Designation: F3129 – 16

Standard Guide for Characterization of Material Loss from Conical Taper Junctions in Total Joint Prostheses[1]

This standard is issued under the fixed designation F3129; 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 surface and estimate the *in-vivo* material loss from the conical taper junctions, such as the femoral head/stem junction or adapter sleeve from explanted modular hip prosthesis, modular knee or shoulder joints. This guide is applicable to any articulating bearing material, stem material and conical taper size. The principles in this guide may be applied to other designs of taper junction, such as the modular stem/neck junction found in some hip joints.

1.2 This guide covers the measurement of the surface and estimation of depth of material loss and volume of material loss and taper geometry using a Roundness Machine (**1-4**), Coordinate Measuring Machine (CMM) (**5**) and Optical Coordinate Measuring Machine (**6**, **7**).[2] Other measurement equipment may be used to measure the surface 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.

NOTE 1—The maximum depth of material loss is sensitive to the number and spacing of data points.

1.3 The measurement techniques in this standard guide use measurements taken on the surface of the taper using stylus instruments. The material loss/corrosion mechanisms in the taper junction may lead to oxide layers or corrosion products deposited on the surface of the taper. These layers may lead to an underestimation of the volume of material loss.

1.4 The explants may have debris or biological deposits on the surfaces of the taper junctions. These deposits will prevent the measurement of the actual surface of the taper junction and their effect on the measurement must be considered when deciding the cleaning protocol. Normally, the taper surfaces will be cleaned before measurements are taken.

1.5 *This standard may involve hazardous materials, operations and equipment. As a precautionary measure, explanted devices should be sterilized or minimally 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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Referenced Documents

2.1 *ASTM Standards:*[3]

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

2.2 *ISO Standards:*[4]

ISO 12181-1-2003 Geometrical Product Specifications (GPS)—Roundness Part 1: Vocabulary and Parameters of Roundness

ISO 12181-2-2003 Geometrical Product Specifications (GPS)—Roundness Part 2: Specification Operators

ISO 4287:1997 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Terms, Definitions and Surface Texture Parameters

ISO 4287:1997/Cor 1:1998 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Surface and its Parameters

ISO 4287:1997/Cor 2:2005 Geometrical Product Specifications (GPS)—Surface Texture: Profile Method—Measurement of Surface Roughness Parameters

ISO 25178-2 Geometric Product Specifications (GPS)—Surface Texture: Areal—Part 2: Terms, Definitions and Surface Texture Parameters

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

[3] 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.

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

3. Terminology

3.1 *Definitions:*

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

3.1.2 *form deviations, n*—deviations from the nominal designed shape of the conical taper implants that are not the result of material loss. Form deviations may result from manufacturing tolerances, or due to deformation during implantation or revision procedures.

3.1.3 *iatrogenic damage, n*—damage induced inadvertently by surgeon during explantion of components.

3.1.4 *material loss, n*—deviations from the as-manufactured shape due to loss of material from the conical taper surfaces.

3.1.5 *maximum depth of material loss, n*—the maximum penetration normal to the taper surface due to *in-vivo* material loss mechanisms. The maximum depth of material loss would normally occur in a highly localized area, which may be significantly deeper than the surrounding area. The estimation of maximum depth of material loss is highly sensitive to the number and pattern of data point measured. There may be little correlation between the maximum depth of material loss and the volume of material loss from the surface.

3.1.6 *volumetric material loss, n*—the volume of material removed from the taper surface as a result of *in-vivo* material loss mechanisms.

4. Analysis Preparation

4.1 All components shall be cleaned in accordance with the procedure detailed in ASTM F561.

NOTE 2—Surface deposits of wear, corrosion or biological products on the surface of the as-manufactured regions will affect the accuracy of the estimated surface unless removed or excluded from the analysis.

4.2 The temperature of the analysis laboratory shall be maintained at 20°C ± 2°C. The components shall be maintained at the temperature of the analysis laboratory for at least 24 hours before the measurement to ensure dimensional stability.

4.3 *Apparatus*—3D Coordinate measuring machine or a CNC controlled Roundness Machine with automated centering and leveling procedure.

4.4 In order to measure axial profiles in the taper, the roundness machine must have the capability to measure "vertical straightness" profiles and "arcuate correction" to compensate for the arcuate motion of the stylus.

4.5 *Stylus*—The stylus acts as a morphological filter, mechanically filtering short wavelength roughness features from the measured surface profile. The use of a diamond stylus allows surface roughness to be simultaneously measured with form (with sufficient spacing of data points) **(8)**.

4.6 The stylus choice may introduce errors into the estimated material loss. The "imprinting' of microgrooves from the stem cone taper onto the head bore taper has been reported in the literature. This may lead to a "saw tooth" topography in the regions of material loss with an amplitude of tens of microns. If a ball stylus (rather than a diamond stylus used for surface topography measurements) is used, the stylus will not contact the bottom of the valleys which will lead to the volume of material loss being under estimated (Fig. 1). Furthermore, measurements with a point spacing of hundreds of microns will not resolve the surface topography and lead to an underestimation of the volume of material loss.

4.7 Generally, the location of material loss in explanted head bore taper will fall into two patterns; Type 1 (Fig. 2) and Type 2 (Fig. 3). In Type 1 pattern of material loss, the stem cone taper contacts the head bore taper in the center, which leaves as-manufactured surface at each end of the taper and the region material loss in the center. In Type 2 pattern of material loss, the stem cone taper contacts the head bore taper at one end of the head bore taper, which leaves as-manufactured surface at only one end of the taper and the region of material loss at the other. All other patterns of material loss can be classified as Type 3.

NOTE 3—Head bore tapers may not be a continuous cone to the bottom of the taper.

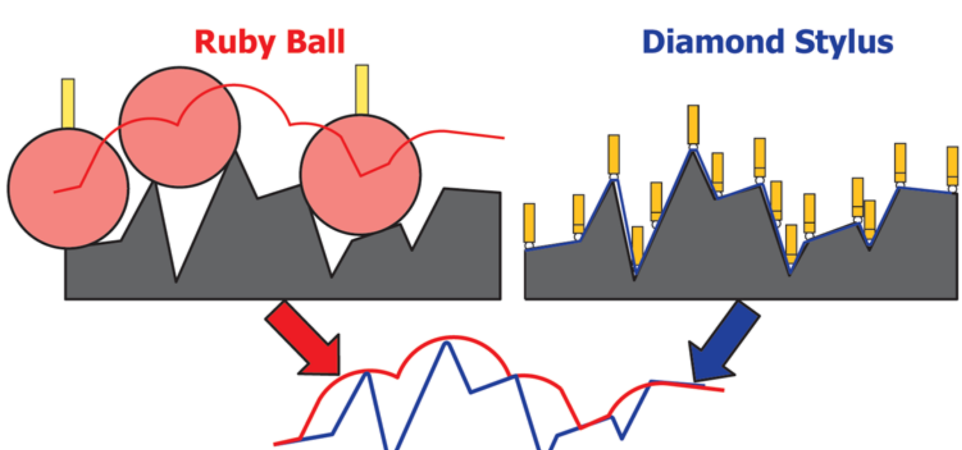


FIG. 1 Schematic Diagram Showing Ball Stylus Acting as a Morphological Filter Which May Lead to an Underestimation of the Material Loss from Taper Junctions

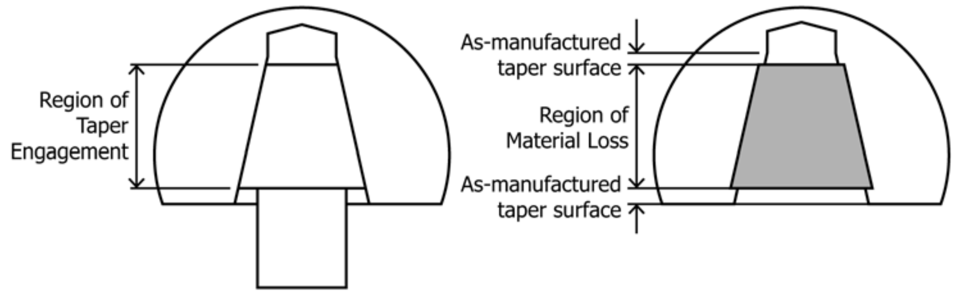


FIG. 2 Schematic Diagram Showing Type 1 Pattern of Material Loss from the Head Bore Taper. The stem cone taper contact is in the center of the head bore taper, leaving as-manufactured regions at each end of the head bore taper.

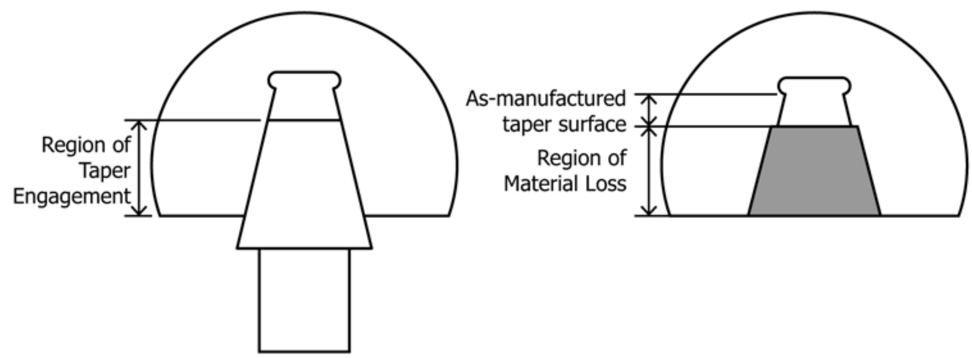


FIG. 3 Schematic Diagram Showing Type 2 Pattern of Material Loss from the Head Bore Taper. The stem cone taper contact at one end of the head bore taper, leaving as-manufactured regions at only one end of the head bore taper (this may occur at the mouth or throat end of the taper).

4.8 Bishop et al (**5**) described "asymmetric" and "axisymmetric" patterns of material loss in explanted heads. These patterns of material loss may be sub divisions of Type 1 and Type 2 material loss.

4.9 Generally, either the whole (Type 1) or most (Type 2) of the stem cone taper surface will have been in contact with the head bore taper taper. This may mean that there is no as-manufactured surface remaining to allow the as-manufactured shape to be estimated. However, it has been reported that explanted stems have "relatively little" material loss (**5, 9**) . Examination of the surface topography of the stem may allow identification of as-manufactured regions and regions of material loss.

4.10 Orthopaedic tapers are not normally intended to have line-to-line contact. Due to design intent or manufacturing tolerances, there is often an angular mismatch between the stem cone taper and head bore taper. This has been described as the taper angle clearance, which is defined as the difference between the head taper angle and stem taper angle (**10**). The taper angle is defined as twice the measured half angle of the geometric cone forming the taper. See Fig. 4.

5. Calibration of Roundness Machine and Alignment of Components

5.1 Calibrate the out of roundness machine according to manufacturer's instructions. When measuring tapers using the vertical axis of a roundness machine, the angle of the stylus relative to the gauge will change as the diameter of the taper changes. As the stylus pivots the effective beam length of the stylus is shortened giving rise to arcuate errors. These errors should be taken account of by using a set of calibration constants in the software that compensate for arcuate errors and other non-linearity errors. See Fig. 5

5.2 Verification of taper angle, straightness and roundness measurements: Use the measurement strategies in this standard to measure the angle, straightness and roundness of a reference taper gauge to verify the calibration of the roundness machine.

5.3 Align the taper axis of rotational symmetry with the spindle axis of rotation of the roundness machine using centering and leveling routines. Ensure that as-manufactured regions of the taper surface are used for alignment as the regions of material loss may not be concentric to the taper axis.

NOTE 4—If a large proportion of the taper surface has material loss or iatrogenic damage, then a ring (head) or plug (stem) gauge may be placed on top of the taper for the leveling procedure.

NOTE 5—The face must be perpendicular to the contact surface.

5.4 Nondestructively mark the retrieved taper axis component, or identify a landmark feature to provide an angular reference around the axis of rotational symmetry, so that the measured location of material loss can be co-registered with the position on the actual component. Set a height datum.

NOTE 6—It may not be possible to get an accurate measurement of a feature to set as height datum, especially if there is a large chamfer at the end of the taper. However, it should be possible to get an approximate height datum by aligning the stylus by eye with the top of the taper.

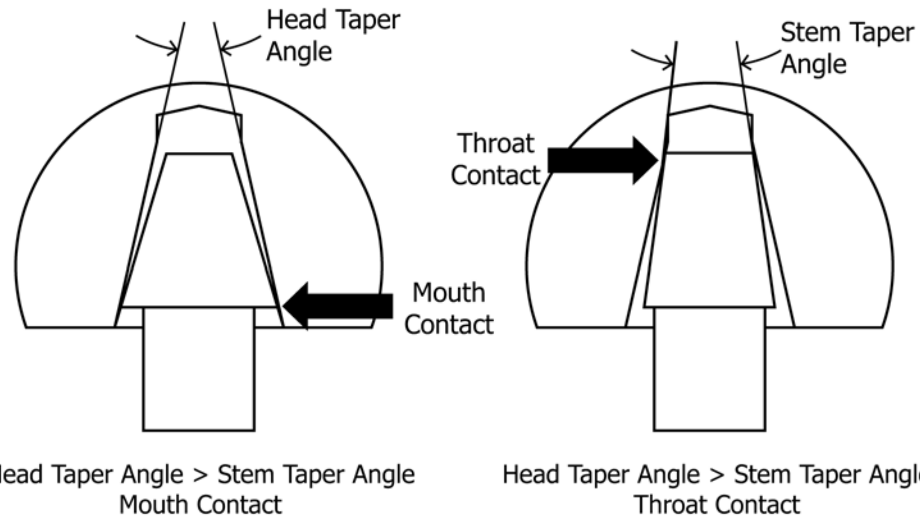


FIG. 4 Schematic Diagram of Head and Stem Taper Showing the Concept of Taper Angle Clearance

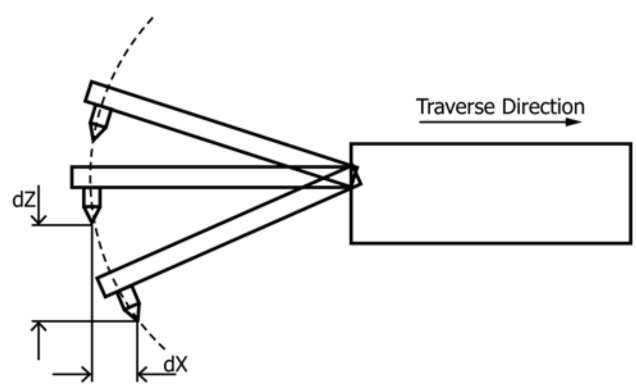


FIG. 5 Diagram Showing Change in Beam Length of Stylus Instruments, such as Roundness Machine Which Can Lead to Arcuate Errors in Measured Profile

6. Calibration of Coordinate Measuring Machine and Alignment of Components

6.1 Calibrate the CMM according to the manufacturer's instructions.

6.2 Verification of taper angle, straightness and roundness measurements: Use the measurement strategies in this standard to measure the angle, straightness and roundness of a reference taper gauge to verify the calibration of the roundness machine.

6.3 Align the taper axis of rotational symmetry with the coordinate system of the CMM. Ensure that as-manufactured regions of the taper surface are used for alignment as the regions of material loss may not be concentric to the taper axis.

NOTE 7—If a large proportion of the taper surface has material loss or iatrogenic damage, then a ring (head) or plug (stem) gauge may be placed on top of the taper to for the leveling or the top face of the stem taper and sleeve may be used as datum surfaces.

6.4 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 location of material loss can be co-registered with the position on the actual component. If possible set a vertical height datum.

7. Measurement of Taper Surface

7.1 The surface of the taper may be measured using axial profiles or circumferential profiles or a combination of both. The use of circumferential or axial profiles will allow individual profiles to be analyzed. For 3D measurements, other measurement strategies may be used.

7.2 *Circumferential Profiles*—Measure a series of 360° roundness profiles around the inner surface of the head bore taper inside the femoral head or the outer surface of the stem cone taper on the femoral stem as shown in Fig. 6. The measurements should extend as close to the base of the head taper as possible, without causing the stylus to contact the end of the taper.

NOTE 8—Some stem tapers may have a micro-grooved structure on the surface and "imprinting" of the microgrooves onto the head surface has been reported. These surfaces are highly anisotropic, and circumferential profiles will be almost parallel to these features. Generally these micro-groves are in the form of a helix and care must be taken to ensure that any circumferential measurements are not misinterpreted; in a circumferential profile, the stylus may cross a microgroove.

7.3 *Axial Profiles*—Measure a series of vertical straightness profiles from the base of the taper as shown in Fig. 7. For the roundness machine, ensure that the whole measurement can be

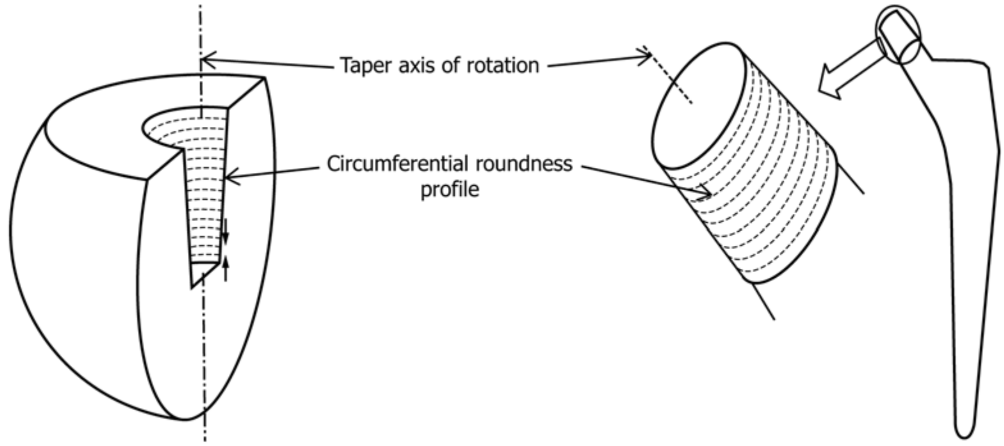


FIG. 6 Schematic Diagram Showing Circular Roundness Profiles for the Cylindricity Measurement. Head diagram is sectioned to illustrate position of measurement profiles.

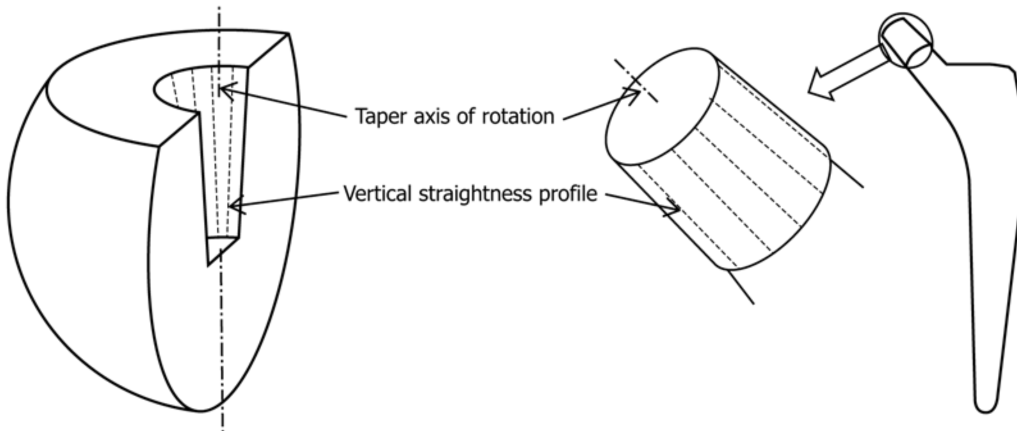


FIG. 7 Schematic Diagram Showing Vertical Straightness Profiles for Vertical Straightness Measurement. Head diagram is sectioned to illustrate position of measurement profiles.

captured within the range of the gauge of the instrument and that the gauge travel is equal on either side of zero for the gauge reading during that measurement.

7.4 During the development of the measurement protocol, a sensitivity study should be conducted to establish the optimum spacing of data points along each profile and between profiles to ensure a reliable estimation of depth of material loss, volume of material loss and taper geometry.

NOTE 9—For surface roughness measurements, the minimum point spacing along the profiles should be calculated according to ISO 4287.

7.5 *Optional Surface Topography*—The surface topography of the taper surfaces may provide further information to help understand the mechanisms that lead to material loss. The surfaces of the tapers may be highly anisotropic (i.e., the surface topography is dependent on direction) as a result of the manufacturing processes, especially in the case of "micro-grooved" surfaces.

7.6 Limited areas of surface topography may be measured or visualized with instruments such as SEM, White Light Interferometry or optical laser.

7.7 With some measuring instruments it may be possible to measure the surface topography of the whole taper surface and produce topography maps. These maps will show the areas of material loss and surface topography in one plot. Graphical illustrations of the taper surface, depth of material loss and topography can be produced from analysis of these measurements.

8. Analysis of Taper Data Points

8.1 Visual inspection or inspection with microscope of the taper surfaces is essential to the interpretation of the measured data.

8.2 The pattern and regions of material identified from the measured profiles or 3D surface maps shall be visually co-registered with the pattern of material loss on the surface of the taper to ensure that the as-manufactured regions are correctly identified.

8.3 The analysis of the tapers by fitting least squares lines to the axial profiles, least squares circle to the circumferential profiles and a perfect cone to the 3D data assumes that the tapers have no form deviations. Ideally, new components should be measured to verify this assumption. Regions of material loss should not be included in the estimation of the as manufactured surface.

9. Analysis of 2D Circumferential Profiles

9.1 The as-manufactured regions and regions of material loss from each profile must be identified—visible co-registration with the taper surface from the explanted components is essential.

9.2 The circumferential profiles shall be analyzed in conjunction with axial profiles; circumferential profiles may not identify a symmetric material loss pattern and axial profiles may be required to identify the regions of material loss.

9.3 For asymmetric material loss patterns, the regions of material loss should be identified and a least squared circle fitted through the as-manufactured regions as an estimate of the as-manufactured surface according to ISO 12181.

NOTE 10—The user must ensure that this method is repeatable, the as-manufactured regions are correctly identified, any regions of surface deposits or iatrogenic damage are excluded and that the resultant fitted circle is an accurate estimation of the as-manufactured surface of the taper.

9.4 The maximum depth of material loss is the maximum deviation between the measured profile and least squares circle in all measured profiles. The maximum depth of material loss would normally occur in a highly localized area, which may be significantly deeper than the surrounding area. The estimation of maximum depth of material loss is highly sensitive to the number and pattern of data point measured. There may be little correlation between the maximum depth of material loss of the volume of material loss from the surface.

9.5 The taper angle may be estimated by plotting the relative radius of the least squares circle fitted to each profile and the vertical height. The taper angle can be then be estimated for the gradient of the least squares line fitted through the points (**10**). Regions of material loss should not be included in the estimation of the taper angle.

10. Analysis of 2D Axial Profiles

10.1 The regions of material loss and as-manufactured regions from each profile must be identified. Visible co-registration with the taper surface from the explanted components is essential.

10.2 A least squared line can be fitted through the as-manufactured regions of the axial profile to estimate the as-manufactured surface of the taper.

NOTE 11—If the material loss is Type 2 pattern (i.e., there is only a single as-manufactured region on the surface of the taper) the estimation of the as-manufactured surface by fitting a line to the as-manufactured region is extremely sensitive to surface deposits, other deviations and the length of the as-manufactured region. If the length of the as-manufactured region used for the fit is short relative to the total length of the profile, large errors may occur.

NOTE 12—The location of the as-manufactured region relative to the whole measured profile may also have a large effect on the error. Fig. 8 shows an example of a profile where the least squares line is only fitted to one as-manufactured region representing a Type 2 pattern of material loss (the other as-manufactured region is retained to illustrate the errors in the fit of the least squares line to estimate the as-manufactured shape). If possible, a mathematical algorithm should be used to remove "outlying" points from the as-manufactured region to remove surface deposits or pits from the surface.

NOTE 13—For roundness machines without arcuate correction, there may be a form introduced into the axial profiles of several microns in amplitude which must not be confused for material loss or manufacturing form deviations.

10.3 The geometry of the region of material loss (length, depth and cross sectional area) scar can be measured from the vertical straightness profile.

10.4 Surface topography may be analyzed according to guidelines in ISO 4287 for the whole vertical straightness profile, or for segments of the profile, for example from the as-manufactured regions or regions of material loss.

NOTE 14—The operator must be aware of the effect of filtering on the surface topography features of the surface, and select the cutoff lengths accordingly.

10.5 The taper angle can be measured directly from the vertical straightness profiles (only for roundness machines with arcuate correction or CMMs) from the angle between the least squares line of best fit representing the as-manufactured surface and part datum axis.

NOTE 15—The column axis or axis of rotation may be used, but this may introduce errors for components which are not perfectly leveled

10.6 The measured taper angle should be averaged from a number of equally spaced vertical straightness profiles around the taper to cancel out the effects of any angular misalignment. A sensitivity study should be performed.

11. Estimation of Volume of Material Lost from Taper Surface

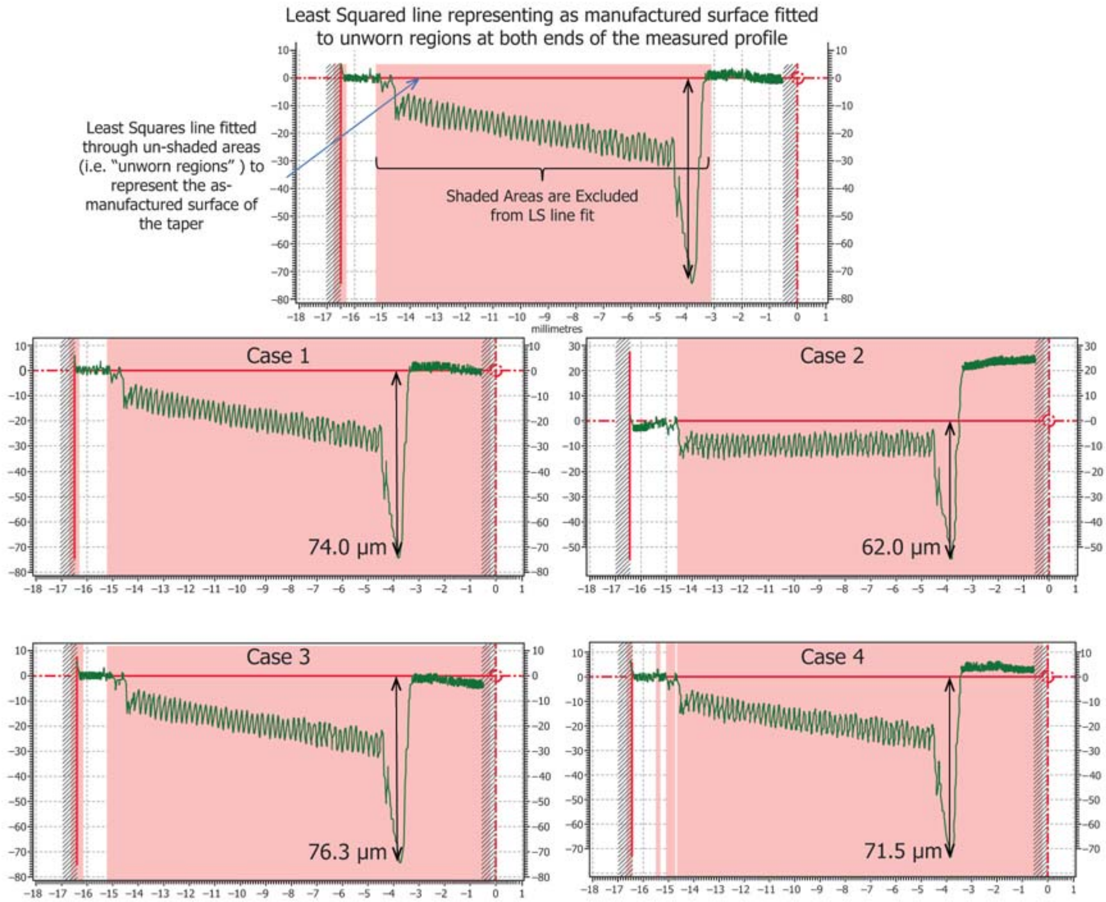
11.1 The volume of material lost from the surface of the taper may be estimated from deviation between the estimated as-manufactured shape of the taper and the measured surface of the taper.

11.2 The volume of material loss may be estimated from 2D axial profiles: the area of the material loss can be split into a series of 3D annuli and the volume of each partial annulus calculated and totaled to calculate the total volume of material lost (**1, 2**).

11.3 An alternative method is to use the 3D point cloud of measured data points from either the roundness machine or coordinate measuring machine. A cone can be fitted to the as-manufactured regions through an iterative process to exclude the data points furthest away from the estimated as-manufactured surface (**5**). Care must be taken to exclude positive points (which may result from biological or other surface deposits) and negative points which may result from material loss. A numerical iteration may be used to optimize the fitting of a cone to the as-manufactured regions and exclude the data points that are within the regions of material loss or regions of surface deposits within the as-manufactured regions.

11.4 Inspect the graphical material loss plots to ensure that the estimated as-manufactured shape is reasonable. The range of colors should be optimized to allow visualization of the cone fit to the as-manufactured region not the depth of material loss.

11.5 Use a numerical integration method to estimate the volume of material lost from the surface of the taper from the difference between the estimated as-manufactured surface and the measured data points. Estimate the maximum depth of material loss from the greatest deviation between any measured data point in the region of material loss and the estimated



NOTE 1—The shaded areas are excluded from the fit of the least squares line representing the as-manufactured shape. A profile from a head with as-manufactured regions at each end of the taper is used in this example (with one as-manufactured region always excluded) to illustrate the magnitude of errors that may occur.

FIG. 8 Example of Errors That Can Occur in the Location of the Least Squares Line Resulting from Surface Deposits and Other Irregularities in the As-Manufactured Regions

as-manufactured shape of taper. The maximum depth of material loss would normally occur in a highly localized area, which may be significantly deeper than the surrounding area. The estimation of maximum depth of material loss is highly sensitive to the number and pattern of data point measured. There may be little correlation between the maximum depth of material loss of the volume of material loss from the surface.

11.6 The as-manufactured taper angle may be estimated from the cone angle of the estimated as-manufactured surface.

12. Report

12.1 Include in the material loss report:

12.1.1 Type and model of the instrument used for measurement.

12.1.2 Details and date of calibration, and identity of calibration artifact.

12.1.3 The component type, manufacturer, serial number, and lot number.

12.1.4 Details of any pre-measurement verification measurements.

12.1.5 The pattern of material loss (Type 1 or Type 2).

12.2 *For 2D Profiles:*

12.2.1 Graphical illustration of the location and shape of the region of material loss.

12.2.2 The maximum depth of material and the volume lost for the taper.

12.2.3 The rate of material lost per year (depth and volume).

12.2.4 Angle of taper (if applicable).

12.2.5 Dimensions of the region of material loss.

12.2.6 Surface topography analysis (if applicable).

12.3 *For 3D Measurement:*

12.3.1 Graphical illustration of the location and shape of the region of material loss.

12.3.2 Graphical illustration of the fit of estimated as-manufactured shape to the as-manufactured regions.

12.3.3 The maximum depth of material and the volume of material lost from the taper.

12.3.4 The rate of material lost per year (depth and volume).

12.3.5 Angle of taper (if applicable).

12.3.6 Dimensions of region of material loss.

13. Precision and Bias

13.1 The precision and bias associated with this estimation of material loss protocol have not been established.

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