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The role of tribology and metrology in the latest development of bio-materials

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Developing techniques for the dimensional assessment of true clinical wear in retrieved total joint replacements.

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Introduction

The introduction of what we now recognise as the modern total joint replacement prostheses in the mid twentieth century, firstly with the total hip and later the total knee replacement, is rightly thought to be one of the major medical breakthroughs of our times, especially in the treatment of chronic arthritis. Total joint replacement is an increasingly common elective surgical procedure worldwide, with over 50,000 operations being performed annually in the UK out of a worldwide total of over half a million procedures [1]. The current raft of joint replacement designs are expected to function fully for around 10-15 years, however, as continued improvements in healthcare has led to a consequent increase in overall life expectancy in the general population there is an ever greater call for all types of joint replacement to improve joint function and offer longer term improved quality of life for patients.

It has long been recognised that wear analysis of total joint replacements is an important means in determining and modelling failure mechanisms, functionality and improving longevity of these devices as most replacement joints fail as a complication of the basic wear and debris generation process [2-4]. The quest for longer life from replacement joints has consequently concentrated on developing materials and designs which minimise the generation of wear particles [5-7].

The standardised method for assessing wear volumes in orthopaedic joint replacements is through gravimetric means [8, 9] and it has been shown that this method is a useful tool for indicating wear volumes via simulator studies. This method has been shown to be of little value, however, when trying to ascertain the wear of a clinically explanted bearing surface for which there is evidently no 'pre-wear' data [10, 11].

The purpose of this paper is to present a technique for accurate estimation and assessment of such clinical wear through use of a co-ordinate measuring machine (CMM) allied to application of reverse engineering methodologies. By way of illustrating the proposed techniques a series of relevant case studies will be used.

Materials & Methods

Two techniques are developed and proposed for determination of the true clinical wear of total joint replacement components, the results of which are detailed in the following case studies. The first utilises reverse engineering techniques so that measurement data from the unworn portion of the explanted component can be used to create a 'zero-cycle' three-dimensional CAD entity. From these pre-wear surfaces, it is possible to directly calculate volumetric material loss and to graphically map the wear 'scar' i.e. the penetration of the femoral head into the acetabular cup.

The second technique uses an unworn identical component as a baseline measurement artefact, surface characterisation techniques are then used to overlay the surfaces and create surface wear maps.

By application of these techniques to represent the initial unworn surface it is possible to directly compute an estimation of the volumetric material loss and to graphically represent the wear 'scar' i.e. the penetration of the femoral head into the acetabular cup.

Case Studies
Case Study 1: Clinical wear determination in retrieved resurfacing-type total hip replacement components.

It has been shown previously that geometric methods can be utilised repeatably for the determination of wear volumes in orthopaedic implants [12]. In this case study these methods are further developed and adapted for the determination of wear in retrieved total hip replacement components for which there is no pre-wear data.

Two explanted metal on metal resurfacing-type hip bearing pairs of undetermined size and manufacture were assessed to determine their clinical wear volume and determine a measurement of the maximum wear scar depth. The components were measured using a Zeiss PRISMO co-ordinate measuring machine (Carl Zeiss Ltd, Rugby, UK) with a stated probing accuracy of 0.7?m and a scanning accuracy of around 1?m. It has been proposed that the minimum accuracy of a CMM for three dimensional wear analyses of hard-on-hard orthopaedic bearings should be 2?m [13], the machine used in this study has far greater accuracy than this, but most common CMM's have a stated accuracy of around 3?m and as such would not have the resolution or repeatability required for useful volumetric measurements.

A probing strategy was adopted to maximise accuracy and minimise dynamic effects through application of best practice. In addition to this a gaussian filter and outlier elimination were applied to the measurement data to remove the influence of any dynamic data effects such that the resultant data accuracy exceeded the stated error values.

Due to the lack of pre-wear data a null surface had to be constructed for each component. This was done by use of reverse engineering methods and measurement of the unworn area of the surface. Firstly an approximated CAD model of the component was created to define the location of measurement points which were taken in the unworn zones of the bearing surface, i.e. the non-contacting area of the bearing. Non-uniform Rational B-splines (NURBS) were then used to fit a surface through the unworn zone surface data points and this surface was then assigned as the normalised 'pre-wear' component surface. Through use of such surfaces in each case an estimation of the wear volume and location could be determined. To do this, a grid of measurement points was applied and enacted over the whole bearing surface. This then allowed for the wear scar map and volumetric wear of each component to be calculated directly. An overall outline of the measurement method is shown in figure 1.
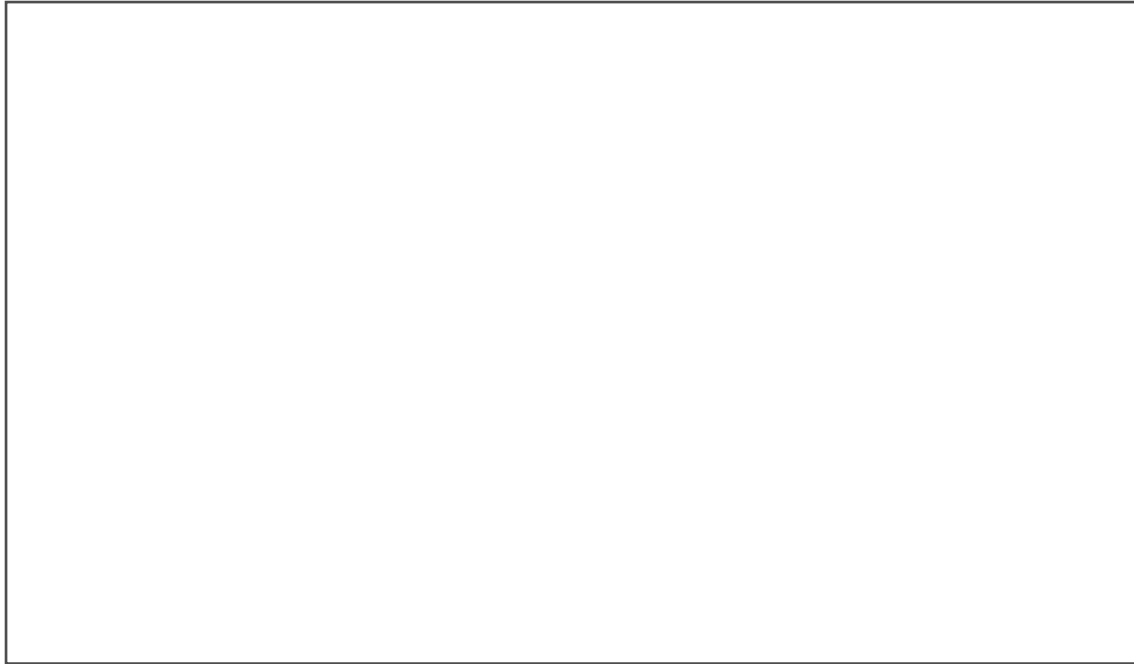
Figure 1: **CMM wear measurement method for retrieved total hip replacement components.**
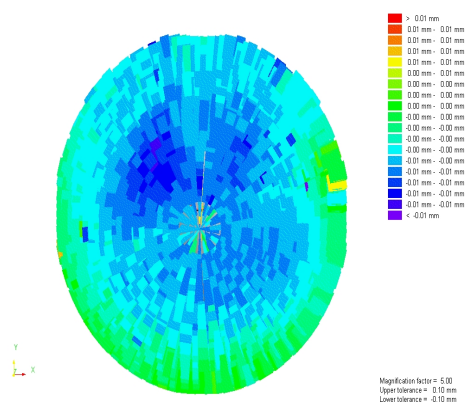
Each component was measured three times and an average volumetric wear value was determined, the mean volumetric wear results are shown in table 1. The results illustrate the relative component volumetric wear potential in each bearing pair, in both cases showing that relative wear contribution of the acetabular component being much higher than that of the femoral head. This trend could be influenced by a number of factors including material factors, however, it is certainly true that the femoral head will generally display a much lower level of component form error at implantation relative to that seen in the acetabular component. This is related to the relative ease of machining and finishing the components.

	Volumetric wear (mm3)	Max penetration (mm)
Head	2.2	0.005
Cup	6.1	0.025
Head 2	2.9	0.008
Cup 2	4.3	0.019

Table 1: **CMM measured volumetric wear of explanted components**

The measurement produced component wear scar maps which highlighted the deviation from the approximated unworn surface. Figure 2 shows these mapped wear scars illustrating the penetration depth both of the femoral head and acetabular cup components. The wear maps show that the main area of wear is offset at an angle from the pole, which is concomitant with the component implantation angle.

It is noted that the original component form deviation cannot be determined by regression techniques and as such the results make no adjustment for this. However, the constructed maps

and measured wear volumes show good correlation with both visual observations and expected wear rates derived from simulator studies [14]. Maximum component 'penetration' in the case of the heads was 0.005mm and 0.008mm respectively, a relatively small amount, whereas in the case of the acetabular cups the component penetration depth was larger at 0.025mm and 0.019mm. This difference is largely in line with the difference in overall component wear contribution in each case. Use of wear mapping was shown to give useful information on the location of the wear. These use of these methods allow for observations to be made such that an insight is given into the way in which bearing surfaces conform to steady state wear and into true clinical wear behaviour and performance.

a)   (b)

Legend:

> 0.03 mm
0.02 mm - 0.03 mm
0.02 mm - 0.02 mm
0.01 mm - 0.02 mm
0.01 mm - 0.01 mm
0.01 mm - 0.01 mm
0.00 mm - 0.01 mm
0.00 mm - 0.00 mm
-0.00 mm - 0.00 mm
-0.00 mm - -0.00 mm
-0.01 mm - -0.00 mm
-0.01 mm - -0.01 mm
-0.02 mm - -0.01 mm
-0.02 mm - -0.02 mm
-0.03 mm - -0.02 mm
< -0.03 mm

Magnification factor = 5.00
Upper tolerance = 0.10 mm
Lower tolerance = -0.10 mm

(c)   **(d)**

Figure 2:   **Wear maps of explanted bearings as determined with Zeiss CMM.**
a) Explanted metal-on-metal head 1.
b) Explanted metal-on-metal acetabular cup 1.
c) Explanted metal-on-metal head 2.
d) Explanted metal-on-metal acetabular cup 2.

Case Study 2: Clinical wear determination in a retrieved total knee replacement component.

In this case study a method was developed to determine the clinical wear of a retrieved total knee replacement component. An explanted tibial insert bearing or undetermined size, design and origin was supplied by West Riding Knee Unit, Huddersfield Royal Infirmary. The component was a UHMWPE tibial insert of a fixed bearing type, figure 3. No pre-wear data or design data was available, however an unworn insert of the same design and size was available for analysis. This was used to create a baseline, null, pre-wear surface, and this was then used to give an estimation of the clinical volumetric wear.

Figure 3: **Explanted tibial bearing supplied West Riding Knee Unit, Huddersfield Royal Infirmary**

Both components were measured on a Zeiss PRISMO co-ordinate measuring machine (Carl Zeiss Ltd, Rugby, UK) as in the previous case study. Firstly an approximate boundary-defined CAD surface was produced to provide a platform for measurement point location definition. The free-form nature of the condylar surfaces meant that reverse engineering analysis was complicated and as such the analysis was performed post measurement using surface characterisation techniques. A 0.1mm x 0.1mm net of points was applied to the condylar surfaces of the approximated model and both the unworn and retrieved components were measured according to this strategy. The volume of the individual surfaces in each case was recorded and this method was repeated three times to gain average values. The volume of the worn surface was then subtracted from that of the unworn surface to give the wear in the case of each condyle (see Table 2, below).

Volumetric Wear		
Right Condyle	Left Condyle	Overall
(mm3)	(mm3)	(mm3)
42.9	52.7	95.6

Table 2: **Average wear results for explanted bearing.**

The determined overall average volumetric wear value seems not unreasonable when examined visually, as upon inspection, the bearing exhibited gross volumetric wear. The result also seems reasonable when set against simulated volumes which have been previously seen in other designs [12]. In this case study the implantation period of the worn component is thought to exceed 5

years, and the clinical wear rate is reasonable though subject to some deviation resulting form lack of data on implantation time.
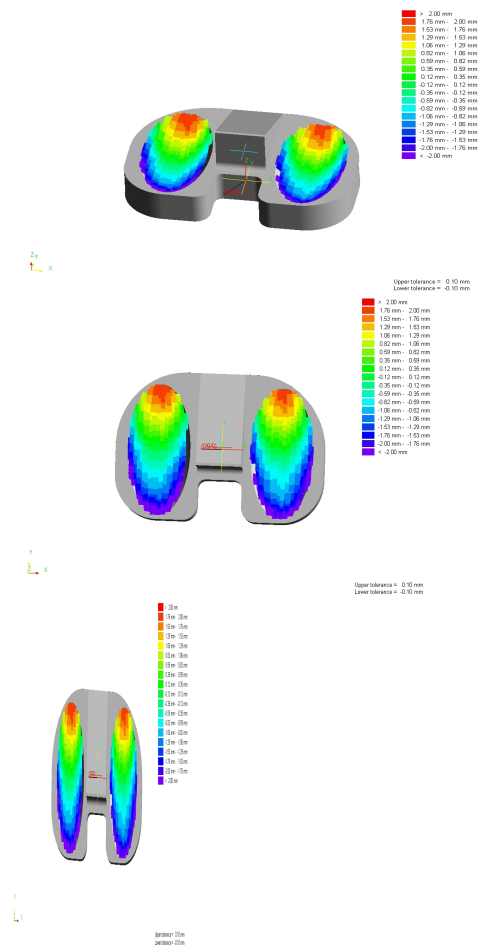

Figure 3:   **Measured data from worn condyles of explanted TKR meniscal component**

A component wear scar map was constructed using the approximated CAD model, this was found to give a distorted map that included elements of part geometry and wear scar geometry (see figure 3). As this gave no usable result due to the complex nature of the measured surfaces, the data was separated and manipulated using three-dimensional surface analysis software. Using this technique allowed for form removal from the measurement data prior to comparison of the two surfaces. The data from the surfaces of the unworn and retrieved components was then over laid and manually fitted together, the difference between the two being determined as the wear scar surface (see figure 4).

(a)   (b)

Figure 4:   **Wear scar maps of normalized explanted bearing surfaces:**
    a)   **Left condylar surface.**
    (b)   **Right condylar surface.**

The wear areas visible on each condyle, centrally on the right condyle and towards the bottom right hand area on the left condyle, correspond well with what can be observed visually. Use of an unworn component as a baseline is, however, not ideal and could well have contributed significant error to the measurement. As such the result can only be considered an estimation of the actual clinical wear of the component. It should be noted, however, that in the case of a component of unknown source this method, though subject to error is a valuable tool in forensic wear determination.

Discussion and Conclusions

The differential wear between head and cup components, in study 1, could be due to differences in form error at implantation. The influence of this factor in the overall bearing optimisation process merits further investigation and it is thought that through control of form error in manufacture, as well as clearance, the volumetric wear of a metal-on-metal implant pair could be reduced even more, leading to development of prostheses with increased longevity.

It has been shown previously that geometric wear assessment tools are useful in determining orthopaedic wear in situations where industry standard methods have proven to be unable to give a useful or meaningful result [12]. These studies have gone further in showing that development and application of such methods can lead to their increased use in determining volumetric wear in components where there is no pre-wear data. Geometric assessment of orthopaedic bearing surfaces using CMM technology has been shown, in certain situations, to have potential for determining clinical wear rates with the scope for full spatial location and wear characterization in retrieved orthopaedic components.

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