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Comparison of wear behaviors for an artificial cervical disc under flexion/extension and axial rotation motions

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ABSTRACT

The wear behaviors of a ball-on-socket (UHMWPE-on-Ti6Al4V) artificial cervical disc were studied with 1.5 MC (million cycles) wear simulation under single flexion/extension and axial rotation motion and their composite motion. The wear rates, wear traces, and contact stress were analyzed and contrasted based on mass loss, optical microscopy and SEM as well as 3D profilometer, and ANSYS software, respectively. A much higher wear rate and more severe wear scars appeared under multi-directional motion. Flexion/extension motion of 7.5° lead to more severe wear than that under axial rotation motion of 4°. The above results were closely related to the contact compression stress and shear stress. The wear surface in FE motion showed typical linear wear scratches while revealing obvious arc-shaped wear tracks in AR motion. However, the central zone of both ball and socket components revealed more severe wear tracks than that in the edge zone under these two different motions. The dominant wear mechanism was plowing/scratching and abrasive wear as well as a little oxidation wear for the titanium socket while it was scratching damage with adhesive wear and fatigue wear due to plastic deformation under cyclic load and motion profiles for the UHMWPE ball.

1. Introduction

Total disc arthroplasty (TDA) aims at restoring the function of the intervertebral disc, providing long-term pain relief and avoiding adjacent segment disease [1]. Based on the short and midterm clinical observations, TDA may be a viable option to fusion in patients with symptomatic disc degeneration. However, there are concerns that these articulating designs may be subject to long-term failure due to wear, which has been widely documented in total hip and knee arthroplasty [2]. Particulate debris and ion release resulting from in vivo degradation of TDA-C (total cervical disc arthroplasty) implant components may be recognized as a factor limiting the longevity of the procedure. There is a growing body of evidence that polyethylene and metal wear debris have osteolytic potential in the spinal disc and other artificial joints [3,4], and specific cases of TDR-related osteolysis have now begun to emerge [5]. In order to assess the durability of the devices, in vitro wear simulations are considered as a necessary component of pre-clinical safety and effectiveness evaluations.

Wear simulations are generally conducted under load and motion profiles which should be consistent with the actual spinal movement as far as possible. Nowadays, several testing procedures are described in different standard systems. Most often, wear testing is carried out according to ISO (International Organization for Standardization) 18192-1 or ASTM (American Society of Testing Materials) F2423 for spinal wear simulation [6,7]. However, there are still many differences between these two guidance documents. The international standards need to be further improved to meet the requirement of uniform and comparable testing conditions for standardized pre-clinical testing. But the improvement process is difficult because many test parameters have an influence on the final wear behaviors including loading and kinematic patterns [8], frequency [9], anterior–posterior shear load [10,11], lubrication [12], etc. As an example, T. M. Grupp et al. [13] have investigated the influence of loading and kinematic patterns and believed it would be safer to predict the clinical wear behavior of an artificial disc replacement based on the multidirectional method. A. Kettler et al. [9] have found that wear testing with lumbar intervertebral disc prostheses composed of cobalt–chrome endplates and a polyethylene core resulted in higher wear rates if carried out at 2 Hz than at 1 Hz. Hence, they have suggested testing of polyethylene-on-metal couplings at 1 Hz. R. Vicars et al. [10] have assessed the effect of an additional DOF, anterior–posterior (AP) shear on the wear of the ProDisc-L TDR and found that it had no significant effect on the overall wear rate. As a result, these representative studies above reveal that it is necessary and important to clarify the wear properties influenced by

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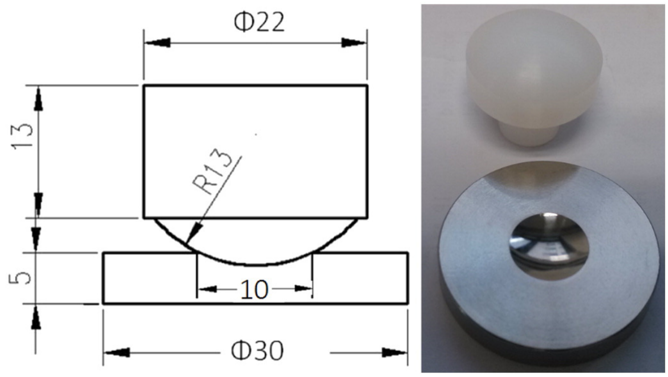

Fig. 1. The schematic and actual picture of the artificial cervical disc model.

different test parameters. Although many factors have been studied before according to the literature [8–12], the influence of different single-directional motions is still seldom involved.

Nowadays, most of the current TDA implants include three parts in structural design; they are superior endplate, inferior endplate and nucleus pulposus. The nucleus pulposus is generally inlaid in the inferior endplate. Thus, it forms a ball-on-socket structure between the convex nucleus pulposus and the concave superior endplate. Since the material combinations of superior endplate–nucleus pulposus–inferior endplate mainly include metal–polyethylene–metal or metal–metal–metal [13], the articulating surface of the ball-on-socket design also reveals two representative friction pairs including metal-on-polyethylene and metal-on-metal. According to ISO 18192-1 and ASTM F2423, the motion profiles of TDA-C consist of flexion/extension (FE), axial rotation (AR) and lateral bending (LB). Because the ball-in-socket model is axially symmetrical, FE and LB motions are equivalent. Hence, the flexion/extension and lateral bending can be considered as the rolling of the ball around different coordinate axes. So the motion profiles can be simplified as the rolling (flexion/extension and lateral bending) and torsional motion (axial rotation) of the ball for spinal implants. According to the literature [14], various kinematic profiles could lead to different wear paths between the articulating surfaces of the implants. In addition, previous studies [15] also revealed that the wear of Charité lumbar discs showed a spatial variation and it was important in modeling the wear processes and providing strategies for reducing wear. Considering that the wear between materials is influenced by the type of relative motion, the rolling and torsional motion may also lead to different wear behaviors and damage patterns. And these different wear characteristics are of great importance to prevent prosthesis failure. However, there is still little knowledge existing about the biotribological behavior of TDA devices and the characteristics of contact stress between the two simplified motions.

The objective of this study was to investigate and contrast the influence of FE and AR single-directional with multi-directional motions on the in vitro wear behavior of TDA-C prostheses. A ball-on-socket model was designed to simulate an artificial cervical disc. Then the in vitro wear assessment was conducted using a wear simulator. Finally, the wear rates, wear scars and traces, contact stress under flexion/extension and axial rotation motions were analyzed and compared.

2. Materials and methods

2.1. Ball-on-socket model

In this study, the artificial cervical disc was simplified as a ball-on-socket model. It consisted of a convex shaped inlay made of UHMWPE and a concave shaped superior titanium alloy endplate forming a spherical joint. The schematic and actual picture of the ball-on-socket contact configuration is shown in Fig. 1. The radius of the ball/socket was 13.0 mm and the contact area was 26π(~81.7) mm^2 according to the calculation formula of spherical surface area. UHMWPE (ultra high molecular weight polyethylene) (GUR 1020, Chirulen® 1020) and biomedical Ti6Al4V alloy (Baoji Titanium Industry Company Limited, China) were selected as the material of the ball and socket, respectively. Then, the ball-on-socket contact configuration was machined using a CNC (computerized numerical control) controlled 5-axis machining center. Considering that the articulating surface of prosthesis should be very smooth, both the UHMWPE ball and titanium socket were finally polished with the average surface roughness (Ra) of 0.10 ± 0.02 and 0.05 ± 0.01 μm, respectively.

2.2. Wear simulation test

The wear simulation was performed using a customized 6 station Prosim Knee Simulator (Prosim Corporation, University of Leeds, UK) to simulate the force and movement of the cervical spine. Five separate groups of three implants each were utilized in this wear study. The test methodology was shown in Table 1. The motion angular displacement, load profile as well as frequency were selected according to ISO 18192-1 (2011) [6]. Groups 1 and 2 were tested under an FE motion with an angular displacement of ±7.5° while Groups 3 and 4 were tested under an AR motion with an angular displacement of ±4°. Group 5 was a control test combining FE (±7.5°) and AR (±4°) as well as LB (±7.5°) and AR (±4°) motions. The motion profiles for FE and AR were shown in Fig. 2(a). On the other hand, Groups 1 and 3 were tested without any lubricant while Groups 2, 4 and 5 were under 25% bovine serum (5 g protein/L, also including amino acids, peptides, fats, carbohydrates, growth factors, hormones, inorganic substances) (Hangzhou Si Ji Qing Co., Ltd., China) at 37 °C. All groups were tested at a frequency of 1 Hz under a load of 50–150 N for 1.5 MC(million cycles). The load profile was shown in Fig. 2(b).

Before wear simulation, the polyethylene balls were soaked in calf serum for 2 weeks in order to stabilize fluid absorption, and then stored in a sealed, dust free container, in a temperature (37 ± 2 °C) and humidity (45%) controlled environment for 24 h to stabilize their mass. Their pretest masses were determined by a digital balance with a resolution of 0.01 mg. After this pre-soak period, the ball and socket parts were mounted to custom fixtures, respectively. The fixtures were then placed inside the bath and mounted to the machine with the socket endplate connected to the base of the simulator and the ball to the top. The custom fixtures manufactured by polymer were designed to make sure that

Table 1
Summary of all tested groups and corresponding methodology.

	Motion	Test medium	Load (N)	Frequency (Hz)	Test duration (million cycles)
Group 1	FE: ±7.5°	No	50–150	1	0–1.5
Group 2	FE: ±7.5°	5 g/L bovine serum at 37 °C	50–150	1	0–1.5
Group 3	AR: ±4°	No	50–150	1	0–1.5
Group 4	AR: ±4°	5 g/L bovine serum at 37 °C	50–150	1	0–1.5
Group 5	FE: ±7.5° and AR: ±4°	5 g/L bovine serum at 37 °C	50–150	1	0–0.5
	LB: ±7.5° and AR: ±4°	5 g/L bovine serum at 37 °C	50–150	1	0.5–1.0
	FE: ±7.5° and AR: ±4°	5 g/L bovine serum at 37 °C	50–150	1	1.0–1.5