Designation: F3161 – 16

Standard Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions[1]

This standard is issued under the fixed designation F3161; 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 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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4.2 Ensure that material property units are consistent with geometric units in the CAD model. SI units are the preferred units of measurement.

5. Loading

5.1 The loading location and orientation of the knee femoral component shall be guided by the loading location and boundary conditions described below. The areas of particular interest are the stresses at the posterior aspect of the condyle, anterior notch, and other design-specific critical regions.

5.2 The worst-case condyle shall be loaded. If the weaker condyle cannot be justified, each condyle shall be analyzed individually. Centrally locate a 7.62 mm diameter projected circle over the apex of the posterior articulating surface with the knee femoral component positioned in 90 degrees of flexion. Apply an anterior directed 1 N load uniformly over the face generated by the intersection of this projected circle with the articulating surface. Refer to Fig. 1 and Fig. 2.

NOTE 1—Do not introduce additional solid material to the femoral component model.

NOTE 2—It is recognized that the loading conditions in this test method will not be identical to those of a physical testing standard currently under development. However, the differences in loading conditions (e.g., load application differences; potting level differences; use of bone cement which is not modeled in FEA) do not significantly affect identification of the worst-case stress condition and construct for subsequent bench testing, which is the primary objective of this test method.

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

6. Boundary Conditions

6.1 The prescribed boundary condition idealizes embedding the anterior flange within a potting medium. The femoral component shall be fixed in all translations on all "embedded" anterior flange surfaces. Refer to Fig. 1 and Fig. 3. A horizontal plane shall be constructed to define a closed perimeter around the anterior flange periphery. Note that the horizontal plane may not be parallel to the anterior flange bone cut face. The use of other stress evaluation levels and/or constraint levels shall be justified.

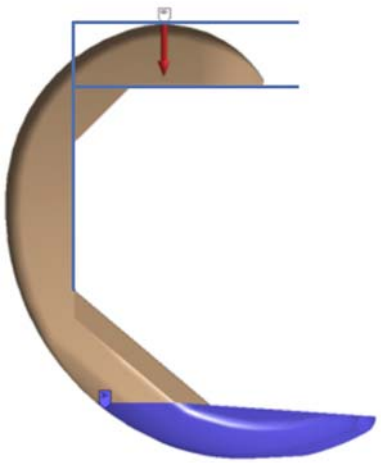

FIG. 1 Apex Location and Anterior Flange Constraint (lateral view)

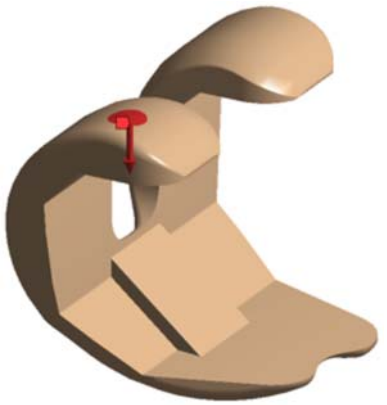

FIG. 2 Apply 1 N Load onto Load Footprint

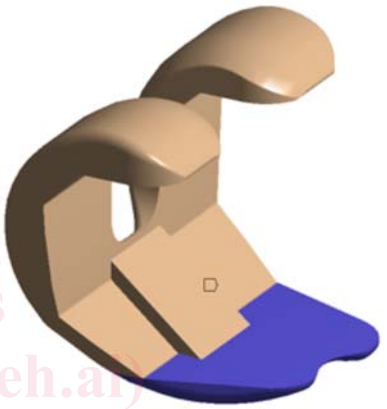

FIG. 3 Anterior Flange Constraint

7. Analysis

7.1 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 and/or simplifications.

7.2 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.

7.3 The number and spacing of nodes (i.e. 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 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 mesh refinement levels be evaluated and a model convergence of ≤5% be demonstrated on all measures and regions of interest. If differences in peak stresses between two sizes in a product family are calculated to be less than 5%, a tightening of the model convergence is recommended to increase the likelihood of establishing the worst-case size within a product family. Reporting of the degrees of freedom is not necessary if the model satisfies the convergence criterion.

7.4 The choice of element type is left to the analyst; however, it is recommended for analysis of a knee femoral component 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, documentation which demonstrates their validity shall be provided in the FEA report.

7.5 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.

7.6 The measure of interest is the Maximum (1st) Principal Stress. Refer to Fig. 4. Stress concentrations near the boundary condition regions are considered to be artifacts and shall not be considered to be regions of interest. If other stress values are used, their validity for use should be documented.

8. Report

8.1 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:

8.1.1 A complete description of device being analyzed including detailed dimensions. The report should reference a source CAD geometry file by name and revision number. If the evaluation is not being performed on the final design of the device or if there are other significant assumptions that may limit the use of the results, this shall be clearly stated.

8.1.2 A description of boundary constraints, loads, and material properties. The source of the material property data utilized should be referenced.

8.1.3 A summary of the finite element modeling and analysis system used for the analysis. If current versions of widely used, commercially available software are used, this summary can be by name and reference to the version used. For non-commercially available proprietary tools, or custom user modification of commercially available software, sufficient technical background and results of test problems should be provided to demonstrate the utility, verification, applicability and limitations of the software tool.

8.1.4 A description of the procedure used to convert the geometric or CAD representation of the device to the finite element model. Any geometry simplifications should be documented.

8.1.5 A description of the finite element model and its relation to the device being evaluated. The number of nodes and elements (or the degrees of freedom in the model), the finite element type selected including its capabilities, and any special considerations involved in the model should be included. For each region of interest, the maximum (1st) principal stress and von Mises stress at the location of maximum (1st) principal stress shall be reported. Additional stress components can be included and their incorporation shall be justified.

8.1.6 A description of mesh convergence considerations and how they were applied to the analysis.

8.1.7 A description of any numerical considerations or convergence criterion associated with the analysis.

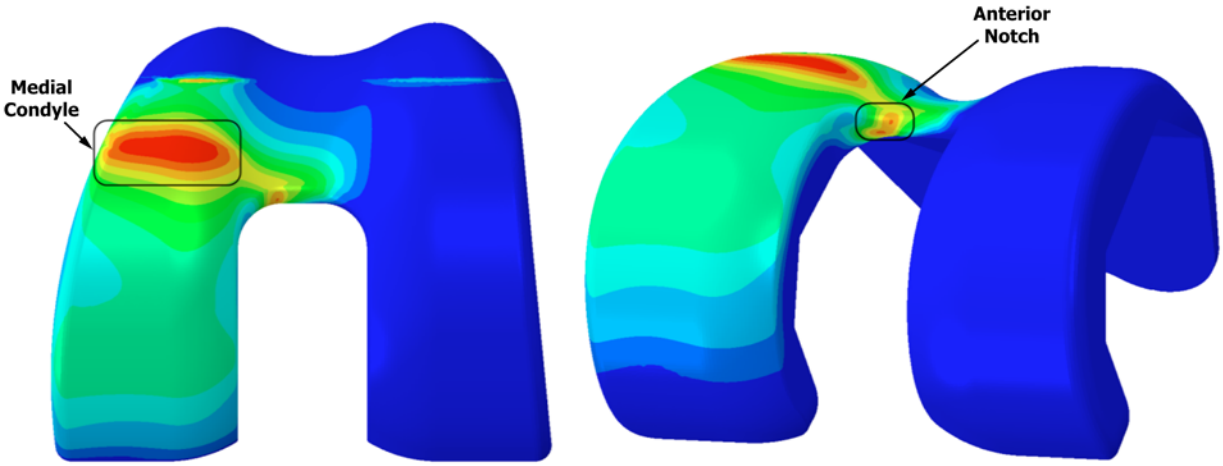

FIG. 4 Stress Plot (arrows point to regions of interest)