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Improvement in the assessment of wear of total knee replacements using coordinate-measuring machine techniques

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Abstract: Total joint replacement is one of the most common elective surgical procedures performed worldwide, with an estimate of 1.5×10^6 operations performed annually. Currently joint replacements are expected to function for 10–15 years; however, with an increase in life expectancy, and a greater call for knee replacement due to increased activity levels, there is a requirement to improve their function to offer longer-term improved quality of life for patients.

Wear analysis of total joint replacements has long been an important means in determining failure mechanisms and improving longevity of these devices. The effectiveness of the coordinate-measuring machine (CMM) technique for assessing volumetric material loss during simulated life testing of a replacement knee joint has been proved previously by the present authors. The purpose of the current work is to present an improvement to this method for situations where no pre-wear data are available.

To validate the method, simulator tests were run and gravimetric measurements taken throughout the test, such that the components measured had a known wear value. The implications of the results are then discussed in terms of assessment of joint functionality and development of standardized CMM-based product standards. The method was then expanded to allow assessment of clinically retrieved bearings so as to ascertain a measure of true clinical wear.

Keywords: wear assessment, total knee replacement, coordinate-measuring machine technique

1 INTRODUCTION

Every year about 0.5×10^6 patients experiencing osteoarthritis undergo total knee replacement (TKR) surgery worldwide, and around 22 000 of these take place in the UK [1]. The most common reason for TKR is severe pain and immobility directly attributable to osteoarthritis; it is estimated that 80 per cent of all joint replacements are carried out as a result of osteoarthritis of the hip and knee.

The orthopaedic industry invests enormous amounts of time and money into researching

methods to improve design and performance of replacement joints. In the hip joint sector, the most recent development is the evolution of hard-on-hard bearings. Traditionally a metal femoral head would articulate with an ultra-high molecular weight polyethylene (UHMWPE) cup. Developments in materials and methods of manufacture have seen an increase in metal-on-metal and ceramic-on-ceramic designs [2–6]. This trend is now translating to the knee market, where the geometry of the joint poses more of a challenge. The overall aim is to reduce the amount of debris caused by wear of the joints as this debris contributes to loss of function and premature failure of the joints through processes such as osteolysis [2, 3].

To evaluate new knee designs, over the last 10 years or so, a number of increasingly complex knee

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simulators have been developed and manufactured, both in academia and commercially [7, 8]. This has also partly been as a response to the increase in regulatory and pre-clinical testing required for assessing product reliability and patient safety. Upon simulation of clinically relevant wear it is then important to be able to quantify accurately this wear and the consequent TKR functionality.

1.1 Quantification of wear

In developing new joints or in assessing the applicability of new materials the industry standard wear measurement methodology is to use gravimetric methods. Although there is provision within standards for use of basic geometric wear quantification, it is vague and gives no guidance on any detailed methodology for achieving this [9]. As such, industry at this time does not have the capability or inclination to lead any research into methods optimization, perhaps owing to the lack of leadership and clarity in standardizing a methodology. The most obvious method for measuring geometry is the coordinate-measuring machine (CMM); CMMs are a relatively large capital cost for a company to incur and, as such, many do not have funds, or indeed staff, to go through such a research-and-development exercise for no discernible financial

gain, thus there is continued use of gravimetric methods. These methods are well established and standardized but do suffer from serious limitations.

This is highlighted when significant errors in the measured wear volume are caused through metal wear debris inclusion into the plastic component or when trying to consider the effects of fluid uptake into the UHMWPE counterface [10]. In both of these cases, it would be impossible to determine precisely the contribution to the wear volume of such errors using merely gravimetric methods.

In a knee simulator test, the measurement of the change in mass of the test components is complicated by three main problems (Fig. 1): fluid absorption of the UHMWPE component, the presence of a cement mantle, and the mass of any fixturing. The net effect of these problems is that only the UHMWPE component is assessed for mass loss during the test, as the other two problems only effect the metal counterface and the femoral and tibial components, and these would not normally be considered as worn unless any abnormal contact had occurred. It is important to note, however, that these problems would very much have to be considered in the case of case of hard-on-hard joint systems. Additionally, when assessing hard-on-hard joint pairings such as metal-on-metal or ceramic-on-ceramic systems, the volume of material

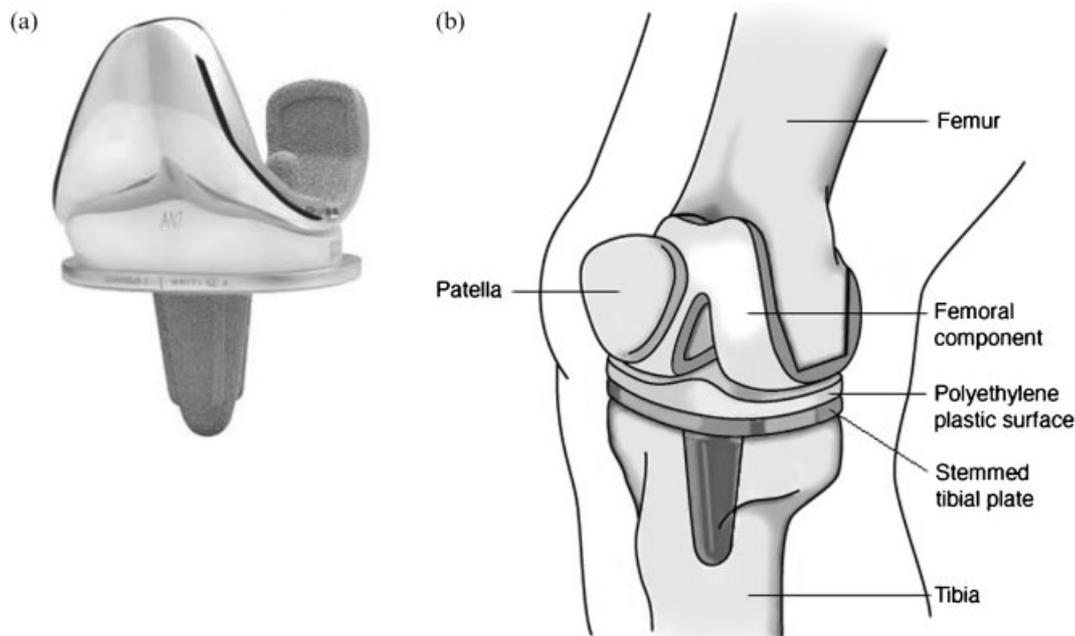


Fig. 1 (a) A rotating-platform design TKR, namely LCS Complete (DePuy). (b) Schematic diagram showing components *in vivo*

removed as a result of wear is small compared with the mass of the component. As a consequence it is difficult to assess small mass changes against such large component masses using even the best large-range high-resolution balances. Therefore it is important to have an alternative measurement method that accounts for these factors.

Problems with gravimetric measurement of orthopaedic wear has led to a call for alternative methodologies to be developed that have higher resolution and greater accuracy. To this end it seems that an elegant solution would be to measure the part dimensionally before, during, and after testing and, by comparing the changing dimensions, to calculate the wear volume directly as this is theoretically much more stable and repeatable than gravimetric weighing. Such a method using a CMM has been developed by the present authors and has been proved to be of use for measurement of wear when gravimetric methods give no useful result owing to the previously highlighted problems [10].

A logical extension to this dimensional assessment technique is to use dimensional assessment to characterize and measure wear in a situation where there are no pre-test or pre-wear data. In such a case, gravimetric methods would be useless as by definition there would be no way of knowing the mass of the component prior to the occurrence of wear. This is quite a commonly encountered issue as components are frequently explanted either at failure or revision or at patient mortality. In either case it would be useful to have a more reliable method of wear assessment, as a way of helping to characterize failure modes or simply to get a true measure of *in-vivo* wear rates for comparison with *in-vitro* laboratory results.

A major consideration when performing physical measurements of UHMWPE test components is the relative contribution of creep that may give a false wear volume measurement. It has been suggested by Derbyshire *et al.* [11] that allowing the component to stabilize unloaded for a period of 48 h also allows for a relaxation of creep of 80+ per cent of possible total recoverable creep. At about 100 h this number is about 90 per cent of possible recoverable creep. If components are allowed to stabilize for a similar period prior to measurement, then the relative contribution of creep can be minimized successfully. Derbyshire *et al.* [11] went on to report that almost 100 per cent of creep takes place in the first 10^6 cycles during simulator tests and that penetration that takes place after this can therefore be regarded as genuine wear with negligible creep.

The aim of the present study is to assess the feasibility of using advanced CMM techniques to assess the wear of both conventional metal-on-polymer and metal-on-metal knee implants that have been worn in controlled tests and also on explanted knees where no prior knowledge of their original surface geometry is available.

2 MATERIALS AND METHODS

As an initial validation of the coordinate measurement method for assessing wear volumes a simulator test was carried out and post-test measurements taken using a CMM. Six TKR bearing couples were tested. During the test the TKR bearings were all assessed gravimetrically in accordance with international and industry standards [9]. This allowed for testing of the CMM method against components of known volumetric wear as assessed gravimetrically. Simulator testing was performed using a five-degrees-of-freedom knee simulator (AMTI, Boston, USA) (Fig. 2). Force and kinematics data were taken directly from international standards and with reference to the literature [12–14] and the test was run in force control. Newborn calf serum diluted to 25 per cent was used as lubricant and the temperature was maintained at 37 °C. The design of total knee replacement used was an LCS Complete (DePuy) rotating-platform bearing (see Fig. 1(a)).

The weight of the tibial inserts was measured, in accordance with international standard procedure [9], using a high-precision balance prior to testing and approximately 0.5×10^6 cycles thereafter. The average result from a set of unloaded soak controls was calculated and this mean value used to compensate for fluid absorption. The wear volume was then determined using a value of 0.934 g/cm^3 for the density of the UHMWPE tibial bearing surface material. Post-test measurements of the articulating surface were taken with a CMM (Zeiss Prismo, Carl Zeiss Ltd, Rugby, UK) and surface maps were constructed.

2.1 CMM measurement method

The purpose of this study was to try to ascertain the location of wear on a series of tested total knee replacement meniscal bearings. A set of previously tested LCS Complete components were measured post-test using a Zeiss Prismo CMM (Carl Zeiss Ltd, Rugby, UK). To discover the location of wear in such



Fig. 2 AMTI Boston five-axis knee simulator

components an estimation of the unworn surface is required to use as a comparison.

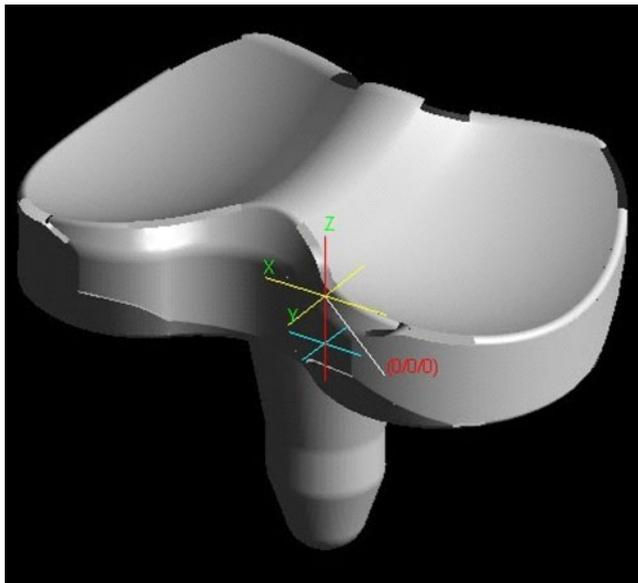
As no pre-wear data were taken, an approximation methodology for assessing the wear volume had to be developed. It has been noted that during normal wear conditions a significant portion of the bearing surface is not in contact and, as such, does not experience wear and thus could be used as a possible datum. First a three-dimensional computer aided design (CAD) model of the meniscal bearing was built and developed to be used to define the location of the measurement points to be taken. The next part of the methodology involved taking a large number of evenly distributed points in the unworn zones of the bearing surface, i.e. the non-contacting area of the bearing. The data gained from this measurement routine were then converted into non-uniform rational *b* splines (NURBSs) by software and these were then used in combination with the base CAD data to fit a surface through the unworn zone surface data points. This fitted 'surface' model was then assumed to be an approximation of the pre-worn surface; as a consequence the worn and approximated unworn surfaces could be compared, and accordingly the wear location and penetration could be accurately mapped. Each measurement was

performed six times and an average taken. Representations of the wear scar maps for the tested UHMWPE meniscal components are shown in Fig. 3 where the scale represents the deviation from the approximated unworn surface.

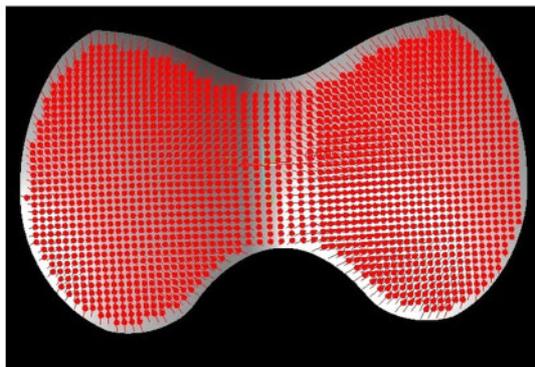
A previous study has suggested that the minimum accuracy of a CMM if used for three-dimensional wear analyses of hard-on-hard orthopaedic bearings should be $2\ \mu\text{m}$ [15]; the instrument used in this study has far greater accuracy than this, although it should be noted that most commercially available CMMs which are routinely employed in quality control have an accuracy of around $3\ \mu\text{m}$ or worse. This being the case, an average CMM would not be accurate enough or have the repeatability required for useful volumetric measurements of such components. The Zeiss CMM used in this study has a stated U3 probing accuracy of $0.7\ \mu\text{m}$ and a stated scanning accuracy of around $1\ \mu\text{m}$. In addition to this, both the hardware and the software allow for the filtering and removal of dynamic data effects.

2.1.1 Explanted bearing

A UHMWPE total knee replacement tibial insert component that had been explanted during revision



(a)



(b)

Fig. 3 (a) Three-dimensional CAD representation of the TKR meniscal component. (b) Isolated bearing surface saturated with measurement points

surgery and was supplied for measurement by Huddersfield National Health Service (NHS) Trust. The component supplied was of undetermined design (Fig. 4), although it was clear that it was of a fixed bearing type. There were no pre-wear data available and, upon inspection, the bearing exhibited gross volumetric wear. It was decided that the methodology developed for the measurement of volumetric wear in explanted total hip replacements could not be used with a great degree of accuracy as the original surface was considered to be too complex to estimate and reconstruct merely by measuring the unworn surface and using NURBSs to construct the CAD surface model. An unworn component of the same design was available from the same source and a decision was taken to use this as a baseline and estimator of the null pre-wear



Fig. 4 Explanted tibial bearing supplied by Huddersfield NHS Trust

surface. The volumetric difference between the two surfaces was then to be calculated to give an estimation of the clinical volumetric wear.

A series of points was taken over the surface of the unworn component and the coordinates used to create an approximated CAD surface model. This CAD model was then used as a basis for constructing a measurement routine that would allow for taking of a cloud of measurement points fully covering the bearing surfaces. The components were then both measured on a Zeiss Prismo CMM (Carl Zeiss Ltd, Rugby, UK) using this cloud point routine. The volumetric differences between both the worn and the unworn components and the approximated model were then calculated, each bearing condyle being assessed in turn. By subtracting these two values of volumetric difference from one another, it was then possible to gain an estimation of the volumetric wear of the worn explanted bearing component.

3 RESULTS

The mean volumetric wear results for each of the tested TKR meniscal components are shown in Table 1.

In all six cases the wear obtained with the CMM corresponded closely to the gravimetrically measured value but was, in almost all cases, higher. It was also seen that the average wear per 10^6 cycles, equivalent to a year of clinical wear, corresponded closely to the results seen when measured gravimetrically.

Figure 5 shows the mapped wear scars of three tested TKR meniscal components, showing the penetration depth of the metal femoral component. The scales used demonstrate where the

Table 1 Volumetric wear results comparing gravimetric and geometric wear measurement methods

	Wear of meniscal components at 5×10^6 cycles for the following components					
	1	2	3	4	5	6
Gravimetric wear (mm^3)	30.9	26.7	46.1	43.7	30.1	43.6
CMM measured wear (mm^3)	34.6	39.9	43.7	47.1	31.0	48.8
Average gravimetric wear ($\text{mm}^3/10^6$ cycles)	6.2	5.3	9.2	8.7	6.0	8.7
Average CMM measured wear ($\text{mm}^3/10^6$ cycles)	6.9	7.9	8.7	9.4	6.2	9.7

individual measurement points are relative to the nominal surface, i.e. -0.1 mm denotes an indentation of 0.1 mm. It can be seen in each case that the lateral (left) condyle is less worn than the medial (right) condyle and the wear in each case falls in broadly similar areas, i.e. the anterior medial quadrant. This corresponds directly to the loading of the components in the knee wear simulator. In order to replicate the physiological load and motion profile accurately the components are offset slightly from centre so as to create a 60–40 per cent load share on the two condyles; the results seem to show that this differential loading causes the medial condyle to experience proportionally more wear. The extrapolation of the unworn area of the component gave a reasonably accurate determination of wear location as it was clearly visible. It is apparent that the corresponding femoral component penetrated much further into component 4 than in the case of either component 1 or 2 (see Fig. 5) and this corresponds directly to their relative *in-vitro* wear volumes.

3.1 Explanted bearing results

The mean volumetric wear for the explant TKR meniscal component was determined. Each measurement was carried out three times and the mean volumetric wear result for the explanted TKR meniscal component is shown in Table 2.

This estimated value for the total volumetric wear of the insert does not seem to be unreasonable when examined visually and compared with simulated volumes which have been previously seen in other designs [10]. In this case study the implantation period of the worn component is not known but is thought to exceed 5 years; unfortunately it is therefore not possible to make an estimate of clinical wear rate in this case.

As the component surfaces were of a free-form nature and the approximated CAD data were thought to be far from ideal, normal CAD–CMM manipulation and analysis was complicated and would possibly result in error. Although it was possible to determine the wear volume by direct calculation, construction of a wear surface map was

not possible; therefore it was decided that a different approach be explored and adopted if possible.

To check and illustrate this, the worn zones of the condylar bearing were mapped using the approximated CAD model and the results are shown in Fig. 6. It can be seen that, as the CAD data were only an approximated representation of the surface, using the previously developed method for this case resulted in a distorted map that included elements of part geometry and wear scar geometry.

As this turned out to be the case, an alternative strategy was adopted on the basis of experience in the comparison of different surfaces in surface characterization software. The raw data from the measurement process were modified, for both the worn and the unworn components, in ASCII plain text format so as to be in x, y, z coordinates only. These data sets were then imported into a three-dimensional surface analysis package (Talymap, Taylor Hobson, Leicester, UK) for manipulation and comparison. The two data sets were imported as two separate surfaces and overlaid. The surfaces were then manipulated manually to obtain a good surface match in an attempt to gain edge matching and to highlight areas of wear.

Once surface matching was completed, the two surfaces were ‘subtracted’ from each other so as to give a composite surface, or volume, difference. Finally this composite data set was manipulated such that the influence of component form was removed to give the normalized wear scar surface (Fig. 7).

It can be seen from the composite data set wear scar maps that there are definite discrete wear areas visible on each condyle. These wear scars appear centrally on the right condyle and towards the bottom right-hand area on the left condyle. This corresponds well to observed visual evidence, and in particular the area of wear highlighted on the left-hand condyle was observed to be particularly severe with possibly edge ploughing of the counterface component in this area.

The method gives a good definition of the position of the wear scar on the bearing component; however, the magnitude of component penetration

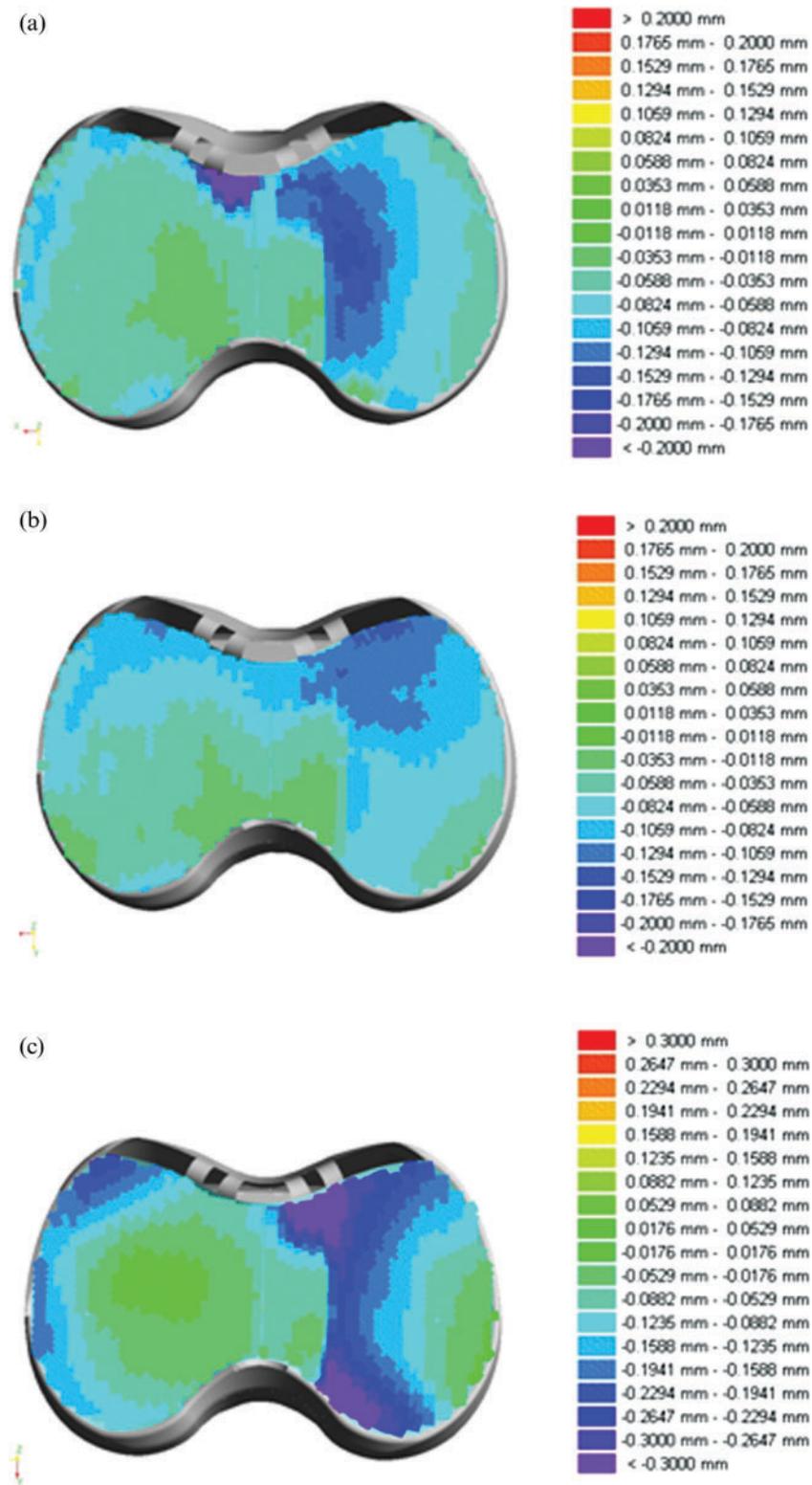


Fig. 5 Wear scar maps of three tested TKR meniscal components: (a) component 1; (b) component 2; (c) component 3

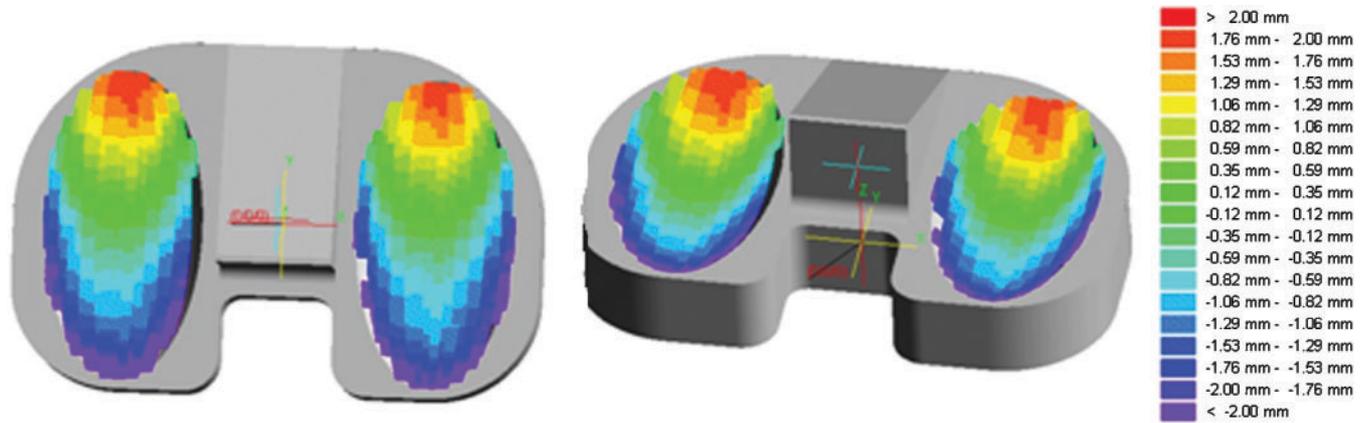
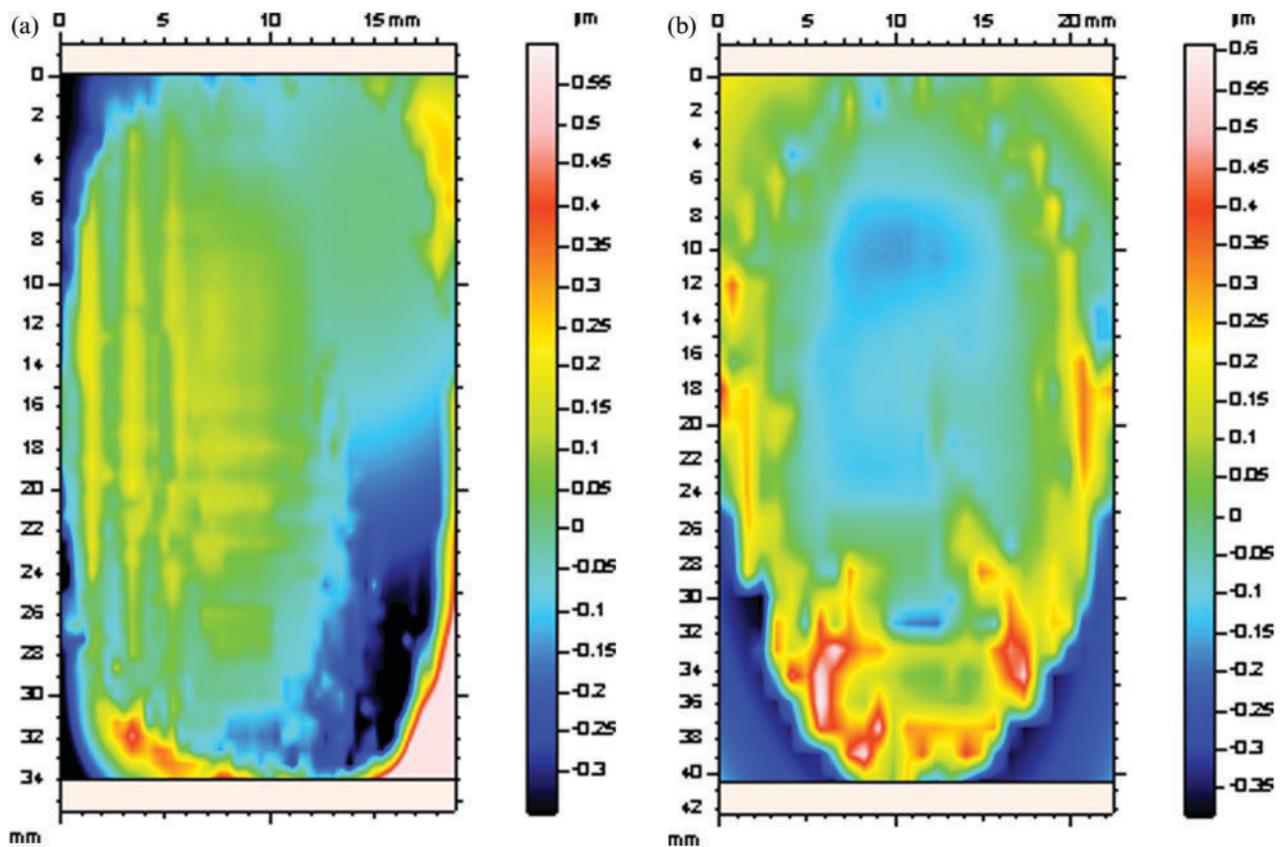
depth is considerably lower than would be expected both for the amount of wear measured but also by visual inspection. There were possible sources of

error in the fitting process and in the use of form removal filtering in creating the results. The use of form removal was required to obtain a good

Table 2 Average wear results for explanted bearing

Mean volumetric wear		
Right condyle (mm ³)	Left condyle (mm ³)	Overall (mm ³)
42.9	52.7	95.6

estimation of the wear scar but, owing to the complex freeform nature of the bearing surface and possible inaccuracies in the fitting process which led to inexact edge definition, the form removal function of the software may have been influenced by edge effects and/or removal of form differentially across

**Fig. 6** Measured data from worn condyles, of the explanted TKR meniscal component**Fig. 7** Wear scar maps of normalized explanted bearing surfaces: (a) left condylar surface; (b) right condylar surface

the surface. In both the mapping of the surface and the estimation of component volumetric wear the result will have been greatly influenced by the difference in the form deviation seen between the unworn component surface and that which the pre-wear worn component surface would have contained. As the components in this study were UHMWPE TKR tibial insert components, the magnitude of this form error could be significant.

Because of these highlighted possible error sources the result can only be considered an estimation of the clinical wear of the component. However, in the case of a component with a complex geometry and of unknown source this method can be utilized to give a good amount of useful information. It is clear that a number of factors related to this method require refinement and further development before it is more widely applied. It is suggested that a number of trials are undertaken to ascertain the usefulness of utilizing, modifying, and developing surface analysis software techniques such as this for use in measuring and ascertaining the location of wear in total joint replacements.

4 DISCUSSION AND CONCLUSIONS

It has been previously shown that geometric wear assessment methods are a useful tool for measuring wear in situations where traditional industry standard methods have proved to be unable to give a useful meaningful result [10]. In that case, measurements were taken alongside gravimetric measurement methods to highlight the problems encountered in such situations.

However, this study has gone further and shown that this method can be used reliably to determine an estimation of wear in components where there are no taken pre-wear data, as could be the case when trying to assess explanted TKR components. In the present study, it has been shown that geometric assessment of orthopaedic bearing surfaces using CMM technology has potential for use in ascertaining true clinical wear rates and characterizing wear from explanted components. Using a three-dimensional CAD representation of the idealized component as a basis for plotting measurement points, an estimation of true wear was achieved by firstly estimating the 'zero-cycle' volume. This gives the method a measure of robustness by not relying on the CAD data for anything other than the basis for the measurement points and the component alignment data. This is further enhanced by the

post-measurement use of three-dimensional surface analysis methods to allow for removal of form from measurements. This allows for much more complex components to be measured using minimal CAD input and is of particular use when measuring a component for which there are very few nominal data such as an explanted bearing.

Table 1 shows the wear volume data for both the industry-standard gravimetric method and the geometrical approximation technique. It is clear from the results that the figures for wear volume are comparable when using both methods. Closer inspection of the figures shows that in the majority of cases the gravimetric method gives lower values of wear volume than the geometrical technique does. This could arise for one of three reasons. First, creep in the polymer, which is wrongly assessed as wear, could give falsely high wear values for the geometric CMM approximation method. Second, differential fluid uptake in the polymer material could give falsely lower values of wear for the gravimetric method. Third, errors could be introduced through using the approximation technique. In this study the test components were allowed to stabilize for approximately 72 h prior to determining the masses and were geometrically measured during the ensuing 24 h period. This meant that about 85–90 per cent of recoverable creep had been recovered by the time that CMM measurement occurred [15] and as such the contribution of creep can be considered to be small.

The wear mapping results (see Fig. 5) show the apparent correspondence between the scale of the component indentation to the relative volumetric wear that each component experienced. It is noted that, however, use of such techniques in post-test wear determination makes no allowance for pre-test component form deviation and it is suggested that this may have a skewing effect on the data. A much more effective and accurate methodology for future study would be to map the bearing surface at every wear interval so as to map wear scar development and thus true pre-wear data would be available for comparison. This would also allow for pre-test component surface digitization using reverse engineering techniques and give a true representation of the component zero-cycle CAD entity.

As consideration of recoverable creep has been made in the measurement method the disparity between the results of the two techniques is considered to be a result of a combination of the differential lubricating fluid uptake in the polymer and errors in approximation caused by the

geometrical fitting error and a contribution from the unknown initial form error of the component. These approximation errors are now the subject of further study by the present authors.

The method described in this paper does require further refinement but it is clear that it provides the basis for development of methods that fully characterize and spatially locate wear in explanted components and thus hopefully lead to a greater understanding of the tribology and true clinical performance of total replacement joints. This has been initiated with the study of an explanted bearing discussed here, and it is envisaged that this method will be improved and expanded such that a large-scale study of explanted bearings will be performed to examine true clinical wear.

Upon further development of a reliable geometric wear assessment method it would be advisable to establish fully the uncertainty of the CMM techniques and to promote subsequent development of industry standards in this area in order to ensure continuity and consistency across the board so that confident comparisons of wear data can be made between clinical and test data.

The methodology adopted for determination of wear in the case of the unknown retrieved knee component requires further work if its reliability and accuracy are to be improved. Important information can still be gained from such methods; however, when measuring free-form complex surfaces, qualitative surface knowledge aids accuracy.

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