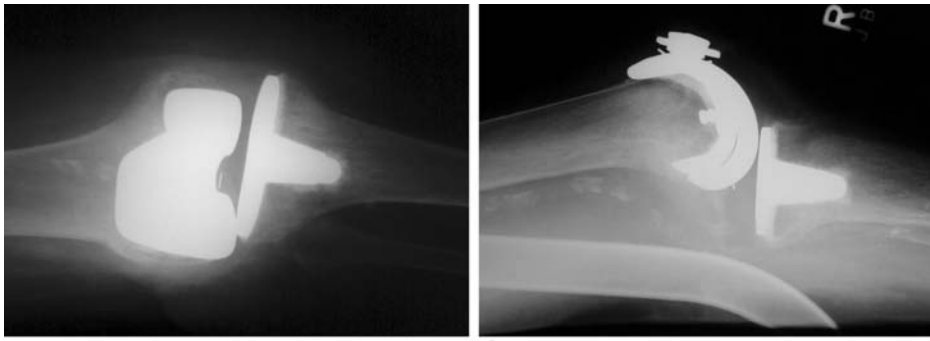

FIG. 1—*(A) and (B) Case RB-3. Anteriorposterior and lateral radiographs of a rotating platform design with complete dislocation of the polyethylene.*

Symptoms occurred at a mean of 9.20 ± 21.29 months (range, 0-92 months) following the index procedure. Eighteen cases had symptoms immediately postoperatively. Twenty-three of the twenty-five cases had symptoms within two years postoperatively (see Table 3).

Radiographic evaluation demonstrated the mean pre-operative axial alignment for the overall group of 25 cases to be 7° valgus (range, 8° varus–22° valgus). The 16 cases that did not undergo revision had a mean axial alignment of 9.7° valgus (range, 7° valgus–12° valgus). The mean preoperative axial alignment for the 9 cases revised was 5.8° valgus (range, 8° varus–22° valgus). The postoperative mean axial alignment for these cases was 5.5° valgus (range, 4°valgus–9° valgus).

Prior to presentation at our institution, treatment had consisted of bracing or casting in nine cases, the use of assistive ambulatory devices in four cases, polyethylene exchange in four cases, miscellaneous other surgical procedures in five cases, and no specific treatment had been initiated in nine cases. Three separate surgical procedures had been performed in two cases, two in one case, and one in five cases (see Table 4).

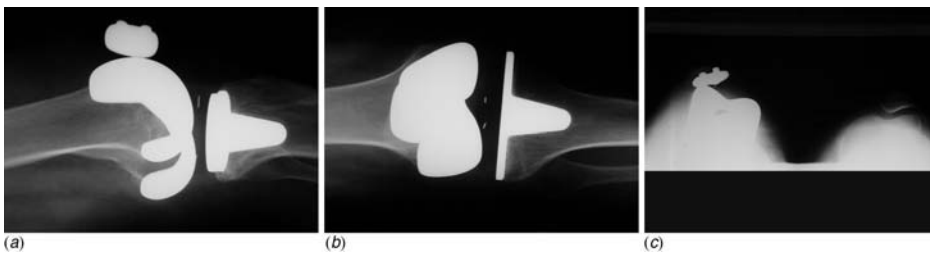

FIG. 2—*(A), (B), and (C) Case JL-21. Anteriorposterior, lateral, and sunrise radiographs of a rotating platform design with lateral subluxation of the patella. The femoral component was felt to be internally rotated at the time of revision. There was midflexion instability and intermittent subluxation of the tibial polyethylene as well.*

TABLE 3—*Onset of symptoms.*

Case	Side	Onset of Symptoms, Months
JS-1	Right	18
JS-2	Left	18
RB-3	Right	0
MP-4	Right	0
MP-5	Left	0
JU-6	Right	19
GW-7	Left	54
RH-8	Right	0
MG-9	Left	0
JS-10	Right	5
HD-11	Right	0
HD-12	Left	0
JJ-13	Right	0
JH-14	Right	24
GJ-15	Left	92
CF-16	Right	0
CF-17	Left	0
JW-18	Left	0
ET-19	Right	0
ET-20	Left	0
JL-21	Right	0
EP-22	Left	0
LC-23	Right	0
WD-24	Left	0
WD-25	Right	0

Nine cases were revised at our institution by the authors (see Table 5). At the time of revision, there were five subluxated or dislocated menisical bearings, four fragmented menisical bearings, and three cases of malpositioned components felt to be contributing to failure. The type of revision was dictated by the findings at the time of revision. The degree of instability found at the time of revision dictated the degree of constraint utilized. Four cases were revised to rotating platform tibial components only. One case was completely revised to a cruciate substituting implant. Three cases with severe coronal plane instability required revision to more constrained implants with two having varus-valgus constrained prostheses and one receiving a hinged implant. One case with a tibial stress fracture immediately below the tibial component was managed with a revision to a posterior stabilized implant along with a long stemmed tibial component with bone grafting. The stress fracture was felt to be due to severe coronal plane instability with subsequent abnormal stresses at the meta-diaphyseal junction.

TABLE 4—*Treatment prior to presentation.*

Case	Side	Treatment Prior to Presentation	Number of Prior Procedures
JS-1	Right	None	0
JS-2	Left	Poly exchange	1
RB-3	Right	1. Poly exchange, brace; 2. Inbrication of medial structures, casting, and brace	2
MP-4	Right	Brace, cane/walker	0
MP-5	Left	Brace, cane/walker	0
JU-6	Right	Casting	0
GW-7	Left	Brace, crutches	0
RH-8	Right	Brace	0
MG-9	Left	Arthrotomy and debridement	1
JS-10	Right	Brace	0
HD-11	Right	1. Manipulation with retinacular release; 2. Lateral release; 3. Removal of adhesions	3
HD-12	Left	1. Manipulation with retinacular release; 2. Lateral release; 3. Removal of adhesions	3
JJ-13	Right	Cane	0
JH-14	Right	None	0
GJ-15	Left	None	0
CF-16	Right	Poly exchange	1
CF-17	Left	None	0
JW-18	Left	Extensor mechanism allograft, brace	1
ET-19	Right	None	0
ET-20	Left	None	0
JL-21	Right	None	0
EP-22	Left	None	0
LC-23	Right	Poly exchange	1
WD-24	Left	Brace	0
WD-25	Right	None	0

The HSS knee score for all 25 cases was a mean of 49 (range, 35–66) at the time of initial presentation. Those 16 cases that were not revised had a mean HSS score of 49 (range, 35–59). The 9 cases that were revised had a mean pre-op HSS score of 51 (range, 36–66). The mean post-op HSS score for the revised cases at one year was 85 (74–95).

Discussion

Mobile bearing knees were introduced with the goal of providing an implant that would allow increased congruity without compromising motion. The

TABLE 5—*Findings at revision.*

Case	Side	Revision Surgery Findings	Revision Procedure
JS-1	Right	Fragmented, subluxated medial bearing, malrotation of femur	Tibial revision with rotating platform
JS-2	Left	Fragmented, dislocated lateral bearing, metallosis, burnished femur	Varus valgus constrained implant with stems
RB-3	Right	Dislocated medial bearing, severe medial ligament deficiency, medial tibial plateau bone deficiency	Hinged implant
MP-4	Right	N/A	0
MP-5	Left	N/A	0
JU-6	Right	Tibial component loose, midflexion laxity	Posterior stabilized implant with long tibial stem and bone graft
GW-7	Left	Fragmented, subluxated medial bearing, metallosis	Tibial revision with rotating platform
RH-8	Right	Marked anterior and posterior instability, tibial component medially displaced and malrotated	Tibial revision with rotating platform, patella poly exchange
MG-9	Left	Marked instability, osteolysis, fibrous ingrown tibia, metallosis	Posterior stabilized revision
JS-10	Right	N/A	0
HD-11	Right	N/A	0
HD-12	Left	N/A	0
JJ-13	Right	N/A	0
JH-14	Right	Fragmented, dislocated medial bearing	Tibial revision to rotating platform
GJ-15	Left	N/A	0
CF-16	Right	N/A	0
CF-17	Left	N/A	0
JW-18	Left	N/A	0
ET-19	Right	N/A	0
ET-20	Left	N/A	0
JL-21	Right	Severe coronal plane instability, patellar instability, marked malrotation of femoral component	Varus valgus constrained implant with stems
PE-22	Left	N/A	0
LC-23	Right	N/A	0
WD-24	Left	N/A	0
WD-25	Right	N/A	0

Note: N/A = no revision performed.

implant was made more conforming at the tibiofemoral articulation thereby decreasing contact stresses. Motion at the polyethylene-tibial component interface was designed to avoid the compromise in the knee range of motion expected with increased articular conformity with fixed bearing designs [1,2]. In theory, this design would provide an ideal biomechanical situation—decreased polyethylene wear from increased articular conformity while improving the knee range of motion with the additional articulation at the tibial-polyethylene interface. Additionally, proponents of this design have indicated that it has a more forgiving surgical technique, citing its "self-aligning" characteristics in the axial plane.

These advantages are theoretical, however. There are several clinical series of mobile bearing knee designs in the literature that indicate that intermediate and relatively long-term results are comparable to standard fixed-bearing designs [1,2,5–11] Thus far, however, there have not been any clinical studies that indicate that mobile bearing designs are superior in longevity or motion when compared to well-functioning fixed-bearing knees. Some authors have indicated that there are relatively unique complications and manifestations of typical TKA problems that may compromise the outcome with mobile bearing knees. Among the manifestations of instability are bearing breakage, subluxation, and dislocation [1,3–5,12]. In evaluating the clinical significance of this problem, the timing, incidence, natural history, response to treatment, and the eventual treatment necessary are critical.

Instability may occur at any time, however, when it leads to early failure it can be devastating to the patient and for the surgeon. Reasons for instability at any time may include periprosthetic fracture and extensor mechanism disruption. Other causes of instability may include posterior cruciate ligament (PCL) rupture or attenuation in PCL retaining implants [13–15] or post fracture in posterior stabilized implants [16]. The most likely common cause, however, is flexion-extension gap mismatch leading to mid-flexion instability [17,18]. The severity of this mismatch and the design of the implant determines the timing and presentation of this problem. Additionally, with this type of mobile-bearing implant, the surgical technique requires that balancing be performed prior to preparing the femur as the femoral cuts are judged from the initial tibial cut. If the balancing is inadequately done, the femoral component can easily be placed in excessive rotation. This leads to increased laxity in flexion of one side relative to another with adequate stability in extension. This is a scenario that may be tolerated with fixed-bearing designs but, if severe enough, leads to bearing and platform dislocation in mobile bearing knees.

In this series, which is the largest known from a single institution, we report twenty-five cases of symptomatic instability in mobile-bearing TKAs. All twenty-five cases had clinical instability and pain. Seven cases also had radiographic evidence of a dislocated or dislodged bearings. Additionally, four menisical bearings were found to be fragmented at the time of revision surgery. Nineteen cases became symptomatic within six months of the index procedure. Four additional cases were symptomatic within two years. Only two cases presented at midterm follow-up—54 months in one and 92 months in the other. Therefore, 92 % presented in the early post-operative period.

We have, then, found two patterns of symptomatic instability with mobile-bearing knees. The one leading to early instability is likely a more severe balance problem from the time of the index procedure. Flexion-extension gap matching, avoiding joint line elevation, appears to be critical with this type of implant. Any gap mismatch or trapezoidal shaped gaps may lead to "spit-out" of bearings or "spin-out" of platforms. A second pattern with less severe mismatches or joint line elevation may simply produce pain and intermittent effusions. Eventually, this more subtle instability may lead to failure of the polyethylene articulation. This may present as severe wear, gradually worsening instability, and in its more obvious form, bearing breakage or late dislocation.

There is relatively little in the literature discussing clinical patterns of instability in TKA. This is particularly true with fixed-bearing designs in early follow-up. It is unknown whether this represents a failure of clinical recognition in various studies or a genuinely low incidence. There are cases of early instability presenting as post fracture in posterior stabilized [14] or posterior cruciate ligament (PCL) rupture in PCL retaining knees [15]. It appears, however, that fixed bearing knees most often present with mid-term to late signs of instability as a consequence of polyethylene wear or fracture [13]. This would be analogous to the second pattern of instability in the mobile bearing TKAs indicating more subtle instability. Whether fixed-bearing knees are technically easier to balance or more "forgiving" of imbalance in the short-term is a matter of conjecture.

As previously mentioned, the current study is comprised of patients that had their index surgery elsewhere. Consequently, preoperative information such as axial alignment, presence of instability, and functional level were unavailable. Additionally, comments on the incidence of symptomatic instability based on this series are not possible. The literature does report on bearing breakage along with bearing and platform dislocation. However, instability without radiographic or clinical dislocation or subluxation is rarely mentioned. The timing of symptoms is also noted however, there is significant variability among the reports.

Buechel and Pappas [12] reported two rotating platform dislocations in a series of 108 mobile bearing TKAs. Both occurred within five months of the index procedure. In their ten-year evaluation of meniscal bearings [1], these same authors indicated that the rotating platform is more susceptible to this complication with a 1.2 % incidence compared to a 0.6 % rate with menisical elements. Bert [4] reported an incidence of 9.3 % (4 of 43) of subluxating or dislocating menisical elements. Three occurred postoperatively within thirteen days and one within six months. All four required revision. Sanchez-Sotelo et al., in their series [3], had two menisical bearing dislocations occur relatively late—four and six years, post-operatively. Jordan et al. [5] had 12 of 473 menisical bearing TKAs experience polyethylene fracture or dislocation. Additionally, five in the series had tibial subluxation secondary to instability occur an average of 21 months, post-operatively.

Thirteen procedures had been performed in this series prior to presentation to our institution. Essentially, none addressed the underlying issue of instability. Subsequently, nine cases were revised by the authors with a variety of revision techniques to specifically address stability. Although revision surgery was

recommended to the other patients, they declined further intervention as of the latest follow-up evaluation. Of note, two cases had, as a significant factor in failure, rotational malalignment of the components. This raises the question about whether the technique is truly more forgiving of rotational malalignment with its "self-aligning" nature. Of the nine cases, four were tibial component revisions, three for malrotation of the tibial component associated with instability, and one for malalignment of the tibial component and instability. However, the remaining five required more complex revision to more constrained prostheses. It is encouraging that with appropriate revision surgery the HSS knee scores improved from a mean of 51 (range, 36–66) to a mean of 85 (range, 74–95).

Despite the evolution in the surgical technique, implant design, and manufacturing methods, instability is becoming an increasingly recognized source of failure in TKA. To our knowledge, this is the largest series of mobile bearing TKAs with clinical instability. This problem is potentially an issue in all designs. The relative incidence, pattern of presentation, and response to treatment may be variable, however. The current series demonstrates a pattern of failure secondary to instability, specifically with mobile-bearing knees. As the use of mobile bearing knees is gaining popularity, it is important to recognize and study this problem in accessing the relative advantages and disadvantages of this type of implant relative to other implants. It may be that achieving satisfactory balance is more critical or difficult to achieve with mobile bearing implants than with other designs.

In summary, we found that with mobile bearing TKAs, instability may present as one of two clinical presentations: painful coronal plane instability accompanied by painful effusions or frank subluxation, dislocation, or fracture of the polyethylene bearing elements. Most commonly, the instability presents within the early post-operative period. Diagnosis of the more subtle forms of instability may be difficult, leading to surgical treatment that does not address the underlying problem. Operative treatment requires a complete repertoire of surgical techniques ranging from simple tibial revision to complete revision with more constraining components.

We recommend continued careful evaluation of all TKA designs for implant-specific issues involving stability. An effort should be made to identify specific surgical technique and patient selection issues. Any potential long-term benefit of design innovations must be balanced with known problems leading to early failure.

Acknowledgments

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Utilizing Validated Computational Models to Predict Tibial Insert Abrasion in Mobile Bearing Knees: A Design Performance Standard

ABSTRACT: Validated computational models that successfully predict clinically observed outcomes, such as damage occurring in the polymer insert component of a Mobile Bearing Knee (MBK) replacement design, are powerful predictive tools. This paper demonstrates the long term use of a validated computational model that uses the finite element method to visualize the magnitude and location of stresses on the polymer insert associated with abrasive wear damage that occurs in vivo. The use of component geometries generated from three-dimensional laser scans of sterilized, implantable quality components allows detection of poor fit between manufactured component articulations, which is key to successful prediction of observed clinical wear patterns in tibial inserts. The robustness of the model is demonstrated by its ability to predict expected and unexpected wear simulator and clinical retrieval outcomes for a wide variety of MBK designs. It can then be used with some confidence to determine the effect that new, innovative component design changes will have on polymer damage. Validated computational models provide rapid evaluations of anticipated design and material performance at a lower cost than other methods, with results that are predictive of clinical outcomes and allow direct comparison between devices. These methods should be accepted as an a priori evaluative tool by standards and regulatory bodies.

KEYWORDS: mobile bearing knee, finite element, stress, abrasive wear

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Introduction

ASTM benchtop testing standards must be sufficient to differentiate safe and effective performance across mobile bearing knee (MBK) devices. At their best, they should be predictive of clinical outcomes. A laboratory testing method that has been successfully used to that end over the last 16 years with commercially available finite element (FE) software is described. The FE model applies the loading environments that occur in the knee during activities of daily living to reverse engineered component geometries. The use of component geometries generated from three-dimensional laser scans of sterilized implantable quality components allows detection of poor fit between manufactured component articulations, and is the key to successful prediction of clinical wear patterns in tibial inserts.

Background

Primary to the longevity of total joint replacement is the long-term efficacy of the joint bearing surface. In contemporary knee designs, this is directly related to the durability of the Ultra-High Molecular Weight Polyethylene (UHMWPE) tibial insert component. Sharkey et al. [1] found that UHMWPE wear was the primary reason for 25 % of revision total knee arthroplasty (TKA) surgeries. UHMWPE components contribute to the failure of joint arthroplasty through component creep, debris generation, "wear through," delamination, and fracture [2,3]. UHMWPE debris has been linked to a biological response leading to osteolysis, loosening, and pain [4–6].

Many researchers [7–9] have associated accumulated damage observed in UHMWPE to specific states of cyclic stress that arise when a femoral component articulates with a tibial insert. Abrasive wear is related to the magnitude and distribution of compressive normal (contact) stresses on the surface of the tibial insert and relative tangential velocities between components. This relationship implies that an understanding of the contact stress distributions, coupled with component motions that arise during tibiofemoral articulations, can lead to predictions of clinical wear patterns observed during component retrieval analysis. FE models that employ a general contact method between the femoral and tibial insert components allow the determination of these stress patterns.

Methods

The FE method is used widely in computational mechanics to determine the location and magnitudes of stress in product components of arbitrary geometrical shape given a known loading environment of applied forces and torques. A computation finite element model of a MBK allows a bridge to be constructed between the loading environment of the knee and the stresses associated with polymer insert damage.

Material science can predict the mechanical response of a material with a very simple geometry, such as a cube, with a single equation when a load is applied. If a cube of stainless steel resting on a table has a force applied equally

across its topmost face, the decrease in height and increase in width can be readily calculated. The FE method allows the mechanical response of a material with a complex geometry such as a tibial insert to be calculated by breaking the shape down into a large number of finite elements of a simpler shape, such as a cube. The same simple equation can be used for each finite element, but the response of one element affects all of the elements around it. A large number of equations arise that are mathematically coupled to their neighbors' equations and the use of a powerful computer is needed to determine the overall response of the complex geometry.

Advanced finite element application software is needed to successfully model the articulations of a MBK design. It must capture the nonlinear material response of the three-dimensional polymer insert material. Further, the software should be able to handle contact of the femoral component in a general manner, allowing femoral component sliding and rolling to occur. Hexahedral (brick element) meshing development tools are needed to accurately capture the mathematical nonlinearities that can occur during MBK articulations. A repeatable method of building a three-dimensional FE model (Fig. 1) for several contemporary MBK designs was developed using commercially available

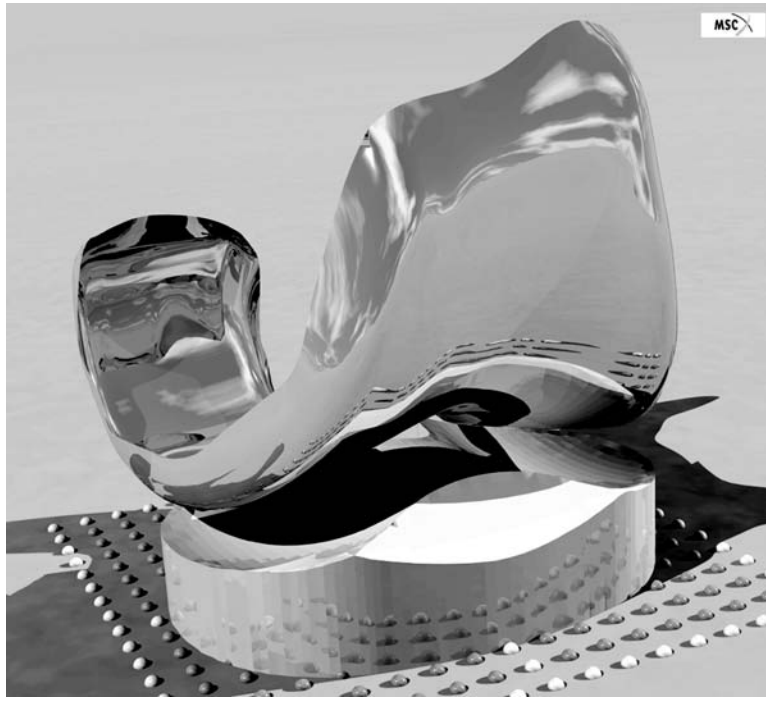

FIG. 1—*Typical finite element model used for testing mobile bearing total knee arthroplasty designs. The polymer tibial insert is free to slide and rotate on a bed of frictionless spring loaded elements to achieve an optimal component alignment with balanced loads applied in the medial and lateral compartments.*

software. FE models were developed and results displayed using MENTAT (MSC Software, USA) preprocessor and postprocessor software. The resulting set of nonlinear equations was solved using MARC nonlinear solver software (MSC Software, USA).

The finite element models developed in this study used measurements of actual component surfaces to define the geometry of the articulating surfaces. This method was preferred over working with computer aided design (CAD) files due to observed differences between the designed CAD geometry and the final implantable quality product that can affect articulation significantly. These measurements guaranteed an independent, reliable, and accurate method for describing system component geometries for subsequent modeling.

Femoral and tibial insert components were measured using a Hawk 544 non-contact, floating head, point laser digitizing system (Nextec LTD, Israel) that demonstrates a volumetric accuracy of 7 microns and repeatability of 2 microns at 1 sigma. The components were very lightly sprayed (4 micron thickness) with developer to attenuate reflectivity in the femoral component and translucency in the tibial insert. A point of laser light was projected onto the component along the medial edge and XYZ coordinates were gathered every 0.1 mm in the Y direction. The laser then shifted 0.5 mm in the X direction and gathered data along a line parallel to the first. In this manner a "cloud of points" data set was created that represented the articulating surface (Fig. 2).

This data set was imported into SURFACER (ImageWare, USA) a surface CAD software package. A non-uniform rational B-spline (NURB) surface was initially fit through every data point, creating a highly constrained surface. This surface was numerically relaxed until it represented 98 % of the articulating surface data within plus or minus 15 microns (Fig. 3). The relaxed surface accurately

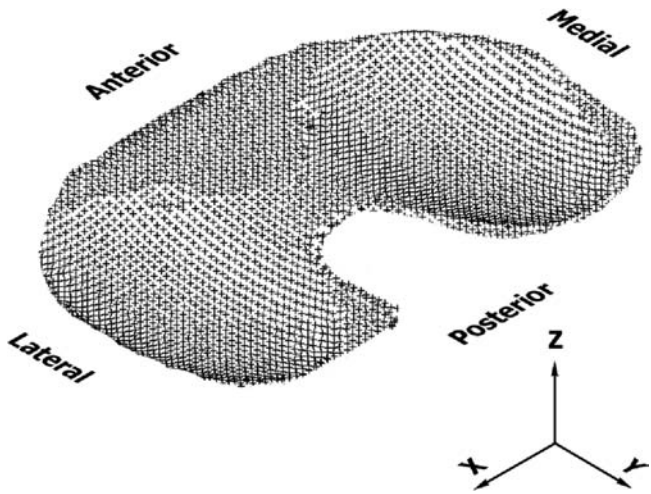

FIG. 2—*A typical "cloud of points" measurement data set that is used in building a finite element model that represents actual manufactured component geometries.*

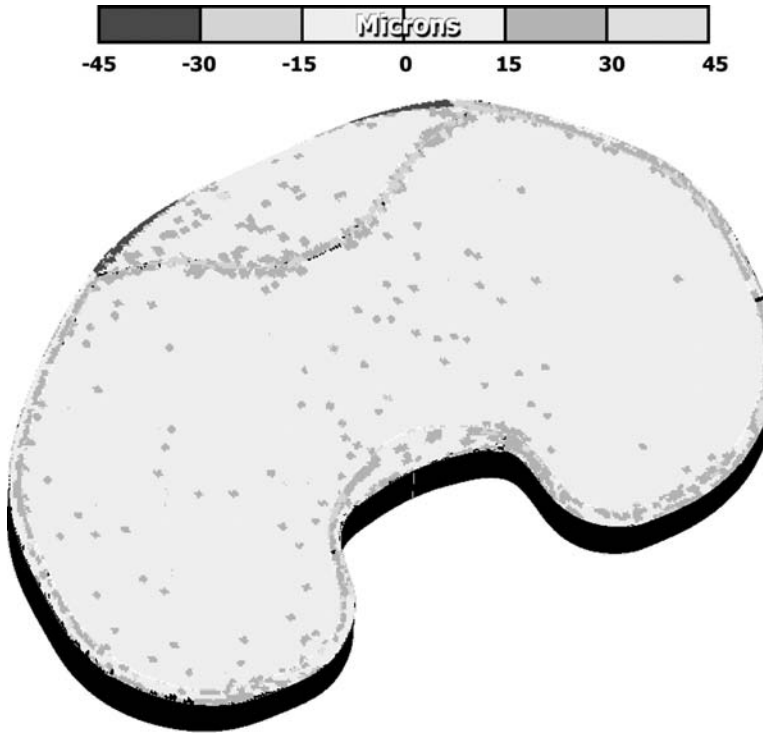

FIG. 3—*Comparison of typical measurement data and relaxed surface. Gray areas indicate data is within ±15 microns of the relaxed surface.*

represented the articulating surface with considerably less surface control point data, significantly reducing solution time.

The NURB representing the proximal articulating surface of the tibial insert was imported into a finite element preprocessor. An earlier parametric convergence study indicated that elements with 1.4 mm edge lengths accurately captured contact stress within 1 % error of its asymptotic value. Thus, a mesh of quadrilateral elements with an average edge length of 1.4 mm was projected onto the surface such that the nodes at their vertices rested on the NURB surface. Manual adjustments were made to the location of nodes near sharp geometry transitions to ensure that these important features would be modeled accurately. These quadrilateral elements were then expanded distally into four layers of hexahedral (brick) elements of increasing thickness; 0.67 mm for the articulating surface layer, 1.33 mm, 2.67 mm, and 5.33 mm for the subsequent layers. The thickest and most distal layer had its back surface flattened in the transverse plane, creating a finished hexahedral mesh of the tibial insert with a minimum polymer thickness of 10 mm. To satisfy the requirements of the general contact algorithm and nonlinear material model, the FE model employed full integration (8 gaussian points plus a 9th hydrostatic pressure point), with first-order, isoparametric, hexahedral elements.

The mechanical response of UHMWPE is overall viscoelastic in nature; it exhibits creep behavior [10] and rapid stress relaxation [11] in compression at 37°C. However, it has been observed in our laboratory that the mechanical response of a typical total knee device to loading is nonlinear and repeatable after the tenth loading cycle, because the short term time dependent effects of UHMWPE have dissipated to an equilibrium point. This suggests that after an initial preconditioning, the response of UHMWPE to a ramp loading can be modeled in an elastic nonlinear manner. Figure 4 illustrates the preconditioned, uniaxial, compressive, experimental data gathered by Waldman and Bryant [11] on gamma sterilized, UHMWPE samples at 37°C loaded at a rate of 90 % strain per second, simulating the impulse of heel strike loading.

This data set was used to develop a nonlinear elastic Ogden formulation [12] to describe the nonlinear mechanical loading response of the UHMWPE material of the tibial insert. The Ogden formulation uses a strain energy based formulation that improves stress calculation accuracy by considering the polymer's bulk modulus and nearly incompressible properties.

A FE model of Waldman and Bryant's experimental setup and test samples was created using the derived Ogden material model. The resulting material response curve (the solid yellow line in Fig. 4) compares favorably to the original data set, suggesting that the material model was accurate at predicting compressive loading of UHMWPE.

The NURB representing the articulating surface of the femoral component was also imported into the preprocessor as a basis for creating a rigid body to articulate against the hexahedral mesh of the tibial insert. The goal was to define the femoral articulating surface as a NURB in the finite element model, not to create a mesh of that surface. A NURB surface offers a single, continuous mathematical description of the complex femoral curvatures. This allows a continuously defined surface normal to be established, which increases efficiency and accuracy of the finite element contact algorithm. No meshing was required

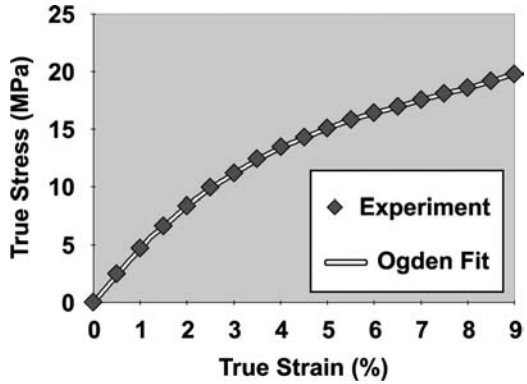

FIG. 4—*Compressive response of a finite element model using an Ogden material formulation compares favorably to compressive UHMWPE experimental data.*

of the femoral NURB, thus reducing the finite element model's df, file size, and time to converge on a solution.

Simulations of the most highly loaded positions during activities of daily living (ADL) such as walking gait, chair rise, stair ascent, and kneel rise were conducted. The maximum loading environment of the knee for a variety of these activities was determined through a summary of the literature. Maximum joint loads [13–15] and the angle of knee flexion that they occur at [16–18] were determined for three highly loaded positions of the stance phase of level walking gait: heel strike, mid stance, and toe off. Additionally, three high flexion activities; stair ascent [13,19–21] (60°), rising from a chair [22] (90°), and rising from a double leg kneel [21,23,24] (135°) were determined. A body weight of 71 kg [25] was used to determine the applied forces for the six loading environments; their averaged values are summarized in Table 1.

The hexahedral mesh of the tibial insert was combined with the femoral NURB surface that was rotated to the appropriate flexion angle for each activity load case. The corresponding normal and shear joint forces were applied, bringing the femoral surface and tibial insert mesh together for a complete stress analysis.

To ensure that an appropriate neutral position was achieved by each design, the FE model allowed the virtual components to "settle" together into their optimal alignment. The tibial tray was modeled as an infinitely rigid, frictionless, flat surface extending beyond the edges of the insert. The tibial insert was free to slide and rotate in the transverse plane of the tray, without friction, as contact developed between the femoral, tibial insert, and tibial tray components. Additional constraints were applied to the distal surface of the tibial insert mesh to simulate the mobile bearing mechanism particular to each design studied. Further, the tray behaved as if it rested on a uniform bed of stiff springs, allowing varus/valgus load balancing to occur. The resulting stress distributions on and within the polymer insert were then photorealistically imaged allowing visual comparison of the different implant designs.

Model validation was achieved by a variety of methods, the details of which have been previously published [26,27]. In summary, pressure sensitive paper film (Fuji Film) was interposed between less conforming tibial femoral

TABLE 1—*Maximum joint loads and the knee flexion angle at which they occur for a variety of activities of daily living.*

Activity	Flexion Angle (degrees)	Compressive Force (N)	Shear Force (N) Applied to Femoral Component
Walking gait (heel strike)	0	1950	not applied
Walking gait (mid stance)	20	1560	not applied
Walking gait (toe off)	15	2340	not applied
Chair rise	90	2570	780 anteriorly
Stair ascent	60	3050	140 posteriorly
Kneel rise	135	3510	280 anteriorly

articulations under the same loading conditions used in the FE model to provide an experimental measure of contact area and stress for comparison. Further, laboratory wear simulations of a mobile bearing knee design provide evidence of unexpected abrasive wear locations during high cycle activities like level walking gait, which compare favorably to unexpected FE model results of the same design. Polymer damage analysis of multiple clinical retrievals of a tibial insert design yield visual maps of unexpected observed surface abrasive wear scars, which also compare favorably to the FE model predictions. In all cases, creating the FE model from reverse engineered component geometries was critical topredicting results that closely matched expected and unexpected results of clinical or preclinical benchtop tests.

Results

The proximal contact area and contact stress results for the tibial insert component presented in this paper are selected from a large collection of searchable, publicly available mobile bearing total knee arthroplasty results available at the authors' website [28]. They represent the extremes of knee flexion, from full extension to deep flexion, and run the gamut from poorly fitting tibiofemoral articulations to hyper conforming proximal articulating surfaces. The results presented serve as a bounding box of extreme results, with the balance of our experience within the range available online. Additional flexion angles and photorealistic images of contact and other stresses associated with polymer damage for a variety of activities of daily living are available for review.

Tabulated results are presented below for the heel strike portion of level walking gait (Table 2) and the high flexion activity of kneel rise (Table 3). The photorealistic images of proximal contact stress distributions (Figs. 5 and 6) are anecdotal selections from the tabulated results to illustrate the range of outcomes for a given activity, depending on the manufactured tibiofemoral articulation conformity and design.

Discussion

The FE protocol focuses on the effect of articulating geometry on stresses that are associated with long-term wear response of the tibial insert. Design features known to affect stress magnitudes and distributions, inclusive of polymer thickness and different polymer formulation material response, were modeled for each design in the same manner. By holding these aspects of all designs constant, direct comparison of results of new, innovative designs with classic, clinically successful designs is possible.

UHMWPE wear is a function of polymer stress and the kinematics of articulation. While the model results presented in this paper convey detailed maps of contact stress associated with clinically observed damage, it is only for a snapshot of the most highly loaded position during the modeled activity. The kinematics of component articulation during cyclical activities such as walking gait and stair climb will propel the visualized stress patterns about the tibial insert

TABLE 2—*Proximal contact area and contact stress for a variety of mobile bearing total knee arthroplasty designs during the heel strike portion of level walking gait (1950 newtons of compressive force applied at a knee flexion angle of zero degrees, i.e., full extension).*

Product Name	Manufacturer of Record	Date of Manufacture (year)	Proximal Heel Strike Contact Area (mm^2)	Proximal Heel Strike Contact Peak Stress (MPa)
LCS A/P Glide	DePuy	1996	909	8.8
LCS Rotating Platform	DePuy	1996	902	10.4
SAL	Sulzer	1997	551	13.5
Interax	Howmedica	1997	553	10.9
MBK*	Zimmer	1997	530	25.7 (largest)
LCS PS Rotating Platform	DePuy	1998	1169 (largest)	10.7
Profix MBK	Smith + Nephew	1998	507	13.9
T.A.C.K.*	Link	1998	520	20.4
TRAC	Biomet	1998	469	16.8
MBK	Zimmer	1998	429	11.4
Rotaglide+*	Corin Medical	1999	301 (smallest)	23.2
PFC Sigma Rotating Platform Curved	DePuy	2001	381	14.1
PFC Sigma Rotating Platform Stabilized	DePuy	2001	326	16.0
Innex Ucor	Sulzer Medica	2001	551	10.8
e.motion	Aesculap	2003	666	8.5 (smallest)
Dual Bearing Knee	Finsbury	2003	595	15.0
Gemini MK II*	Link	2003	327	16.0

*Indicates design exhibits poor fit during heel strike.

TABLE 3—*Proximal contact area and contact stress for a variety of mobile bearing total knee arthroplasty designs during kneel rise (3510 newtons of compressive force, 280 newtons of anteriorly directed force applied to the femoral component at a knee flexion angle of 135 degrees).*

Product Name	Manufacturer of Record	Date of Manufacture (year)	Proximal Kneel Rise Contact Area (mm^2)	Proximal Kneel Rise Contact Peak Stress (MPa)
e.motion	Aesculap	2003	345 (largest)	21.9 (smallest)
Dual Bearing Knee	Finsbury	2003	292	32.4
PFC Sigma Rotating Platform Flexion	DePuy	2004	287 (smallest)	39.8 (largest)

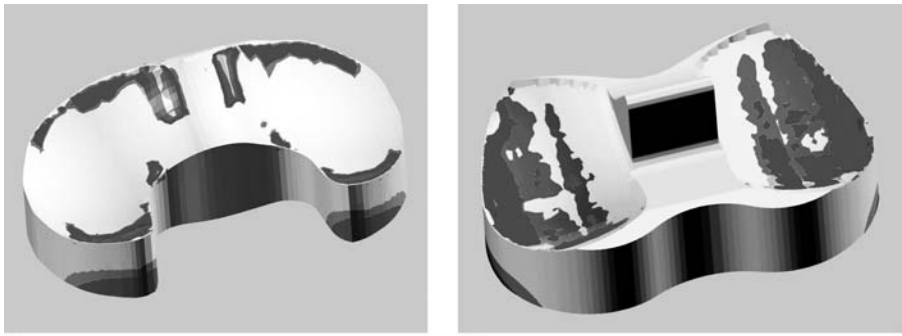

FIG. 5—*(a) Heel strike of walking gait, T.A.C.K. with a contact area of 520 mm² and peak contact stress of 20.4 MPa. This is an example of poor tibiofemoral fit leading to the unusual case of displaying both high contact area and high contact stresses. (b) Heel strike of walking gait; LCS PS rotating platform with a contact area of 1169 mm² and peak contact stress of 10.7 MPa. At full extension, this hyper-conforming design has the highest contact area measured with corresponding low contact stresses.*

and they will change in shape and intensity. Phenomena such as rollback, internal/external rotation and anterior/posterior sliding were not captured in these models because of the "settling" methods used to position the femoral and tibial components together in a repeatable and consistent manner for all designs.

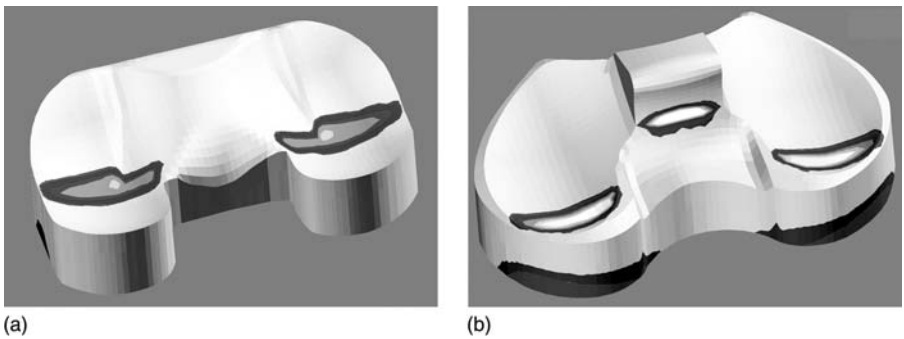

FIG. 6—*(a) Kneel rise, e.motion with a contact area of 345 mm² and peak contact stress of 21.9 MPa. This design promotes contact in the central portion of the tibial insert, which has the benefit of lower contact stress during this demanding high flexion, high load, activity of daily living. However, the central contact location may reduce the amount of flexion possible before femoral posterior bony impingement occurs. (b) Kneel rise, PFC Sigma RPF with a contact area of 287 mm² and peak contact stress of 39.8 MPa. This design promotes high flexion contact in the posterior portion of the tibial insert with a tibial insert post and femoral component cam mechanism that promotes higher flexion, but at the expense of high stresses near the edge of the insert.*

The results represent best-case scenarios, due to nominal loads being applied to optimally aligned components. The effect of soft tissues is not considered in this model; only the intrinsic, articulating surface curvatures of the components guide their optimal alignment. The results also serve as a detailed spot check of manufacturing processes, because models were built from measurements of actual manufactured components and not perfect geometries contained in CAD files.

Mobile bearing implant designs allow motion between both the femoral and tibial tray components and the polymer insert in an effort to distribute the kinematic requirements of knee joint function between the proximal and distal surfaces of the tibial insert. This allows more conforming geometries between the components to be used in mobile bearing designs. In theory, higher conformity allows the reduction of damaging polymer stresses and should improve component longevity.

However, in practice, achieving the desired hyper-conformity through precision manufacture can be a difficult proposition, as evidenced by the fact that one in four mobile bearing designs presented in this paper demonstrated poorly fitting components that lead to damaging polymer stress levels [29–31]. The fit of hyper-conforming design components is much less forgiving of small variations in dimension than a less conforming design. The effort of using component geometries generated from three-dimensional laser scans of sterilized implantable quality components allowed poor fit to be detected by the FE model.

Large contact area (conformity) is often a major design goal because it is assumed that increasing contact area always leads to lower stresses that in turn lead to less abrasive wear of the tibial insert. Basic pin on disk material science studies of UHMWPE support this concept [8,9]. However, recent tribological counter evidence has become available [32–34] suggesting that larger contact areas provide more opportunities for abrasive and adhesive wear to occur, and are associated with increases in the volume of wear debris generated. In aggregate, these apparently conflicting studies suggest that a happy medium between low conformity/high stress designs and hyper conformity/high wear debris articulations may lead to a moderately conforming design that is more readily manufactured. Such designs, between approximately 300 and 500 mm^2 of contact area during heel strike loading, may achieve the goal of minimizing the generation of abrasive wear debris in the joint space while improving the chances of good component fit.

The magnitude of contact stresses and the manner in which they are distributed across the articulating surface of the tibial insert influences polymer damage. The general concept that a given loading force distributed across a larger contact area will have a lower contact stress holds true for most tibiofemoral articulations. A counter example where high contact area does not yield low stresses can be visualized in Fig. 5(*a*). It depicts a poorly fitting heel strike articulation that presents with both high contact areas, distributed in a ring around the edge of each compartment of the tibial insert, and high stresses where a pinching effect is occurring in the eminence between compartments. Figure 5(*b*) depicts a successfully manufactured, hyper-conforming design with the largest contact area measured with this method. It also presents with low contact stress, supporting the general concept that large contact areas yield low contact stress.

The component geometries of each design studied define their respective conformity and intrinsic constraint. The cruciate retaining design of the e.motion depicted in Fig. 6(*a*) promotes contact in the central portion of the tibial insert, which has the benefit of lowering contact stress during this demanding high flexion, high load, ADL. However, the central contact location may reduce the amount of flexion possible before femoral posterior bony impingement occurs.

In contrast, the PFC Sigma RPF design in Fig. 6(*b*) features additional constraint through a tibial insert polymer spine/femoral cam interaction. This feature constrains contact to the central and posterior portions of each compartment during high flexion activities. The PFC Sigma RPF geometries promote wedging of the femoral component between the polymer spine and posterior sloped surfaces of the compartments during kneel rise loadings, creating large contact stress values. Further, the posterior stabilized design promotes contact near the posterior edge of the insert to increase the opportunity for patients to achieve high flexion. However, this is at the expense of high stresses being located near the posterior edge, where permanent deformation (cold flow) of the tibial insert can more easily occur.

Conclusions

The validated finite element computational method described has been used over the past 16 years to evaluate a wide range of total knee arthroplasty designs. It has proven useful in the manufacturer's design stage to vet product concepts computationally prior to the time and expense required for physical laboratory wear testing and clinical trials. It may also prove to be a valuable tool for extending the clinician's vision by determining a priori the expected stress performance of new implant designs.

This long term use of this method has created a large compendium of directly comparable performance results for a variety of classic and contemporary designs of which only a subset is presented in thispaper. A searchable database of additional results using this methodology is available at the authors' website [28].

The mobile bearing results in this paper illustrate that a wide range of well manufactured conformities can lead to a successful outcome. Highly conforming mobile bearing designs with more than three times the contact area of a fixed design demonstrate only a marginal improvement in stress performance, and are more difficult to successfully manufacture. Coupled with evidence that good component fit is often not achieved in the manufacture of highly conforming designs, and that large contact areas may be associated with an increase in the volume of wear debris generated, a case can be made for a happy medium when designing component conformity.

Validated computational models provide rapid evaluations of anticipated design and material performance at a lower cost than other methods, with results that are predictive of clinical outcomes and allow direct comparison between devices. These methods should be accepted as an a priori evaluative tool by standards and regulatory bodies.

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Mobility and Contact Mechanics of a Rotating Platform Total Knee Replacement

ABSTRACT: Despite their increasing clinical usage, mobile-bearing total knee replacements have not been well characterized biomechanically. An experimental and finite element analysis was done to asses the mobility and contact mechanics of a widely used rotating platform total knee replacement. Parameters that varied were axial load, condylar load allocation, flexion angle, and static versus dynamic loading. Similar results from the physical model and finite element model lend credence to the validity of the findings. The torque required to initiate rotation (static torque) was greater than that to sustain rotation (dynamic torque). At four times body weight axial load, peak resisting torque measured was 9.47 ± 0.61 and 5.51 ± 0.38 N-m, for static and dynamic torque, respectively. A 60–40 condylar load allocation produced slightly less resisting torque than the 50-50 load. For all practical purposes, the polyethylene insert rotated simultaneously with the femoral component, leading to maintenance of high contact area, desirable behavior clinically. Walking cycle simulations produced a total axial rotation range of motion of 6°. The high frictional torques observed at the mobile interface may explain why a percentage of these mobile-bearings fail to rotate under routine functional load.

KEYWORDS: mobile-bearing, rotating platform, total knee, finite element, mechanics

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Introduction

Mobile-bearing total knee replacements are increasing in popularity because they potentially avoid the conformity and constraint tradeoff of fixed-bearing designs. Their highly conforming geometry theoretically decreases contact stresses, helping to reduce fatigue and delamination wear. In addition, the mobility of the polyethylene insert theoretically reduces constraint, which may help prevent loosening at the bone-cement interface. Intermediate-term clinical performance of mobile-bearing knee replacements has been encouraging [1–6]. In addition to the emerging concern about backside wear, another issue is that recent fluoroscopic data suggest that bearing motion actually may not occur in a substantial fraction of patients [7]. Frictional defeat of bearing motion implies alteration of the intended articulation kinetics, perhaps with adverse consequences in terms of accelerated wear, loosening, or both.

The natural knee accommodates complex rolling, sliding, and rotational motions. Many studies have investigated these three-dimensional kinematics, using techniques such as electrogoniometry, [8] or cine film or video, coupled with reflective markers on the skin surface [9] or attached to the bone through intracortical pins [10]. During normal level walking, the total range of flexion reported has varied from 57° [9] to 71° [11]. Total axial rotation has ranged from 9.4° [10] to 16° [9]. The medial condyle is loaded more than the lateral condyle, at a ratio in the range of approximately 6:4 to 7:3 [12]. Kinetics have been less well documented, because internal forces cannot be measured directly, and because the mathematics for indirect force models are complex. Many simplifications and assumptions must be made, such as regarding joint geometry and location of joint centers. During normal gait, estimates of peak joint forces have ranged between 4 times [12] and 7.1 times [13] body weight. Peak axial torque has been reported at 10 N-m and 7 to 17 N-m [12,14] in healthy subjects, and 6 to 8 N-m for a patient fitted with an instrumented total knee prosthesis [15]. Peak anteroposterior (AP) shear forces have been reported to be just greater than 2 times body weight [13]. Peak mediolateral shear forces have ranged from 0.26 times body weight [12] to approximately 1 times body weight [13].

Total knee replacements must accommodate these motions and loads to be successful. Fixed-bearing total knee replacements generally have achieved these complex motions at the expense of incongruent contact. Small contact areas, coupled with high joint loads (even in normal gait), often result in fatigue and delamination type wear of the polyethylene, [16,17] and ultimate failure. In more conforming designs, increased constraint carries enhanced tendency for backside wear with modular tibial trays, and loosening at the implant-bone interface.

Understanding the conditions under which component motion does or does not occur seemingly is important to the success of mobile-bearing and modular fixed-bearing total knee replacements. The purpose of the current study was to investigate the mobility of a widely used rotating platform mobile-bearing total knee replacement, under parametrically controlled loading conditions. The authors have attempted to answer the following questions: (1) Can a valid finite element model be developed to adequately characterize the contact stress and motion patterns in the multiple surface construct of a mobile-bearing knee

replacement?; (2) Can an experimental model be developed to evaluate the validity of the finite element model?; and (3) If so, what are the contact stress and motion patterns at the various bearing surfaces of a rotating platform total knee replacement?

Materials and Methods

The mobility of a widely used (posterior cruciate-sacrificing) rotating platform total knee replacement (LCS Standard, DePuy, Inc, Warsaw, IN; femoral component: standard left; tibial tray: MBT, size 3; polyethylene insert: standard, 6 mm thickness) was investigated (Fig. 1). This device has two contact interfaces, one between the femoral component and the polyethylene insert (the bearing interface), and one between the tibial tray and the polyethylene insert (the mobile interface). The tibial tray has a beveled hole that accepts the mating stem of the polyethylene insert; thus providing the insert with rotational freedom about the superoinferior axis.

Experimental Analysis

The femoral and tibial tray components were potted in polymethyl methacrylate and secured to a custom made testing fixture (Fig. 2). The upper section of the

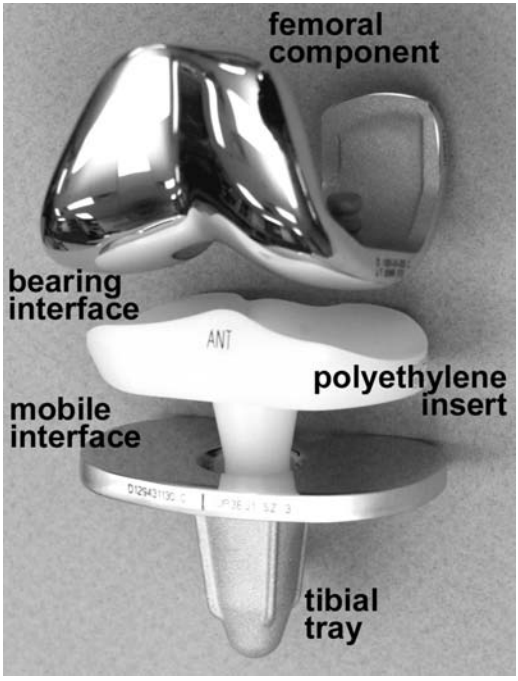

FIG. 1—*The DePuy LCS Standard (posterior cruciate-sacrificing) rotating platform total knee replacement is shown.*

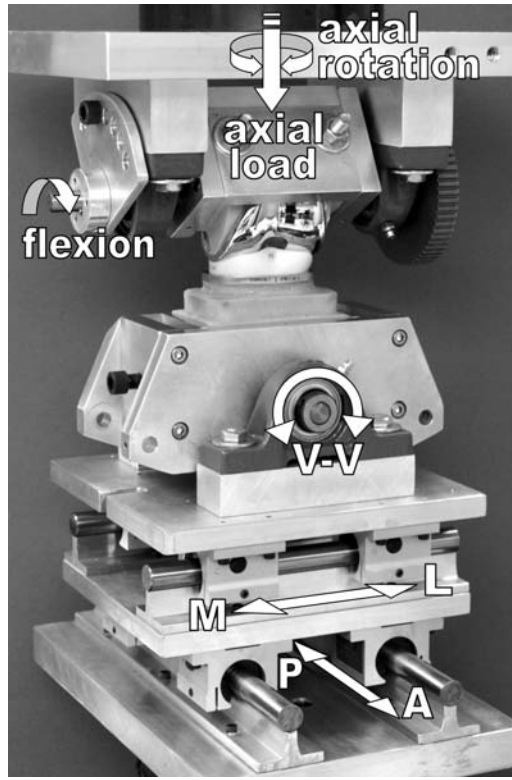

FIG. 2—*A custom made testing fixture is shown. The femoral component was attached to the actuator, and the tibial component was attached to the load cell. The arrows represent translational and rotational motions. M = medial; L = lateral; A = anterior; P = posterior; V-V = varus-valgus.*

fixture (housing the femoral component) was attached to the actuator of a servohydraulic materials testing machine (MTS Bionix, Minneapolis, MN), whereas the lower section (housing the tibial tray) was attached to the load cell. The AP slope of the tibial tray was 0°. To ensure unrestricted component alignment, the fixture had translational freedom in the AP and mediolateral directions (horizontal plane) via linear bearings, and varus-valgus rotational freedom via pillow blocks. This allowed the components to self-seat. In addition, the mediolateral center of the tibial tray could be repositioned from the varus-valgus axis to achieve unequal condyle load allocations.

The loadings delivered to the components were representative of those experienced in vivo during level walking. General loading conditions were comprised of axial loads of 1 to 4 times body weight (1 body weight = 686.5 N = 70 kg), axial rotations of 10°, and (fixed) flexion angles of 0° to 90°. In addition, all experiments were done with the components immersed in 10% fetal bovine serum (Life Technologies, Gaithersburg, MD).

Experiments were designed to investigate how friction between the components influenced the axial torque resisting motion. Parameters that varied were axial load, condylar load allocation, and flexion angle. All experiments were split into two different types of loading histories, termed static, and dynamic. These two loading histories were designed to determine the difference in torque required, respectively, to initiate versus to sustain rotational mobility of the polyethylene insert. Any resisting torque differences essentially would be attributable to the difference between static and dynamic friction.

For the static experiments, the MTS axial actuator applied a predetermined constant axial load to the components. While under torsional load control, the torsional actuator applied a linearly increasing internal torque to the femoral component. When the torque applied exceeded the torque developed by friction at the mobile interface, the polyethylene insert slipped abruptly, so as to rotate with the femoral component. Just before slip initiation, a peak (static) resisting torque was developed [Fig. 3(*A*)]. Once the actuator reached 10° of internal rotation, the axial load was removed and reapplied, and a (mirror) ramp of external torque was applied until a peak resisting torque was reached and the actuator reached 0° of rotation. This loading history constituted one trial. For each trial initiated with internal rotation (termed an endorotation sequence), a complementary trial was run that began with external rotation (termed an exorotation sequence).

During the dynamic experiments, the components were given a predetermined constant axial load, and with the torsional actuator in rotational displacement control, the femoral component was given a constant angular velocity, producing relatively steady levels of resisting torque. Starting from 0° of rotation, the femoral component was rotated internally to 10°, externally rotated to 10°, and then brought back to 0° [Fig. 3(*B*)]. This loading history constituted one trial. For each trial initiated with internal rotation (again termed an endorotation sequence), a complementary trial again was run that began with external rotation (again termed an exorotation sequence).

During femoral component axial rotation, the polyethylene insert remained fixed on the tibial tray until the rotating femoral component engaged with it and forced it to rotate. The corresponding lag was termed "insert rotation lag." During rotation, a load cell measured the torque required to overcome friction to produce this motion.

To detect the peak resisting torque (static) and compute the average resisting torque (dynamic) during these endorotation and exorotation sequences, and to determine insert rotation lag during the transition from internal to external rotation, custom PV-Wave (Visual Numerics, Inc, Houston, TX) computer programs were written to process the raw data files recorded by the MTS.

The physical testing study design (Table 1) involved three sets of experiments. Experiment Set 1 considered the effect of axial load on resisting torque. The rate of torque increase for all static experiment sets was 0.06 % P-meters per second, where P is axial load in Newtons. A constant angular velocity of 10° per second was used for all dynamic experiment sets. The components were loaded in full extension (0° flexion) with an equal condyle allocation, axial load was varied (1, 2, 3, 4 times body weight), and endorotation and exorotation sequences were done. The internal and external peak torques (static) were

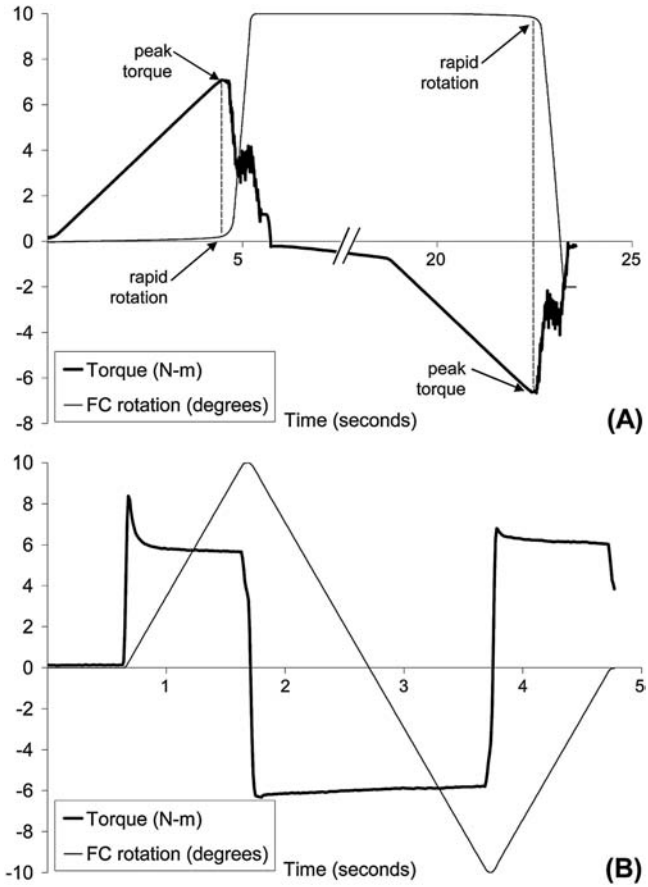

FIG. 3—*Typical resisting torque and femoral component (FC) rotation plots for static and dynamic experiments. (A) The static experiments developed a peak resisting torque, whereas (B) the dynamic experiments developed a relatively constant resisting torque.*

averaged, and the plateau segments of steady torques (dynamic) were averaged together, to obtain one characteristic torque value in each trial. With six trials for each loading variation (order randomized), the static and dynamic experiments involved 48 trials each.

TABLE 1—*Parameters varied during torque experiments.*

Set	Axial Load (Body Weight)	Load Allocation	Flexion Angle (Degrees)
1	1, 2, 3, 4	50-50	0
2	3	50-50	0
		60-40	
3	3	50-50	0, 15, 30, 45, 60, 90

Experiment set 2 addressed the effect of condylar load allocation on resisting torque. One allocation, termed 50-50, transferred the load equally through each condyle. The other allocation, termed 60-40, transferred 60% and 40% of the load through the medial and lateral condyles, respectively. The components were loaded to 3 times body weight in full extension, and endorotation and exorotation sequences were done. Static and dynamic torque values were obtained again as in Experiment set 1. With 6 trials for each loading variation (order randomized), the static and dynamic experiments required 24 trials each.

Experiment set 3 evaluated the effect of flexion angle on resisting torque, and on insert rotation lag during endorotation and exorotation sequences. In the static experiments, lag was measured as the change in femoral component rotation angle from ramp initiation to peak resisting torque. In the dynamic experiments, lag was measured as the change in femoral component rotation angle between regions of steady torque. The components were oriented in various flexion angles (0°, 15°, 30°, 45°, 60°, 90°), loaded to 3 times body weight with a 50-50 load allocation, and endorotation and exorotation sequences were done. With 6 trials for each loading variation (order randomized), the static and dynamic experiments involved 72 trials each.

To visualize the contact stress distributions at the (flat) mobile interface, super-low range Fuji Pressensor film (Inteque Resources Corporation, Fort Lee, NJ) stains were collected. Only static (nonmoving) loads were used. At full extension, three stains were obtained for each level of axial load (1, 2, 3, 4 times body weight). For each stain, an effective moment arm was determined by measuring the distance from the axis of rotation to the visually apparent center of pressure. Combined Fuji film and torque data thereby allowed back-calculation of the apparent static and dynamic friction coefficients needed for finite element modeling.

Finite Element Analysis

The geometry of the total knee components was obtained directly from the manufacturer, in the form of IGES files. These files were imported into a solid modeler, PATRAN 8.5 (MSC Software, Los Angeles, CA). Because the IGES format does not represent solids, the imported surfaces, curves, and points were used to reconstruct the solid polyethylene insert. The polyethylene insert was meshed with solid eight-noded hexahedral elements (Fig. 4). The polyethylene was treated as a geometrically and materially nonlinear deformable body, with a Poisson ratio of 0.45 and a tangent elastic modulus (E) exhibiting a constitutive fourth-order relationship [18] with von Mises stress (σ)

$$\mathrm{E}(\sigma) = 634.92 - 12.31\sigma - 3.61\sigma^2 + 0.199\sigma^3 - 0.00283\sigma^4 \mathrm{MPa}$$

Because the elastic modulus of CoCrMo alloy (220 GPa) is more than 300 times that of ultra-high molecular weight polyethylene, only the contact surfaces of the femoral component and tibial tray were meshed. These were modeled as rigid surfaces (three-noded triangular facets). This simplification greatly

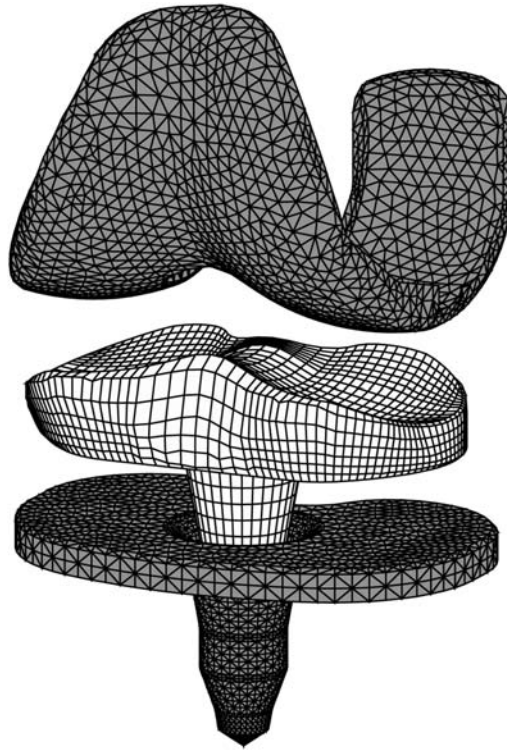

FIG. 4—*A finite element model of the LCS Standard rotating platform total knee replacement is shown. The femoral component and tibial tray were meshed with 3062 and 3707 triangular elements, respectively. The tibial tray was meshed with 7390 hexahedral elements.*

increased computational efficiency. The PATRAN model was exported as an input deck for analysis by ABAQUS 5.8 (Hibbitt, Karlsson, Sorensen Inc, Pawtucket, RI), which was used to do a nonlinear, large-displacement contact analysis. The polyethylene constitutive model was discretized and inserted into the ABAQUS input deck, using the *PLASTIC keyword command.

A novel contact formulation was used for this model. Unlike finite element models with prescribed bearing surface traction, this model used the actual component geometry to transfer loads, creating multiple, independent contact interfaces, which permitted a more realistic load transfer analysis. The experimentally measured dynamic friction coefficient of 0.089 was used at the bearing and the mobile interfaces. Because this interface contact model did not incorporate a static friction treatment, the finite element results only can be compared with the dynamic experimental results, and not with the static experimental results.

To simulate motions accurately, the finite element model was given the same degrees of freedom as the physical experiments. Numerically, the femoral component was given complete translational freedom, and varus-valgus rotational

freedom about the AP axis. The tibial tray was fixed against all translations, and only allowed to rotate about the superoinferior axis. The polyethylene insert, by contrast, had complete translational and rotational freedom, constrained only by (computed) contact with the femoral and tibial components.

Numerical experiments were designed to investigate how the interfacial contact parameters (contact area, contact stress, and resisting torque) changed with loading. The same dynamic loadings as for Experiment sets 1, 2, and 3 were delivered to the components, except that only the endorotation sequence was done. In addition, an entire series (1, 2, 3, 4 times body weight) was completed for the 60-40 load case. Peak stress, contact area, resisting torque, and insert rotation lag were extracted from the output data files.

The physical and finite element experiments parametrically measured the quasi static contact mechanics of a rotating platform total knee replacement, and allowed direct comparison of the results for finite element validation. However, to determine insert mobility for specific functional activities, full-cycle simulations were done using the phasic relationships between respective axial load and axial torque waveforms.

Waveforms from the proposed ISO standard 14243-1 [19] were used as input for the finite element model. Created for use in wear testing machines, this standard includes force-controlled axial load, axial torque, and AP force waveforms, and also a displacement-controlled flexion waveform. These waveforms were discretized into 100 piecewise linear segments, each increment being a finite element analysis step. As described in the standard, linear soft tissue constraints (30 N/mm AP and 0.6 N-m/degree rotational displacement) were included. Finally, the required medially biased condylar load allocation (60-40) was achieved by moving the concentrated axial load 4.9 mm medially (constant throughout the cycle). Axial rotation of the tibial tray was measured.

Results

Fuji film stains at the mobile interface showed that at 1 times body weight [Fig. 5(*A*)], the majority of the axial load was transferred through the peripheral edges of the polyethylene insert. However, as axial load increased [Figs. 5(*B*)–5(*D*)], the contact stress distribution broadened appreciably and moved centrally toward the axis of rotation, thereby decreasing its effective moment arm.

There was a nearly linear relationship between resisting torque and axial load (Fig. 6). Static torque was much greater than dynamic torque. The relationships (linear regression) between resisting torque, T (N-m), and axial load, P (N), were calculated to be $T = 0.003614$ P, and $T = 0.002097$ P, for the 50-50 experimental static and dynamic cases, respectively. The corresponding apparent static and dynamic coefficients of friction were 0.154 and 0.089, respectively, for the 50-50, 0° flexion load case. When this experimentally derived dynamic friction coefficient was used in the finite element model, computed resisting torque matched closely with that measured from physical testing (Table 2).

At an experimentally applied axial load of 3 times body weight, the 60-40 load case generated slightly less resisting torque than the 50-50 load case: 3.2 %

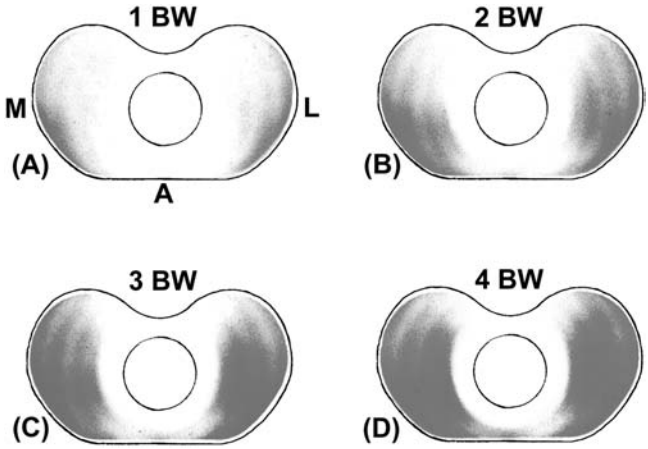

FIG. 5—*Beyond 1 times body weight, the contact stress distribution at the mobile interface broadened appreciably, effectively reducing the frictional moment arm. M = medial; L = lateral; A = anterior; BW = body weight.*

and 4.9 % reductions for the static and dynamic loadings, respectively. The finite element data showed comparably small differences (Fig. 6).

As flexion angle increased, experimental data showed that dynamic torque remained relatively unaffected (Fig. 7). Finite element analysis showed very much the same behavior (Table 2). However, static torque dropped abruptly after 15° flexion, reaching a minimum at 30°. Beyond 30° flexion, resisting torque climbed slightly with increased flexion.

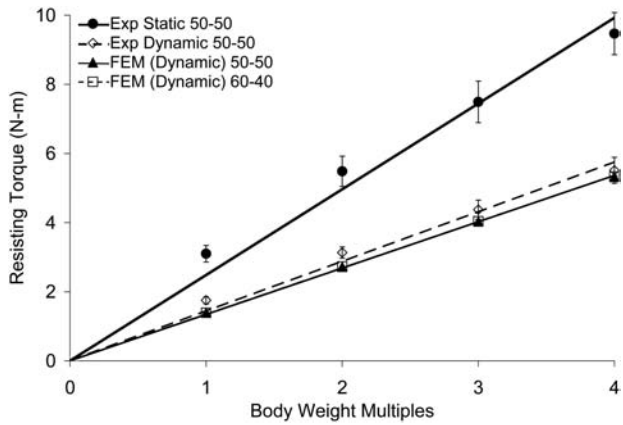

FIG. 6—*Resisting torque was approximately proportional to axial load. There was close correspondence between the (dynamic) finite element model (FEM) results and the dynamic experimental (Exp) data (Experiment set 1).*

TABLE 2—*Summary outcome measures.*

Axial Load (Body Weight)	Flexion Angle (Degrees)	Dynamic Torque (N-m)		Maximum von Mises Stress (MPa)		Contact Area Before Axial Rotation (mm^2)	
		Experimental	FEM[a]	0° Rotation	10° Rotation	Bearing	Mobile
50-50							
1	0	1.75	1.39	10.17	10.08	337	1170
2	0	3.13	2.72	14.38	14.29	548	1269
3	0	4.37	4.03	15.13	15.71	673	1347
4	0	5.51	5.32	15.96	15.95	778	1389
60-40							
1	0	…	1.39	10.05	10.35	349	1174
2	0	…	2.73	13.80	13.71	531	1267
3	0	4.34	4.04	15.40	15.45	662	1330
4	0	…	5.33	15.69	15.64	770	1377
50-50							
3	0	4.08	4.03	15.13	15.71	673	1347
3	15	4.03	3.96	26.71	26.86	406	806
3	30	3.92	3.81	27.05	26.71	231	720
3	45	3.95	3.83	27.04	27.22	233	726
3	60	3.96	3.81	26.52	26.65	250	713
3	90	4.10	3.79	27.25	27.29	205	734

[a]FEM = finite element model.

Insert rotation lag (relative motion between the femoral component and the polyethylene insert) was small and somewhat variable but was less than 0.8° for flexion angles of 15° or less (Fig. 8). There was an apparent increase in insert rotation lag after 15° flexion for the experimental and finite element data. However, although there seemed to be load and flexion dependence, insert rotation lag in all cases was very small in absolute terms.

As expected in this multiple-contact nonlinear finite element system, peak stress increased far less than proportionally with applied axial load (Table 2). Changes in the load allocation and in axial rotation had no appreciable effect on peak stress. Contact stress plots of the backside surface (Fig. 9) agreed well with Fuji film stains (Fig. 5). Increasing flexion angle significantly increased peak contact stress.

At 0° flexion, computed contact area at the bearing surface more than doubled from 1 to 4 times body weight, whereas the much larger contact area at the mobile interface increased only slightly [Fig. 10(*A*)]. As flexion angle increased, contact area decreased abruptly during the first 20° of flexion, after which point it held relatively steady [Fig. 10(*B*)].

During the walking cycle simulation, the tibial tray peaked at 0.4° of external rotation just after heel strike (Fig. 11). This was followed by internal rotation

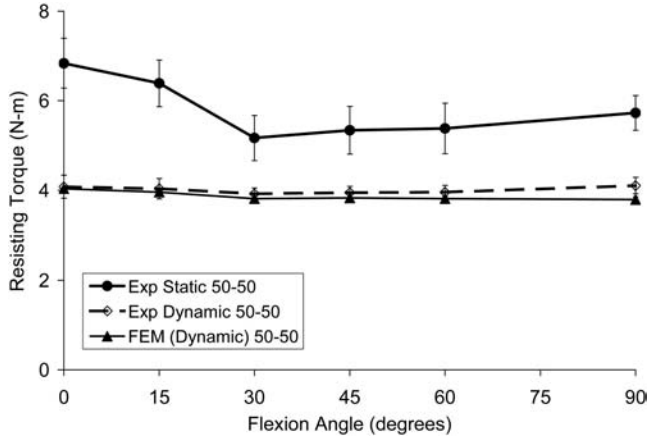

FIG. 7—*As flexion angle increased, dynamic torque remained steady for experimental (Exp) and finite element model (FEM) data. However, static torque decreased abruptly after 15°, reaching a minimum peak at 30°, after which it increased steadily.*

for nearly the remainder of stance phase (0%–60% of the walking cycle), peaking at 5.8° of internal rotation at 54% of the walking cycle. This was followed by rapid external rotation, continuing through toe-off, until leveling out at approximately 0.6° of internal rotation during swing phase.

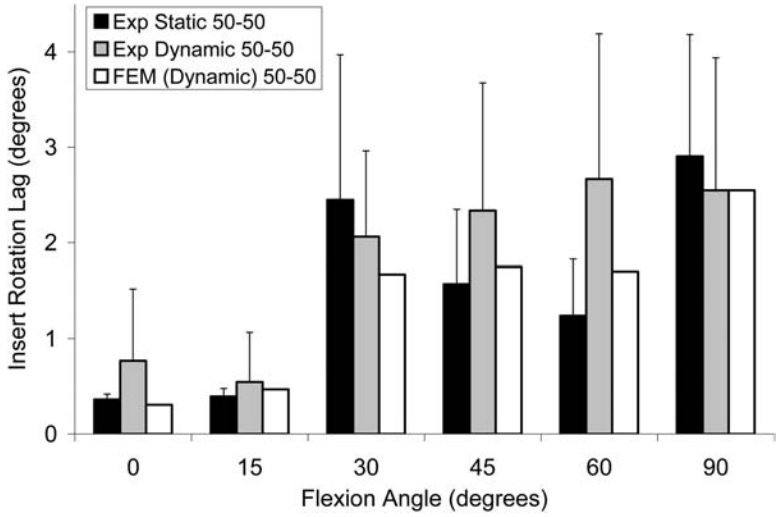

FIG. 8—*After 15° flexion, insert rotation lag (relative rotation between the femoral component and the polyethylene insert) greatly increased, peaking at 2.9° at 90° flexion. Finite element data showed similar trends. Exp = experimental; FEM = finite element model.*

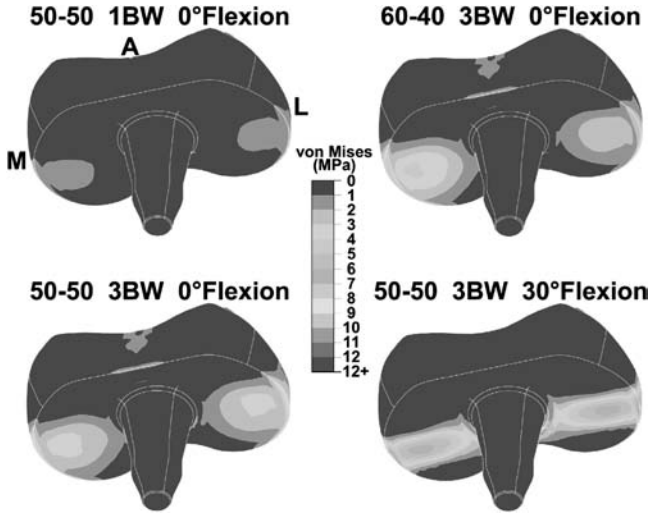

FIG. 9—*Contact stress distributions at the mobile interface for various loading conditions matched well with Fuji film stains. BW = body weight.*

Discussion

Realistically modeling an implant construct with multiple moving surfaces is a formidable challenge. The technical difficulties in obtaining numerically well-behaved finite element solutions for this class of two contact surface problems are appreciable and lie beyond the scope of the current study. They are reported elsewhere [20]. The current series represents among the first applications (to the authors' knowledge, the very first) of a multiple-interface sliding contact finite element model to study a total joint replacement implant. Absolute values of computed resisting torque agreed very well with corresponding physical experiments, and trends in other input parametric variations were very similar. This lends credence to the finite element model's ability to assess how design parameters influence the kinetic performance of this increasingly widely used class of mobile-bearing devices. Although the current study was for a specific rotating bearing design, other mobile-bearing design concepts [21] also can be studied similarly.

During surgery, the tibial tray is implanted with a 10° posterior slope, and the femoral component is flexed 5°. Therefore, the flexion angle reporting convention used in this study is 15° less than corresponding clinical flexion angles. If positioned in the appropriate posterior slope, the normal force (that affects friction) still would be 98.5 % of the axial load. Therefore, resisting torque would remain relatively unaffected by this change. However, a small component of the axial load (17.4 %) would be directed posteriorly. This force would cause the femoral component to contact the polyethylene insert slightly more posteriorly. The stem would prevent translation of the insert, which presumably would result in slightly higher contact stresses in the stem area.

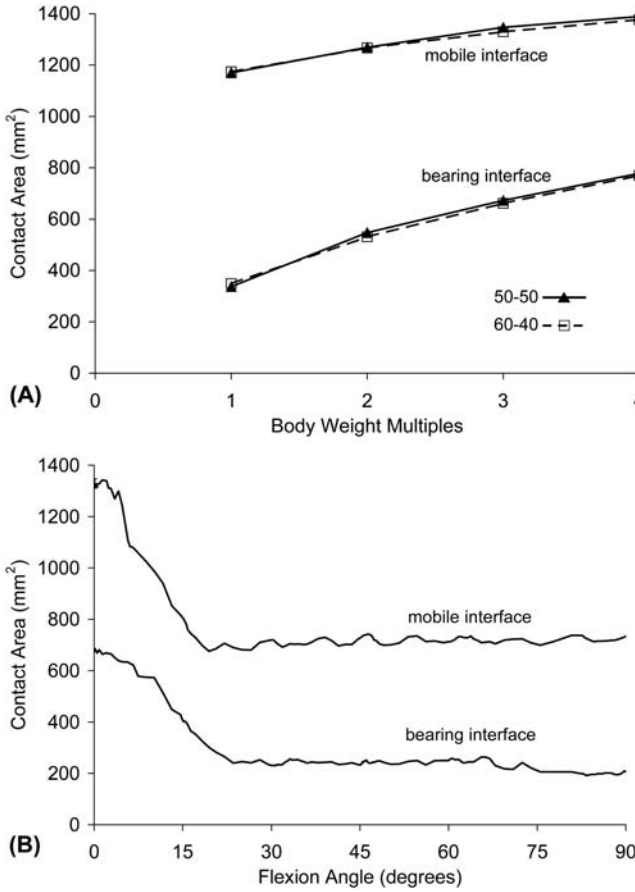

FIG. 10—*(A) As expected in this nonlinear finite element system, the computed contact area did not increase proportionally with axial load. (B) Contact area decreased abruptly during the first 20° flexion, after which it remained relatively steady.*

The current experimental and computational results suggest that most of the rotating platform mobile-bearing knee replacement design goals are achieved: AP and mediolateral conformity and high contact area near full extension, and decreasing AP conformity with flexion until approximately 20°. Almost all axial rotation is accommodated at the mobile insert undersurface, rather than at the bearing surface. The conical-like pivot mechanism seems well designed in terms of not developing appreciable polyethylene stress concentrations, and computed stresses at the bearing surface were reasonably low. Although the insert undersurface had preferentially peripheral contact at low load levels (implying relatively high resisting frictional torque caused by the high moment arm), that situation rectified appreciably as axial loading was increased beyond 1 times body weight. These characteristics probably account for the clinical success of this device.

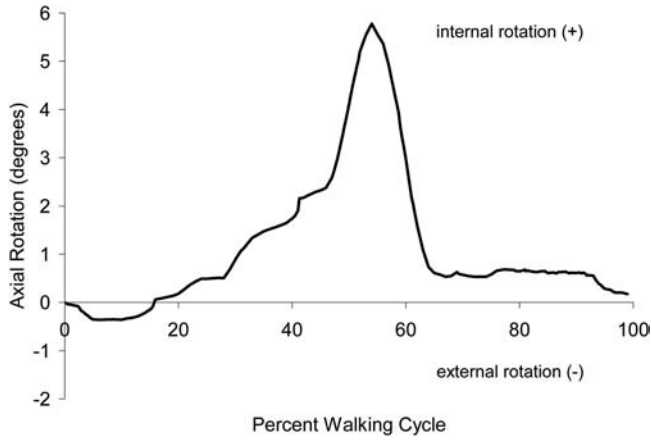

FIG. 11—*The walking cycle simulation produced 0.4° of tibial tray external rotation and 5.8° of internal rotation.*

Recently, comparative resisting torque experiments (Table 3) were made on nine mobile-bearing total knee replacements [22,23]. At 0° flexion, an axial load of 2900 N was applied to the implants, which then were rotated internally and externally. As a point of reference, an axial load of 2900 N was substituted into the dynamic 50-50 regression equation to compare the resisting torque of the LCS Standard knee replacement with these other mobile-bearing total knee replacements. At this particular load, the LCS Standard knee replacement would be expected to provide 6.08 N-m of resisting torque, ranking it near the high end of the group.

The peak resisting torques measured in this study (9.47 ± 0.61 and 5.51 ± 0.38 N-m for static and dynamic torque, respectively) extend into the

TABLE 3—*Resisting torque values for nine mobile bearing designs under 2900 N of axial load.*

Implant Name	Company	Location	Resisting Torque (N-m)
SAL	Sulzer Orthopedics, Ltd.	Austin, Texas	3.73
MBK	Zimmer, Inc.	Warsaw, Indiana	4.18
LCS Deep Dish Rotating Platform	DePuy, Inc.	Warsaw, Indiana	4.52
Interax ISA	Howmedica International	Limerick, United Kingdom	5.08
Profix	Smith & Nephew, Inc.	Memphis, Tennessee	5.54
TRAC	Biomet, Inc.	Warsaw, Indiana	5.88
TACK	Waldermar Link	Hamburg, Germany	5.99
Rotaglide	Corin Medical Group Ltd.	Cirencester, United Kingdom	6.67
Genesis II	Smith & Nephew, Inc.	Memphis, Tennessee	7.01

range of peak level walking torques reported for healthy patients, 7–17 N-m, [12] and well into the range reported for a patient with a transducer-instrumented total knee replacement, 6–8 N-m [15]. At the beginning of stance phase, the small axial torque barely can overcome the friction created by the large axial load; consequently producing only 0.4° of tibial tray external rotation. However, at the end of stance phase, the large axial torque easily overcomes the friction created by the declining axial load, producing approximately 6° of axial rotation. Therefore, certain functional motions by patients with mobile-bearing total knee replacements may produce insufficient axial torque to overcome friction at the supposedly mobile interface, especially if begun from a static posture.

The apparent friction coefficients, herein inferred experimentally, were consistent with other cobalt alloy-on-polyethylene interfaces [24–26]. For all practical purposes, especially at flexion angles of 15° or less, the polyethylene insert moved simultaneously with the femoral component, such that nearly all motion accommodating the imposed axial rotation occurred at the mobile interface.

Summary relationships between resisting torque and axial load were inferred as linear for regression purposes, even though the underlying relationship was consistently, albeit slightly, nonlinear. As noted previously, increasing the axial load decreased the effective moment arm at the mobile interface. This would seem to explain the slightly less than proportional increase in resisting torque (such as the slightly downwardly concave relationship in Fig. 6). The transition from a large to a smaller radius of curvature on the femoral component would explain the dramatic drop in contact area at the bearing interface and the increase in insert rotation lag between 15° and 30° flexion. The computed contact patches were relatively large and the peak contact stresses were relatively low, compared with fixed-bearing devices [27,28]. However, at some extreme sites, absolute von Mises stress levels exceeded 12 MPa, suggesting that it may not be prudent to assume that these devices are immune to fatigue and delamination wear.

Backside wear is an emerging concern, and wear has been linked to sliding distance. The mechanisms of wear expected at the flat, highly congruent mobile interface would be adhesion and abrasion. Based on precedent from work with total hip devices, [29] the current finite element model would be applicable to design-oriented studies of sliding distance-coupled contact mechanics. However, the current finite element formulation represents an important advance from that used by Maxian et al. [29] for total hip arthroplasty, owing to key differences in the sliding distance treatment. In total hip arthroplasty, except for bipolar total hip devices, the sliding distance distribution histories can be inferred directly from global joint kinematics [30]. In mobile-bearing total knee arthroplasty, however, backside motions also depend on, and in turn influence, the contact stress distribution at the bearing surface.

The authors also would point out that although this multicontact surface finite element formulation was developed to study mobile-bearing total knee arthroplasty, it also is applicable to fixed-bearing total knee arthroplasty studies. In the latter situation, if backside wear occurs because of sliding abrasion or adhesion of an imperfectly captured insert, the fixed-bearing unintentionally

behaves as a mobile-bearing. Obviously, in such applications, it would be important to have appropriate friction coefficient information, because a nonpolished fixed-bearing tray surface would have very different frictional (and wear) interaction with the insert backside.

As a final point of future applicability of this new multicontact finite element formulation, there is no reason that the multiple contact surfaces need be restricted to just the bearing surface and the insert undersurface. Cases in point include modular tibial tray capture mechanics for fixed-bearing designs and cruciate substituting posts for both fixed and mobile-bearing designs [31].

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Colin Hopley[1] *and Lawrence Crossett*[2]

Systematic Review of Complications in TKA Mobile Bearing Knees

ABSTRACT: The objective of this paper is to describe the incidence of different types of re-operations following total knee replacement (TKR) with mobile bearing designs and to understand the extent to which they are susceptible to spin-out, a specific complication that may arise with these designs. The design is a systematic review of the incidence of re-operations, classified by the type of re-operation and stratified by study date, reported by clinical publications following TKR with fixed and mobile bearings from a single manufacturer. A search for relevant papers was conducted in online databases including EMBASE and Medline and a manual search of bibliographies. Studies following 8739 mobile bearing knees implanted in 1985–1997 and studies following 3413 mobile bearing knees implanted in 1997–2006 were identified. In the pre- and post-1997 studies, the number of insert revisions was 190 (2.3%) and 16 (0.4%), respectively; the number of revisions of the tibial tray/femoral components was 295 (3.6%) and 43 (1.2%), respectively; the number of revisions for spin-out,dislocation, and instability was 117 (1.4%) and 10 (0.26%), respectively. In the fixed bearing studies there were no spin-outs, but the number of revisions for instability were 6 (0.16%) and 6 (0.21%) in pre- and post-1997 studies. For knees implanted between 1985 and 1997 the incidence of all wear related insert or component revision was 2% in the fixed bearing knee studies and 2% in the mobile bearing knee studies. For knees implanted in 1997–2006, the incidence of all wear related insert or component revision was 0.1% in the fixed bearing knee studies and 0.3% in the mobile bearing knee studies. In conclusion, polyethylene spin-out remains a unique complication of mobile bearing knees symptomatic of instability. Recent trends (after 1997) suggest that improved awareness of surgical

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technique and/or changes in design (posterior stabilization) have significantly decreased the incidence of this complication, with no evidence of a higher overall risk of revision for instability with contemporary mobile bearing versus fixed bearing knees.

KEYWORDS: knee, arthroplasty, mobile bearing, low contact stress, press fit condylar, Sigma

Introduction

Over the last 40 years, total knee replacement (TKR) has become one of the most common surgical procedures that has been found to provide patients with substantial improvements in function [1,2]. The number of these procedures performed yearly has grown and is forecast to continue growing at a rapid rate. Changing population demographics mean that the section of the population in which TKR is most prevalent, those over the age of 55, is increasing [3]. The age specific incidence of TKR is also increasing, especially in relatively young patients, and the availability of this procedure is expanding in evolving countries around the world [3]. In 2006, in the United States alone, 542 000 primary knee replacements and 39 000 revision knee replacements were performed. By 2030, it is estimated that there will be an 85% increase in TKR [4].

The economic burden of healthcare is felt in every country, and is increasingly becoming a fiscal challenge to maintain [5]. Therefore, it is safe to assume that increasing survivorship and decreasing complication rates are an essential aspect in maintaining the present availability of TKR procedures.

In 1977, mobile bearing TKR became available as an alternative to conventional fixed bearing TKR. The basic design premise was that by optimizing wear through design, failure due to wear, lysis, and loosening would decline. Although clinical evidence of this goal has not firmly been established, recent evidence using meta-analysis review suggests that mobile bearing TKR had indeed increased survivorship compared with knees in general [6].

When considering survivorship and long term clinical results it is imperative to track complication rates, considering both the overall incidence and type of complications reported. Frequently in survivorship analysis, only the absolute revision rate is reported and little consideration is made of the type of revision. Some complications may have a more significant impact on patient outcomes than others, particularly those that necessitate the exchange of tibial and femoral components compared with those that only involve an exchange of the patella or tibial insert. Identifying the type of re-operation can also help reveal whether certain designs of TKR are more susceptible to certain complications than others.

Due to the unique, uncoupled design of the polyethylene insert in mobile bearing knees, the potential complication of bearing spin-out is present [7]. Spin-out, where the polyethylene bearing dislocates behind the femoral condyle, has been reported consistently when looking at the clinical results of mobile bearing knees. The primary purpose of this paper is to evaluate the incidence of the different types of complications with mobile bearing TKR necessitating re-operation, focusing on spin-out and failure due to wear, such as lysis and

loosening, and to assess whether this has altered with time and changes in mobile bearing design. A review of re-operations reported by all the clinical studies following TKR patients treated with mobile bearing TKR from a single manufacturer has been conducted, stratified by the date of the study. This has been benchmarked with re-operations reported by all the studies following TKR patients treated with fixed bearing knees from the same manufacturer.

Methodology

Search

A systematic search of EMBASE and Medline on-line databases for all published papers reporting clinical follow-up of TKR manufactured by DePuy Orthopaedics Worldwide was conducted. Two separate searches were made for the low contact stress LCS mobile bearing knee and for the PFC (press-fit condylar) Sigma knee system and its predecessor the original PFC modular knee (Figs. 1 and 2). The searches were supplemented by hand searches of bibliographies, a review of the library of publications at DePuy and national joint registers, such as the Swedish, Norwegian, and Australian national joint registers [8–10].

Study Inclusion

All published randomised controlled trials, quasi-randomised controlled trials, and case series reporting re-operations following total knee arthroplasty using the LCS mobile bearing knee or PFC Sigma knee system or the PFC modular knee system were eligible for inclusion. Trials were included irrespective of the language in which they were reported and the indication for surgery.

Trials that were excluded were those that followed revision TKR patients, or those with specific knee related co-morbidities such as extensive bone loss. Publications that duplicated reporting on the same patients were also excluded from the analysis with only the publication with the longest follow-up included.

Data Extraction

Two independent reviewers extracted data from the papers identified by the search using a set data extraction sheet. Differences in data were resolved by

1. (PFC or (press adj fit adj condylar) or (PFC adj sigma)).dv,mp.
2. Knee$.mp.
3. Sigma.dv,mp.
4. arthroplast$.mp.
5. 2 or 4
6. 1 or 3
7. 5 and 6
8. remove duplicates from 7

FIG. 1—*PFC modular knee and PFC Sigma knee search strategy.*

Database: EMBASE (emed), Ovid MEDLINE(R) (mesz)
Search Strategy:

---

1 (LCS or (low adj contact adj stress) or RP or R$P).dv,mp.
2 ((mobile adj bearing$) or (rotat$ adj platform$) or (meniscal adj bearing$) or AP?glide).dv,mp.
3 knee$.mp.
4 1 or 2
5 3 and 4
6 arthroplasty.mp.
7 5 and 6
8 remove duplicates from 7

FIG. 2—*LCS knee search strategy.*

discussion. Complications that involved further surgery reported in each paper were identified and classified according to the type of complication and whether they involved the removal of the tibial tray or femoral component. The following classifications were used:

Re-operation not requiring revision of tibial tray/femoral component—

- instability,
- tibial wear,
- patellar and tibial wear,
- patellar poly wear,
- patella complications,
- spin-out, and
- insert exchange other.

Re-operation requiring revision of tibial tray/femoral component—

- infection,
- insufficient surgery,
- recurrent dislocation (dislocation of bearing insert),
- insert wear,
- trauma,
- osteolysis,
- loosening of femoral component,
- loosening of tibial component,
- instability/complication of patellar component, and
- instability.

Data Analysis

The complications reported following knee replacement with the mobile bearing knees and the fixed bearing knees in DePuy knee portfolio were analysed. The mobile bearing knees included all variants of the LCS mobile bearing knee and the Sigma rotating platform (RP) knee, analysed as a single group. The fixed bearing knees included the PFC Sigma fixed bearing knees and the PFC modular knee, analysed as separate groups. The LCS mobile bearing knee was first

launched in 1977 and the clinical results span this whole period. From 1984 to 1997 the original PFC modular knee system was available. After 1997 the PFC Sigma knee system, with a modified patella femoral groove and the use of vacuum sterilized polyethylene, has been available.

An estimate of the incidence of each type of complication following surgery with each type of knee was made by calculation of the number of each type of complication reported by the studies divided by the total number of knees in the group of studies. Re-operations that were due to insert wear, osteolysis, or component wear were all classified as potentially being associated with polyethylene wear.

The Swedish Arthroplasty Register has reported that there is a reduction in the revision rate of total knee replacements with year of operation [8]. This is attributed to improvements in technique, patient selection, and knee design, such as the introduction of vacuum sterilized polyethylene. The mobile bearing data include knees implanted across a wide span of time, from 1984 to 2006. To eliminate confounding due to improvements in technique, implant design, and material properties, the mobile bearing studies have been split into two groups, those with knees mainly implanted prior to 1997, when the PFC modular knee system was available, and those with knees mainly implanted since 1997 when the PFC Sigma knee system was available.

Statistical analysis of the incidence of complication is normally conducted using Kaplan Meier or life table survivorship analysis that takes into account the incidence and timing of revisions and baseline characteristics. This was not possible for this paper as the papers included did not report on the timing of the revisions or the patient characteristics of those with re-operations. The different patient characteristics and lengths of patient follow-up in each study are potential confounding factors that also limited the ability to make reliable comparisons of one data set with another using statistical techniques.

To eliminate study length as a confounding factor, and to identify the long term progression of complications in mobile and fixed bearing knees the complications data sets on the PFC modular knee system and mobile bearing knees implanted prior to 1997, in comparable dates, were stratified according to mean length of study follow-up. The incidence of all revisions, revisions associated with polyethylene wear and revisions associated with knee instability, such as spin-out, were all analysed. Revisions that were potentially associated with wear were considered to be those due to tibial wear, patellar wear, osteolysis, or component loosening. Revisions that were potentially associated with instability were considered to be those due to spin-out, recurrent dislocation, and general instability. An estimate of the 95% confidence interval of each type of revision at each reporting time point was estimated from the incidence of the revision and the total number of knees in the groups of studies reporting revisions at each follow-up. An estimate of the p value for any differences in the incidence of revisions was not calculated as there is still a substantial potential for confounding in the analysis despite the stratification that may give a precise estimate. The width of the confidence intervals was used to determine whether any differences were statistically significant or not. Any difference in the incidences of revisions reported were considered to be potentially statistically significant if the 95% confidence intervals did not coincide.

Results

Study Flow

The searches for LCS knee, PFC modular knee, and Sigma knee publications returned 1008 citations (Fig. 3). Of these, 147 were potentially relevant studies to the analysis. In total there were 36 studies reporting complications following mobile bearing knees involving 11 749 knees. Of these, 27 studies were on LCS knees and 9 were on Sigma RP knees. There were 13 studies reporting complications following knee replacement with Sigma fixed bearing knees, of which 5 were controlled studies with Sigma RP knee cohorts. These contained 16 individually identifiable cohorts of patients involving 2697 fixed bearing knees. There were also 28 studies reporting complications following knee replacement with the PFC modular knee system, within which there were 38 individually identifiable cohorts of patients involving 7795 fixed bearing knees.

The studies identified in the review included 9 level I randomized clinical trials, 14 level II prospective cohort studies, 9 level III retrospective controlled studies, and 36 level IV prospective case series and 4 level IV retrospective case series (Table 1) [11–82].

The remaining 75 studies were excluded as they duplicated reporting on a single series of patients, they had a high loss to follow-up, they followed a combination of different implants not included in this paper, they did not report complications.

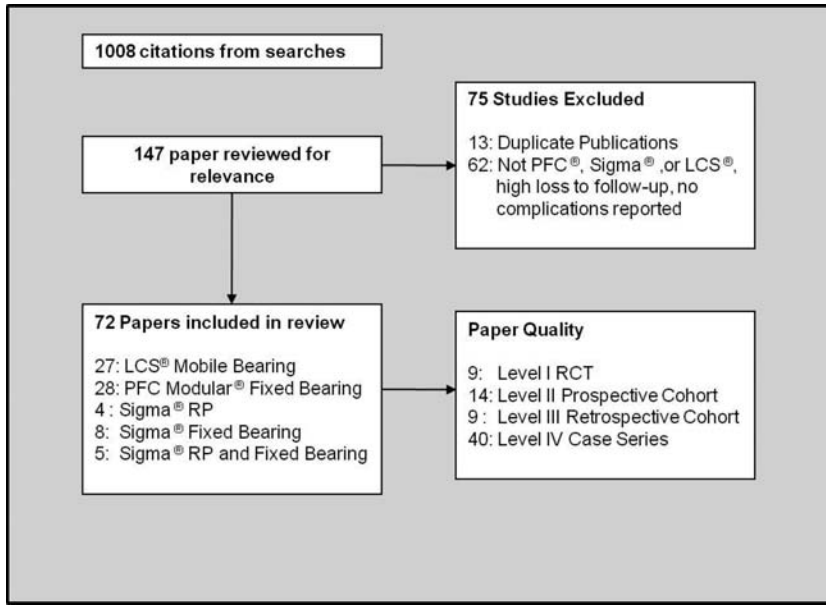

FIG. 3—*Study flow.*

TABLE 1—*Overview of the designs of the studies included in the analysis.*

Study Design	Mobile Bearing	PFC Modular Fixed Bearing	Sigma Fixed Bearing	Total
Level I RCT	7	1	1	9
Level I Prospective Cohort	7	6	1	14
Level III Retrospective Cohort	6	2	1	9
Level IV Prospective Case Series	12	19	5	36
Level IV Retropsective Case Series	4	0	0	4

Study Characteristics

The key characteristics of all the study groups are summarised in Table 2. Considering all 100 individually identifiable cohorts of patients in the studies, the mean patient age was between 60 and 70 years in 64 cohorts, over the age of 70 in 10 cohorts, under the age of 60 in 2 cohorts, and not reported in 24 cohorts. The indication for surgery was osteoarthritis in more than 90% of patients in 49 cohorts, less than 90% in 22 cohorts, and not reported in 29 cohorts. There were more than 60% females in 58 cohorts, less than 60% females in 14 cohorts and gender was not reported for 28 cohorts.

Complication Rates of Mobile Bearing Compared with Fixed Bearing

Considering all the mobile bearing TKR studies (Table 3), 338 (2.9%) re-operations were reported in which the tibial tray or femoral component were

TABLE 2—*Overview of the patient characteristics in the studies included in the analysis.*

Study Group Characteristic	Mobile Bearing	PFC Modular Fixed Bearing	Sigma Fixed Bearing	Total
Age < 60	0	2	0	2
Age 60–70	35	16	13	64
Age > 70	5	2	3	10
Age NR	6	18	0	24
Indication OA > 90%	13	26	10	49
Indication OA < 90%	18	0	4	22
Indication NR	15	12	2	29
Gender > 60% female	25	23	10	58
Gender < 60% female	9	0	5	14
Gender NR	12	15	1	28
Study date 1985–1997	19	38	0	57
Study date 1997–2006	27	0	16	43

exchanged and 206 (1.7%) re-operations were reported in which only a polyethylene insert was exchanged. In all the fixed bearing PFC modular studies there were 194 (2.5%) re-operations in which the tibial tray/femoral component was exchanged and 184 (2.4%) in which only a polyethylene insert was exchanged. In the fixed bearing Sigma knee studies there were 56 (1.8%) re-operations in which the tibial tray/femoral component was exchanged and 9 (0.3%) in which only a polyethylene insert was exchanged. Other than infection the most frequent reason for revision of the tibial tray/femoral component was osteolysis or loosening. Recurrent dislocation was the reason for revision in 27 (0.2%) knees in the mobile bearing knees and spin-out was the reason for exchange of insert in 59 (0.5%) of these knees. Re-operations for patella complications were performed in 72 (0.6%) mobile bearing knees of which 20 (0.2%) required the exchange of the tibial tray/femoral component. Re-operations for patella complications were performed in 147 (1.9%) of the PFC modular knees and 2 (0.1%) of the Sigma fixed bearing knees, all of which were insert exchanges only.

TABLE 3—*Overview of complications reported in studies following fixed and mobile bearing knees.*

		Mobile Bearing		Sigma FB		PFC	
No revision of metal compenent	Instability	13	0.1%	2	0.1%	6	0.1%
	Tibial wear	76	0.6%	1	0.0%	25	0.3%
	Patellar and tibial wear	11	0.1%	0	0.0%	39	0.5%
	Patellar poly wear	12	0.1%	0	0.0%	46	0.6%
	Patella complications	29	0.2%	2	0.1%	62	0.8%
	Spin-out	59	0.5%	0	0.0%	0	0.0%
	Insert exchange other	6	0.1%	4	0.1%	6	0.1%
	Total exchange of insert	206	1.7%	9	0.3%	184	2.4%
Revision of metal component	Infection	60	0.5%	37	1.4%	62	0.8%
	Insufficient surgery	37	0.3%	0	0.0%	0	0.0%
	Recurrent dislocation	27	0.2%	0	0.0%	0	0.0%
	Insert wear	39	0.3%	0	0.0%	9	0.1%
	Osteolysis/loosening	95	0.8%	2	0.0%	108	1.4%
	Trama	10	0.1%	1	0.0%	1	0.0%
	Instability/complication of patellar component	20	0.2%	0	0.0%	0	0.0%
	Instability	28	0.2%	4	0.1%	7	0.1%
	Other	22	0.2%	12	0.4%	7	0.1%
	Total revision of metal component	338	2.9%	56	2.1%	194	2.5%
	Knees	11 749		2697		7795	

Complication Rates of Mobile Bearing Compared with Fixed Bearing Stratified by Study Date

The range of mean length of follow-up was 1–15 years in both the PFC modular knee studies and the mobile bearing studies 1985–1997, and 1–7 years in both the Sigma fixed bearing knee studies and the mobile bearing studies 1997–2006. Considering both the fixed and mobile bearing studies, there were fewer revisions overall in those conducted after 1997 than in those conducted before 1997 (Table 4). In particular, there were substantial reductions in the incidence of femoral and tibial component loosening, wear related revisions, and patellar complications for both fixed and mobile bearing designs.

In all the fixed bearing PFC modular knee studies there were 196 (2.5%) re-operations in which the tibial tray/femoral component was exchanged and 184 (2.4%) in which a polyethylene insert was exchanged. In the mobile bearing studies from 1985 to 1997 there were 295 (3.5%) re-operations in which the tibial tray/femoral component was exchanged and 184 (2.4%) in which only a polyethylene insert was exchanged. In the Sigma fixed bearing knee studies there were 56 (1.9%) re-operations in which the tibial tray/femoral component was exchanged and 9 (0.3%) in which only a polyethylene insert was exchanged. In the mobile bearing studies from 1997 to 2006 there were 43 (1.2%) re-operations in which the tibial tray/femoral component was exchanged and 16 (0.5%) in which only a polyethylene insert was exchanged. The incidence of re-operation related to instability (spin-out recurrent dislocation and instability) was substantially lower in the mobile bearing studies from 1997 to 2006 than in those from 1985 to 1997, with only 10 of 3413 (0.26%) knees reported re-operated on for these reasons in the more recent studies. The incidence of re-operation related to general knee instability in the fixed bearing knee implanted after 1997 was 6 of 2819 (0.21%).

Complication Rates of Mobile Bearing and Fixed Bearing Knees Implanted Before 1997 Stratified by Study Length

In the studies of mobile bearing knees implanted prior to 1997, the incidence of all revisions increased with increasing length of study follow-up (Fig. 4). In the groups of studies following patients for 1–2, 5, 7–8, 10, and 15 years on average, the incidence was 4.3% (95% confidence interval 1.6%–6.8%), 5.4% (95% confidence interval 4.8%–6.1%), 7.7% (95% confidence interval 6.3%–9.0%), 8.5% (95% confidence interval 6.8%–10.1%), and 7.9% (95% confidence interval 4.1%–11.8%), respectively. The estimated confidence intervals of the incidence of revisions all coincide, except for the group of studies with 9–10 years mean follow-up, meaning that the incidence of revision was significantly higher in this group only. The incidence of revisions due to wear, osteolysis, and loosening also increased with increasing length of follow-up in the groups of studies following patients up to 10 years on average. In the groups of studies following patients for 1–2, 5, 7–8, and 10 years on average, the incidence of revision due to wear, osteolysis, or loosening was 0.0%, 2.1% (95% confidence interval 1.7%–2.5%), 5.3% (95% confidence interval 4.2%–6.4%), and 5.7% (95% confidence interval

TABLE 4—*Overview of complications reported in studies following fixed and mobile bearing knees stratified by study date.*

		Mobile Bearing 1997–2006		Sigma FB 1997–2006		Mobile Bearing 1985–1997		PFC 1985-1997	
No revision of metal compenent	Instability	2	0.1%	2	0.1%	11	0.1%	6	0.1%
	Tibial wear	0	0.0%	1	0.0%	76	0.9%	25	0.3%
	Patellar and tibial wear	0	0.0%	0	0.0%	11	0.1%	39	0.5%
	Patellar poly wear	1	0.0%	0	0.0%	11	0.1%	46	0.6%
	Patella complications	6	0.2%	2	0.1%	23	0.3%	62	0.8%
	Spin-out	4	0.1%	0	0.0%	55	0.6%	0	0.0%
	Insert exchange other	3	0.1%	4	0.1%	3	0.0%	6	0.1%
	Total exchange of insert	16	0.5%	9	0.3%	190	2.2%	184	2.4%
Revision of metal component	Infection	17	0.5%	37	1.4%	43	0.5%	62	0.8%
	Insufficient surgery	0	0.0%	0	0.0%	37	0.4%	0	0.0%
	Recurrent dislocation	1	0.0%	0	0.0%	26	0.3%	0	0.0%
	Insert wear	0	0.0%	0	0.0%	39	0.5%	9	0.1%
	Osteolysis/loosening	10	0.3%	2	0.1%	85	1.0%	108	1.4%
	Trama	1	0.0%	1	0.0%	9	0.1%	1	0.0%
	Instability/complication of patellar component	0	0.0%	0	0.0%	20	0.2%	0	0.0%
	Instability	3	0.1%	4	0.1%	25	0.3%	7	0.1%
	Other	11	0.3%	12	0.4%	11	0.2%	7	0.1%
	Total revision of metal component	43	1.2%	56	2.1%	295	3.5%	194	2.5%
		3413		2697		8379		7795	

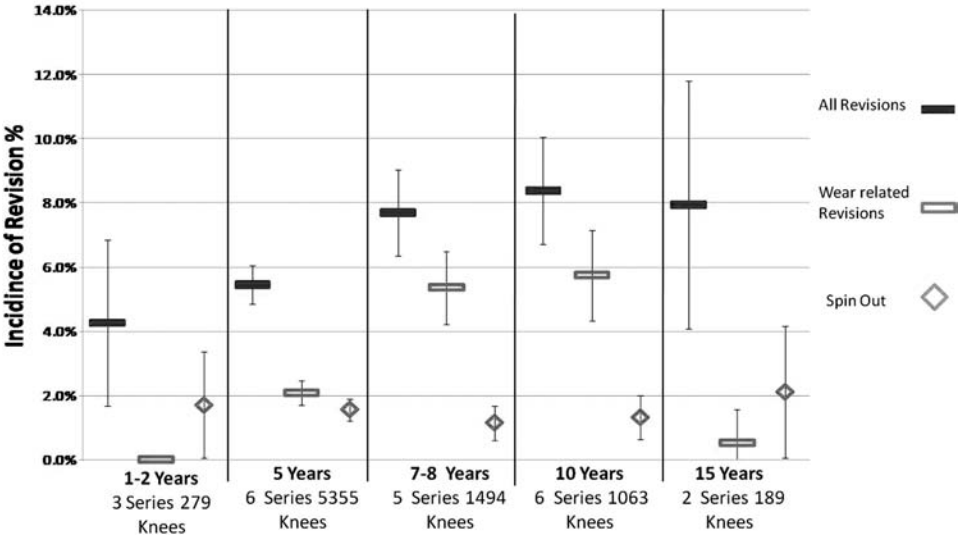

FIG. 4—*Incidence of revision with the mobile bearing knees implanted before 1997 reported in the peer reviewed literature, stratified by mean length of study follow-up.*

4.3%–7.1%), respectively. In the group of studies following patients for 15 years this incidence was 0.5% (95% confidence interval 0.0%–1.6%). The estimated confidence intervals of the incidence of revision due to wear, osteolysis, or loosening coincide except for the group of studies with 9–10 years mean follow-up, suggesting that the incidence of these revisions was significantly higher in these groups. The incidence of revision related to instability (spin-out, recurrent dislocation, and instability), in mobile bearing knees implanted prior to 1997 was similar in all the groups of studies. In the groups of studies following patients for 1–2 years, 5, 7–8, 10, and 15 years on average, the incidence was 1.7% (95% confidence interval 0.0%–3.4%), 1.5% (95% confidence interval 1.2%–1.9%), 1.1% (95% confidence interval 0.6%–1.7%), 1.3% (95% confidence interval 0.6%–2.0%), and 2.1% (95% confidence interval 0.1%–4.2%), respectively. All the confidence intervals coincide meaning that none of the differences in revision related to instability with length of follow-up were considered to be significant. The majority of the revisions related to instability were for spin-out or recurrent dislocation accounting for 81 of the 117 instability related revisions in the data set.

With the original PFC modular knee the incidence of revisions increased with increasing length of study follow-up (Fig. 5). In the group of studies following patients for 1–2, 3–5, and 6–8 years on average, the incidence was 2.6% (95% confidence interval 1.6%–3.6%), 3.1% (95% confidence interval 2.4%–3.7%), and 4.0% (95% confidence interval 3.3%–4.7%), respectively. However, the estimated confidence intervals coincide, suggesting that the differences were not significant. The group of studies of the PFC modular knee with mean follow-up of 9–10 years, had a much higher incidence of revision than the groups of studies with shorter mean follow-up, 11.0% (95% confidence interval 8.8%–13.3%), with the confidence

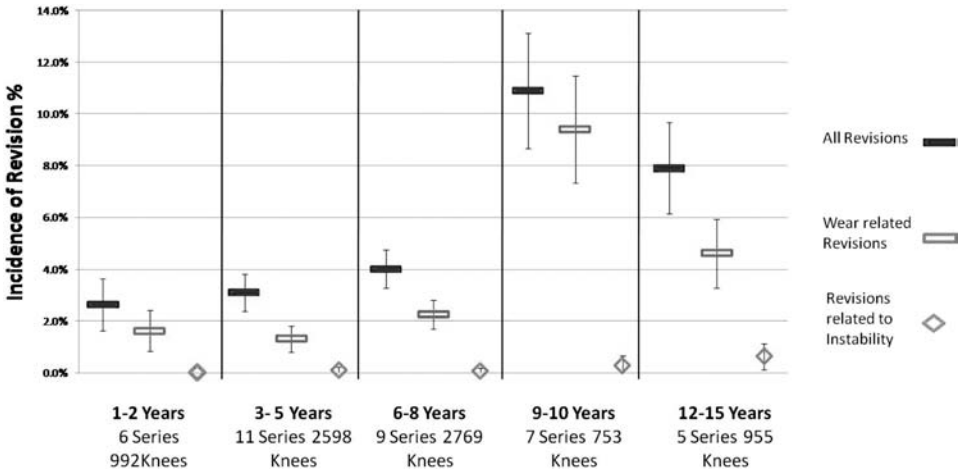

FIG. 5—*Incidence of revision with the original PFC Knee reported in the peer reviewed literature, stratified by mean length of study follow-up.*

intervals indicating that this was significant compared to the groups of studies with shorter follow-up. The studies following the PFC modular knee for 12–15 years on average had a lower incidence of revision than those following for 9–10 years on average (7.9%) (95% confidence interval 6.1%–9.6%), but the confidence intervals of these estimates coincide and the difference may be due to chance. The incidence of wear related revisions with the PFC modular knee were similar in the groups of studies following patients for 1–2, 3–5, and 6–8 years on average and the incidence was 1.6% (95% confidence interval 0.8%–2.4%), 1.3% (95% confidence interval 0.9%–1.8%), and 2.2% (95% confidence interval 1.7%–2.8%), at each time point, respectively. The incidence of wear related revisions was higher in the groups of studies following patients for 9–10 years (9.4%) (95% confidence interval 7.3%–11.5%) and at 12–15 years (4.6%) (95% confidence interval 3.3%–5.9%). The estimated confidence intervals of the incidence of wear related revisions all coincide except for the group of studies with 9–10 years mean follow-up, suggesting that only this group of studies had a significantly different incidence of revision for wear, osteolysis, or loosening. The incidence of revisions related to instability in the groups of studies following patients for 1–2, 3–5, and 6–8 years were 0.0%, 0.1% (95% confidence interval 0.0%–0.2%), 0.1% (95% confidence interval 0.0%–0.2%), respectively. The incidence of revision related to instability was higher in the groups of studies following patients for 9–10 years and 12–15 years, 0.3% (95% confidence interval 0.0%–0.6%) and 0.63% (95% confidence interval 0.1%–1.1%). This was not significantly higher than in the studies with shorter follow-up.

Discussion

The purpose of this paper is to provide some insight into the incidence of complications reported in an extensive body of observational data on fixed and

mobile bearing knee replacement and to observe the trends in these complications over time. It is apparent that spin-out remains a unique complication of mobile bearing knees. When reviewing all mobile bearing results, revision of the polyethylene insert for spin-out was a reported incidence of 0.5% (0.0% for fixed bearing). Revision of components for recurrent dislocation was 0.2% (0.0% for fixed bearing). The term insufficient surgery was used and reported at 0.3%. This term is common in the literature on the LCS knee and refers to a complication obviously due to surgical error. Although we cannot comment on the exact occurrences, it would seem safe to assume that many of these were reported in lieu of recurrent dislocation. Therefore, the 0.2% rate of component revision for recurrent dislocation may be an underestimate

The results have been stratified by date of study into those conducted before and after 1997. This was due to the release of the Sigma knee system, a modification of the existing PFC modular knee system that includes an asymmetric trochlear groove designed to improve the tracking of the patella. Also with this release was the wide spread use by Johnson & Johnson of polyethylene's improved by γ vacuum sterilization. This was introduced to prevent degradation of the polyethylene with time caused by oxidation of the plastic, initiated by the use of radiation in the presence of oxygen, which has been cited as a significant cause of polyethylene related revisions in total knee replacement [83]. Although there are no results beyond seven years available at present, we feel that the issue of component spin-out and recurrent dislocation were predominately short-term complications and not likely expected to increase with time. When stratifying the studies of mobile bearing knees implanted prior to 1997 by mean length of follow-up, the incidence of spin-out, recurrent dislocation, and instability was similar at each stratification time point and there was no apparent trend of a higher incidence of spin-out or recurrent dislocation in those papers with longer follow-up. This suggests that in the mobile bearing knees implanted prior to 1997 there was a 1%–2% risk of spin-out in the first 1–2 years following surgery, but that spin-out tended not to occur progressively thereafter with time.

These results show significant reductions in spin-out, tibial wear, and recurrent dislocation,as well as osteolysis and loosening compared with the earlier studies. In the studies of mobile bearing knees implanted before 1997 with follow-up of between 1 and 8 years, the incidence of dislocation and spin-out was approximately 3% and the incidence of wear, osteolysis, and loosening was 2%–5%. In the studies following mobile bearing knees implanted after 1997, with up to 7 years follow-up, the incidence of recurrent dislocation or spin-out was 0.1% and revision for wear, osteolysis, and loosening was 0.3%. The very low incidence of revision for osteolysis and loosening in both the post-1997 fixed and mobile bearing knee studies may be attributed to the improved quality of the polyethylene used in the later studies, remembering that the longest follow-up in these studies was relatively short, 7 years. For both the PFC modular knee and mobile bearing knees implanted before 1997, the incidence of wear, osteolysis, and loosening was higher in the studies with more than 10 years follow-up than in those with less than 10 years follow-up. Between the groups of studies of mobile bearing knees implanted before 1997 with 5 years follow-up and 10 years follow-up, the rate of increase in the incidence of all revisions was

approximately 1% per additional year of follow-up. Given the low incidence of revisions due to wear, osteolyis, and loosening reported in contemporary knees it might be reasonable to expect this to continue with better overall survivorship for all designs in the long term. However, it remains to be seen how the newer grades of polyethylene used in the knees implanted after 1997 perform in the long term and whether there is any difference in the performance of fixed and mobile bearings with these materials at 10 years and beyond. Although spin-out is unique to mobile bearing knees in many cases these authors consider that it is a manifestation of knee instability. As we have observed in this paper, knee instability is possible with fixed bearing knees, as well mobile bearing knees, but does not normally present itself through the dislocation of the insert with fixed bearing designs. Considering all revisions related to instability (instability as well as spin-out and recurrent dislocation), in the studies of knees implanted after 1997 there was no difference in the incidence with mobile bearings (9 from 3143) compared with the incidence with the fixed bearing knees (6 from 2819). With the reduction in the risk of spin-out observed in studies before and after 1997 there is no evidence in this study that the risk of revision due to instability in contemporary mobile bearing knee replacement is higher than with fixed bearing knees. This reduction is difficult to explain by polyethylene quality and could possibly be a result of improved surgical technique. For example the availability of additional femoral sizes may have helped with flexion gap balancing. These writers also suspect that a contributing reason is the increased use of posterior stabilized mobile bearing knees, which are quite difficult to spin-out, although it should be noted that many of the mobile bearing knees in the studies after 1997 were non-posterior stabilized LCS knees ($n = 2124$). With non-posterior stabilized knees the introduction of modifications such as deep dish inserts may similarly reduce the risk of spin-out with these designs. As spin-out has been reported as a pitfall with mobile bearing knees, this decrease could represent substantial alteration of the benefit to risk ratio of using a mobile bearing.

Although there did not appear to be any statistically significant differences in the incidence of all revision in the studies of knees implanted prior to 1997 with the PFC modular knee and mobile bearing knees, there was a trend for a higher incidence of revision at, 2, 5, and 8 years with mobile bearing knees reporting around 1% higher than with the fixed bearing design. This difference could have been caused by spin-out. The incidence of revisions due to instability was in the order of 1% higher with the mobile bearing knees than with the fixed bearing knees and this difference could largely be accounted for by spin-out. However, the difference may also have been due to chance, as the confidence intervals coincide, slight differences in the study lengths that remain despite stratification, or other confounding factors that remain between the studies. In the studies of mobile bearing knees implanted prior to 1997 the rate of increase in the incidence of all revisions was approximately 0.6% per additional year of follow-up, and the incidence of revisions in the group of studies following patients for 7–8 years on average is consistent with this rate.

It is apparent that the revision rate for wear, lysis, or loosening was significant in the mobile bearing results (insert revision; mobile bearings 0.7%, Sigma fixed bearing knee 0.1%, PFC 0.8%: component revision; mobile bearing 1.1%,

Sigma 0%, PFC knee 1.4%). This would appear disappointing given the specific design goals of mobile bearing knees. However it must be remembered that these reports include all mobile bearing knee designs at that time, including the rotating platform (cruciate sacrifice), the posterior cruciate retaining menisci bearing knee, and the bi-cruciate retaining menisci bearing knee. The present authors have completed a meta-analysis review of survivorship of mobile bearing knees compared to all knees in the Norwegian knee registries [7,10]. Observed was a marked increase in failure rates of meniscal bearing knees at the twelve-year follow-up. These failures were a result of failure of oxidized polyethylene both in the meniscal bearings, as well as in modular polyethylene patella bearing. These polyethylene bearings were all sterilized by radiation in air. We believe that these failures significantly added to the failure rates of mobile bearing knees due to wear, lysis, or loosening as the rotating platform results have maintained a lower cumulative revision rate. This is demonstrated by the low incidence of revision for wear, lysis, or loosening in mobile bearing knees after 1997 in which vacuum sterilized polyethylene was generally used and included no meniscal bearing knees. Additionally, in the studies of knees implanted prior to 1997 the incidence of these potentially wear related revisions were lower in the mobile bearing studies following patients for more than 10 years, 5.5% at 10 years and 0.5% at 15 years, compared with the studies of PFC modular knees with similar follow-up, 9.4% at 10 years and 4.5% at 15 years.

This study is somewhat limited due to the quality of the data on which it is based and the simple approach taken to estimate the incidence of each type of re-operation. The data were drawn from studies of varying quality that including prospective and retrospective case series. The way in which the data were presented in each study meant that it was neither possible to determine the timing of each re-operation following the primary surgery, nor the characteristics of those patients with re-operations. Additionally, when combining the incidence of re-operations across studies there are a number of confounding factors that make direct comparison between designs difficult. There were variations in patient age, gender, indications for surgery, knee prosthesis used, and length of study follow-up. Consequently, it was not possible to perform a formal survivorship analysis, or make any adjustments for patient characteristics. Also, it may have been preferable to pool the data using standard meta-analysis techniques, such as fixed or random effects models. This was not possible with these data sets as a zero incidence was frequently reported for some of the types of re-operation. Where this occurs the estimated variance is zero and consequently the weighting of the study in a pooled estimate of the incidence of that type or re-operation using the inverse variance method cannot be calculated as it is one divided by zero.

An attempt to control for length of follow-up was made by stratifying the studies large data sets of PFC modular knee and mobile bearing knees implanted before 1997, according to the average length of patient follow-up was made. However, there was a limited ability to detect any difference in the crude incidence of revision across time points with the same design and between the PFC modular knee and mobile bearing knees, as the confidence intervals of each estimate coincided in many cases. For longer studies, the total number of

knees at each stratification time point was relatively small ranging from 1063 to 189 knees for the mobile bearing studies with 10 and 15 years mean follow-up, respectively. Some of the results were counter-intuitive as in both the PFC modular knee and mobile bearing studies, the incidence rates for revision were lower in the studies following patients for 12–15 years compared with those following patients for 9–10 years. This in particular casts doubt on the finding that in the studies of knees implanted prior to 1997 the incidence of these potentially wear related revisions were lower in the mobile bearing studies following patients for more than 10 years compared with the studies of PFC modular knees with similar follow-up.

Despite these drawbacks the major benefit of the paper is to observe the trends in these complications over time, classifying the studies according to date. The design of the mobile bearing knee creates the potential for the unique complication of bearing spin-out. The findings of the Swedish Knee Arthroplsaty Registry of decreasing TKR revision rates implies improvements in fixation and wear related complications, including spin-outs in mobile bearing knees. This is also reflected by lower complication rates in our combined knee studies after 1997. Despite the unique risk of spin-out, there was no evidence of a difference in the overall incidence of revision with mobile bearing knees compared to the fixed bearing comparator both for earlier knee designs implanted before 1997 and more contemporary designs implanted after 1997. In particular, there was no apparent difference in the incidence of revision related to instability with the fixed and mobile bearing knees after 1997. Further, mobile bearing knees may have the added benefit of improved knee kinematics allowing more physiological tibial femoral internal rotation and patella femoral tracking. This has been demonstrated to occur in vivo in studies using fluoroscopy [84,85]. However, controlled studies have failed to detect any difference in outcome with fixed and mobile bearing knees [86].

Conclusion

Although the results show that polyethylene spin-out remains a unique complication of mobile bearing knees we believe that in many cases it is a manifestation of knee instability that can occur with both fixed and mobile bearing knee replacement. Recent trends (after 1997) suggest that improved awareness of surgical technique and/or changes in design (posterior stabilization) have significantly decreased the incidence of this complication and no difference was found in the risk of all revision related to instability in contemporary fixed and mobile bearing knee replacement. We further believe that the increased use of designs with greater potential to resist spin-out, such as posterior stabilized mobile bearing knees and deep dish inserts, should further reduce the incidence of spin-out and overall complication rates in mobile bearing knees. The current data available do not allow for comparisons of the long term performance of contemporary designs of fixed and mobile bearing knees. In the medium term the more recent studies (after 1997) report a very low incidence of revision for osteolysis and loosening with both fixed and mobile bearing knees that may be

attributable to the improved quality of the polyethylene used in these knees. However, there was no evidence of a difference in the overall incidence of revision with mobile bearing knees compared to the fixed bearing comparator both for earlier knee designs implanted before 1997 in the long term and more contemporary designs implanted after 1997 in the short term. Any further conclusions about differences in the performance of fixed and mobile bearing knees are limited by the quality of the data analysed and the techniques used.

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James B. Stiehl[1]

The Contribution of Mobile Bearing Knee Design in Optimizing Tibial Rotation in Total Knee Arthroplasty

ABSTRACT: This study assessed the alignment and rotation in mobile bearing total knee arthroplasty (TKA) with the tibia cut first technique using an imageless referencing computer navigation protocol evaluating 41 patients. Prerelease mechanical alignment (MA) averaged 7° varus +/−5° (Range: 8° valgus to 20° varus). Post implant MA was 0.5° varus +/−1.2° (Range: 2° valgus to 3° varus). Post operative radiographic MA was 0.3° varus +/−1.3° (Range: 2° valgus to 2° varus). The baseline measurement of tibial rotation from 0° to 90° flexion was 6°+/−7.2° of tibial internal rotation (Range: 8° external rotation to 19.5° internal rotation). The post implant tibial rotation from 0° to 90° flexion was 3.6°+/−8° of tibial internal rotation (Range: 17° external rotation to 29° internal rotation). Of the baseline group, 25 % demonstrated tibial external rotation with flexion. After TKA, 28 % had tibial external rotation with flexion. When comparing the nominal tibial position in relation to the femur at 0° before and after TKA, the tibial rotation point at 0° moved more externally in 21 % and more internally in the rest with mean change for the overall group of 3.9° of internal rotation (Range: 17° internal to 5° external). This study identified significant changes in knee rotation that may be caused by correction of alignment and deformity. Mobile bearing implants by nature of unconstrained rotation are likely to accommodate these variations. This feature could be defined as a significant advantage over fixed-bearing prostheses.

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Introduction

Mobile bearing total knee arthroplasty (TKA) has nearly 40 years of continuous successful experience with signal implants such as the Oxford unicondylar prosthesis and the low contact stress (LCS) mobile prosthesis [1,2]. Worldwide, the concept continues to proliferate with the introduction of numerous copies and variations on the basic theme of the device. Principally, there are two potential advantages of a mobile bearing device over the typical fixed polyethylene prosthesis. The mobile bearing allows for dramatically increasing the surface contact areas of the metal prosthesis on the polyethylene. This has been shown to reduce surface contact stresses and the sliding ploughing movement known to increase implant wear [3]. Secondly, the mobile bearing device allows a margin of error for creating an optimal position match of the femur with the tibia. This accounts for the significant variations in the individual anatomy and the changes caused by the arthritic disease process.

Axial femorotibial rotation during flexion of the healthy knee has been seen in numerous in vitro and in vivo kinematic analyses [4–6]. With knee flexion, the tibia typically internally rotates relative to the femur, and conversely, externally rotates with knee extension (i.e., normal screw-home mechanism) [4–7]. Previous TKA studies have been limited and have analysed small numbers of patients, often using non-weight-bearing conditions or only throughout a limited percentage of the entire flexion range [8–14]. It is assumed that different axial rotation magnitudes and patterns (i.e., direction of rotation, internal or external tibial rotation versus the femur) may occur after TKA because of removal or alteration of the cruciate ligaments and failure to exactly duplicate the geometry of the medial and lateral femoral and tibial condyles. Fluoroscopic video kinematic studies have demonstrated that while some cases demonstrate the expected internal rotation with knee flexion, others will actually exhibit paradoxical external rotation with knee flexion [15,16]. Knowledge of rotational movement is an important consideration for understanding polyethylene wear patterns where exaggerated sliding motion coupled with rotation may produce detrimental delamination wear [17,18].

Imageless computer aided surgery (CAS) offers a unique opportunity to evaluate tibial rotation intraoperatively along with numerous other parameters such as mechanical alignment (MA), joint flexion, ligament balance, and tibial axis alignment in flexion. This study assessed the parameters of alignment and rotation with the tibia cut first technique using an imageless referencing computer navigation protocol. Specifically, cases were assessed looking for trends with the particular operative technique such as changes in tibial rotation with ligament balancing, and to see the particular effects of the method on implant placement. The primary objective was to learn the spectrum of changes noted with tibial rotation after total knee prosthetic placement.

Methods

A group of 41 patients underwent primary TKA using the “tibia cut first” technique performed by a single surgeon experienced with this technique (James B Stiehl MD). The implant used was the LCS mobile bearing prosthesis in all patients (Table 1). The low contact stress mobile prosthesis is a total condylar

TABLE 1—*Data from assessment of non-weight-bearing alignment and tibial rotation of the LCS mobile bearing total knee implant.*

Measurement	Average (SD)	Range
Baseline mechanical axis	7° varus +/−5	8° valgus to 20° varus
Implant mechanical axis	0.5° varus +/−1.2°	2° valgus to 3° varus
Implant mechanical axis (radiographic)	0.3° varus +/−1.3°	2° valgus to 2° varus
Baseline tibial shaft axis	3.6° varus +/−4.3°	8° valgus to 12° varus
Implant tibial shaft axis	0.6° valgus +/−3.6°	7° valgus to 6° varus
Baseline tibial rotation	6°+/−7.2° internal rotation	8° external rotation to 19.5° internal rotation
Implant tibial rotation	3.6° +/−8° internal rotation	17° external rotation to 29° internal rotation
Baseline to implant tibial position change at 0°	3.9° internal rotation	17° internal to 5° external

design that offers very high conformity of the femoral and tibial insert from 0° to 40° of flexion, followed by less congruity with deeper flexion resulting from diminished radii of curvature of the posterior femoral condyles. The tibial insert has a central cone that articulates with a matching reverse cone on the tibial tray. Tibial rotation is unconstrained with this device. (Fig. 1)

The patients were selected from a consecutive series of navigated cases performed from 2003 to 2005. There were 25 males and 16 females. The average age was 56 and average body mass index was 31. The Medtronic Stealth Treon system with the Universal Imageless Total Knee software (Medtronic, Inc., Louisville, CO, USA) was used in all cases with dynamic reference base markers attached to either the medial proximal tibia or the distal medial femur over the medial epicondyle. The tibial rotation was defined mathematically by the relationship of the transepicondylar axis and a vector measured from the tibial center to the midpoint prominence of the tibial tubercle. More recently, the Medtronic imageless protocol added the femoral anterior/posterior (AP) axis of Whiteside as an additional mark to determine femoral rotation, eliminating the need for the transepicondylar axis reference [19].

The specifics of the navigation referencing are an important element of the technique and require a detailed description. Hip center determination is done using the kinematic method originally described by Saragaglia et al. [20]. Femoral referencing is done with the two most important points being the femoral center and the cortical reference of the anterior femoral cortex. For the tibia

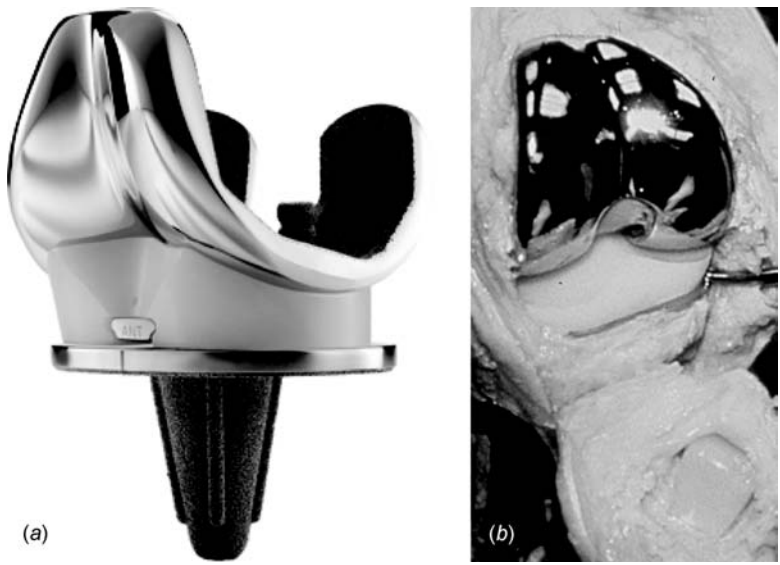

FIG. 1—*(a) LCS (Depuy, Inc., Warsaw, IN) mobile bearing rotating platform implant utilized in this study features a central peg on the tibial insert that allows rotation around the center axis of the proximal tibia; (b) retrieval from a patient who had a successfully performing LCS mobile bearing rotating platform implant for over 10 years.*

reference, the tibial center is defined as the bisection of the transverse tibial axis [21]. The transverse tibial axis is a line that connects the AP midpoints of the medial and lateral condylar surfaces. The tibial center approximates the lateral insertion of the anterior cruciate ligament (ACL). The AP tibial axis is a perpendicular extension of the tibial center of the transverse tibial axis. This point typically matches the extension of the femoral AP axis that may be extended onto the anterior surface of the tibia. The computer algorithm then picks a point on the transmalleolar axis, which is 40 % from the most medial point that has been shown by anatomical studies to approximate the center of the dome of the talus.

The tibia cut first method with TKA follows the original technique of Insall where ligament balancing is done initially in extension before any bone cuts are made [22]. The tibia cut is made perpendicular to the mechanical axis with a 7° posterior slope to the proximal tibia. The anterior distal femoral cut is made precisely at the distal anterior surface of the femur, and the flexion gap is cut with a block that removes the posterior condyles after ligament tensioning is done. Ligament tension is determined either with a gap spacer or a custom tensioner that adjusts and measures the amount of tension to cut a specific gap. Distal femoral chamfer and notch cuts complete the femoral preparation. Following final preparation for femoral implantation, trials are inserted to assess the tension of the gaps that are created. These gaps typically will not have laxity over 3 mm, with a maximum allowed laxity in any plane of 5–6 mm.

Results

The CAS measurement of the prerelease MA for the cohort averaged 7° varus +/−5° (Range: 8° valgus to 20° varus). The CAS post implant MA was 0.5° varus +/−1.2° (Range: 2° valgus to 3° varus). This compared to post operative radiographic MA of 0.3° varus +/−1.3° (Range: 2° valgus to 2° varus). The CAS measurement of the prerelease tibial shaft axis at 90° flexion was 3.6° varus +/−4.3° (Range: 8° valgus to 12° varus). The CAS post release tibial shaft axis at 90° flexion was 0.6° valgus +/−3.6° (Range: 7° valgus to 6° varus). I noted that the tibial shaft axis at 90° changed significantly from baseline to post implant position. Of varus knees, 25 % moved over 5° of more valgus and 18 % moved over 10° valgus at 90° flexion. Two varus knees had post tibial shaft axes of greater varus. Finally, the final tibial shaft axis compared to the transepicondylar axis was greater than 2° in 56 % and greater than 5° in 15 %. Ordinarily, if the MA was corrected to neutral, the tibial shaft axis could be expected to be the same or 0° to the transepicondylar axis unless the ligament release had caused abnormal femoral rotation.

The baseline measurement of tibial rotation from 0° to 90° flexion was 6°+/−7.2° of tibial internal rotation (Range: 8° external rotation to 19.5° internal rotation). The post implant tibial rotation from 0° to 90° flexion was 3.6°+/−8° of tibial internal rotation (Range: 17° external rotation to 29° internal rotation). Of the baseline group, it was found that 25 % demonstrated tibial external rotation with flexion. After TKA, 28 % had tibial external rotation with flexion. When comparing the nominal tibial position in relation to the femur at

0° before and after TKA, it was noted that the tibial rotation point at 0° moved more externally in 21 % and more internally in the rest but the mean change for the overall group was 3.9° of internal rotation (range: 17° internal to 5° external). This would indicate that for the vast majority of knees, 79 % had a permanent change of the tibia to a more internal position in relation to the femur. Again, the factors that could cause an abnormal preoperative external tibial rotational position are loss of the ACL and arthritic deformity, which moves the femoral/tibial articulation point more posterior on the medial femoral condyle. A change in direction of rotation in knees was noted before and after TKA with 21 % moving more external after surgery, and 31 % moving less internally. Most of these later cases had an abnormal prerelease external rotation of the proximal tibia in relation to the femur that was reduced to a more normal position after ligament release.

Discussion

This clinical study defined tibial rotation in total knee reconstruction where a mobile bearing design has been employed using the classic tibial cut first technique. Non-weight-bearing measurements were done intraoperatively using an imageless CAS system in 41 patients. The neutral mechanical axis alignment was restored within 3° of variation in all cases. The mobile bearing prosthesis was found to accommodate the specific tibial rotation of each patient and this feature could be defined as an important attribute.

This study demonstrated some important findings regarding tibial rotation measured from prerelease of ligaments to the final positioning of the implants. There is high variability of tibial rotation in the diseased knees, with many knees showing tibial external rotation with flexion. This rotation was modified by surgical intervention. When compared with prior studies that use kinematic fluoroscopy, these changes are not unexpected. One could postulate a number of causes in the diseased state that affect tibial position. Disruption of the ACL will force the tibia more external in full extension. Lewis et al. identified this condition in patients who manifest a movement of the medial femoral tibial contact in a posterior direction as the proximal tibia moves into external rotation. This caused implant wear and failure to occur on the posteromedial surface of polyethylene inserts [23]. With abnormalities in ligaments and with medial osteophytes, the tibia does necessarily externally rotate as the knee goes from flexion to extension.

This study identifies issues that may have an impact on the surgeon's specific surgical technique. There is a very clear change in position of the anterior posterior tibial axis in extension from prerelease measurement to the post release post arthroplasty measurement. This implies that release of ligaments, correction of the mechanical axis alignment, and placement of the prosthesis have an effect on this position. Many experts currently recommend a specific point on the proximal medial tibial plateau for centering the tibial prosthesis such as the medial 1/3 of the tibial tubercle. Additionally, the contemporary concept of a minimally invasive surgical approach increases the difficulty of placing the tibial base plate in the more external position, which may be optimal if the

external rotation of the anterior cruciate deficient knee is considered. Both of these problems are resolved by a mobile implant that seeks the best fit or relationship between the femur and tibia when the implants are finally inserted.

A limitation of the current study is that all CAS measurements were made non-weight-bearing. The radiographic control in this study was made with standardized weight-bearing long leg radiographs, giving results similar to CAS measurements. However, most cadaveric studies and kinematic studies with roentgenographic spectro-photogrammetry (RSA) have also been done non-weight-bearing. Secondly, the inaccuracy of referencing the transepicondylar axis and the tibial tubercle are such that only relative numbers are possible. Siston et al. showed significant variability with attempting to identify the transepicondylar axis during surgery and when attempting to use computer navigation [24]. The same authors evaluated methods to determine tibial tray rotational alignment, finding that tibial tubercle referencing in computer navigation produced greater variability than even conventional total knee instrumentation [25]. Another source of error could be the positioning of the knee and how the leg is held as the surgeon passes the knee through a passive range of motion. Cadaveric studies have shown that 14°–19° of internal tibial rotation (positive screw-home) occurs throughout the arc of knee flexion in the normal knee [5–7] (Table 2). Several studies have assessed the effect of ACL disruption on non-weight-bearing tibial rotation, finding that rotation is typically diminished compared to normal. Throughout the flexion range tested, ACL-deficient knee tibias were positioned more externally relative to the distal femur compared to that seen in normal knees. Additionally, although an average positive screw-home rotation pattern was noted in ACL-deficient knees, other reports note that aberrant external rotation (reverse screw-home) may occur in some knees (Table 2). Results of this paper would confirm the presence of reverse screw-home in abnormal arthritic knees as this was identified in 25 % of arthritic knees at baseline. While the current methodology cannot show that the arthritic tibias were more externally placed than normal at baseline measurement; a trend towards reduction of external tibial position was seen after placement of a prosthesis. Kinematic studies have shown diminished tibial rotation with flexion in patients after total knee replacement (Table 2). Studies using RSA have found that rotation may vary from 1° to 10° depending on the prosthesis and surgical technique [12–14]. in vivo weight-bearing video fluoroscopy has been used to evaluate tibial rotation in a large number of patients following TKA compared to normal and ACL-deficient knees [15]. In one study, screw-home rotation in normal knees averaged 16.5° while that found in ACL-deficient knees averaged 8.1° and following total knee replacement, 3.7°. However, the maximum range of motion on deep knee bend was notable, with internal rotation of 21.3° and external rotation of 22.3° in total knees. The results noted in this study are consistent with most prior studies and offer new insights when comparing the baseline and post operative total knee findings. It has been stated in the recent literature that TKA will result in abnormal kinematics. Siston et al. showed in cadavers and intraoperative patients that osteoarthritic knees have reduced normal screw-home rotation, which also persists after TKA [24]. One could argue that arthritic joints often have loss of normal ACL function, altered articular

TABLE 2—*Comparison of kinematic and clinical data regarding tibial rotation after TKA.*

Author	Test Method	Knee Condition, Prosthesis	Findings	Significance
Lafortune et al. [6]	In Vivo, gait, cortical pins	Normal ($n = 5$)	5° (SD: 1.6°) internal rotation at heel strike; 9° (SD: 2.7°) external rotation at toe off	14° of rotation with normal gait
Ishii et al. [5]	In Vivo, non-weight-bearing, flex to 60°, linked hinge with cortical pins	Normal ($n = 5$)	10.6° (SD: 2.8°) internal rotation with flexion to 60°	Positive screw-home in all patients
Jonsson et al. [11]	RSA, non-weight-bearing, 30° flexion to extension	ACL deficient ($n = 13$)	6° internal rotation on extension followed by external rotation	
Kärrholm et al. [17]	RSA, non-weight-bearing, flex to 60°	ACL deficient ($n = 10$)	Reduced internal rotation in flexion for ACL deficient	Tibia more external to femur. 50 % negative screw-home rotation
Nilsson et al. [13]	RSA, non-weight-bearing, extension to 55°	Normal ($n = 23$) Tri-Con M ($n = 11$)	6.5° internal rotation 3.9° internal rotation	Tibia more external to femur in TKA than normal
Nilsson et al. [14]	RSA, non-weight-bearing, extension to 55°	Miller–Galante ($n = 10$) LCS ($n = 5$)	4° internal rotation 1° internal rotation	Tibia more external to femur compared to normal
Stiehl et al.	In Vivo fluoroscopic; deep knee bend	Whiteside PCR ($n = 6$)	4.7° (SD: 3.7°) internal rotation; maximum 9° internal rotation	Rotation coupled with medial condyle AP motion
Stiehl et al. [18]	In Vivo fluoroscopic; deep knee bend	LCS ($n = 20$)	0.5° internal (ave.); range 9° internal to 6° internal	40 % reverse screw-home rotation; 50 % medial condylar rotation greater than lateral

TABLE 2—*Continued*

Author	Test Method	Knee Condition, Prosthesis	Findings	Significance
Banks et al. [9]	In Vivo fluoroscopic; weight-bearing gait	Posterior cruciate retaining ($n = 6$) Posterior stabilized ($n = 5$)	PCR: 6.5° (SD: 2.6°) PS: 4.9° (SD: 2.4°)	PS had lower rotation ($p < 0.05$) than PCR PS may be sensitive to axial alignment of implant
Dennis et al. [15]	In Vivo fluoroscopic; deep knee bend	Normal ($n = 10$)	16.5° internal (ave.); maximum 27°	Positive screw-home in all knees
Dennis et al. [15]	In Vivo fluoroscopic; deep knee bend	ACL deficient ($n = 5$)	8.1° internal (ave.); maximum 11.8°	40 % reverse screw-home rotation
Dennis et al. [15]	In Vivo fluoroscopic; deep knee bend (overall)	Total knee ($n = 760$)	3.7° internal (ave.); range: 21° internal to 22° external	26 % reverse screw-home rotation
Dennis et al. [15]	In Vivo fluoroscopic; deep knee bend	Posterior stabilized ($n = 212$) Mobile bearing cruciate sacrificing ($n = 76$)	PS: 3.1° internal (ave.) range: 8° internal to 11° external MB: 3.3° internal (ave.) range: 6° internal to 11° external	PS: 24 % reverse screw-home rotation MB: 27 % reverse screw-home rotation
Argenson et al. [8]	In Vivo fluoroscopic, deep knee bend	LPS high flex ($n = 20$)	5.4° internal (ave.) (SD: 5.6°); range 9° external to 13° internal rotation	Results similar to current study

load bearing position, and altered ligament tension, and are not likely to perform as a normal joint would. These changes could explain the tendency of the tibia to be externally rotated in the baseline arthritic state.

In conclusion, tibial rotation in the arthritic knee is abnormal and is disturbed by the disease process. The surgeon seeks to optimize the prosthetic knee articulation by placing the implants in a neutral rotational position. This study demonstrates that tibial rotation can be quite variable and may be affected by changing alignment and releasing ligaments. The mobile bearing by its inherent rotational freedom allows the surgeon to compensate for these variables by allowing the bearing to seek the optimal position, which may be difficult to identify during the surgical procedure. This feature could be defined as a significant advantage over fixed-bearing prostheses.

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In-Vitro Wear and Radiographic Analyses of High Flexion Posterior Stabilized Mobile- and Fixed-Bearing Knee Implants

ABSTRACT: In vitro wear tests results and 2-year follow up radiographic analyses of implanted fixed- and mobile-bearing LPS Flex knees are compared. The two knee designs use gamma-sterilized GUR 1050 ultra high molecular weight polyethylene (UHMWPE) patellae and tibial inserts, and the same CoCrMo alloy (ASTM F 75) femoral components. The in vitro wear tests were performed on six fixed- and six mobile-bearing knee implants using modified ISO 14243-3 load and kinematic waveforms. Tests were conducted at a frequency of 1 Hz for 5×10^6 cycles (Mc) in bovine serum lubricant. Two year follow up radiographic analyses were performed on 341 patients implanted with 173 mobile- and 168 fixed-bearing implants. Average accumulative in vitro polyethylene wear rates of the mobile- and fixed-bearing knees were 19.9 ± 5.1 mg/Mc and 14.2 ± 2.1 mg/Mc, respectively. There is no statistically significant difference in the wear rates of both devices ($p > 0.05$, Mann–Whitney test). Overall survivorship at two years with revision for any reason as the endpoint was 99.3 % for the mobile group and 100 % in the fixed group. There was no evidence of tibial, femoral, or patella bone loss at the two year follow up. The mean active range of motion increased from 110.8° to 127.0° in the mobile- bearing group and from 110.7° to 127.2° in the fixed-bearing one. Overall, radiographic evaluation showed similar performance of both devices.

KEYWORDS: wear, wear debris, fixed- and mobile-bearing knees, radiographic analyses, UHMWPE

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Introduction

Mobile-bearing knee implants were introduced in the late 1970s as a means to reduce polyethylene wear-induced osteolysis that occurred with fixed-bearing knees [1,2]. Other postulated advantages of mobile-bearing knees over their fixed-bearing counterparts include rotating laxity, ability to more easily accommodate slight femur/tibia misalignments, and reduced torsional and shear forces at the bone/implant interfaces [3,4]. Polyethylene wear in mobile-bearing knee implants comes from two decoupled tibio-femoral articulations: at the superior femur-polyethylene and the inferior polyethylene-polished tibia tray interfaces. In fixed-bearing knees, articulation occurs primarily between the femoral component and the upper surface of the tibial insert. Secondary micro-motions between the tibial inserts and the tray as well as polyethylene extrusions into the tray screw holes also contribute to polyethylene wear in fixed bearing knees [5,6].

Several in vitro studies have compared the wear of these two knee designs. McEwen et al. [7] showed that under high internal/external rotation kinematic input, platform mobile-bearing knees can produce two- to fourfold reduction in the volumetric polyethylene wear rate when compared to the PFC Sigma fixed-bearing knees. However, Johnson et al. [8] and Utzschneider et al. [9] found no statistically significant difference in polyethylene wear in both designs. Grupp et al. [10] also found no significant difference in total polyethylene wear between the two designs but noted that wear per unit area of polyethylene in mobile-bearing knees is significantly less than that in fixed-bearing ones. Prospective and retrospective clinical studies that compare mobile- and fixed-bearing knees also produced mixed results. Atwood et al. [11,12] performed in vitro and retrieval analyses of LCS RP mobile bearing knees and found them to be prone to polyethylene wear, tibia tray, and femoral component scratching caused by third body particles of bone, bone cement, or porous coating; and suggested lower wear than fixed bearing knees. Huang et al. [13] reported osteolysis in 47% (16 out of 34) of mobile-bearing and in 13% (6 out of 46) of fixed-bearing knees during revision surgeries after an average of eight years of in vivo duration. In a randomized prospective trial involving 312 arthroplasties (136 fixed and 176 rotating platform designs) in 273 patients, Gioe et al. [14] concluded that neither design showed a clear clinical advantage at 42 ± 14.2 months follow up. In a multi-center single-blind randomized-controlled trial involving 39 bilateral surgeries, Price etal. [15] reported better Knee Society Score and Oxford knee score at 1 year post operatively for a mobile-bearing implant but the differences disappeared after 3 years. Likewise, Munoz et al. [16] and Harrington et al. [17] found significantly better clinical performance of mobile-bearing knees over fixed-bearing ones after 6 months to 1 year post-operatively but the differences disappeared after 2 years. The prospective study of Bhan et al. [18] which compared the performance both knee designs in thirty two patients with bilateral surgeries found no significant difference in the survival rate of both designs at a minimum of 4.5 years of follow up.

The sizes and shapes of the polyethylene wear particles produced by mobile- and fixed-bearing knee devices have also been compared in order to determine and rank the potential for cytokine-mediated inflammatory reactions that cause osteolysis and bone resorbtion. Huang et al. [19] isolated particles from tissues

harvested from revised total knee replacement (TKR) sites and found that the wear particles from mobile- and fixed-bearing devices have average particle sizes of 0.58 ± 0.12 μm and 1.17 ± 0.09 μm, respectively, and suggested that mobile-bearing knees may be associated with higher risk of osteolysis. However Callaghan et al. [20] reported that no knee was revised because of loosening, osteolysis or wear in their cohort of 53 knees in 37 patients after 15 years. In vitro studies of Grupp et al. [10] and Utzschneider et al. [21] found no size differences in the polyethylene particles generated by both designs.

Most of the aforementioned in vitro and clinical studies compare mobile- and fixed-bearing devices of mixed designs (e.g., all polyethylene tibia versus modular, cruciate-retaining versus cruciate-sacrificing or posterior-stabilized, anterior posterior glide versus rotating platform,…), materials (GUR 1020 versus GUR 1050 polyethylene), and sterilization techniques (gamma-irradiation versus gas-plasma) which make it difficult to draw definitive conclusions about their relative performances. The objective of this study is to compare the in vitro and in vivo wear behaviors of posterior-stabilized mobile- and fixed-bearing knee implants that employ the same polyethylene tibia and patellae material, sterilization technique and identical femoral components. In vitro wear studies were performed on anatomic knee simulators while the In vivo wear was evaluated by radiographic evaluation of 341 patients implanted with 173 mobile- and 168 fixed-bearing devices at 2 years postoperatively.

Materials and Methods

Materials

Twelve commercially available left posterior-stabilized (six 10 mm thick LPS Flex Fixed and six 9 mm thick LPS Flex Mobile, Zimmer, Inc., Warsaw IN) TKR implants were tested. Both implant designs use identical CoCrMo alloy (ASTM F75) femoral components and are designed to safely accommodate up to 155° of knee flexion. The polyethylene tibial inserts were machined from compression molded GUR 1050 bars, 27–36 KGy gamma irradiation-sterilized and packaged in nitrogen. The LPS Flex Mobile tibia tray is also made of CoCrMo alloy (ASTM F75) has a trunnion which is centered mediolaterally on the baseplate, is anterior of center, and permits a ± 25° rotation of the polyethylene insert relative to the tray with no translation. The mobile tibial tray and trunnion surfaces were polished to a surface roughness of $Ra = 0.1$ μm to minimize friction during articulation against the polyethylene insert. The titanium alloy (ASTM F1108) fixed tibial baseplate utilizes a double-faceted dovetail locking mechanism to secure the articular surface within a circumferential containment rail. The surface of the fixed knee tibial tray was finished to $Ra = 1.6$ μm. The polyethylene inserts and tibial trays of both implant designs are shown in Fig.1. All the in vitro tested polyethylene inserts were artificially aged in accordance with ASTM F2003-02 [22] (i.e., 70 °C under 5 atmosphere oxygen for 14 days).

Wear Testing

Both knees were subjected to walking gait load waveform and motion kinematics adapted from ISO 14243-3 and previously described by Johnson et al. [23] (Fig. 2).

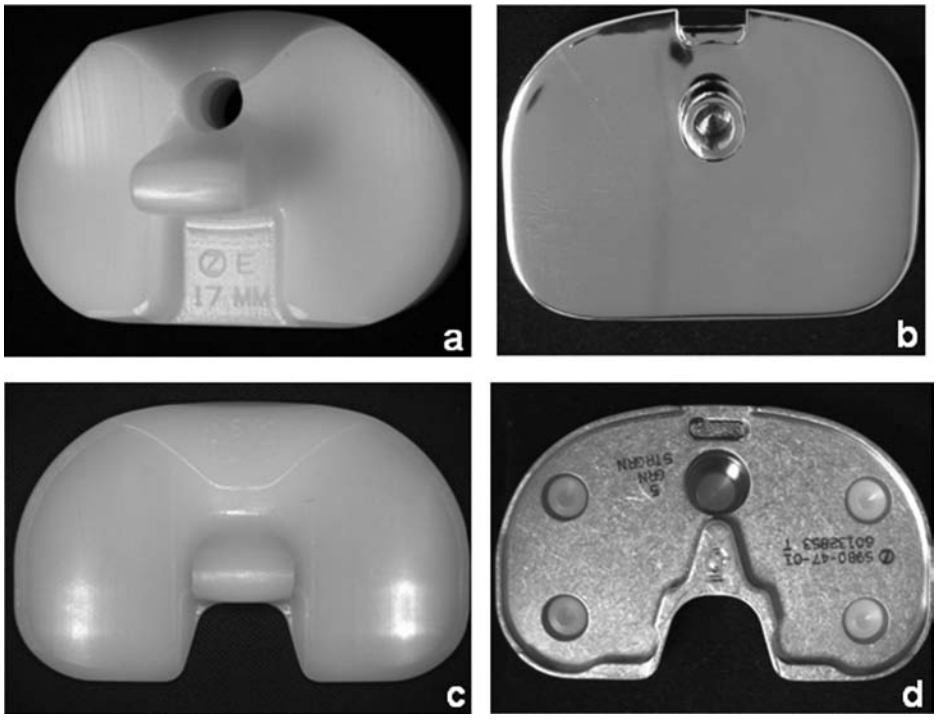

FIG. 1—*Photographs of polyethylene inserts and metal tibial trays of LPS Flex (a),(b) mobile- and (c),(d) fixed- bearing implants.*

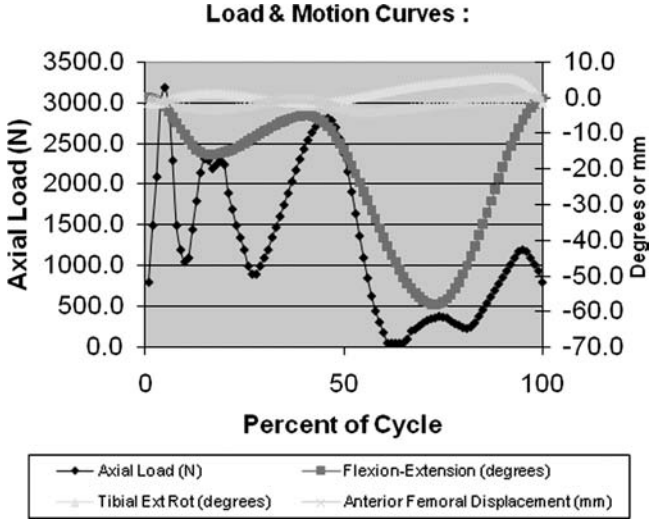

FIG. 2—*Load and motion waveforms used during wear simulation of LPF Flex mobile- and fixed-bearing implants.*

Fluoroscopic studies of Dennis et al. [24,25] showed that fixed and mobile-bearing posterior-stabilized TKA designs experienced similar kinematic patterns during gait as the cam and post mechanism of most posterior-stabilized TKA designs do not engage during low flexion gait activity. The tests were performed using six-station displacement-control knee simulators (AMTI, Watertown MA) under femoral extension of 0 to −58°, external tibia rotation from −1.9 to 5.7°, and anterior-posterior femoral translation range of 4.2 mm. The peak load was 3188 N. The ISO 14243-3 load waveform calls for a constant 168 N during the swing phase while the load waveform used in the current study had two load peaks; 378 and 1195 N at 74 and 95% gait cycles, respectively. The tests were run at a frequency of 1 Hz and lasted for 5×10^6 cycles (Mc). Undiluted bovine calf serum (protein concentration of 68 mg/mL) mixed with sodium azide and EDTA was used as lubricant, which was changed and salvaged every 0.5 Mc. Load soak controls were used to correct for fluid absorption by the polymer. Weight loss of the polyethylene inserts was measured gravimetrically every 0.5 Mc with analytical balances (Satorius AG, Goettingen, Germany) to a precision of ±0.02 mg. The wear patterns on the front and back sides of the polyethylene articular surfaces were studied using a Stereoscope (Carl Zeiss Microimaging, Thornwood, NY). The polyethylene wear of both designs were compared using a Mann–Whitney test with the confidence interval set at 95%.

Wear Debris Analyses

Polyethylene wear particles were isolated from the salvaged serum lubricant using the acid digestion method described by Scott et al. [26]. Briefly, 10mL of spent serum was mixed with 40 mL of hydrochloric acid (37%, Fisher Scientific, Fairlawn, NJ) and the solution was heated to and maintained at 60 °C for 2 h. 1 mL of the digest thus produced was mixed with 100 mL of methanol (Fisher Scientific, Fairlawn, NJ) and passed through 50 nm (pore size) polycarbonate filters (Nuclepore, Whatman, Maidstone, England). The filters were allowed to dry in air for 6 h and sputter-coated with thin gold film. Photomicrographs of representative areas of the debris-laden filters were obtained using a LEO 1550 scanning electron microscope (LEO Electron Microscopy, Thornwood, NY) operated at 15 kV and magnification of 10000 × . Two thousand particles from each design type were characterized using Clemex Vision PE 4.0 software (Clemex, Inc., Longueuil, Quebec, Canada). The equivalent circle diameter (ECD) and aspect ratio (AR) of the particles were calculated using the definitions described in ASTM F1877-98 [27].

Clinical Evaluation

Between May 2001 and Jun. 2004, 341 patients were enrolled in a prospective, randomized device investigational exemption study at 15 sites. All of the participating sites obtained local Institutional Review Board approvals throughout the duration of the study. The patients were randomized into either an investigational group that was implanted with LPS Flex mobile-bearing knees (173 patients) or a control group that was implanted with LPS Flex fixed-bearing

knees (168 patients). Preoperative diagnoses (mainly osteoarthritis and post-traumatic arthritis) were similar between the two patient populations. Mean patient age was 64 years (94 females and 79 males) and 63 years (105 females and 63 males) in the mobile- and fixed-bearing groups, respectively. The mean body mass index was 29.7 kg m^{-2} and 29.3 kg m^{-2} in the mobile- and fixed-bearing groups, respectively. The average preoperative maximum flexion was 114.7° and 114.4° for the mobile- and fixed-bearing groups, respectively. The mean active range of motion was 110.8° and 110.7° in the mobile- and fixed-bearing groups, respectively. Anterior-posterior, lateral and optional skyline and standard radiographic evaluations were performed at 6 weeks and 24 months postoperatively by a single, independent expert radiologist with no knowledge of the patients' functional status. Clinical outcomes ranking at the two year follow up was based on pain scores, range of motion, and evidence of 2 mm of osteolysis or subsidence in all zones/views of prosthetic-cement or cement-bone interfaces. Radiographic comparison to determine the success of the investigational LPS Flex mobile versus the control LPS Flex fixed knees was based upon a non-inferiority test (delta = 5.7 % and 98 % CI) using a Student t-test.

Results

In-Vitro Wear

The polyethylene weight losses exhibited by both designs after various testing periods are shown in Fig. 3. Average cumulative polyethylene wear rates of the mobile- and fixed-bearing knees were 19.9 ± 5.1 mg/Mc and 14.2 ± 2.1 mg/Mc, respectively. Though the mobile-bearing knees have a higher arithmetic wear average than the fixed ones, there is no statistically significant difference in wear rates at any period between both devices ($p > 0.05$, Mann–Whitney test).

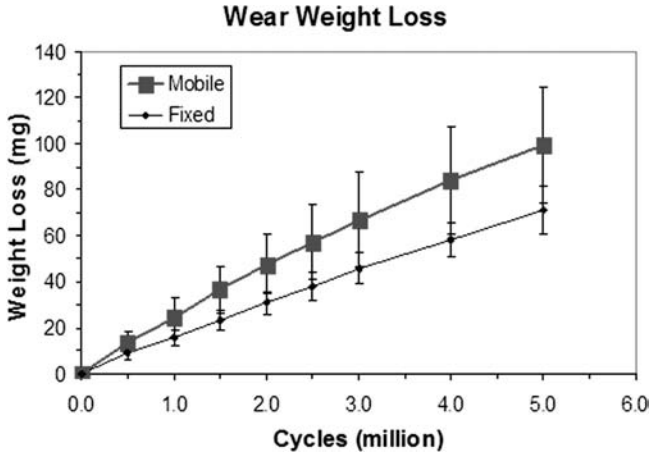

FIG. 3—*Polyethylene weight losses as a function of test cycles during in vitro wear testing of LPS Flex mobile- and fixed-bearing knees.*

Posteriorly-located wear scars with topographical patterns characterized by smooth burnished areas with few scratches, indicative of adhesive/abrasive wear were observed on the superior polyethylene surfaces of both devices. The wear scar on the backside of the fixed-bearing polyethylene inserts was broadly distributed on the posterior region and had areas where the polyethylene had been extruded into the screw holes (Fig. 4(*a*)). The laser etched markings are clearly visible on the extruded areas and appear to have been worn away to various degrees in adjacent burnished regions. The backside of the mobile-bearing inserts also showed broadly distributed, posteriorly located burnished areas with scratches (Fig. 4(*b*)) and pitting. The opposing polished tibial trays' surfaces demonstrated several curvilinear scratches mainly in the posterior region (Fig. 4(*c*)). Most of these scratches had lengths smaller than the expected arc of rotation (−1.9°–5.7°) but a few were longer with depths of several micrometers to 1 mm. A few scratches, along the anterior-posterior direction were also present on the femoral condyles.

Wear Debris

SEM micrographs of the wear debris from the mobile- and fixed-bearing knees are shown in Fig. 5 and their corresponding equivalent circular diameter and aspect ratio distributions are shown in Fig. 6. Most of the particles were

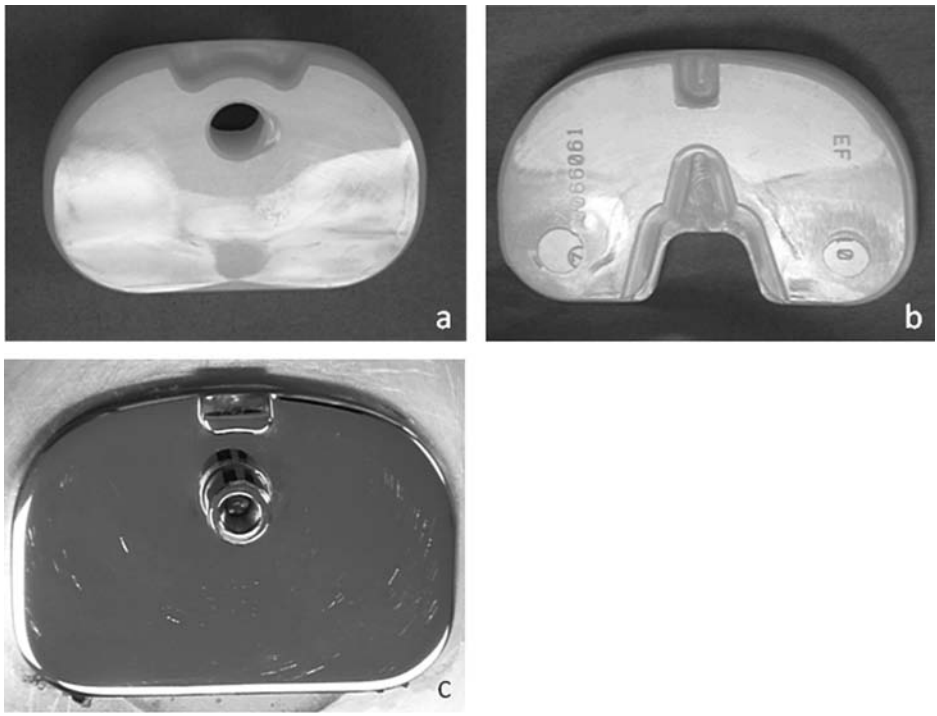

FIG. 4—*Photographs of (a),(b) backsides of polyethylene inserts of mobile- and fixed-bearing knees and (c) mobile-bearing tibial tray after 5 Mc of wear testing.*

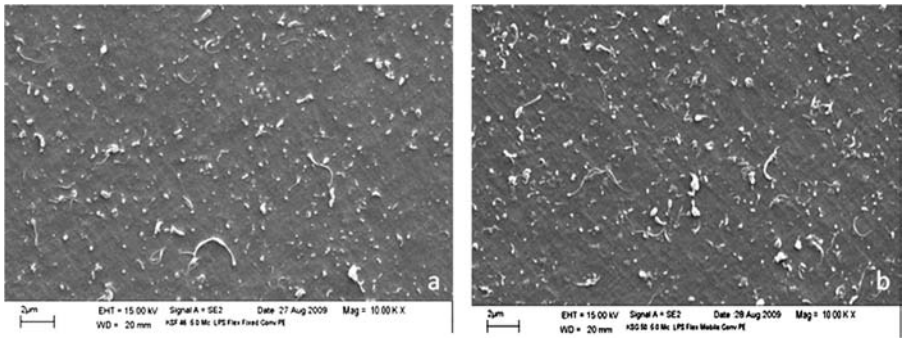

FIG. 5—*SEM micrographs showing the particles generated during wear testing of (a) mobile- and (b) fixed-bearing knees.*

sub-micrometer in size. Corresponding mean ECDs and ARs were 0.26 $\pm$ 0.15 μm and 0.33 $\pm$ 0.27 μm and 1.82 $\pm$ 0.68 and 1.84 $\pm$ 0.71, respectively. Using the definition per Sieving et al. [28], (particles with $1 \leq AR \leq 2.39$ are globular/circular in shape while those with $2.4 \leq AR \leq 5$ are fibrillar/elongated) 84% of particles generated by both designs were globular/circular in shape.

Radiographic Evaluation

There was no evidence of tibial, femoral, or patella bone loss at the two year follow up. Overall survivorship at two years with revision for any reason as the endpoint was 99.3% for the mobile group and 100% in the fixed group. Overall, radiographic evaluation showed similar performance of both devices. Review of two year films in the anterior-posterior and lateral views showed four knees with tibial radiolucencies greater than 2 mm. One mobile-bearing knee and one fixed bearing knee demonstrated tibial radiolucencies greater than 2 mm in both anterior-posterior and lateral views. Two knees, both in the fixed-bearing group,

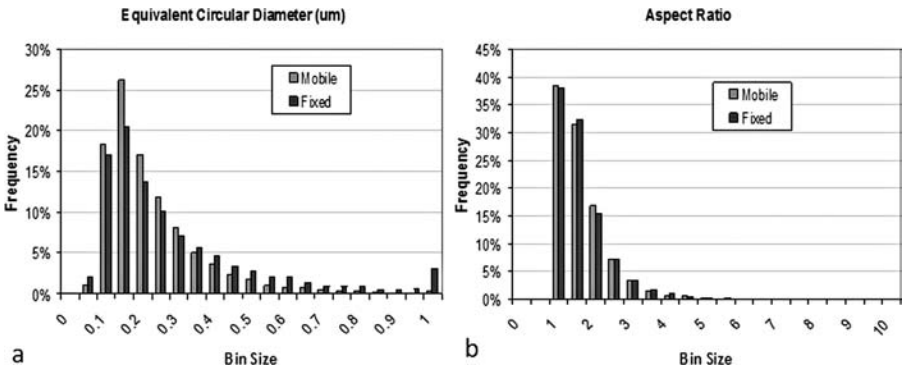

FIG. 6—*Distribution of (a) equivalent circular diameter and (b) aspect ratio of wear particles generated during in vitro testing of mobile- and fixed-bearing knees.*

demonstrated a tibial radiolucency greater than 2 mm in either the anterior-posterior or lateral view. Tibial radiolucencies in the lateral view were more common at the cement-bone interface than in the prosthesis-cement interface for both anterior-posterior and lateral views. One knee in the fixed-bearing group demonstrated a femoral radiolucency greater than 2 mm in lateral view. Lateral radiographs revealed that femoral radiolucencies were more common at the cement-bone interface than the prosthesis-cement interface. The average range of motion improvement in both device groups was 16°. The mean active range of motion increased from 110.8° to 127.0° in the mobile-bearing group and from 110.7° to 127.2° in the fixed-bearing one. Range of motion improvement in this study is comparable to the improvement reported by Tarabichi et al. [29] even though the preoperative flexion of the patients in that study was higher.

Discussion

The controversy about the wear advantages of mobile-bearing over fixed-bearing knees persists because in situ clinical, retrieval, and in vitro studies have, so far, produced inconclusive results. This study found no statistically significant difference in the in vitro wear rates under the simulated kinematics or in the 2-year clinical outcome of both design, in agreement with previous studies [8,9,30]. The curvilinear scratches observed on the mobile-bearing tibial trays (and on the femoral condyles) during in vitro testing were most likely caused by errant particles that dislodged from the bone cement mantle used to attach the femoral components and tibial trays to the test fixtures. Such particles embedded in the polyethylene or lodged between the tibial tray and the backside of the polyethylene insert may have scratched both surfaces as the inserts underwent rotational motions during wear testing according to the design intent of the device. The bone cement used in this study contained hard radiolucent ZrO_2 particles which can readily scratch CoCr alloy surfaces. Atwood et al. [11] observed curvilinear scratches on explanted CoCr alloy tibial tray surfaces of LCS-RP knees and postulated them to be caused by particles of bone, bone cement, or porous coatings. Advances in UHMWPE manufacturing, sterilization, and packaging technologies have significantly improved the wear and delamination resistance of UHMWPE tibial inserts which may make it difficult to differentiate between the polyethylene wear in both designs. Further wear reduction and oxidative stability of polyethylene inserts in mobile knees may be achieved through the use of irradiation-crosslinking and vitamin E (α-tocopherol) doping [31–33]. This study shows that both designs generate mostly sub-micrometer particulate debris with overlapping equivalent circular diameters and aspect ratios in agreement with published in vivo and in vitro data [34,35].

There are several limitations to this study. Only walking gait and not the more demanding higher load and range of motion activities such stair climbing or deep squatting was simulated. This may explain why the wear scars observed in this study are posteriorly located and do not sweep across the entire insert surfaces as observed in most clinically retrieved components. Nevertheless, this study provides adequate comparison wear data on the two designs when subjected to identical kinematics. Recent in vitro data [31] showed significant increase in wear of aged

polyethylene inserts during deep squatting (155° flexion) in cruciate retaining fixed-bearing knees. The fluoroscopic studies of Dennis et al. [24] showed that mobile knees experience higher tibio-femoral rotations during deep knee bend. The effects of higher loads and rotations of the insert relative to the tray on wear of mobile-bearing knees during squatting are not quantified in this study.

This study does not differentiate the wear or wear debris from the back and front articulations. However, the front and backside wear footprints on both designs and the distribution of wear debris from both designs were similar. It can be argued that it is the total polyethylene wear volume and shape and size distribution of wear debris that determine the potential for osteolysis rather than the provenance of the particles. Some extra wear may have occurred on the backside of the mobile-bearing knees due to the presence of third body particles that scratched the tibial tray surfaces. This may account for the arithmetic difference between the observed wear rates; however, both are statistically equivalent. The 2 year follow up study results showed that 4 knees (1 mobile bearing and 3 fixed bearing) had tibial radiolucencies greater than 2 mm. 1 fixed bearing knee demonstrated a femoral radiolucency greater than 2 mm in lateral view. The clinical performances observed in this study are in agreement with previous studies. Nakamura et al. [36] evaluated 20 LPS-Flex Mobile patients fluoroscopically during weight-bearing single-leg stance, 90° flexion kneeling, and maximum flexion kneeling. The subjects averaged 125° flexion during maximum flexion kneeling. The fluoroscopic study of Dennis et al. [37] wherein 97 post-TKA patients with four different prosthesis designs implanted by six different surgeons were analyzed during a deep knee bend from full extension showed that LPS-Flex Mobile Bearing and LPS-Flex Fixed Bearing knees achieved average weight-bearing flexion of 125.4° and 116.3°, respectively.

In conclusion, the results of this study strongly suggest equivalent wear performance when both designs are subjected to identical walking gait load and kinematic waveforms. With the improved polyethylene processing, sterilization and packaging technologies, the clinical success of either bearing type may be more dependent on implant designs, surgeon experience, surgical techniques, and is probably patient specific. Proving the postulated long term benefits of mobile knees may require decades of clinical follow up studies particularly in young active patients.

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Clinical Results of a Total Knee Prosthesis with Floating Platform at 5.5 Years

ABSTRACT: In this study, 117 patients who had received the e.motion FP prosthesis between 2001 and 2003 were followed up for 5.5 years to assess the clinical and radiological outcomes and survival of this mobile platform prosthesis. As this design is intended to improve the mobility of the replaced knee, particular emphasis was placed on the clinical and functional results. The hypothesis was that they would be comparable to the excellent results reported in the literature of state-of-the-art total knee arthroplasty. After 66 months, the average Knee Society clinical and functional scores were 93.8 points (KSS-C) and 90.5 (KSS-F) points, respectively. The clinical and radiographical results were excellent, with a low rate of anterior knee pain of 2.3 %.

KEYWORDS: mobile bearing, floating platform, TKA, range of motion, anterior knee pain

Introduction

Arthritis of the knee joint is widespread with almost one-tenth of the population older than 55 years suffering from it [1]. This percentage will probably grow continuously due to a longer life expectancy and the tendency to overweight.

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Total knee arthroplasty (TKA) is a proven treatment for patients with advanced degenerative cartilage as it can relieve pain, correct deformities, and sustain or restore mobility [2]. Knee endoprostheses with a symmetric tibial inlay, firmly attached to the tibial plateau, have shown good long-term results. However, complications have also been observed relating to patello-femoral articulation, polyethylene wear, osteolysis, as well as aseptic loosening [3–8].

These undesired side effects have prompted the development of new prosthesis designs. To replicate the natural rolling and gliding movements within the knee joint, the fixed bond between tibial inlay and tibial plateau was replaced by a mobile polyethylene inlay. The basic idea of these "mobile bearing" knees, known since the end of the 1970s [9], is to reduce peak tension between the polyethylene components by maximizing surface contact between the femoral component and the tibial inlay. Therefore the mobile bearing knee shows mainly abrasive wear, whereas the fixed bearing knee shows more pitting and delamination on the upper tibial inlay surface due to higher contact stress with low surface contact [10]. Only a few prospective, randomized studies have shown actual benefits [11]. The clinical results seem to be comparable to those of the fixed bearing TKA [12].

Theoretically, rotational mobility should allow the implant to self-align and accommodate small rotational misalignments in component placement, reducing the pressure between femur and patella and leading to better pain-free patellar tracking. A recent in vitro study reported a lower femoro-patellar pressure in a mobile bearing knee prosthesis [13], which was confirmed clinically by Breugem et al. [14].

The purpose of this study was to evaluate clinical and radiological data at mid-term follow-up on a new prosthesis design with mobile bearing, focusing on the overall functional and clinical results. The hypothesis was that clinical results would be comparable to those of modern state-of-the-art arthroplasty.

Materials and Methods

Demographic Data

Of the first 130 patients who had received the new prosthesis, 117 of them were reviewed after an average of 66.4 months (minimum = 54.8, maximum = 78.3 months, standard deviation (SD) = 5.7). There was no selection criteria, every patient scheduled for TKA being included in the review. There were 80.3 % women ($n = 94$) and 19.7 % men ($n = 23$) with a mean age at surgery of 65.1 years (SD = 10.6), body height of 167.6 cm (SD = 9.5), and body weight of 79.3 kg (SD = 17.2). Average body mass index (BMI) was 28.1 (minimum = 18.6, maximum = 45.3, SD = 5.4). The implantations were performed on 66 right and 51 left knee joints (56.4 %/43.6 %). None of the patients received a knee prosthesis in her/his second knee during the follow-up.

There were 82 patients (70.1 %) with primary gonarthrosis, 28 (23.9 %) with rheumatoid arthritis, 3 (2.6 %) with post-traumatic osteoarthritis, 2 with psoriatic arthritis (1.7 %), and 2 with other diagnoses (1.7 %).

The implant used was a cemented version of the e.motion FP knee prosthesis (BBraun Aesculap AG, Tuttlingen, Germany, see Fig. 1) with a floating platform

FIG. 1—*The e.motion floating platform knee prosthesis.*

that allows both an axial rotation of ±15° and a controlled anterior–posterior (4.5–8.0 mm) and medio–lateral (2.0–4.0 mm) translation between the polyethylene inlay and the tibial platform [15]. A hook-shaped peg limits the movement of the onlay in order to prevent dislocation and interaction of the patella tendon with the polyethylene inlay. The congruency of the femoral component with the polyethylene inlay is significantly larger than in a conventional fixed-platform design. The distal radius of the femoral component remains constant through 90° of flexion, which provides the large contact areas also for activities like sitting or kneeling and might contribute to an improved longevity of the implant. The system was designed to permit a range of motion between 5° of hyperextension and 150° of flexion.

Two TKA-experienced orthopedic surgeons (UC, RKM) performed the surgery under general anesthesia and used a navigation system (OrthoPilot, BBraun Aesculap AG, Tuttlingen), described previously [16]. A preoperative dose of a second-generation cephalosporin (Zinacef; GlaxoSmithKline, Zeist, The Netherlands) was administered preoperatively to all patients. After applying a tourniquet, the surgeons used a midline skin incision with a standard medial parapatellar approach in all patients. The patellae were everted to the lateral side. The femoral and tibial bones were resected under navigation control. The desired alignment angle was always 0° between the mechanical tibial and femoral axis. The rotational alignment of the femoral component was achieved by balancing the flexion gap and further cross-checked against Whiteside's line. Patellae were treated by resecting osteophytes and a circumferential denervation to prevent anterior knee pain. Twenty-six patients received a patellar implant during the primary TKA procedure. There was no special indication compared to the patients receiving circumferential denervation. All prosthesis components were cemented. Patellar tracking was adjusted by an appropriate soft tissue balancing.

All patients underwent the same postoperative treatment. They received a low vacuum drain for 48 h. On the third postoperative day, they began continuous passive motion. For prophylaxis, they were given a low-molecular-weight heparin for 6 weeks. They were supervised by a physiotherapist from the first postoperative day on. They were discharged when they were able to bend the knee actively in greater than 90° flexion and walk independently with crutches. After discharge, they continued physiotherapy at home to improve function and independent walking.

Follow-Up Times

Out of the initial 130 patients invited to a follow-up examination to assess the clinical and radiological outcome, 117 patients completed postoperative follow-up examinations at 1, 3, and 5 years. Only 5 patients did not attend any follow-up assessments. The average follow-up period was 66.4 months (SD = 13.9 months; range = 6–78).

Results

Drop Outs

Thirteen patients were classified as dropouts. Seven patients dropped out of follow-up for personal reasons because they had moved, were untraceable, or unwilling. Four patients underwent a revision (two due to infection, one due to aseptic loosening, and one exchange of the polyethylene inlay due to an instability). Two patients died, both of causes unrelated to the knee replacement. The revisions were treated as treatment failures.

Six patients dropped out after the initial examination, eight after the 1-year follow-up examination.

Pre- and postoperative Knee Society Score

The preoperative clinical Knee Society score (KSS) (KSS-C) averaged 48.6 points (minimum = 19, maximum = 90, SD = 13.9), and the functional KSS

(KSS-F) 49.9 points (minimum = 10, maximum = 90, SD = 11.2). Before operation, the total KSS was 98.6 points on average (minimum = 60, maximum = 164, SD = 18.7, see Fig. 2(*a*)).

After 5.5 years, the total Knee Society score (Fig. 2(*b*)) was 184.3 points on average (minimum = 120, maximum = 200, SD = 18.7) made up of the KSS-C of 93.8 points (minimum = 46, maximum = 100, SD = 8.8) and the KSS-F of 90.5

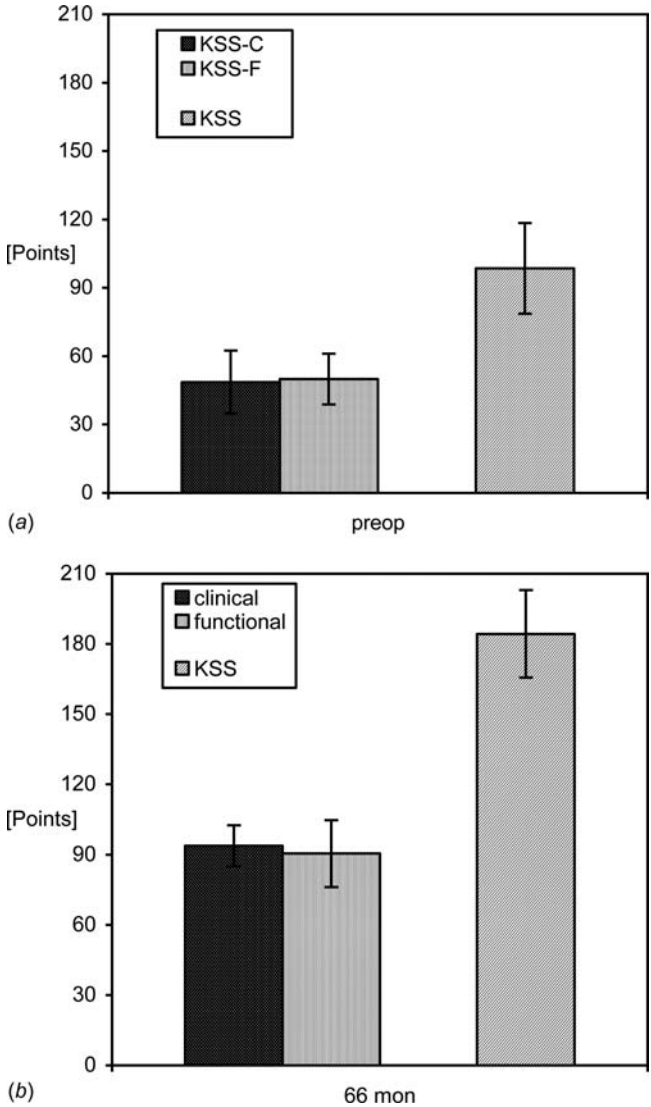

FIG. 2—*(a) Average preoperative clinical (KSS-C), functional (KSS-F) and total Knee Society score (KSS); (b) average postoperative Knee Society scores (at the 5.5-year follow-up).*

points (minimum = 50, maximum = 100, SD = 14.3). The KSS-C increased by 45.2 points, the KSS-F by 40.5 points. The total KSS improved by 85.7 points.

The preoperative range of motion averaged 107.7° (minimum = 40°, maximum = 135°, SD = 18.0) and improved to an average 121.3° (minimum = 80°, maximum = 140°, SD = 10.3) at the 5.5-year follow-up. The range of motion of all patients is depicted in Fig. 3(*a*). Of the knees, 74.3 % had a range of motion of 120° or more (Fig. 3(*b*)).

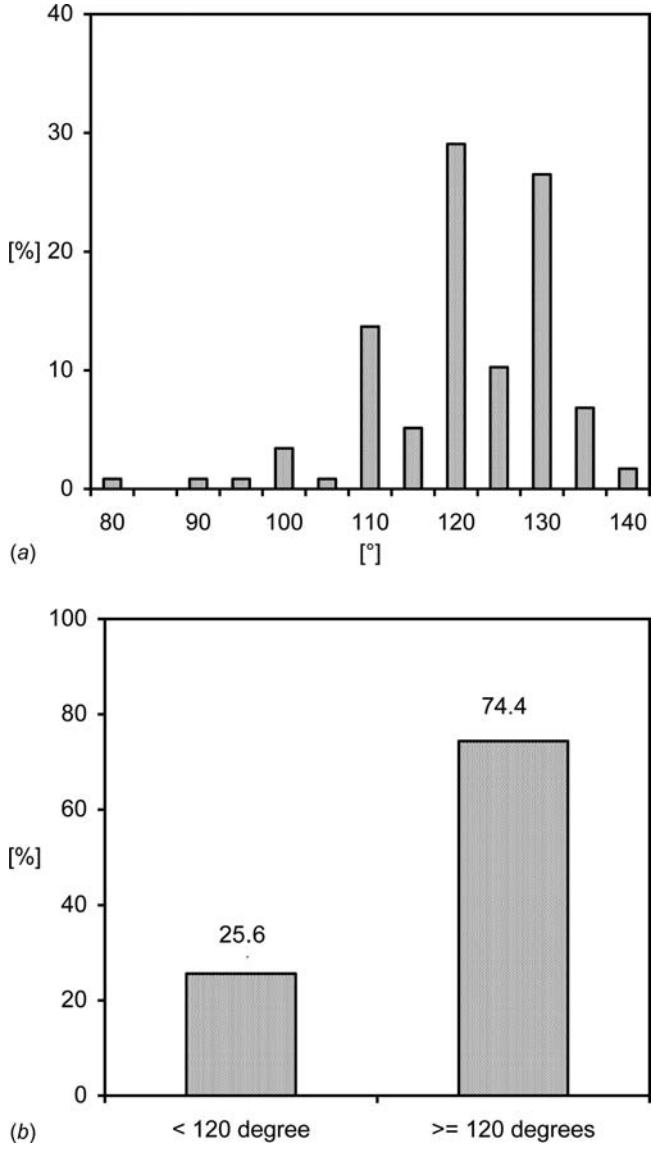

FIG. 3—*(a) Postoperative range of motion; (b) postoperative range of motion groups.*

In some patients, the functional results were adversely affected by significant pathological changes in neighboring joints and the spine. Nineteen patients suffered from degenerative changes in the lumbar spine, and two had to undergo a fusion of the lumbar spine. Seven patients had coxarthrosis of the ipsilateral hip and four of the contralateral hip. In 36 patients, the contralateral knee required treatment.

Complications

Immediately after operation, one patient developed a superficial wound healing disorder that was treated by secondary suture and another developed a deep vein thrombosis (early complication rate 1.5 %). Four patients had their knee mobilized under analgesia during the third postoperative week. Three patients complained of anterior knee pain and required an additional lateral patellar release.

The implant-related complication rate was 3.8 % in five patients (three patients with anterior knee pain, one aseptic loosening, and one instability of the meniscal bearing component that lead to revision).

Discussion

Controversy exists regarding the differences in outcomes between fixed and mobile bearing total knee replacements. Knee replacements based on the mobile bearing concept showed very good clinical results and high survival rates [17]. However, there is no proof that longevity and clinical results are superior to those of fixed bearing knees [18].

Theoretical and empirical benefits from a mobile bearing knee stem from an ability to better reproduce the natural knee kinematics during gait and "self-alignment." In a recent clinical study, fixed bearing total knees demonstrated significantly less rotation than a healthy knee [19]. Combined with misalignment of the femoral and tibial component, restricted rotation can cause serious patellofemoral problems [20]. Self-adjust to a limited extent, might avoid patellofemoral problems as shown in vitro [13] and in vivo [14]. This study included a high percentage of unresurfaced patellae (80 %) with a low rate of anterior knee pain (2.3 %). These results suggest improved mobility of the tibial inlay to adjust to the individual patellar track of the patient. Forster [21] reported a revision rate as high as 11 % due to anterior knee pain in unresurfaced TKA patients in a fixed bearing prosthesis.

A third factor in favor of mobile bearings is reduced polyethylene wear that, at high rates, led to aseptic loosening in hip [22–24] and knee endoprosthetics [25]. Better wear behavior of mobile bearing knee prostheses was shown in vitro [26–29]. Morra et al. [30,31] demonstrated in vitro the influence of lower contact stresses for the mobile bearing prosthesis model used in this study, i.e., less wear and subsequently less polyethylene particles.

At 55- to 78- month follow-ups, this study reported good functional results with a KSS-F value of 90.5 points. In addition, more than 74 % of the patients experienced a good range of motion with flexion of more than 120°. In an East

Asian population, Kim demonstrated an average range of motion of over 130° with the PS version of the same prosthesis model [32]. In traditional fixed bearing knee prostheses, the range of motion seldom achieves more than 110° to 115° [33–36] although certain activities of daily life require higher flexion. For example, ascending and descending stairs requires 90°–120° of flexion; getting in and out of a bathtub up to 135° [37]; and cultural and religious activities such as squatting, kneeling, and cross-legged sitting up to 165° [38].

The present study report is the first collection of mid-term clinical and functional results for this new mobile bearing prosthesis concept, an important look at the clinical performance of a new implant concept. This study demonstrated low rates of device-related complications and revisions at an average 5.5 years of follow-up. Clinical outcomes also reported KSS scores comparable to those reported in the literature and good postoperative range of motion and a lower rate of anterior knee pain. However, these results are early and longer term studies of a higher level of evidence, preferably randomized, are necessary to substantiate the findings in this study [39].

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Damage and Wear: An Important Distinction in Rotating Platform Knee Bearings

ABSTRACT: Rotating platform mobile bearing knees are an appealing approach to the problems of tibial loosening and rotational malignment in fixed bearing knees. A potential disadvantage is the additional large articular surface that accommodates tibio-femoral rotation. Accurately assessing the tribological performance of this additional articular surface is important to understanding how mobile bearings perform in terms of generating polyethylene wear debris and associated osteolysis. A series of 76 retrieved Sigma Rotating Platform bearings were assessed for damage rating according to conventional protocol and through-thickness wear measurements were taken. The results show that the rotation surface of these bearings is very commonly subject to moderate and severe damage and that damage can occur early following implantation. The decrease of the through-thickness dimension is strongly correlated with time in vivo. The rotation surface damage rating shows a weak though statistically significant correlation to through-thickness wear. Three dimensional surface profilometry on the bearings illuminates phenomena that can explain the paradoxical observations that severely damaged bearings may not be worn and worn bearing areas are smoother and show less damage than unworn areas. This study finds that bearing damage is distinct from bearing wear and the two terms are not interchangeable in the context of assessing material loss from artifi-cial knee bearings. While both processes are important in the tribology of knee devices, it is not accurate to use damage on ultrahigh molecular weight polyethylene as a proxy for wear.

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KEYWORDS: knee wear, UHMWPE wear, mobile bearing knees, backside wear, bearing damage

Background

Damage and wear are terms often used interchangeably in the evaluation of the performance of ultrahigh molecular weight polyethylene (UHMWPE) knee bearings. "Polyethylene wear" frequently is cited as the cause of device failure and revision by surgeons. This convention has arisen from the fact that most failures of early UHMWPE knee bearings were due to contact fatigue damage of the articular surface [1–5]. Fatigue failure (cracking or delamination) is often secondary to oxidation and can result in gross visible damage and large amounts of material removal, potentially altering the kinematic function of the device or causing catastrophic failure. Fatigue failure has been shown in all types of gamma-sterilized tibial inserts regardless of design, material, or method of fabrication [6] (Fig. 1). Adhesive/abrasive wear of the UHMWPE also occurs on the loaded articular surfaces of knee bearings and generates fine debris, but it is easily masked by the much more evident contact fatigue damage whereby large flakes of material are removed through delamination.

As contact fatigue failure has been addressed by efforts to minimize oxidative degradation of the polyethylene, more attention is being focused on the backside wear of knee inserts. It has been recognized that in modular knee bearings, backside wear mechanisms of abrasion and burnishing can produce small debris particles of the size implicated as the cause of osteolysis [7–9]. Other studies have documented the effect of backside wear on the locking

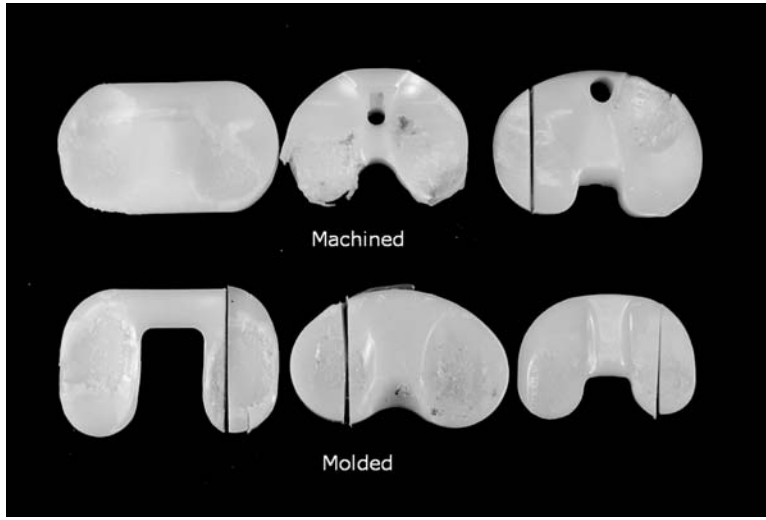

FIG. 1—*Fatigue failure occurs in most types of gamma-sterilized tibial inserts regardless of design, material, or method of fabrication: Machined (top row) or molded (bottom row).*

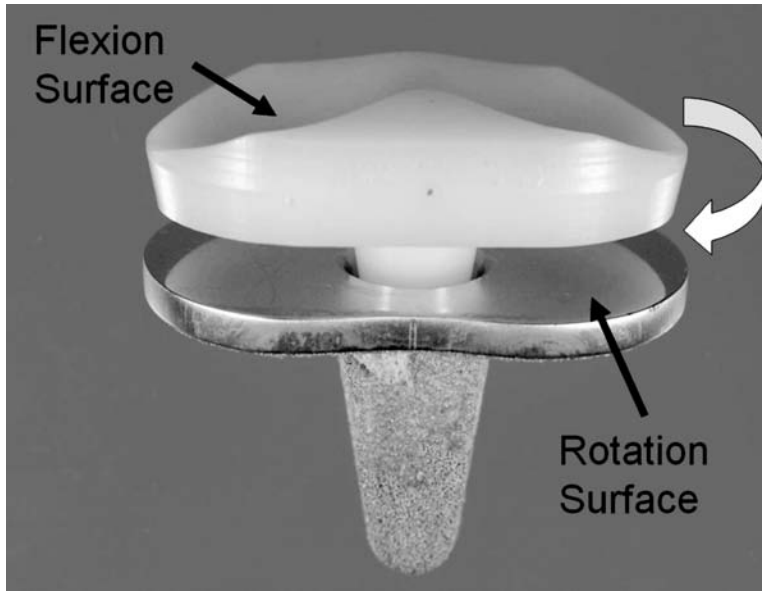

FIG. 2—*On rotating platform knee bearings, the top surface articulates against the femoral component and accommodates knee flexion and the bottom surface accommodates tibio-femoral rotation around a central peg that mates the UHMWPE bearing to the Co—Cr alloy tray.*

mechanisms for different modular knee systems, leading to increased bearing motion within the tray and resultant bearing wear [2,10–13].

Mobile bearing knees are an appealing approach to the problems of tibial loosening and rotational malignment. However, a potential disadvantage of mobile bearings is the additional articular surface of relatively large areal extent compared to fixed bearing knees (Fig. 2). The concerns about backside wear being a source of fine debris in knees warrants careful study of the tribological performance of the rotating platform mobile bearings to ascertain how they sustain damage and how they wear.

Materials and Methods

The knee bearings used in this study were a series of 76 Sigma Rotating Platforms (DePuy/J&J, Warsaw, IN) retrieved and sent to the authors' institution for analysis (Fig. 3). The average in vivo duration for the bearings was 36 months (range 0.4 to 105). 28 % (21/76) were of the Curved articular design and 72 % (55/76) were of the Stabilized articular design which incorporates a central post-and-cam mechanism to facilitate rollback of the femur on the tibial bearing during knee flexion. The counter-face for both the top bearing surface (the flexion articulation) and the backside (the rotation articulation) was a highly polished cobalt-chrome-molybdenum alloy (Fig. 3).

FIG. 3—*The Sigma® Rotating Platform knee in the current study. This example is a stabilized articular design that incorporates a central post-and-cam mechanism to facilitate the rollback of the femur on the tibial bearing during knee flexion.*

Each polyethylene tibial bearing was inspected visually using a dissecting microscope at 10 to 60 times magnification. The rotation surface of each component was rated for clinical damage on a scale of 0 (none) to 3 (severe) following the method described by Hood et al. [3].

White light interferometry was used to perform three dimensional (3D) surface profilometry on the backside (rotation surface) of the rotating platforms (NewView 7300, Zygo, Middlefield, CT). The profilometer depth resolution is <0.01 μm on the backside surfaces of UHMWPE knee bearing inserts.

The wear of the retrieved rotating platform bearings was determined by measuring the minimum thicknesses within the concave bearing areas on the medial and lateral sides, respectively, with a dial indicator. The wear penetration was calculated by subtracting the measured thickness dimension from the as-manufactured dimension provided by the manufacturer. This thickness

dimension has a manufacturing tolerance of +/−0.127 mm. The wear value for a given device is the average of the wear on the medial and lateral bearing areas. This method gives the total wear because it captures thickness changes due to wear both on the top flexion surface and the backside rotation surface.

The relationships between the bearing parameters and post-retrieval observations and measurements were performed using bivariate correlations in the statistical package SPSS v. 18 (PASW Statistics, Chicago, IL).

Results

The damage assessment of the rotation surfaces of the bearings gave the following distribution of ratings: 8 % (6/76) were rated 0; 51 % (39/76) were rated 1; 25 % (19/76) were rated 2; and 16 % (12/76) were rated 3.

The average linear wear of the bearings was 0.07 mm (the manufacturing tolerance of this thickness dimension is ±0.127 mm) and the average linear wear rate was 0.023 mm/year. Linear wear is shown to be correlated with time in vivo; Spearman's rho = 0.726, significance <0.0005 (Fig. 4).

The damage rating distribution as a function of in vivo duration of the bearings is shown in Fig. 5. The bivariate correlation for damage rating versus duration gives Spearman's rho = 0.259, significance = 0.029. The damage rating distribution as a function of average linear wear of the bearings is shown in Fig. 6. The bivariate correlation for damage rating versus linear wear gives Spearman's rho = 0.345, significance = 0.002.

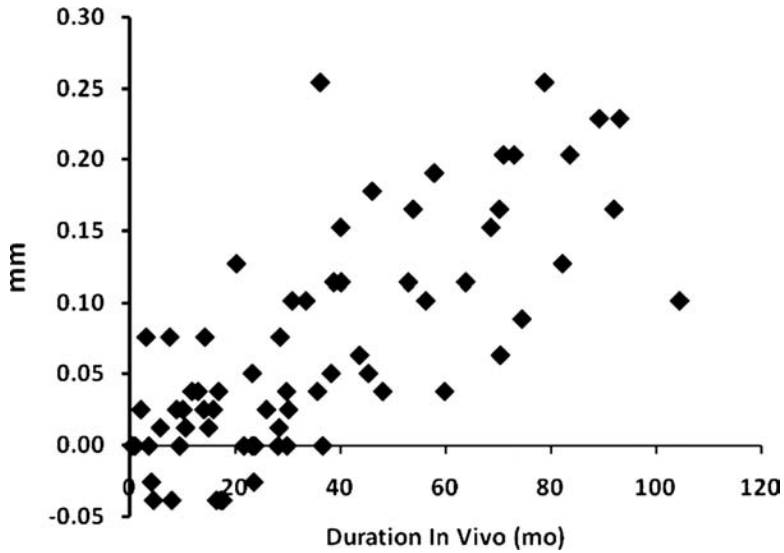

FIG. 4—*Linear wear penetration on both the flexion and rotation surfaces of the series of Sigma® Rotating Platforms versus duration in vivo.*

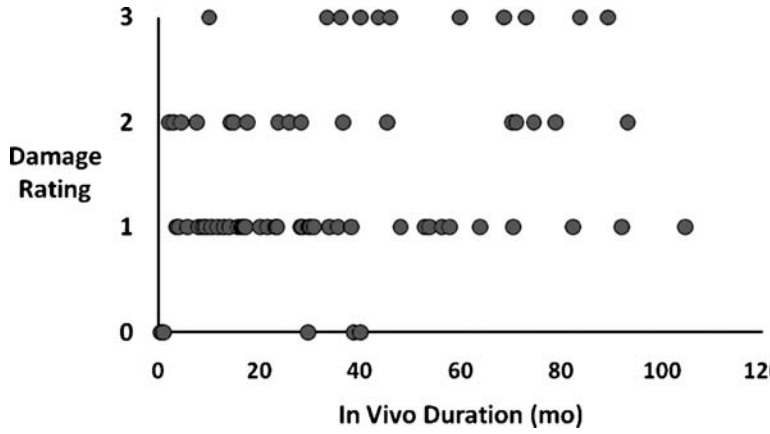

FIG. 5—*Damage rating versus in vivo duration for the rotating platform knee bearings.*

Discussion

The quantitative wear measurements indicate that the bearings are becoming thinner with time, as would be expected. Because the wear measurements are derived from through-thickness dimensions of the retrievals, the wear values include both wear on the flexion surface and wear on the rotation surface. Thinning of the bearing as measured by through-thickness dimension would also encompass plastic deformation of the polyethylene on both the top and bottom surfaces, and this deformation would not be distinguishable from wear (loss of

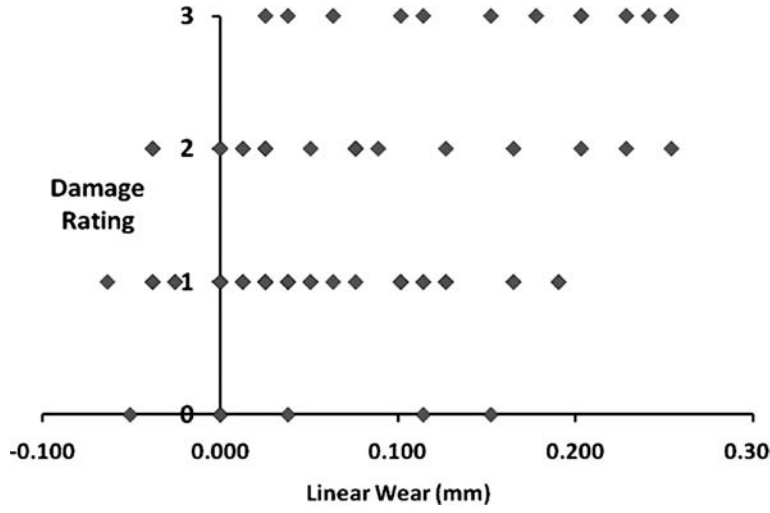

FIG. 6—*Damage rating versus measured linear wear penetration for the rotating platform series.*

material) given the method being used. It therefore follows that the backside (rotation surface) wear is less than the total measured wear.

The damage ratings on the rotation surface show a weak correlation with in vivo duration (Fig. 5). Although statistically correlated, damage rating is clearly not as closely related to in vivo duration (Spearman's rho = 0.259) as is wear (Spearman's rho = 0.726). It is reasonable to expect that with time in service, the damage on the bearing would increase and longer-term retrievals therefore would be more likely to receive higher damage ratings. That appears to be occurring, as indicated by the fact that no retrievals of a duration greater than 40 months received a rating of 0, and the highest rating of 3 are prevalent among the longer term retrievals in this series (Fig. 5). However, confounding this correlation is the fact that numerous cases of mild and moderate damage appear at very low in vivo durations (<20 months). Similarly, there is a high proportion of bearings with damage ratings of 2 and 3 that have very low or zero wear (Fig. 6). An example is shown by a 5.7 month retrieval with moderate damage and linear wear of 0.013 mm (Fig. 7).

The statistically significant correlation between wear penetration and damage rating indicates that they are related. The correlation coefficient (Spearman's rho = 0.345) indicates that about a third of the damage is accounted for by the measured wear. This means that damage is driven to a greater extent by factors other than wear.

The 3D high resolution surface profilometry helps illuminate the observation that the rotation surface experiences a lot of damage and deformation that is not explained by wear penetration. The features documented show phenomena that give rise to the apparent paradox that moderately and highly damaged

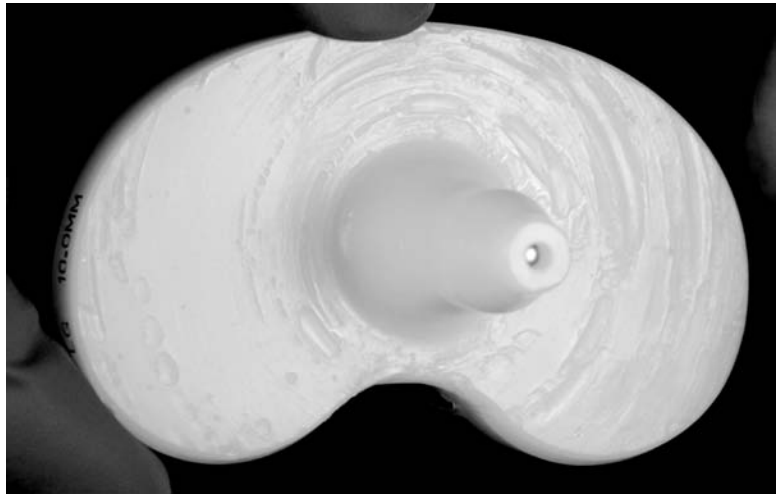

FIG. 7—*A retrieved rotating platform shows moderate rotation surface damage after only 5.7 months in vivo. Wear penetration on this bearing was 0.013 mm, well below the average of 0.07 mm for the series.*

surfaces often are not significantly worn. The rotation surfaces of the bearings are widely characterized by pits from the embedment of third body debris particles of bone cement and bone. These pits are numerous and readily visible, and therefore contribute strongly to a damage rating based on a visual image. Looking within the pits at high magnification, however, it is common for the original machining marks to persist right through the pits (Fig. 8). This is consistent with plastic deformation of the UHMWPE rather than material removal.

Evidence of an original machined surface that has worn very little is common even on rotation surfaces that have obviously been very severely damaged by extensive third body debris and entrainment (Fig. 9).

Many deformation features are shown to be comprised of both indentations into the original surface and raised edges where material has been plowed up at the margins (Fig. 10). This deformation profile is consistent with damage whereby a readily visible feature is formed but the UHMWPE surface is deformed and displaced locally with little actual loss of material.

Because the tibial trays are flat polished surfaces, raised features of several microns in height on the rotating platform will become the bearing area of the UHMWPE. The tops of the raised features will subsequently wear while shielding the surrounding topography from loaded articulation.

This phenomenon is depicted in Fig. 11 where a bearing showing mild damage (rating 1) has transitions between smooth regions, where the UHMWPE appears to have been worn smooth by abrasive/adhesive wear, and adjacent regions where the surface is notably rougher.

An aspect of the rotating platform bearing design that is likely important to its damage and wear and the relationship between the two phenomena is the circular unidirectional articulation. The very common arc-shaped grooves are often shown under close inspection to be a series of pits formed by a debris particle as it preferentially migrates or "ratchets" around the surface with gait cycle (Fig. 12). Pitting and scratching features that are formed in this way undergo subsequent articulation only along the direction that formed the feature; it does not undergo cross-shear motion. Multi-directional motion that crosses the texture of a surface feature is more effective in abrasively wearing the feature. This effect is exemplified by a fixed bearing in an earlier study [14] that had loosened in its tray such that multidirectional motion occurred (Fig. 13). This bearing was in vivo for 245 months, had an estimated backside wear of 0.5 mm, and yet had a smooth featureless surface under the loaded area. This bearing's backside surface is typical of fixed bearings in its extensive remodeling of the surface and its lack of features such as machining marks, discrete pits, and arc-shaped scratches with raised edges.

Summary

The investigation of this series of 76 Sigma Rotation Platform knee bearings indicates that the rotation surface of these bearings is very commonly subject to surface damage and this damage is frequently characterized as moderate to severe according to the conventional protocol of rating clinical retrievals. This

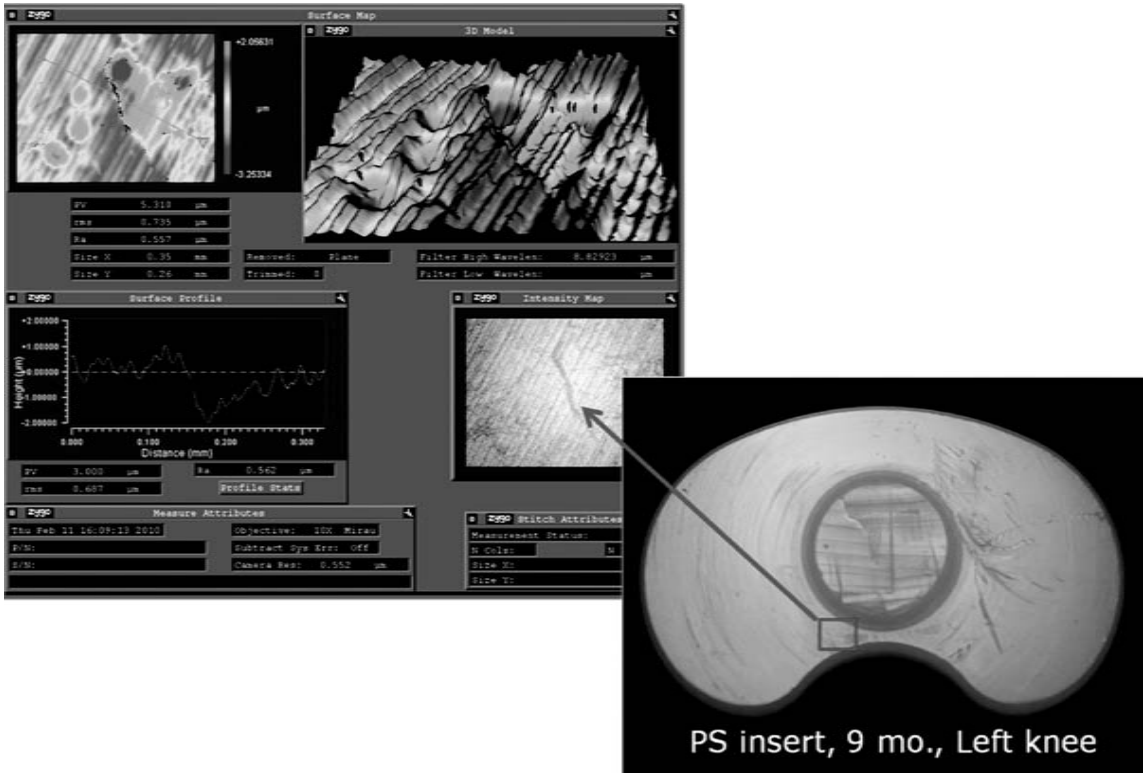

FIG. 8—*White light interferometer output and analysis. Analysis output layout, clockwise from upper left: Areal profile data in color spectrum; 3D perspective of topography; camera image of profiled area (grid appearance indicates stitched images); linear profile along trace indicated in upper left field, roughness calculations shown. Evidence of debris particles is almost ubiquitous on the backsides of mobile bearings. Debris particle embedment is common, characterized by discrete indentations with original machining marks persisting across them. This indicates plastic deformation of the UHMWPE surface rather than material removal.*

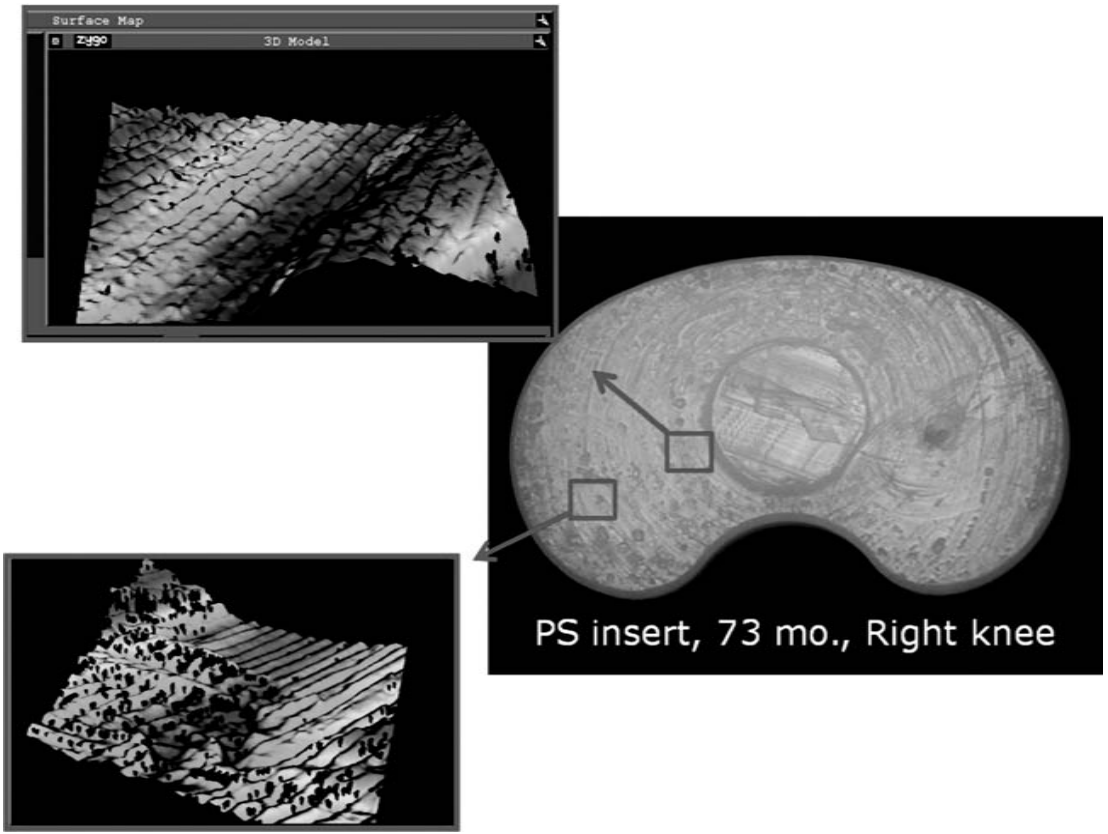

FIG. 9—*Severely damaged rotation surfaces of mobile bearings can show evidence of the original machined surface that has been significantly deformed locally from its original planar surface.*

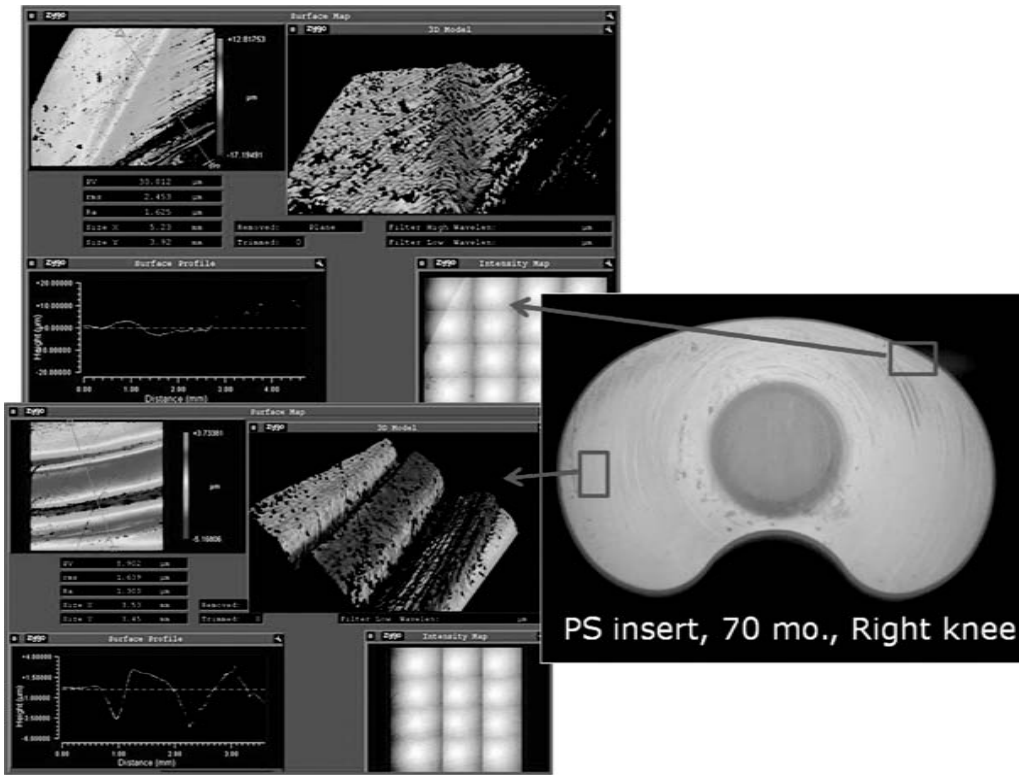

FIG. 10—*3D surface analysis of linear damage features shown to be indentations into the prevailing surface of the poly but with raised edges that represent material being plowed out of the valley (profile locations shown by trace in upper left of analysis windows; linear profile in lower left of analysis windows). The striking appearance and width of many scratches is produced by the indentation plus the raised edges on both sides.*

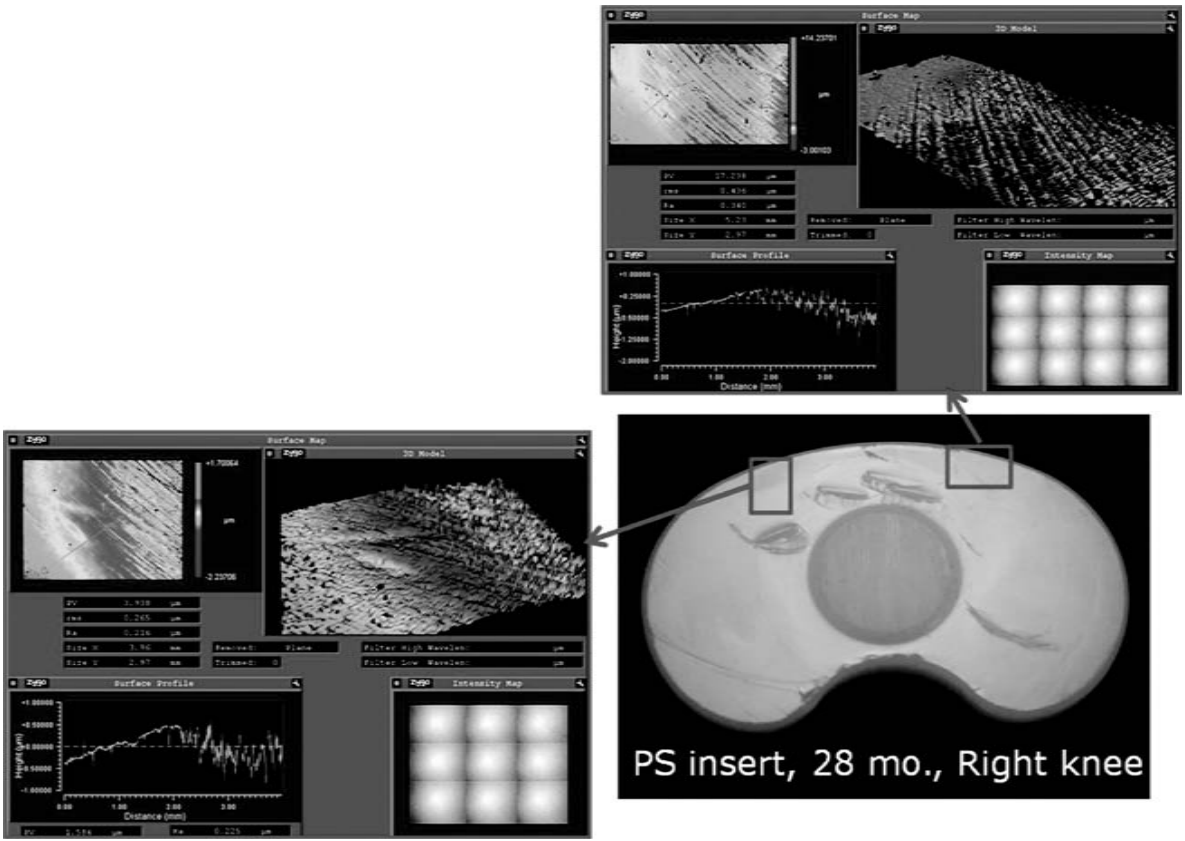

FIG. 11—*This bearing showing mild damage (rating 1) demonstrates transitions between regions that have been worn smooth by abrasive/adhesive wear and adjacent protected regions where the surface is notably rougher.*

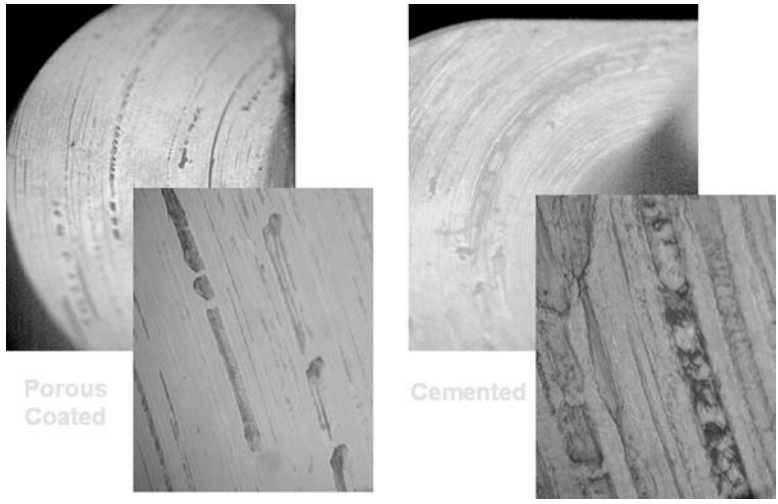

FIG. 12—*The arc-shaped scratches that appear on many rotating platforms are shown to be a series of distinct particle embedments formed as a particle gets "ratcheted" around in a circle. We see this in a similar fashion on both cemented (right) and porous coated (left) knees.*

level of damage can occur early following implantation. The wear of this series of bearings, as measured by change in through-thickness dimension, is shown to increase with time in vivo. Wear is correlated with rotation surface damage rating with statistical significance, though that relationship is relatively weak. Surface profilometry on the bearing surfaces illuminates phenomena that help explain the paradoxical observations that severely damaged bearings may not be worn and worn bearing areas are smoother and show less damage than unworn areas.

Aspects of rotating platform knee design likely play a role in their distinct wear and damage behavior: Third body debris has relatively easy access to the rotation surface to create damage features; the relative motion of the UHMWPE bearing and the tray is unidirectional with no cross-shear to facilitate the abrasive wear of existing texture/features; and the tibial tray has a highly polished surface that does not promote abrasive wear of the UHMWPE bearing.

The results of this study indicate that bearing damage should be considered distinct from bearing wear (loss of material resulting in UHMWPE debris) and the two terms are not interchangeable in the context of assessing the wear of artificial knee bearings. While both processes are important in the tribology of knee devices, it is not accurate to use damage on UHMWPE as a proxy for wear.

Study Limitations

This study considered a limited series of retrieved bearings, and as with any retrieval series, all the devices were surgically removed because of unsatisfactory

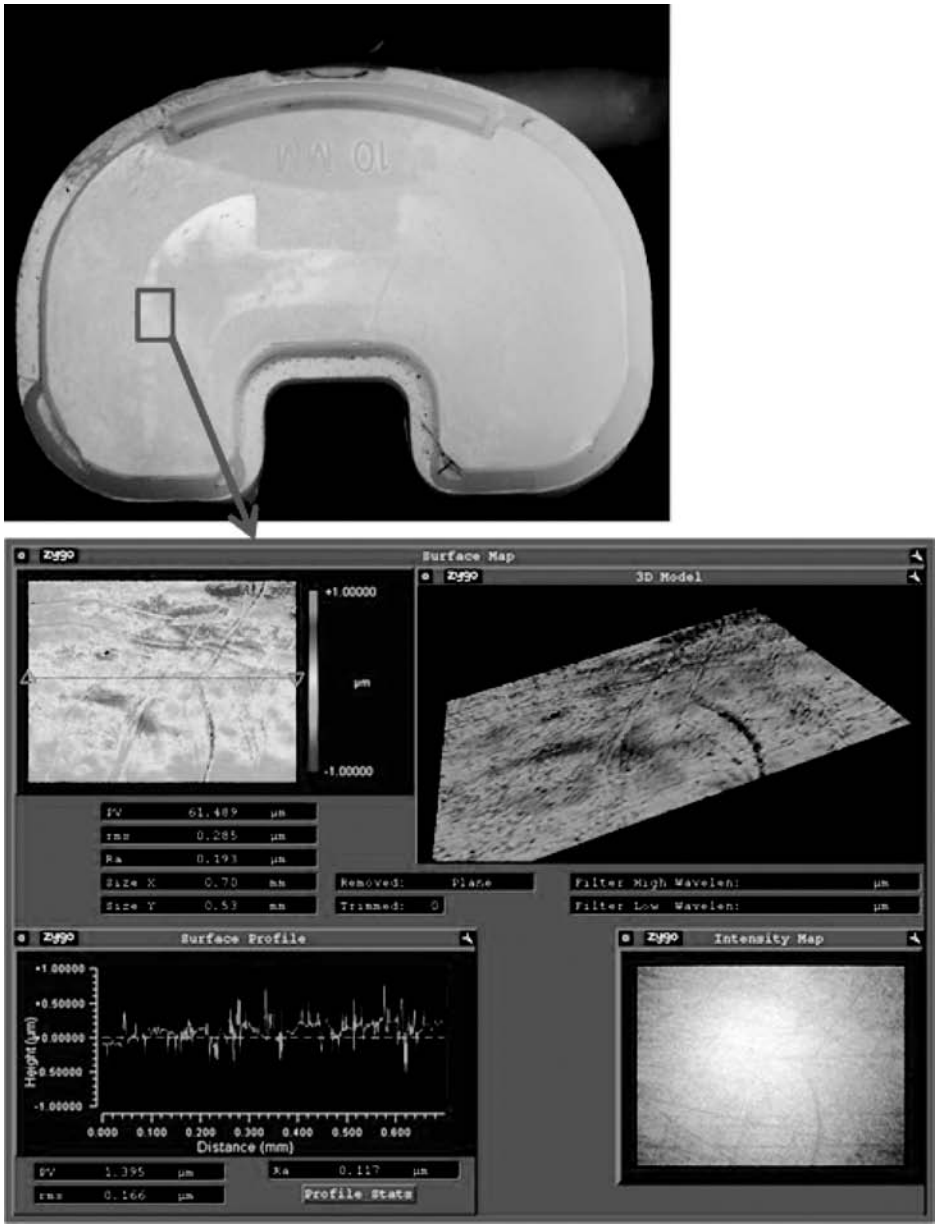

FIG. 13—*This PFC® fixed bearing insert was in vivo for more than 20 years and has an estimated backside wear depth of 0.5 mm yet has a smooth featureless backside surface under the loaded area.*

outcome in some regard. The time of implantation extends only to about 8 years and may not accurately reflect the experience of the population of these devices over the longer term.

The wear measured on this series included wear on both the top and bottom articulating surfaces and the surface damage focused on the bottom surface only. Thus, the quantity of wear does not correspond uniquely to the single surface being rated.

The images from the 3D surface profilometry are examples from a subset of the knees in this series. They are used to show examples of the phenomena being discussed and do not represent an exhaustive survey of all bearing surfaces.

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Wear Rate in a Series of Retrieved RP Knee Bearings

ABSTRACT: Rotating platform mobile bearing knees are an appealing approach to the problems of tibial loosening and rotational mal-alignment that are of concern with fixed bearing knees. A potential disadvantage of rotating platform (RP) bearings is ultra-high molecular weight polyethylene (UHMWPE) wear debris from the large additional backside articular surface that accommodates tibio-femoral rotation. The investigation of a series of 76 rotating platform knees (Sigma® RP, DePuy/J&J, Warsaw, IN) indicates that UHMWPE bearing wear, as measured by change in through-thickness dimension, increases monotonically with time in vivo. Total wear penetration rate is 0.023 mm/year and shows a decreasing trend, though this trend is not statistically significant. The current study results are consistent with the decreasing wear rate previously reported in a series of LCS® RP (DePuy/J&J, Warsaw, IN) knee. This decreasing wear rate stands in contrast to an increasing backside-only wear rate reported in fixed bearing knees. An important contribution of the current study is that it provides a conservative measurement of total wear penetration and penetration rate in one mobile bearing design over time out to >8 years.

KEYWORDS: knee wear, UHMWPE wear, mobile bearing knees, backside wear

Background

Polyethylene wear frequently is cited by orthopaedic surgeons as the cause of failure and revision of knee arthroplasty devices. Historically, most failures of early ultra-high molecular weight polyethylene (UHMWPE) knee bearings were

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due to contact fatigue damage of the articular surface [1–5]. Fatigue failure (cracking or delamination) is often secondary to oxidation and can result in gross visible damage and large amounts of material removal, potentially altering kinematic function of the device or causing catastrophic failure. As contact fatigue failure has been addressed by efforts to minimize oxidative degradation of the polyethylene, more attention is being focused on abrasive/adhesive wear. Abrasive/Adhesive wear is the process by which small particles of bearing material are generated at the contact surface and become fine debris. It has been recognized that in modular knee bearings backside wear mechanisms of abrasion and burnishing can produce small debris particles of the size implicated as the cause of osteolysis [6–8]. Other studies have documented the effect of backside wear on the locking mechanisms for different modular knee systems, leading to increased bearing motion within the tray and resultant bearing wear [2,9–12].

Mobile bearing knees are an appealing approach to the problems of tibial loosening and rotational mal-alignment that are of concern with fixed bearing knees. Knee replacements with rotating tibial platforms are a widely used type of mobile bearing device (Fig. 1). A potential disadvantage of the rotating platform (RP) knees is the addition of the large backside articular surface that accommodates tibio-femoral rotation. The concerns about backside wear being a source of fine debris in knees extend to RP knees and warrant careful study of their wear performance.

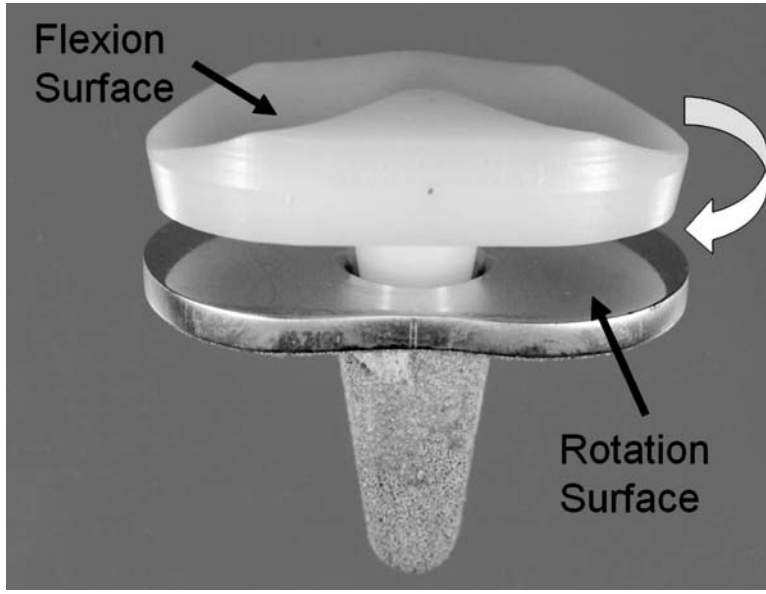

FIG. 1—*On RP knee bearings the top surface articulates against the femoral component and accommodates knee flexion, and the bottom surface accommodates tibio-femoral rotation around a central peg which mates the UHMWPE bearing to the Co–Cr alloy tray. The device shown is an LCS® RP (DePuy, Warsaw, IN).*

The quantitative measurement of wear on knee bearings presents difficult challenges, especially in clinical knee retrievals. Gravimetric methods are not useful with retrievals because reference weights are not known. Knee bearing inserts, by nature of their complex geometry, lack the intra-device reference frame provided by the spherical geometry of a hip implant. Geometry on the top side surfaces of knee inserts is complex, consisting of curved surfaces with sweeps and blends between them, usually with few reliable datum surfaces from which bearing thickness can be measured. Surface scanning and coordinate measuring machine metrology has been used with some success [13,14], but warping of the inserts from extended in vivo duration and from the process of retrieval can far exceed the dimensional changes due to wear, especially those due to adhesive/abrasive wear.

The current study measures wear in a series of retrieved RP knees using thickness measurements and corresponding design dimensions. These results are compared to previously published findings on wear of a different design of rotating platform bearings. Wear results from both mobile bearing series are considered in the context of a previously published study on backside wear on fixed bearing knees.

Materials and Methods

The knee bearings used in this study were a series of 76 Sigma RP® knees (DePuy/J&J, Warsaw, IN) retrieved and sent to the authors' institution for analysis (Fig. 2). The average in vivo duration for the bearings was 36 months (range of 0.4–105). Twenty-eight percent (21/76) were of the Curved articular design, and 72 % (55/76) were of the Stabilized articular design, which incorporates a central post-and-cam mechanism to facilitate rollback of the femur on the tibial bearing during knee flexion. The counter-face for both the top bearing surface (the flexion articulation) and the backside (the rotation articulation) was highly polished cobalt-chrome-molybdenum alloy (Fig. 2).

Wear of the retrieved RP bearings was determined by measuring the minimum thicknesses in the concave bearing areas on the medial and lateral sides, respectively, with a dial indicator (Fig. 3). Wear penetration was calculated by subtracting the measured thickness dimension from the as-manufactured dimension provided by the manufacturer. This thickness dimension has a manufacturing tolerance of $+/-0.127$ mm. The wear value for a given device is the average of the wear on the medial and lateral bearing areas. This method gives total wear penetration because it captures thickness changes due to wear both on the top flexion surface and the backside rotation surface.

The relationships between the bearing parameters and post-retrieval observations and measurements were performed using the statistical package SPSS v. 18 (Chicago, IL).

Results

Average linear wear of the medial condyle bearing areas was 0.072 mm and wear of the lateral condyle bearing area was 0.065 mm. The fit to a linear trend with time was similar for both the medial and lateral measurements (Fig. 4). A paired samples *t*-test showed there was no statistical difference between the

FIG. 2—*The Sigma® RP knee (DePuy) in the current study. This example is a stabilized articular design, which incorporates a central post-and-cam mechanism to facilitate rollback of the femur on the tibial bearing during knee flexion.*

medial and lateral wear measurements in this series ($p = 0.465$ at the 0.05 significance level).

The composite average wear including both condylar bearing areas was 0.07 mm. The composite average wear (Fig. 5) is shown to be correlated with time in vivo; Spearman's rho = 0.726, significance of <0.0005. The manufacturing tolerance for the thickness dimension being measured is +/−0.127 mm.

Average calculated wear rate was 0.023 mm/year. The correlation between linear wear rate and time in vivo resulted in Spearman's rho = 0.198, significance of 0.100 (Fig. 6).

Discussion

Wear penetration measurements showed that wear is a function of time, as would be expected. Consideration of the medial and lateral bearing areas

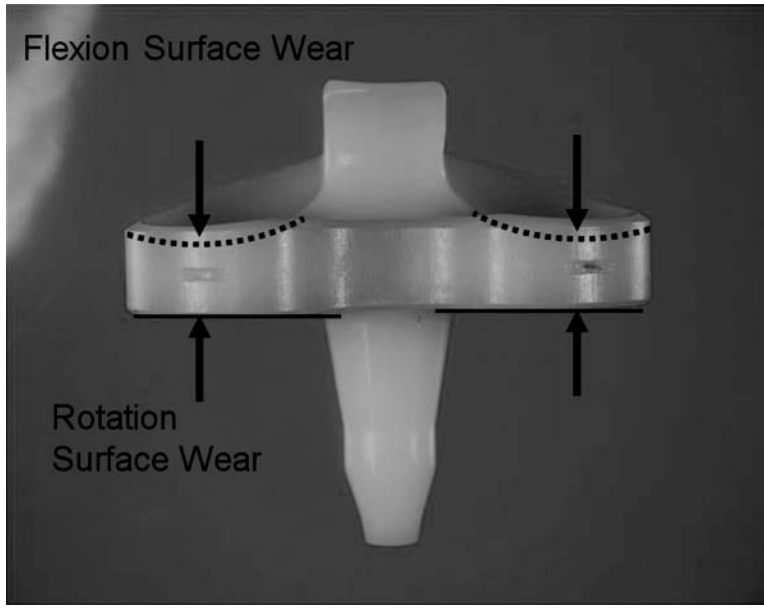

FIG. 3—*Wear measurements were made by measuring the thickness of the retrieved knee bearings at their thinnest point on both the medal and lateral condylar bearing areas, respectively, and comparing those dimensions to the specified minimum thickness from the manufacturer's design drawings.*

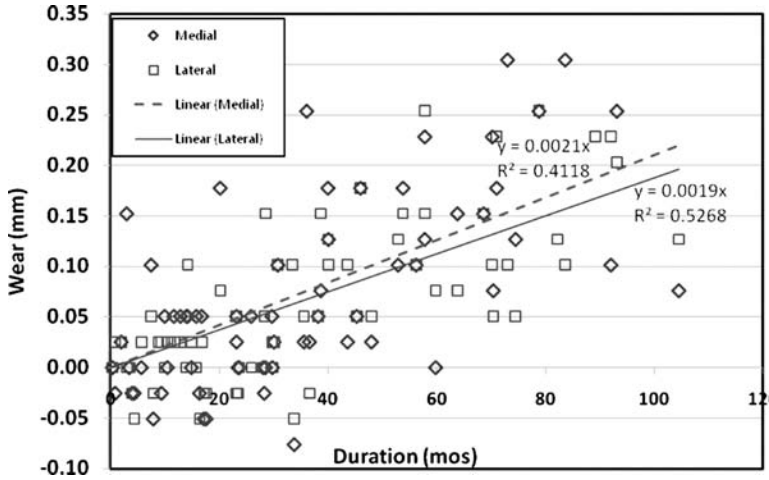

FIG. 4—*Bearing insert wear, defined as the specified minimum thickness of the insert in the medial and lateral condylar bearing areas at manufacture, minus the measured thicknesses of the inserts after retrieval. The manufacturing tolerance for the thickness dimension being measured is +/−0.127 mm. The decrease in thickness of the bearings for the medial and lateral measurement, respectively, are plotted versus in vivo duration of the device.*

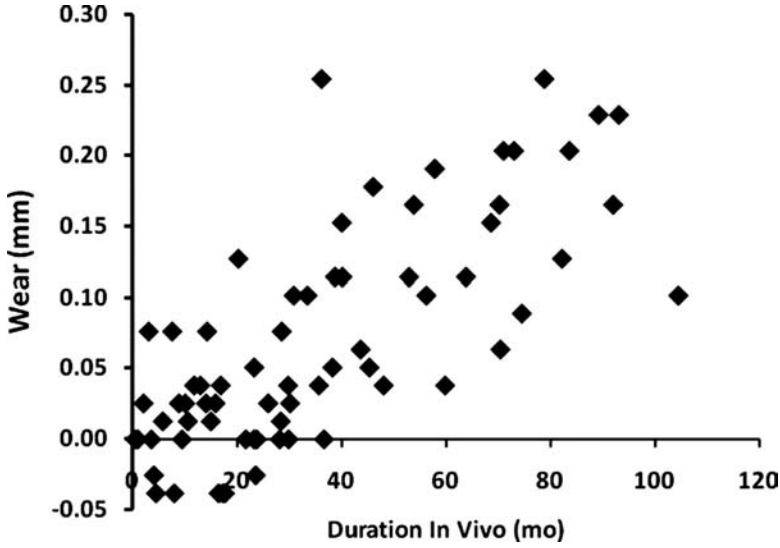

FIG. 5—*Composite wear penetration versus time in vivo of the series of Sigma® RP inserts. Wear included penetration on both the flexion and rotation surfaces, averaging medial and lateral bearing areas.*

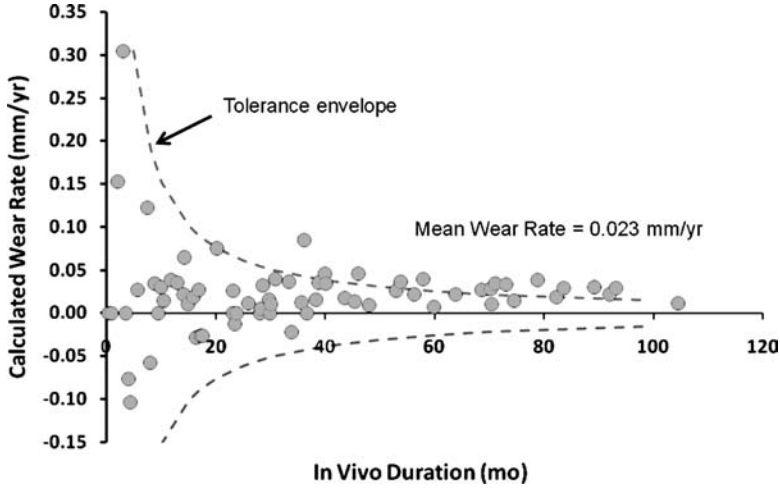

FIG. 6—*Linear wear rate for the series of Sigma® RP knees versus duration in vivo. The mean wear rate for the series is 0.023 mm/year. The tolerance envelope represents the apparent wear rate that would result from a device which had zero actual wear, but which had a thickness at the bounds of the manufacturing tolerance band (+0.127 mm, giving negative wear rate, and −0.127mm, giving positive wear rate).*

independently indicates that wear in each area increases with time. Statistical analysis indicates there is no medial - lateral bias in the measured wear in this series.

Most previously published work on clinical retrievals has focused on visual assessment of damage mechanisms following the protocol of the foundational work by Hood et al. [3]. This type of analysis on fixed bearing knees has indicated that the inserts in fixed bearing knees tend to wear more on the medial side. Cameron (1994) reported that in a small series of fixed bearing knees the wear pattern began in a posterior medial aspect, affecting rotational kinematics of the knee and leading to progressive wear in that location [15]. Wasielewski et al. (1994) reported similar observations of greater medial wear in a larger series (55 knees), however that study associated medial wear with the tighter pre-arthroplasty compartment and with pre-arthroplasty varus deformity [5]. An analysis of articular wear pattern asymmetry in a series of 94 fixed bearing knees by Currier et al. (2005) also indicated more severe damage ratings on the medial side [16].

Considering damage in mobile bearings, a recent study of 40 RPs by Garcia et al. (2009) [17] showed no significant difference in damage observed between the medial and lateral aspects of the bearings. This result held for both the proximal surface (flexion articulation) and the distal surface (rotation articulation) of those inserts.

All the aforementioned studies deal with visual damage assessment and do not present data on actual wear (i.e., loss of material). A study by Conditt et al. (2005) that used scanning technology to quantify volumetric backside wear on a series of 15 fixed bearing Anatomic Modular Knees (DePuy) showed significantly more volume loss on the medial aspect of the bearings than on the central or lateral aspects [14]. A previous study at the authors' institution reported quantitative material loss from backside wear in a series of 187 PFC® fixed bearing knees (DePuy) and showed more wear posteriorly and medially [18]. A study by Atwood et al. (2008) reported linear wear (thinning of bearings) in a series of 100 LCS® RPs and showed no medial-lateral difference in wear [19]. Thus the current study concurs with previous damage and wear studies on RP bearings in the observation of no significant medial-lateral bias. This result differs from the results of studies on fixed bearing knees which have addressed medial-lateral bias; those report a consistent bias toward medial side wear.

The average total wear penetration of 0.07 mm measured on this series of Sigma® RP knees agrees closely with the corresponding total penetration of 0.08 mm measured in the series of 100 LCS® RP knees reported by Atwood et al. in 2008 [19]. The mean in vivo duration for the LCS® series was 41 months, somewhat longer than the mean duration of 36 months for the current Sigma® RP series.

The wear rates in the current study (0.023 mm/year of penetration) is lower than the calculated wear rate of the LCS® series (0.06 mm/year) [19]. However, a graph overlaying the distribution of the wear rates from the two series shows important similarities (Fig. 7). Both series appear to have a trend of decreasing wear rate with increasing duration, though neither series shows a statistically significant relationship between wear rate and duration (current Sigma® RP

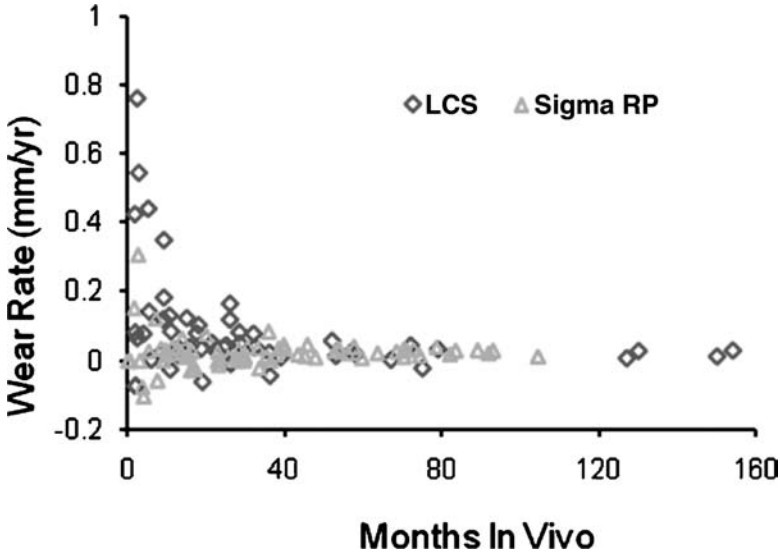

FIG. 7—*Linear wear rate versus time in vivo for the current Sigma® RP series and a series of LCS® RP knee bearings previously published by Atwood et al. [19].*

study: Spearman's rho of 0.198, $p = 0.100$; Atwood LCS® study: Spearman's rho of −0.128, $p = 0.334$). Both series show the largest calculated wear rates at short durations, and there are several factors which might contribute to this: (1) An initial "bedding in" period, such as that documented in hip wear studies [20,21], (2) thickness measurement error being more highly leveraged at shorter time in vivo, and (3) variation in bearing thickness within manufacturing tolerance being more highly leveraged at shorter time in vivo. The occurrence of negative wear rates for both series would indicate that measurement error and/or dimension tolerance are contributing factors in the relative high early wear rates. The effect that dimension tolerance at manufacture can have on calculated wear rate of the Sigma® RP series is shown in Fig. 6. All the wear rates for durations <3 years and all the negative wear rates at all durations fall within the envelope of apparent wear that could result from manufacturing tolerance.

A benchmark comparison can be made between wear rate in the current RP series and wear rate in the fixed bearing AMK® knees in the Conditt et al. study [14] by estimating an average linear penetration rate from the latter study. In that study the average volumetric wear rate was 138 mm^3/year. Although the implant sizes are not specified in that study, by measuring devices of that same design from the current authors' retrieval archive, the average area of the insert/tray interface is estimated to be in the range of 2200 to 3000 mm^2. This would give an average linear wear rate of 0.046–0.055 mm/year for that group of fixed bearing inserts, approximately twice the linear wear rate in the current Sigma® RP series (0.023 mm/year).

An informative comparison of wear rates over time is offered by considering the wear rates for the two mobile bearing series, LCS® RP and Sigma® RP, with

backside wear rate in the previously reported series of 187 PFC® fixed bearing knees (Fig. 8) [18]. The fixed bearing PFC® knees showed average backside wear penetration rate of 0.05 mm/year. An overlay of the calculated wear rates versus time in vivo (Fig. 9) shows that while both series of RPs fall within an envelope of decreasing wear rate over time, the fixed bearings increase in wear rate over time (Spearman's rho = 0.21, $p = 0.006$). It is important to note that the fixed bearing series data includes only backside wear and thus likely underestimates total wear penetration, whereas both RP series report total through-thickness wear.

The fixed bearing series in this comparison had a significantly longer average time in vivo (91 months, compared to 36 months for the Sigma® RP, and 41 months for the LCS® RPs), and had a large proportion of its sample population documenting wear out beyond 100 months, whereas the mobile bearings series show relatively few data in that range of duration. However, neither of the mobile bearing series had any of their longer term retrievals indicating an increasing wear rate with time, and the nature of their design does not point to a mechanism whereby abrasive/adhesive wear would be expected to make a significant upturn.

The increase in backside wear rate in the fixed bearings is consistent with the fact that the geometry by which the modular UHMWPE bearing locks into its tray can wear over time, allowing increasing relative motion and thus increasing wear. This process has been reported in numerous studies of modular fixed bearing knees. Parks et al. (2008) measured medial-lateral and anterior-posterior

FIG. 8—*PFC® Fixed Bearing knee, which had a titanium alloy tibial tray with a grit-blasted surface. Relative motion of the UHMWPE bearing insert and the tray has been shown to cause increasing wear rate of the bearing with duration in vivo.*

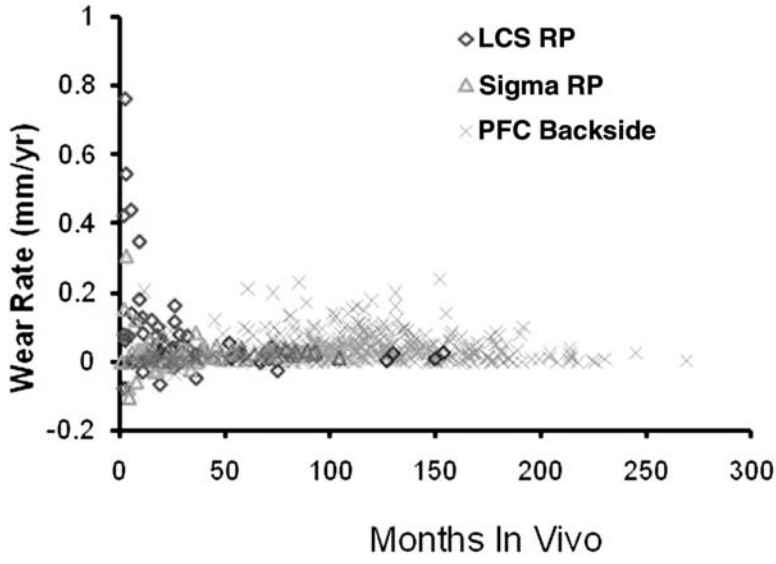

FIG. 9—*Wear rate for the LCS® and Sigma® RP series plotted alongside backside-only wear rate for the PFC® Fixed Bearing series previously reported [18].*

insert motion within tibial trays of nine contemporary modular knee designs and showed that, even in never-implanted devices, inserts shift hundreds of microns when shear force is applied [11]. Engh et al. (2001) extended this work using revised and post-mortem devices and found that the relative motions increased significantly with in vivo service, leading to increased wear over time [12]. Conditt et al. (2004) looked at retrievals from 12 different designs of modular knees and concludes that moderate-to-severe wear occurs on the backside of bearing inserts, independent of the capture mechanism in the tray [9]. The relationship between the amount of insert-to-tray motion and the severity of visually assessed wear modes was further established by Rao et al. [10].

In contrast to fixed bearing knee designs, the RPs have no insert/tray locking mechanism; both designs are allowed to rotate freely as knee kinematics require. In conjunction with this design approach, the tibial trays of both mobile bearing series have a highly polished cobalt-chrome alloy as a counter-face for bearing rotation. This aspect of the designs, specifically the highly polished tray surface, has been shown in other studies to significantly reduce backside insert wear [22,23]. A factor important to the wear of the fixed bearing series used for comparison here is that those devices had titanium alloy trays with a grit-blasted surface mated to the polyethylene bearing inserts (Fig. 8).

Although the RP inserts in the current series are designed to move on the trays, the central post (Fig. 2) constrains the relative motion to be unidirectional. This likely plays an important role in reducing wear on the rotation surface compared to the backside surface of fixed bearing knees that have much less extensive, but multi-directional motion. The increased wear of polyethylene

under conditions of multidirectional motion has been extensively documented by in vitro wear studies [22,24–27].

Summary

The investigation of this series of 76 Sigma® Rotating Platform knee indicates that UHMWPE bearing wear, as measured by change in through-thickness dimension, is shown to increase with time in vivo. Total wear penetration rate is 0.023 mm/year, and shows a decreasing trend, though this trend is not statistically significant. The current study results are consistent with those reported for a series of LCS® RP knees and stand in contrast to an increasing backside-only wear rate reported in a fixed bearing knee series. The calculated wear rate for the current series is consistent with the expected influence of measurement error and dimensional tolerance at short in vivo time periods.

The current study showed no medial-lateral bias in measured wear, which is again consistent with the previously reported RP series, and again stands in contrast to the medially biased patterns of both wear and damage reported for fixed bearing knees.

While modular fixed bearing knees employ locking mechanisms to affix inserts to the trays and prevent backside motion, RP knees readily allow motion on the rotation surface (backside), but constrain it to unidirectional motion. Thus there is no mechanism by which wear or other dimensional changes allow the insert to become looser, promoting increasing wear. The duration of retrievals in this RP series is shorter than the duration of previously published results on fixed bearing damage and wear, so although no mechanism of accelerating wear is evident, continued monitoring and measurement of retrievals is prudent.

Study Limitations

This study considered a limited series of retrieved bearings of one design. As with any retrieval series, all the devices were surgically removed because of unsatisfactory outcome in some regard. The time of implantation extends only to about 8 years, and therefore may not accurately reflect the wear performance over the longer term.

The wear measured on this series of bearings was aggregate wear penetration on both the top and bottom articulating surfaces because there are no known reference points on this bearing design to allow top and bottom wear to be distinguished. The effective area over which top and bottom surface wear act, respectively, are likely very different and therefore an accurate estimation of wear volume cannot be made.

Acknowledgments

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thank DePuy/J&J for providing the design and manufacturing data for the implants studied in this investigation, without which this type of clinical retrieval analysis is not possible.

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Wear of a Mobile Bearing Uni-Compartmental Knee Replacement Prosthesis: A Comparison of In Vitro and In Vivo Wear Rates

ABSTRACT: Wear induced osteolysis is cited as the primary cause of aseptic loosening in knee replacements. It has been postulated that mobile bearing (MB) knee prostheses reduce wear as they allow lower contact stress through high congruency between components while maintaining a wide range of joint motion. In vitro wear simulations are preclinical tests for predicting the performance of new designs of partial and total knee replacements. This study investigates the wear of a leading design of MB uni-compartmental knee replacement (UKR) by quantifying the in vitro wear rate and linear penetration of the polyethylene meniscal bearing. Three medial and three lateral MB UKRs (Uniglide, Corin, Ltd., U.K.) were tested in a three station wear simulator using force control as defined in ISO 14243-1. Volumetric wear was determined gravimetrically every half million cycles (MC) up to 10 MC. Maximum linear penetration wear was measured after 10 MC. Volumetric wear rates of 1.65 ± 0.28 mm^3/MC (mean $\pm$ SD) and 1.66 ± 0.31 mm^3/MC were recorded for the medial and lateral bearings, respectively, and the wear of all bearings was linear. Previous simulator studies have reported mean wear rates of 3.8 to 10.4 mm^3/MC for MB UKRs. Maximum linear penetration wear rates of 0.013 ± 0.001 mm/MC and 0.012 ± 0.001 mm/MC were recorded for the medial and lateral bearings, respectively, after 10 MC. This was in agreement with that reported for well functioning MB UKRs through in vivo measurement (0.01 mm/year) and compared favourably to that reported for fixed bearing designs (0.15 mm/year). The results of this study show that in vitro measurements correlate well to in vivo measure-ments of wear. This

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indicates that the current in vitro methodology for the simulation of wear in MB UKRs is a valid tool for preclinical assessment of MB UKR prostheses.

KEYWORDS: knee, arthroplasty, wear, uni-compartmental, replacement

Introduction

Uni-compartmental knee replacement (UKR) is becoming an increasingly popular alternative to total knee replacement (TKR). UKR is less invasive, allowing the preservation of the cruciate ligaments and neighbouring compartment. As a result, postoperative recovery times are reduced and the range of motion is better. As with TKR, wear-induced osteolysis as a result of polyethylene wear debris remains a major factor in the development of aseptic loosening following UKR [1–3]. Preclinical in vitro wear simulations are commonly used to predict the wear performance of new designs of partial and TKRs. It has been postulated that mobile bearing (MB) knee prostheses reduce wear as they allow lower contact stress through high congruency between components while maintaining a wide range of joint motion.

There has been minimal further investigation of the correlation between in vivo and in vitro rates of wear quantified using linear penetration and how they relate to volumetric wear rates predicted in vitro. This study investigates the wear of a leading design of MB UKR by quantifying the in vitro wear rate and linear penetration of the polyethylene meniscal bearing and a comparison is made with published in vivo data.

Materials and Method

Wear performance was evaluated using an EndoLab ISO 14243-1 knee simulator (Endolab, Rosenheim, Germany) with four active degrees of freedom. Three wear stations were run simultaneously as well as a loaded soak control station to allow fluid absorption to be accounted for in gravimetric wear analysis. The femoral components and tibial trays were cobalt chrome alloy. The meniscal bearings were machined from compression moulded GUR 1020 ultra high molecular weight polyethylene (UHMWPE) and sterilised in nitrogen using gamma irradiation to a nominal dose of 3.5 Mrad (Fig. 1). This resulted in moderate cross-linking of the UHMWPE. In total, three medial and three lateral replicate identical prostheses were tested to a maximum of 10 million cycles (MC). In each station, two UKR systems were mounted anatomically to simulate a bicondylar knee system.

A time-dependent force control routine as described in ISO 14243-1 (ASTM 1715) [4] was applied to the three wear stations. The axial loading curve had a peak load of 2.6 kN following heel strike and a minimum of 0.17 kN during the swing phase (Fig. 2(*a*)). The axis along which the axial load was applied was offset 7 % of the tibial width in the medial direction. The flexion-extension displacement cycle had a minimum of 0° at heel strike and a maximum of +58° mid-stance (Fig. 2(*b*)). The anterior-posterior (A-P) loading curve had a peak of −265 N directly following heel strike, which was then reversed to 110 N

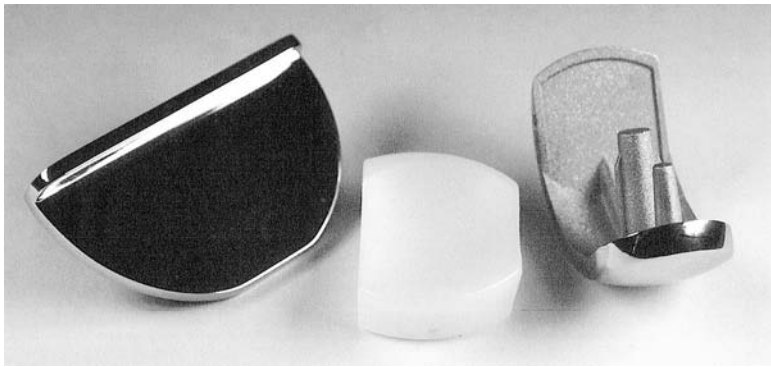

FIG. 1—*Uniglide UKR system. The picture shows the tibial tray (left), the UHMWPE meniscal bearing (middle), and the femoral component (right).*

(Fig. 2(*c*)). In addition, motion was constrained through a passive motion restraint of 30 N/mm that was proportional to A-P displacement. The internal-external torque curve had a minimum of −1 Nm directly after heel strike and a peak of 6 Nm prior to toe off (Fig. 2(*d*)). In addition, the motion was further constrained by a rotation restraint of 0.6 Nm/°. Tests were run at a cycle rate of 1 Hz. The lubricant used throughout testing was 60 % (*v*/*v*) calf serum (Sigma Aldrich, Taufkirchen, Germany) with 0.05 % (*w*/*v*) ethylenediaminetetraacetic acid and 0.1 % (*w*/*v*) Partricin solution in de-ionised water. This resulted in a protein content of 30 g/L. The lubricant was changed every 0.5 MC and the temperature was maintained at 37°C.

Gravimetric analysis of the mensical bearing components was performed using loaded soak controls to isolate the effect of weight gain due to the uptake of lubricant. This method was adapted from that outlined for TKR wear testing in ISO 14243-2 [5].

Linear penetration was measured using the dial gauge technique reported by Argenson and O'Connor [6]. The minimum thickness of each bearing was measured after 10 MC. For each bearing, three independent measurements were taken and the mean value was calculated. The unworn minimum thickness was calculated by measuring five unworn bearings in a similar manner. The linear wear penetration was then calculated by subtracting the mean minimum thickness of each tested bearing from the minimum thickness of the unworn bearings.

Results

Wear scars were observed on the superior and inferior surfaces of the meniscal bearings (Figs. 3 and 4). In both cases, the scars initiated at the medial and lateral edges of the components and extended towards the centre of the surface as the test duration increased. Wear scars on the medial bearings were observed to cover both surfaces after 2 MC, indicating that conformity had been reached. The growth of the wear scar on the superior and inferior surfaces of the lateral

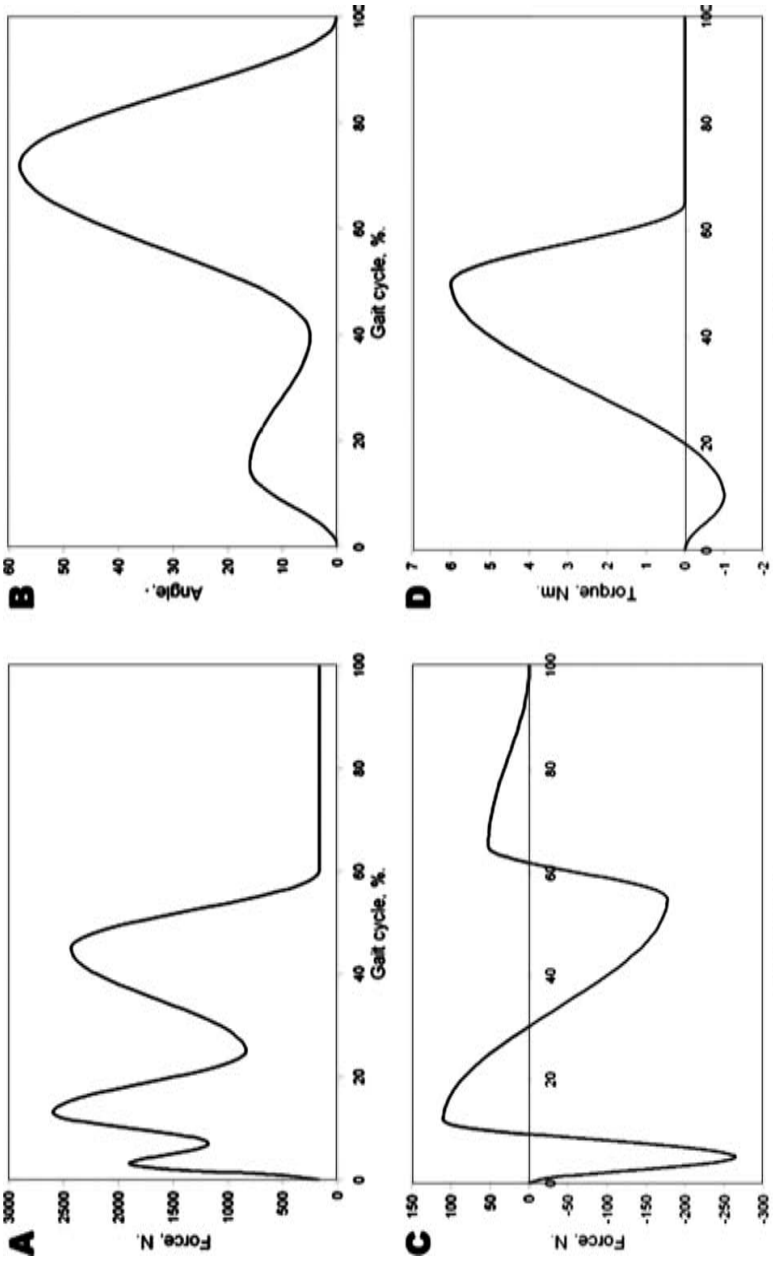

FIG. 2—*Loading and displacement inputs for wear test as defined by ISO 14243-1: (a) Axial force; (b) flexion-extension displacement; (c) A-P force; and (d) internal-external torque.*

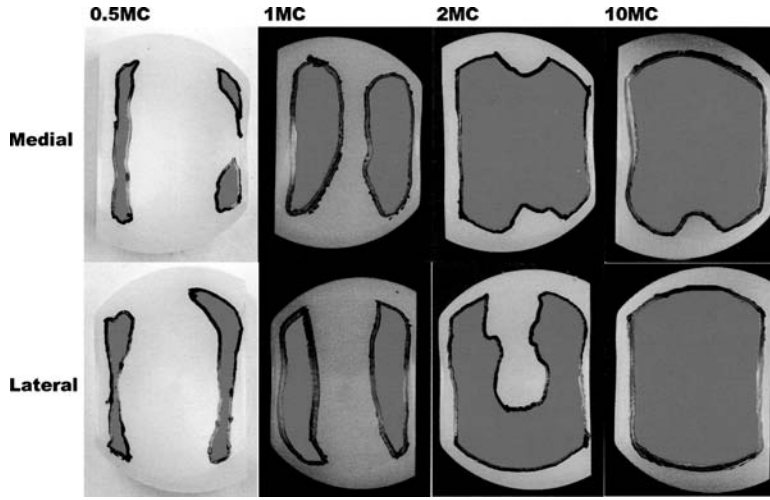

FIG. 3—*Example of contact area on the superior surface of the medial and lateral meniscal bearings at 0.5, 1, 2, and 10 MC.*

bearings was slower and at 2 MC, the surfaces were only partially covered. The UHWMPE contact surfaces were highly polished with evidence of scratching.

Gravimetric analysis yielded a linear wear rate ($r^2 = 0.93$ and 0.98) of 1.65 ± 0.28 mm^3/MC (mean ± SD) and 1.66 ± 0.31 mm^3/MC for the medial and lateral bearings, respectively (Fig. 5). Maximum linear penetration wear rates of

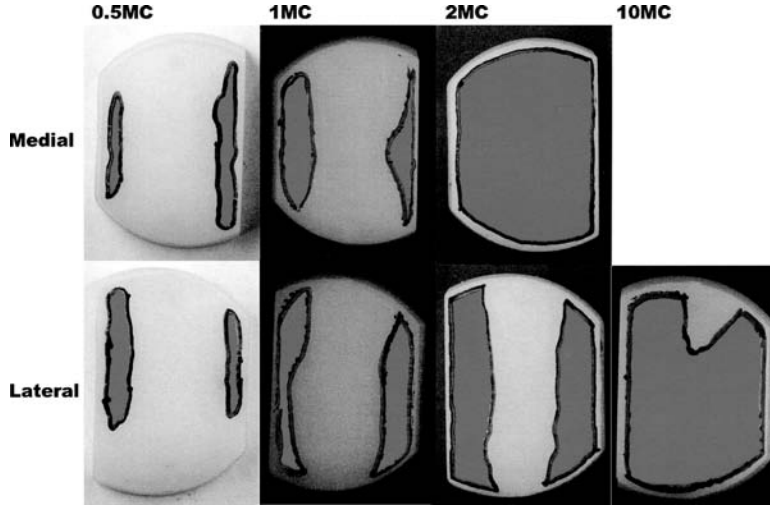

FIG. 4—*Example of contact area on the inferior surface of the medial and lateral meniscal bearings at 0.5, 1, 2, and 10 MC.*

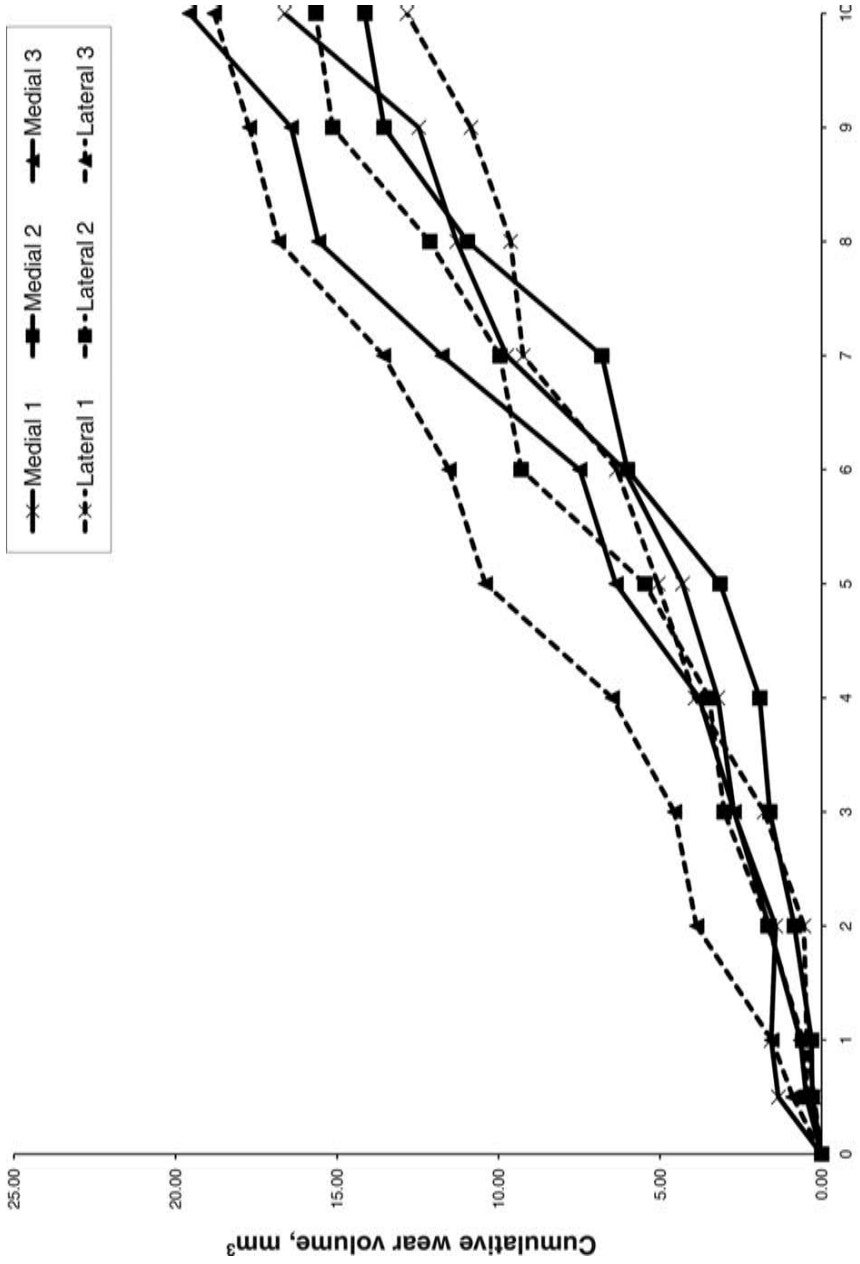

FIG. 5—*Cumulative meniscal bearing volume loss over the test duration measured through gravimetric analysis.*

0.013 ± 0.001 mm/MC and 0.012 ± 0.001 mm/MC after 10MC were recorded for the medial and lateral bearings, respectively.

Discussion

Wear within lateral and medial UKR prostheses has been successfully simulated and quantified experimentally over 10 MC. The wear scars on the superior and inferior surfaces of the components initiated at the peripheral medial and lateral edges of the intended contact surfaces. The wear scars increased in size over the duration of the test as the conformity of the bearing surfaces increased. The lower conformity of the virgin components was due to the inherent deviation from the components' target dimensions and had been expected as any difference in the profile of the contacting surfaces will create localised areas of loading. Conformity increased rapidly over the first 2 MC. Coverage on the lateral bearing developed at a reduced rate when compared to the medial bearing. The slower increase in the size of the wear scar on the lateral bearing appears to be due to the reduced loading as a result of the offset of the axial load towards the medial compartment.

Volumetric wear rates of 1.65 ± 0.28 mm^3/MC (mean $\pm$ SD) and 1.66 ± 0.31 mm^3/MC were recorded for the medial and lateral bearings, respectively (Table 1). These results are of a similar magnitude to that reported previously [7–10]. in vivo studies have also demonstrated inferior lateral UKR survivorship when compared to medial UKR systems [12]; however, no significant difference between the wear rate of the medial and lateral bearings was observed during this testing.

Maximum linear penetration wear rates of 0.013 ± 0.001 mm/MC and 0.012 ± 0.001 mm/MC were recorded for the medial and lateral bearings, respectively, after 10 MC. This figure is in agreement with that reported for well functioning MB UKRs through in vivo measurement (0.01–0.043 mm/year [6,11,13,14]) and is considered to represent a low wear rate [13]. The maximum linear penetration reported here is an order of magnitude lower than that reported for fixed bearing designs (0.15 mm/year [12]). However, this was expected after consideration of the differences in contact geometry between fixed and MB designs. The MB design has a high level of congruency, and therefore, low contact stresses and a larger wear area. Fixed bearing designs have low levels of congruency; for example, the St Georg Sled is a biconvex femur on a flat tibial geometry. Such geometry leads to point loading, high contact stresses, and small contact areas; therefore, from a tribological perspective, high levels of penetration wear would be expected.

When comparing UKR wear rates, it is important to recognise the complex relationship between the two measures of wear (linear penetration and gravimetric). The latter is a measure of volumetric wear rate (the volume of debris generated) and is proportional to the linear penetration and to the area of contact. This can create difficulties when using single point measurements of linear penetration to compare the wear rates of different prosthesis designs with varying levels of congruency. Ashraf et al. [12] highlighted this problem, reporting that whilst the St Georg Sled fixed bearing UKR had higher linear wear; the level

TABLE 1—*Published values of polyethylene wear in UKR.*

Reference	In Vitro/In Vivo	Prosthesis	Volumetric Wear (mm^3/MC or mm^3/year)		Maximum Linear Penetration Wear (mm/MC or mm/year)	
			Medial	Lateral	Medial	Lateral
This study	In vitro	Uniglide MB	1.65	1.66	0.013	0.012
Brockett et al. [7]	In vitro	Oxford MB	5.98–7.73	3.89–3.7	...	
Burton et al. [8]	In vitro	Preservation MB	3.8–7.1	6.9–9.9	...	
Scott and Schroeder [9]	In vitro	Oxford MB	10.37		0.019	
Brockett et al. [7]	In vitro	GCK Fixed	2.12–2.7	1.3–1.8	...	
Burton et al. [10]	In vitro	Preservation Fixed	0.9–1.8	1.4–1.9	...	
Argenson and O'Connor [6]	In vivo	Oxford MB	...		0.043	
Psychoyios et al. [11]	In vivo	Oxford MB	6–47		0.01–0.08 (0.01 for normal wear)	
Ashraf et al. [12]	In vivo	St Georg Sled Fixed	17.3		0.15	
Price et al. [13]	In vivo	Oxford MB	...		0.02	
Kendrick et al. [11]	In vivo	Oxford MB	...		0.01–0.07 (0.01 for normal wear)	

of volumetric wear was comparable to that of the Oxford MB design. The evolution of the wear scar areas from the periphery to the centre of the bearing that have been presented in this study indicate that the measurement of the linear penetration of congruent bearings can contain similar errors, which can be confounded by the two bearing surfaces of a MB design. It is therefore evident that further validation of the measurements of the linear penetration must be conducted before this technique can be used as a method of accurately determining the wear of UKRs.

Conclusion

This study has investigated the wear of a leading design of MB UKR by quantifying the in vitro wear rate and linear penetration of the polyethylene meniscal bearing. Mean volumetric wear and maximum linear penetration wear rates were quantified as 1.66 mm^3/MC and 0.013 mm/MC, respectively. This represents a low wear rate for UKR devices. The results correlate well with in vivo measurements of wear, indicating that the current in vitro methodology for the simulation of wear in MB UKRs is a valid tool for preclinical assessment of these prostheses.

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Wear Advantage of a Rotating Bearing Knee–An *In Vitro* Study

ABSTRACT: Mobile-bearing knees such as rotating platform knee (RPK) prosthetic implant systems were developed to improve knee kinematics, reduce torque transmitted to the implant-bone interface, allow implant self-alignment, and reduce wear. This study evaluated the wear performance of a RPK implant [the Optetrak® (RBK™)] characterized by a wave-shaped distal bearing intended to reduce the risk of central tibial insert peg wear by shielding it from loading. This system was compared to its clinically proven fixed-bearing knee counterpart (the FBK) (1) as well as other historical RPKs (2). Wear tests were conducted by an independent laboratory using a procedure following ISO 14243-1 with the exception of the fluid test medium. The laboratory disclosed individual wear rates for historical RPK systems ($n = 9$). After correcting for fluid test medium absorption, the net wear rate averaged 2.11 ± 0.47 and 3.00 ± 0.47 mg/Mc for the RBK and the FBK, respectively ($P > 0.05$), while the mean wear rate reported for the historical RPK systems was 6.65 mg/Mc. Visual analysis after testing showed all evaluated RBK inserts exhibited identical contact patterns. Microscopic visual examination revealed minimal central peg and tibial tray bore wear. Based on this study, wear performance was similar for both the RBK and FBK systems. Compared to historical RPKs, the RBK was associated with a lower wear rate, demonstrating that the wave-shaped bearing reduces wear caused by contact between the central peg and tibial tray bore (when tested on a knee simulator).

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KEYWORDS: total knee joint, wear testing, ultra-high molecular weight polyethylene (UHMWPE), knee simulator

Introduction

Total knee arthroplasty (TKA) is a successful surgical procedure with several reports of survivorship greater than 90 % in 15 years. [1–3] However, articulation against ultra-high molecular weight polyethylene (UHMWPE) may release polymeric debris, which can deteriorate bearing performance and is a continuing clinical concern in TKA. Due to increases in life expectancy and the number of younger patients undergoing knee replacement surgery, efforts to increase implant longevity by decreasing wear are part of a continued effort to improve patient outcomes.

One of the potential advantages of rotating platform knee (RPK) systems is reduced overall wear compared with standard fixed-bearing knee (FBK) systems. Other potential advantages include reduced torque transmitted to the implant-bone interface and the possibility of implant self-alignment. However, based on current scientific literature, RPK wear advantage cannot be clearly confirmed when evaluated on a knee simulator. The purposes of this study were to compare wear performance of a RPK [the Optetrak® RBK™)] to a clinically proven fixed-bearing counterpart with similar proximal bearing geometry (the FBK) (1), as well as to compare RBK wear performance to other historical RPK systems tested using the same general procedure. [4,5]

Materials and Methods

Knee Simulator

A servo-hydraulic knee simulator with four stations (Endolab, Rosenheim, Germany) was used for this study (Fig. 1). The test chambers were individually sealed and could be removed from the simulator without opening. The test fluid

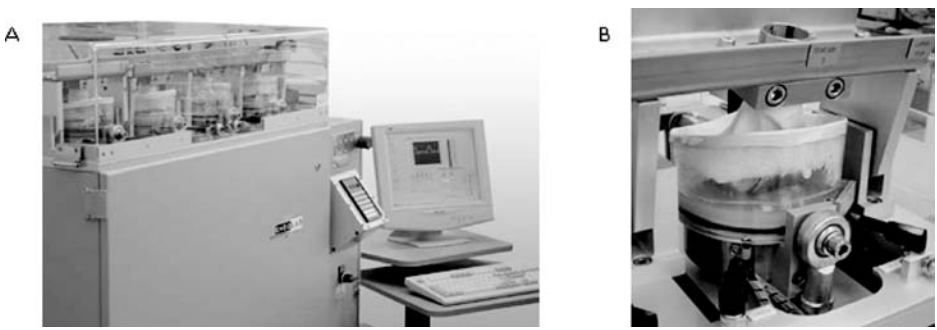

FIG. 1—*Computer-controlled four-station knee simulator: (a) Provides a general view of the simulator while (b) showing a detailed view of one station (with the permission of Endolab).*

temperature was individually controlled to achieve tolerances recommended by ISO 14243-1. All test stations were equipped with sensors to ensure maintenance of correct temperature and fluid level.

The simulator provided closed-loop control of three degrees of motion: The femoral flexion/extension angle, the tibial internal/external rotation, and the tibial anterior/posterior translation.

Kinematic Condition of the Knee

The kinematic input was derived from the modified Paul knee load profile [6] and met ISO 14243-1 requirements.

The inputs used were axial force (Fig. 2), antero-posterior (AP) force (Fig. 3), and tibial rotation torque (Fig. 4). The axial force followed a specified cyclic variation while the AP force included two components: One, a specified cyclic variation, and the other, replicating ligament constraint, proportional to AP displacement.

The axial load axis was shifted using an offset of 7 % of tibial width in a medial direction and the flexion/extension axis was set according to ISO 14243-1. Despite a recommended posterior slope of 3°, the tibial component was set up in neutral slope. This was not expected to have an effect on wear performance. The femoral component was placed in a neutral position relative to the tibial components.

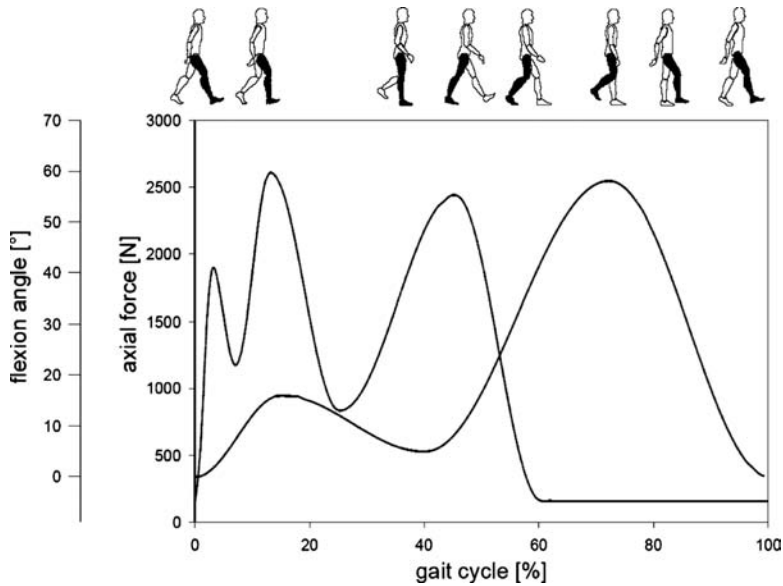

FIG. 2—*Variation in axial force for the gait cycle ranged from 2600 N during the stance phase to 166 N during the swing phase. The femoral component is flexed to a maximum of 16° during the stance phase and 58° during the swing phase.*

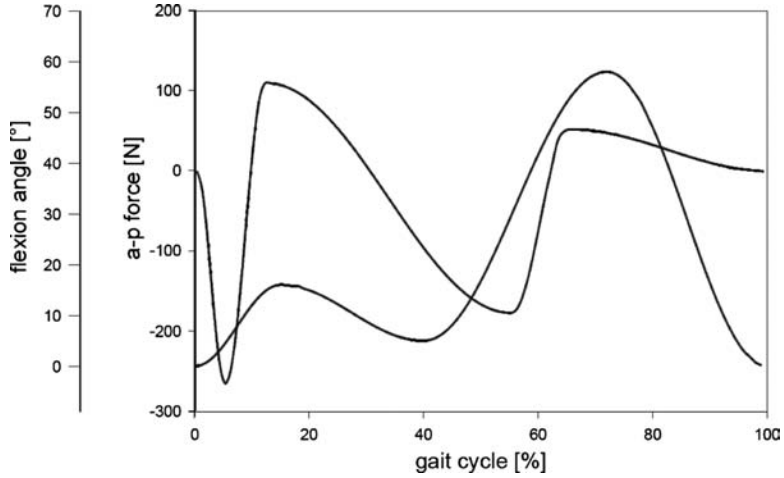

FIG. 3—*Variation of AP force with the gait cycle: From −265 to 110 N.*

Prosthetic Knees

In the first wear test, two postero-stabilized (PS) FBK implants (Optetrak® PS, Exactech, Gainesville, FL) were used. Size 3 9 mm thick tibial inserts made from direct-compression molded UHMWPE were combined with size 3 CoCr alloy femoral components and size 3F/3T Ti alloy finned tibial trays.

In the second wear test, three PS RBK knee implants (Optetrak® RBK™[4], Exactech, Gainesville, FL) were used. Size 3 9 mm thick tibial inserts made

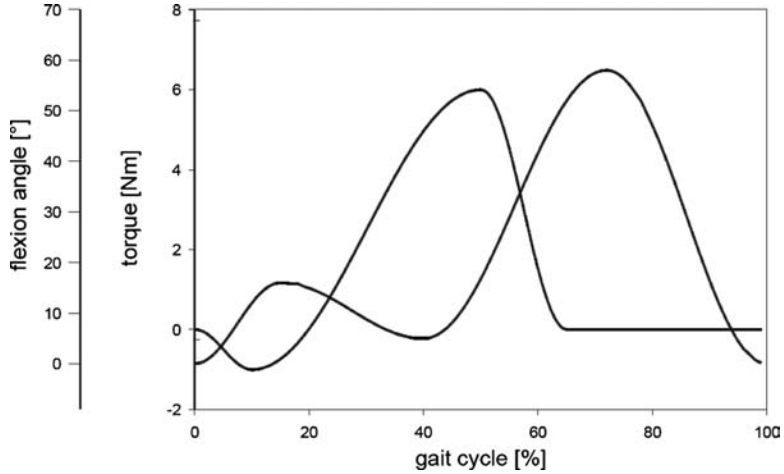

FIG. 4—*Variation of tibial torque with the gait cycle: From −1 to 6 N m.*

[4]Optetrak® RBK™ is not available for sale in the United States.

from direct-compression molded UHMWPE were combined with size 3 CoCr alloy Hi-Flex® femoral components and size 3F/3T CoCr alloy tibial trays. The proximal bearings of both knee systems shared the same articular geometry, characterized by a patented high frontal congruency between femoral component and tibial insert. The only differences (at the level of the proximal bearing) were in the antero-posterior aspect of the tibial spine and posterior scallops on the RBK inserts, intended to accommodate high flexion. These differences were not expected to affect wear comparison as the simulated flexion angle was below the theoretical spine/cam engagement angle.

The major difference between these two systems occurs at the distal bearing, where the tibial insert is locked relative to the tibial tray for the FBK system but is free to axially rotate relative to the tibial tray for the RBK system (Fig. 5).

Finally, the RBK is characterized by a wave-shaped distal bearing intended to reduce the risk of peg wear by shielding the central tibial insert peg from loading, a feature distinguishing it from other currently marketed RPK systems where the distal bearing is typically flat.

Procedure

The test procedure was based on ISO/FDIS 14243, with the exception of fluid test medium formulation. Rather than diluting the serum to 25 % as per ISO 14243-1, the protein concentration used for all Endolab tests is set at 30 g/L, a final protein content commonly used in simulation testing as reported in the literature [7] but which may affect wear rate values.

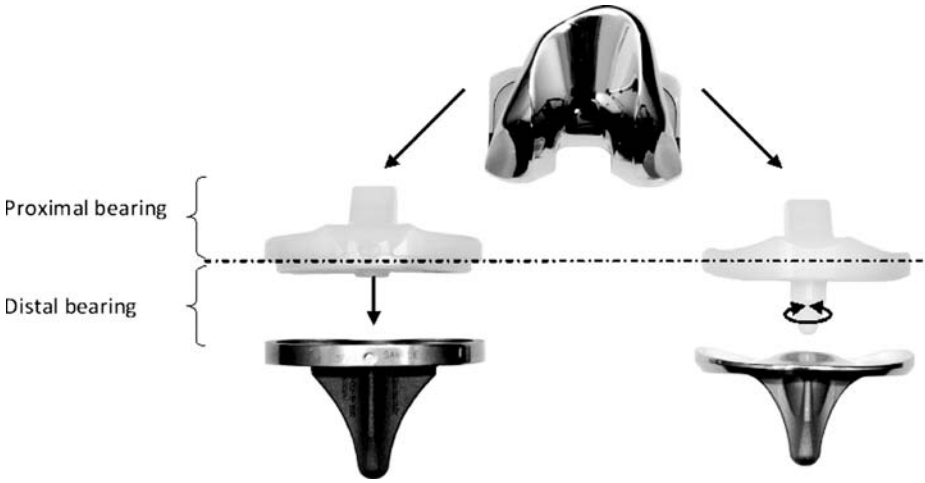

FIG. 5—*The FBK and RBK systems distinguish themselves at the level of the distal bearing. The FBK features a tibial insert intended to be locked with the tibial tray. The RBK features a tibial insert free to axially rotate relative to the tibial tray while subjected to tibial torque. The RBK is characterized by a patented wave-shaped distal bearing.*

For both the FBK and RBK, gravimetric wear of direct-compression molded UHMWPE tibial inserts was measured at half-million-cycle intervals during the first million cycles and every million cycles thereafter until 5 million cycles were reached. These two tests were performed on the same knee simulator with the same calf serum lot number used for the fluid test medium. Due to the set-up of the FBK wear test (where no additional station was available), the FBK control specimen was soaked but unloaded while the RBK control specimen was loaded.

To compare the RBK with other RPK systems, the laboratory performing this study (Endolab, Rosenheim, Germany) disclosed wear rates for all of the systems they have tested ($n = 16$). For confidentiality reasons, the laboratory did not share brand names for these systems. In vivo, RPKs have demonstrated rotation between the femoral and tibial components [8]. As a result, systems exhibiting less than 1° of rotation ($n = 7$) between the femoral and tibial components during testing were excluded from the comparison.

Results

Wear trends were linear for the FBK and RBK, with the correlation coefficient (R^2) ranging from 0.93 to 0.98 (Fig. 5). After correcting for fluid test medium absorption, the net wear rate for the direct-compression molded UHMWPE tibial inserts averaged 3.00 ± 0.47 mg/Mc (range 2.67–3.33 mg/Mc) and 2.11 ± 0.47 mg/Mc (range 1.69–2.92 mg/Mc) for the FBK and RBK, respectively. No significant difference ($P > 0.05$) could be found using Student's t-test. It should be noted that the wear rate exhibited by the FBK was similar to results previously reported by another laboratory on the same implant [9]. Despite the different control specimen set-up, fluid absorption was comparable (i.e., a difference of 0.53 mg after 5 Mc).

The mean wear rate reported for the historical RPK systems ($n = 9$) exhibiting more than 1° of rotation between the femoral and tibial components was 6.65 mg/Mc (range 2.42–16.7 mg/Mc), which is higher than the RBK (Fig. 6).

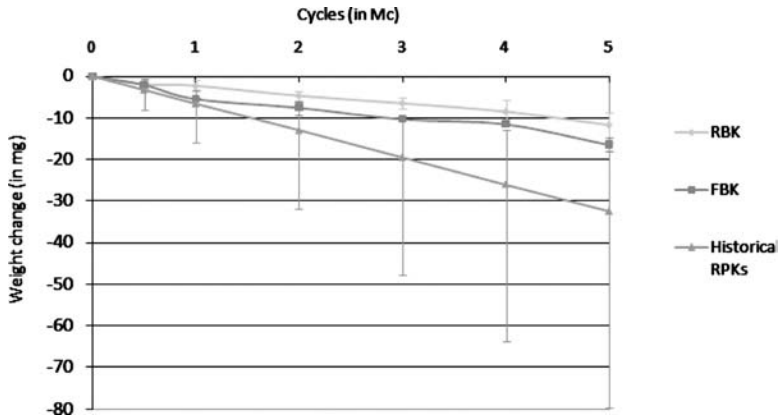

FIG. 6—*Graph showing mass changes of the RBK, FBK, and historical RPKs. The error bars indicate the min and the max.*

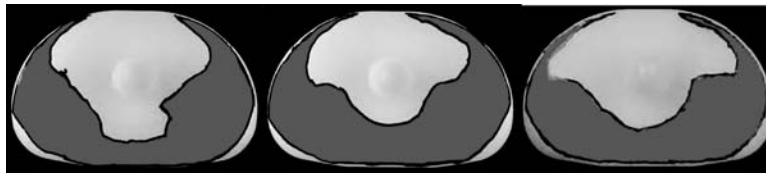

FIG. 7—*Major contact areas (tibial side) after 5 million cycles were similar for all evaluated RBK test specimens.*

Both the FBK and RBK showed similar levels of anterior-posterior translation (about 5 mm). Also, both the FBK and RBK showed similar trends for axial rotation, with a gradual increase during the stance phase. The axial rotation peaked at the end the stance phase, reaching an average maximum of 5° for the RBK versus 4° for the FBK, indicating that part of the axial rotation occurred at the level of the RBK distal bearing.

Low kinematic variation in response to the simulated cycle was observed for the three evaluated RBK stations. This may be due to controlled surface contact between the tibial insert and tibial tray along the "deepest" portion of the wave, so the torque required to initiate rotation at the distal bearing is predictable. An analysis of the evaluated RBK inserts revealed identical contact patterns on the distal bearing (Fig. 7).

The extent of central peg wear for the evaluated RBK inserts was minimal, as evidenced by microscopic and visual examination [Fig. 8(*a*) and 8(*b*)]. This is unusual for rotating bearing knee designs with flat distal bearings, which when exposed to anterior-posterior force typically demonstrate wear patterns along the anterior face of the central peg.

Discussion

Several studies compare wear performance for RPK and FBK implants, with mixed conclusions. On one hand, McEwen et al. [10] compared six fixed-

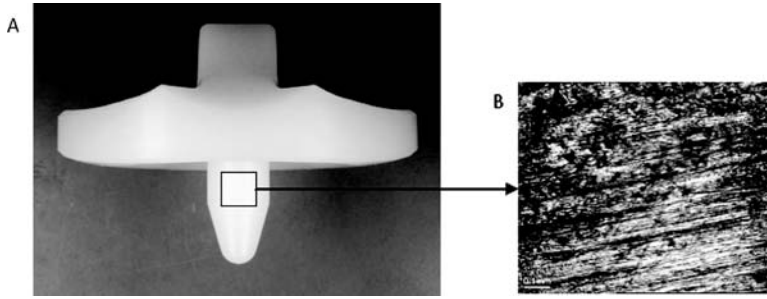

FIG. 8—*(a) Wear on the anterior face of the central peg is not visible macroscopically. (b) A microscope was required to detect lightly polished contact regions with residual machine marks at the completion of the wear test.*

bearing implants with six RPK implants using a physiological knee simulator with high-rotation kinematic inputs. They found that the RPK inserts exhibited 1/3 the mean wear rate of the fixed-bearing inserts, despite having increased femoral contact areas and additional tibial wear surfaces. Recently, Haider and Garvin [11] compared the wear and kinematics of a RPK knee system with a FBK system of otherwise identical design on a force-controlled knee simulator using ISO force inputs and simulated soft-tissue restraint. They concluded that the polyethylene wear was similar for both designs. Another example is a study performed by Bell et al. [12] comparing wear between fixed-bearing and mobile-bearing (i.e., associated with translation and rotation) knees using a displacement-controlled knee simulator and reported that the mobile-bearing inserts were associated with a mass loss about three times higher than the fixed-bearing inserts. Also, the authors reported that most of the mobile-bearing insert wear was on the distal bearing. Due to the significant differences for both inputs and implants, a cross comparison between these studies is not possible.

The present study includes a few limitations. First, the number of test specimens ($n = 2$ for the FBK and $n = 3$ for the RBK) was low. Next, only axial rotation between the femoral component and the tibial baseplate was monitored, so for the RBK no strong conclusions can be made about the rotation of the tibial insert relative to the femoral component or tibial baseplate. Finally, the study did not quantify wear between the proximal and distal bearings.

Both the FBK and RBK systems shared the same articular geometry for the proximal bearing, and the wear tests were performed according to the same protocol. This presented ideal conditions for evaluating the effects of the rotational degree of freedom at the level of the distal bearing. According to the two wear tests, both the FBK and RBK had similarly very low wear rates, but no wear advantage was established between the two designs.

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In Vitro Knee Wear, Kinematics, and Particle Morphology Among Different Bearing Geometries in a Mobile Bearing Knee System

ABSTRACT: Excellent clinical long term results were reported from individual clinical centers for both of the two fundamental design principles—fixed and mobile bearing knee designs. Several pre-clinical studies are dealing with a direct comparison between fixed and mobile bearing knee replacements, but to our knowledge there is no published data comparing the in vitro wear and kinematic behaviour of mobile bearing designs with floating, rotating and posterior stabilized gliding surfaces. The objective of our study was to evaluate the influence of the tibio-femoral bearing type on abrasive wear, tibio-femoral kinematics and particle release for a mobile bearing knee system with three different design alternatives. Wear simulator testing on 12 e.motion® TKA devices (Aesculap, Germany) was performed according to ISO 14243-1. The knee replacements were tested for 5 million cycles on a customized 4 station knee wear simulator (Endolab, Germany) in the bearing configurations floating platform (FP), ultra-concruent rotating platform (UC) and posterior stabilized (PS). The amount of wear in the polyethylene gliding surfaces was estimated to 4.4 ± 0.9 mg/million cycles (FP design) to 2.3 ± 0.1 mg/million cycles (UC) and 5.2 ± 1.0 mg/million cycles (PS). The amplitudes of A/P displacement during 5 million cycles showed a mean value

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of 3.7 ± 0.33 mm (FP design), 2.3 ± 0.14 mm (UC) and 2.9 ± 0.26 mm (PS). For the I/E rotation angle, the amplitudes of the recorded mean values were 6.3° ± 0.82° (FP design), 3.7 ± 0.41° (UC) and 4.9° ± 0.48° (PS). The polyethylene particle release (mean size and morphology) is comparable for the mobile bearing articulations FP, UC, and PS. The present study demonstrates the influence of different mobile bearing types on abrasive wear, tibiofemoral kinematics, and particle release under elimination of bearing material influences.

KEYWORDS: total knee arthroplasty, in vitro knee wear, mobile bearing design, influence of bearing geometries

Introduction

Gonarthrosis, rheumatoid arthritis, osteonecrosis, and severe injuries leading to severe pain or loss of function of the knee are typical indications for total knee replacement [1–8].

Among the various design principles in clinical use, mobile bearings offer the advantage of high mobility in combination with low contact stresses and little constraint.

Contact stresses should be minimized to reduce the risk of material damage of the gliding surface and the constraining stresses should be reduced to minimize the stresses on the bone and/or bone-cement implant interface [9,10]. The latter is important to reduce the risk of failure of the fixation [11,12].

Several pre-clinical studies have been performed to compare fixed and mobile bearing knee replacements [9,10,13–16], but to our knowledge there are no published data comparing the in vitro wear and kinematic behavior of mobile bearing designs with floating, congruent rotating and posterior stabilized rotating gliding surfaces.

The objective of our study was to evaluate the influence of the tibio-femoral bearing type on wear, tibio-femoral kinematics and particle release for a mobile bearing knee system with three different design alternatives, namely floating platform (FP), ultra-concruent rotating platform (UC), and posterior stabilized rotating platform (PS).

Material and Methods

Wear simulator testing according to ISO 14243-1:2002(E) was performed with 12 e.motion® total knee replacements (TKR) (Aesculap, Germany) with different bearing configurations: Floating platform (FP1-3), ultra-concruent rotating platform (UC1-3) and posterior stabilized (PS1-3). The femoral design for the three configurations is based on two main radii. The anterior radius for the stable guiding of the patella and the radius of the distal and dorsal portion of the condyles. The transversal radius of the condyles is identical to the second radius. Together with the FP mobile bearing component a ball in socket design is realized to achieve a large contact area up to 90° flexion. This design type realizes flexion extension by articulation between femoral component and mobile

bearing whereas anterior posterior and medial lateral displacement and internal external rotation is realized between tibial component and mobile bearing. The UC and PS designs which are based on the rotating plateau concept have a decreasing conformity in the sagittal plane of the condyles (Fig. 1) to realize anterior posterior displacement as well as flexion extension between the femoral component and the mobile bearing whereas the internal external rotation is allowed by the movement between the tibial component and the mobile bearing. To provide sufficient stability for weaker soft tissue structures the UC design is deep dished and a post cam design is used for the PS type (Fig. 2).

Femoral and tibial component were made from CoCrMo alloy according to ISO5832-4. Ultra high molecular weight polyethylene (UHMWPE) mobile bearing components were machined from compression molded GUR 1020 plates and sterilized by irradiation (30 ± 2 kGy) in nitrogen atmosphere.

The wear test was performed for a total of 5 million cycles (MC) with 1 Hz on a customized 4 station knee wear simulator (Endolab, Germany). The applied wave form for flexion-extension, axial load, anterior-posterior (AP) load, internal-external (IE) torsion as well as the restraining systems for AP motioned IE rotation were based on level walking. According to ISO 14243-1:2002(E), the applied axial load has a three peak profile during the stance phase of gait with the maximum peak of 2600 N at 15° of flexion. During swing, the load is reduced to constant 166 N. The axial load is shared to 60 % by the medial condyle and 40 % by the lateral condyle. The flexion-extension profile follows a typical gait pattern and is applied to a maximum of 58°. The anterior-posterior load oscillates between +110 N and −265 N, and the internal-external torsion ranges from +6 Nm to −1 Nm. "Soft tissue" springs restrain the translational and rotational movements with 30 N/mm and 0.6 Nm/°, respectively (Fig. 3).

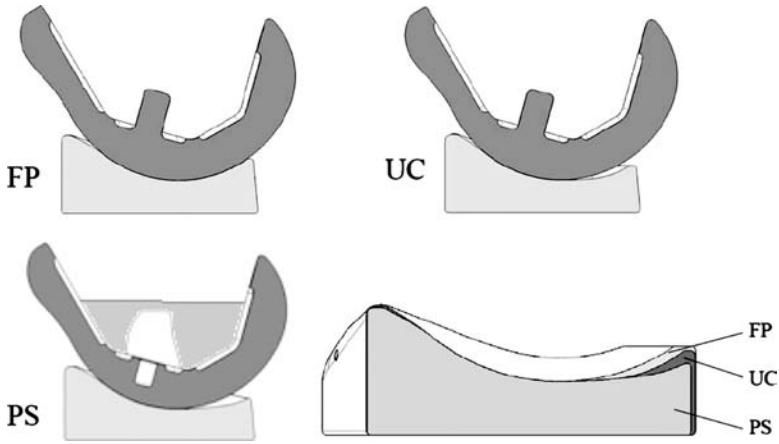

FIG. 1—*Differences in intended articulations and congruency at the femoral bearing surfaces for the floating platform (FP), ultra-concruent rotating platform (UC), and posterior stabilized (PS) design.*

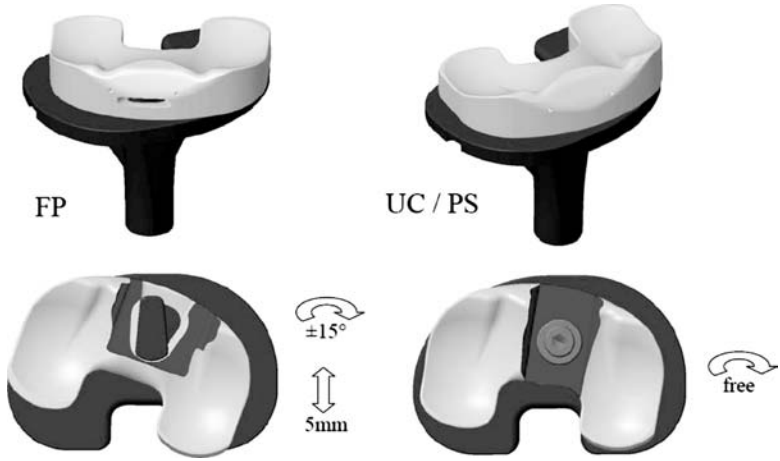

FIG. 2—*Differences in mobile bearing configurations and intended articulations at the tibial bearing surfaces for the floating platform (FP), ultra-congruent rotating platform (UC) and posterior stabilized (PS) design.*

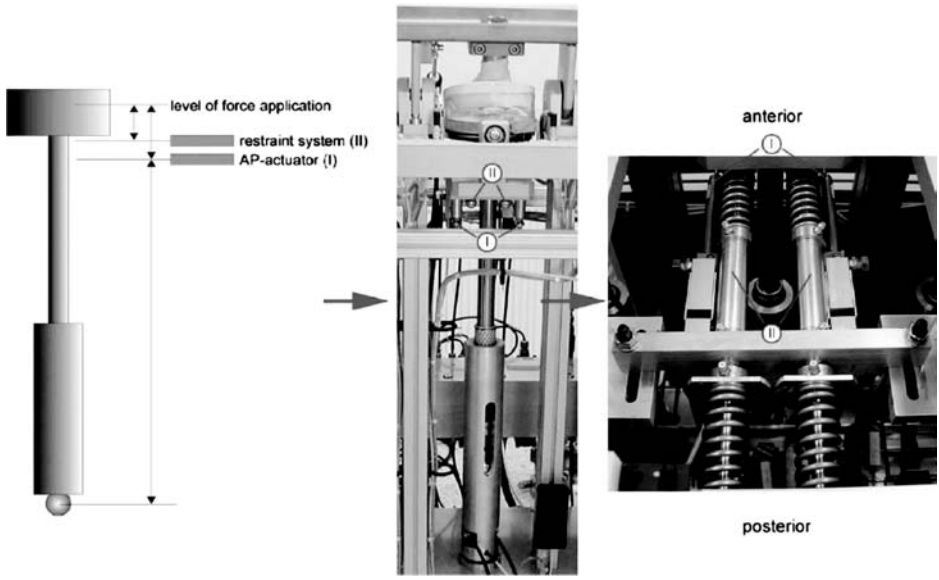

FIG. 3—*Schematic view of the load application and constraint system of the EndoLab 4 station knee wear simulator – in a single station view the axial load is applied via an actuator to the tibial baseplate and the anterior-posterior shear load and internal-external torsion via vector addition by the AP actuators (i). The restraint system (ii) realizes the load control constraints by a spring system.*

To analyze the resulting tibio-femoral knee kinematics, the movement of the tibial tray relatively to the femur was periodically read out. The specimen FP1-3, UC1-3, and PS1-3 were rotated across stations after each MC to reduce a possible influence of interstation variability. The samples were tested in a solution of new born calf serum with a protein content of 30 g/L [17–19] at 37°C. Ethylene diamine tetraacetic acid (EDTA) was added to the solution to prevent calcium-phosphate precipitation, Amphotericin was used to prevent microbiological contamination. The serum was replaced every half MC and stored frozen until particle analysis.

Gravimetric wear was assessed according to ISO 14243-2:2000(E) with an analytical balance (Mettler Toledo Type AG 204, Balingen) with a precision of ±0.1 mg at 0.5, 1, 2, 3, 4, and 5 MC after cleaning the polyethylene bearing components according to the protocol described in the standard. Fluid absorption of the polyethylene components was adjusted by one only axially loaded reference samples for each design (FP0, UC0, PS0). Cumulative wear, wear rate and tibio-femoral kinematics where compared statistically using Statistica 7 (Stat Soft Europe GmbH, Hamburg). The level of significance was set to $p < 0.05$ (ANOVA and post hoc test: Newman–Keuls Test). The worn areas on the polyethylene components were identified by visual inspection. The wear patterns were then analyzed by optical microscopy (Wilde M3Z Herrenbrugg, Switzerland). Particle analysis was conducted using the digestion protocol described by Niedzwiecki et al. [20] and Affatato et al. [21]. The serum was digested in 37 % hydrochloric acid, diluted in methyl alcohol and filtered through alumina filters with a pore size of 0.02 μm. Subsequently a SEM micrograph analysis (Zeiss EVO 50, Carl Zeiss NTS GmbH, Oberkochen) was performed with software (Leica QWin V3 Standard, Leica, Bensheim) to determine particle size. A minimum of 900 particles were analyzed for each TKR design to obtain a representative particle size distribution.

Results

Cumulative wear after 5 million load cycles was 20.9 ± 3.1 mg for the FP design, 11.2 ± 0.7 mg for the UC design and 27.1 ± 4.7 mg for the PS design (Fig. 4).

Using linear regression, the wear rates of the three different polyethylene gliding surfaces were estimated to 4.4 ± 0.9 mg/MC (FP1-3 design) to 2.3 ± 0.1 mg/MC (UC1-3 design) and 5.2 ± 1.0 mg/MC (PS1-3 design). Wear rate and cumulative wear did not differ significantly between the FP and PS designs. The UC design, however, was significantly different ($p < 0.05$) from the FP and the PS designs. Figures 5 and 6 summarize the results graphically.

Frontside and backside wear for the three design groups are shown in Fig. 7. The femoral and tibial contact and wear areas of the chosen specimen are representative for each design configuration with only little variancy in the design groups. For better visibility the wear scars are animated with colour. In general it can be observed that the wear scars are influenced by design. Thus, the FP design showed wear on nearly the complete proximal and distal surfaces intended as bearing. Based on the ball-in-socket principle in the FP design the

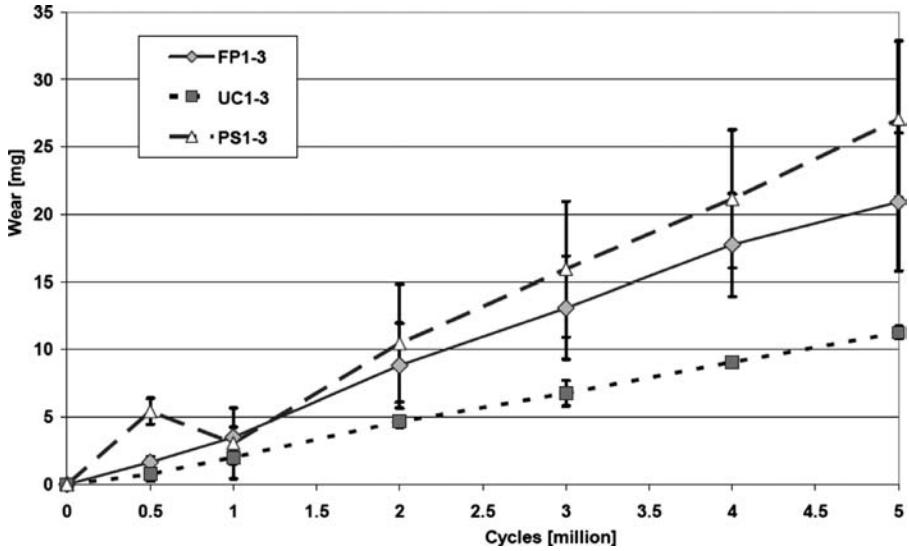

FIG. 4—*Calculated mean and standard deviation of the polyethylene gliding surfaces wear for the FP, UC and the PS design at each measurement interval. The gravimetric wear assessment acc. to the ISO 14243–2 protocol is based on loaded soak controls to account for the effect of fluid absorption and to estimate the linear association between cycle count and mass change.*

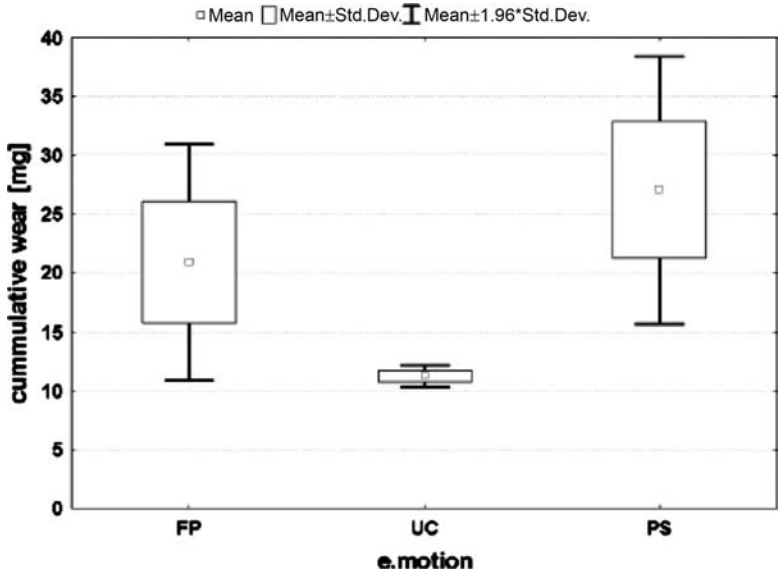

FIG. 5—*Box-Wisker-Plot for statistical analysis of the cumulative wear between the groups.*

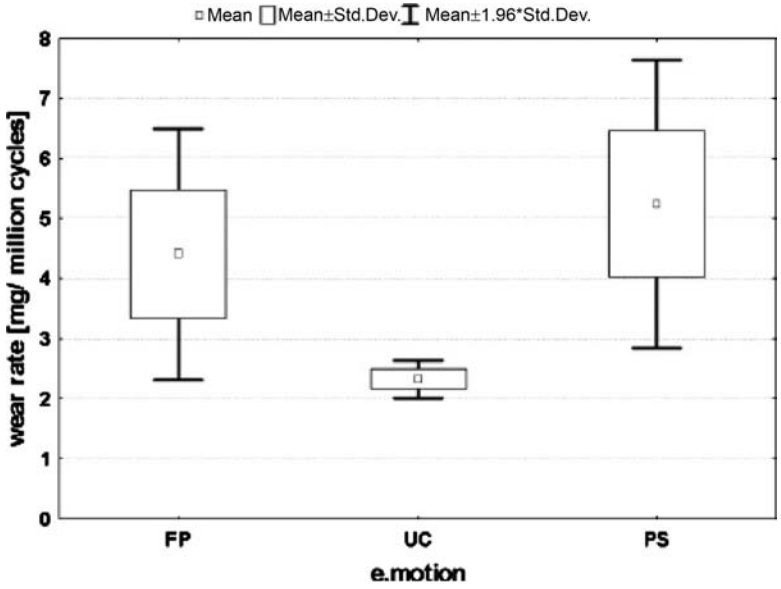

FIG. 6—*Box-Wisker-Plot for statistical analysis of the wear rates between the groups.*

femoral articulations were polished due to flexion only and the floating gliding surfaces were polished in the tibial articulation due to a combination of AP translation and IE rotation. The proximal bearing surface of the UC and PS designs exhibited worn areas predominantly centrally, while the distal bearing surfaces were worn centrally and posteriorly. The comparably reduced wear areas for the UC and PS design are based on the decreasing congruency in the femoral articulation from FP (ball-in-socket) to UC and to PS. In the femoral

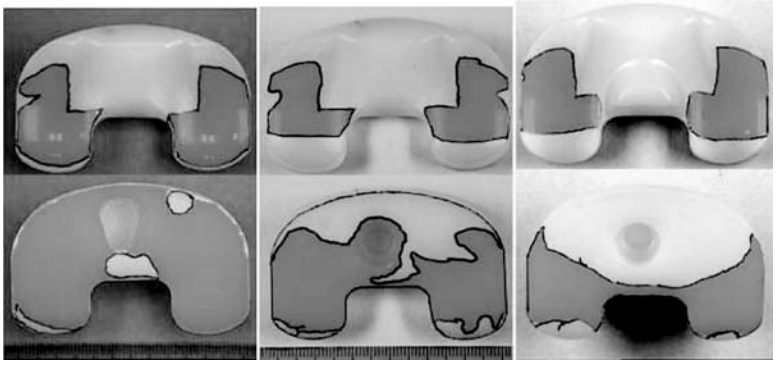

FIG. 7—*Femoral and tibial contact areas (lower row) of the three bearing types floating platform (left), rotating platform (center) and posterior stabilized (right column).*

articulation of UC and PS the central wear areas with a slight shift anterior are produced by AP translation due to an acting anterior shear force in combination with the highest peak of knee loading at 15° flexion (mid-stance). The posterior wear areas at the tibial articulation of the UC and PS gliding surfaces are originated by the rotating platform design and mainly generated at toe off by a combination of IE rotation and a posterior directed shear force shifting the axial load of the knee condyles dorsally. Burnishing and scratching were found on all components on all surfaces indicating adhesive/abrasive types of wear (as examples see Figs. 8–10). No signs of cracks, pitting or delamination were detected during microscopic inspection.

Particle analysis revealed that more than 90 % of the detected particles were in a size range ≤ 1 μm. The median of the particle size distribution is 0.2 μm for all three designs. For the PS and UC design the particle size distribution was slightly shifted towards larger particles, however, the polyethylene particle release (mean size and morphology) is comparable for all bearing designs (FP, UC, and PS) (Fig. 11).

AP displacement amplitudes over 5 MC showed a mean value of 3.7 ± 0.33 mm (FP design), 2.3 ± 0.14 mm (UC) and 2.9 ± 0.26 mm (PS). For the IE rotation angle, the amplitudes of the recorded mean values were $6.3° \pm 0.82°$ (FP design), $3.7 \pm 0.41°$ (UC) and $4.9° \pm 0.48°$ (PS). The tibio-femoral kinematics in AP displacement and in IE rotation were substantially different ($p < 0.0001$) between the groups FP versus UC, UC versus PS, and FP versus PS.

FIG. 8—*Polished wear area of the femoral articulation of specimen PS3 (original magnification 100×).*

FIG. 9—*Scratched wear area of the femoral articulation of specimen PS2 (original magnification 100×).*

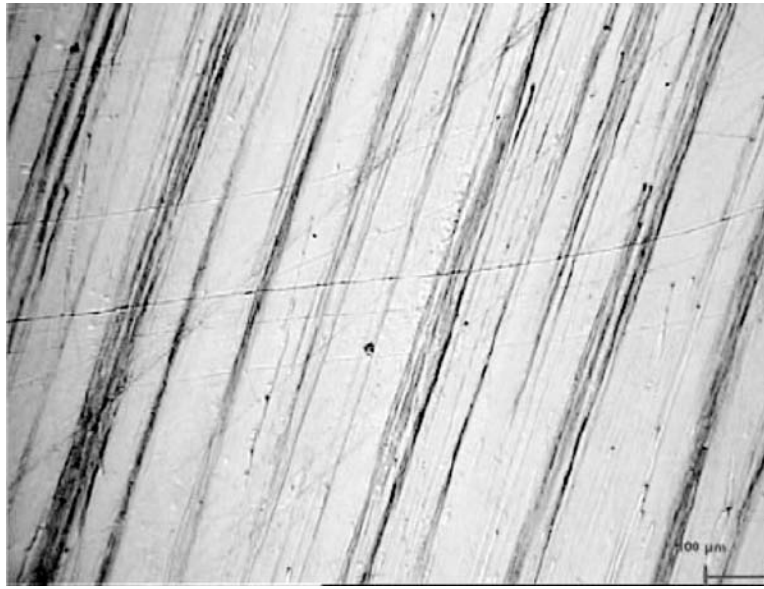

FIG. 10—*Polished with scratches wear area of the tibial articulation of specimen PS3 (original magnification 100×).*

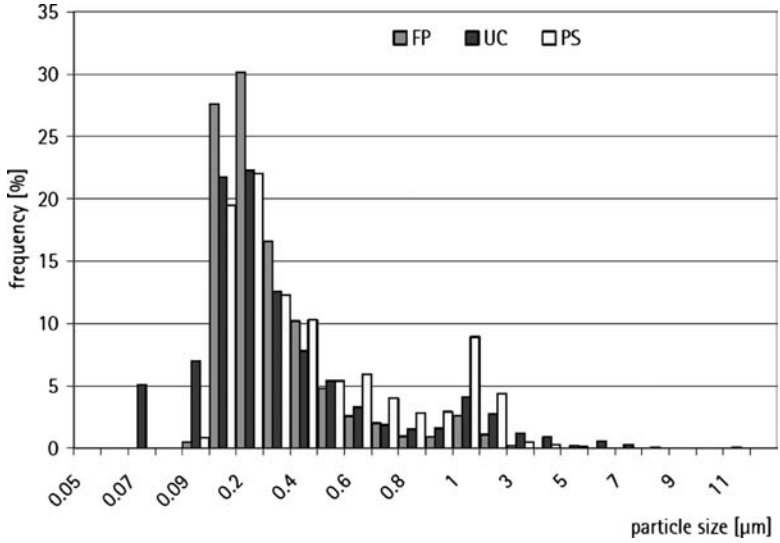

FIG. 11—*Mean particle diameter distribution for the FP, UC and PS knee design.*

Discussion

Three different mobile bearing designs with identical bearing geometry of femur and tibia have been evaluated concerning their wear behaviour. The degree of constraint is increasing from the FP design with low constraint to more constraint for the UC design to again higher anterior-posterior constraint for the PS design. Additionally the bearing geometry of the gliding surface leads to full congruency for the FP design up to 90° of flexion. Therefore the FP design permits only flexion extension between femur and meniscal bearing, anterior posterior, and medial lateral displacement as well as internal external rotation is related to relative movement between tibia tray and meniscal bearing. The UC and PS design are from the rotating platform type, with additional guiding of the anterior posterior translation for the PS design. These design differences provoke different wear behaviour due to differences in wear path and contact area. A limitation may have been arised by the decision to apply anterior posterior shear and internal external rotation under force control. In several studies [13,22–25] it has been obviously demonstrated that the applied kinematics for anterior posterior translation and internal external rotation are an important factor of influence on knee wear generation. DesJardins et al. [26] has shown that the simulation of in vivo gait kinematics for level walking could be reproduced with a force controlled testing methodology. The intention of our study was to display as accurate as possible the kinematic behaviour of the floating, high congruent rotating and posterior stabilized mobile bearing knee designs.

Cross-shear initiated by a combination of AP translation and IE rotation on the tibial bearing of the FP design contributes to increased wear [27–29]. Under conditions of multidirectional motion it was previously demonstrated that cross-shear is detrimental to the wear behaviour of UHMWPE [27,29]. The

polyethylene surface molecules align in the principal direction of sliding given in knee arthroplasty by flexion-extension coupled with AP translation, initiating a polymer strengthening in these particular direction. The transverse direction is given in the knee joint by IE rotation, which leads to orientation weakening of the polymer chains if cross-shear is acting on a single bearing surface. In basic tribological experiments with a rotating polyethylene pin on a transversal oscillating cobalt-chromium plate the wear rate increased by an order of a magnitude with increasing cross-shear angle [27,29]. Kang et al. [28] quantified the effect in a comparable multidirectional pin-on-plate test and described that cross-shear increased the apparent wear factor by more than five times in relation to unidirectional sliding. In contrast, the relative motion between the bearing interfaces is predominantly uniaxial for the UC and PS designs due to the rotating platform principle. Nevertheless due to the ball-in-socket design of the FP meniscal bearing the highest bearing area is given, resulting in very low contact stresses [9,10] partially counteracting the disadvantage of cross-shear in the tibial bearing. In comparison to the FP the contact area of the UC and PS design is reduced, leading to slightly higher contact stress in the femoral articulation. Furthermore, the dished design of the UC type reduces the ability of anterior posterior translation. Therefore the wear behaviour of the different mobile bearing design configurations is influenced by the specific tibio-femoral kinematics, which were substantially different for AP translation and IE rotation between the design groups FP, UC, and PS.

In the current study the gravimetric wear rate was 4.4 mg/MC for the FP design to 2.3 mg/MC for the UC design and 5.2 mg/MC for PS design, respectively. For a widely used mobile bearing design with good long-term clinical outcome wear rates were measured in a range between 6.6 and 16 mg/MC [11,13,30]. In a study from McEwen et al. [13] about a different mobile bearing design a mean gravimetric wear rate of 4.9 mg/MC was reported. In previous studies about a direct comparison of two different rotating platform designs based on the similar femur components as in the fixed bearing designs wear rates of 6.8 mg/MC [15] and 6.6 mg/MC [16] were analyzed.

The three design modifications FP, UC and PS release particles in a similar size range during the wear process. Therefore no influence of the tibio-femoral kinematics - in regard to the amount of cross-shear or uniaxial shear—on size and morphology of the generated particles in knee wear simulation was given. The basic experiments of Wang et al. [27] and Kang et al. [28] on the wear behaviour of polyethylene under different cross-shear angles supports evidence that the applied kinematics do not influence particle size and shape. Currently there exists no threshold value for the particle release of orthopaedic implants. There are indications for critical concentrations of wear mass or particles reported. Particle concentrations around implants with and without osteolysis indicate that a particle concentration of particles, with a mean submicron diameter, this is the biologically most active size range [31,32], above 1×10^{10} particle per gram tissue might lead to osteolysis.

Conclusion

The present study examined the influence of different mobile bearing types on polyethylene wear, particle release, and tibio-femoral kinematics under

elimination of bearing material influences. The wear amount for all tested mobile bearing configurations was relatively low compared with the literature [11,13,15,16,30]. The examined bearing types FP, UC, and PS demonstrated significant differences in gravimetric wear amount and tibio-femoral kinematics (FP versus UC) amongst each other. The significantly reduced wear generation of the UC design is possibly related to the reduction of cross-shear motion at the tibial articulation [27,28].

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Wear of Mobile Bearing Knees: Is It Necessarily Less?

ABSTRACT: Some well-known mobile bearing designs have had truly excellent long-term clinical results. Their lower constraint and ability for some self-alignment might have helped reduce the shear forces and torques transmitted to the prosthesis–bone interface, thereby lowering the risk of loosening. However, the most commonly assumed benefit of mobile bearings is the reduction in wear due to less contact stress and reduced cross shear. In a rotating platform, wear can be reduced because the rolling/sliding motion is separated from the transverse rotational motion, which reduces cross-shear. Although it has not been categorically proven clinically, such lower wear expectations with mobile bearings might have influenced the thinking of some total knee replacement (TKR) designers and test engineers. This paper amalgamates in vitro TKR wear results from two separate laboratories (in Nebraska and Germany) to present the largest data set ever published on wear, across the widest variety of fixed and mobile bearing TKR designs. Many hundreds of TKR samples were tested with largely similar methodologies using the ISO 14243-1 force-control method. These tests covered 133 different fixed and mobile bearing designs and materials, in total (bicondylar) and unicompartmental forms, and of a wide range of sizes. Clear differences in wear resulted with known superior bearing materials. This illustrates how sensitive and capable of discriminating between low and high wearing implants the force-control wear testing methodology is. However, between both labs, and across all tests, no statistically significant differences were found in wear overall between fixed and mobile bearings. Therefore, the wear of mobile bearing knees is not necessarily less than that of fixed bearings. In

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both, it depends on the detailed design and materials of the TKR. Testing appears to be necessary with *all* implant designs, regardless of the history of clinically successful predicates of seemingly similar generic design.

KEYWORDS: wear, total knee replacement, TKR, in vitro testing, knee simulator, fixed bearing, mobile bearing, rotating platform

Introduction

Some well-known rotating platform total knee replacement (TKR) and unicondylar designs have had truly excellent long-term clinical results. These include the LCS TKR (DePuy) and the Oxford Unicompartmental Knee (Biomet). With the cementless rotating platform LCS, survivorship greater than 97 % at 18 years has been reported [1]. Similarly, for the Oxford Uni, a success rate of greater than 98 % has been reported with over 10 years of follow-up. As the latter is unicompartmental, it allowed for the rapid recovery of patients with more natural function [2]. Mobile bearing TKR implants are by definition less constrained, especially rotationally. It has been known for a long time [3] that a lower constraint of a prosthetic joint can help reduce the shear forces and torques transmitted to the prosthesis–bone interface, and this in turn helps reduce the risk of implant loosening. In a relatively recent in vitro cadaveric study, the strain of the proximal tibia in response to torsional loading of a rotating-platform knee prosthesis was measured [4]. It showed better tolerance of the axial rotation through less shear strain transfer to the implant–bone interface in the short term. Some argue that a rotating-platform knee is also forgiving of surgical rotational misalignments, and thus acts as an adjustable implant with tibial self-alignment encouraging more central patellar tracking [5,6].

However, the most commonly assumed theoretical benefit of mobile bearings is the reduction in contact stress, which has been typically expected to reduce fatigue and wear. In a rotating-platform TKR, wear is also expected to be less because the rolling/sliding motion is separated from the transverse rotational motion onto two separate articulating surfaces, thus presenting fewer cross-paths and less wear. Compared to simply reciprocating linear or curvilinear motion, cross articular shear causes higher wear in ultrahigh-molecular-weight polyethylene (UHMWPE) [7–9].

The above expectations of lower wear in mobile bearings might have had an influence on the thinking and expectations of TKR wear test engineers. Such wear reduction has not, however, been categorically proven clinically.

Meanwhile, fixed bearing TKRs have in general had comparable success in terms of kinematic ability, wear, osteolysis, and loosening [1,7,10–19]. Among many examples of products with good long-term results are the IB (Zimmer) (98 % good to excellent) [20], AGC (Biomet) (98.8 % at 15 years) [21], Genesis (Smith & Nephew) (96 % at 10 years) [18], second-generation PFC Sigma fixed-bearing knee (DePuy) (97 % at 10 years) [16], and Total Condylar Knee Prosthesis (Howmedica) (98 % at 20 years) [12,17,19].

Indeed, some studies have questioned whether there was actually a difference between fixed-bearing and mobile-bearing TKRs in terms of clinical and

radiological results regarding polyethylene wear and osteolysis [22,23]. A recent clinical study compared the results of 146 patients who received a fixed bearing TKR in one knee and a rotating-platform design in the other [24]. The study found no evidence of the superiority of one design over the other at long-term follow-up (11.0 to 14.5 years) in terms of fewer radiolucent lines and, therefore, less osteolysis and wear.

In a recent study [25], the important question was asked of whether the mobility of the bearing had been the main reason, or even an important reason, for the low wear and the reported excellent results of the mobile bearing knees. Various other in vitro studies [9,26,27] had compared mobile bearings with fixed-bearing TKRs, but the mobility of the bearing had not been the only difference; either the femoral component or other design details were different, and/or the testing had been performed under a displacement-control or hybrid regime. It was typical of such studies for the two types of bearings to have been given different pre-selected kinematics as test inputs. As the kinematics affect wear, it could be argued that prescribing different motions as inputs indirectly dictates the wear results.

In contrast, the in vitro study of Ref 25 compared the wear of a mobile (rotating-platform) tibial insert to that of a fixed-bearing version of the PFC Sigma TKR (DePuy), with the two being of identical design otherwise. Four samples of each TKR system were tested on force control knee simulators using identical International Organization for Standardization (ISO) standard force inputs and simulated soft tissue restraint for 6×10^6 walking cycles. The wear rates were very low compared with those of most other implants tested similarly in the same laboratory. Interestingly, however, with this very well-known rotating-platform TKR system, and with enough sample numbers producing $>97\%$ statistical power, no significant difference was found ($p = 0.298$) between the polyethylene wear rates of the mobile and fixed bearing designs.

The above-described case study [25] was conclusive, but it could not be generalized. In that single clinically proven TKR design, the mobile bearing was neither significantly better nor worse in terms of wear than the fixed-bearing version, the latter having also been very successful clinically [16].

In the current study, we ask the more ambitious and general question of whether the wear of mobile bearing knees is necessarily less from in vitro test results across a wide range of knee designs.

Materials and Methods

We amalgamated in vitro wear data from the two separate laboratories of the two authors, in Nebraska (USA) and Germany. In Nebraska, (originally) Stanmore Knee Simulators that were redesigned in-house and upgraded by the first author were used (Fig. 1). In Germany, EndoLab Knee Simulators (Fig. 2), built by the second author, were used. Fortunately, those simulators were essentially similar, and the test methodologies used in the two labs for all the results presented here—force-control wear testing according to ISO 14243-1 and ISO 14243-2—were largely similar and had fully converged since 2009. There

FIG. 1—*One of the three knee simulators at the University of Nebraska Medical Center. The simulator has 4 test stations that are servo-electrically and pneumatically driven. Loaded-soak controls are implemented on a separate, dedicated external machine. Middle right: Example flexion bracket custom made for optimum sagittal plane alignment of an individual implant. Top: Large stainless steel tibial component dishes for high range TKR motion. Bottom: Serum bags used in some tests to increase the amount of lubricant per station with some TKR designs.*

FIG. 2—*Knee simulator at EndoLab/Germany. Force-control testing with soft tissue simulation. Loaded soak control is implemented on one of the four test stations.*

were two relatively important exceptions (differences) related to some of the EndoLab tests prior to 2009, and one minor other difference.

The first difference was in the soft tissue simulation, due to a revision of the ISO standard that occurred in 2009 and which is summarized in Table 1. Prior to 2009, the standard prescribed a simple linear restraint model [30 N/mm for anterior-posterior (AP) and 0.6 Nm/deg for internal-external (IE) rotation] to be imposed throughout the range of AP and IE motions. Also, too simplistically at that time, the ISO standard did not specify that this restraint setup should be varied when testing posterior cruciate ligament (PCL) substituting [e.g., posterior stabilized (PS)] versus PCL retaining cruciate retaining (CR) TKR implants. In a later (2009) revision of the ISO standard, a more physiologically realistic non-linear model for both AP movement and rotation were prescribed, and it included differentiation between the PCL retaining and substituting implant designs (see Table 1 for details, as well as Ref 28).

The results for the tests done at EndoLab (Germany) prior to 2009 had simulated the soft tissue exactly according to the version of ISO 14243-1 issued prior to 2009, and the EndoLab results after 2009 followed the revised version of the standard.

The Nebraska TKR wear results presented here (from tests conducted in the period spanning 2000–2011) were all done in exactly the same way, according to the post-2009 revision of the ISO standard.

The second difference between the methodologies employed at EndoLab prior to 2009 was a small variation in the serum lubricant concentration. In EndoLab, prior to 2009, the bovine serum lubricant was diluted to a protein

TABLE 1—*Soft tissue restraint simulation requirements for TKR wear testing under force control according to ISO 14243-1, showing the versions prior to and after 2009 [28].*

Linear AP Restraint		
ISO 14243-1 prior to 2009 (no gap; same for PCL retained and resected) (some of the EndoLab tests)	30 N/mm	
ISO 14243-1:2009 (all Nebraska results and some of the EndoLab results)	Within ± 2.5 mm of the neutral position	Beyond
PCL sacrificing TKR	0	9.3 N/mm
PCL retaining TKR	0	44 N/mm
Rotational IE Restraint		
ISO 14243-1 prior to 2009 (no gap; same for PCL retained and resected)	0.6 Nm/deg	
Proposed revision and settings used in Nebraska since 2000	Within ± 6° of the neutral position	Beyond
PCL sacrificing TKR	0	0.13 Nm/deg
PCL retaining TKR	0	0.36 Nm/deg

concentration of 30 g/l, and after 2009 this was changed to 20 g/l. Nebraska used a concentration of 20 g/l throughout the period of 2000–2011. In all cases, in order to slow bacterial growth, the lubricant contained 0.2 % sodium azide and 20 mM (7.45 g/L) ethylene diaminetetraacetic acid to reduce calcium precipitation.

In all cases, the simulator test for a particular group of TKRs involved 2 to 4 identical TKR samples representing a combination of TKR designs, sizes, and materials. Each test would involve at least 5×10^6 simulated walking cycles. In all cases, wear was measured gravimetrically according to the strict cleaning and weighing protocols of ISO 14243-1 and -2. The wear measurements in each test were conducted at the start and at frequent intervals throughout the test. Herein lies the third minor difference: In Nebraska, those intervals did not exceed 0.5×10^6 cycles. In Germany, although the cleaning and serum lubricant exchange occurred at intervals of 0.5×10^6 cycles, the actual wear measurements after the first million were conducted every million cycles up to the end of each test run.

Other than the soft tissue simulation difference and a minor difference in the protein concentration in the EndoLab results from prior to 2009 and the fewer wear measuring intervals at EndoLab once a test got going, the testing methods were very similar and were conducted according to ISO 14243-1.

One hundred and thirty-three different groups ($n = 2$ to 4 in each group) of implants were tested on knee wear simulators as described above, covering fixed and mobile designs, total (bicondylar) and unicompartmental, and various sizes

and bearing materials. Some mobile bearings had rotating platforms, and some were both rotating and translating.

The bearing materials presented here were all UHWMPE of various basic resins (mostly GUR 1020 or GUR 1050). The processing of those resins and the manufacturing of the final bearings ranged from what is typically loosely termed "conventional UHMWPE," without any deliberate cross-linking beyond what had occurred during radiation sterilization, to the deliberately highly crosslinked varieties (e.g., up to a 10 MRad dose of radiation). Some of the highly crosslinked bearing materials even had modern oxidation stabilization techniques applied to them, such as with vitamin E and/or various combinations and sequences of remelting, annealing, radiation, and even artificial aging for some harsh cases.

Twenty groups were tested in Nebraska: 16 groups of fixed bearing and 4 groups of mobile bearing (of various types, sizes, and materials). Fifteen groups were tested in Germany with an identical test method (post-2009 ISO 14243-1 revision), and 98 groups were tested prior to 2009, with the differences in method described earlier.

Results

The results have been aggregated into the three major groups above, as shown in Figs. 3, 4, and 5. The 22 groups from Nebraska include enough detail to illustrate (for example) that the fixed-bearing TKRs with highly crosslinked UHMWPE (FB10, FB14, and FB16) showed lower wear than conventional poly implants of the same design and size (Fig. 3). This can be solidly proven by comparing each type with its own control (but this is not done here). These highly crosslinked fixed-bearing TKRs (FB10, FB14, and FB16) were of various designs, sizes, and types, and some had artificially aged bearings. Even if the samples in that sub-group (FB10, FB14, and FB16), which contained different design and size TKR combinations, were lumped together and compared to the conventional poly fixed bearing knees, they would show an average of 80% lower wear than the fixed bearings. This difference was associated with very high statistical significance ($p < 0.005$), and an 80% average wear reduction was of very worthy clinical significance, too. We present this example in order to illustrate that the force-control test methodology is highly discriminating for wear when such differences in wear exist between TKR designs/materials and at clinically significant levels. There are many similar examples in our data (not highlighted or labeled as such here) for such differences, and some were deliberately investigated in studies with special controls (see, e.g., Ref 25).

When the 4 groups ($n = 16$ samples total) of mobile bearing TKRs from the Nebraska results (Fig. 3) were compared as a whole to the 16 fixed-bearing TKR groups/types ($n = 50$ samples), the wear rate of the mobile bearing knees of all types (from the Nebraska tests) averaged 7.80 mg/MC (standard deviation ± 4.40 mg/MC). This was lower than for fixed bearings (of all types) (12.7 ± 7.23 mg/MC). The 40% lower wear does not reach statistical significance. The two-tailed probability would be $p = 0.21$, and the one-tailed $p = 0.11$ (the latter is, strictly, more appropriate, because we chose to treat a hypothetically higher

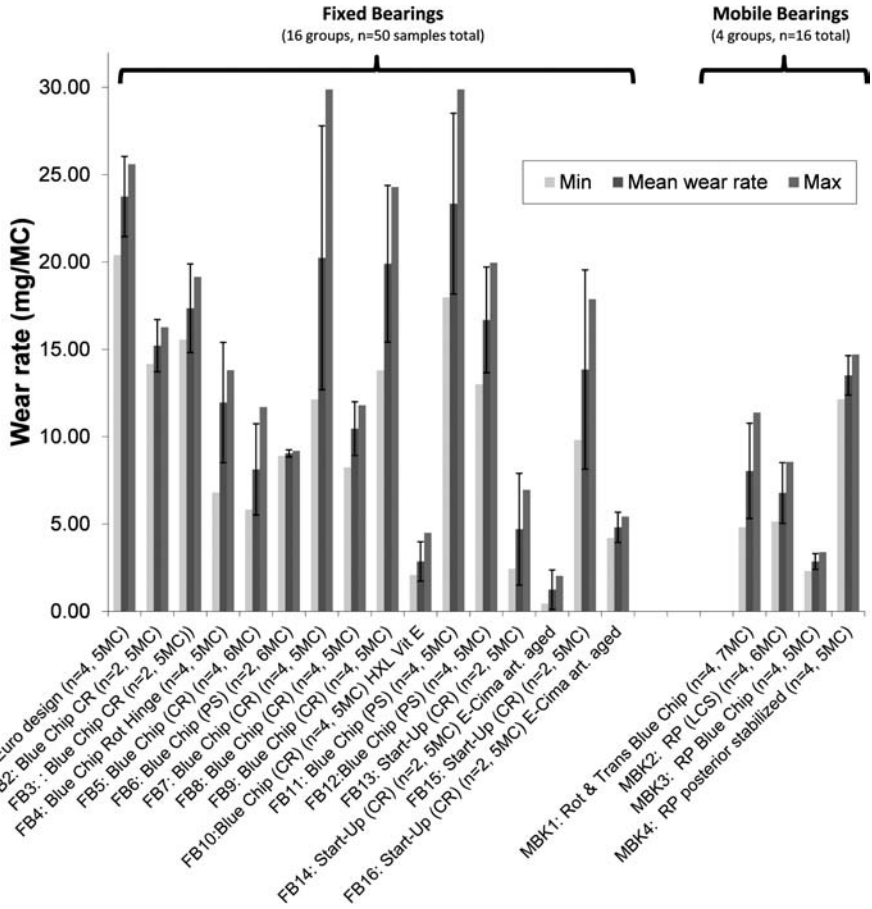

FIG. 3—*TKR wear results from the University of Nebraska Medical Center. The term "Blue Chip" was used here only to symbolize a widely used and clinically successful TKR implant from a large implant manufacturing company.*

wear of the mobile bearing than of the fixed the same as the null hypotheses; we are interested only in proving or disproving that the mobile bearing knee wear is necessarily lower).

The same result emerges from the much higher number of TKR wear results of EndoLab/Germany (Fig. 4). If mobile bearings of all kinds (from Fig. 4) were lumped together, their wear (5.35 ± 3.76 mg/MC), compared to that of fixed bearings (5.86 ± 4.44 mg/MC), would not be statistically significantly different (one-tailed $p = 0.28$). One sub-type of mobile bearing from Fig. 4 was interesting when compared to the fixed bearings. The 6 groups of rotating and translating mobile bearings showed, on average, 60 % *greater* wear than the fixed bearings, an interesting result that verged toward marginal statistical significance (two-tailed $p = 0.07$, one-tailed $p = 0.034$). However, the 30 overall groups

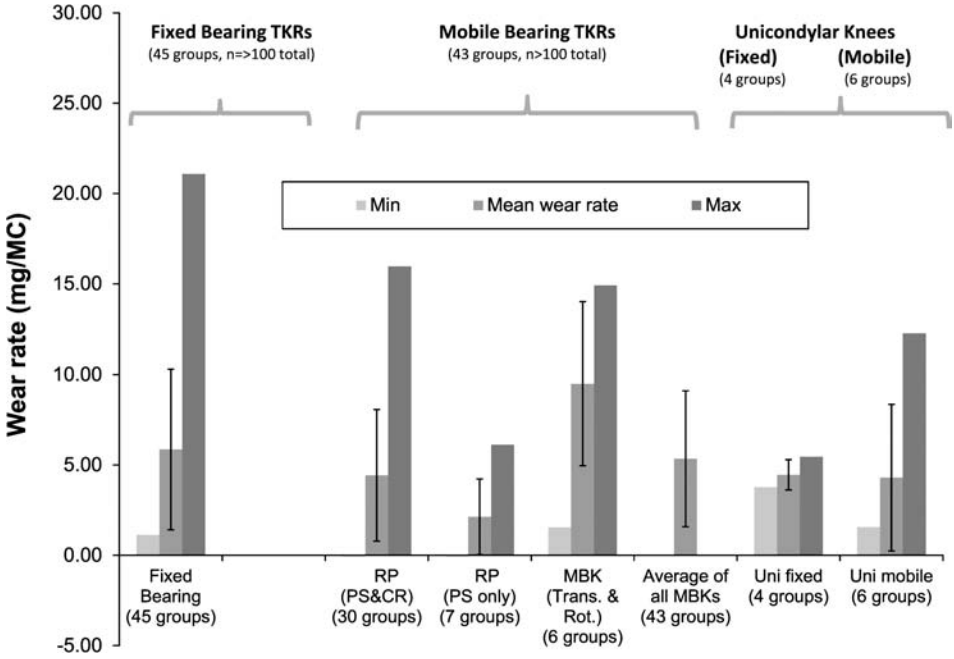

FIG. 4—*TKR wear results from EndoLab/Germany performed prior to the 2009 revision of ISO 14243-1.*

of rotating-platform designs (PS and CR) from the tests of Fig. 4 showed 25 % lower wear, which is not statistically significant (one-tailed $p = 0.07$). Interestingly, if the 7 groups of PS rotating-platform designs were considered alone, they would yield an average of less than half the wear of the fixed bearings, a difference that is statistically significant (one-tailed $p = 0.02$).

In contrast, from the same dataset (Fig. 4), the EndoLab pre-2009 results showed that for the unicondylar designs, the 6 different mobile bearing types showed approximately the same wear (4.30 ± 4.06 mg/MC) as the 4 fixed bearing design groups (4.46 ± 0.84 mg/MC), but the wear of the mobile unicondylar designs showed a much larger variability (one-tailed $p = 0.47$).

With the smaller dataset for the post-2009 tests at EndoLab (Fig. 5), the three types (groups) of mobile TKR bearings (all coated metallic surfaces) averaged 3.70 ± 2.14 mg/MC, 60 % lower than the 10.4 ± 5.62 mg/MC for the 12 fixed bearing groups/types tested in the same way (one-tailed $p = 0.04$). But for the low (33 %) statistical power associated with this subset of data, this difference verged toward statistical significance at the 95 % confidence level.

Discussion

The purpose of the amalgamation of knee simulator wear testing data presented here was to find out whether any trends would support the notion of mobile

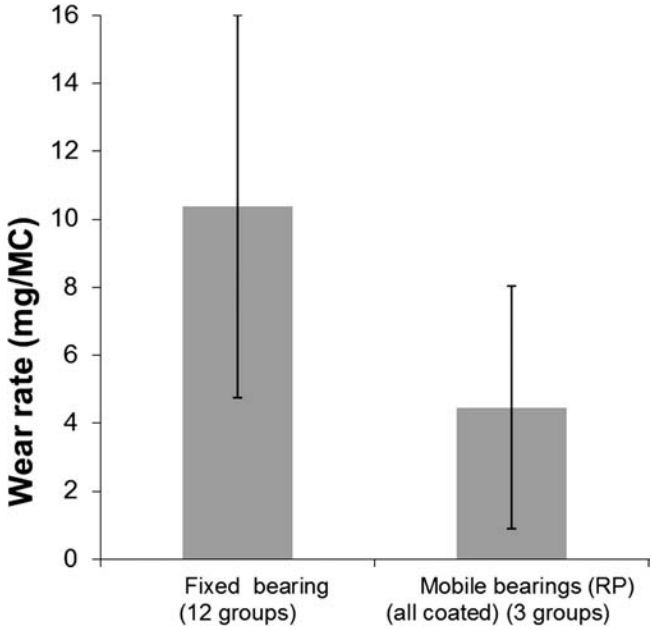

FIG. 5—*TKR wear results from EndoLab/Germany performed after and according to the 2009 revision of ISO 14243-1.*

bearing knees being expected to exhibit lower wear because their bearings are mobile. What resulted was the largest ever dataset of in vitro TKR wear testing data, spanning across the widest variety of fixed and mobile bearing TKR designs, materials, and sizes.

TKR wear depends on the combination of joint forces and motions at the implant's articulating surfaces. Two principal test methods have been standardized to experimentally simulate wear in the knee: force-controlled testing and displacement-controlled testing (see Ref 28 for a comprehensive description of both methods that contrasts the pros and cons of each). In both, flexion-extension motion is actuated through angular control, and a varying axial load is controlled with it in synchrony. The difference is in how the AP motion and IE rotations are instigated. In vivo, the kinematics of knees with TKRs can be highly dependent on the design of the knee implant. In the displacement control method, the AP motion and IE rotation of the tibial component are directly imposed and controlled as motions. This assumes that they would be known for that implant, which is typically not the case, especially for new designs.

Fortunately, the test methodology employed for all the TKR wear results presented in this paper was the other method (force-control) [28]. Here, the AP force and IE torque were imposed (controlled) dynamically as those required for quasi-static equilibrium at each phase/posture of the walking gate cycle of an average human knee. The standard test method of ISO 14243-1 provides such force and torque waveforms to be treated as "standard inputs" to simulate

walking and to be applied in the testing of any TKR design. The waveforms were originally based on "quasi-static" analyses of a geometrical model of the knee with electro-myographic data and ground-to-foot force and kinematic data [29,30]. These were verified as physiologically realistic with direct telemetry data from a distal femoral knee replacement [31] and, finally, an instrumented TKR [32]. This scheme requires additional simulation of the ligament and other soft tissue constraints that would occur invivo and which depend on the instantaneous AP position and IE angle. The levels of such simulated constraints depend on whether the TKR is PCL retaining or sacrificing [28,33,34]. In our tests, these have been simulated with springs [28,34,35].

In the force-control method, therefore, the TKR kinematics (as well as wear) are dependent variables and form the results of testing rather than its inputs. This force-control methodology and the simulators used in this study have been widely published on (see Ref 28 for a comprehensive description of the method and its history, as well as a comparison with other methods).

Considering the method used, and assuming the inputs in the tests to all knees were the same and there was appropriate soft tissue simulation, between both labs and across all tests, no consistent statistically significant difference was found that could characterize mobile bearings as having to have lower wear than fixed bearings. Yet such differences were clearly featured in the example shown in the preceding section, of significantly lower wear in highly crosslinked UHMWPE (from the results of Fig. 3) than in the conventional UHMWPE bearings.

By close examination of the plots in Figs. 3–5, especially the standard deviations and min/max extremes, one can see that depending on the TKR design and materials, the ranges of wear of mobile bearing knees clearly overlap those of fixed bearings. This alone is categorical enough to shed doubt on any claim that mobile bearing knees should simply wear less than fixed bearings. It also confirms the need for all TKR systems, mobile as well as fixed, to be tested for their individual detailed design and materials.

If the question presented in this paper were modified in order to speculate on which would generally more likely have less wear (mobile bearing designs or fixed bearing TKR designs), then the answer becomes more complex. From the results shown here, there appears to be some tendency for mobile bearing knees to wear less, but our results do not support this difference as statistically significant with sufficient power across all the types we tested.

The above implies two things: The mobility of the TKR bearing versus that of a fixed bearing is one of many variables, all of which are influential, and it is the combination of mobility and good design and materials that can bring less wear, not mobility alone. Also, the effectiveness of a mobile bearing design can more usefully be assessed and compared to that of a fixed bearing when the same TKR is tested in two versions (fixed and mobile), with materials and all design details other than those that provide the bearing mobility being kept the same. As mentioned in the introductory section, a previous dedicated study [25] did precisely that and showed no significant difference in wear on one well-known deign that is frequently used as an example of the superiority of mobile bearing knees.

Among the limitations of our data are that our wear tests simulated only human walking gait, without more demanding daily activities such as turning while walking, stair climbing, or higher flexion squatting. It is questionable how less frequent activities such as these would add to the wear assessed for walking. It is even less clear which way the trends found here would turn if such activities were simulated. The simulation of more severe daily activities in order to measure TKR wear has not been standardized, and it is rare to find data that could be compared across TKR designs, let alone laboratories.

Another limitation of our data is inherent in the scope of the study presented. The question addressed wear as an isolated variable. However, the efficacy of an implant would include its functional "performance," and this might indeed sway the overall answer differently. It is clear that mobile bearings would be expected to show less constraint against either rotation or translation, or both. Although the overall knee joint laxity would result from the combination of the implant constraint and the soft-tissue constraint as tuned in surgery, a less constrained implant clearly has implications for less loosening and better survival, as mentioned earlier. It is important to note, however, that the implant constraint can also be too little, thus demanding a more exacting soft tissue balance and surgical technique.

In the same way, our data are limited by our not addressing the (debated) potential new risks with mobile bearings, such as intermittent sticking due to edge loading or the small reported risks of subluxation, and the possibility of introducing more adhesive and even abrasive backside wear. The latter can be induced by trapped bone/cement debris.

Just as with fixed bearings, any benefits and risks of mobile bearings should be considered multi-factorial and should be addressed, and tested, preferably one factor/variable at a time.

Our data and conclusions do not show the wear of mobile bearing TKRs to be necessarily less than that of fixed bearings. The wear of both will depend more on the detailed design and materials of the TKR than on the mobility of the bearing. With the high ability of the force-control test method to discriminate and thus predict wear, all TKR implant designs, fixed and mobile, should be tested in vitro for preclinical screening against the potential risk of excessive wear.

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