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Standard Test Method for Determining Femoral Head Penetration into Acetabular Components of Total Hip Replacement Using Clinical Radiographs[1]

This standard is issued under the fixed designation F2385; 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]

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

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.

[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.

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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.

3.2.2.2 *cage markers*—tantalum beads held in an external reference frame used to create a three dimensional coordinate system for measuring relative displacements.

3.2.2.3 *segment*—a three dimensional rigid body defined by a minimum of three markers.

3.2.3 *edge detection*—method of image analysis used to determine the two dimensional or three dimensional center point of a curved surface. Many computational methods of edge detection exist.

3.2.4 *coordinate system/axes*—three orthogonal axes are defined as follows:

3.2.4.1 *origin*—the center of the coordinate system is located at either the geometric center of the acetabular component segment or the center of a circle defined using the edge of the acetabular component.

3.2.4.2 *X-axis*—the positive X-axis is to be directed in the medial direction independent of which hip is to be studied. Some software programs correct the sign of this value but the user must insure that the protocol maintains the convention, (that is, which way is the patient facing).

3.2.4.3 *Y-axis*—the positive Y-axis is to be fixed in the superior direction.

3.2.4.4 *Z-axis*—the positive Z-axis is to be fixed in the posterior direction.

3.2.5 *radio pair*—one set of RSA radiographs which were taken simultaneously.

3.3 There are a number of computational methods that can be used to measure creep/wear of a polyethylene component. A description of a few of the commonly used current methods is given. This is not meant to be at the exclusion of other methods.

3.3.1 *Martell method*—as this software is informally referred to in reference to its developer Dr. John Martell of Chicago University, is a semi-automated computer technique using edge detection and the Hough transformation for the determination of polyethylene wear. This technique uses sequential A/P films for two dimensional analysis and A/P and lateral sequential films for three dimensional analysis (**2**).

3.3.2 *Polywear method*—a software program developed by Dr. Peter Devane of the Wellington School of Medicine, New Zealand is a semi-automated computer technique using edge detection for the determination of polyethylene wear. This technique uses sequential A/P films for two dimensional analysis and A/P and lateral sequential films for three dimensional analysis (**3**).

3.3.3 *UmRSA*—an RSA software program developed by Biomedical Innovations AB in Umea Sweden. It utilizes sequential radio pairs in order to measure relative displacements between two segments or a point relative to a segment. It utilizes a model based edge matching method for determining the center of the markers (**4**).

3.3.4 *CMS-RSA*—an RSA software program developed at the University of Leiden, Sweden. It utilizes sequential radio pairs in order to measure relative displacements between two segments (**5**).

4. Significance and Use

4.1 This test method uses clinical radiographs of the hip joint of a patient that has received a total hip replacement to measure the combined effect of plastic deformation and wear at the articular interface which results in three dimensional displacements of the femoral head into the acetabular component.

4.2 This test method addresses the validation of the various computational methods available for measuring the magnitude of creep/wear accruing at the articular surface of THRs.

4.3 This test method addresses the type of radiographic projections needed for an analysis as well as general radiographic parameters needed for obtaining high quality films.

4.4 This test method addresses the criterion for evaluating clinical radiographs for inclusion in a study.

4.5 This test method addresses the conversion of radiographic images to the appropriate digital format needed for the various computer assisted computational methods.

5. Validation

5.1 A physical phantom model which is capable of replicating the three dimensional displacement of the femoral head at magnitudes of displacements that are expected to occur clinically should be used to validate new software programs, modifications to existing programs, and variations to the experimental protocol which may effect the results of the measurements. A recent publication describes such a phantom and its use (**6**). Figs. 1 and 2 show an example of a model which can be used for this purpose. For comparative purposes, the method described by Bragdon et al (**6**) for calculating accuracy and precision can be used. Illustrative values for the accuracy and precision as measured by this method are listed in the appendix.

5.2 To generate data for a precision and bias statement, the Practice E177 should be followed.

6. Material

6.1 *Non-RSA Methods of Obtaining Clinical Radiographs for Measuring Femoral Head Penetration:*

6.1.1 These methods utilize an Anterior/Posterior (A/P) and a cross-table lateral projection of the pelvis. The A/P projection is used for measuring two dimensional penetration vector. The cross-table lateral is used to determine the magnitude and direction of the three dimensional penetration vector.

6.1.2 These radiographs are typically taken in the supine position. However, the A/P projections can be obtained from the standing position. The method must be consistent throughout the subsequent examinations.

6.1.3 The A/P projection is to be pubic centered including both hips, typically taken using a 14 by 17 film or larger size.

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