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A hybrid apparatus for friction and accelerated wear testing of total knee replacement bearing materials

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ABSTRACT

The statistical survivorship of total knee replacement (TKR) devices declines dramatically after fifteen years of use because the articulating surfaces wear, and biologically active wear particles may induce osteolysis and subsequent loosening of the implant. This lack of durability leads to revision surgery or surgery postponement. Thus, friction and wear evaluation is of primary concern when designing the next generation of TKR bearings. Presently, knee simulators are used to aid in the development of TKR devices, mimicking six degrees of freedom of the knee joint under simulated gait. However, these simulator experiments are lengthy and, thus, do not allow for efficient testing of large numbers of bearing material pairs and designs. Conversely, inexpensive pin-on-disk (POD) tests allow for efficient testing, but the results may have limited clinical relevance. This paper presents the design of a hybrid friction and accelerated wear testing apparatus that combines elements of both a POD apparatus and a knee simulator. The apparatus simulates dynamic axial loading and flexion/extension rotation, and it enables fast and inexpensive screening of TKR bearing materials with boundary and loading conditions that are more clinically relevant than those of a POD apparatus.

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1. Introduction

1.1. Significance

More than 650,000 total knee replacement (TKR) surgeries are performed in the US each year to treat degenerative joint diseases that cause pain and disability [1]. The statistical survivorship of TKR devices declines dramatically after fifteen years of use [2,3]. This lack of durability has unacceptable effects, such as riskier revision surgery or surgery postponement. A TKR consists of a femoral component, usually made of Cobalt-Chromium (CoCr), which articulates against a tibial insert, almost always made of Ultra-High Molecular Weight PolyEthylene (UHMWPE) or highly Cross-Linked PolyEthylene (XLPE). The polyethylene part is clamped in a tibial plate that is anchored in the tibia. The two main reasons for a TKR to fail are [4,5]: (1) wear of the polyethylene insert resulting from articulation with the CoCr femoral component in combination with abrasive bone and metal wear particles, oxidation from gamma ray sterilization, and subsurface fatigue induced by high contact stresses, create biologically active wear debris [6–10]. (2) Adverse biological reaction to indigestible microscopic wear debris leads to osteolysis [11-14], which

undermines the implant and causes loosening and instability [14]. Thus, in-vitro durability wear testing is of primary concern to reduce in-vivo wear of TKR bearing material pairs.

1.2. Durability wear tests

A spectrum of different durability TKR wear testing methods exists. Perhaps one of the most simple and affordable methods is the pin-on-disk (POD) experiment. This type of experiment is used to screen different bearing materials rather than entire TKR systems. In a POD experiment, one bearing material is attached to a flat or spherical pin that is loaded against another bearing material affixed to a plate. The friction and wear characteristics of the material pair are measured while creating relative motion between the bearing materials. Several variations of POD experiments exist as summarized by Gevaert et al. [15]. For instance, a rotary POD experiment consists of a stationary pin loaded against a rotating disk, and a reciprocating POD experiment involves a pin that linearly translates back and forth along the same wear path while loaded against a stationary disk. Since polymer chains in UHMWPE have been found to align with the sliding direction [16–18], a new class of more sophisticated POD experiments based on multi-axis translation was introduced. The bearing materials are subject to multi-axis shear stresses similar to what occurs in a knee joint. For instance, in a circularly translating POD experiment, a stationary pin is loaded against a disk that translates in a circular





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pattern without rotation. Finally, multi-axis POD experiments based on the traditional reciprocating POD experiment exist as well, but include additional degrees of freedom. Important distinctions in the latter method include multi-directional [19,20], change path [21] and cross-path [21–23] wear tracks.

While it is desirable to reduce the complexity of knee kinematics and loading when performing initial screening of TKR bearing materials, the simple POD experiments are often performed under conditions that have limited clinical relevance to the in-vivo application [18,24,25]. Hence, to simulate in-vivo wear of TKR bearing materials, sophisticated knee simulators are employed to perform durability wear tests under simulated gait, and to obtain clinically relevant results. Knee simulators can account for the six degrees of freedom in the knee joint [26] and the corresponding forces and moments. The six degrees of freedom include the anterior/posterior (AP), medial/lateral (ML) and proximal/distal (axial-along tibia) translations, and flexion/extension (FE), internal/external (IE), and varus/valgus (VV) rotations. However, the most important kinematic components for TKR wear testing are the FE rotation, which spans a -5° to 140° range of motion [27], the IE rotation, and the AP translation. Large muscle forces produce large joint reaction forces in a TKR. Loading varies during normal walking gait between 168 N and 2433 N in the axial direction, -265 N to 52 N in AP direction, and -1 Nm to 6 Nm of IE rotational torque [27-29]. The resulting maximum contact stress between the femoral component and the tibial insert ranges between -20.7 MPa (compression) and 7.74 MPa (tension), which may exceed the yield stress of UHMWPE [30]. Creating these forces in a knee simulator is achieved by actuating them as forces in force-control knee simulator tests, or by reproducing the expected motions from the forces in displacement-control knee simulator tests [31]. The earliest knee simulators only included flexion/extension and axial loading [32]. Dowson et al. [33] designed the first simulator to specifically measure TKR wear. Axial and AP forces were applied hydraulically, synchronized with the FE rotation. Distilled water was used as a lubricant. Pappas et al. [34,35] included FE and IE rotations, AP translation, and axial compressive loading in their simulator design, motivated by the need to test mobile TKR bearings. Furthermore, the Durham [36] and Stanmore [37] simulators provided multi-station force-controlled wear testing of TKRs according to the ISO 14243-1 standard [38], while the AMTI, Shore Western [39], and ProSim simulators [40] enabled displacementcontrolled wear testing according to ISO 14243-3 [27].

The use of knee simulators is time consuming and costly. At least 5 million gait cycles must be simulated to obtain clinically meaningful data. In addition, the gait frequency is typically chosen to be 1 Hz and does not exceed 1.5–2.0 Hz. Hence, such a knee simulator experiment lasts 3–9 months [31] and, thus, it cannot be used for testing a vast number of different TKR designs and bearing material pairs. On the other hand, POD experiments are fast and efficient, but the testing conditions and environment are sometimes remote from the in-vivo application one attempts to

replicate. An accelerated wear test that is inexpensive and fast, yet still provides an environment relevant to the in-vivo application is needed to enable screening of large sets of TKR bearing material pairs, prior to testing a select number of materials and TKR designs in a knee simulator. Several authors have attempted to bridge this gap. Currier et al. [41] describe the design of a device that uses a stationary femoral component and a sliding tibial insert. The FE rotation range can be varied but is limited to 35° in their experiments. Load is applied by coil springs as the drive mechanism pushes the tibial insert up against the femoral component. However, the applied force depends on the stiffness of the coil springs, and no arbitrarily prescribed load as a function of time can be applied. Van Citters et al. [42] and Kennedy et al. [43] describe a tribotester based on an articulating CoCr and UHMWPE puck submerged in a lubricant bath. This design permits both sliding and rolling contact and the slide to roll ratio is calculated as the difference in puck velocities divided by the average puck velocity at the contact area. Schwenke et al. [44] describe a tribostester that enables twodirectional sliding, rolling, and rotation between a polished CoCr ball and a flat polished UHMWPE disk. Using physiologically relevant loading, speed, and lubrication, the link between cross-shear motions and wear is investigated. Patten et al. [44] describe a wheel-on-flat tribotester that allows applying a force-velocity input sequence to determine the influence of slip velocity on wear. Saikko et al. [45] describe a three-axis ball-on-flat tribotester that permits FE rotation, AP translation, and IE rotation. The load is held constant at 2 kN and lubrication is implemented by submersion in diluted calf serum.

All these testing apparatus designs focus on measuring wear between surrogate TKR components under operating conditions that are more clinically relevant than POD tests, but not as sophisticated as knee simulators. Friction forces between the articulating surfaces do not appear to be measured in these studies. However, monitoring friction could yield important information about the inception and evolution of contact and wear of the TKR bearing surfaces, and it enables monitoring the transition between boundary and (elasto) hydrodynamic lubrication. Hence, the objective of this paper is to describe the design of a hybrid apparatus that combines aspects of both a POD and a knee simulator and enables measurement of friction and wear to enable efficient durability screening of TKR bearing materials, prior to simulator testing. The focus of this paper is to describe the design and features of this novel friction and accelerated wear testing apparatus, rather than discussing specific friction and wear results obtained with this apparatus.

2. Apparatus

2.1. Concept

Fig. 1 illustrates the concept of the apparatus. A cylindrical specimen (surface 1), representing the femoral component of the



Fig. 1. Concept of the apparatus, showing two articulating TKR bearing surfaces subject to a torque moment M_t and normal load N for (a) cylindrical on flat (b) convex cylindrical on concave cylindrical, and (c) fully conformal contact.

TKR is mounted on a horizontal shaft that rotates reciprocally, representing FE rotation. A mating specimen (surface 2) representing the tibial insert is loaded perpendicular to the rotation axis of the cylindrical specimen, mimicking dynamic axial loading. The magnitude of the normal load is synchronized with the angular position of the shaft to mimic a knee gait cycle. The torque M_t to rotate the shaft and the normal load *N* acting on the articulating surfaces are measured, and the friction coefficient as a function of time is computed from these measurements. The entire articulating surface is submerged in a reservoir filled with lubricant (typically, boyine serum with protein concentration of 20 mg/ml to simulate joint fluid [46]) and, thus, traditional gravimetric wear measurements with or without soak controls can be performed to supplement the friction measurements [47]. Different contact scenarios from cylindrical on flat (Fig. 1(a)) to fully conformal convex and concave cylindrical (Fig. 1(c)), and anything in between (Fig. 1(b)) can be implemented. The apparatus is a significant simplification of a knee simulator and is more sophisticated than a POD experiment. It mimics FE rotation synchronized with dynamic axial loading but neglects the AP and ML translations and the IE and VV rotations, i.e., the apparatus only simulates sliding without rolling and no cross-shear can be created.



Fig. 2. Mechanical design of the apparatus, isometric view.

Neglecting cross-shear motion is particularly appropriate for highly-constrained TKR designs with rotating platform articulating surfaces, because these highly-conforming designs display minimal cross-shear during articulation. The simplifications are implemented because this apparatus is geared towards measuring friction between the bearing surfaces of surrogate TKR components, and studying the effects of (elasto)hydrodynamic lubrication induced during articulation. Friction is an early indicator of wear and, thus, an important parameter when performing shortduration wear tests. Since a majority of the relative motion in a TKR is uniaxial resulting from FE rotation and AP translation, it seems desirable to measure friction in a uniaxial sliding test. Thus, the time-evolution of friction can be monitored throughout the entire imposed kinematic cycle. This is particularly important during changes in sliding direction when the bearing may transition between boundary and (elasto)hydrodynamic lubrication. Direct measurement of the friction coefficient in addition to traditional wear measurement is not possible in most knee simulators. This apparatus is also more economical and faster than a knee simulator for screening bearing material pairs.

2.2. Mechanical design

The mechanical assembly of the apparatus consists of three parts: the FE rotation drive mechanism, the dynamic loading mechanism, and the base structure with lubricant reservoir. Fig. 2 shows a schematic of the apparatus, and Fig. 3 shows the implementation of this design. The FE mechanism consists of a reciprocally rotating shaft driven by a stepper motor with a 10:1 gear reduction to increase torque. The gearbox is connected to the shaft via a helical coupling (which absorbs misalignment in the drive mechanism) and an in-line torque sensor. The shaft is supported in two bearings mounted on the inside of the lubricant reservoir sidewalls as depicted in Fig. 3(b). A cylindrical specimen (surface 1) is mounted on the shaft in the reservoir by means of four set-screws. It is centered with respect to the shaft rotation axis using a temporarily positioned dial indicator (not pictured). A rubber seal between the bearing housing and the lubricant reservoir wall avoids joint fluid leakage.

The normal loading mechanism is illustrated in Fig. 4 and works as follows. Four precision shafts, anchored in the frame of the apparatus, are guided through brass bushings in two separate square plates. One plate holds an ACME nut and is driven up and down the precision shafts by a DC motor, which rotates an ACME threaded rod through this ACME nut (power screw). The second plate serves as a specimen holder for surface 2 and has a load cell embedded in it to measure the normal load. Four compression springs separate the two square plates. These springs are compressed when the plate that seats the ACME nut is driven towards



Fig. 3. Design of the apparatus (a) overview picture, (b) detail of the cylindrical specimen mounted on the shaft, and (c) detail of the articulating surfaces.

the specimen holder, thus loading the articulating surfaces. The normal load is synchronized with the angular position of the cylindrical specimen (surface 1), and it varies with time to replicate the axial loading during the knee gait cycle. The normal loading mechanism is designed to self-align the articulating surfaces. The only misalignment results from manufacturing tolerances of the convex/concave surfaces. The base frame provides alignment of the different components that constitute the apparatus and affords rigidity to the entire assembly. Furthermore, the lubricant reservoir is integrated in the base structure and allows regulating the amount of lubricant supplied to the bearing interface by means of regulating the lubricant level in the reservoir.

2.3. Instrumentation

Fig. 5 shows a schematic of the instrumentation. It consists of separate sections that handle the FE rotation drive mechanism, the normal load mechanism, and the input/output of data. A computer reads an input file that contains the axial bearing load as a function of time throughout the knee gait cycle. This load is



Fig. 4. Detail of the load mechanism, showing the threaded rod and ACME nut, as well as the precision shafts with compression springs that create the normal load.

synchronized with the angular position of the stepper motor using an open loop controller. The required normal load is the input to the controller of the DC motor driving the power screw that loads the articulating surfaces. A load cell (Futek LTH300) measures the normal load and closes a force-feedback control loop that adjusts this load as a function of time. Furthermore, the stepper motor rotates reciprocally, controlled by a stepper motor driver, and the torque to rotate the shaft is measured by a torque sensor (Futek TTF350). Both load cell and torque sensor signals are amplified (Futek CSG110) and then digitized using a DAQ card (Sensoray 626). Continuous measurement of the normal load and the torque enables computing the friction coefficient as a function of time, an important indicator of expected wear.

3. Experimental methodology

3.1. Specimens and contact area

Any axisymmetric specimen (surface 1) can be mounted on the reciprocating shaft. The contour of the second test specimen (surface 2) is computed such that a prescribed contact area is obtained when loaded against bearing surface 1. Sanders and Brannon [48] demonstrated that any arbitrary Hertzian contact pair can be substituted by another surrogate contact pair that replicates the contact area and contact pressure distribution of the original contact pair to second-order accuracy. Hence, the complex contact between a curved condyle of a femoral component and a curved indentation of a tibial insert can be replaced by a much simpler contact pair, for instance the combination of a circular cylinder or a flat surface and an ellipsoid. In one dimension, the equivalent radius of curvature R_{eq} of two curved surfaces with radius of curvature R_1 and R_2 , respectively, is given as [49]

$$\frac{1}{R_{eq}} = \frac{1}{R_1} + \frac{1}{R_2}.$$
(1)

Thus, the elastic contact of a bearing material pair with radius of curvatures R_1 and R_2 can be replaced by a specimen with radius of curvature R_{eq} in contact with a flat one. The surface roughness of each specimen is controlled to match that of actual commercial TKRs. Fig. 6 shows typical specimens used in this apparatus. Fig. 6 (a) shows a CoCr cylinder of diameter 50 mm and width 25 mm



Fig. 5. Instrumentation of the normal load mechanism, FE rotation drive mechanism, and data input/output.

(surface 1), finished to a surface finish of R_a =50 nm. The section with reduced diameter seats four set-screws for mounting on the reciprocating shaft. Fig. 6(b) displays two possible UHMWPE shapes for surface 2; a flat surface that together with surface 1 results in curved on flat contact (as in Fig. 1(a)), and a curved surface that results in convex on concave contact (as in Fig. 1 (b) and (c)). The polyethylene parts are finished to R_a =500 nm. These surface finish values are typical for commercial TKR devices.

3.2. Friction and wear measurement

While practically any load and sliding velocity as a function of time sequence can be implemented in this apparatus, the ISO 14243-1 standard prescribes the loading and displacement during gait for friction and wear testing of TKRs. The friction coefficient is calculated from the continuous normal load and torque measurements during a friction experiment. Wear measurements may be performed using the traditional gravimetric technique based on weight loss of the polyethylene part as a result of wear, with or without soak control [31,50]. White light interferometry of the worn surfaces can be used as well to obtain an estimate of the wear volume of the specimen. The latter technique, while quick, is known to cause error by neglecting the deformation created by creep.



Fig. 6. Typical examples of TKR bearing pair specimens, showing (a) CoCr cylindrical surface 1 mounted on reciprocating shaft, and (b) UHMWPE surface 2 mounted on the loading mechanism.

The lubricant reservoir has a volume of approximately 1.5 liter and is filled with joint fluid for durability wear testing. The composition of the joint fluid affects the results of a wear durability test; see for instance [46,51,52]. The ISO 14243-1 standard [38] prescribes a protein concentration of 20 mg/ml, a value that is often reported in the literature and appears to represent a consensus among wear test practitioners.

Figs. 7 and 8 show results obtained for the specimens shown in Fig. 6, i.e., a convex CoCr cylinder in conformal contact with a concave (contact angle of 90°) and flat UHMWPE specimen, respectively. The contact geometry of an actual TKR joint falls in between convex and concave conformal contact, and convex on flat contact. Both Figs. 7 and 8 show (a) the kinematic cycle. characterized by velocity and angular position, (b) the normal load, (c) the torque normalized with the maximum torque, and (d) the friction coefficient *f* normalized with the maximum friction coefficient f_{max} . Three seconds extracted from a long duration measurement performed with this apparatus are presented. Using Hertz contact theory, the normal loading results in a maximum contact pressure of 1.1 MPa and 9.4 MPa for the conformal and flat UHMWPE specimens, respectively. These values are realistic for part of the gait cycle during walking on flat ground for in-vivo TKR devices [30]. The sliding direction is indicated as counterclockwise (CCW) and clockwise (CW), and the gait cycle frequency is 1 Hz. The friction coefficient varies dynamically and is periodic with reversals between CCW and CW rotations. Moreover, the magnitude variation during each period can be interpreted to identify the different phases of the kinematic input cycle. For example, f/f_{max} is maximal surrounding the starts and stops, and it is minimal throughout the middle of each cycle, corresponding to constant-speed rotation and sliding (0.1 m/s) realistic for in-vivo TKR devices [27]. Also, the friction coefficient is found to increase with increments of normal load, as expected (not shown). Note that the variation in normal load is due to slight eccentricity of the convex CoCr specimen.

4. Discussion

An important aspect of this newly developed apparatus is that it provides means for performing fundamental friction and wear tests in a more clinically realistic context than is provided by other



Fig. 7. Typical friction measurement of a convex CoCr cylinder articulating against a conformal concave UHMWPE specimen (contact angle is 90°), (a) kinematic input cycle, (b) normal load, (c) normalized torque, and (d) normalized friction coefficient, as a function of time.



Fig. 8. Typical friction measurement of a convex CoCr cylinder articulating against a flat UHMWPE specimen, (a) kinematic input cycle, (b) normal load, (c) normalized torque, and (d) normalized friction coefficient, as a function of time.

screening wear test systems such as POD systems. While this apparatus neglects AP and ML translations as well as IE rotation investigated by other authors, the hydrodynamic wedge effect, which can strongly influence friction and wear, can be simulated by designing the bearing surfaces as in Fig. 1(b). Thus, a multitude of elastohydrodynamic conditions using differently shaped polyethylene components can be evaluated. This same effect cannot be induced using the flat-on-flat surface configuration of the ASTM standard POD wear test [53], much less to represent any particular design of a knee condylar contact pair. Also, the possibility to vary the normal loading as a function of time, synchronized with the angular position of the CoCr cylinder enables changing the contact stress in a single gait cycle, while measuring the friction coefficient between the articulating surfaces. With this new system, no actual, finished TKR devices are required, yet the contact mechanics of a specific condylar contact pair can still be accurately simulated by means of a simplified surrogate contact pair that creates the same contact area and contact pressure as the actual bearing pair [48]. Indeed, the simplified surrogate pair is easier to manufacture. Thus, it is suggested that a principal benefit of the new system is for measuring the friction and wear of prospective designs, rather than finished designs, to optimize them before they enter the lengthy stages of manufacturing development, whereupon it becomes quite difficult for manufacturers to enact further important design changes.

The new apparatus also enables evaluating the effect of clearance between the two components of a TKR bearing on the friction coefficient during a gait cycle, as well as wear after many cycles. Furthermore, it is significantly more sophisticated than most POD experiments because it simulates dynamic axial loading and FE rotation; yet, the expense and difficulty of performing experiments on this new apparatus is similar to that of POD experiments and much less expensive than complicated simulator testing. Multi-station testing can easily be implemented.

Doubt exists about the clinical relevance of friction and wear data obtained with POD experiments. Clinically relevant data must be obtained with knee simulators. The value of this apparatus lies in that it allows fast and inexpensive friction testing of TKR bearing materials with boundary conditions that are more clinically relevant than those of a POD apparatus. This device could benefit from an additional degree of freedom, such as medial/ lateral translation. This would add cross-shear to the wear testing, which has been demonstrated to increase wear by avoiding alignment of polyethylene fibrils. However, the ML translation is much smaller than the combined sliding resulting from the AP translation and the flexion rotation. Hence, many TKR wear experiments neglect the ML translation.

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