Designation: F3495 – 23

Standard Test Methods for Determining the Static Failure Load of Ceramic Knee Femoral Components[1]

This standard is issued under the fixed designation F3495; 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 The test methods included in this standard cover two procedures for static burst testing of a ceramic femoral component used in total knee replacement (TKR). The two procedures are used to determine the static ultimate failure load of a ceramic femoral knee component. Both procedures are simulating *in vivo* loading conditions. One of the procedures additionally simulates intraoperative loading conditions. The standard applies to cruciate retaining (CR) femoral components which cover both the medial and lateral condyles and the patellar surface of the femur. These test methods may require modifications to accommodate other femoral component designs.

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

1.3 *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.*

1.4 *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]

C1161 Test Method for Flexural Strength of Advanced Ceramics at Ambient Temperature

F2083 Specification for Knee Replacement Prosthesis

F3161 Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions

F3210 Test Method for Fatigue Testing of Total Knee Femoral Components Under Closing Conditions

2.2 *Other Standards:*

ISO 14704 Fine ceramics (advanced ceramics, advanced technical ceramics)—Test method for flexural strength of monolithic ceramics at room temperature[3]

3. Terminology

3.1 *Definitions*—The definitions and terms of Specification F2083 apply.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *component size*—size of femoral component as given by the manufacturer.

3.2.2 *compression force*—used for the compression load test and is referred to as F.

3.2.3 *corner*—angular design feature of the inner contour of a femoral component; to be seen in the sagittal view; see Fig. 1 for details.

3.2.4 *counter force*—used for the tension load test, is acting along the force axis and is referred to as F_2.

3.2.5 *distal face*—the distal face is part of the inner contour of the component. The distal face is touching the femoral bone at the transverse resection plane. Typically the pegs are part of the distal face; see Fig. 2 for details.

3.2.6 *force axis*—line of action of the tensile force F_1 and the counter force F_2 applied to the femoral component.

3.2.7 *lower unit*—bearing frame attached to the test machine to apply the counter force.

3.2.8 *stroke rate*—the rate of the stroke displacement of the force applicator.

3.2.9 *tensile force*—used for the tension load test, is acting along the force axis and is referred to as F_1.

3.2.10 *upper unit*—bearing frame attached to test machine to apply the tensile force.

[1] These test methods are under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and are 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] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.

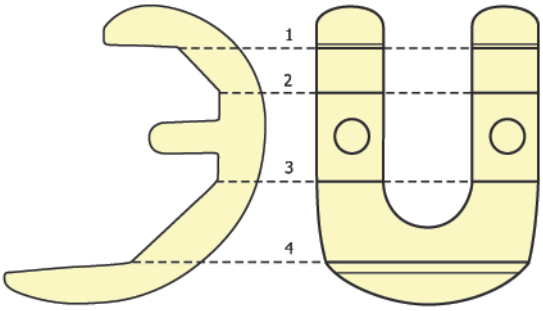

FIG. 1 Corners of a Femoral Component

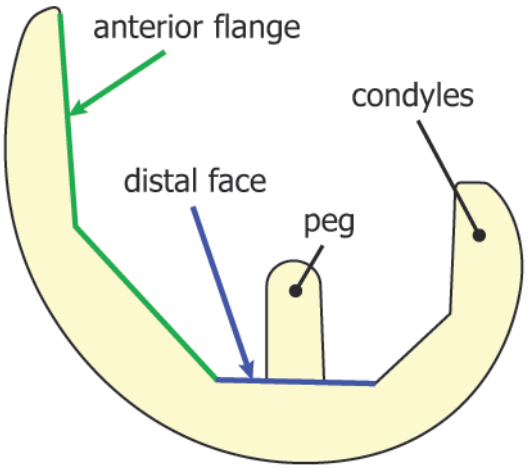

FIG. 2 Locations of the Anterior Flange, Distal Face, Condyles, and Peg of a Femoral Knee Component

4. Summary of Test Method

4.1 In this standard, two test methods are included to determine the static ultimate failure load of a ceramic femoral knee component. Two test methods are included in this standard to represent the "opening" and "closing" loading conditions the femoral component experiences during use. Opening loading conditions, meant to simulate both loading on the articulating surface in proximity to a corner on the inner contour of the femoral component which causes high tensile stresses on the inner surface at the corner feature and intraoperative impaction, are simulated by the tension load test method and closing loading conditions, meant to simulate loading on the articulating surface not in proximity to a corner or loading of the component after loss of supporting bone which causes high tensile stresses on the articulating surface, are simulated by the compression load test method in this standard. Intraoperatively, the component is pounded onto the prepared end of the femur under loading conditions which can force it to open and again are simulated by the tension load test method outlined in this standard.

4.2 The tension load test method provides a means to measure the ultimate failure load of the inner contour of the femoral component.

4.3 The compression load test method provides a means to measure the ultimate failure load of the outer contour of the femoral component.

5. Significance and Use

5.1 These test methods are intended to determine the ultimate failure load of a ceramic femoral knee component. This information can be used for evaluation of different ceramic component designs or different ceramic materials, or for series production control.

5.2 Although the test methodology described attempts to identify physiologically relevant intraoperative and *in vivo* loading conditions, the interpretation of results is limited to an *in vitro* comparison between ceramic femoral component designs and materials regarding their static ultimate failure load under the stated test conditions.

6. Equipment Characteristics

6.1 Generally, the ultimate failure load tests should be performed on uniaxial testing machines. Note: Mechanical load frames with power screws are recommended, but all other types of uniaxial testing machines with adequate load capacity and stroke rate control may be used.

6.2 The loading fixtures should be capable of sustaining forces up to the anticipated fracture level. Note: Add a safety margin to the anticipated fracture level.

7. Apparatus

7.1 For the tension load test setup, the femoral knee component shall be positioned in a way that the applied forces F_1 and F_2 are acting along a common force axis when viewed in the sagittal plane. Misalignment in the sagittal plane must be avoided throughout the full loading cycle. As the femoral knee component is subjected to deformation while loaded, the means of the tension load test setup shall incorporate moveable parts to level the specimen in place and keep the forces F_1 and F_2 on their common force axis.

7.2 The force is applied to the inner contour of the femoral component in a way that the force is opening the femoral component. Depending on the position of the force axis, the number of stressed corners may vary; see Figs. 1-4.

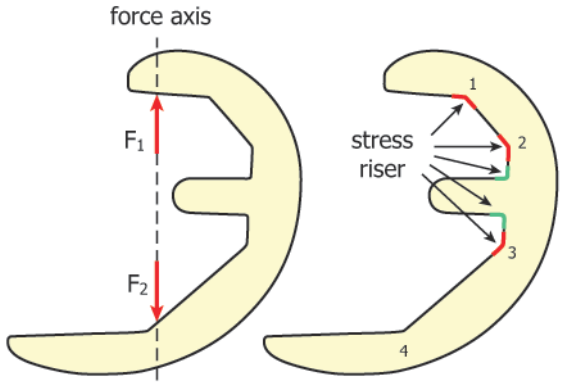

FIG. 3 Forces F_1 and F_2 Along the Force Axis Are Stressing Only Three Corners and the Pegs of the Femoral Component