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Method for characterization of material loss from modular head-stem taper surfaces of hip replacement devices

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ABSTRACT: Assessment of the head-stem taper junction requires the estimation of material loss from the taper surfaces of both femoral head and stem. This paper describes a method for the measurement and analysis of material loss from the modular taper junction of hip replacements, in particular femoral stem tapers where generally the entire taper surface has been engaged. In such cases no direct unengaged datum surface is readily identifiable to assess material loss. The highly anisotropic topology of some stem designs poses additional challenges to the measurement and analysis process. Estimation of material loss of retrieved femoral stems is further complicated by retrieval damage or surface deposits often present on the taper surface. The femoral head tapers typically exhibit areas of pristine surface attributed to the difference in taper length compared to the engaging stem. These areas can be selected as unworn when employed in the analysis process, provided they do not show surface damage or deposits. Measurement of the taper surfaces has been performed using a Talyrond (Ametek, Inc., US) out-of-roundness measurement instrument equipped with a 5µm diamond tip stylus. Vertical axial traces were employed to digitize the surface of the taper. Measurement data has been analyzed using a multi stage process that has been specifically adapted for stem tapers. The underlying stem taper geometry is determined by means of a morphological filter applied to the high aspect ratio microstructure. This paper presents a study of 40 retrieved LHMoM hip replacements that have been analyzed to ascertain the material loss at the modular taper junction. The purpose of this study was to ascertain the viability of characterizing material loss from the stem taper junction and to provide insight into the overall material loss contribution.

KEYWORDS: taper measurement, stem taper, material loss volume, metal-on-metal

1. Introduction

The revision rate of large head metal-on-metal (LHMoM) total hip replacement is higher compared to similar sized metal-on-metal (MoM) hip resurfacing [1-2]. Data published in the annual report of the National Joint Registry of England, Wales and Northern Ireland shows five year revision rates of 7.67% and 6.38% for uncemented and cemented MoM total hip replacements respectively [2].

The head-stem taper junction has been identified as a possible source of fretting wear and corrosion debris [3-14]. Several previous studies have performed a qualitative assessment at the
taper junction and have identified the presence of fretting and corrosion damage [3-11, 19, 20]. These studies largely rely on a semi-quantitative corrosion and fretting scoring system developed by Goldberg et. al. [3] for assessing the condition of the modular taper junction.

The underlying characterization of material loss from modular taper surfaces requires the measurement of the component surface such that changes in form and surface roughness can be detected and quantified. Furthermore, the measurement of femoral stems poses additional challenges due to the high anisotropic topology of some stem designs. Recently published methods that attempt to quantify material loss at the head-stem taper interface focus on the measurement of material loss in the case of the female head taper surface and utilize a variety of techniques and metrology tools including out of roundness measuring machines [11, 12, 18], optical profilers [13] and coordinate measuring machines. [14-15].

It has been shown that there is a general correlation between the Goldberg score and the taper material loss volume, but quantification of material loss volume is important as the range of material loss values that a Goldberg score of 4 can represent is significant [16]. A previous study has highlighted that the taper junction can, in some cases, be a significant contributor to the overall material loss occurring at the modular taper junction [17]. Considering the significance of material loss at the head-stem taper junction it is important to be able to quantify and characterize the processes that lead to material loss. Further studies have also been published investigating the angle mismatch between the stem and head taper to determine where the contact between the surfaces initially occurs [19].

The paper outlines a method for estimating the volume of material loss at the modular head-stem taper junction focusing on the analysis requirements for stem tapers. Building on the previous studies performed [11, 12, 22] we have developed a comprehensive method to allow the investigation taper surfaces including stem tapers with a high aspect ratio surface. The aims of the study were: (1) to determine the material loss volume at the head-stem taper junction; (2) determine the contribution attributable to stem tapers to the overall material loss of the taper junction.

2. Materials and methods

The focus of this paper is the establishment of a measurement protocol and analysis framework with appropriate algorithms to estimate the volume of material loss on both taper surfaces at the head-stem junction.

2.1 Equipment

In the case of a male taper with a highly anisotropic surface as described in this study the use of a coordinate measuring machine to measure the taper surface is considered to be inappropriate due to the level of mechanical filtering of the surface texture caused by the large size of even a 1mm stylus relative to the high aspect ratio and short wavelength of the surface features encountered in such a surface. As such it is necessary to utilize a method with a high data sampling density and surface roughness level resolution. This study utilizes a Talyrond 365 (Ametek Inc, US) out-of-roundness measurement machine, which is used in a variety of industries primarily to characterize form deviations of spherical and cylindrical parts and has been used in previous studies to measure material loss in female head tapers [11, 12].
The Talyrond measures roundness, straightness and cylindricity with a sub-micron resolution and is schematically shown in figure 1. The machine employs an inductive transducer with a gauge resolution of 1.2nm, has a ±1mm gauge range, and a centering and leveling spindle with a runout value of 20nm.

In operation a number of proprietary styli of different sizes can be employed. The styli available range from a diamond styli of 2µm tip radius, shown in figure 1, to ruby styli that are more akin to those used in coordinate measuring machines. The measurement force can be optimized between 0 to 15g dependent on the measured surface to allow for constant contact between the part and stylus during travel. A gram gauge is to be used to set the desired measurement force before calibrating the stylus range.

2.2 Measurement protocol

2.2.1 Head taper measurement protocol
The femoral heads are mounted on a platform comprised of an x-y manual stage and a two axis goniometer stage to change pitch and roll. On top of this platform the component is mounted on a three sphere fixture (see figure 1).

The alignment routine consists of an iterative process by which two roundness traces are recorded at predefined positions along the z axis on the surface of the taper. The traces should be located in at least one area of as-manufactured surface either at the open or closed end of the taper.

The two roundness traces are analyzed to calculate the eccentricity between the center position of the spindle and that of the part. The angle between the axis of the spindle and the axis of the taper is also determined. Based on the results of the analysis process an automatic adjustment process is performed. This adjustment process of the rotating table is a combination of xy translational movement along with adjustment for the pitch and roll angle of the table. Once the adjustment has been performed the entire alignment process is iterated until the alignment
criteria are reached. The iterative alignment process is performed to achieve a sub-micron eccentricity and an angle of less than 0.01° between the vertical column and the taper axis.

Following a successful alignment process the measurement strategy parameters are defined. The radial position of the initial trace should be set using relevant markers on the surface of the component. Such markers should be used to correlate the position of traces in relation to the actual component orientation.

The measurement arm is positioned to allow for constant contact between stylus and part during the vertical trace measurement and vertical range of travel is defined along with other relevant measurement parameters (measurement speed, number of vertical traces, angular spacing between traces and number of points per trace).

The data from each trace is stored individually as a vertical trace that allows for additional 2D profile analysis to be performed. A total of 180 traces are combined to produce a surface map of the taper, which consists of parallel stacked traces coregistered in z and positioned in y based on circumferential spacing. Typically each trace consists of 7000 points leading to the total number of points recorded for each taper surface being greater than 1.2 million points.

2.2.2 Stem taper measurement protocol

In preparation for measurement the femoral stem components they are mounted rigidly by means of soft jaws vice. In the case of a number of the stem components the entire taper surface has been in contact with the female femoral head taper. As a consequence the centering and leveling process requires additional steps where by the operator should alternatively select reference planes in areas that exhibit no visual surface damage and monitor the results alignment process. Furthermore, in some cases there is the potential for the stylus movement to be affected by the high aspect ratio topography of the stems. An example of this is shown in figure 2 where the surface texture peaks have a periodicity of approximately 200µm. To minimize the effect of the surface texture on the alignment process use of a ruby stylus for this operation is recommended.

Figure 2 Representation of measurement strategy (vertical traces) and leveled trace showing highly anisotropic stem taper surface topology

The measurement is carried out in the same manner as for the head taper. The measurement speed and measuring force must be adjusted to ensure the stylus is kept in constant contact with
the surface during the measurement process, even when considering the highly anisotropic taper surfaces.

2.3 Analysis protocol

The analysis process consists of a multistage approach based on a two stage form removal process followed by the calculation of the volume of material loss. In both the cases of head and stem tapers the analysis is broadly common but the anisotropic nature of some stem surfaces mean that some additional intermediate steps are required in such cases. The required functions and algorithms used in the analysis process have been implemented using the Matlab (The Mathworks Inc., Natick, USA) software package and in the case of female head tapers have been described previously [11, 12]

2.3.1 Head taper analysis protocol

Form removal and fitting process
The first stage of the analysis process involves the levelling of the measured data and removal of the conical form. In this process all traces in the surface map are interpolated using a least squares fit applied all the data.

The second stage is performed based on a subjective manual fitting process to fit a first or second order polynomial to areas of a generated average profile that are specified by the operator. Figure 3 presents such a fitting process in which the operator manually identifies the as-manufactured areas highlighted in green, and a real-time fit is produced to graphically show the result of the fitting process in the right image. The outcome of the fitting process directly influences the material loss volume estimation as the defined fitting plane is then further defined as the zero level plane in subsequent bearing area analysis.

![Figure 3 Manual fitting process. Average 2D data profile with selected as-manufactured data in green (left image) and real-time representation of fitting process (right image)](image)

The fitting process requires a robust algorithm that is stable and produces valid results and this has been demonstrated previously for the case of female head tapers [12]. The process is subjective and requires the operator to identify and select areas of as-manufactured taper surface. It is common to have at least one area of as-manufactured surface at one end of the head taper surface.

Material loss volume estimation
Once the fitting process is completed, a graphical map of the leveled surface is generated. An example of such a map is shown in figure 4. The x axis shows the length of the traces in mm while the y axis shows the radial coverage of the traces performed from 0 to 360 degrees. The z axis shows linear deviations of the measured traces in µm.

A bearing area curve (BAC) is generated from the measurement data and is used to determine the volume of material loss. Figure 4 shows an example of a plotted BAC for a retrieved femoral head taper surface. The initial peak above the median (zero line) represents data that is proud of the reference surface. This area of peaks is generally attributed to surface deposits but can also correlate with the edges of areas of extraction damage in the case of stem tapers. Use of the BAC allows the operator to identify surface deposits (marked as debris in figure 4) and remove them from the volume calculation by thresholding to the zero plane. It is clear that the accurate determination of volume loss requires the elimination of any such deposits from the analysis. Conversely the area below the zero plane can be attributed to material loss and this when correlated with the original form parameters leads to the determination of material loss. A repeatability study looking and in depth explanation of the volume calculation algorithm has been previously carried out [12].

![Figure 4 Bearing area curve employed to delineate material loss volume and exclude surface debris.]

2.3.2 Stem taper analysis protocol

In the case of stem tapers which do not exhibit highly anisotropic surface features the analysis process can be performed in the same manner as for the head taper surface. However, in the case of stem tapers that have an anisotropic topology the analysis process whilst following broadly the same principles as that for the female head taper has additional steps regarding the lack of as-manufactured surface, presence of extraction damage and highly anisotropic texture. As is the case for the head taper, the first step once the measurement process is complete, all the vertical traces are assembled to produce a surface map.

Defect and debris removal
Extraction damage represents material removed during the revision procedure performed by the surgeon. This is typical for the stem taper as the taper surface is exposed during revision surgery. The surgeon is often required to grasp the taper surface to extract the stem during revision...
surgery. An example of such extraction damage is shown in figure 5 and can be easily identified by the operator by means of a visual inspection process.

The process to remove defects related to extraction damage is carried out using the Surfstand (CPT, Huddersfield University, UK) software package. The high point density and resolution of the instrument make it possible to readily identify the extraction damage regions within the surface map of the taper. In order to accurately determine the volume of material loss it is important to eliminate such areas from the analysis process. Areas of extraction damage are selected by the operator and a process of surface interpolation (4\textsuperscript{th} order inverse distance weighting) is used such that a maximum level plane is applied to the area. This process was originally developed for surface measurement analysis.

![Image of extraction damage highlighting and result after removal process](image)

**Figure 5 Defect removal process: area of extraction damage highlighted (left image) and corresponding result after the removal process using the 4\textsuperscript{th} order inverse distance weighting (right image)**

Morphological filtering form removal and fitting process
The form removal process used for head tapers is not suitable for stem designs with highly anisotropic topography. A morphological filtering method described by Lou et al. [22] is required to identify the contact points defined as local texture peaks and use those points to perform the fitting process. A “digital sphere” is rolled over the measured vertical trace and the resulting contact points are linked to create a minimum zone profile. The user can manipulate the diameter of the sphere to control the location of the contact points. The use of a morphological filter is akin to the mechanical filtering effect induced by using a large diameter ruby stylus on a coordinate measuring machine. However the accuracy of that mechanical filtering process is not easy to control leading to the likelihood of erroneous points being included in the measurement.
A morphological filter allows for visual feedback to be provided regarding the determined contact points thereby improving the accuracy the fitting method. The morphological filter method searches for the contact points in the surface map. The method automatically determines the contact points and calculates a minimum zone profile that encompasses those points as shown in figure 6. The minimum zone profile is used to perform the fitting and form removal process.

Material loss volume estimation
The volume of material loss of stem tapers that don’t exhibit a high anisotropic surface is determined based on the BAC by employing the same methodology as for head tapers.

When determining the volume of material loss for stems with a high anisotropic topology it is important to account for the volume of material between the grooves. As such the areas of material loss are isolated and the volume calculation is performed locally taking into account the local topology and the cone shape parameters.

Results
The method was used to measure and analyze a cohort of 40 retrieved hip replacements. The purpose of the study is to determine the overall volume of material loss from the head- cup bearing interface and the head-stem taper interface and the contribution of each interface. The components represent retrievals from the collection of the London Implant Retrieval Centre (University College London, UK). The components from the cohort included metal-on-metal total hip replacements of various sizes and manufacturers. The head-stem junction taper surfaces consisted of 12/14 taper sizes with both a smooth taper and a high aspect ratio surface design. Of the 40 retrieved metal-on-metal hip replacements considered in this study 28 had stems manufactured from Ti6Al4V, 8 stems were CoCr, 2 Stainless Steel and 2 were undisclosed.

Both the head-cup bearing interface and the head-stem taper interface were measured and analyzed to quantify the overall volume of material loss as well as the contribution of each interface.

The first part of the study looked at measuring the head-cup bearing surfaces of the components to determine the volume of material loss at the bearing surface. The bearing surface of the head
and cup was measured using a Zeiss Prismo CMM and the data was analyzed following the procedure described in [22]. The median volume loss for the cup bearing surface (2.86 mm³) was less than the median volume of material loss from the femoral head bearing surface (4.14 mm³). A summary of the results is presented in Table 1.

The second part of the study focused on the head-stem taper interface. Visual inspection of the taper surfaces was carried out to identify as-manufactured regions and areas exhibiting extraction damage.

Of the total number of 40 measured stem tapers, material loss estimations were produced for a total of 38. Two stems exhibited large extents of surface damage present on the taper surface. While the method allows for surface damage to be excluded from the measurement process in these two cases the extent of extraction damage was too extensive to enable meaningful and representative material loss estimation.

![Figure 7 Graphical surface map representations of the analysis results of the head-stem taper surfaces](image)

The measurements were analyzed to produce deviation plots for each taper surface. Figure 7 shows the deviation plots for both taper surfaces of the head-stem junction. The imprinting on the head taper is visible toward the distal end of the taper. The wavelength of the imprinting
matches spaces of the stem microstructure. The area of maximum penetration on the head taper is located at the open end of the head taper.

The results of the study have shown that in 7 of the 40 measured stem tapers no measurable amounts of material loss could be determined. The median value of the reported volume loss estimates for the stem tapers is 0.26 mm$^3$ (range 0 – 0.9 mm$^3$) and is considerably less than the median material loss volume from the femoral head taper surface 1.63 mm$^3$.

Table 1 Summary of the volume of material loss at the head-cup bearing interface and head-neck taper junction

<table>
<thead>
<tr>
<th>Taper interface - Material loss</th>
<th>Bearing interface - Material loss</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stem (mm$^3$)</td>
<td>Head(mm$^3$)</td>
</tr>
<tr>
<td>Mean</td>
<td>0.3</td>
</tr>
<tr>
<td>Median</td>
<td>0.26</td>
</tr>
<tr>
<td>Range</td>
<td>0 - 0.9</td>
</tr>
<tr>
<td>Standard dev.</td>
<td>0.29</td>
</tr>
</tbody>
</table>

Although extraction damage can be excluded from the analysis process it is not possible to account and quantify any material loss from those areas prior to extraction. Furthermore, where extensive extraction damage is present on the taper surface the results obtained would have an increased level of uncertainty.

Repeatability study

A study was carried out to assess the repeatability of the measurement and analysis protocol. One retrieved femoral head component was selected to perform the study. The measurement protocol was repeated for a total of 20 times by a single operator. After each measurement the component was removed from the machine table and repositioned. The alignment routine was carried out each time and a total of 180 vertical traces recorded for each measurement.

The measurements were analyzed by a single operator to determine the volume of material loss. The results presented in table 2 show a range of values for the volume of material loss of 0.541 to 0.675.

Table 2 Results of the repeatability study for estimation of material loss volume

<table>
<thead>
<tr>
<th>Material loss volume (mm$^3$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
</tr>
<tr>
<td>Median</td>
</tr>
<tr>
<td>Range</td>
</tr>
<tr>
<td>Standard deviation</td>
</tr>
<tr>
<td>Coefficient of variance</td>
</tr>
</tbody>
</table>

The component selected consisted of a femoral head presenting a low volume of material loss. This was chosen to test the sensitivity of the method along with the repeatability. Although care was taken to ensure a consistent angular positioning of the first trace of each measurement the
position of the first trace is not consistent (±1° deviation) to allow for an overlap between deviation plots.

Further validation regarding the repeatability and reproducibility of the method and algorithms is presented in [12].

Discussion

The method presented has been shown to enable quantitative measurement and analysis of material loss from both surfaces of the head-stem taper interface. A comprehensive methodology has been developed that provides specific solutions to the measurement and analysis process. Specific protocols have been developed to allow the estimation of the volume of material loss for stem taper surfaces with a high anisotropic topology as well as components exhibiting extraction damage.

The method allows for surface deposits to be excluded from the analysis process. When surface deposits are present below the fitting plane it is not possible to eliminate these deposits from the volume estimates thereby potentially underestimating the amount of material loss. Therefore it is recommended that a cleaning protocol be put in place for removal of debris from the taper surface prior to the measurement process.

An advantage of the proposed method lies in the accuracy and resolution achieved by the measuring instrument. This allows the measurement of male taper surfaces that present a high aspect ratio with minimal mechanical filtering compared to a cmm stylus. Another advantage consists in the multistage analysis process that provides estimates for volume loss of both head and stem taper components thereby enabling the quantification of material loss of the entire taper junction.

The method protocols provide guidance and visual feedback for the operators during the initial alignment phase and in the analysis process. During the alignment process the nature of the routine allows for feedback to be provided in relation to the outcome of the alignment process mitigating systematic errors. The analysis process relies on the skill of the operator in identifying as manufactured surface areas during the fitting process. A real-time graphical representation of the fitting process is shown allowing the operator to mitigate any potential operator errors.

The results of the case study have shown that it is feasible to estimate the amount of material loss for both components of the modular taper junction. The results have highlighted that the amount of material loss from stem tapers is considerably lower compared to the head tapers in the cohort suggesting preferential material loss is occurring. Published in vitro studies [24-26] suggest that the same pattern of preferential material loss and imprinting especially in the cases of stems that present a highly anisotropic surface topography.

Conclusions

The paper describes a method for characterization of material loss at the modular taper junction for both the femoral heads and stem taper. The focus has been on development of a complete
protocol for estimation of material loss based on surface maps of stem tapers. The method presented has been shown to have a stable analysis algorithm and a high level of repeatability.

The method has been shown to be able to characterize the taper surface to micron-sized texture features. This high resolution allows the operator to differentiate within the measured data between areas of material loss, debris and areas of as manufactured surface and perform an accurate fitting process.

The method described uses an out of roundness machine to determine the volumetric material loss from the taper junction. Previous studies [18, 19] have looked primarily at 2D profiles and assessing the geometry and surface changes of the stem-taper junction. Further work is still required to completely assess the measurement uncertainty of the method and identify all possible sources of error. Standard taper artefacts are required that replicate the geometry and microstructure of the stem-head taper junction to allow for a uncertainty budget to be determined based on the guidelines outlined in the Guide to the expression of expression of uncertainty in measurement (GUM)[27] and ISO 15530-3:20007 [28].

The study conducted provides quantitative information regarding the overall volume of material loss that stems from both the bearing surfaces of metal-on-metal retrieved hip replacements as well as the head-stem taper interface. The volume of material loss from the stem taper has been shown to be the smallest contributor to the overall volume.

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