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The evolution of polymer wear debris from total disc arthroplasty

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ABSTRACT

Total disc arthroplasty is an alternative to spinal fusion, aimed at preserving flexibility; these devices typically involve a cobalt chrome molybdenum alloy socket articulating against an ultra-high molecular weight polyethylene (UHMWPE) ball. As with all artificial joints, wear debris is of particular concern due to its effect on both implant life and the *in vivo* biological reactions that can occur.

In this paper, a profile of the UHMWPE wear debris generated from disc arthroplasty, tested on a spine simulator, is built with a combination of SEM image analysis tools. SEM images were analysed by computer vision, which allowed size and shape information to be extracted and images to be categorised by the shared topological features on individual wear particles. The computer visions techniques were based on a Scale Invariant Feature Transform (SIFT) to extract key point data from individual images and a Support Vector Decision Machine (SVM) to filter images based on a series of trained parameters. As certain wear particle morphology is predominantly produced by a particular wear regime, grouping wear particles by morphology and size made it possible to infer the relative rates of various wear regimes responsible for wear debris generation. By sampling synovial lubricant at intervals throughout the tribological test, the predominant wear regimes and particle sizes were tracked over the course of the implant life. Wear debris samples were taken at 12 intervals over a 5 million cycle test.

The majority of debris was found to be 0.88 μm in equivalent circle diameter, with an aspect ratio (defined as the major over the minor diameter of the smallest possible encompassing ellipse of the debris) of 1.55. There was a decreasing trend in average particle size as the number of cycles increased. During the early stages of the test, adhesion and abrasion were dominant in forming particle morphologies, however after 2 million cycles; particles generated as a result of fatigue became the major particle morphology.

1. Introduction

Ultra-high molecular weight polyethylene (UHMWPE) is a common choice for joint arthroplasty as a bearing counter-face, in part due to its low chemical reactivity and tribological properties. Current total disc replacements (TDRs) such as the SB Charité and PRODISC-L (DePuy Synthes Spine, Raynham, MA, USA) both make use of a CoCrMo (Cobalt Chrome Molybdenum alloy) on a UHMWPE bearing. This tribological combination is the obvious choice for TDRs given the long standing and successful use in hip and knee arthroplasty, where it was found that older, less active patients were best served by metal-on-polymer (MoP) implants [1]. Interest in wear debris has grown over the years as their various adverse effects have been further understood, that can reduce implant life, and induce unwanted biological reactions within the body [2,3].

For example the wear debris from UHMWPE on metal joint replacements, particularly those in the size range of 0.1–1.0 μm, have been shown to cause aseptic loosening of implanted devices [4]. In addition to the effects on bone, debris has been shown to induce short-term fibrosis and histiocytic reactions within the spinal column in *in vivo* animal studies [5]. There have therefore been numerous studies which focused on the quantification, characterisation and compatibility of wear debris generated from hip and knee implants, both from *in vitro* and *in vivo* wear debris [6–8]. Studies have found the majority of UHMWPE debris exists in the range of 0.1–1 μm, with low instances of particles greater than 10 μm in size. A summary of the results of several studies in this area are shown in Table 1.

It is important, therefore to characterise generated wear debris to ensure implant designs and material choices minimise the formation, and release into periprosthetic tissue, the debris morphologies that correlate with the adverse biological reactions outlined above. There are various methods to characterise wear debris. Scanning electron micrographs provide excellent qualitative information of wear particles, and with the aid of computer vision techniques, can also provide quantitative analysis. The methods and analysis gained through computer vision can range in degrees of sophistication [9–12], from simple area and aspect ratio measurements to machine

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Table 1
A comparison of UHMWPE wear debris from hip and knee implants, based on the work of Nine et al. [8]. Note: AFM = Atomic Force Microscope (FEG) SEM = (Field Emission Gun) Scanning Election Microscope, IR = infrared, EDX/EDS = Energy-Dispersive X-ray Spectroscopy, TEM = Tunnelling Electron Microscope.

Type	Source	Shape	Size	Instrument
Mobile bearings [9]	Knee joint simulator	Elongated, fibril like, and spherical	0.2–0.8 μm	AFM, SEM
Revision surgery of THRs [15]	Periprosthetic tissues	Cylindrical, slice and spherical	0.1–10 μm and >10 μm	SEM, IR, EDX/EDS
Mobile bearing [16]	Hip joint simulator	Round, flake, stick, and twig	Frequently occurs within range of 1–30 μm, but overall size range is 0.1 –320 μm	SEM, EDS
Revision surgery of THRs [17]	Periprosthetic tissues	Elongation, 1.29 ± 0.13, 1.35 ± 0.29 and circularity, 0.97 ± 0.07, 0.93 ± 0.09	ECD, 18.5 ± 5.29 nm and 21.2 ± 8.01 nm	FEGSEM, EDS, IR
Revision surgery of THRs [18]	Periprosthetic tissues	Rounded, fibril, and flake	<35%, 30 nm and 0.1–0.99 μm, rest are >1 μm	FEGSEM, EDS
Revision surgery of THRs [19]	Periprosthetic tissues	Rounded, flattened, and flakes or fibrils	87.9% < 1 μm	TEM, SEM
Hip joint [20]	Periprosthetic tissues	Rounded, beads, fibrils, flakes	ECD range is from 0.48 to 0.95 μm	SEM, Micro-Raman spectrometry
Hip joint [21]	Periprosthetic tissues of THRs	Fibril, platelet	Most of particles, 0.1– 0.5 μm and very few > 10 μ	SEM

learning and object recognition. A further benefit of this is that by classifying debris by morphology, the wear regime can often be inferred [13].

Retrieval studies of Charité disc replacements have shown the main form of wear within the articulating cup is abrasion and adhesion [14]. It is important to ensure *in vitro* simulations mirror what is found *in vivo* for their results to remain meaningful. This paper, therefore, investigates the nature of debris produced in an *in vitro* simulation of a TDR implant, using SEM micrographs analysed with computer vision techniques. The efficiency of assessing the debris images has been greatly increased, using a Scale Invariant Feature Transform (SIFT) to extract key point data from individual images and a Support Vector Decision Machine (SVM). The SVM was trained to filter images of debris into appropriate morphologies, using wear particles generated from idealised adhesion and abrasion tests. The debris morphology assessment tool is then used to examine how debris changes over the course of a 5 million cycle endurance test. The debris is compared against UHMWPE debris generated in a reciprocating tribometer, using test parameters that would predominately run in specific wear regimes.

2. Materials and Methods

2.1. In vitro wear debris

In vitro wear debris was generated by Moghadas [22], using a Charité (DePuy Spine, Raynham, MA, USA) TDR implant which has two CoCrMo alloy endplates articulating with a UHMWPE core (Fig. 1). The study involved long term wear tests where the lubricant containing wear debris was replaced at 12 intervals over 5 million cycles. The tests were conducted using a Bose ElectroForce Spinal Disc Fatigue/Wear system (Bose Corp., ElectroForce Systems Group, Eden Prairie, Minnesota, USA). The implant was run in a bath of 30 g/l calf bovine serum lubricant (Sera Laboratories Int, West Sussex, United Kingdom) according to BS ISO standard 18192-1:2011 [23]. The lubricant samples were taken at the following cycle counts: 0.25, 0.75, 1, 1.25, 1.5, 1.75, 2, 2.25, 2.5, 3, 4 and 5 million cycles. The bovine serum samples were refrigerated at 4 °C until the debris was isolated and analysed.

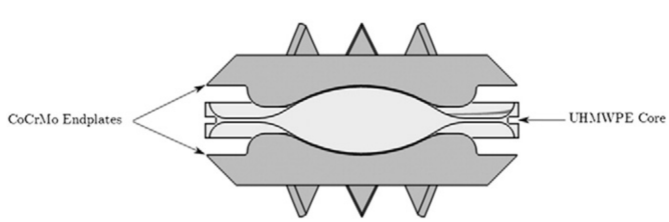

Fig. 1. An illustration of the cross section of a Charité implant.

2.2. Bovine serum digestion and filtration

The isolation of debris was performed using the method presented in BS ISO 17853:2011 [24]. A volume of 10 ml of bovine serum containing debris was mixed with hydrochloric acid, 32% w/w, using a vortex mixer and this was then incubated at 50 °C for 1 h in a water bath. From the digested bovine serum 0.5 ml was diluted into 100 ml of analytical grade methanol (Fisher Scientific UK Ltd, Loughborough, United Kingdom) and vacuum filtered through 0.1 μm Nuclepore filters (Whatman International Ltd, Maidstone, United Kingdom). The filter was cut with a scalpel to 2 mm × 2 mm squares and fixed to an SEM stub with copper tape, and allowed to dry in a desiccator for 24 h. The filters were splutter coated with gold for 60 s at 30 mA using an Agar automatic splutter coater (Agar Scientific, Elektron Technology UK Ltd, Essex, United Kingdom). Silver conductive paint (RS components Ltd, Northants, United Kingdom) was dabbed on an edge to create a conductive bridge between the coated surface and the SEM stub.

2.3. High frequency reciprocating rig (HFRR)

For the purpose of finding abrasion and adhesion training debris, a High Frequency Reciprocating ball on disc tribometer (PCS Instruments, London, United Kingdom) using a steel ball on UHMWPE disc was used in two scenarios and in deionised and filtered water to prevent contamination (Fig. 2). The scenarios were designed to deliberately induce either abrasion or adhesion in a simplified manner to allow for the identification of these wear debris morphologies [25,26]. The two scenarios were: a roughened ball of roughness Ra = 0.5 μm run at 20 Hz over a short time period (20 min) and a 0.05 μm roughness ball at 25 Hz for 4 h.

The surface roughnesses of the balls were measured before testing using an Alicona Infinite Focus optical 3D micro coordinate system (Alicona Imaging GmbG, Raaba/Graz, Austria). Both sets of conditions were run in 1 ml of lubricant comprising of ultra-pure deionised water (Resistivity: > 18 MΩ-cm, Inorganic content: <2 ppb). The lubricant, containing debris, was vacuum filtered using the same type of 0.1 μm