Designation: F3334 – 19

Standard Practice for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Tibial Components[1]

This standard is issued under the fixed designation F3334; 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 establishes requirements and considerations for the numerical simulation of metallic orthopaedic total knee tibial components using Finite Element Analysis (FEA) techniques for the estimation of stresses and strains. This practice is only applicable to stresses below the yield strength, as provided in the material certification.

1.2 *Purpose*—This practice establishes requirements and considerations for the development of finite element models to be used in the evaluation of metallic orthopaedic total knee tibial 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 series of different implant sizes of the same implant design to reduce the physical test burden. Recommended procedures for performing model checks and verification are provided as an aid to 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 practice is limited in discussion to the static structural analysis of metallic orthopaedic total knee tibial components (which excludes the prediction of fatigue strength).

1.4 *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.*

1.5 *This international standard was developed in accordance with internationally recognized principles on standardization 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 *ASTM Standards:*[2]

F1800 Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements

3. Significance and Use

3.1 This practice is applicable to the calculation of stresses seen on a knee tibial component when loaded in a manner described in this practice. This practice can be used to identify the worst-case size for a particular implant. When stresses calculated using this FEA method were compared to the stresses measured at two locations on the tibial tray using physical strain gauging techniques performed at one laboratory, the difference observed was -6.8 % at one location (with the strain gauges reporting the higher stress) and 3.1 % at the other location (with the FEA method reporting a higher stress). This difference should be considered when determining the worst-case size(s) of the same implant design.

3.2 The loading of tibial tray designs *in vivo* will, in general, differ from the loading defined in this practice. However, this practice is designed to allow for comparisons between the fatigue performance of different metallic tibial component designs, when tested under similar conditions.

4. System Geometry

4.1 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 geometric simplification and shall be justified.

[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.

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 tibial 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.

5. Material Properties

5.1 The required material properties for input into a linear, elastic FEA model for the calculation of strains and displacement are modulus of elasticity (E) and Poisson's ratio (ν). These values can be obtained from material certification data. It should be noted that the fatigue test described in Practice F1800 is run under load control; the corresponding FEA shall be run under an applied force. When the FEA is run under an applied force, the modulus of elasticity will not affect the stress calculations under small displacement theory (assuming a monolithic component), 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 measurement.

6. Loading Conditions

6.1 The loading location and orientation of the knee tibial component shall be guided by the loading location and boundary conditions described below. The loading location and orientation are consistent with Practice F1800. The area of interest is the location of the maximum principal stress and other design-specific critical regions (e.g., sharp corners, threads, locking mechanisms).

6.2 In the medial-lateral (ML)/anterior-posterior (AP) plane (refer to Fig. 1), locate a 6.35 mm (0.25 in.) diameter solid cylinder (actual dimensions of the spacer may vary as smaller tibial tray designs may require a smaller diameter disk) on the superior surface of the knee tibial component, per the method for determining the position of the load point described in clause 6.6 of Practice F1800. Locate the cylinder in the *SI* direction (refer to Fig. 2) such that the cylinder intersects the superior surface of the tibial component. Create an intersecting circular contour onto the superior face that defines the periphery of the load footprint, and then delete the cylinder from the model. No solid material should be added to or removed from the tibial component model by the operation. Apply a unit (1 N) load uniformly in the inferior direction over the load footprint (refer to Fig. 2). An alternative load magnitude can be applied, if that load magnitude does not result in developing stresses above the yield strength of the material. The use of alternative loading conditions shall be justified.

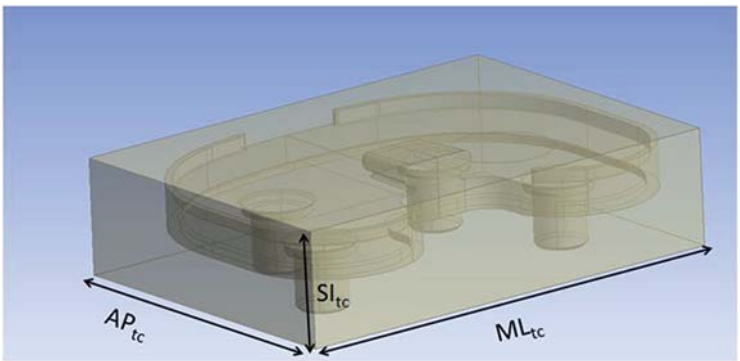
6.3 It is recognized that the loading conditions in this practice will not be identical to those of Practice F1800. However, the difference in loading conditions (e.g., load application differences, fixation differences) should not significantly affect identification of the "worst-case" stress condition and implant size for subsequent bench testing, which is the primary objective of this practice. When subsequent physical testing per Practice F1800 is performed, comparison of the physical test results (i.e., location of tray fracture) should be compared to the FEA test results to determine if there were any significant differences. If so, the reason for this difference shall be evaluated, necessary adjustments shall be made to the physical test fixtures or finite element model, and, depending on the results of the analysis, testing of additional components may be necessary.

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

7. Boundary Conditions

7.1 Either the medial or lateral half of the tibial component shall be fully encased in a CAD-generated block with bone cement material properties. This methodology has been demonstrated to minimize boundary condition-induced stress artifacts, which develop along the protruding inferior tibial component edge when a stiff block is used. A subtractive Boolean operation (i.e., removing tibial component volume from the solid block volume) is commonly used for this step.

7.2 Considering reference tibial component bounding box dimensions AP_{tc}, ML_{tc}, and SI_{tc} (refer to Fig. 1), the bone



NOTE 1—SI_{tc} excludes the stem length for stemmed designs.

FIG. 1 Tibial Component Bounding Box

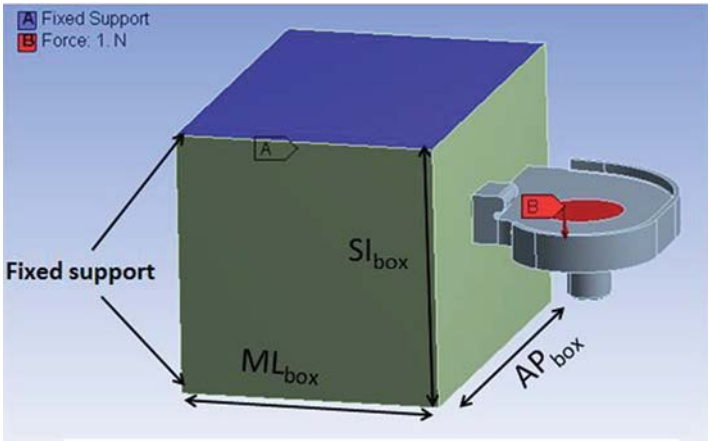


FIG. 2 Loading and Boundary Condition Dimensions

cement block dimensions AP_{box}, ML_{box}, and SI_{box} (refer to Fig. 2) shall have the minimum values of $AP_{box} = 1.5 \times AP_{tc}$, $ML_{box} = 0.75 \times ML_{tc}$, and $SI_{box} = 3.0 \times SI_{tc}$. For stemmed designs, calculate $SI_{box} = 3.0 \times SI_{tc}$ + stem length. These dimensions have been demonstrated to minimize any constraint-induced stress artifacts (as defined below). The encased half of the tibial component shall be centrally positioned in the *AP* and *SI* directions within the block. In the *ML* direction, the tibial component shall be positioned such that the block vertical face that is closest to the load location is aligned with the centerline of the tibial component, or along the *AP* centerline of the central keel or other prominence, when applicable.

7.3 Merged nodes or bonded contact between the bone cement block and tibial component shall be used to bond the tibial component to the block along their shared surfaces.

7.4 The top and bottom surfaces of the cement block shall be fixed in all three translational degrees of freedom (refer to Fig. 2).

7.5 The use of alternative tibial component constraints shall be justified.

8. Analysis

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 and/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 simulate the expected behavior without significant numerical limitation or complication. Check the element quality by examining aspects such as skewness, aspect ratio, Jacobian, etc. If this tool is not available, then additional checks are needed.

8.3 The mesh density should be adequate for the calculation accuracy requirements. 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 levels of mesh refinement be performed and a model convergence of ≤5 %[3] be demonstrated on the quantity of interest (see 8.6) and at all regions of interest. A stress convergence of >5 % shall be justified based on the context of use.

8.4 The choice of element type is left to the analyst; however, it is recommended for analysis of a knee tibial 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 using elements that are not directly identified in this practice, documentation that demonstrates their validity shall be provided in the FEA report.

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 to properly represent the behavior of the *in vitro* test condition.

8.6 The primary measure of interest is the maximum (first) principal stress generated by a unit load (refer to Fig. 3 and Fig. 4). A secondary measure of interest is the von Mises stress at the location of maximum (first) principal stress generated by a unit load. If other stress values are used, their validity for use should be documented.

[3] Bischoff S., "Whitepaper: Cleaning up a Meshy Situation – A Guide for Troubleshooting Meshing Issues in SolidWorks Simulation," *3DVision Technologies*, 2009.

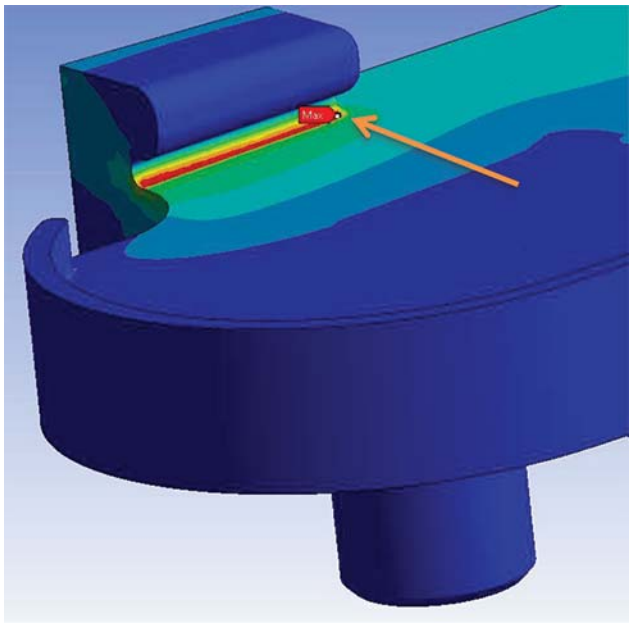


FIG. 3 Central Compartment Stress Plot (Arrow Points to Region of Maximum Stress Generated by a Unit Load)

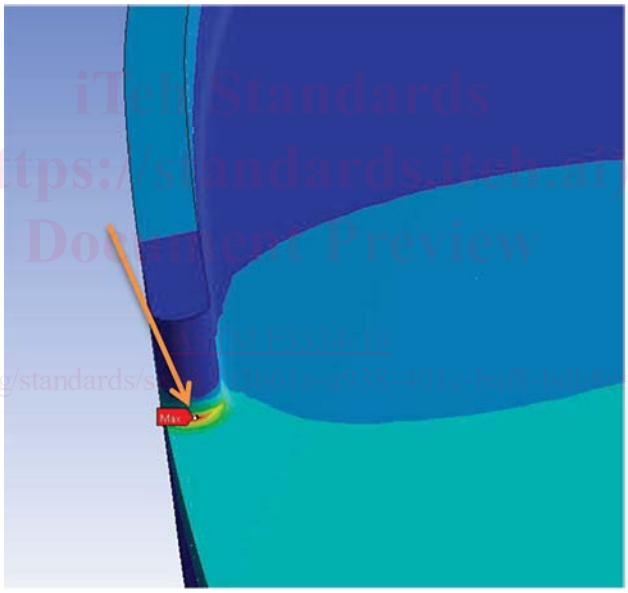


FIG. 4 Anterior Fillet Stress Plot (Arrow Points to Region of Maximum Stress Generated by a Unit Load)

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, but not be limited to, the following:

9.1.1 A complete description of the device being analyzed including detailed dimensions. The report can 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.

9.1.2 A description of boundary constraints, loading conditions, and material properties. The source of the material property data utilized should be referenced.

9.1.3 A summary of the finite element modeling and analysis software 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 user modifications of commercially available software, sufficient technical