A metrology solution for the orthopaedic industry

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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 million 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. The amount of wear that a joint incurs is seen as a good indicator of performance, with higher wear rates typically leading to reduced function and premature failure. New technologies and materials are pushing traditional wear assessment methods to their limits, and novel metrology solutions are required to assess wear of joints following in vivo and in vitro use. This paper presents one such measurement technique; a scanning co-ordinate metrology machine for geometrical assessment. A case study is presented to show the application of this technology to a real orthopaedic measurement problem: the wear of components in total knee replacement. This technique shows good results and provides a basis for further developing techniques for geometrical wear assessment of total joint replacements.

1. Introduction
Total joint replacement is one of the most common elective surgical procedures performed worldwide, with an estimate of 1.5 million 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. The orthopaedic industry continuously invests 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[1,2,3]. This trend is now translating to the knee market, where the geometry of the joint poses more of a challenge. The whole 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. To evaluate these new designs, the industry standard is to simulate wear using hydraulic or pneumatic machines which mimic the walking cycle likely to be incurred during the lifetime of the joint. The typical indicator of performance in simulation is volumetric wear loss, at present it is typical to assess the magnitude of volumetric wear loss through means of gravimetric measurement. The
introduction of new lower wearing materials has pushed gravimetric wear assessment to the limit, and affordable equipment sensitive enough to discern between materials is not currently available. With this in mind alternative solutions must be sought that have higher resolution and greater accuracy.

2. Co-ordinate Measuring Machine (CMM) Geometric Method

The purpose of this study was to establish the effectiveness of the CMM technique for assessing volumetric material loss during a simulated life test of a replacement knee joint. A standard design total knee replacement joint was chosen and samples were tested to simulate 5 years worth of wear from walking. At commencement of the test the bearing surface was scanned and digitised into CAD data, by use of a CMM (Toccata, Eley Metrology, Derby, UK), to use as a baseline comparator. Further measurements were then taken at various points throughout the test and compared with simultaneously taken gravimetric data. The implications of the results are discussed here in terms of assessment of joint functionality and development of standardised CMM based product standards.

A grid of 0.5mm x 0.5mm was set up on the part to digitise the surface using a Renishaw SP600 scanning probe. The first set of data was collected prior to the test and this digitised surface was converted to a readable CAD surface model to use as a baseline for comparison with subsequently collected data. A reference surface (see Fig. 1) was also used as a datum to provide accurate relocation of the data points; this surface would not be under contact conditions during testing and as such should experience no wear. This allows for excellent repeatability and is a robust method for accurately relocating data points.

![Measured wear surfaces and reference surface](image)

Figure 1. CAD image of RPF meniscal component, showing reference surface, and measured articulating surfaces.

The geometric wear data was calculated by firstly ascertaining the difference in vertical position (z axis error or z-shift) between the baseline data and the data measured at the wear interval. This was achieved by use of a simple fitting operation in the comparison software using the reference surface as its datum. This z-shift represents the indentation of the CoCr femoral component into the UHMWPE meniscal component. The volumetric wear was then determined by calculating the average z-shift over the measured area and multiplying that by the cross sectional area projected into the perpendicular plane.

An important factor that should not be overlooked, although often is, in such wear assessment of UHMWPE is creep. It has been suggested by Dowson et al [4] that, in the case of explanted total knee replacements, 15-30% of ‘wear’, i.e. indentation of the meniscal insert, can be attributed to creep. An *in vitro* simulator test is different as the test is stopped periodically and the components are unloaded
and cleaned for measurement. It is standard practice to allow these UHMWPE components to stabilise in controlled conditions for at least 48 hours prior to weighing. This allows for an equilibrium drying state to be reached and an equilibrium core temperature to be set up in the components as they are stabilised in a temperature controlled environment. It has also been suggested by Fisher et al [5] that allowing the component to stabilise unloaded for a period of 48 hours also allows for a relaxation of creep of 80+% of possible total recoverable creep. At about 100 hours this number is about 90% of possible recoverable creep. In this study the test components were allowed to stabilise for approximately 72 hours prior to weighing and were geometrically measured during the ensuing 24 hour period. This meant that about 85-90% of recoverable creep had been recovered by the time that CMM measurement occurred.

3. Results
The robustness of the geometric measurement method against the gravimetric measurement method can clearly be seen in Figure 2, which shows directly the comparison of wear volume determined using both methods.

This study has thrown more evidence of inherent problems with gravimetric assessment of wear in UHMWPE meniscal knee components. It can be clearly seen from data taken in the period 0 – 1.5 million cycles, where the gravimetrically measured volumetric wear appears to be negative. The fluid absorption and desiccation can clearly not be predicted in this instance despite strict adherence to ISO 14243-1 [6] and ISO 14243-2 [7] and the setting up of soak controls. It is suggested that the problem was caused by micromotion of a stabilisation pin in the stem of the meniscal component. It would appear that there was fluid uptake around this pin due to capillary action induced by micromotion and that this situation did not stabilise until approximately 1.5 million cycles into the test. At this point it can be seen that a more stable linear wear state was reached.

However, it can be seen, from the geometric wear results that, after stabilisation had occurred, the wear measured on the CMM can be seen to correlate roughly to the subsequent wear measured gravimetrically.

![Figure 2. Comparison of Wear Measured Gravimetrically and Geometrically](image)

4. Discussion
This initial study shows that development of a geometric wear assessment method for orthopaedic components has definite possibilities. This is highlighted by the fact that, in this case, the wear could
not be measured to an accurate degree using traditional gravimetric methods for the first 1-1.5 million cycles.

With the introduction of new lower wearing materials [1,2,3] for articulating surfaces in the orthopaedic industry it has been shown that gravimetric methods have reached their limit in resolution[2]. There is therefore a pressing need to develop novel measurement methods that give accurate predictions of wear. This study indicates that geometric assessment through CMM technology shows potential for development into an accurate measurement method of simulated wear. Whilst the software used was fairly a fairly exhaustive and time-consuming method for calculating wear in orthopaedic components, the overall methodology showed great promise. The main limitation of the software is CAD format acceptance as only basic translation formats are accommodated at present. Another major issue is the number of iterations required to get a good fit for the measured data to the CAD data for geometric comparison. A more user friendly interface and more flexible CAD translator would be required to improve the measurement accuracy and efficiency, but even so it is clear that this method is more accurate than the current industry standard practice in this case.

5. Conclusions
Upon development of a reliable geometric wear assessment method it would be advisable to establish the resolution of CMM techniques and promote subsequent development of industry standards in this area in order to ensure continuity and consistency across the board so confident comparisons of wear data can be made.

6. Further Work
It is proposed that the method used in this study is expanded and improved such that a quicker and more accurate method is developed. The study will be extended with use of a Zeiss Prismo CMM and accompanying software, as this has greater native CAD integration and the ability to produce better graphical output than previously. This will allow for the method to expand and allow mapping of wear scar position and depth in a graphical format. In the longer term the ultimate aim is to produce a more general and translatable method that is less software specific, and thus can lead to standardisation of the method across the industry.

References
[1] Saikko VO, Pfaff HG, Low wear and friction in alumina/alumina total hip joints, Acta Orthop Scand, 69 (5), pp 443-448, 1998.
[2] Skinner HB, Ceramic Bearing Surfaces, Clinical Orthopaedics and Related Research, 369, pp 83-91, 1999.
[3] Dowson D, A comparative study of the performance of metallic and ceramic femoral head components in total replacement hip joints, Wear, 190, pp 171-183, 1995
[4] Dowson D, McCullagh PJJ, Wright V, An Assessment of the Relative Importance of Wear and Creep in the Overall Performance of Load-Bearing Total Replacement Knee Joints, ‘UHMWPE as a biomaterial in orthopaedic surgery’, eds Willert HG, Buchhorn GH, Eyerer P, Hogrefe & Huber Publishers, Germany, 1991.
[5] Derbyshire B, Hardaker CS, Fisher J, Dowson D, Brummitt K, Assessment of the change in volume of acetabular cups using a coordinate measuring machine, Proc. IMechE, 208, pp 151-158, 1994.
[6] BS ISO 14243-1:2002, Implants for surgery – Wear of total knee joint prostheses – Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test.
[7] BS ISO 14243-2:2000, Implants for surgery – Wear of total knee joint prostheses – Part 2: Methods of measurement.