Wear 376-377 (2017) 236–242

Contents lists available at ScienceDirect

Wear

journal homepage: www.elsevier.com/locate/wear

Method for volumetric assessment of edge-wear in ceramic-on-ceramic acetabular liners

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ARTICLE INFO

Article history:
Received 2 September 2016
Received in revised form
20 December 2016
Accepted 26 December 2016

Keywords:
Hip prosthesis
Ceramic-on-ceramic
Edge-wear
Roundness measurement

ABSTRACT

This paper details a novel method to characterize and quantify edge wear patterns in ceramic-on-ceramic acetabular liners using a roundness measurement machine to measure the post-wear surface. A 3D surface map is produced which encompasses the measured surface covering the wear patch, the uncontrolled edge geometry and form of the bearing surface. The data is analysed to quantify linear penetration and volume. The developed method was applied in a blind study to a set of six 36 mm ceramic-on-ceramic acetabular cup liners that were measured and analysed to characterise the edge wear. The in-vitro linear wear penetration ranged from 10 µm to 30 µm. The computed volumetric wear results obtained from the blind roundness measurement study were compared against the measured gravimetric results indicating a strong correlation between the results (0.9846). This study has also highlighted that measured liners exhibited an area of localised edge wear locates above the bearing surface as well as a smearing effect on the bearing surface caused by debris from edge wear. A study was carried out to test the repeatability of the measurement method and the inter-operator variability of the analysis. The results of the study show a standard deviation for the entire measurement and analysis process of 0.009 mm^3 for first user and 0.003 mm^3 for second user over twenty datasets. Hence the method displays high repeatability of the measurement and analysis process between users. This method allows for the delineation of form and wear through the determination of local geometry changes on what is essentially a freeform surface. The edge geometry is only partially controlled from a GD&T perspective and its geometry relative to the bearing surface varies from part-to-part. This method whilst being subjective allows for the determination of wear in this area with a high level of repeatability. However the limitation of this method is that it can only measure 5mm wide band of the liner due to the limited gauge travel range of 2mm

1. Background

The life expectancy of a hip prosthesis is commonly expected to be 15–20 years. In the UK during the last decade 711,765 primary surgeries have been carried out in comparison to 80,042 revision surgeries [1] to replace joints that have failed either prematurely or at the end of their useful life. The use of fourth generation ceramic-on-ceramic bearings have proved to be very efficient and has grown in popularity for primary hip surgery in the last decade [1]. This is due to the low reported wear volumes associated with all ceramic bearings [2] as well as the fact that ceramic debris being bio-inert overcomes the commonly reported issues of systemic cobalt chromium ion concentration as reported in metal-on-metal bearings [3,4] and issues of osteolysis induced by polyethylene wear debris in metal-on-UHMWPE [5,6]. The interest in ceramic-on-ceramic is elevated also due to significant improvements in material properties and manufacturing process [7].

Of all current commonly used bearing surface combinations, ceramic-on-ceramic have been reported to wear at the lowest rate [8,9]. From previous simulator studies it has been observed that levels of wear in ceramic-on-ceramic bearing surface can be of the order of 0.2 mm^3/million cycles [2]. With such excellent material properties and high survival rates, ceramic-on-ceramic hip prosthesis has been widely implanted into ever younger, more active patients [10–12], and yet very few long term large set retrieval studies have been carried out due to the survivorship of the implants [13–15]. The analysis of retrieved implants (explants) is an essential step in the audit of orthopaedic healthcare provision [16]. This principle holds true irrespective of whether a device has failed early [17] or has been removed after decades of use in a satisfied patient [18]. Ceramic-on-ceramic hip prosthesis are reported to squeak in-vivo [19,20]

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http://dx.doi.org/10.1016/j.wear.2016.12.039
0043-1648/

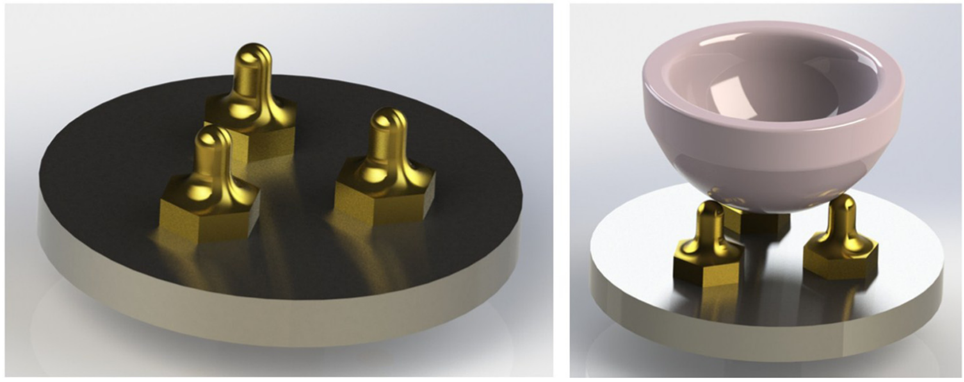

Fig. 1. Image displaying a CAD model of a custom made 3-Sphere fixture.

which appears to be linked to edge-loading [21]. Also, it has been reported that an unusual stripe pattern of wear can occur in some retrieved acetabular cup liners [22] and it has further been postulated that this is caused by cup liner edge loading [23]. The combined measurement challenge of wear occurring at the edge of the acetabular liner of a low-wearing ceramic-on-ceramic prosthesis is therefore considerable.

Various wear measurement methods have been developed to measure wear in hip prostheses [20,24–26], yet current recognised industrial practice regarding in vitro measurement of wear for hip joint prostheses involves either gravimetric assessment or co-ordinate measurement [27].

Due to the considerable challenge in determination of edge wear geometrically, current literature regarding assessment of edge-wear in acetabular cup liners has been confined to in-vitro simulator studies and use of gravimetric measurement only. This approach is clearly limited due to the lack of spatial characterisation and determination of wear extent and location [24]. Geometric characterisation of wear is essential in determining the contact conditions during gait and subsequent calculation of point and magnitude of the maximum stress condition. It is therefore vital that a robust and reliable method for geometric measurement and analysis of edge wear is created.

This paper details a novel method to characterize edge wear distribution in ceramic-on-ceramic acetabular liners and ascertain wear volume and linear penetration using a roundness measurement machine (RMM). The method is able to measure wear from the bearing surface and beyond the edge and eliminates the limitations of previous geometric methods which focused on just the bearing surface.

2. Method and materials

2.1. Study design

Six 36mm diameter ceramic-on-ceramic bearings (BIOLOX® delta, Pinnacle®, DePuy Synthes, Leeds, UK) were tested on the Leeds II hip joint simulator (Institute of Medical and Biological Engineering, University of Leeds) for three million cycles under edge loading conditions. Edge loading between the femoral head and acetabular cup occurred during gait due to dynamic separation driven by translational mismatch between the centres of rotation of the femoral head and acetabular cup [28]. This method was proven to generate clinically relevant wear mechanisms on the femoral head and acetabular cups and generate the bimodal wear debris distribution seen clinically with ceramic-on-ceramic bearings [29–32].

Under such condition the wear occurred on the chamfer region of the acetabular cup. At the end of three million cycles, the components were cleaned from contaminants using local standard operating procedures before measured in a temperature and humidity controlled environment using a microbalance (Mettler-Toledo XP205, UK) under which they were measured before the test commenced. The wear volume was determined gravimetrically by dividing the mass loss by the density of BIOLOX® delta (0.00437 g/mm^3).

Upon completion of the simulator test, components were measured in a blind study at EPSRC CIMAM, University of Huddersfield. The method uses a Talyrond 365 (Ametek, Leicester, UK) stylus-based RMM to measure the worn acetabular surfaces. A 3D surface map is then produced encompassing the area of the liner edge that contains the wear patch. The data is analysed to remove form effects due to the edge geometry and linear penetration and wear volume are then computed in further steps detailed in the following sections. The results obtained from RMM method were compared against the gold standard gravimetric method. Further cup liner 6 was measured 20 times to test repeatability and inter-operator variability.

2.2. Roundness measurement method

In order to assess edge wear without any pre-wear geometric data, the area surrounding the edge of each acetabular cup liner was measured using a Talyrond 365 stylus-based roundness measurement machine. The Talyrond 365 is able to measure straightness, roundness and cylindricity and has a stated gauge resolution of 30 nm with a spindle runout value of 20 nm [33]. A diamond tip pointed stylus with an end radius of 5 µm was used for the measurement to eliminate mechanical filtering error. Given the nano-meter precision of RMM, the room temperature was maintained at 20 °C ± 1 to prevent thermal expansion errors. Prior to performing a measurement the component was mounted on a custom designed three sphere fixture, as seen in Fig. 1, that was attached to a two-stage goniometer and an x-y translation stage. Each component then underwent a centring and levelling routine to establish an eccentricity of under 1 µm between the axis of the spindle and that of the component.

The procedure to define the measurement height requires a vertical trace of the acetabular liner through the wear area. Using this vertical trace, Z-axis values of the first and last roundness trace are determined to cover the required area of the edge and bearing surface. After establishing the component alignment, 500 horizontal roundness traces were measured at height intervals of 0.01 mm covering 5 mm of Z-axis height that includes the wear patch on the edge of acetabular cup liner. Each horizontal trace captures 3600 points and thus each