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Standard Guide for Characterization of Wear from the Articulating Surfaces in Retrieved Metal-on-Metal and other Hard-on-Hard Hip Prostheses[1]

This standard is issued under the fixed designation F2979; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This ~~guide specifies a method to measure the~~ standard guide provides options and a compendium of information for measuring the bearing surface and estimating the *in-vivo* wear of explanted Metal-on-Metal (MoM) and other "hard" ~~(e.g.,~~ (for example, ceramic) hip components. The guide covers the measurement of acetabular cups and femoral heads using a dimensional change method and is applicable to all prosthetic hip types, including stemmed (modular) and resurfacing hip systems.

1.2 The methods specified in this guide are not applicable for measuring the *in-vivo* wear from non-articulating surfaces, for example modular connections (at the stem/neck, ~~neck/head~~neck/head, or cup liner/shell interface) or at the acetabular cup rim.

1.3 The parameters (wear depth and volumetric wear) evaluated and reported in this guide are estimated from the assumed as-manufactured shape of the components. The wear volume is calculated using a numerical integration method and the wear depth is the difference between the assumed as-manufactured shape and the measured surface.

1.4 This guide covers the measurement of the depth of wear and the volumetric wear using a Coordinate Measuring Machine (CMM) and the depth of wear using an Roundness Machine. Other metrology measurement equipment may be used to measure the wear depth or volume if the resolution and accuracy of the measurements are comparable with the instruments detailed in this standard. The measurement and analysis protocols should be based on those described in this standard.

1.5 This guide is applicable to hip joints which are nominally spherical at the time of manufacture. Form deviations resulting from manufacturing or deformation may occur and may necessitate the use of a non-spherical surface to represent the unworn surface of the component. Hip joints designed with asymmetry are considered beyond the scope of this guide, although the principles and techniques may be applicable to the characterization of wear from the articulating surfaces.

1.6 This guide is intended as an extension to ~~ASTM~~Practice F561 as a Stage II nondestructive test.

1.7 *This standard may involve hazardous materials, operations, and equipment. As a precautionary measure, explanted devices should be sterilized or disinfected by an appropriate means that does not adversely affect the implant or the associated tissue that may be the subject of subsequent analysis. A detailed discussion of precautions to be used in handling human tissues can be found in ISO 12891-1. This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate ~~safety~~ safety, health, and ~~health~~environmental practices and determine the applicability of regulatory limitations prior to use.*

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[1] This ~~test method~~ guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F04.22 on Arthroplasty.

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1.8 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

F561 Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids

F2033 Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials

2.2 *ISO Standard:*[3]

ISO ~~12181-1:2003~~12181-1-2011 Part ~~1 – Geometrical product specifications roundness, vocabulary and parameters of roundness~~1—Geometrical Product Specifications Roundness, Vocabulary and Parameters of Roundness

3. Terminology

3.1 ~~*Definitions:*~~*Definitions of Terms Specific to This Standard:*

~~3.1.1 For the purposes of this standard the following definitions shall apply.~~

3.1.1 *cup rim*—the circle formed by the intersection of the articulating surface and the plane normal to the revolution axis that lies coincident with the extreme point of the open cup face. See Fig. 1.

3.1.2 *edge wear*—the pattern of wear observed in acetabular cups in which the maximum wear depth occurs at the cup rim and progressively deceases along a path from the cup rim to the pole (**1-3**).[4] See Fig. 1.

3.1.3 *equator of the articulating surface*—the equator of the articulating surface is the circle ~~normal to the revolution axis of the component and to~~coincident with the nominal spherical surface and lying in a plane that is perpendicular to the axis of rotation and located at 1R from the pole point. See Fig. 1~~the spherical articulating surface.~~.

3.1.4 *form deviations*—deviations from the nominal designed spherical shape of the hip implants that are not the result of wear. Form deviations shall be separated from wear by the analysis and measurement protocol to prevent errors in the calculated wear.

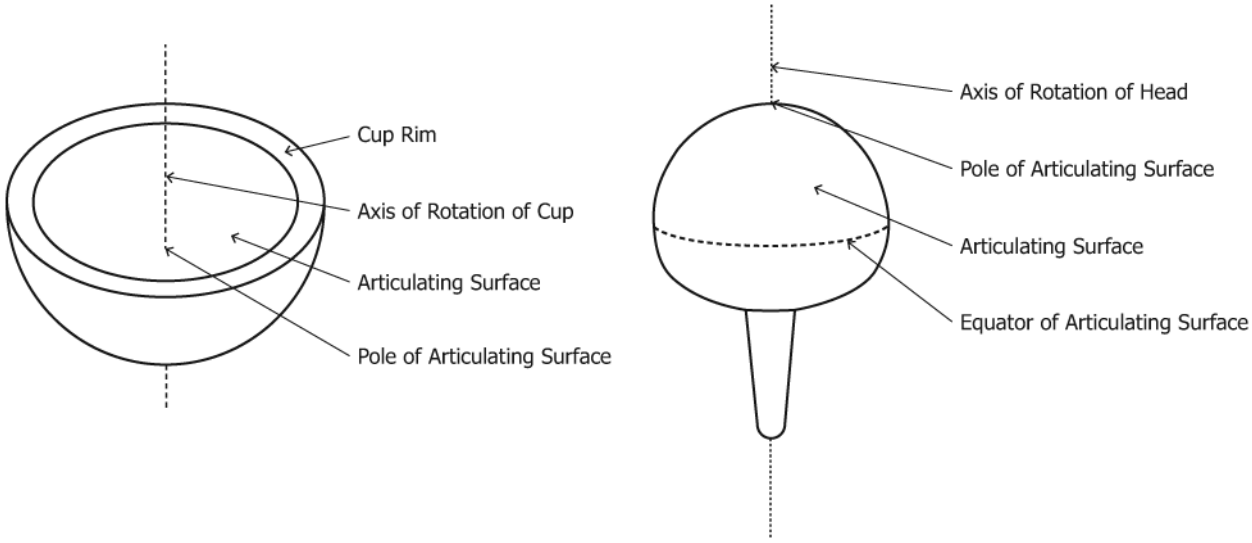

FIG. 1 Schematic Diagram Terminology for Head and Cup Geometry

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

[4] The boldface numbers in parentheses refer to the list of references at the end of this standard.

Form deviations may result from manufacturing tolerances or deformation during implantation or revision procedures. Typically, hip implants are symmetrical around the revolution axis.

3.1.5 *maximum inscribed reference circle*—~~the reference circle of maximum radius that is totally enclosed by the measured~~largest possible circle that can be fitted within the roundness profile. **ISO ~~12181-1-2003~~12181-1-2011**

3.1.6 *minimum circumscribed ~~arc~~ reference circle*—~~the reference arc of the minimum radius that totally encloses the measured~~smallest possible circle that can be fitted around the roundness profile. **ISO ~~12181-1-2003~~12181-1-2011**

3.1.7 *pole of articulating surface*—the pole of an articulating surface is defined by a point at the intercept of the revolution axis of the component and the spherical articulation surface. See Fig. 1.

3.1.8 *root mean square error*—the statistical measure of the magnitude of the variation between the assumed manufactured component shape fitted to the unworn regions and the measured data points in the unworn regions.

$$RMS\ Error = \left(1/n\ \Sigma x_n^2\right)^{\frac{1}{2}} \tag{1}$$

where:

x = the deviation between the assumed shape and each measured data point for n data points.

3.1.9 *volumetric wear*—the volume of material removed from the articulating surface as a result of *in-vivo* wear.

3.1.10 *wear*—deviations from the as-manufactured shape due to loss of material from the articulating surfaces of the components through abrasive, adhesive, or fatigue wear mechanisms, or by corrosion, or any combination of these mechanisms.

3.1.11 *wear depth*—the maximum penetration normal to the articulating surface due to *in-vivo* wear.

3.1.12 *wear rate*—the volumetric wear rate (mm^3/year) or the penetration wear rate (mm/year) is calculated by dividing the wear volume or maximum wear depth by the time implanted in years. The wear rate is an average of the wear over the life of the component. The wear rate of hip joints may change over the life of component with an initial "running in" or "bedding-in" wear rate and the subsequent lower "steady state" wear rate (**4**).

4. Measurement Preparation

4.1 All components shall be cleaned in accordance with the procedure detailed in ~~ASTM~~Practice F561. Ensure that there are no deposits on the articulating surface of the components that might interfere with or induce errors in the measurements.

4.2 The temperature of the analysis laboratory shall be maintained at ~~20°C ± 2°C.~~ 20 °C ± 2 °C and other environmental parameters within specified range for measurement machine. The components shall be maintained at the temperature of the analysis laboratory for at least 24 ~~hours~~h before the measurement to ensure dimensional stability.

4.3 *Apparatus*—3D ~~Coordinate~~coordinate measuring machine with a maximum permissible error of 2 µm over the largest dimension of the component, or a computer numerical control (CNC) controlled ~~Roundness Machine~~roundness machine with automated centering and leveling. The maximum runout of the air-bearing spindle shall be ~~± 20~~ ±20 nm, and the minimum gauge resolution shall be ~~± 30~~ ±30 nm.

NOTE 1—When centering and leveling to align the component coordinate system with the machine coordinate system, care must be taken to reference from unworn regions of the component.

NOTE 2—Measuring machines with a larger error may be used if the measurement and analysis protocol is validated.

5. Measurement of Components Using a Coordinate Measuring Machine

5.1 *Measurement of Acetabular Cup:*

5.1.1 Align the origin of CMM coordinate system with the center of the articulating surface of the component, and the horizontal

plane of the coordinate system parallel to the plane of the cup rim. Nondestructively mark the retrieved component, or identify a landmark feature to provide an angular reference around the axis of rotational symmetry, so that the measured wear location can be co-registered with the position on the actual component.

5.1.2 Measure data points from the bearing surface so that the maximum spacing between the data points along lines of latitude or longitude is not greater than 0.5 mm (**5**) as shown in Fig. 2. The mesh may be applied and profiles measured in a latitudinal or longitudinal pattern, or a combination to give the optimum point spacing over the component. The distance between the measured data points and the cup rim shall not be greater than 1 mm.

NOTE 3—The 0.5 mm mesh spacing is based on minimizing the errors of calculating the wear volume when using a simple linear "triangulation" integration method to calculate the wear volume (**5**). A larger point spacing may be used if a sensitivity analysis is carried out to investigate the effect of mesh spacing on the wear depth and volume, and the values can be shown to converge.

5.2 *Measurement of Femoral Head:*

5.2.1 Align the origin of the CMM coordinate system with the center of the unworn regions of the articulating surface of the component, with the revolution axis of the head perpendicular to the coordinate system horizontal plane. Nondestructively mark the retrieved component, or identify a landmark feature to provide an angular reference around the axis of rotational symmetry.

NOTE 4—The components must be firmly held for the measurement to prevent movement, but care must be taken not to distort the bearing surface or damage the component.

5.2.2 Measure data points from the bearing surface so that the maximum spacing between the data points along the lines of latitude or longitude is not greater than 0.5 mm as shown in Fig. 3 (**5**). The mesh may be applied in a latitudinal or longitudinal mesh pattern, or a combination to give the optimum point spacing over the component. The measured data points may be extended below the equator to ensure that the whole wear scar is captured in the measurement.

NOTE 5—The 0.5 mm mesh spacing is based on minimizing the errors ~~of~~when calculating the wear volume ~~when~~while using a simple linear "triangulation" integration method ~~to calculate the wear volume~~ (**5**). A larger point spacing may be used if a sensitivity analysis is carried out to investigate the effect of mesh spacing on the wear depth and volume, and the values can be shown to converge.

6. Analysis of CMM Measurements

6.1 Fit the assumed unworn shape of the component. Published studies have used ellipsoids, spheres, or nurbs profiles (**6-13**) to represent the unworn (but possible deformed) shape of the hip component. The assumed unworn shape should be fitted to the measured data points in the unworn regions, excluding the data points that are within the worn ~~region.~~ region and/or surface deposits. Several of the published methods use a ~~two stage~~ two-stage or an iterative process to fit the surface and exclude worn regions from the surface fit (**6-13**).

NOTE 6—~~ASTM~~Specification F2033 specifies that the maximum departure from roundness for metallic components shall not be greater than 5 µm for the acetabular component and 5 µm for the femoral component using a least squares or Minimum Zone Centre Method. Due to these deviations, and

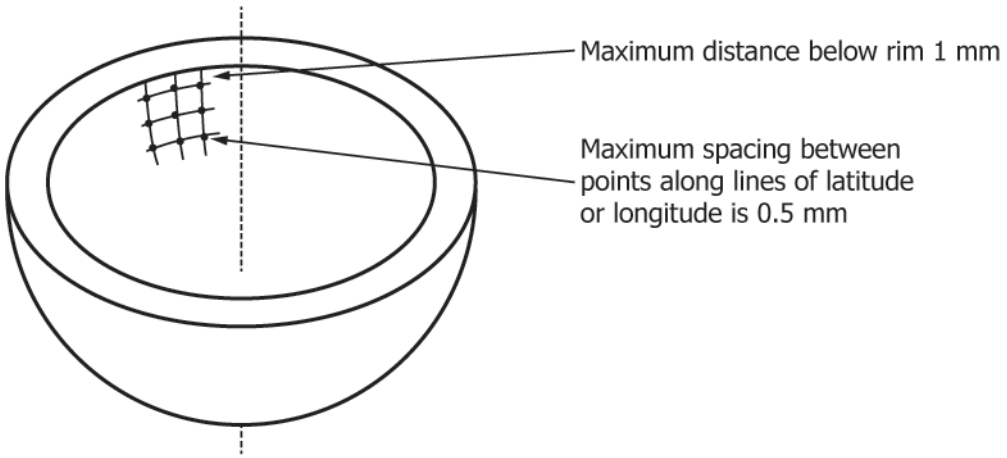

FIG. 2 Schematic Diagram Showing Pattern of Data Points for CMM Measurement of the Acetabular Cup

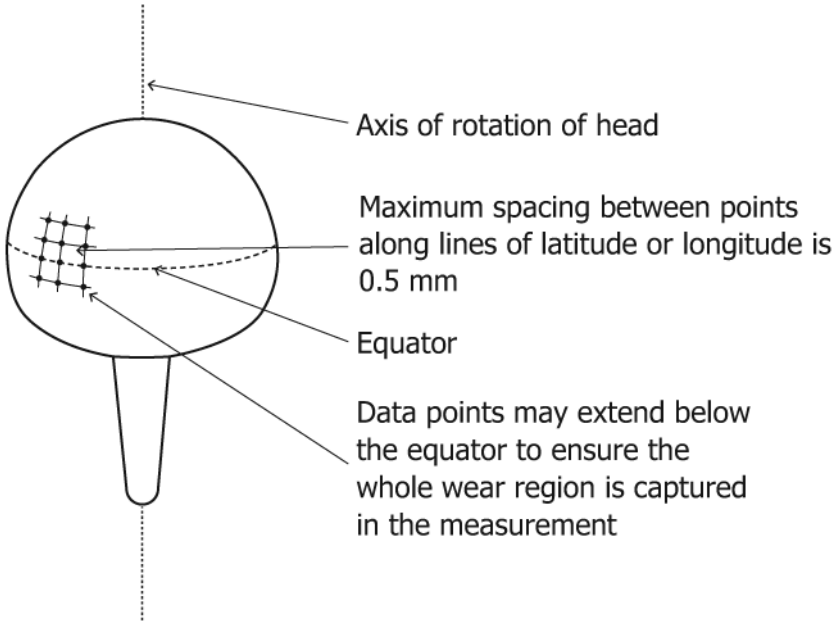

FIG. 3 Schematic Diagram Showing Pattern of Data Points for CMM Measurement of the Femoral Head

possible deformation during implantation or revision procedures, fitting a sphere to the unworn data points might result in significant errors in the calculated wear values. In some cases, ellipsoids and other shapes have been shown to better represent the unworn shape of MoM hip components than a simple sphere (**10**).

NOTE 7—The measurements of acetabular cups will often include the transition between the bearing surface and cup rim, which is typically filleted during manufacture. This filleted region should be excluded from the analysis; however, care must be taken not to exclude data points measured on the bearing surface.

6.2 Visually check the fit of the assumed unworn shape by looking at a graphical illustration of the deviations from the assumed unworn shape in the unworn regions of the component. The color scale should be set to optimize these deviations, not the appearance of the worn regions. Typically, a scale of ±10 µm allows the visualization of form deviations. Normally, the assumed unworn shape should match the measured unworn regions on the surface of the component, with the only substantial deviations being attributed to form and not a poor fit. In the case of femoral heads, the components are often axisymmetric due to the manufacturing process; thus, the form deviations will typically appear axisymmetric around the pole with wear appearing as a more localized deviation. Wear deviations are not axisymmetric. As-manufactured acetabular cups are also often axisymmetric due to the manufacturing process; however, explanted components may be pinched at the rim giving an oval shape. Care must be taken excluding this ovality from wear.

6.3 Check the fit of the assumed unworn shape by calculating the Root Mean Square (RMS) error between the assumed unworn shape and the measured data points in the unworn region of the hip component (**9**). If the calculated RMS error exceeds 2 µm, the ~~fit and the assumed shape shall be modified to reduce the error.~~wear maps must be inspected to ensure the assumed unworn shape is a good fit.

NOTE 8—Care must be taken when using the RMS error to check the fit of the assumed unworn shape as the RMS error will typically decrease as more points are excluded from the fit. However, in the case of components with a form deviation removing data points in unworn regions will reduce the RMS error, but as the proportion of the unworn surface used to fit the surface decreases, the quality of the fit may decrease. The RMS error must be used in conjunction with the wear maps to ensure that data points in unworn regions are not unnecessarily excluded.

6.4 ~~Visually check the fit of the assumed unworn shape by looking at a graphical illustration of the deviations from the assumed unworn shape in the unworn regions of the component. The color scale should be set to optimize these deviations, not the appearance of the worn regions.~~The wear map should be visually co-registered with the explanted component to ensure that the wear map is consistent with the visual evidence of wear and damage on the component. For example, sometimes there may be a change in surface appearance in the worn region, the edge of the wear scar may be visible in the protein deposits, or in the case of edge worn cups the wear may be visible at the transition between bearing surface and cup rim.

6.5 If the whole wear area is not wholly captured within the measurement region and extends below the equator of the head, then the measurement shall be repeated to include the whole area of the wear area.

6.6 The maximum depth of wear shall be taken as the maximum deviation between a point on the measured worn surface and a point on the assumed unworn articular surface along a line normal to the assumed unworn articular surface.

NOTE 9—The stylus will mechanically filter scratches and other short wavelength surface roughness features and, due to the point spacing, short wavelength surface roughness features may not be measured. However, the depth of scratches will typically be small compared to the measured maximum wear depth. Carmignato et al. (**14**) evaluated the contribution of surface roughness on the estimation of wear volume and concluded that it "hardly reaches 0.5 mm^3 when the roughness *Ra* of the worn areas is not greater than 0.3 µm."

6.7 Use a numerical method to calculate the wear volume over the worn regions of the component by calculating the volume between the assumed unworn shape of the component and the worn region.

NOTE 10—Differences in algorithms used to calculate the wear volume may result in variations in the wear volumes. Scratching, indentations, and deformation attributed to the explantation process and/or handling after explantation should not be included in the wear depth and volume estimates.

6.8 In cases of components with form deviations but with little or no wear, the algorithm may calculate a "wear" volume. Based on inspection of the wear maps and the components, if it is clear that the measured deviations are not caused by material loss, then a zero wear value may be reported with an explanatory note in the report.

6.9 The measurement method and analysis algorithm used should be described in detail in the report and suitably validated. Suitable validation methods may include the measurement of a reference sphere (~~14~~15), calculation of the wear from "ideal" datasets with mathematically generated wear scars, comparison of gravimetric and calculated dimensional wear for simulator (components tested in a hip simulator) and artificially (components with material removed to represent a wear scar) worn components (**10**, **11**, ~~14~~15).

NOTE 11—A validation using ideal wear scars and artefacts may not fully represent the technical difficulties of measuring clinically retrieved components and not include all sources of uncertainty.

6.10 If the time implanted is known (whole years and decimal fraction), the calculate the wear rate by dividing the wear depth or wear volume by the time implanted to give the wear rate (µm/year) and the volumetric wear rate (mm^3/year) for the head and cup.

7. Measurement and Analysis of Components Using a Roundness Machine

7.1 *Measurement of Acetabular ~~Cup~~Cup:*

7.1.1 *Cup Circumferential Measurement:*

7.1.1.1 Calibrate the radial position of the roundness machine radial arm so that the machine gives absolute measurement values.

7.1.1.2 Align the cup revolution axis with the spindle axis of rotation of the roundness machine and the cup rim plane perpendicular to the spindle axis of rotation using automatic centering and leveling routines. Set the vertical height datum at the cup rim. Nondestructively mark the retrieved component, or identify a landmark feature to provide an angular reference around the axis of rotational symmetry.

7.1.1.3 Measure a series of circumferential profiles, as shown in Fig. 4, starting 1 mm below the cup rim, at intervals no greater than 0.5 mm, for at least 6 mm.

7.1.2 *Polar Cup Measurement:*

7.1.2.1 Calibrate the radial position of the roundness machine radial arm.

7.1.2.2 Fit the recess stylus ~~(i.e.,~~ (that is, a long shank to allow access to the articulating surface of the cup).

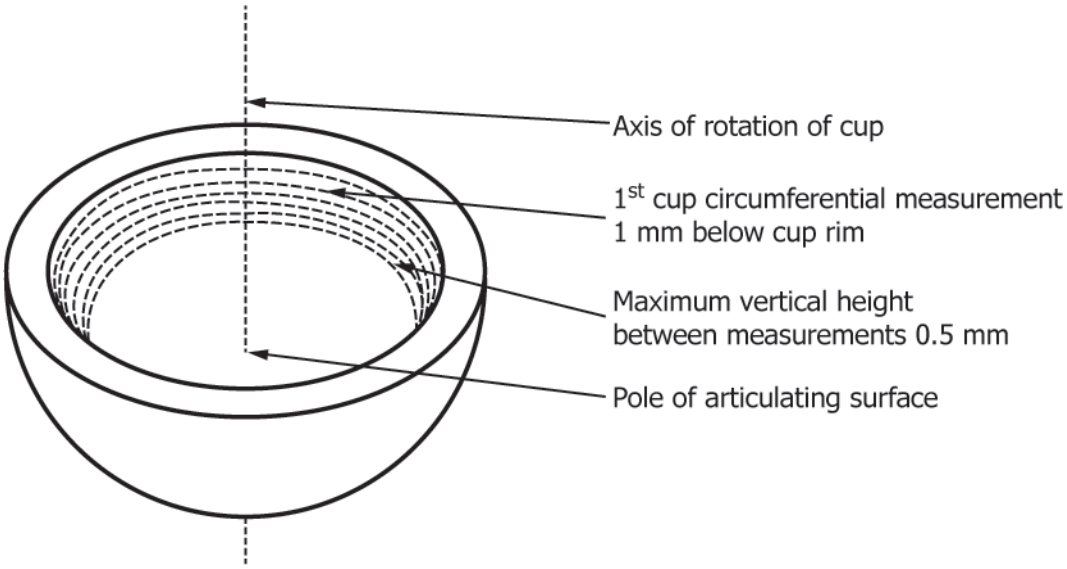

FIG. 4 Schematic Diagram Showing Location of Cup Circumferential Measurements

7.1.2.3 Mount the acetabular cup so that the cup rim plane is perpendicular to the spindle axis of rotation, and center the articulating surface with the spindle axis of rotation. Position the cup so that the measured polar profile is at a known angular location and can be co-registered with circumferential measurement.

7.1.2.4 Use the ~~auto centering~~ auto-centering routine to align the center of the articulating surface with the axis of rotation of the roundness machine spindle.

7.1.2.5 Align the stylus so that it is in the same horizontal plane as the cup pole.

7.1.2.6 Measure a partial roundness profile from the cup rim, through the pole, to the opposite cup rim.

NOTE 12—The measurement angle may have to be reduced for hemispherical acetabular hips to allow access for the recess stylus.

7.1.2.7 Repeat steps 7.1.2.4 to 7.1.2.6 and measure partial roundness profiles at a maximum of ~~10o~~10° intervals around the cup rim, as shown in Fig. 5.

7.1.3 *Femoral Head Measurement:*

7.1.3.1 Calibrate the radial position of the roundness machine radial arm.

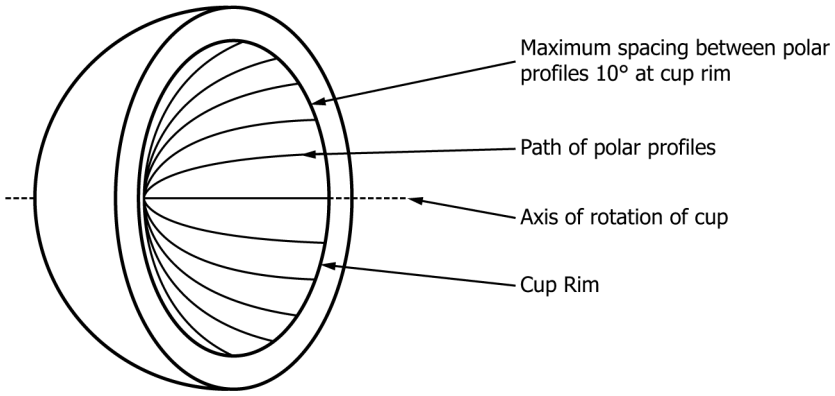

FIG. 5 Schematic Diagram Showing Location of Cup Polar Measurements