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In vitro wear study of PEEK and CFRPEEK against UHMWPE for artificial cervical disc application

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ABSTRACT

Total cervical disc replacement aims at avoiding fusion for the treatment of degenerative disc disease. This paper investigates the wear performances of PEEK and CFRPEEK against UHMWPE for artificial cervical disc application on a knee wear simulator due to the unavailability of a spinal one. The obtained results showed that the average wear rates of PEEK-on-UHMWPE and CFRPEEK-on-UHMWPE were 3.82 mg/MC and 2.34 mg/MC, respectively. The edge area of the bearing surfaces displayed severer wear in comparison with the central zone and was dominated by arc-shaped wear tracks. The main wear mechanisms were abrasion, adhesion and fatigue wear. CFRPEEK-on-UHMWPE has demonstrated superior wear characteristics, and hence, is a potential material configuration for artificial cervical disc application.

1. Introduction

Degenerative disc disease (DDD) is a major reason for chronic spinal pain, leading to the abnormal motion of spine segment and biomechanical instability in which surgery may be required when conservative treatment fails [1,2]. For a long time, anterior cervical discectomy and fusion (ACDF) has been the "gold standard" of surgical procedure for DDD [3]. Recently, an alternative non-fusion surgical treatment, namely total cervical disc replacement (TCDR), has increased in popularity. According to previous literature [4,5], TCDR achieves neural decompression and preserves disc height and motion patterns at the operated segment, which can relieve pain and avoid adjacent level degeneration, showing preeminent clinical success in comparison with ACDF.

The conventional materials of TCDR devices are mainly metal-on-metal (MoM) and metal-on-polymer (MoP), which are adopted from total hip replacement devices, such as stainless steel against stainless steel and cobalt-chromium-molybdenum alloy (CoCrMo) or titanium (Ti) alloys against ultrahigh molecular weight polyethylene (UHMWPE) [6,7]. In fact, many mid- and long-term evaluations have indicated that the metal components may cause metal hypersensitivity and ion toxicity, leading to the aseptic loosening and revision of implanted artificial disc [8]. In addition, it is reported that the MoM and MoP artificial discs have some tribological limitations and the wear debris generated by the tribo-system may induce osteolysis of adjacent segment, resulting in a shorter service life than the designed, which has become one of the most important issues for clinic application of TCDR [9,10]. Furthermore, unlike total joint replacement, the age of the candidates for TCDR varies from 18 to 60 years [11]. It is important to select proper long-term implantable materials for the various components of artificial cervical disc to maintain its design function.

Recently, the polymer-on-polymer (PoP) material combinations of artificial disc prostheses, such as poly-ether-ether-ketone (PEEK) against PEEK [12], have been investigated to meet the requirement of longevity in service. PEEK is an aromatic semicrystalline engineering thermoplastic with preeminent chemical and mechanical performances and proven biocompatibility and biostability [13]. In order to achieve better corrosion resistance and wear resistance for bio-implant applications, PEEK can be reinforced through fibers (e.g. carbon fibers [14,15]) which have been clinically proven safe and harmless to human health. To this end, PEEK based materials are widely used in the lumbar spine for both fusion

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and non-fusion applications [16–18]. Xin et al. [19] investigated *in vitro* tribological behavior of the PEEK-on-PEEK self-mating articulation according to ISO 18192-1 standard. The obtained results suggested that the steady state wear rate and average wear rate of the PEEK self-mating bearing combination are 1.0 mg/million cycles (MC) and 2.50 mg/MC, respectively. Grupp et al. [20] also conducted similar study and obtained a wear rate of 1.4 mg/MC for a PEEK-on-PEEK cervical disc during the steady-state condition. Furthermore, Brown et al. [21] evaluated the *in vitro* wear performances of PEEK-on-PEEK under ASTM F2025-6 and ISO 18192-1 standards, and reported that the PEEK self-mating cervical disc arthroplasty device has the wear rate that are similar to existing material combinations for cervical disc arthroplasty. Those studies mainly focused on the wear properties of PEEK self-mating bearing couples for TCDR. According to previous pin-on-plate studies [22,23], the wear rate of PEEK self-mating bearing couples is higher than PEEK articulate with another polymer. It is indicated that the PEEK based materials against hard counterfaces exhibited a contact-pressure wear response [24]. Thus, UHMWPE, a softer material that is the most widely used in bio-implant applications [25], might be an alternative polymer to articulate with PEEK in artificial cervical disc replacement. However, limited investigations were concerned about the tribological properties of PEEK based composites against UHMWPE for disc arthroplasty applications in the cervical spine.

In order to evaluate the potential use of PEEK based composites against UHMWPE as TCDR bearing materials, this work is to undertake *in vitro* tribological investigations of PEEK-on-UHMWPE and carbon fiber reinforced PEEK (CFRPEEK)-on-UHMWPE articulations of artificial cervical disc using an *in vitro* wear simulator. A better understanding of the long-term tribological performances of the tested bearing combinations will be achieved.

2. Materials and methods

2.1. Samples

In this study, the tested specimens were designed based on the conventional ball-and-socket principle [26]. They had an articulating radius of 13 mm and consisted of three components including superior endplate, inferior endplate and inlay (Fig. 1). The superior and inferior endplates were made from neat PEEK (Victrex PEEK™ grades 450G) or CFRPEEK (Victrex PEEK™ grades 450CA30, i.e., the reinforced grade of the 450G PEEK containing 30 wt% random oriented short carbon fibers derived from polyacrylonitrile) while the inlays were made from highly cross-linked UHMWPE (Chirulen HXLPE 1020X). The properties of the three materials obtain in previous literature are shown in Table 1.

The superior endplate design allows for a concave bearing surface that articulates with a convex inlay. The design for the inferior endplate allows for the inlay interference fit to it (no relative motion), which was preassembled during manufacturing. The dimensions of the tested specimens were 12 mm and 14 mm in the anterior–posterior and lateral directions, respectively. According to previous literature [12], larger initial radial clearances could lead to greater wear rate. Thus, a small radial clearance of 20 μm was selected for the samples in this study. All the samples were machined and then polished using special radial bristle discs with polishing paste to achieve a Ra of 0.10 ± 0.02 μm, measured by a 3D white-light interfering profilometry (MicroXAM 3D, ADE Corp).

Table 1
Important properties of the three materials.

	Density (g cm^{-3})	Young's modulus (Gpa)	Poisson's ratio
PEEK	1.30 [27]	3.60 [27]	0.388 [28]
CFRPEEK	1.40 [29]	18.00 [30]	0.390 [30]
UHMWPE	0.94 [31]	0.85 [32]	0.460 [32]

Before *in vitro* wear testing, the specimens were soaked in a newborn calf serum (Hangzhou Si Ji Qing Co., Ltd, China) with a protein concentration of 20 ± 2 g/L for 2 weeks in order to stabilize fluid absorption [26,33]. The soaked specimens were then stored in a sealed, dust free container at a temperature of 37 ± 2 °C and relative humidity of 45% for 48 h to stabilize their mass. The pre-test masses of the artificial cervical discs were measured using a digital balance with a resolution of 0.01 mg. Then, the artificial cervical discs were placed in the fixtures (Fig. 2), which were designed to ensure the motion accuracy of the articulating samples match that defined by the wear simulator and machined from polymer. Each pair of fixtures was composed of two parts with an inner movable holder cut to accommodate the endplates of the artificial cervical discs. The specimens were positioned in the inner holder using polyurethane resin [12]. A press-fit of the inner holder was assembled to the fixture with the screwed connection.

2.2. In vitro wear testing

In vitro wear testing was conducted on a customized six-station Prosim Knee Simulator (Prosim Corporation, University of Leeds, UK) to simulate the motion and load of the cervical spine. This simulator can provide four degrees of freedom by controlling axial rotation torque, flexion/extension torque, anterior-posterior axial force and shear force. According to the ISO 18192-1 standard, the *in vitro* wear simulation of cervical spine should consist an axial load of 50–150 N, an axial rotation of ±4.0°, a flexion/extension of ±7.5°and a lateral bending of ±6.0° [34]. As shown in Fig. 3, a scheme of the testing load and motion was designed to make up the missing lateral bending motion following our previous process [33,35]. An axial load of 50–150 N, a flexion/extension of ±7.5° and an axial rotation of ±4.0° were applied for the first half of one million cycles (MC) cycle. Later, the tested samples were rotated by 90° followed by application of an axial load of 50–150 N, a lateral bending of ±6.0° and an axial rotation of ±4.0° were applied for the next half of the one MC cycle.

As shown in Table 2, two tribo-pairs (S1 and S2) were studied. The parameters of the wear simulation were set up based on ISO 18192-1 standard. The disc specimens were tested for 5 MC in a frequency of 1 Hz to simulate the in vivo long-term wear conditions. The newborn calf serum (Hangzhou Si Ji Qing Co., Ltd, China) with a protein content of 20 ± 2 g/L was chosen as lubricant. A penicillin-streptomycin solution

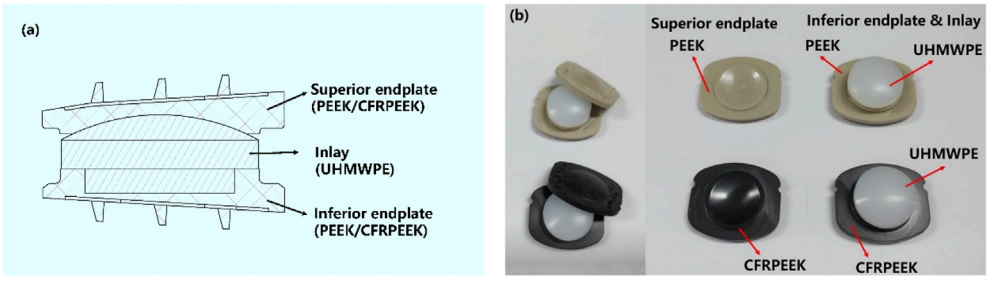

Fig. 1. The specimens for the wear simulation: (a) schematic and (b) actual articulations.