



Standard Test Method for Determining Femoral Head Penetration into Acetabular Components of Total Hip Replacement Using Clinical Radiographs¹

This standard is issued under the fixed designation F 2385; 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 test method provides guidance for the measurement of the relative displacement of the femoral head and acetabular component that result from wear and deformation occurring at the articular interface of a total hip replacement from sequential clinical radiographs.

1.2 This test method is primarily intended for use in evaluating patients receiving THRs composed of a polyethylene acetabular component articulating against a metal or ceramic femoral head.

1.3 So-called hard-on-hard articulations such as metal-on-metal and ceramic-on-ceramic THRs are not intended to be directly addressed.

1.4 This test method will focus on computer assisted computational methodologies for measuring relative displacements over time but not to the exclusion of other methodologies.

1.5 This test method describes methods for conducting a radiographic wear/creep study utilizing various computational methods and is not intended to promote or endorse a particular method.

1.6 It is not the intent of this test method to provide detailed instructions in the use of the various computational methods, which is contained in the respective user manuals.

1.7 It is the intent of this test method to enable comparisons of relative displacements occurring in groups of patients receiving different formulations of bearing materials. It must be recognized, however, that there are many possible variations in the *in vivo* conditions. A single clinical study may not be universally representative.

1.8 This test method is not intended to be a performance standard. It is the responsibility of the user of this test method to characterize the safety and effectiveness of the prosthesis under evaluation.

1.9 The values stated in SI units are to be regarded as the standard, with the exception of angular measurements, which may be reported in either degrees or radians.

1.10 *The use of this standard may involve the operation of potentially hazardous radiographic equipment and does not purport to address the safety precautions associated with radiography. It is the responsibility of the user of this standard to define and establish appropriate safety practices. The standard does not determine the applicability of regulatory limitations prior to operating radiographic equipment.*

1.11 *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:²

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method

3. Terminology

3.1 All radiographic terminology is consistent with the referenced standards, unless otherwise stated.

3.2 Definitions:

3.2.1 *radiostereometric analysis (RSA)*—a method developed by Goren Selvik for measuring relative motion between two parts from clinical radiographs (1).³ This method utilizes *in vivo* tantalum beads, an external reference cage, and two x-ray generators which take two exposures simultaneously. There are several commercially available software/hardware packages for RSA analysis.

3.2.2 *markers*—tantalum beads 1.0 mm, 0.8 mm, or 0.5 mm in diameter.

3.2.2.1 *implant markers*—*in vivo* markers placed on the implant in order to define the implant as a rigid body.

¹ This test method 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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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 The boldface numbers in parentheses refer to the list of references at the end of this standard.

