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.

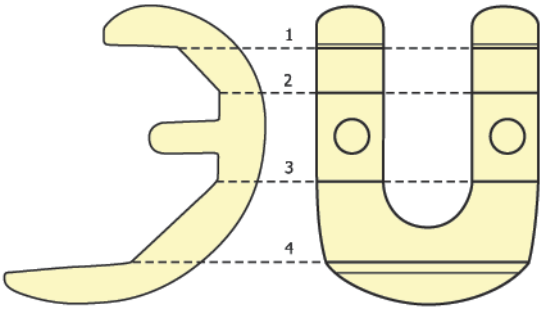

FIG. 1 Corners of a Femoral Component

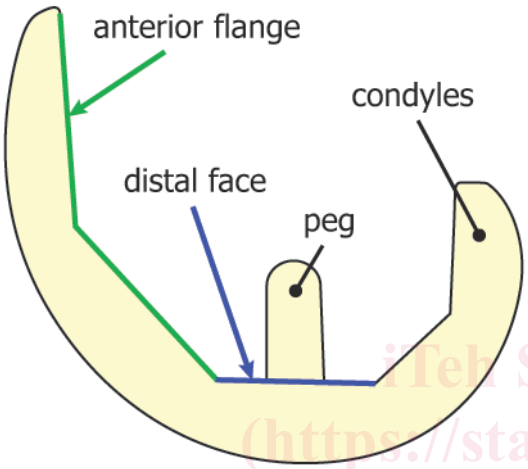

FIG. 2 Locations of the Anterior Flange, Distal Face, Condyles, and Peg of a Femoral Knee Component

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.

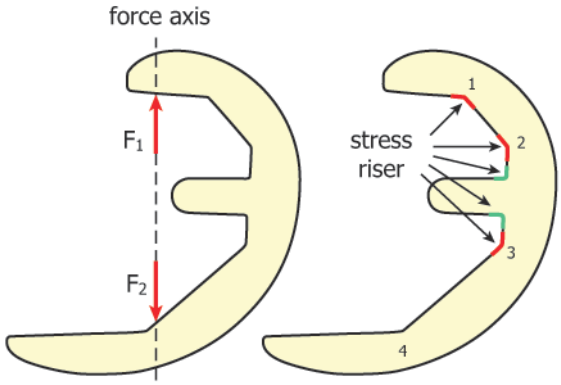

FIG. 3 Forces F_1 and F_2 Along the Force Axis Are Stressing Only Three Corners and the Pegs of the Femoral Component

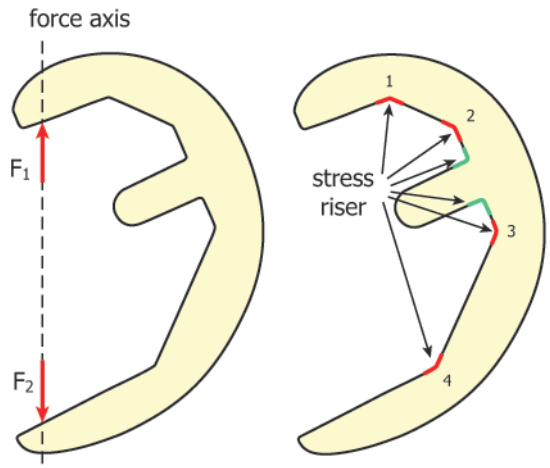

FIG. 4 Forces F_1 and F_2 Along the Force Axis Are Stressing All Four Corners and the Pegs of the Femoral Component

7.2.1 Note: Depending on the details of the femoral knee component design, it is very likely that not all corners are stressed to an equivalent level *in vivo*. As the tension load setup is intended to simulate *in vivo* loading conditions, *in vivo* low stressed corners can be neglected in the tension load test. Please refer to Appendix X1 and Appendix X2 for further explanations.

7.2.2 The bearings for F_1 and F_2 shall be decoupled from each other. The apparatus shall consist of two separate units, an upper unit to apply the tensile force F_1 to the condyles and a lower unit as a counter bearing to apply the counter force F_2 to the anterior flange. Note: The forces F_1 and F_2 have to be on the same force axis when viewed in the sagittal plane. However, the upper and the lower units may be mounted inverted in the loading frame, as long as the forces F_1 and F_2 remain on the same axis. Note: Please refer to the appendixes for an example of the upper and lower units.

7.2.3 The upper unit has two loading points to the femoral component condyles, while the lower unit has two loading points to the femoral component anterior flange; see Fig. 5 for details.

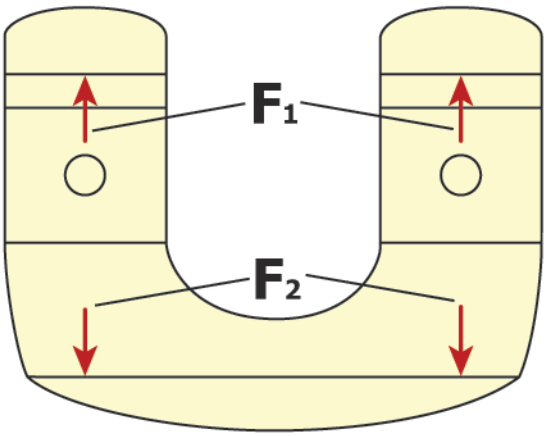

FIG. 5 Loading Points for F_1 and F_2 to the Femoral Component

7.2.3.1 The force for the tension load test will be applied through the four loading points of the upper and the lower unit to the femoral component. Note: Use tapered pins or dome-shaped buttons 1 mm to 10 mm in diameter made of a malleable metal, for example an aluminium alloy like AA-7075-T6 (EN AW-7075-T6), to apply the load to the femoral component and to secure the femoral component between the upper and the lower unit. Large or plane loading points may alter the stress distribution in the femoral component or will lead to undesirable constraints in the femoral component.

7.2.4 The following constraints shall apply to the upper and the lower unit. The constraints of the units are necessary for the femoral component to move freely between the four loading points.

7.2.4.1 The upper unit shall incorporate a ball joint to level between the two condyles and ensure that all four loading points are in full contact to the femoral component; see Figs. 5 and 6 for details.

7.2.4.2 The tensile force F_1 is applied in the Z-direction through the upper unit to the femoral component.

7.2.4.3 The lower unit is connected to an X-Y table to move under force effect of F_1, to compensate any force constraints in the X- and Y-directions, and to act as the counter force F_2 in the Z-direction.

7.2.5 The details of the tension load apparatus shall be designed to the requirements of the femoral component under consideration, meaning that the loading points shall fit and fix into the cement pockets or alternative fixtures. Note: For further guidance, examples, and alternative fixtures, please refer to the appendixes.

7.3 For the compression load test setup, the femoral component shall be positioned in a way that the distal face is

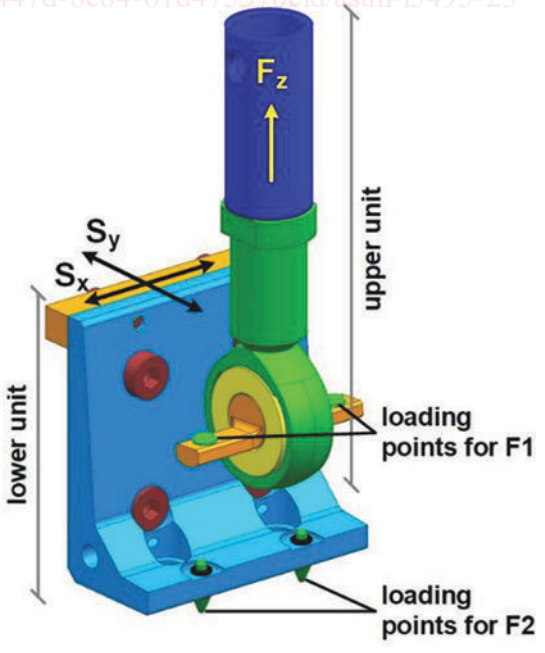

FIG. 6 Examples of an Upper and a Lower Unit to Apply F_1 and F_2

parallel to the back surface of the test rig. By applying the compression force F, the outer contour of femoral component is stressed; see Fig. 7 for details.

7.3.1 The corners of the femoral component shall be parallel to the ground surface of the test rig; see Fig. 8 for details.

7.3.2 The details of compression load apparatus shall be designed to the requirements of the femoral component under consideration, meaning asymmetric condyles or an asymmetric anterior flange have to be levelled to the parallel requirements.

7.3.3 The compression force F is applied to the apex of both condyles. A rocker should be used to level the force between the two condyles. The force should be applied evenly distributed to both condyles to avoid rocking of the specimen. Note: The fixation methods of the compression load setup are different from the methods described in Test Methods F3161 and F3210. Test Methods F3161 and F3210 recommend anterior flange potting, while the femoral knee component is not clamped, fixed, or potted in any way in the compression load test setup.

7.3.4 The compression force F shall be applied to the center of the medio-lateral width (MLW) of the femoral component; see Fig. 8 for details.

8. Hazards

8.1 Due to the high forces anticipated in this type of destructive test, appropriate shielding of the femoral component test site is required.

9. Sampling, Test Specimens, and Test Units

9.1 *Number of Test Specimens*—A minimum of five specimens is recommended per test group for each test method. A test group shall represent one single size of the femoral implant portfolio. The manufacturer shall justify the worst-case selection if not all sizes of the implant portfolio are tested.

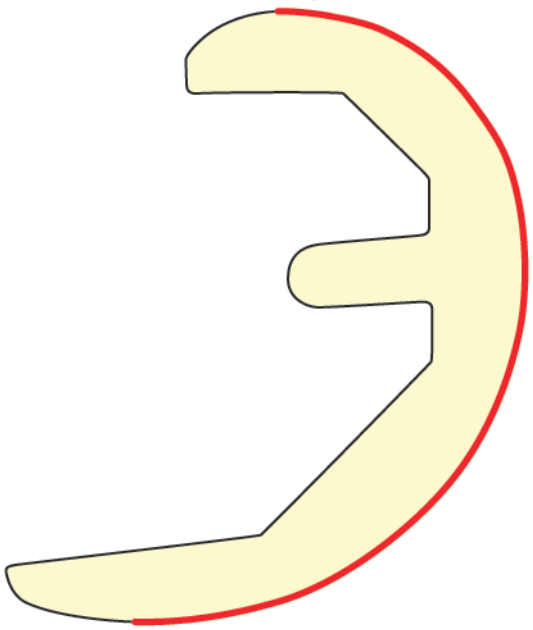

FIG. 7 By Applying the Compression Force F the Outer Contour of the Femoral Component Is Stressed

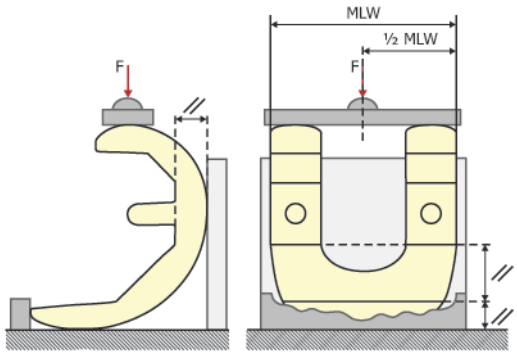

FIG. 8 The Distal Face Shall Be Parallel to the Back Surface of the Test Rig. The Corners Shall Be Parallel to the Ground Surface of the Test Rig. The Upper Unit Shall Incorporate a Rocker to Level the Force Between the Two Condyles

9.2 *Loading Rate*—For tension load testing, a stroke rate of 5 mm/min is set as the default stroke rate. For compression load testing, a stroke rate of 40 mm/min is set as the default stroke rate. Note: It is suspected that slow crack growth is active during testing, therefore a fast testing rate should be used so that the fracture of the ceramic specimens occurs within a 5 to 15 s interval. Please refer to Test Method C1161 and ISO 14704 for guidance. Depending on the ceramic material and the femoral component design, other stroke rates may be applicable. The user of this standard shall justify if other stroke rates have been used as the default stroke rates.

10. Procedure

10.1 *Tension Load Test:*

10.1.1 Following normal laboratory cleaning procedures to remove any debris or other surface contaminants, the femoral component is positioned in the upper unit of the test rig first.

10.1.2 Care should be taken to position the femoral component to the loading points of the upper unit. The femoral component shall be self-locking to the loading points of the upper unit. Note: The femoral component may swing when placed on the pins or buttons, respectively. Wait until the femoral component stops swinging before further processing.

10.1.3 Move the X-Y table to position the lower unit opposing the loading points of the femoral component.

10.1.4 Displace the upper unit with a low constant stroke rate (approximately 2 mm⁄min) to hook in the two loading points of the lower unit. Load the assembly to a pre-force of 300 N. Note: The X-Y table may move when applying the pre-force, especially when the loading points have not been within the common force axis before start.

10.1.5 Check the force axis with a plumb line.

10.1.6 Load the femoral component with a constant stroke rate until fracture.

10.1.7 Fracture origin of the ceramic femoral component should appear away from the loading points. If fracture origin appears at a loading point, the test result is invalid. If this happens, it is recommended that a root cause analysis be performed on the test setup and the ceramic material of the

specimen prior to testing additional specimens using the same test setup, as changes may be necessary.

10.2 *Compression Load Test:*

10.2.1 Following normal laboratory cleaning procedures to remove any debris or other surface contaminants, the femoral component is positioned in the test rig.

10.2.2 Load the assembly to a pre-force of 1000 N with a low constant stroke rate (approximately 10 mm/min).

10.2.3 Load the femoral component with a constant stroke rate until fracture.

10.2.4 Fracture origin of the ceramic femoral component should appear away from the loading points. If fracture origin appears at a loading point, the test result is invalid. If this happens, it is recommended that a root cause analysis be performed on the test setup and the ceramic material of the specimen prior to testing additional specimens using the same test setup, as changes may be necessary.

11. Report

11.1 The report shall identify the femoral component manufacturer, the femoral component size, the femoral component side, and the femoral component material.

11.2 The report shall also describe the test equipment and all test parameters, ambient conditions including humidity and temperature, the control mode, the loading rate, and a description of the loading contact.

11.3 For the tension load test and the compression test, the location (corner) of the origin of the fracture shall be reported.

11.4 *Test Results*—The report shall include the number of samples tested, the failure force for each sample, and the mean, standard deviation, and range for the test group.

11.5 Provide photographs of the components before and after fracture to document fracture mode and location.

12. Precision and Bias

12.1 *Precision*—It is not possible to have a precision statement because there is not a standard implant available to all users of the test method to develop such a statement. Additionally, it is not possible to specify the precision of the procedure in this test method because of the wide variance in design of the components to be tested.

12.2 *Bias*—No statement can be made as to the bias of this test method since no acceptable reference values are available.

13. Keywords

13.1 ceramics; closing conditions; failure load; opening conditions; total knee arthroplasty

APPENDIXES

(Nonmandatory Information)

X1. LOADING OF A FEMORAL KNEE COMPONENT IN VIVO

X1.1 An artificial femoral knee component is loaded in two distinct joints simultaneously, the patellofemoral joint and the tibiofemoral joint. Depending on the flexion angle of the knee and the load contribution of the two joints on the femoral knee component, the stress reaction of the femoral knee component may vary strongly, as shown in Fig. X1.1. In two simplified approaches the complex *in vivo* load situation can be described as loads that are opening the femoral knee component, which

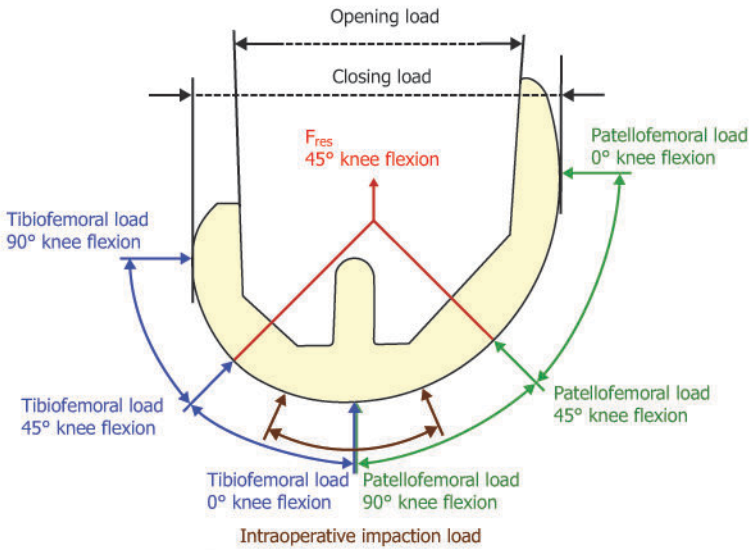

FIG. X1.1 In Vivo Loading, Resulting Force Vector, Intraoperative Loading, and Related Test Loads

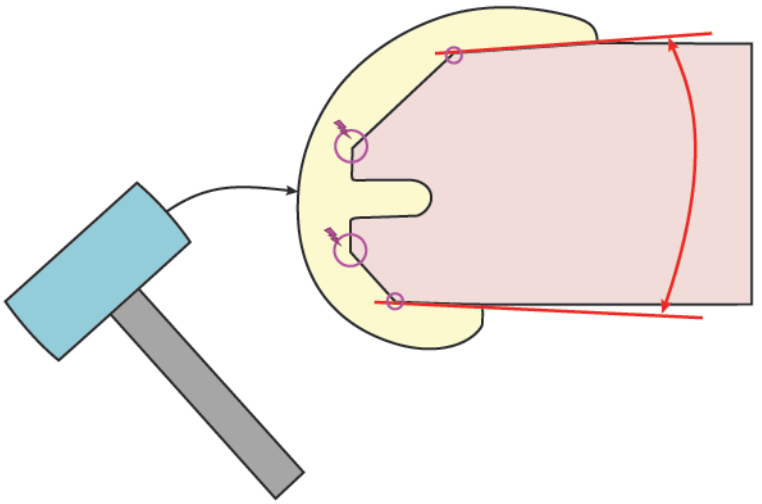

FIG. X1.2 The Corners of the Inner Contour Are Stressed When the Femoral Component Is Pounded on Its Femoral Bed

is simulated by the tension load test, or are closing the femoral knee component, which is simulated by the compression load test.

X1.2 The intraoperative impaction load is an additional load case that is contributing to an opening of the femoral component when the component is pounded on its femoral bed. In most common knee systems, the femoral cutting templates are slightly oversized to achieve good primary stability of the femoral component. The interference fit of the prepared bone to the inner contour of the femoral component is influencing the stress magnitude at the corners while pounding, as shown in Fig. X1.2.

X1.3 The tibiofemoral loads and the patellofemoral loads are applied to the outer contour (articulating surface) of the femoral knee component, as shown in Fig. X1.1. Depending on the knee flexion angle, the *in vivo* loads are applied either in proximity to or away from the location of a corner feature on the inner contour of the femoral component. When loads on the articulating surface are applied in proximity to a corner feature, this causes high tensile stresses on the inner surface at the corner feature through a wedging effect that can be explained by the interference fit, see X1.2; and, when loads are applied away from a corner, for example F_{res} as shown in Fig. X1.1, this causes high tensile stresses on the articulating surface. During all forms of gait activities, the knee flexion angle is shifting rapidly, and the loading and stress patterns of the femoral knee component are following the knee flexion movement. Depending on the femoral component design, not all corners are affected by high loads and stresses during the gait cycle; finite element analysis can help to identify the critical corners.

X1.4 When simulating loading during use, patellofemoral loads at 0° knee flexion are comparably low. Accordingly the examination of corner 4 within the tension load test can be suspended, which is represented by Fig. 3.

X1.5 When simulating intraoperative impaction loading conditions, all corners should be taken into account, which is represented by Fig. 4.

X2. SIMULATING IN VIVO LOADING OF FEMORAL KNEE COMPONENTS

X2.1 Tension Load Test Setup

X2.1.1 Small aluminum (for example AA-7075-T6, EN AW-7075-T6) tapered pins and buttons as loading points for the tension load test have been found to be sufficient. The pins and buttons can hook into the cement pockets or the cement rim of the femoral component, respectively. Please refer to Fig. X2.1.

X2.1.2 Use a retaining clip to secure the pin, as shown in Fig. X2.2.

X2.1.3 Use a four-point loading construct for the tension test setup; two loading points in the upper unit and two loading bearing points in the lower unit, respectively, as shown in Figs. X2.3 and X2.4. Pins or buttons as loading points in the cement pockets or other undercuts are sufficient to constrain the specimens and prevent from dislocation while in the loading frame. Alternative fixtures are needed if the femoral component doesn't have cement pockets, cement rim, undercuts, or other features to place pins and buttons. For example, slot cuts or drilled holes in the femoral component can be utilized to receive the pins or buttons. However, the four-point loading construct shall not be compromised.

X2.1.4 The tension unit of the tension load apparatus consists of the upper unit and the lower unit, as shown in Fig. 6 and Fig. X2.5. The lower unit is fixed to an X-Y table that is rigidly connected to the test machine baseplate. The X-Y table consists of sliders allowing movement in the X- and Y-directions when a force in the Z-direction is applied. The upper unit is connected to the machine's cross head. The upper unit applies the force F_1 in the Z-direction, whereas the lower unit is acting as a counter bearing to apply the force F_2. The ball bearing in the upper unit is leveling uneven deformation of the condyles.

X2.2 Compression Load Test Setup

X2.2.1 Another compression load test setup is mentioned in Test Methods F3161 and F3210. The differences to the test setup described herein are that the specimens must be potted into a potting medium and only one condyle is loaded during testing.

X2.2.2 The overall alignment of the femoral component within the two setups is similar; see Fig. X2.6. But due to the loading of two condyles or of only one condyle, the stress responses are different. It is the intention of this standard to stress both condyles.

X2.2.3 For the setup described herein it is recommended to use blocks, wedges, or sheets to level the femoral component to the desired orientation; see Fig. X2.7. It is within the responsibility of the standard user to level and align the femoral component in the test rig. The anterior stop block can be manufactured as a moveable block to adjust the alignment or to accommodate different femoral component sizes. Note: A malleable metal block, wedge, or sheet can be used to align the femoral component in the test rig and to apply the load to the femoral component. The malleable metal can be an aluminium alloy, for example AA-7075-T6 (EN AW-7075-T6).

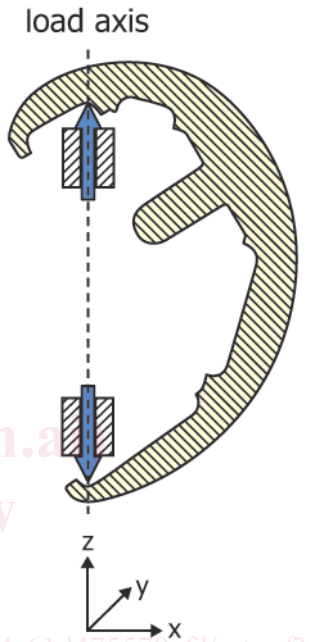

FIG. X2.1 The Tapered Pins Can Hook in the Cement Pockets

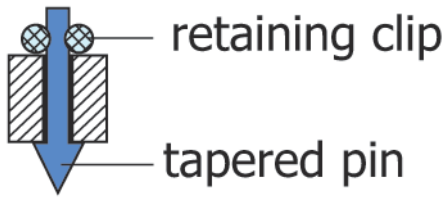

FIG. X2.2 A Tapered Pin Can Be Secured with a Retaining Clip