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Effect of anterior–posterior and internal–external motion restraint during knee wear simulation on a posterior stabilised knee design

Thomas M. Grupp [a,b,*], Khaled J. Saleh [c], William M. Mihalko [d], Martin Hintner [e], Bernhard Fritz [a], Christoph Schilling [a], Jens Schwiesau [a], Christian Kaddick [e]

[a] Aesculap AG, Research & Development, Tuttlingen, Germany
[b] Ludwig Maximilians University, Clinic for Orthopaedic Surgery, Campus Grosshadern, Munich, Germany
[c] Division of Orthopaedics, Southern Illinois University School of Medicine, Springfield, IL, USA
[d] Orthopaedic Reconstructive Research Institute, University of Tennessee, TN, USA
[e] EndoLab Mechanical Engineering GmbH, Thansau, Germany

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ABSTRACT

The objective of our study was to examine the effect of biphaseal AP translation and IE rotation restraint, using a system defined specifically for posterior stabilised knee designs, on wear, kinematics and particle release in comparison to linear motion restraint as required by the established ISO 14243-1:2002(E) protocol. In the ISOlinear groups, an AP motion restraint of 30 N/mm and an IE rotation restraint of 0.6 Nm/° were applied in the knee wear simulation. In the ISOgap biphaseal groups with PCL sacrificing implants, the restraining AP force was zero in a ±2.5 mm range with, externally, a constant of 9.3 N/mm applied proportionally to the AP translation of the tibia plateau, whereas the restraining IE torque was zero in a ±6° range with, externally, a constant of 0.13 Nm/° applied proportionally to the IE rotation of the tibia plateau. Using the ISOgap biphaseal protocol on a posterior stabilised knee design, we found an increase of 41% in AP translation and of 131% in IE rotation, resulting in a 3.2-fold higher wear rate compared to the results obtained using the ISOlinear protocol. Changes in AP translation and IE rotation ligament motion restraints have a high impact on knee joint kinematics and wear behaviour of a fixed bearing posterior stabilised knee design.

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1. Introduction

In total knee arthroplasty (TKA) the biological response to polyethylene wear particles has been found as a key factor for the occurrence of periprosthetic osteolysis and subsequent implant loosening (Amstutz et al., 1992; Algan et al., 1996; Revell et al., 1997) which is the primary reason for implant revision (Robertsson et al., 2001; Sharkey et al., 2002; Fehring et al., 2004). Release rate, total volume and morphology of the submicrometer sized wear particles were identified as the main limiting factors on the implant's longevity (Green et al., 1998; Ingham and Fisher, 2000).

More than a decade ago in vitro wear simulation was introduced to assess the biotribological mechanisms of total knee replacements (Walker et al., 1997; DesJardins et al., 2000) under conditions of level walking. To optimise design and articulation materials of these implants, experimental wear studies were carried out (Muratoglu et al., 2004; McEwen et al., 2005; Grupp et al., 2009a). On two clinically proven knee implants of different design, Walker et al. (2000) demonstrated that articulation wear similar to in vivo wear modes can be generated in vitro.

The vast majority of in vitro wear studies under force control were performed on simulators with mechanical springs to replicate the ligament and soft tissue restraints in anterior–posterior (AP) translation and internal–external (IE) rotation (Walker et al., 1997; Schwenke et al., 2005; Grupp et al., 2009b; Schwenke, 2009). Evaluating the influence of AP translation and IE rotation under displacement control, McEwen et al. (2005) found a correlation between a substantial polyethylene wear increase and high kinematic inputs. Regarding the effect of knee joint laxity on wear and kinematics, Kretzer et al. (2010) found that the relatively high linear motion restraint given in ISO 14243-1:2002(E) does not represent adequately the in vivo conditions. They recommend the use of an asymmetric non-linear ligament and soft tissue restraint model based on the findings of Fukubayashi et al. (1982) and Kanamori et al. (2002) and reported increased AP translation and IE rotation in good agreement with clinical findings (DesJardins et al., 2007). This model is based on polynomial equations to take into account the absence of the surgically removed anterior cruciate ligament (ACL) by using an electronic soft tissue control system.

* Corresponding author at: Aesculap AG, Research & Development, Am Aesculap-Platz, D-78532 Tuttlingen, Germany. Tel.: +49 7461 95 2667; fax: +49 7461 95 382667.
E-mail address: thomas.grupp@aesculap.de (T.M. Grupp).

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However, this interesting sophisticated model is not applicable on most of the established knee wear simulators where the soft tissue restraint is replicated by mechanical components. To simplify laboratory setups, Haider et al. (2006) introduced a triphaseal spring model to reproduce physiological conditions for knee laxity. But due to the mechanical setup a limitation was given by an impairment between the AP and IE motion restraints. To overcome this limitation the current version of ISO 14243-1:2009 (E) provides for a motion restraint system that operates independently for AP translation and IE rotation and describes a biphaseal spring model with different proportionality constants for AP force and IE torque to test posterior cruciate ligament (PCL) retaining and PCL sacrificing knee designs.

The objectives of our study were to evaluate the impact of this newly introduced biphaseal AP and IE motion restraint system on the wear behaviour, tibio-femoral kinematics and particle release of a posterior stabilised knee system with two different gliding surface designs in comparison to the established linear restraint.

Fig. 1. Total knee arthroplasty device (AS Vega System® PS) with femoral and tibial components out of a CoCr29Mo6 alloy with a multilayer ZrN surface coating and a posterior stabilised gliding surface out of UHMWPE.

2. Materials and methods

In vitro wear simulation was performed using the clinically introduced AS Vega System® PS total knee replacement (Aesculap AG Tuttlingen, Germany) with a zirconium nitride-on-polyethylene articulation (Reich et al., 2010) to compare the standard ISO 14243-1:2002 (E) protocol with a linear AP and IE motion restraint (ISO_{linear}) and the new ISO 14243-1:2009 (E) protocol with a biphaseal AP and IE motion restraint ($ISO_{gap\ biphaseal}$) (Fig. 1). "Biphaseal" means that AP and IE motion restraint were defined as zero under specific ranges. whereas outside they are proportional to the reached AP translation and IE rotation. A 3.5–5 μm thick multilayer coating system (AS) with a final zirconium nitride shielding layer is applied to the CoCr29Mo6 alloy femoral and tibial components (Reich et al., 2010). AS Vega System® PS femoral and tibial components were used in an intermediate size F4L combined with T3 and UHMWPE posterior stabilised gliding surfaces PS and PS+ machined from GUR 1020. The only difference between the PS and PS+ gliding surfaces is the width of the post allowing a femoral play in ml direction of 2.25 mm (PS) and 0.5 mm (PS+). The polyethylene gliding surfaces (size T3, height 10 mm) were packed under nitrogen atmosphere and sterilised by electron beam irradiation (30 ± 2 kGy). All tibial inserts were soaked prior to wear simulation in serum-based test medium for 30 days to allow for saturated fluid absorption.

2.1. In vitro wear simulation and motion restraints

The simulation was performed on a customised 4-station servo-hydraulic knee wear simulator (EndoLab GmbH Thansau, Germany). For both test methods (ISO_{linear} and $ISO_{gap\ biphaseal}$), the applied kinematic pattern was based on level walking with 58° flexion and 0° extension. The axial force was applied in a triple-peak loading mode with 2600 N maximum force at 15° flexion during mid-stance phase and with 166 N during swing phase. In addition, an AP shear force (+110 to −265 N) and IE rotational torque (+6 to −1 Nm) were transmitted via a pair of hydraulic cylinders acting on the tibial mounting system in application of the principle of vector addition (DesJardins et al., 2000). The axial force was applied to the tibial tray distally with a line of action taken to pass through a point with a medial offset of 5.3 mm (0.07 × width of the tibial component), which results in a medio-lateral compartment loading of 60 to 40. In the ISO_{linear} test groups, to simulate the stabilising behaviour of the knee ligaments, an AP motion restraint of 30 N/mm and an IE rotation restraint of 0.6 Nm/° were added (Fig. 2). In the $ISO_{gap\ biphaseal}$ test groups with PCL sacrificing implants, the restraining AP force was zero in a ± 2.5 mm range with, externally, a constant of 9.3 N/mm applied proportionally to the AP translation of the tibia plateau, whereas the restraining IE torque was zero in a ± 6° range with, externally, a constant of 0.13 Nm/° applied proportionally to the IE rotation of the tibia plateau.

For posterior stabilised gliding surfaces (PS and PS+), the knee assemblies were fixed with epoxy resin and mounted on the wear test stations, the references being submitted only to axial force for loaded soak control (Table 1). The test groups were tested through five million cycles, performed at a frequency of 1 Hz

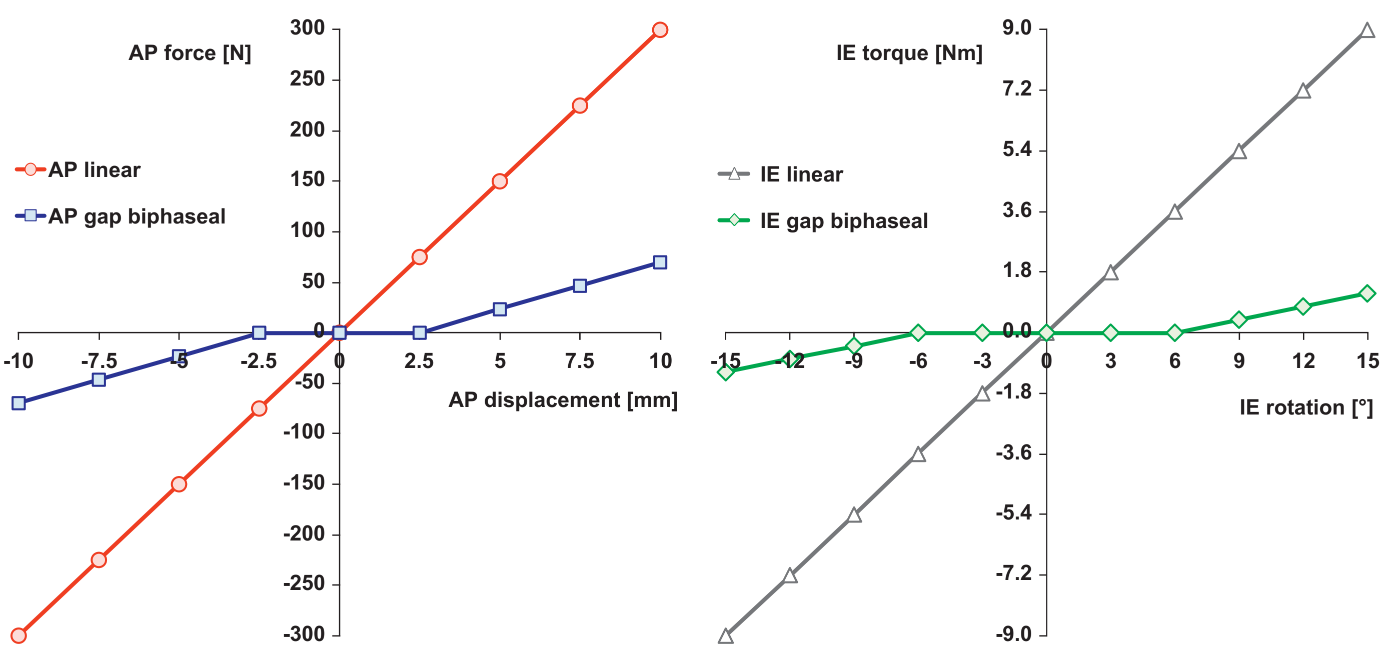

Fig. 2. Restraining AP shear force (left) and restraining IE torque (right) applied in the two test methods ISO_{linear} and $ISO_{gap\ biphaseal}$.

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