



Standard Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions¹

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1. Scope

1.1 This standard establishes requirements and considerations for the numerical simulation of metallic orthopaedic cemented and cementless total knee femoral components 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 metallic orthopaedic total knee femoral component designs for the purpose of prediction of the static implant stresses and strains. This procedure can be used for worst-case assessment within a family of implant sizes to provide efficiencies in the amount of physical testing to be conducted. 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 document is limited in discussion to the static structural analysis of metallic orthopaedic total knee femoral components (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 and health practices and determine the applicability of regulatory limitations prior to use.*

2. Significance and Use

2.1 This standard is applicable to the calculation of stresses seen on a knee femoral component when loaded in a manner

described in this test method. This method can be used to establish the worst-case size for a particular implant family. When stresses calculated using this method were compared to the stresses measured from physical strain gauging techniques performed at one laboratory, the results correlated to within 9%.

3. Geometric Data

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

3.2 It is most appropriate to consider the worst-case stress condition for the orthopaedic implant family being simulated. The worst-case shall be determined from all relevant engineering considerations, such as femoral component geometry and dimensions. If finite element analysis is being used for determining the worst-case, then the worst-case size may not be known. It may be necessary to run several sizes in order to determine the worst-case. If the FEA results do not conclusively determine the worst-case configuration, a rationale should be included (e.g., additional analysis or physical testing) to justify the worst-case size.

4. Material Properties

4.1 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 (ν). These values can typically be obtained from material certification data. It should be noted that the fatigue test 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.

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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