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Spatial variation of wear on Charité lumbar discs

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ABSTRACT

Total disc replacement (TDR) is a modern technique employed to treat degenerative disc disease that has the benefit of preserving motion compared with the clinically established spinal fusion. The wear performance of implants based on articulating designs is a key factor that determines their longevity and it is hypothesized that this will be the case for TDR devices. A detailed analysis of the surface of Charité lumbar disc replacements during simulated wear for five million cycles (MC), with inputs defined by the ISO18192-1 standard, is presented. After each million cycles the disc asperity heights, asperity curvature radii and their distributions on the surface of the core of the implant were determined at different locations. Two distinct areas on the surface of Charité polyethylene disc were identified based on the surface topography change during the wear simulation process. Within the area corresponding to the dome the initial roughness decreased, but after 2 MC the surface appeared to roughen with material build-up. More peripherally on the dome the surface roughness decreased after the first MC and remained constant. No effect was noticed on the rim. Furthermore, no statistical difference was noticed between the inferior and superior sides of the core of the disc. The study demonstrated that the wear on the two surfaces of the disc was uneven. This spatial variation is important in modelling the wear processes and providing strategies for reducing wear through enhanced design and modifications to the biotribological properties of the device.

1. Introduction

It has been reported that low back pain affects between 60% and 85% of the population during their lifetime [1–3]. Of these, 90% recover in 6 weeks [4], while the remainder require more complex interventions that may include surgical approaches [2,3]. Thus, far spinal fusion has been the gold standard surgical intervention where this is indicated for discogenic low back pain [5]. The overall success rates for such procedures vary in the range 32–99% [6,7]. Complications include subsequent problems associated with reduced motion and accelerated adjacent segment disease [8–10].

Total disc replacement (TDR) is an alternative to the clinically established technique of fusion for treating degenerative disc disease. TDR allows a closer approximation to the "normal" spine kinematics by allowing the index level to remain flexible and by reducing the stress sustained by the adjacent spinal units [11–14]. In contrast to fusion, TDR aims to preserve rather than eliminate motion and minimize overall biomechanical changes to the spine. The aims of TDR are to restore the motion segment functionality, provide long-term relief from back pain and prevent adjacent segment disease [15].

The development of an artificial disc is challenging due to the complexity of both the anatomical structure and biomechanical aspects of the joint system [16,17]. The longevity of joint replacement implants is a key consideration that impinges on their success and its importance is growing due to the younger profile of patients into which these TDR devices are implanted. This endurance is partly determined by the wear performance of the implants. Poor wear performance can have an impact on the device both biomechanically and in terms of the body's response to wear debris, which may lead to osteolysis and joint loosening [18–20]. Hence, implants must be engineered to maximize wear performance, thus alleviating wear-related biological reactions [21,22], such osteolysis caused by wear debris [23,24]. Currently little is known about surface changes on the articulating disc through the wear process and their possible effect on both wear performance and functionality of the disc. Further, a thorough knowledge of the interplay between wear and surface characteristics is necessary in the design of devices and material selection for TDR. Within this context, asperity properties such as height and curvature radii

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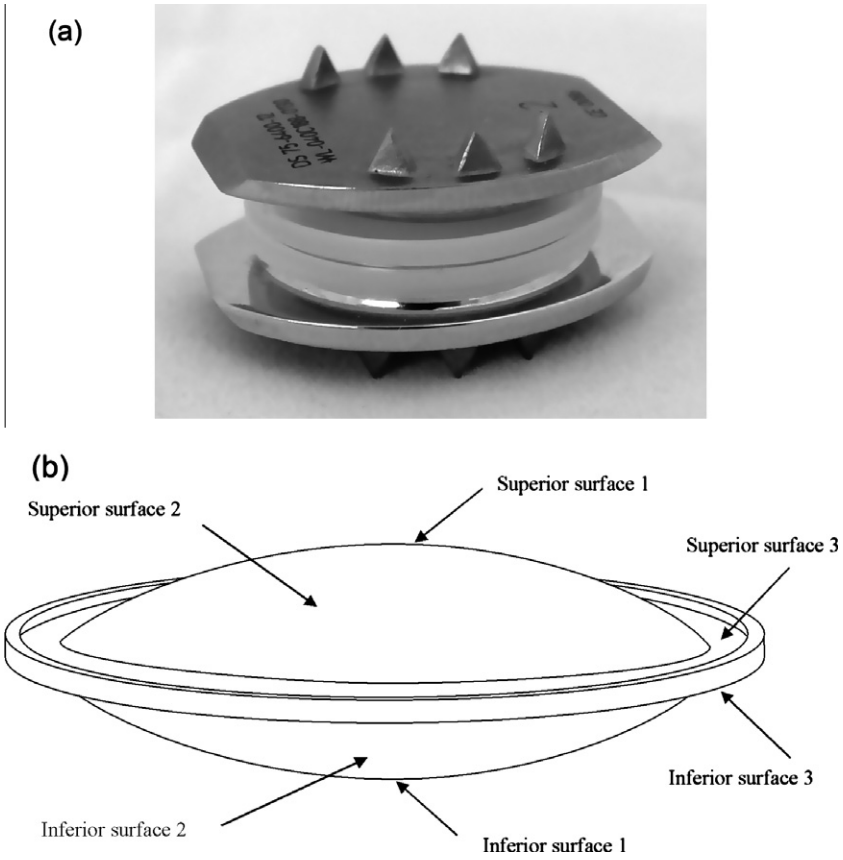

Fig. 1. (a) Image of the Charité disc and (b) schematic representation of the investigated areas.

are important parameters as they determine the adhesion and the effective area of contact within the tribological system.

In this paper, detailed changes in the surface topography at different locations on Charité lumbar discs have been investigated during five million cycles (MC) of wear simulation in order to determine whether areas with different wear and damage occur and to explain variations in the wear rate per MC during the wear process. For this purpose disc asperity heights, average asperity curvature radii and their distributions on the surface of the implant were determined after every MC.

2. Material and methods

2.1. Materials and wear testing

Commercially available Charité artificial lumbar discs (DePuy Spine, Raynham, MA) with metal–polyethylene (PE) coupling were used for in vitro wear simulation testing (Fig. 1a). It represents a ball in socket design that consists of a PE sliding core articulating against two metallic end-plates. The PE core (size 2, height 7.5 mm) was made of ultra-high molecular weight polyethylene (GUR 1020) sterilised using γ-irradiation (2.5–4 Mrad). The end-plates of the disc were manufactured from a cobalt–chromium–molybdenum (CoCrMo) alloy. A schematic of the design of the PE core of a Charité lumbar disc is presented in Fig. 1b.

The wear performance of seven implants was evaluated for 5 MC using a multi-station spine wear simulator (SimSol, Manchester, UK) [25]. In vitro wear simulation of six lumbar discs was performed under four degrees of freedom conditions (4DOF) according to the ISO 18192-1, while a seventh implant was tested under axial loading alone and acted as a soak control. According to the ISO protocol all movements were applied as a sinusoidal waveform with a frequency of 1 Hz and a kinematic pattern with flexion/extension of $+6°/-3°$ and both lateral bending and axial rotation of $\pm 2°$. The corresponding axial force was also sinusoidal, but with a frequency of 2 Hz and a minimum of 600 N with a maximum of 2000 N.

Prior to testing all implants were soaked in distilled water for 2 weeks to allow fluid adsorption saturation. The wear testing was conducted in a lubricant made of newborn calf serum (Harlan Sera-Lab, Loughborough, UK) diluted with distilled water to obtain a protein concentration of 15 g l^{-1}, as this was shown to produce

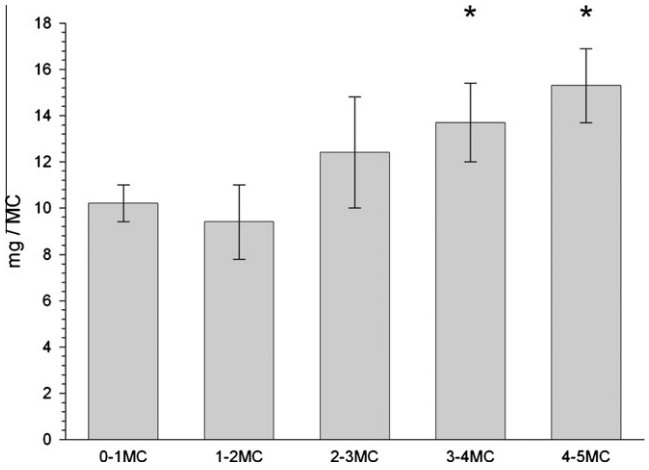

Fig. 2. Wear rate (mean ± standard deviation) vs. different MC time points. *Data statistically different from 0 to 1 MC.