



Designation: F 1691 – 96

Standard Test Method for Determining Axial Pull-Out Strength of Medical Bone Screws¹

This standard is issued under the fixed designation F 1691; 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 test method covers the test procedure for determining the axial pull-out strength of medical bone screws.

1.2 *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. Referenced Documents

2.1 *ASTM Standards:*

E 4 Practices for Load Verification of Testing Machines²

F 117 Test Method for Driving Torque of Medical Bone Screws³

3. Terminology

3.1 *Definitions:*

3.1.1 *axial pull-out strength*—the tensile force required to fail or remove a bone screw from a material into which the screw has been inserted.

4. Summary of Test Method

4.1 *Determination of Axial Pull-Out Strength*—This test method evaluates the axial pull-out strength of medical bone screws from a material as defined in 10.1.6. The bone screws are inserted in accordance with Test Method F 117. To determine the pull-out strength of the bone screw, a tensile load is applied until the screw releases from the material or failure of the screw occurs.

5. Significance and Use

5.1 This test method is used to measure the axial tensile force required to remove a bone screw from a defined material. The results obtained in this test method are not intended to predict the force required to remove the subject bone screw from human or animal bone. This test method is intended only to measure the uniformity of the products tested or to compare the strength of different products.

5.2 This test method may not be appropriate for all types of implant applications. The user is cautioned to consider the appropriateness of the method in view of the materials being tested and their potential application.

6. Apparatus

6.1 *Test Fixture*—A suitable test fixture as shown in Fig. 1 shall be used for testing. This fixture shall incorporate the test block, test block clamp, drill bushing, and bushing support depicted in Test Method F 117. These components shall meet the requirements set forth in Test Method F 117. In addition to these requirements, the test block clamp and bushing support should be sufficiently rigid such that deflection under the required loading conditions is negligible. The test block clamp should have a minimum grip span of five times the major diameter of the bone screw with the screw centered between the grips. The grip span should be consistent throughout testing.

6.2 *Data Acquisition Device*—A suitable recorder to obtain data of load versus load frame displacement.

6.3 *Load Frame*—Machines used for testing shall conform to the requirements of Practices E 4. The loads used for the test shall be within the loading range of the test machine as defined in Practices E 4.

6.4 *Load Fixture*—A suitable fixture shall be used to place a tensile load on the bone screw. The load shall be transferred through the head of the screw and should be aligned with the screw's longitudinal axis. The fixture shall have a slot to capture the head of the screw without contact being made with the screw's shaft. To ensure proper alignment, the slot shall have a spherical recess into which the screw head can be seated directly under the applied load.

7. Sampling, Test Specimens and Test Units

7.1 All test components shall be representative of implant quality products.

8. Procedure

8.1 *Insertion of the Test Specimen*—The bone screws shall be inserted into the standard material in accordance with Test Method F 117. The screws shall be inserted at a rate of 3 r/min to a depth of 20 mm. For fully threaded screws with threaded lengths less than 20 mm, the insertion depth should be 60 % of the threaded length of the screw. Partially threaded bone

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² *Annual Book of ASTM Standards*, Vol 03.01.

³ *Annual Book of ASTM Standards*, Vol 13.01.

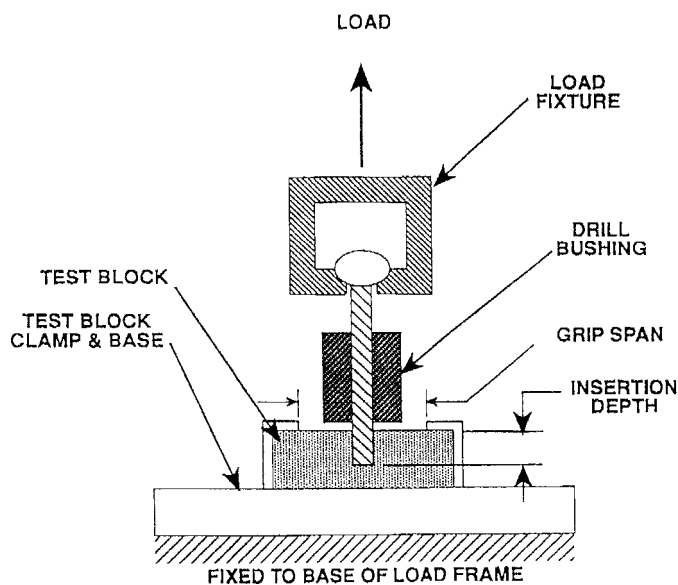


FIG. 1 Test Setup for Pull-Out Procedure

screws should have all threads inserted into the standard material.

8.2 Axial Pull-Out Strength of the Test Specimen—The test block and test block clamp depicted in Test Method F 117 shall be fixed to the base of the load frame so that the longitudinal axis of the screw is aligned with the direction of the applied load. The screw's head shall be placed in the slot of the load fixture and seated in the spherical recess. The load fixture shall then be attached to the load frame. A tensile load shall be applied to the test specimen at a rate of 5 mm/min until the screw fails or releases from the test block. Load (newtons) versus load frame displacement (millimetres) shall be recorded on a data acquisition device, noting the maximum load applied and the mode of failure (screw shaft, screw threads, or material failure).

9. Calculation or Interpretation of Results

9.1 Axial Pull-Out Strength—The axial pull-out strength

(newtons) of the test specimen shall be determined from the load-displacement curve, and is the maximum load reached during the test.

10. Report

10.1 Report the following information:

10.1.1 *Screw Identification*—Reference any applicable ASTM or ISO standard specification that may apply to the specimen. If specifications do not exist, provide head form, thread form, helix angle, major and minor diameter, thread pitch, overall screw length, head and shank length, length of threaded portion of shank for partially threaded screws, and type of screw point.

10.1.2 *Screw Chemical Composition*,

10.1.3 *Surface Finish*,

10.1.4 *Axial Pull-Out Strength* (as defined in 3.1.1),

10.1.5 *Grip Span*,

10.1.6 *Insertion Depth*, and

10.1.7 *Mode of Failure*.

10.1.8 *Test Block Material Description*—Provide the following information and the appropriate test methods used to determine the properties of the test block material:

10.1.8.1 Trade Name,

10.1.8.2 Composition,

10.1.8.3 Density,

10.1.8.4 Tensile Strength,

10.1.8.5 Compression Strength, and

10.1.8.6 Shear Strength.

11. Precision and Bias

11.1 Data establishing the precision and accuracy to be expected from this test method have not yet been obtained.

12. Keywords

12.1 axial pull-out strength; medical bone screws

APPENDIX

(Nonmandatory Information)

X1. RATIONALE

X1.1 This test method is intended to provide a uniform test procedure for measuring the axial pull-out strength of bone screws in a uniform medium. This test method is intended to measure the uniformity of the products tested or to compare the strength of different products provided that the same test block material is used. Since a standard material is not specified, results may vary as a function of the material used. At the present time, no ASTM standards exist for synthetic bone materials. The task group is currently evaluating several materials to be used for bone screw insertion and pull-out testing, including a polyurethane foam. A draft standard

entitled *Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments* is being balloted on the subcommittee level. It is anticipated that this evaluation will take an extended period of time. The task group has determined that there is an immediate need in the industry for a standard testing procedure for measuring the pull-out strength of bone screws, and therefore, this test method is submitted without a standard test block material.

X1.1.1 Until such time that a standard material is chosen and specified, this test method will require a description and