Designation: F2385 – 15

Standard Practice 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 practice 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 practice 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 practice will focus on computer assisted computational methodologies for measuring relative displacements over time but not to the exclusion of other methodologies.

1.5 This practice 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 practice 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 practice 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 practice is not intended to be a performance standard. It is the responsibility of the user of this practice 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. Additionally, pixel density may also be reported in imperial units.

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.

[1] This practice 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.

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.

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 practice 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 practice 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 practice 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 practice addresses the criterion for evaluating clinical radiographs for inclusion in a study.

4.5 This practice 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 affect 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

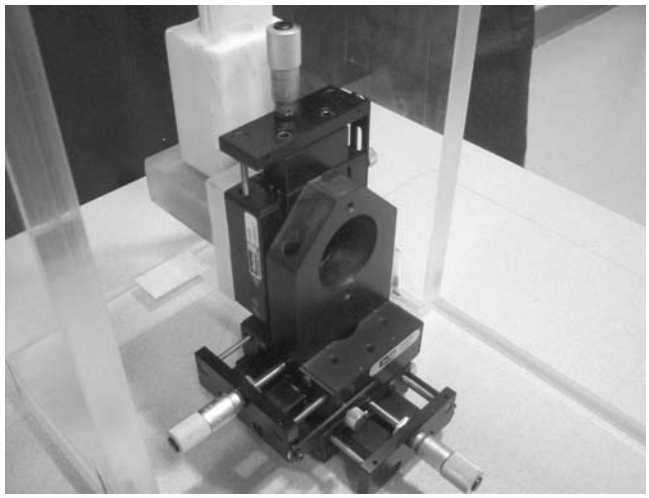
6.1 *Non-RSA Methods of Obtaining Clinical Radiographs for Measuring Femoral Head Penetration:*

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 target size.

FIG. 1 Phantom Model Capable of Moving the Femoral Head by Small Discrete Three Dimensional Displacements



NOTE 1—The displacement mechanism is made of three stages purchased from Edmund Industrial Optics Catalog.

FIG. 2 Medium 2.62 in. Square Linear Translation Stages (xyz)

As a general rule, having the top of the iliac crest and the lesser trochanter of the femur visible results in a proper radiographic projection.

6.1.3.1 A typical radiographic set-up would have a source to plate distance of 101.6 cm (40 in.) and an exposure setting of 80 kV 25-30 mA-s.

6.1.4 The cross-table lateral is obtained in the supine position.

6.1.4.1 A typical radiographic set-up would have a source to plate distance of 101.6 cm (40 in.) and an exposure setting of 80 kV 25-30 mA-s.

6.1.5 Some non-RSA methods have been validated for the use of ninety degree standing oblique radiographs of the hip.

6.1.5.1 A method of accurately and reproducibly positioning the patient for forty five degree oblique projections is needed. One method, using a positioning chariot, has been described. Other methods could be employed for this purpose.

6.1.5.2 A typical radiographic set-up would have a source to plate distance of 101.6 cm (40 in.) and an exposure setting of 85 kV 40-50 mA-s.

6.2 *RSA Method of Obtaining Clinical Radiographs for Measuring Femoral Head Penetration:*

6.2.1 These radiographs can be taken in the supine or standing position. The method must be consistent throughout the subsequent examinations.

6.2.2 The radiographic set-up for RSA analysis requires two x-ray generators which are discharged nearly simultaneously.

6.2.3 The preferred set-up would use two fixed generators.

6.2.4 A more common set-up uses one fixed and one portable generator.

6.2.5 The generators are positioned having a 152.4 cm (60 in.) source to plate distance and angled at 40 degrees. The set-up recommended by the individual software manufacturers is to be followed.

6.2.6 Radiographic settings for the RSA projections focus on obtaining high contrast between the tantalum markers and the surrounding bone and metal. This is accomplished by using high voltage settings. These films are not generally used for clinical evaluation.

6.2.7 A typical radiographic set-up would have an exposure setting of 150 kV 8-12 mA-s.

6.2.8 Many portable x-ray units and some fixed units are not capable of operating at 150 kV. In these situations, settings of 125 kV and 12-16 mA-s can be used.

6.3 *Conversion of Radiographic Images to Appropriate Digital Format:*

6.3.1 *Scanning of Plain Radiographic Films:*

6.3.1.1 Several flat bed scanners have been validated by different software developers for use in converting a plain radiograph into a digital image. Recommendations of the software developer should be followed.

6.3.1.2 Roller scanners, which feed multiple pages into the scanner, shall not be used.

6.3.1.3 Non-RSA films are to be scanned at a resolution of 150 dpi at a grayscale resolution of 8 bit and saved in a TIFF format.

6.3.1.4 RSA films scan resolution varies among software manufacturers. Some require a 300 dpi/16 bit image while others require 150 dpi/8 bit image. All require a TIFF format.

6.3.2 *Conversion of DICOM Formatted Radiographs:*

6.3.2.1 An appropriate DICOM reader is necessary for this process.

6.3.2.2 The resolution, gray scale, and file format should be as described above.

6.3.2.3 The dpi of DICOM formatted films are limited by the hardware used to acquire the image. The output from a given center must be checked.

6.3.2.4 Generally, computer radiographic units have a standard resolution and a high resolution setting which must be selected at the time the images are acquired.

6.4 *Radiographic Exclusion Criterion:*

6.4.1 *Non-RSA Computational Methods:*

6.4.1.1 These methods are sensitive to changes in the position of the acetabular socket relative to the beam center. For an individual patient, to minimize unreliable penetration calculations over sequential examinations, variations in the acetabular position should be minimized.

6.4.1.2 For a given patient examination, the projection of the hip socket in the sequential examinations must fall within the same region of the radiograph, preferably in the middle third of the film. Projections which all fall within the top or bottom third of the film are also usable.

6.4.1.3 Repeated examination of one film using the chosen software should result in similar values of reported distance between the center of the cup and the center of the head. Unstable results indicate a poor image quality and the examination should be excluded.

NOTE 1—Different software programs may have techniques available for coping with poor quality films such as manual edge selection. These techniques must be used with caution and their frequency of use must be reported.

6.4.2 *RSA Computational Methods:*

6.4.2.1 RSA software analysis programs give several quality control values which are to be used to determine an exclusion criterion for a particular film set.

6.4.2.2 The condition number gives an indication of the sufficiency of scatter of the patient markers (**7**). Generally, condition number values lower than 150 are acceptable.

6.4.2.3 Mean error of rigid body fitting gives an indication of how well the relationship of a group of beads compares between examinations. A value of 0.2 or less is generally acceptable.

6.4.2.4 A minimum of the same three visible markers in each projection and between film pairs must be present in order to perform an RSA calculation.

6.4.2.5 Some software packages allow for the assignment of the center point of the acetabular shell to be assigned as an implant marker when only two implant markers are available. The use of this point will affect the results of the quality control parameters.

7. Report

7.1 The pertinent quality control parameters which are reported from a particular software package should be reported.

7.2 The number of patients excluded from a radiographic wear study should be reported along with the reason for exclusion.

7.3 The average and standard deviation of the penetration values should be reported.

7.4 When appropriate, the magnitude of the penetration should be normalized to time and reported as a penetration rate.

7.5 Results of a power analysis should be reported when appropriate.

7.6 Depending on the study design, the appropriate statistical analysis should be reported. There are many manuals designed to guide the researcher in the use of statistics, such as the book entitled “Practical Statistics for Medical Research” (**8**).

8. Precision and Bias

8.1 No precision and bias statement has been established at this time.

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 A number of methods have been established for performing measurements of femoral head penetration into the polyethylene acetabular components used in total hip replacements from clinical radiographs. The purpose of test standard is to document the test parameters which are necessary to perform a clinical evaluation of head penetration (an indirect measurement of the wear of the polyethylene).

X1.2 For clarity of reporting directions of wear when right and left hips are involved, an anatomical rather than a right handed coordinate system is used.

X1.3 The document describes methods for conducting a radiographic wear/creep study utilizing various computational methods and is not intended to promote or endorse a particular method.

X1.4 The various computer assisted computational methodologies can be divided into two families, one using internal and external reference points and the other using only the radiographic projection of the implants. When appropriate, guidance specific to one family or the other has been provided.

X1.5 Relative two dimensional and three dimensional displacements between the femoral head and the acetabular component are assessed from sequential radiographs over time.

X1.6 Validation of new methods of measuring femoral head penetration is necessary when existing data is not available in the peer reviewed literature.

X1.7 Experimental validation by determining the accuracy and precision of the method is described in Section 5. Experimental accuracy and precision values for an existing RSA

system have been reported using this method and are listed in the following table:

	X Medial	Y Superior	Z Posterior	Resultant
Accuracy, μm	±36	±22	±41	±35
Precision, μm	±7	±6	±12	±9

X1.8 Experimental accuracy and precision for the Martell semi-automated method have also been reported and are listed in the following table:

	2-D Vector	3-D Vector
Accuracy, μm	±74	±60
Precision, μm	±23	±22

X1.9 The values listed above are examples from the literature and are not to be used as reflecting a full literature review of any one method.

X1.10 Clinical validation of new methods can also be performed by comparing the results derived from the use of existing methods and a new method using the same patient data set.

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