Acta Biomaterialia 6 (2010) 3601–3610

Contents lists available at ScienceDirect

Acta Biomaterialia

journal homepage: www.elsevier.com/locate/actabiomat

Biotribology of alternative bearing materials for unicompartmental knee arthroplasty

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ARTICLE INFO

Article history:
Received 22 December 2009
Received in revised form 1 April 2010
Accepted 1 April 2010
Available online 4 April 2010

Keywords:
Unicompartmental knee arthroplasty
Wear simulation
Alternative bearing materials
Particle release
Poly-ether-ether-ketone

ABSTRACT

The objective of our wear simulator study was to evaluate the suitability of two different carbon fibre-reinforced poly-ether-ether-ketone (CFR-PEEK) materials for fixed bearing unicompartmental knee articulations with low congruency. In vitro wear simulation was performed according to ISO 14243-1:2002 (E) with the clinically introduced Univation® F fixed bearing unicompartmental knee design (Aesculap AG, Tuttlingen, Germany) made of UHMWPE/CoCr29Mo6 in a direct comparison to experimental gliding surfaces made of CFR-PEEK pitch and CFR-PEEK PAN. Gliding surfaces of each bearing material ($n = 6 + 2$) were γ-irradiated, artificially aged and tested for 5 million cycles with a customized four-station knee wear simulator (EndoLab, Thansau, Germany). Volumetric wear assessment, optical surface characterization and an estimation of particle size and morphology were performed.

The volumetric wear rate of the reference PE1–6 was 8.6 ± 2.17 mm^3 per million cycles, compared to 5.1 ± 2.29 mm^3 per million cycles for PITCH1–6 and 5.2 ± 6.92 mm^3 per million cycles for PAN1–6; these differences were not statistically significant. From our observations, we conclude that CFR-PEEK PAN is obviously unsuitable as a bearing material for fixed bearing knee articulations with low congruency, and CFR-PEEK pitch also cannot be recommended as it remains doubtful wether it reduces wear compared to polyethylene. In the fixed bearing unicompartmental knee arthroplasty examined, application threshold conditions for the biotribological behaviour of CFR-PEEK bearing materials have been established. Further in vitro wear simulations are necessary to establish knee design criteria in order to take advantage of the biotribological properties of CFR-PEEK pitch for its beneficial use to patients.

1. Introduction

For patients suffering from isolated medial gonarthrosis, unicompartmental knee arthroplasty (UKA) has become a successful clinical treatment, providing pain relief, fast recovery and restoration of function [1–5]. Provided there is appropriate patient selection and surgical experience [6], both UKA designs – with fixed or mobile bearing gliding surfaces – have shown excellent long-term results [7–11]. However, despite these encouraging clinical results, polyethylene wear remains a major factor affecting the survival of UKA treatments in young and active patients [12–16].

The biological response to polyethylene wear particles was described as a key factor in inducing periprosthetic osteolysis and subsequent implant loosening [17–19]. This complex mechanism involves activated macrophages and inflammatory cytokine release that is dependent on the amount, morphology, material and size of the wear particles [20–22]. Periprosthetic osteolysis is stimulated by the macrophages activity, which is dependent specifically on the volume of particulate debris in the submicron size range [23–26].

Currently, successful fixed bearing UKA designs are mostly based on a tibia-femoral articulation with low congruency to accommodate the individual patient's knee kinematics [1,7,8]. However, the comparatively low bearing congruency leads to high surface and subsurface stress concentrations in the polyethylene gliding surfaces [27,28] and enhances the risk of abrasive wear [29], delamination and structural fatigue failure [30–34].

As well as optimizations of the mechanical properties and wear behaviour of polyethylene, candidate materials such as poly-ether-ether-ketone (PEEK) have been employed as biomaterials for biotribological examinations [35]. In particular, carbon fibre-reinforced (CFR-PEEK) composites have been evaluated as alternative bearing materials for hip and knee joint articulations [36,37]. In

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1742-7061/$ - see front matter
doi:10.1016/j.actbio.2010.04.003

multi-directional pin-on-plate studies favourable wear factors have been shown for CFR-PEEK in combination with alumina ceramic or cobalt–chromium in comparison to polyethylene, used as the clinical reference material [37–39]. In addition to these screenings, hip simulator testing of CFR-PEEK inlays against alumina ceramic heads demonstrated wear improvement of one order of magnitude compared to conventional polyethylene [35–37,40]. In an ongoing clinical trial about hip articulations with inlays made of CFR-PEEK, Pace et al. [41] performed an analysis on a retrieved inlay and found a comparably small head penetration and only a small amount of particles in the periprosthetic tissue. During knee wear simulation on an unicompartmental mobile bearing knee with high congruency (ball-in-socket design), a substantial wear reduction in comparison to polyethylene was described [37].

Superior biotribological behaviour of CFR-PEEK bearing materials was demonstrated for joint articulations with high conformity and consequently low surface contact stress.

The objective of our wear simulator study was to evaluate the suitability of two different CFR-PEEK materials for fixed bearing unicompartmental knee articulations with low congruency.

2. Materials and methods

An in vitro wear simulation was performed with the clinically introduced Univation® F medial unicompartmental knee replacement (Aesculap AG, Tuttlingen, Germany) with a cobalt–chromium-on-polyethylene articulation as a reference in comparison to gliding surfaces made out of two different CFR-PEEK materials. Taking the study's basic research character into account, the articulation of the Univation® F design was retained unchanged, the prototype gliding surfaces being fabricated out of the experimental CFR-PEEK materials.

In the comparative wear simulation, Univation® F femoral and tibial components made out of casted CoCr29Mo6 alloy were used in an intermediate size F3L combined with T4 and UHMWPE gliding surfaces being machined from GUR 1020. For the experimental cobalt–chromium-on-CFR-PEEK articulations, two different groups of prototypes were machined from CFR-PEEK blended with 30% discontinuous pitch fibres (CFR-PEEK-Optima LT1 CP 30, Invibio Ltd., Thornton-Cleveleys, UK) and a version containing 30% polyacrylonitrile (PAN) based carbon fibres (CFR-PEEK-Optima LT1 CA 30) (Fig. 1).

2.1. The tibio-femoral contact area and surface stress distribution

A three-dimensional FEA model was created for the Univation® F design by using the original three-dimensional CAD data of the gliding surfaces with a nominal height of 7 mm. The peak joint load in mid-stance phase was determined to be the highest occurring load during the walking gait cycle with 2600 N (three times the body weight) at 15° knee flexion, according to ISO 14243-1:2002(E). In view of the unicompartmental design, 60% of this load (1560 N) was used to simulate a medial UKA [27].

The force was applied to the femoral component acting along the vertical axis of the condylar contact point.

Movement of the femoral component was limited to translation along the anatomical axis of the tibia, while the inferior surface of the inserts was defined as frictionless supported to ensure settling of the components by unconstrained movement in the transversal plane. The contact between the femoral condyles and the gliding surface was defined as frictional with a coefficient of $\mu = 0.04$ to capture the influence of friction in the direction of compression [42]. To decrease the computational effort, the PEEK materials were assumed to be linear elastic with the following parameters: CFR-PEEK pitch $E = 6.9$ GPa, $\nu = 0.4$; CFR-PEEK PAN $E = 12$ GPa, $\nu = 0.4$. The polyethylene material was described using a bilinear isotropic material model with $E = 300$ MPa, $E_T = 100$ MPa, $\nu = 0.38$ and $\sigma_{Yield} = 25$ MPa.

2.2. In vitro wear simulation, tibio-femoral kinematics and particle characterization

In vitro wear simulation was performed with a customized four-station servo-hydraulic knee wear simulator (EndoLab GmbH, Thansau, Germany) reproducing exactly the walking cycle as specified in 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 was applied 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/pos-

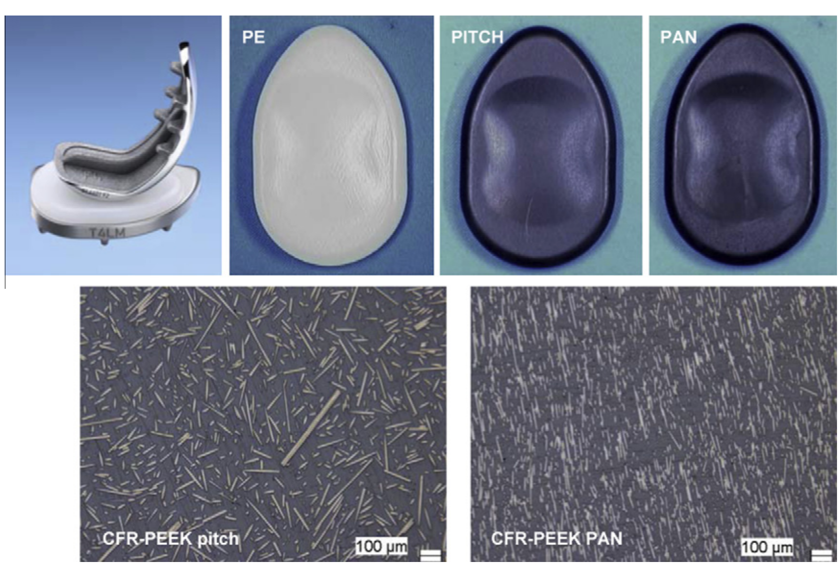

Fig. 1. A unicompartmental knee arthroplasty device (Univation® F) with femoral and tibial components made out of a CoCr29Mo6 alloy, gliding surfaces made out of UHMWPE and two experimental prototype articulations made out of CFR-PEEK pitch and CFR-PEEK PAN. Micrographs (magnification 50:1) demonstrate the different carbon fibre matrix structures for the gliding surfaces made out of CFR-PEEK pitch (left) and CFR-PEEK PAN (right).