



Designation: F3129 – 24

Standard Guide for Characterization of Material Loss from Conical Taper Junctions in Total Joint Prostheses¹

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 features, such as hills and valleys, and to 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 includes information on how to perform measurements using a Roundness Machine (1-4), Coordinate Measuring Machine (CMM) (5), and Optical Coordinate Measuring Machine (6, 7).² Other equipment may be used to estimate material loss if the equipment is reliable and accurate enough to provide comparable estimates to the aforementioned equipment.

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

1.3 The measurement techniques described in this standard guide use measurements taken on the surface of the taper using contact stylus and/or optical instruments. The mating materials and geometries in the taper junction can have changed in form, structure, and composition during use. These changes will impact any final estimation. In addition, any estimation of original surface form will also impact any final estimation of material loss. The material loss/corrosion mechanisms in the taper junction can lead to oxide layers or corrosion products on the surface of the taper. These layers can lead to an underestimation of the volume of material loss.

1.4 The explants can have debris or biological deposits on the surfaces of the taper junctions. These deposits can prevent the measurement of the surface of the taper junction, and their

effect on the measurement must be considered when deciding the cleaning protocol.

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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.6 *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:³

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

2.2 ISO Standards:⁴

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

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

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

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

¹ This 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.

Current edition approved Oct. 1, 2024. Published October 2024. Originally approved in 2016. Last previous edition approved in 2016 as F3129 – 16. DOI: 10.1520/F3129-24.

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 www.astm.org/contact. 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>.

Surface Texture Parameters

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 can result from manufacturing methods, or due to deformation during implantation or revision procedures.

3.1.3 *iatrogenic damage, n*—damage induced during explantation and handling of components.

3.1.4 *material loss, n*—estimation of material removed from estimated original surface and not including iatrogenic damage 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 excluding iatrogenic damage. The maximum depth of material loss can occur in a highly localized area, which can 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 points measured. There can 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 estimated volume of material removed from the taper surface as a result of the measurements and analysis completed.

4. Analysis Preparation

4.1 Careful consideration and review of Practice F561 should be done prior to deciding whether or not any cleaning of the taper surfaces is performed.

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

4.2 The temperature of the analysis laboratory shall be maintained at $20\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$. The components shall be main-

tained at the temperature of the analysis laboratory for at least 24 h 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 can introduce errors into the estimated material loss. The “imprinting” of microgrooves from the stem cone taper onto the femoral head bore taper has been reported in the literature. This can lead to a “sawtooth” 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 underestimated (Fig. 1). Furthermore, measurements with a point spacing of hundreds of microns will not resolve the surface topography and can lead to an underestimation or overestimation of the volume of material loss.

4.7 Generally, the location of material loss in explanted femoral 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 femoral head bore taper in the center of the taper length, which leaves as-manufactured surface at each end of the taper and the region of material loss in the center. In Type 2 pattern of material loss, the stem cone taper contacts the femoral head bore taper at one end of the femoral 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.

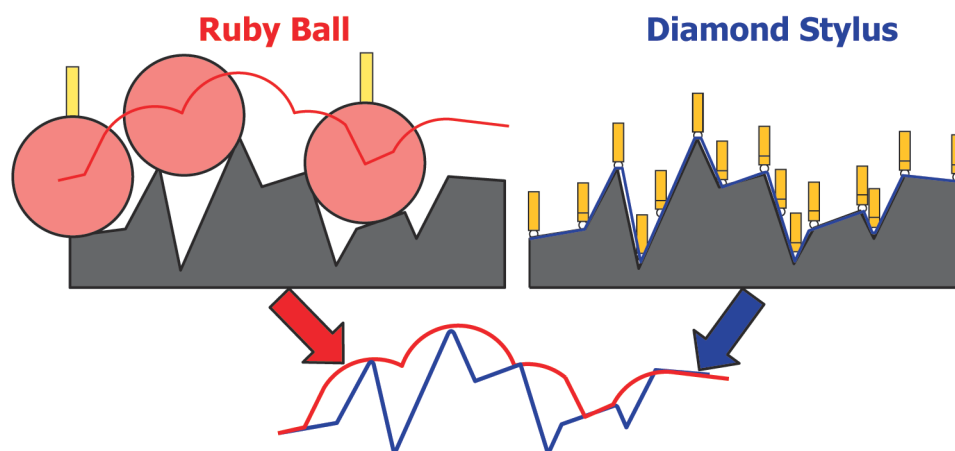


FIG. 1 Schematic Diagram Showing Ball Stylus Acting as a Morphological Filter Which Can Lead to an Underestimation of the Material Loss from Taper Junctions

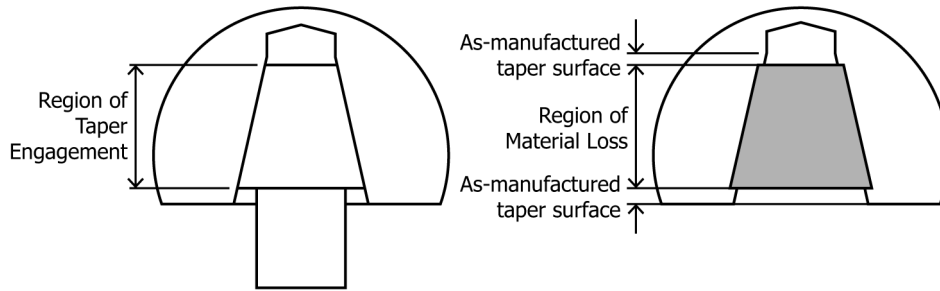


FIG. 2 Schematic Diagram Showing Type 1 Pattern of Material Loss from the Femoral Head Bore Taper. The stem cone taper contact is in the center of the femoral head bore taper, leaving as-manufactured regions at each end of the femoral head bore taper.

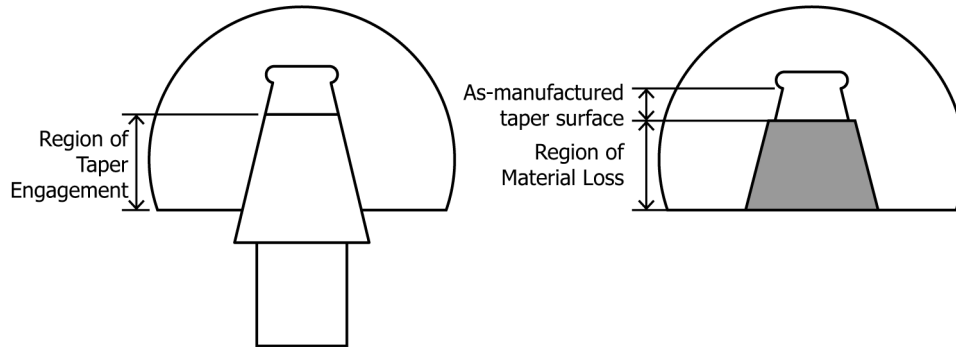


FIG. 3 Schematic Diagram Showing Type 2 Pattern of Material Loss from the Femoral Head Bore Taper. The stem cone taper contact is at one end of the femoral head bore taper, leaving as-manufactured regions at only one end of the femoral head bore taper. (This can occur at the mouth or throat end of the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

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

4.8 Bishop et al. (5) described “asymmetric” and “axisymmetric” patterns of material loss in explanted femoral heads. These patterns of material loss can be subdivisions 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 femoral head bore taper. This can 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 can 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 femoral stem cone taper and femoral head bore taper. This has been described as the taper angle clearance, which is defined as the difference between the femoral 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 nonlinearity 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 taper axis.