



Designation: F2996 – 24

# Standard Test Method for Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems<sup>1</sup>

This standard is issued under the fixed designation F2996; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

## 1. Scope

1.1 This standard establishes requirements and considerations for the numerical simulation of non-modular (that is, limited to monolithic stems with only a femoral head/trunnion taper interface) metallic orthopaedic hip stems using Finite Element Analysis (FEA) techniques for the estimation of stresses and strains. This standard is only applicable to stresses below the yield strength, as provided in the material certification.

1.2 *Purpose*—This test method establishes requirements and considerations for the development of finite element models to be used in the evaluation of non-modular metallic orthopaedic hip stem designs for the purpose of prediction of the static implant stresses and strains. The context of use is to apply the finite element method to identify the worst-case size within a series of different sizes of the same implant design and to subsequently test that worst-case size (as is typically required). Recommended procedures for performing model checks and verification are provided to help determine if the analysis follows recommended guidelines. Finally, the recommended content of an engineering report covering the mechanical simulation is presented.

1.3 *Limits*—This test method is limited in discussion to the static structural analysis of non-modular metallic orthopaedic hip stems (which excludes the prediction of fatigue strength).

1.4 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.5 *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 standard-*

*ization 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 *ISO Standards:*<sup>2</sup>

[ISO 7206-4 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 4: Determination of Endurance Properties and Performance of Stemmed Femoral Components](#)

2.2 *FDA Guidance Document:*<sup>3</sup>

[Reporting of Computational Modeling Studies in Medical Device Submissions](#)

2.3 *ASME Standard:*<sup>4</sup>

[V V 40 Assessing Credibility of Computational Modeling and Simulation Results Through Verification and Validation: Application to Medical Devices](#)

## 3. Significance and Use

3.1 This standard is applicable to the calculation of stresses seen on a femoral hip stem when loaded in a manner described in ISO 7206-4. This method can be used to establish the worst-case size for a particular implant. When stresses calculated using this method were compared to the stresses measured from physical strain gauging techniques performed at two laboratories using two different methods, the results correlated to within 8 %.

3.2 This test method can be used to estimate the effects of design variables on the stress and strain of metallic hip femoral stems in a setup mimicking that described in ISO 7206-4.

## 4. System Configurations

4.1 Finite element models are based on a geometric representation of the device being studied. The source of the

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<sup>2</sup> Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland, <http://www.iso.org>.

<sup>3</sup> Available from U.S. Food and Drug Administration (FDA), 10903 New Hampshire Ave., Silver Spring, MD 20993, <http://www.fda.gov>.

<sup>4</sup> Available from American Society of Mechanical Engineers (ASME), ASME International Headquarters, Two Park Ave., New York, NY 10016-5990, <http://www.asme.org>.

geometric details can be obtained from drawings, solid models, preliminary sketches, or any other source consistent with defining the model geometry. In building the finite element model, certain geometric details may be omitted from the orthopaedic implant geometry shown in the computer-aided design (CAD) model if it is determined that they are not relevant to the intended analysis. Engineering judgment shall be exercised to establish the extent of model simplification and shall be justified.

4.2 It is most appropriate to consider the “worst-case” stress condition for the orthopaedic implant being simulated. The “worst-case” shall be determined from all relevant engineering considerations, such as stem geometry, dimensions, and head offset. If finite element analysis is being used for determining the worst case, then the worst-case head offset may not be known. It may be necessary to run several variants of head offset to determine this.

## 5. System Properties

5.1 The required material properties for input into an FEA model for the calculation of strains and displacement are modulus of elasticity ( $E$ ) and Poisson’s ratio ( $\nu$ ). These values can be obtained from material certification data. It should be noted that as ISO 7206-4 is run under load control, the FEA should also be run under load control. When the FEA is run under load control, the modulus of elasticity will not affect the stress calculations under small displacement theory, but will

affect displacement and strain. The influence of Poisson’s ratio on the stress calculations is negligible.

5.2 Ensure that material property units are consistent with geometric units in the CAD model. SI units are the preferred units of measure.

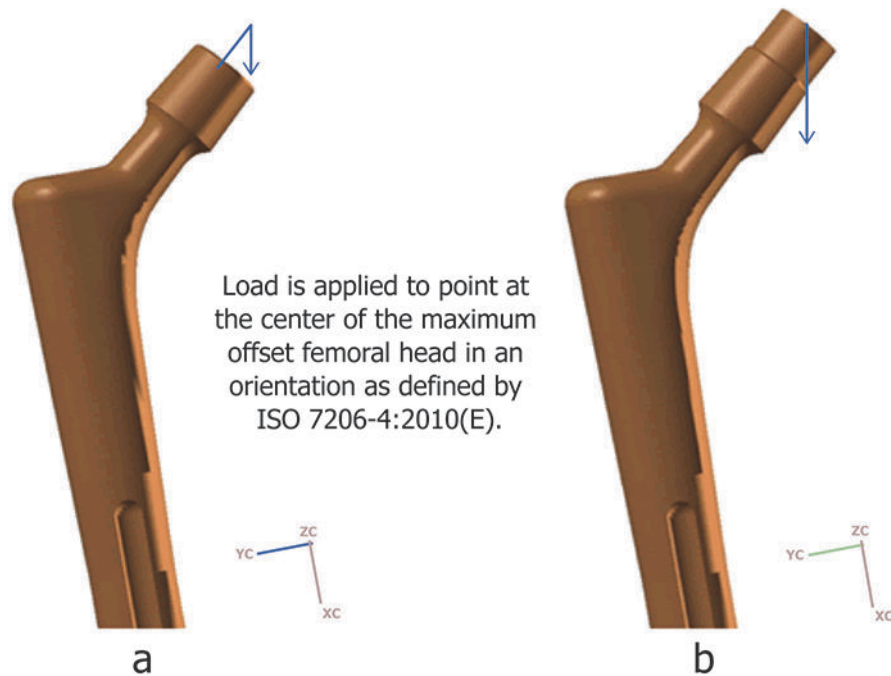
## 6. System Conditions—Loading Conditions

6.1 The loading and orientation of the hip stem shall be guided by ISO 7206-4. The areas of particular interest are the stresses in the neck region, driver hole region, potting level, and other design-specific critical regions.

6.2 The load shall be applied such that the magnitude and direction are identical to those defined in ISO 7206-4. The point of load application shall produce a statically equivalent bending moment to a load applied through the head center with its head offset.

6.2.1 The load in the model will be applied to the end circular face of the hip stem trunnion or in a justifiably equivalent manner. The trunnion may be extended or truncated to approximate the loading conditions that simulate the worst-case head offset, which may be determined via an iterative process. This approximation should be reported if performed. Alternatively, a rigid couple can be used to tie the load point to the trunnion end circular face. Refer to Fig. 1.

6.2.2 It is recognized that the loading conditions in this test method are not identical to that of ISO 7206-4. However, the differences in loading conditions (for example, load applied to



NOTE 1—Generating the statically equivalent maximum bending moment by (a) an offset node tied rigidly to the circular trunnion face, or (b) a cylindrical extension or truncation of circular trunnion face which equals the maximum femoral head offset (which is an approximation of the offset node method, to be documented if utilized). As an example, the modeling of a +8 mm femoral head offset is shown here. Figures are for illustration purposes only.

NOTE 2—Boundary condition is located at the distal face/cut region of the stem.

FIG. 1 Load Application

surface of head versus face of stem trunnion; potting level differences; use of bone cement which is not modeled in FEA) should not significantly affect identification of the “worst-case” stress condition, which is the primary objective of this test method. If subsequent physical fatigue testing per ISO 7206-4 is performed and a fracture occurs, the fracture location shall be compared to the FEA to confirm the predicted high stress location was correctly identified. If there are significant differences, the reason for these differences shall be evaluated, necessary adjustments shall be made to the physical test fixtures or finite element model and, depending on the result of the analysis, testing of additional components may be necessary.

6.3 Ensure that load units are consistent with material property units.

## 7. System Conditions—Boundary Conditions

7.1 The hip stem shall first be sectioned at a distance from the center of the head as described in ISO 7206-4 with the worst-case head/neck offset. This sectioned region represents the potting level to which stresses and strains shall be evaluated. A second parallel cut shall then be made 10 mm below the first sectioned region. The hip stem shall be constrained in all directions on all faces distal to the second cut. Constraining the stem in this manner ensures that excessive erroneous stresses are not generated at the region of interest due to the influence of rigid fixation. Refer to Figs. 2-4, which present three stem

length variants provided in ISO 7206-4. The use of other stress evaluation levels or constraint levels, or both, shall be justified.

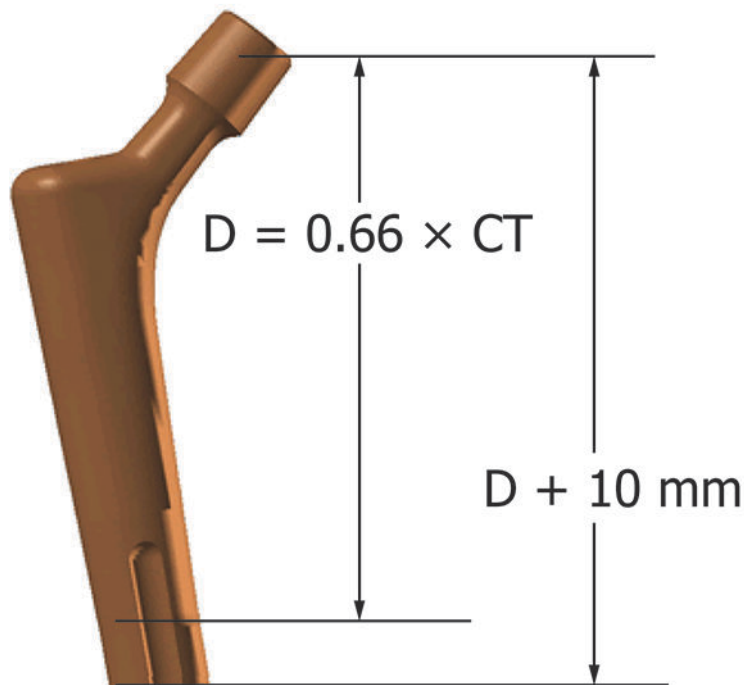
## 8. System Discretization, Numerical Implementation, and Model Results

8.1 The analysis and modeling system, programs, or software used for the finite element model creation and analysis should be capable of fully developing the geometric features and idealizing the loading and boundary condition environment of the orthopaedic implant. An engineering justification shall be provided to support any assumptions or simplifications.

8.2 The finite element mesh can be created using automatic meshing, manual meshing, or a combination of the two techniques. The overriding consideration is that the type, the size, and the shape of the elements used must be able to represent the expected behavior without significant numerical limitation or complication. Most FEA packages have a built-in program which checks the shape of the element for the type of analysis selected. If this tool is not available, then additional checks are needed.

8.3 The number and spacing of nodes (that is, mesh density) should be consistent with the type of element used and the type of result desired. This may be demonstrated with a mesh density study whereby a series of models with increasing mesh refinement in the critical stress regions is used to demonstrate solution convergence. This allows the error associated with

Load = 1,200 N

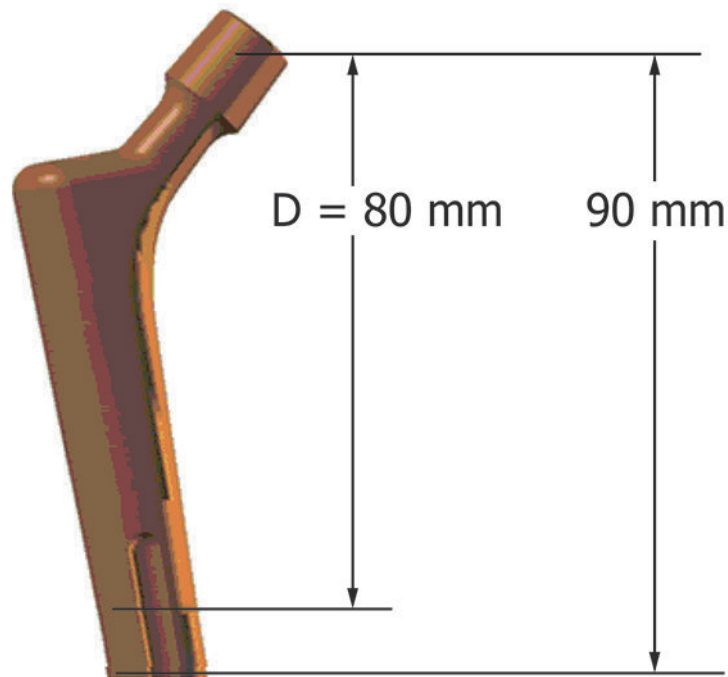


NOTE 1—CT is the distance between center of the head and the most distal point of the stem.

NOTE 2—Boundary condition is located at the distal face/cut region of the stem.

FIG. 2 Boundary Condition Location for Hip Stem Length  $\leq 120$  mm

Load = 2,300 N



NOTE 1—CT is the distance between center of the head and the most distal point of the stem.

NOTE 2—Boundary condition is located at the distal face/cut region of the stem.

**FIG. 3 Boundary Condition Location for Hip Stem Length of  $120 \text{ mm} < \text{CT} \leq 250 \text{ mm}$**

subsequent models to be estimated. The method used to demonstrate mesh convergence, in analysis cases where it is not performed directly onto the model being analyzed, shall be documented in the FEA report. It is recommended that a minimum of three levels of mesh discretization be used, representing two mesh refinement activities. Note that each mesh refinement activity should decrease the element size by a factor of two. A model convergence of less than or equal to 5 % on the quantity of interest (refer to 8.6) is recommended. A convergence of greater than 5 % shall be justified based on the context of use. If differences in peak stresses between two sizes in a series of sizes of the same implant design are calculated to be less than 5 %, a tightening of the model convergence is recommended to increase the likelihood of establishing the worst-case. Alternatively, identify both device sizes as potentially worst cases for subsequent physical testing and/or evaluation. Note that this standard may not provide sufficient evidence of mesh convergence in all applications; the analyst shall justify the adequacy of the mesh refinement activities.

8.4 The choice of element type is left to the analyst; however, it is recommended for analysis of a hip stem that tetrahedral or hexahedral elements be used. If tetrahedral elements are considered, use of 4-noded elements should be avoided to prevent stress and strain incompatibilities across elements. Additionally, the linear, 4-noded tetrahedron element is a constant strain element. This means that displacement interpolation is linear and the corresponding stresses and strains are constant within any element. Therefore, a very

refined mesh is required around locations where high stress/strain gradients are present when utilizing these elements. When elements which are not directly identified in this test method are used (for example, p-version), documentation shall be provided in the FEA report which demonstrates their validity.

8.5 The finite element results should be examined to ensure that the geometrical models of the implant, boundary conditions, and applied loads have been appropriately defined in the analysis and properly represent the behavior being analyzed. Examples of model behavior which should be examined include the reaction forces and moments as well as the overall deflected shape and deflection magnitude.

8.6 The quantity of interest is the Maximum (1st) Principal Stress. Refer to Fig. 5. Stress concentrations near the boundary condition regions are considered to be artifacts and shall not be considered to be regions of interest. If other quantities of interest are used, their validity for use shall be documented.

## 9. Report

9.1 The finite element analysis for the evaluation of an orthopaedic implant should be fully documented in an engineering report. The actual format of the report should comply with any acceptable proprietary or non-proprietary engineering report format; however, the report shall include, at a minimum, the following:

(1) A complete description of the device being analyzed, including detailed dimensions. The report shall include a