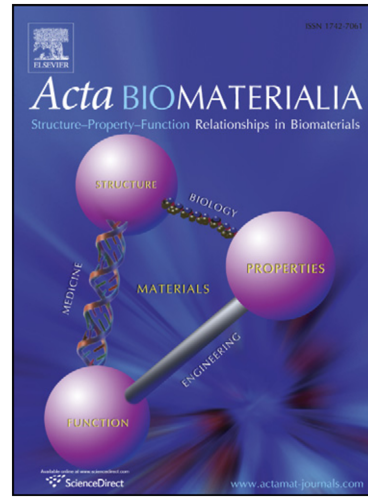

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Biotribology of alternative bearing materials for unicompartmental knee arthroplasty

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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 customised 4 station knee wear simulator (EndoLab Thansau, Germany). Volumetric wear assessment, optical surface characterisation and an estimation of particle size and morphology was performed.

The volumetric wear rate of the reference PE1-6 was 8.6 ± 2.17 mm^3/million cycles, compared to 5.1 ± 2.29 mm^3/million cycles for PITCH1-6 and 5.2 ± 6.92 mm^3/million cycles for PAN1-6 but without statistically significant differences between the test groups.

From our observations, we conclude that CFR-PEEK PAN is obviously unsuitable as 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 UKA 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 interesting biotribological properties of CFR-PEEK pitch for a patient beneficial use.

Keywords
unicompartmental knee arthroplasty, wear simulation, alternative bearing materials, particle release, polyaryletherketone

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 longterm 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 depending on the amount, morphology, material and size of the wear particles [20-22]. Periprosthetic osteolysis is stimulated by the macrophages activity which is, in particular, dependent 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].

Apart from optimisations of the mechanical properties and wear behaviour of polyethylene, candidate materials such as polyaryl-ether-ether-ketone (PEEK) were employed as biomaterials for biotribological examinations [35]. Especially carbon fiber reinforced (CFR-PEEK) composites were evaluated as alternative bearing materials for hip and knee joint articulations [36,37]. In multidirectional pin-on-plate studies favourable wear factors were shown for CFR-PEEK in combination with alumina ceramic or cobalt-chromium in comparison to polyethylene as 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 low 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.

Objectives

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.

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 carbon fibre reinforced polyaryl-ether-ether-ketone 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) (Figure 1).

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 (3 times BW) 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 compressive direction [42]. To decrease computational effort, the PEEK materials were assumed to be linear elastic with the following parameters: CFR-PEEK pitch E = 6.9 GPa, v = 0.4; CFR-PEEK PAN E = 12 GPa, v = 0.4. The polyethylene material was described using a bi-linear isotropic material model with E = 300 MPa, E_T = 100 MPa, v = 0.38 and σ_{Yield} = 25 MPa.

In vitro wear simulation, tibio-femoral kinematics and particle characterisation

In vitro wear simulation was performed with a customised 4-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/posterior (A/P) force (+110 to -265 N) and internal/external 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. The axial force was applied to the tibial tray distally with a medial offset of 4.9 mm. To simulate the behaviour of the knee ligaments, an A/P motion restraint of 30 N/mm and an I/E rotation restraint of 0.6 Nm/° were added.

The polyethylene and both CFR-PEEK material gliding surfaces (size T4, height 7 mm) were packed under nitrogen atmosphere and sterilised by γ-irradiation (30 ± 2 kGy). All tibial inserts were used after artificial ageing according to ASTM F2003-02 (parameters: 70 °C, pure oxygen at 5 bar, duration 14 days), and were soaked prior to wear simulation in serum-based test medium for 30 days to allow for saturated fluid absorption. For the medial unicompartmental gliding surfaces made out of polyethylene (specimen PE1-6), CFR-PEEK pitch (PITCH1-6) and CFR-PEEK PAN (PAN1-6) material, the knee assemblies were fixed with epoxy resin and mounted on the wear test stations, two references (specimen PE7-8, PITCH7-8, PAN7-8) being submitted only to axial force for loaded soak control. They were tested through five million cycles at a frequency of 1 Hz in a lubricant of newborn calf serum (Biochrom AG Berlin, Germany) diluted with deionized water to achieve the target protein content of 30 g/l. The lubricant was incubated at 37°C, pH-stabilised by ethylene diamine tetraacetic acid (EDTA) and replaced at intervals of 0.5 million cycles. Patricine was added to prevent fungal decay.

At each measurement interval (0.5, 1, 2, 3, 4, 5 million cycles), the devices were cleaned as prescribed in ISO 14243-2:2002(E) protocols for gravimetric wear assessment of knee joint articulations. Wear of the polyethylene tibial inserts was determined gravimetrically using an analytical balance (Mettler-Toledo Type AG 204 Balingen, Germany) to a precision of 0.1 mg, taking air buoyancy into account. The bearing surfaces were inspected with a stereo microscope (Leica MZ 16 Bensheim, Germany) and after completion of the wear test by scanning electron microscopy (SEM) (Zeiss Evo 50 Oberkochen, Germany). To calculate the wear volume, the specific densities of UHMWPE (0.934 mg/mm^3), CFR-PEEK (Pitch) (1.4 mg/mm^3) and CFR-PEEK (PAN) (1.4 mg/mm^3) were considered. To assess the resulting knee kinematics, the movement of the tibial tray was periodically read out. The component sets were rotated across stations after each million cycles to minimise the effect of inter-station kinematic variability.

For each material combination, the lubricant was replaced at 0.5 million cycles intervals and stored for wear particle isolation and analysis following the procedure described by Affatato et al. [43] and Niedzwiecki et al. [44]. The particles were digested in 37% hydrochloric acid, diluted in methyl alcohol and filtered through an alumina filter with a pore size of 0.02 µm. Subsequently, SEM micrograph analysis was performed with at least 10 images per filter for the software-assisted particle count (size and morphology) at each measurement point to obtain a representative particle size distribution. The serum of the six tested specimens of each material combination (PE1-6, PITCH1-6 and PAN1-6) and the loaded references (PE7-8, PITCH7-8 and PAN7-8) were analysed to determine the size and shape of the wear particles after 0.5, 1, 2 and 5 million cycles according to ASTM F1877-05. The mean particle diameter (ferrite diameter) was used to describe the size of the particles and the aspect ratio (AR), elongation (E), roundness (R) and form factor (FF) to describe their shape.

Finally, a statistical analysis (Statistica 7, StatSoft Europe GmbH, Hamburg) was carried out to verify the normal distribution (Kolmogorov-Smirnov-test), followed by direct comparisons to differentiate the volumetric wear amount between the gliding surfaces made out of polyethylene, CFR-PEEK pitch and CFR-PEEK PAN (paired Student-t test, $p < 0.05$).

Results

Tibio-femoral contact area and surface stress distribution

Due to different material properties (e.g. Young's modulus), the contact areas as determined by the FEA models with a surface stress threshold of 2 MPa decreased from 117 mm^2 (PE) to 28 mm^2 (PITCH) and to 24 mm^2 (PAN) whereas the peak surface contact stresses increased from 24.8 MPa (PE) to 137 MPa (PITCH) and 184 MPa (PAN). For the gliding surfaces made out of polyethylene, CFR-PEEK pitch and CFR-PEEK PAN, the distribution of surface contact stresses and corresponding contact areas indicates the contact conditions at the articulation with the femoral component (Figure 2).

In vitro wear simulation, tibio-femoral kinematics and particle characterisation

For the three different gliding surface materials subjected to wear simulation at the articulation with femoral components made out of cobalt-chromium, the mean and standard deviation of the volumetric wear amount were calculated at each measurement interval (Figure 3). The cumulative volumetric wear was estimated to be 52.7 ± 10.5 mm^3 for PE1-6 , 25.1 ± 11.4 mm^3 for PITCH1-6 and 26.2 ± 26.8 mm^3 for PAN1-6. Statistical analysis demonstrated a significant difference between the cumulative wear volume of PITCH1-6 versus PE1-6 ($p = 0.0093$), but no substantial difference between PAN1-6 versus PE1-6 ($p = 0.058$) and PAN1-6 versus PITCH1-6 ($p = 0.926$). In order to illustrate the dramatic increase of volumetric wear on the gliding surface PAN6 in the measurement interval between 3 and 4 million cycles, we plotted this single curve (white circles) in addition to the mean PAN1-6 to better grasp the specific wear behaviour of CFR-PEEK PAN in unicompartmental fixed bearing knee articulations. To put this striking result in a comprehensive perspective, it should be noted that, in this interval between 3 to 4 million cycles, specimen PAN6 generated a volumetric wear amount of 66.4 mm^3 corresponding to a unique wear rate of 19.2 mm^3/million cycles for the complete test duration. After 4 million cycles however, volumetric wear of specimen PAN6 clearly dropped back to a comparatively low rate of 3.8 mm^3.

The volumetric wear rate of the reference PE1-6 was 8.6 ± 2.17 mm^3/million cycles, compared to 5.1 ± 2.29 mm^3/million cycles for PITCH1-6 and 5.2 ± 6.92 mm^3/million cycles for PAN1-6. In the wear assessment of the gliding surfaces PITCH1-6, a 1.7-fold decreased wear rate was found in a direct comparison to the clinically established reference, but without statistically significant differences between the test groups ($p = 0.067$). Furthermore there was no significant difference in the group comparisons PAN1-6 versus PE1-6 ($p = 0.29$) and PAN1-6 versus PITCH1-6 ($p = 0.96$). For visualisation of the apparently high variations in the PAN group the wear rates were presented in a Box-Wisker-Plot with median, percentiles (25 and 75 %) and outliners (Figure 4).

All images of the optical wear surface analysis were taken in a planar view perpendicular to the tranversal plane of the gliding surfaces. In the articulation of UHMWPE against CoCr29Mo6, we detected polishing of the polyethylene bearing surfaces due to adhesive and abrasive wear with slight scratches. Neither crack formation, nor pitting, nor delamination was observed on the polyethylene gliding surfaces after 5 million cycles. The images of the tibio-femoral bearing of the polyethylene gliding surfaces and also of the cobalt-chromium counterpart clearly illustrate the wear pattern specific to the articulation design (Figure 5). These characteristic wear patterns were consistent for all tested specimens (PE1-6).

Homogeneous wear traces can be seen on the gliding surfaces of the UKA devices made out of CFR-PEEK pitch (PITCH1-6) (Figure 6).

The gliding surfaces of the unicompartmental knee articulations made of carbon fibre CFR-PEEK PAN (PAN1-6) show visible signs of wear after 5 million cycles comparable to CFR-PEEK pitch (Figure 7). Only slight polishing took place as indicated by a darkening of the articulating surface areas in the specimen PAN1-5. The above described process of pronounced surface wear for specimen PAN6 can be directly correlated to a substantial increase of wear area between 3 and 4 million cycles, clearly illustrated by the widespread standard deviation between the six single specimens tested. The visible scratches in the direction of flexion-extension movement on the femoral component made out of cobalt-chromium are comparable for polyethylene, CFR-PEEK pitch and CFR-PEEK PAN. Also specimen PAN6 with pronounced gliding surface wear does not show any signs of increased scratching. The microscopic wear mechanism for CFR-PEEK pitch and CFR-PEEK PAN could be described by abrasion, deformation and creep of the PEEK matrix and exposition of wear resistant carbon fibres. In some articulating areas fragmentation of singular carbon fibres was visible (Figure 8).

After the running-in period (up to 1 million cycles), the resulting knee kinematics of the tibial tray relative to the femur were in a stable condition in the force and torque controlled loading mode.

The amplitudes of A/P displacement during 5 million cycles had mean values of 4.9 ± 1.2 mm for the unicompartmental knee articulations made of polyethylene (PE1-6), 5.1 ± 0.3 mm made of CFR-PEEK pitch (PITCH1-6) and 5.2 ± 0.4 mm made of CFR-PEEK PAN (PAN1-6). The amplitudes of the I/E rotation angle had mean values of 6.1° ± 1.5° for the gliding surfaces PE1-6, 6.3° ± 1.2° for PITCH1-6 and 6.3° ± 1.1° for PAN1-6.

For the given inspection intervals between 0.5 and 5 million cycles, the particle size distribution demonstrated steady state characteristics for polyethylene, CFR-PEEK pitch and CFR-PEEK PAN. The average values and standard deviations of the mean particle diameter (ferrite diameter), aspect ratio, elongation, particle roundness and form factor were recorded for the gliding surfaces made out of PE, PITCH and PAN in the inspection intervals between 0.5 and 5 million cycles (Table 1).

A direct comparison of the frequency and cumulative percentage of the particle size distribution demonstrates the wear debris behaviour of the different gliding surface materials polyethylene, CFR-PEEK pitch and CFR-PEEK PAN (Figure 9). For PE1-6, PITCH1-6 and PAN1-6, most of the particles were observed in a size range between 0.1 and 1 µm, the largest particles ranging between 2 – 13 µm with a frequency below 11 % for PE1-6, below 24 % for PITCH1-6 and below 31 % for PAN1-6. The smallest particles, detected on a 0.02 µm filter, were in a size range of approximately 0.06 µm in all tested lubricants.

The morphology of the particles found at the articulation with gliding surfaces made out of polyethylene, CFR-PEEK pitch and CFR-PEEK PAN was mainly granular and stable with a mean roundness of approximately 0.5 to 0.6 for all size ranges in all lubricants (Figure 10).

Discussion

The objective of our wear simulator study was to evaluate the suitability of two different CFR-PEEK materials for fixed bearing unincompartmental knee articulations with low congruency. Superior wear properties of CFR-PEEK bearing materials were demonstrated for hip and knee joint articulations with high conformity ball-in-socket designs [36,37,40,45] and comparatively low surface contact stresses. To our knowledge, the biotribologial behaviour of CFR-PEEK bearing materials in fixed bearing UKA designs with low congruency and consequently high surface contact stress conditions has not yet been investigated.

In our study gliding surfaces made out of two alternative CFR-PEEK materials were tested in a knee wear simulator under force control and compared with a separate group of polyethylene inserts as a clinically established reference. As loads were applied under force control, a potential limitation of this study could have arisen from differences in the material specific friction coefficients leading to different tibio-femoral kinematics. But the tibio-femoral kinematics were regularly assessed on each test station, clearly demonstrating that the A/P tranlation and I/E rotation were equivalent in the groups PE1-6, PITCH1-6 and PAN1-6.

In the γ-irradiated and artificially aged gliding surfaces of the Univation® F UKA design a volumetric wear rate of 8.6 mm^3/million cycles was recorded for the medial components. Our observations fit well with those of Scott et al. [46] on shelf-aged gliding surfaces of the Oxford unicompartmental ball-in-socket knee design, reporting a linear volumetric wear rate of 10.4 mm^3/million cycles tested on a 4-station Stanmore simulator under force control. For a fixed bearing knee design with low congruency, Laurent et al. [47] found for a comparable volumetric wear rate of 7.1 mm^3/million cycles on the medial side under displacement control on an AMTI knee wear simulator. In spite of artificial ageing and after completion of 5 million cycles, the main wear mechanism on the polyethylene gliding surfaces (PE1-6) was burnishing due to abrasive/ adhesive wear and creep without any signs of pitting, delamination or crack formation as previously described by Walker et al. [48] and Currier et al. [49].

At the moment, there is considerable interest in alternative bearing materials as substitute to polyethylene to optimise the wear properties of orthopaedic joint replacements, with the goal to substantially reduce the osteolytic potential. Especially CFR-PEEK composites have been tested for wear resistance and biological activity [35,36,40,50]. Wang et al. [36] examined the wear behaviour of acetabular inserts made out of CFR-PEEK pitch and CFR-PEEK PAN in a hip simulator test and found in articulations with cobalt-chromium, alumina and zirconia ceramic heads wear rate reductions between 10- and 20-fold compared to conventional polyethylene. For acetabular inserts made out of CFR-PEEK (30 wt.% pitch) articulating against zirconia heads, a reduction in wear rate was achieved from 35 mm^3/million cycles for conventional polyethylene to 0.39 mm^3/million cycles [45]. In another study on acetabular cups made out of CFR-PEEK pitch combined versus alumina ceramic heads, Latif et al. [40] reported a wear rate of 0.93 mm^3/million cycles compared to 17 mm^3/million cycles (UHMWPE) after a test duration of 25 million cycles. For orthopaedic applications Scholes and Unsworth [38,39] emphasize the suitability of CFR-PEEK/ cobalt-chromium bearing combinations based on a multi-directional pin-on-plate test with wear factors between 0.12 to 0.18 * 10^{-6} $mm^3N^{-1}m^{-1}$ in comparison to a previous study on polyethylene (1.1 * 10^{-6} $mm^3N^{-1}m^{-1}$) [51]. In unicompartmental knee arthroplasty using a gliding surface made out of CFR-PEEK, Scholes and Unsworth [37] reported a comparatively low medial wear rate of 1.7 mm^3/million cycles for a highly congruent ball-in-socket mobile bearing design with cobalt-chromium femoral and tibial components.

As for the fixed bearing UKA design with low congruency used in our study, we came to a different conclusion. Using CFR-PEEK pitch instead of polyethylene (PE1-6) did lead to a significant reduction of cumulative wear and to a 1.7-fold wear rate decrease, but the mean wear rate (5.1 mm^3/million cycles) was due to the large standard deviation not substantially different from the wear rate of the clinical reference. Thus, the individual results for CFR-PEEK pitch range from 7.3 mm^3/million cycles (PITCH1) to 0.9 mm^3/million cycles (PITCH2), a decrease of between 1.2- and 9.6-fold compared to polyethylene (mean PE1-6).

In the CFR-PEEK PAN group, we found no significant difference in cumulative wear and wear rate. Showing a wide scattering in wear behaviour, the individual wear rates for the experimental CFR-PEEK PAN bearing material range from 0.9 mm^3/million cycles (PAN1) to 19.2 mm^3/million cycles (PAN6), exhibiting a huge variance from a 9.6-fold reduction to a 2.2-fold increase compared to the mean wear rate of polyethylene. The experimental CFR-PEEK PAN bearing material obviously exhibited a huge variance in individual wear rates. During our in vitro wear simulator study on two candidate CFR-PEEK materials, depending on the specific structure of the reinforced gliding surfaces, the largely ductile PEEK matrix wore down in some phases exposing wear resistant carbon fibres. This mechanism leads to a step of a staircase wear profile of the CFR-PEEK pitch and PAN specimens, but without substantial release of carbon fibre fragments in the described multi-micron length range mentioned above, or extended fibre-matrix-separation. In our opinion, these findings clearly indicate that CFR-PEEK PAN is not suitable for use in fixed bearing UKA designs with low congruency. The wide scattering of results may be due to high stress concentrations in the femoral articulation (Figure 2); the biotribological capability of CFR-PEEK PAN is in the vicinity of the specific material threshold. This hypothesis was substantiated by basic wear screening tests performed by Wang et al. [36] using a line-contact machine to apply axial load on a non-conforming alumina ceramic ring reciprocating linear motion on a flat geometry made out of CFR-PEEK pitch and PAN. Both CFR-PEEK composite materials with 30 wt.% fibre content exhibited lower wear rates compared to 10 and 50 wt.%, but demonstrated significantly 3- to 5-fold increased wear rates in comparison to polyethylene. The dramatic increase in CFR-PEEK wear rates under line contact situations described by Wang et al. [36] on the one hand and, on the other hand, the low wear rates of a high conformity ball-in-socket UKA design reported by Scholes and Unsworth [37] supports our findings that the fixed bearing UKA design with low congruency and high stress concentrations creates certain threshold conditions for the use of these materials in orthopaedic joint articulations. This statement is further evidenced by the fact that, for both experimental CFR-PEEK materials, nearly every individual specimen demonstrated periods of high wear followed by periods of low wear and vice versa – resulting in a staircase profile of the specific wear curves. This staircase phenomenon was also clearly correlated to the visible grade of dark colouration of the test serum.

The generation of wear particles in orthopaedic joint replacements is recognised as the main factor in initiating periprosthetic osteolysis and aseptic loosening [17,19,21,52]. Since the polyethylene particles are not biodegradable in vivo, their deposit in the periprosthetic tissue leads to the activation of macrophages and subsequent release of cytokines which stimulates bone resorption [18,20,23,50,52]. The size, shape and concentration of polyethylene particles are the main factors influencing the macrophage response [20], with the particles in a size range between 0.1 to 1 micron being the most biologically active [21,23,23,52]. Regarding mean diameter, aspect ratio and roundness, our particle debris characterisation is in good accordance with the description of wear particles resulting from in vitro testings on different total knee replacements [53]. In our particle analysis, compared to polyethylene, we did not detect any influence of the experimental CFR-PEEK bearing materials on particulate wear debris generation. The size and shape of the released wear particles out of the CFR-PEEK pitch and PAN gliding surfaces were in the same range as in the polyethylene group, with most of the particles in the submicron size. In the light of the results of the particle characterisation in the CFR-PEEK bearing materials, it may be appropriate to indicate that the biological response to be expected in vivo may be comparable to the response to polyethylene. This suggestion is also supported by cell culture experiments carried out by Howling et al. [50] who reported that CFR-PEEK wear particles had no cytotoxic effects and would possibly not cause adverse tissue reactions in vivo. On the other hand, no in vivo biocompatibility study using an appropriate animal model has been published on this subject.

Apart from that, a carbon fibre reinforced polyethylene (CF-UHMWPE) for tibial inserts in total knee arthroplasty was clinically introduced decades ago [54]. These inserts exhibited grossly abraded articulating surfaces, severe delamination and fragmentation after 1 to 9 years in vivo [55-57]. Busanelli et al [58] reported a retrieved fractured CF-UHMWPE insert 5 years post-operatively with signs of a granulomatous foreign body reaction and a layer of black tissue consisting of extremely irregular fibre fragments of approximately 10 to 15 µm in length. The carbon fibres nearly completely peeled off from the surrounding amorphous polyethylene matrix. Rosenthall [59] described three cases of tibial insert failures 12 to 14 months post-operatively with a giant cell foreign body reaction and an intense synovitis due to particulate carbon fibre debris in the intraarticular space. Analysing a CF-UHMWPE insert 8.5 years post-operatively in a 142 kg weight male patient, Bauer et al. [60] described a predominant histiocytic cell reaction in the synovial tissue and fibrous membrane with intercytoplasmic fragments of carbon.

In vitro examinations and retrieval analyses have unequivocally demonstrated that CF-UHMWPE offers significantly less resistance to fatigue crack propagation than plain polyethylene. Severe wear and insert fragmentation were attributed to poor bonding between the carbon fibres and the ductile nature of the polyethylene matrix [54,61,62].

Tests of the carbon fibre/ polymer matrix interface strength demonstrated that the carbon fibre/ matrix bonding for CFR-PEEK is an order of magnitude higher than that of CF-UHMWPE [63-65], accounting for a completely different wear behaviour and particulate debris generation in these two carbon fibre reinforced bearing materials. These in vitro findings are supported by the retrieval analysis of Pace et al. [41] on a CFR-PEEK pitch acetabular liner articulating with an alumina ceramic head, where they described a grey synovium due to black wear particles but without evidence of a serious inflammatory reaction.

Conclusion

During our in vitro wear simulator study on two candidate CFR-PEEK materials threshold conditions for the biotribological behaviour of CFR-PEEK PAN in fixed bearing UKA applications have been established. From our observations, we also conclude that CFR-PEEK pitch is able to substantially reduce wear in comparison to the clinically proven reference polyethylene in fixed bearing knee articulations with low congruency.

In a more global view, the current findings suggest potential applications of CFR-PEEK pitch in the field of knee arthroplasty. But as every time during the introduction of a new biomaterial orthopaedic research must be dedicated to evaluate the threshold conditions and appropriate applications. Further in vitro wear simulations are necessary to establish knee design criteria in order to take full advantage of the interesting biotribological properties of CFR-PEEK pitch for a patient beneficial use. Subsequently, the biological response to particulate wear debris from carbon fibre reinforced PEEK should be investigated using an appropriate animal model.

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Tables and Figures

Table 1: Parameters of size and shape description of the wear particles generated by the different gliding surface materials during knee wear simulation

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

Figure 2: Surface contact stresses and related contact areas at 15° flexion (mid-stance phase) and 1560 N axial load for the gliding surfaces made out of polyethylene, CFR-PEEK pitch and CFR-PEEK PAN at the articulation with the femoral component made out of cobalt-chromium (left to right)

Figure 3: Volumetric wear amount of the gliding surfaces made out of polyethylene (PE1-6), CFR-PEEK pitch (PITCH1-6) and CFR-PEEK PAN (PAN1-6) – calculated based on gravimetric wear assessment according to the ISO 14243-2 protocol

Figure 4: Box-Wisker-Plot to visualise the variations in volumetric wear rates for the groups PE1-6, PITCH1-6 and PAN1-6 (median, interquartile range, 25 and 75 percentiles and outliners)

Figure 5: Characteristic wear traces on the tibio-femoral articulation of the polyethylene gliding surfaces PE1-3 and slight scratches on the cobalt-chromium femoral component counterfaces after 5 million cycles

Figure 6: Characteristic wear traces on the tibio-femoral articulation of the CFR-PEEK pitch gliding surfaces PITCH1-3 and visible scratches on the cobalt-chromium femoral component counterfaces after 5 million cycles

Figure 7: Characteristic wear traces on the tibio-femoral articulation of the CFR-PEEK PAN gliding surfaces PAN1-2 and PAN6 (right) and visible scratches on the cobalt-chromium femoral component counterfaces after 5 million cycles. Due to a dramatic increase of volumetric wear in the measurement interval between 3 and 4 million cycles, the gliding surface PAN6 demonstrates a wear area completely different from that of the remaining five specimens PAN1-5 (volumetric wear amount increased from 9.5 mm^3 after 3 million cycles to 75.9 mm^3 after 4 million cycles).

Figure 8: SEM pictures of the articulating wear surfaces of specimen PITCH1 (left) and specimen PAN2 (right) after 5 million cycles (magnification 500:1 and 1000:1) – characterised by matrix deformation, creep and singular carbon fibre fragmentation indicating the tribological demands

Figure 9: Mean particle diameter distribution after 5 million cycles for the gliding surface materials PE1-6, PITCH1-6 and PAN1-6 using a filter with a pore size of 0.02 µm

Figure 10: Morphology of the wear particles for the gliding surface materials PE1-6, PITCH1-6 and PAN1-6 after 5 million cycles – particle roundness in dependence of the mean particle diameter (logarithmic scale) using a filter with a pore size of 0.02 µm

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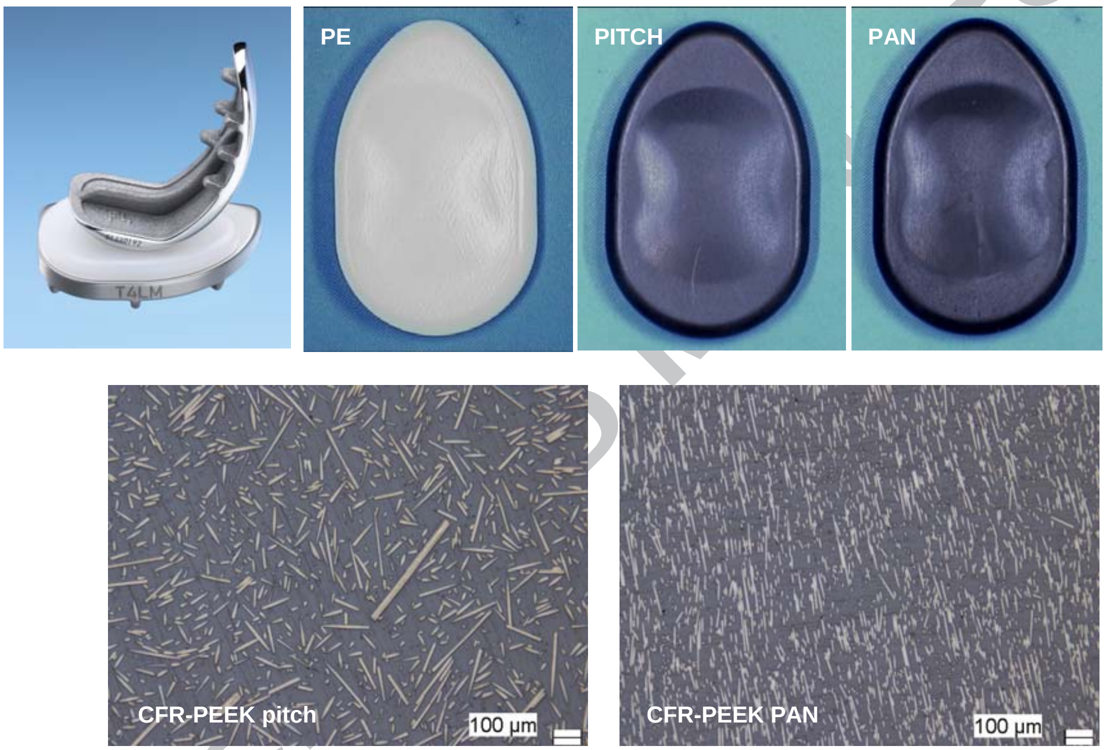
Gliding surface material	Mean diameter [µm]	Aspect ratio (AR)	Elongation (E)	Roundness (R)	Form Factor (FF)
PE1-6	0.72±0.99	1.77±0.94	3.89±2.88	0.54±0.21	0.55±0.14
PITCH1-6	1.27±5.18	1.69±0.81	3.46±2.21	0.58±0.22	0.57±0.12
PAN1-6	0.98±1.75	1.65±0.65	3.12±1.61	0.61±0.24	0.59±0.11



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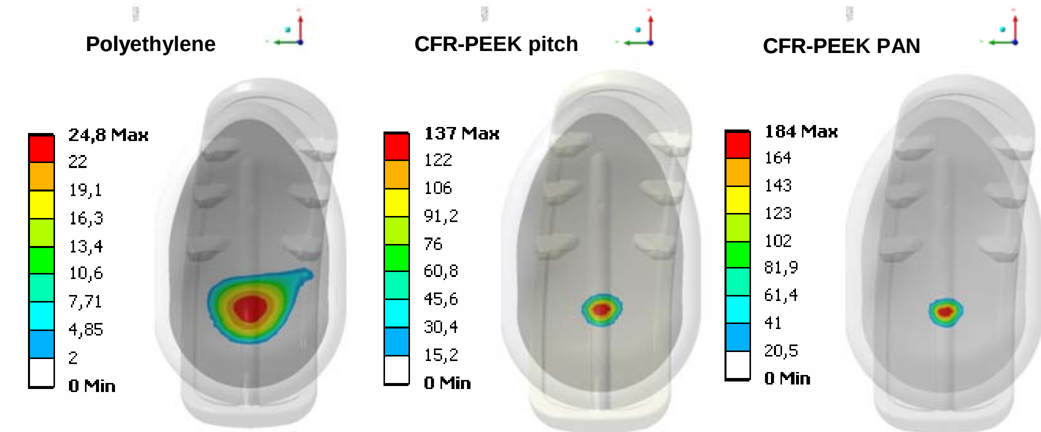

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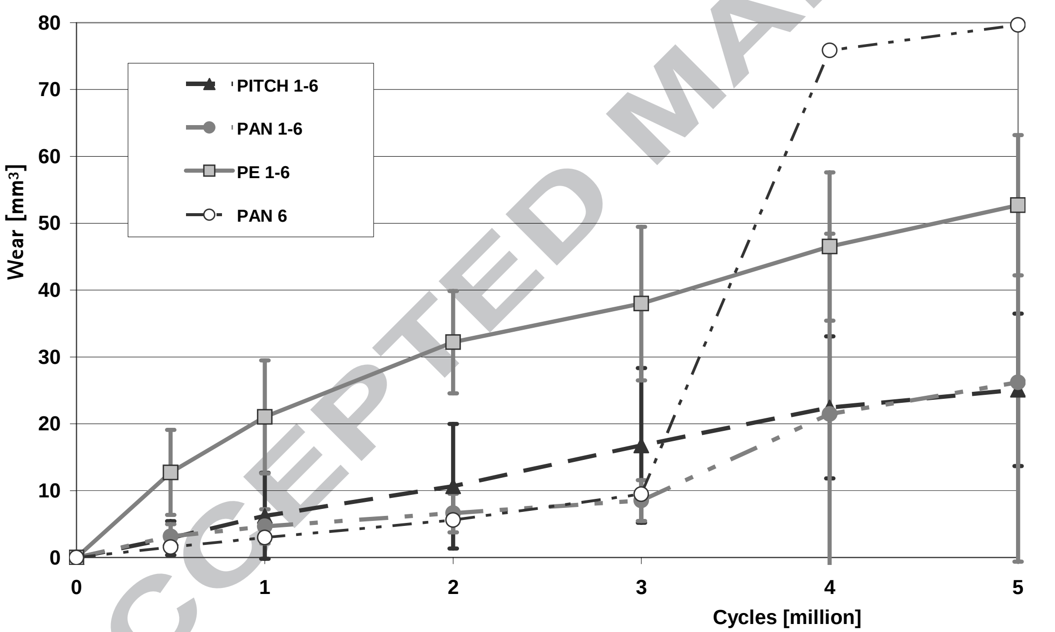

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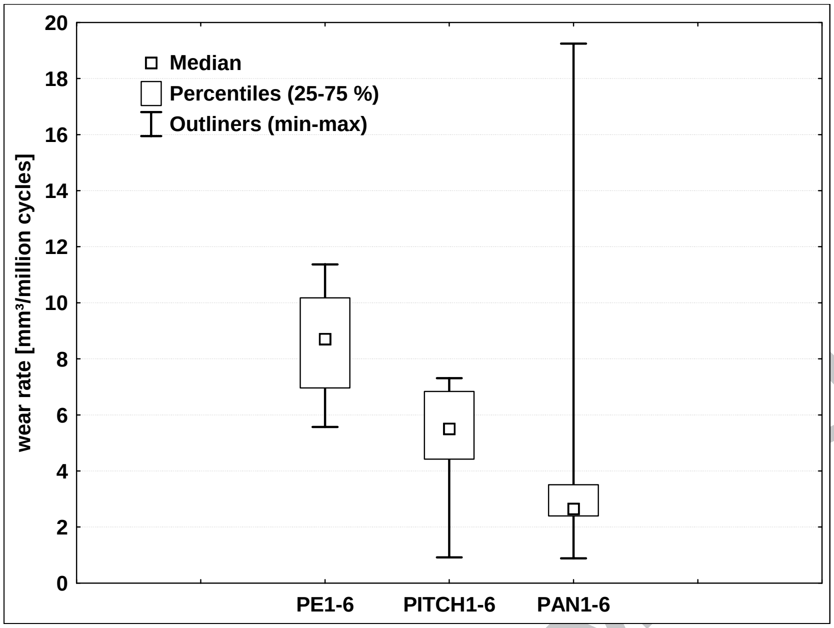

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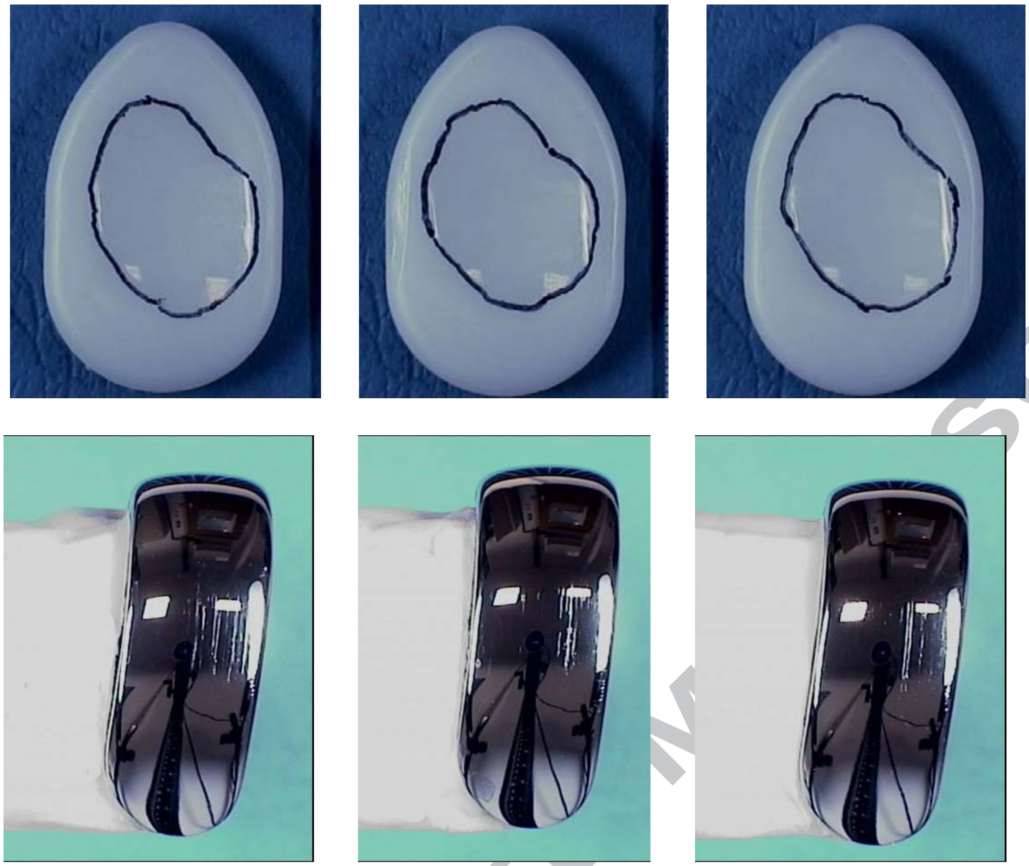

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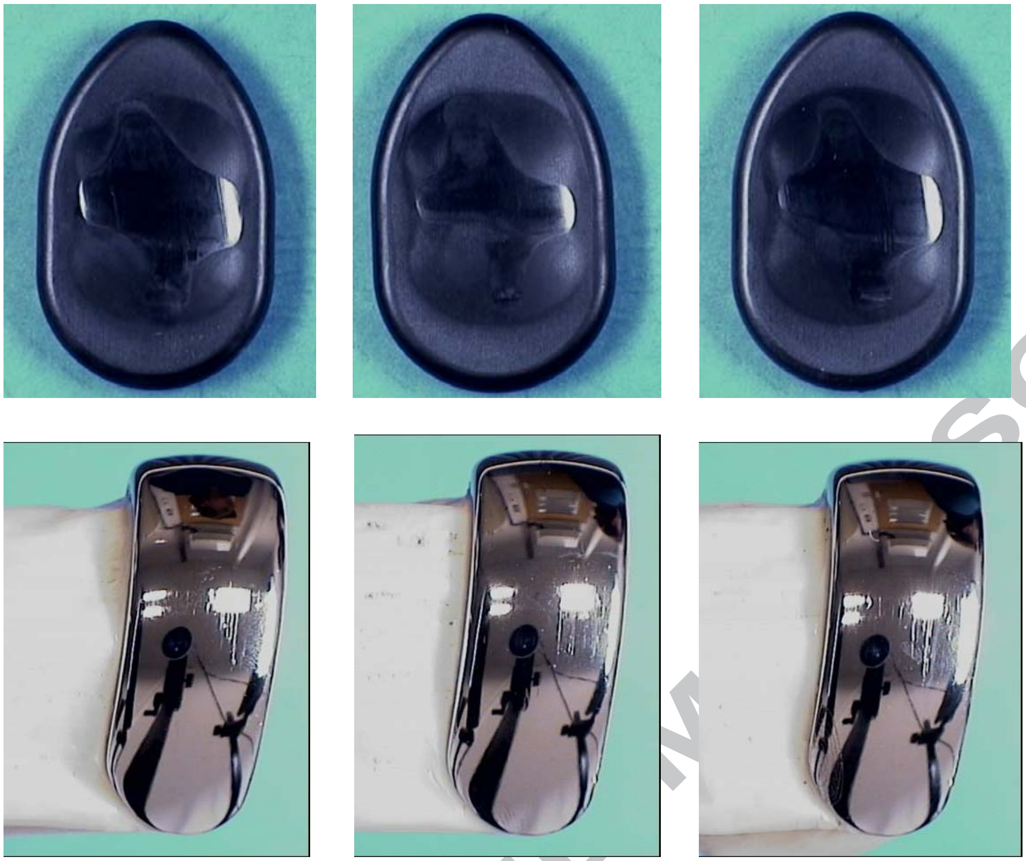

Figure 6: Characteristic wear traces on the tibio-femoral articulation of the CFR-PEEK pitch gliding surfaces PITCH1-3 and visible scratches on the cobalt-chromium femoral component counterfaces after 5 million cycles

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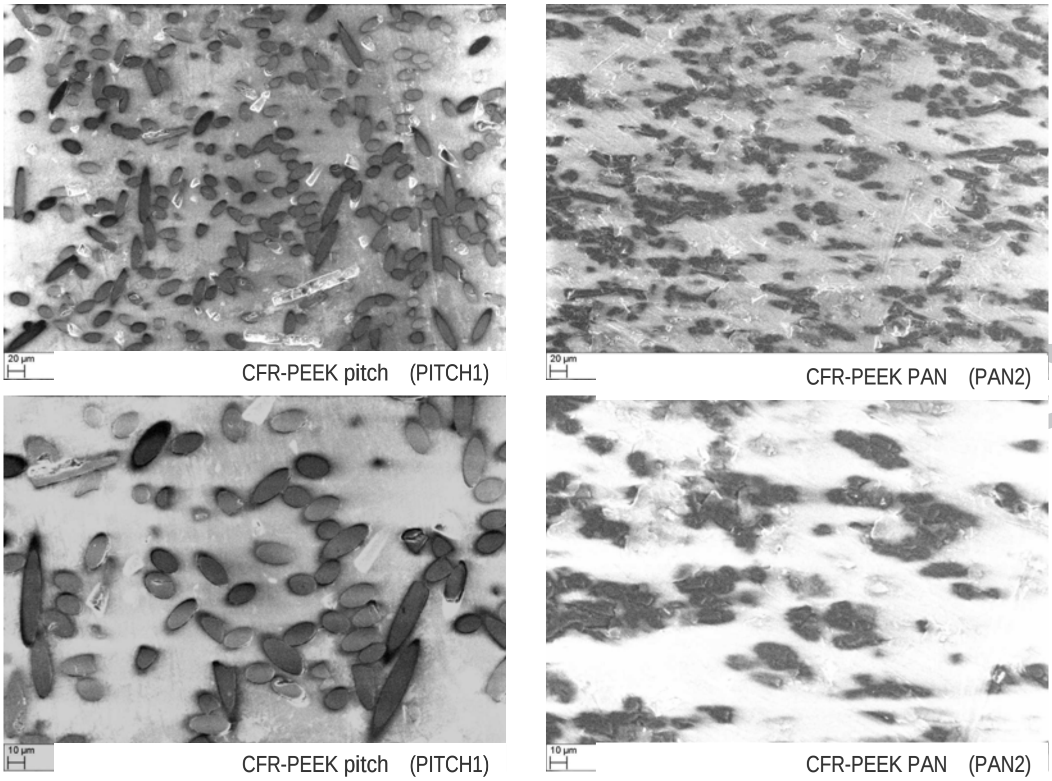

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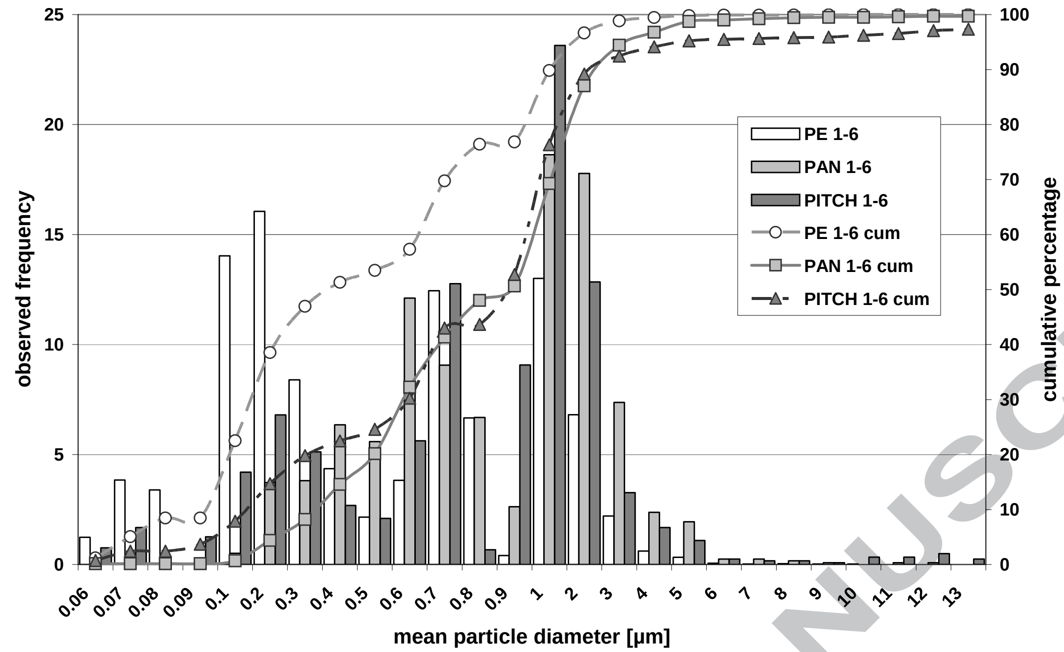

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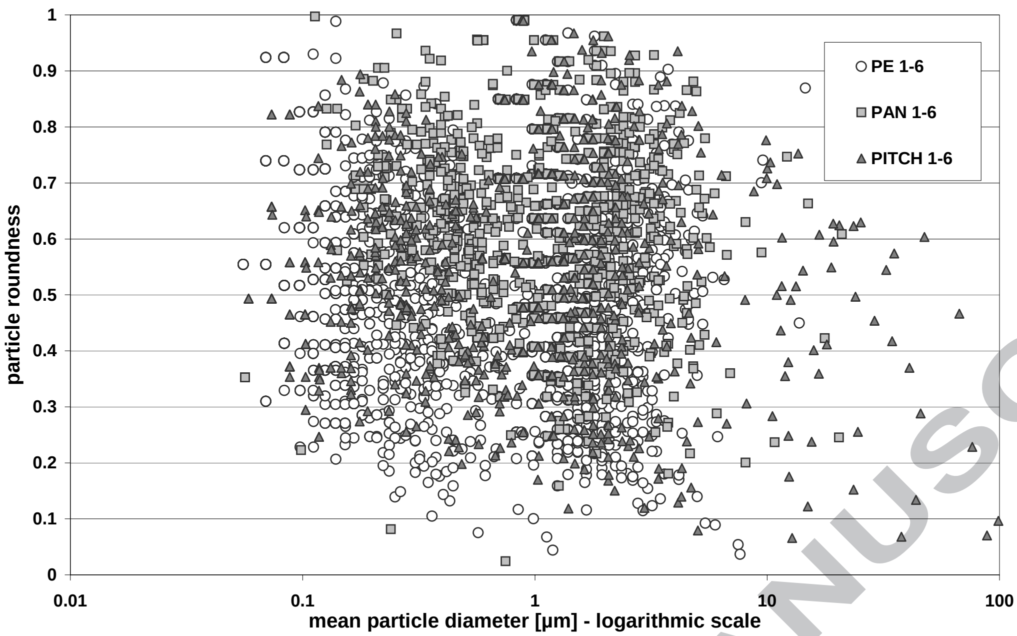

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