Research Article

Comparison of CMM and Micro-CT Volumetric Analysis of Polyethylene Tibial Knee Inserts in Total Knee Replacement

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Ultrahigh molecular weight polyethylene (UHMWPE) bearings are used widely in orthopaedic joint replacement as a prominent material for improving the longevity, which is dramatically influenced by wear of polyethylene. Polyethylene tibial knee components from knee simulators under two different input conditions were analyzed using CMM and Micro-CT measurement techniques for volumetric loss with gravimetric measurement as reference. Based on the coordinates and image slices obtained, the surface curve fitting and image digitization methodology were used for the creation of nominal “original” surface in the case of no prewear data provided. The comparison results indicate that gravimetric remains the gold standard and the CMM measurement took less time and had better precision, accuracy, and repeatability compared to Micro-CT measurement technique.

1. Introduction

As an outstanding material for orthopaedic joint replacement, polyethylene can provide excellent abrasion resistance, low friction, high impact resistance, a self-lubricating surface, insignificant water absorption, good chemical resistance, high-energy absorption, and no temperature sensitivity in the human biological environment [1]. Ultrahigh molecular weight polyethylene (UHMWPE) components are being widely used in total knee replacement (TKR) as a bearing surface to improve the longevity, if well designed and properly implanted, products made of this material can function for more than fifteen years or even longer. Currently, the major issue in TKR is the wear of polyethylene and results in more than 16% failure of TKR [2]. Thus, wear measurement is very important for accurate determination of wear rate and volume loss in total knee replacements. The most standard method is gravimetric analysis [3, 4]. However, the fundamental issue with gravimetric measurement is that it needs a reference from which to calculate the wear. In addition, gravimetric measurement has limitations such as inclusion of wear debris in the polyethylene component, transfer of materials into the tibial tray, changes in mass of the

polyethylene due to fluid uptake, and the cementation of the components [5], which may result in inaccurate volumetric determination from gravimetric analysis [6]. Since it is necessary to have a reference measurement for gravimetric analysis, it is not possible to use this method for retrieved samples. Therefore, to avoid these disadvantages, advanced volumetric measurement techniques such as coordinate measuring machine (CMM) [7] and micro computed topography (Micro-CT) [8, 9] have been used to determine the volume change of polyethylene in hip, knee, and spinal replacement devices and validated for accuracy and repeatability. The aim of this study was to compare CMM (Legex 322, Mitotoyo) and Micro-CT 100 (Scanco Medical, Bussardorf, Switzerland) measurement techniques for volumetric measurement of knee simulator specimen using gravimetric measurement of volume loss as reference.

2. Materials and Methods

A total of 12 UHMWPE tibial knee components (DePuy, UK), which were tested in six station knee simulators (University of Leeds, UK), were used for measurement. The wear tests were carried out by a colleague within the research

institution (C. Brockett) in 2009 and 2011 [10]. Two input profiles were used for the specimens, one is the ISO setup and the other is a standard CR150. Both CMM and Micro-CT measurement techniques were applied to obtain the three-dimensional (3-D) surface coordinates and images slices, respectively. In addition, the images slices acquired via Micro-CT were then transferred into coordinates with the help of image digitization. Therefore, the 3-D surface coordinates acquired from CMM and Micro-CT were analyzed volumetrically to investigate the comparison of those measurement techniques. Since prewear data such as original drawings and CAD models are not always available to determine the volume loss of tibial knee components, the original surface needs to be reconstructed. In this study, a 5th order polynomial curve surface fitting algorithm (1) was applied for the generation of original 3-D surface on the basis of undeformed region, which proved its effectiveness and accuracy based on simulated volume removal and computational tests (maximum errors equal to 0.2 mm^3 and 1.1 mm^3 , resp.) [11]. Prior to the surface fitting process, the wear region should be distinguished and removed from the database for accurate original surface reconstruction, which was considered as prewear data for volumetric analysis. As demonstrated in Figure 1, the wear region was determined according to the difference of Z value between two adjacent coordinates, it can be judged to be worn out when the difference is greater than 0.1 mm . It is worth noting that some clearly wrong coordinates need to be removed for accurate wear region identification. The methodologies of CMM and Micro-CT for volumetric measurements are detailed below.

$$\begin{aligned}
 f(x, y) = & P00 + P10x + P01y + P20x^2 + P11xy + P02y^2 \\
 & + P30x^3 + P21x^2y + P12xy^2 + P03y^3 + P40x^4 \\
 & + P31x^3y + P22x^2y^2 + P13xy^3 + P04y^4 + P50x^5 \\
 & + P41x^4y + P32x^3y^2 + P23x^2y^3 + P14xy^4 + P05y^5,
 \end{aligned} \quad (1)$$

where P_{ij} are parameters in polynomial surface fitting algorithm, i is the degree in x , and j is the degree in y .

2.1. CMM. For CMM measurement, Trigene (MediChem International Ltd., Seven Oaks, UK) was used to clean the specimen before measurement. After removing from the knee simulator, the polyethylene inserts were cleaned using detergent water then soaked in 1% Trigene solution for 30 minutes to remove all visible serum and contaminants from the surface. Then, the inserts were soaked in isopropanol solution (Fisher Scientific, Loughborough, UK) mixed with water (70% isopropanol:30% water) and placed in an ultrasonic bath (VWR Labshop, IL, USA) for 10 minutes (IMBE simulator test protocol, Leeds University, UK). Afterwards, the components were stored in the weighing room, which is temperature and humidity controlled (21°C and 40%, resp.) and allowed to stabilize for a period of 48 hours. The change in mass was assessed using the AT 201 balance (Mettler Toledo Inc., Columbus, Ohio, USA), and the volumetric loss was calculated using the following equation, taking the

FIGURE 1: Identification of undeformed region.

density of polyethylene as 0.931 g/mm^3 [12]. The samples were measured using CMM (Legex 322, Mitutoyo, UK) with known wear volume determined using gravimetric analysis. It is important to note that the scan interval could influence the volumetric determination dramatically. As a result, an investigation of the influence of the CMM scan interval (0.1 mm, 0.2 mm, 0.5 mm, 1.0 mm, 1.5 mm, and 2.0 mm) was performed using an unworn tibial knee insert and the results indicate that with the increasing of CMM scan interval, the points decreased from 31,133 to 90 and the time consumed decreased from more than 8 hours to nearly 2 minutes, which result in the increase of volume difference from 0.1 mm^3 to 8.1 mm^3 (Figure 2). Therefore, 0.2 mm scan interval was used in this study to maintain the equilibrium between accuracy and time consumed. As illustrated in Figure 3, since there was no initial surface data provided, the coordinates of each condyle surface were measured and surface curve fitting methodology was used for volumetric analysis based on the reconstructed “original” surface [13]. The results obtained were compared against gravimetric measurements.

2.2. Micro-CT. For Micro-CT measurement, an accurate threshold was the key parameter for volumetric analysis using Micro-CT (Scanco Medical, Bussardorf, Switzerland). There are two methods to determine the threshold: one is based on gravimetric analysis and the other is reference to a known volume cylindrical reference specimen. Known volumetric difference from gravimetric measurement was essential for the first method to calculate the amount of wear in Micro-CT. However, the specimens before wear were not available. Hence, the latter method was used in this study to determine the threshold based on a cylindrical reference specimen with same material and known volume (936 mm^3). The in-built software image processing language (IPL) was applied to determine the threshold as 665. With the obtained threshold, two-dimensional greyscale image slices were transferred from original ISQ file and stored in

FIGURE 2: The influence of CMM scan interval on volume difference.

FIGURE 3: Surface coordinates obtained using CMM and reconstructed original surface for volumetric assessment.

the form of TIFF images and local iterative fitting method was used for 3-D reconstruction. Based on the image digitization method [13], the surface coordinates of the specimens were obtained for determination of the volume loss of the polyethylene specimens using surface curve fitting methodology. All measurements were performed three times on each specimen to determine an average volume change and 95% confidence limits (CL) calculated, to determine the repeatability of the measurement method. Table 1 demonstrates the parameters of Micro-CT scanner 100 during scanning, and the schematic diagram of Micro-CT procedure is illustrated in Figure 4.

3. Results and Discussion

The comparison of CMM and Micro-CT methodologies against gravimetric is shown in Table 2. At lower volumes, the volume calculated using CMM and Micro-CT measurement was close to gravimetric analysis. At higher volumes, both CMM and Micro-CT measurement overestimated wear compared to gravimetric volume and the volume loss determined using Micro-CT was higher than CMM. The measurement time cost for the CMM and Micro-CT was

approximately 40 minutes and 90 minutes per scan, respectively. It can be seen from Figure 5 that both CMM and Micro-CT measurement appear to be an overestimate compared to gravimetric measurement. Gravimetric measurement methodology is the standard method used in the determination of volume loss [3, 4]. However, fluid absorption and metallic debris inclusion may affect the measurement. Methodologies with greater accuracy and repeatability without these limitations are required. CMM and Micro-CT measurement techniques were used in this project to determine the volume loss of polyethylene tibial knee specimens and compared against gravimetric analysis, which was considered as the reference. However, it should be noticed that gravimetric measurement does not include creep whereas CMM and Micro-CT do as they are geometry-based measurement techniques. Besides, backside wear will be included in gravimetric measurement but not in CMM/Micro-CT in this project since geometry changes only in the left and right condyles of the tibial knee components were considered.

In this study, both CMM and Micro-CT analysis were based on the coordinates of the articulating surface. For CMM measurement, the coordinates were obtained directly from the scanning probe and stored on the PC in the form

TABLE 1: Scanning parameters of Micro-CT100.

Peak voltage	Current	Specimen holder	Integration time	Resolution	Gaussian
70 kVp	114 μ A	74 mm	300 ms	1024 $\times$ 1024	0.8, 1

FIGURE 4: Schematic diagram of Micro-CT procedure.

TABLE 2: CMM and Micro-CT volumetric measurement results.

Specimen	Gravimetric (mm ³)	CMM (mm ³)	Micro-CT (mm ³)
Specimen 1	20.12	22.85	23.31
Specimen 2	18.41	19.52	21.15
Specimen 3	9.12	10.05	11.16
Specimen 4	9.96	10.87	11.86
Specimen 5	14.90	16.78	16.18
Specimen 6	11.02	12.16	13.35
Specimen 7	45.74	49.39	51.56
Specimen 8	38.87	41.76	45.47
Specimen 9	49.92	52.57	55.95
Specimen 10	47.44	51.26	53.68
Specimen 11	40.06	43.65	42.54
Specimen 12	37.47	39.61	41.39

of txt file for analysis. For Micro-CT measurement, the two-dimensional greyscale images were transferred into coordinates for volumetric analysis. The threshold is a key parameter in Micro-CT scanning and may vary depending on the type and manufacturer of the polyethylene tibial knee components [14]. It has been reported that differences in the measured volumetric wear may be due to errors in thresholding and in the scanner which affect the intensity of the image

[15]. In order to obtain accurate surface geometry, a known volume reference specimen with the same material and X-ray absorption as the specimens measured was used to determine the threshold, which was the most important parameter for image digitization. However, even with the determined threshold, the average repeatability of Micro-CT ($\pm 3.26 \text{ mm}^3$) was still higher than that of gravimetric measurement ($\pm 0.02 \text{ mm}^3$). The CMM ($\pm 0.89 \text{ mm}^3$) had better repeatability than Micro-CT, but still higher than gravimetric. Concordance correlation coefficients (CCC) [16] were used to evaluate the two measurement techniques against gravimetric measurement. As demonstrated in Figures 6(a) and 6(b), both CMM and Micro-CT measurement indicated higher wear compared to gravimetric analysis. With the help of web tool created by Lin and validated by Yu [17], the CCC, precision (Pearson correlation coefficient measuring how closely the observations deviate from the best-fit line), and accuracy (the closeness of the observations and target values in terms of both means and variances) coefficients were calculated, which are illustrated in Table 3. CMM (CCC = 0.990 and 0.979 for statistic and 95% CL, resp.) measurement shows a higher concordance than Micro-CT measurement (CCC = 0.975 and 0.947 for statistic and 95% CL, resp.) versus the gravimetric analysis, this is more likely due to the thresholding in Micro-CT and image digitization from two-dimensional greyscale image slices. Besides, both precision (1.000 and

FIGURE 5: CMM and Micro-CT measurement results of laboratory specimens with 95% confidence limit.

FIGURE 6: Comparison of CMM and Micro-CT volumetric analysis against gravimetric measurement.

0.999 for statistic and 95% CL, resp.) and accuracy (0.999 and 0.996 for statistic and 95% CL, resp.) of CMM measurement were greater than Micro-CT. In addition, as demonstrated in

Figure 6(c), the minimum and maximum volume difference of CMM analysis was 0.91 mm^3 and 3.82 mm^3 . The corresponding volume difference of Micro-CT analysis was

TABLE 3: CMM and Micro-CT measurement versus gravimetric measurement.

CMM measurement versus gravimetric measurement			
	CCC	Precision	Accuracy
Statistic	0.990	1.000	0.991
95% CL	0.979	0.999	0.980
Micro-CT measurement versus gravimetric measurement			
	CCC	Precision	Accuracy
Statistic	0.975	0.999	0.976
95% CL	0.947	0.996	0.949

1.90 mm³ and 6.60 mm³. These studies indicated that CMM had better precision and accuracy compared to Micro-CT analysis. Nevertheless, the voxel size used in the Micro-CT analysis was 79 μ m and studies show that the volumetric measurements would be underestimated with the increasing of voxel size [18], lower voxel size and higher resolution could result in better volumetric determination compared to CMM measurement with scan interval of 0.2 mm, which needs further analysis.

Since the IPL software can determine the volume of the specimen, Micro-CT can also be used to determine the volume loss with reference data provided [19, 20], which is like gravimetric measurements. However, for retrievals or cases similar to the present study, due to the absence of prewear data, the reference surface is not available, surface curve fitting methodology based on CMM coordinates and image digitization would be more appropriate to determine the volume loss. Gravimetric measurement was used as reference in this study to investigate the surface curve fitting methodology based on CMM and Micro-CT measurement techniques. Both CMM and Micro-CT can be used for retrievals when no prewear data exists; however, more specimens should be measured to investigate the applicability and accuracy of the method at higher volume loss, especially when no unworn area was available as reference for surface curve fitting.

4. Conclusions

In summary, gravimetric volume analysis remains the most accurate and easiest method to determine the volume loss of polyethylene specimens. However, gravimetric analysis cannot be used at all for retrieval studies, which is an important area of interest in clinical performance. CMM and Micro-CT are alternative measurement techniques used for volume loss determination. In the study, scan interval of 0.2 mm was adopted to balance the accuracy and time cost for CMM measurement and a known volume cylindrical reference with the same material was used for accurate greyscale threshold determination. Since no prewear data was available for reference, a 5th polynomial surface curve fitting algorithm was performed to reconstruct a nominal "original" surface based on the unworn surface. In addition, both CMM and Micro-CT techniques could determine the back-side wear of tibial knee inserts, which is not available for gravimetric measurement. The CMM measurement took

less time and had better precision, accuracy, and repeatability compared to Micro-CT measurement technique.

Conflicts of Interest

The authors declare that there is no conflict of interest regarding the publication of this paper.

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