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Fixed and mobile bearing total knee arthroplasty – Influence on wear generation, corresponding wear areas, knee kinematics and particle composition

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ABSTRACT

Background: Several studies in literature are dealing with a direct comparison between fixed and mobile bearing knee replacements, but to our knowledge there is no published data comparing the wear behaviour of the two design principles based on the same femur and superior gliding surface geometry. The objective of our study was to investigate a fixed and mobile bearing knee design with identical femoral articulation in regard to wear, tibio-femoral kinematics and particle size distribution.
Methods: In vitro wear simulation according to ISO 14243-1 has been performed with the Columbus® knee system (Aesculap, Tuttlingen) in the configurations fixed and mobile bearing for five million cycles on a customized four station knee wear simulator. The tests were running under force control and the tibio-femoral kinematics were assessed. A particle analysis has been undergone after each inspection interval when the lubricant was replaced.
Findings: Due to the additional wear in the tibial articulation of the mobile bearing design the mean gravimetric wear rates are not statistically different between the two groups. Apart of that there is a substantial reduction in the amount of wear per area unit for the mobile versus the fixed bearing gliding surfaces. Both groups show comparable tibio-femoral kinematics and a similar wear debris morphology.
Interpretation: Our investigation of a fixed and mobile bearing knee design with identical femoral articulation demonstrates that there are no significant differences in wear rate, resulting kinematics and polyethylene particle release. Therefore it can be recommended that surgeons decision for one or the other design principle should be based on the individual patient profile.

1. Introduction

During the last decades total knee arthroplasty (TKA) has become a successful procedure for the relief of pain, correction of deformity and restoration of function in elderly patients with knee arthritis (Furnes et al., 2006; Pradhan et al., 2006).

Excellent clinical and radiological long term results have been reported from individual clinical centers for both of the two fundamental design principles – fixed and mobile bearing knee prostheses (Buechel, 2004; Callaghan et al., 2005; Pradhan et al., 2006; Ranawat et al., 1993). Improvements in TKA designs, materials, sterilization techniques and surface finish have led to superior performance of total knee prostheses by reducing the prevalence of disastrous wear, delamination and structural fatigue failure of the polyethylene (UHMWPE) gliding surfaces (Emerson et al., 2000). Articular gliding surface damage is based on two main clinical failure mechanism: delamination and adhesive/abrasive wear.

Delamination is caused by high contact stresses and subsurface stress concentrations, often related to originally round-on-flat knee designs with low congruency in combination with degradation of the polyethylene due to radiation-induced oxidation (Burnett et al., 2007; Wright et al., 1992). The structural fatigue failure caused by oxidation-induced embrittlement, degradation and crack concentration below the articulating surface has been addressed by sterilization under nitrogen atmosphere and optimized packaging (Bell et al., 1998; Collier et al., 1996). In addition to that the introduction of increased congruency of fixed and especially mobile bearing femoral articulations reduces significantly contact and subsurface stresses and in consequence the risk for delamination (Morra et al., 2001; Morra and Greenwald, 2005).

Adhesive and abrasive wear generates particulate debris in micron and submicron size, which is a key factor under the aspect of biological response and subsequently osteolysis (Algan et al., 1996; Revell et al., 1997). The phagocytosis and inflammatory cytokine

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release as stimulus for osteolysis depends on the amount, material, shape and size of the particles generated by adhesive and abrasive wear during the lifetime of the knee prosthesis (Catelas et al., 1998; Ingham and Fisher, 2000). The macrophages activity level is in particular dependent on the volume of particles in the most critical size range between 0.1 and 1.0 μm (Ingham and Fisher, 2000). For the first generation of knee designs with low conformity articulations and high stress concentration, the polyethylene wear particles found in revisions in the surrounding tissue were in a size range of 1–2 μm and larger and only a minority with a diameter less than 1 μm (Schmalzried et al., 1994). Despite the disastrous wear behaviour and fatigue failure, aggressive osteolysis was not the dominant clinical failure mode (Schmalzried et al., 1994).

For modern mobile bearing knee designs with enhanced congruency in the tibio-femoral articulation more and more implanted in young, active and demanding patients questions are arising about the volume of adhesive and abrasive surface wear with accumulation of submicron size particles which may lead to clinical long term osteolysis (Howling et al., 2001). There are several papers dealing with a direct comparison between fixed and mobile bearing knee replacements (McEwen et al., 2005; Sathasivam et al., 2001; Sharma et al., 2007), but often with the limitation that the parameter "bearing type" is overlaid by different femoral articulation design, polyethylene material, manufacturing process and sterilization.

Therefore the objective of our study was to investigate a fixed and mobile bearing knee design with identical superior articulation between femur and gliding surfaces in regard to differences in wear volume, corresponding wear area, tibio-femoral kinematics and particle size distribution.

2. Methods

A comparative finite element analysis (FEA) has been undergone with the Columbus® knee system (Aesculap AG Tuttlingen, Germany) in the configurations fixed and mobile bearing. The femoral component was the same for both configurations and could be characterized by a symmetrical condyle design with multi-radius shape. Two tibial inserts with curved shape, both intended for posterior cruciate retaining procedures – Columbus® CR (fixed) and Columbus® RP (mobile) – were analyzed. The congruency of the femoral articulation was identical for the hand coronal section of both fixed (CR) and mobile (RP) tibial inserts. The tibial articulation of the mobile design (RP) was based on a planar, highly polished surface of the tibial tray with a central pin for free rotation.

The FEA models analyzed in this study were built by using the original 3D CAD data of the Columbus® CR (fixed) and Columbus® RP (mobile) knee system. According to subsequent wear simulation, the peak load during walking gait was set to 2600 N (three times BW) at a knee flexion angle of 15° (ISO 14243-1:2002(E) mid-stance phase). The force was applied at the femoral component acting along the anatomical axis of the tibia. Movements of the femoral component were limited to two degrees of freedom (DoF), the translation along the anatomical tibia axis and the varus–valgus rotation. The UHMWPE insert of the fixed system (CR) was frictionless supported at the tibial surface, able to move translational in the transversal plane while the mobile gliding surface (RP) was able to rotate around the central pin additionally. This conditions should ensure that the femoral components were able to settle in their final positions when the force was applied. All surfaces in contact were coated with non-linear contact elements and assumed to be frictional with a coefficient of $\mu = 0.04$ to preserve possible frictional stresses during the deformation of the UHMWPE (Wang, 2001). This method was chosen to determine the areas in contact by analyzing the element areas inside the contact zone. Due to the findings of Fregley et al. (2003), a linear elastic material model with a Young's modulus of 400 MPa and a Poisson's ratio of 0.46 has been used for the UHMWPE.

For the comparative wear simulation Columbus® CR/RP femoral components made out of casted CoCr29Mo6 alloy have been used in an intermediate size F4L. The polyethylene tibial inserts (size T3, height 10 mm) were machined from GUR 1020, packed under nitrogen atmosphere and sterilized by gamma irradiation ($\gamma = 30$ (SD 2) kGy). All tibial inserts were soaked prior to simulation in serum based test medium for 30 days to allow for saturated fluid absorption.

In vitro wear simulation has been performed with a customized four station servo-hydraulic knee wear simulator (EndoLab GmbH Thansau, Germany) according to ISO 14243-1:2002(E). For the ISO protocol the applied kinematic pattern was based on level walking with 58° flexion and 0° extension. The axial force has been applied with a medial offset of 5.3 mm in a triple peak loading mode with 2600 N maximum force at 15° flexion (mid-stance phase) and 166 N during swing phase. In addition an anterior/posterior (A/P) force (+110 to −265 N) and internal/external torque (+6 to −1 N m) has been applied via a pair of hydraulic cylinders acting on the tibial mounting system and following the principle of vector addition. To simulate the knee ligaments an A/P motion restraint of 30 N/mm and I/E rotation restraint of 0.6 N m/° was given.

For the two implant configurations (CR and RP) four total knee assemblies were fixed with epoxy resin and mounted in the wear test stations (specimen F1–F3 (fixed) and M1–M3 (mobile)) and two loaded references (specimen F0, M0) got only axial force for loaded soak control. Testing was performed for five million cycles at a frequency of 1 Hz in a lubricant of newborn calf serum (Biochrom AG, Berlin) diluted with deionized water to install a defined protein content of 30 g/l. The lubricant was tempered at 37 °C, pH-stabilized by ethylene diamine tetraacetic acid (EDTA) and amphotericin was added for fungal decay preservation. The test chambers were sealed with an elastic membrane to avoid contamination during the test and the serum solution was replaced at intervals of 0.5 million cycles.

At each measurement interval (0.5, 1, 2, 3, 4, 5 million cycles) cleaning was performed following a procedure described in ISO 14243-2:2002(E) for gravimetric wear assessment of knee joint articulations. The wear of the polyethylene tibial inserts was estimated gravimetrically with an analytical balance (Mettler Toledo Type AG 204, Balingen) to a precision of ±0.1 mg under consideration of the air buoyancy and the bearing surfaces were inspected with a stereo microscope (Wilde M3Z Herrenbrugg, Switzerland).

For the assessment of resulting knee kinematics there has been a periodic readout of the movement of the tibial tray. The tibia movement in A/P deflection and I/E rotation was measured relative to the initial position of the tibia in full extension, axially loaded by contact to the femur, which results in a self adjustment by the design. Component sets were rotated across stations after each million cycles to minimize the effect of inter-station kinematic variability.

The lubricant was replaced at each station after each inspection interval and stored for wear particle isolation and analysis following a procedure described by Affatato et al. (2001) and Niedzwiecki et al. (2001). The particles were digested in 37% hydrochloric acid, diluted in methyl alcohol and filtered through polycarbonate filters with a pore size of 0.1 μm. Subsequently a SEM micrograph analysis (Zeiss EVO 50, Carl Zeiss NTS GmbH, Oberkochen) has been performed with software (Leica QWin V3 Standard, Leica, Bensheim) assisted particle count (size and morphology) with at least 100 particles at each measurement point to obtain a representative particle size distribution. The serum of the tested specimens of both design options (F1–F3 (fixed) and M1–M3 (mobile)) and also of the two loaded references (F0, M0) was analyzed for size and shape of the wear particles after 0.5 million cycles and every