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Technical Note

Wear testing of crosslinked polyethylene: Wear rate variability and microbial contamination

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ABSTRACT

The wear performance of two types of crosslinked polyethylene (Marathon™ and XLK™, DePuy Synthes Inc., Warsaw, IN) was evaluated in a pin-on-disc wear tester, a hip wear simulator, and a knee wear simulator. Sodium azide was used as the microbial inhibitor in the calf serum-based lubricant. In the pin-on-disc wear tester, the Marathon wear rate of 5.33 ± 0.54 mm^3/Mc was significantly lower ($p = 0.002$) than the wear rate of 6.43 ± 0.60 mm^3/Mc for XLK. Inversely, the Marathon wear rate of 15.07 ± 1.03 mm^3/Mc from the hip wear simulator was 2.2-times greater than the XLK wear rate of 6.71 ± 1.03 mm^3/Mc from the knee wear simulator. Differences in implant design, conformity, GUR type, and kinematic test conditions were suggested to account for the difference between the wear rates generated in the different types of wear testing apparati. In all wear tests, sodium azide was ineffective at inhibiting microbial growth in the lubricant. Eight different organisms were identified in the lubricant samples from the wear tests, which suggested the necessity of using an alternative, more effective microbial inhibitor. Careful sample preparation and thorough cleaning has shown to improve the consistency of the wear results. The wear rates generated in the hip and knee wear simulators closely reflected the wear behaviour of Marathon and XLK reported in published data that were tested under similar conditions.

1. Introduction

The demand for total joint arthroplasty continues to increase rapidly, and is becoming more evident in younger, more active patients (Kurtz et al., 2007). To ensure the durability of bearing materials for total joint replacements *in vivo*, new bearing materials, such as different types of crosslinked polyethylene (XPE), are routinely subjected to wear testing

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(McKellop et al., 1999; Saikko et al., 2002; Fisher et al., 2004; UHMWPE, 2009). As part of product development and pre-clinical screening, the wear testing of XPE has become a standardized procedure (ASTM-F732, 2011; ISO-14242-1, 2009; ISO-14243-3, 2004) for simulating conditions found in the clinical environment (Tipper et al., 2000; Silva Schmalzried, 2003; Brandt et al., 2013). More frequently, these wear tests on XPE are performed on pin-on-disc (POD) wear testers (Dressler et al., 2011), hip wear simulators (Saikko et al., 2002; Clarke et al., 2001; Kaddick and Wimmer, 2001; Chen et al., 2006), and knee wear simulators (Barnett et al., 2002; Schwenke et al., 2005; DesJardins et al., 2006, 2008; Brandt et al., 2011a, 2012, 2013; Dressler et al., 2012); however, recent studies (Brandt et al., 2011a; Brandt et al., 2013; Wimmer et al., 2013) have shown that a continuous sterile environment may not be maintained during wear testing. Despite the use of sodium azide (SA) as the microbial inhibitor during wear testing, microbes have been shown to grow in calf serum-based lubricants, which have been shown to affect the wear rate (Brandt et al., 2011a, 2012, 2013; Wimmer et al., 2013). It remains uncertain as to the range of microorganisms that could be grown between wear testing apparati and wear testing laboratories.

The wear results generated in orthopaedic wear testing apparati can vary among laboratories (Clarke et al., 2001; Schwenke et al., 2005; DesJardins et al., 2006; Brandt et al., 2011a, 2012). These differences may originate from subtle variations in test protocols, implant design, hardware setup, and lubricant composition (Schwenke et al., 2005; DesJardins et al., 2006; Brandt et al., 2011b, 2012), all of which have the potential to affect the wear behaviour of XPE. Before using newly acquired wear testing apparati for product development, it is essential to commission the apparati to ensure its appropriate and reliable operation (Kaddick and Wimmer 2001; Barnett et al., 2002; Schwenke et al., 2005; Brandt et al., 2011a). Subtle mechanical differences between wear stations have been shown to affect the PE wear rate during *in vitro* wear testing. These differences can potentially affect the ability to accurately evaluate the wear performance of new bearing materials for total joint replacements. This cost- and time intensive undertaking is an essential part of validating wear testing apparati, particularly for independent wear testing laboratories.

The primary purpose of the present study was to evaluate the wear performance of two types of XPE bearing materials in a pin-on-disc (POD) wear tester, hip wear simulator, and knee wear simulator. Secondly, the types of microorganisms were characterized from fresh and used wear testing lubricant while using SA as the antimicrobial agent. The wear behaviour of two types of XPE was monitored; the findings from these wear tests were discussed in detail, and compared with published data.

2. Materials and methods

Wear tests were performed on a POD wear tester (OrthoPOD, AMTI, Boston, MA), a hip simulator (ADL-Hip, AMTI, Boston, MA), and a knee simulator (ADL-Knee, AMTI, Boston, MA) for a total of 5.94 million cycles (Mc; three intervals of 1.98 Mc), 3.5 Mc, and 3 Mc respectively. The POD tester consisted of six wear stations with six XPE pins articulating against six individual polished cobalt-chromium (CoCr) alloy discs, similar to those used by Dressler et al. Dressler et al. (2011). The XPE pins, 9.5 mm in diameter, articulated on polished CoCr alloy discs following a square wave form at a test frequency of 1.6 Hz (Dressler et al., 2011) and recommendations made as per ASTM-F732 (ASTM-F732, 2011). Three additional pins of each XPE material were soaked in the lubricant at 37°C for every 0.33 Mc interval; these soak control pins were used to account for the weight gain due to fluid absorption during the POD wear tests. Both the hip and knee simulator consisted of a left bank (LB) and right bank (RB). Each bank of the hip simulator accommodated six wear stations and two load-soak stations that could accommodate four load-soak implants. Each bank of the knee simulator accommodated three wear stations and two load-soak stations. The load and motion parameters were based on the recommended standards for hip and knee simulator wear testing (ISO-14242-1, 2009; ISO-14243-3, 2004), but were identical to the loading conditions used by Chen et al. (2006) and the motion conditions used by Dressler et al. (2012). In the knee simulator wear tests, the load and motions were slightly modified to follow *high kinematics*, as performed by Dressler et al. (2012) at a test frequency of 1 Hz.

The bearing materials used in the present wear tests were donated by an implant manufacturer (DePuy Synthes Inc., Warsaw, IN). For the POD wear tests, the XPE pins were machined from Marathon (Marathon™, DePuy Synthes Inc., Warsaw, IN) and XLK (XLK™, DePuy Synthes Inc., Warsaw, IN). In the POD wear tests only, conventional, non-crosslinked polyethylene (PE; ram-extruded GUR 1050 resin) was used as the reference bearing material to illustrate the effect of cross-linking on wear. POD wear tests were performed for a test duration of 1.98 Mc using conventional PE, Marathon, and XLK pins. In the hip simulator wear tests, each implant consisted of a 32 mm diameter CoCr alloy femoral head articulating against a Marathon acetabular liner; these components were contained within a 52 mm titanium alloy Pinnacle® acetabular shell. The liners were machined from ram-extruded GUR 1050 bar stock, crosslinked at 5 Mrad, and subsequently subjected to a thermal treatment process. In the knee simulator wear tests, each implant consisted of a right-sided, size three CoCr alloy femoral component with a polished CoCr alloy tibial tray that had a full-peripheral locking mechanism; these components were part of the PFC Sigma® knee system. The XLK tibial inserts were machined from ram-extruded GUR 1020 bar stock and wear also moderately crosslinked at 5 Mrad. On the hip and knee simulator, wear tests were performed for 2 Mc once a steady-state wear rate was established. The titanium alloy acetabular shells, CoCr alloy tibial trays, and CoCr alloy femoral condyles were mounted onto custom simulator fixtures using dental bone cement (Bosworth® Fastray™, Harry J. Bosworth Company, Skokie, IL).

Bovine calf serum (Lot # AWA92916, HyClone, Logan, UT) was used as the base lubricant and was diluted with deionized water to a target total protein concentration of 54 g/L for the POD wear tests and 17 g/L for both the hip and knee simulator wear tests. The protein concentrations chosen for the POD, hip and knee simulator wear tests were based on published data supplied by Dressler et al. (2011), and previously conducted hip and knee simulator wear tests (Chen et al., 2006; Dressler et al., 2012).