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Implants for surgery — Partial and total hip-joint prostheses —

Part 10:
Determination of resistance to static load of modular femoral heads

Implants chirurgicaux — Prothèses partielles et totales de l'articulation de la hanche —

Partie 10: Détermination de la résistance à la charge statique de têtes fémorales modulaires

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Foreword

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This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

This second edition cancels and replaces the first edition (ISO 7206-10:2003), which has been technically revised.

Introduction

Some designs of stemmed femoral components of total hip-joint prostheses comprise a stem/neck component and a component that forms the articulating surface, which is commonly in the form of a partial sphere incorporating a female conical taper connection for attachment to the neck of the stem. It is important, therefore, that the head and neck are of sufficient strength to withstand the static axial forces likely to be exerted on the prosthesis during use. This method addresses the static strength and attachment of the head. It should be noted that the test conditions described in this document do not exactly reproduce all the factors in the clinical situation.

Implants for surgery — Partial and total hip-joint prostheses —

Part 10:
Determination of resistance to static load of modular femoral heads

1   Scope

This document specifies methods of determining the compressive (fracture) or the tension (disassembly) loads required, under specific laboratory conditions, to cause failure of a modular head system.

This document applies to components made of metallic and non-metallic materials, such as femoral heads of partial or total hip-joint replacements of modular construction (i.e. a head/neck conical taper connection).

This document excludes methods of examining and reporting the test specimens.

2   Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 4288, *Geometrical Product Specifications (GPS) — Surface texture: Profile method — Rules and procedures for the assessment of surface texture*

ISO 6506-1, *Metallic materials — Brinell hardness test — Part 1: Test method*

ISO 7206-1, *Implants for surgery — Partial and total hip joint prostheses — Part 1: Classification and designation of dimensions*

ISO 7500-1, *Metallic materials — Calibration and verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Calibration and verification of the force-measuring system*

3   Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7206-1 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
bore
conical blind hole in the surface of the modular femoral head

3.2
bore angle
included angle of the conical surface of the bore

Note 1 to entry: See Figure 1 a).

3.3
cone
metal truncated right-circular cone (male component) used to engage with a mating conical bore (female component) of the modular femoral head

Note 1 to entry: See Figure 1 b).

3.4
cone angle
included angle of the conical surface of the cone

Note 1 to entry: See Figure 1 b).

3.5
basic design control
<Morse taper system> parameter that governs the self-locking potential of a Morse taper system

EXAMPLE   Engagement length between the bore and the cone, bore surface roughness, cone surface roughness, and, the three-dimensional (3D) control elements

3.6
3D control elements
<Morse taper system> set of three-dimensional (3D) elements that, along with the other basic design controls, are required to govern the self-locking potential of a Morse taper system

EXAMPLE   Bore and cone circularity, bore and cone straightness, cone angle, bore angle, bore and cone concentricity and bore and cone diameter at a reference point

Note 1 to entry: All the 3D control elements can affect the other 3D control elements. For maintaining the viability of the system, is important that the tolerance ranges for all 3D control elements are well defined.

3.7
head
spherical, modular femoral component which includes a conical bore and is engaged by a cone

Note 1 to entry: See Figure 1 a).

3.8
installation force
force used to connect the head and neck components prior to testing

3.9
load axis
line of action of the compressive force applied to the head

Note 1 to entry: See Figures 2, 3, 4 and 5.

3.10
head/neck conical taper connection
<Morse taper system> precision machined truncated conical tapers and bores intended to self-lock together with application of compressive force along the axes of the tapers

3.11
neck
region of the femoral stem component between the cone and the stem

Note 1 to entry: See Figures 1 b), 2, 4 and 5.

2

3.12
neck axis
centreline of the femoral cone

Note 1 to entry: See Figures 2, 3, 4 and 5.

3.13
stroke rate
nominal rate of movement of the moving component of the test machine

4   Principle of the test method

A static compressive or tensile force is applied to the head/neck assembly of the hip-joint prosthesis and increased until either the head or the neck, or the connection between them, fails, or until the chosen maximum force has been applied without the occurrence of failure.

5   Apparatus

5.1   Static compression test

5.1.1   Testing machine, according to ISO 7500-1, capable of applying and recording an axial compressive force to the head/neck assembly, with an accuracy of ± 2 %.

5.1.2   Loading fixtures, capable of sustaining forces up to the anticipated fracture or deformation level of the femoral head constructed so that the line of load application passes through the centre of the femoral head and is aligned with the neck axis as indicated in Figure 2.

5.1.3   Conical loading bore, of dimensions shown in Figure 3 and made of metal having a hardness of at least 150 HB, when determined according to ISO 6506-1.

5.1.4   Copper ring load distributing device, as shown in Figure 3 shall be made from soft annealed copper. The copper ring inner diameter (a) as shown in Figure 3. $a = 0,643 \times$ nominal head diameter – 3 mm.

NOTE   The copper ring load distributing device has a complementary function of protecting the contact surface of the head and the conical loading bore.

5.1.5   Neck unit, comprising a neck/cone of the type to which the head is to be mounted in service, or a dummy having the same dimensions and being made of the same material, by the same manufacturing process and to the same specification [see Figure 1 b)]. In cases of dispute, the test should be performed using the complete stemmed femoral component.

5.2   Static tension test

5.2.1   Testing machine, according to ISO 7500-1 capable of applying and recording an axial tensile force to the head/neck assembly, with an accuracy of ± 1 %.

5.2.2   Loading fixtures, capable of sustaining expected forces and constructed so that the line of force application passes through the centre of the femoral head and is aligned with the neck axis as indicated in Figure 5. The design of the fixture used to pull against the head requires either an opening on one side or a modular design. This fixture shall be sufficiently rigid to prevent deformation which might apply a bending moment or torque to the neck.

5.2.3 Neck unit, comprising a neck and cone of the type to which the head is to be mounted in service, or a dummy having the same dimensions and being made of the same material, by the same manufacturing process and to the same specification [see Figure 1 b)]. In cases of dispute, the test should be performed using the complete stemmed femoral component.

6 Test Specimens

6.1 Manufacture of the cones and bores used in femoral head modularity requires precision control in order that the cone and bore mate and lock consistently. Basic design controls include engagement length between the bore and the cone; bore surface roughness; cone surface roughness; and, the three-dimensional (3D) control elements. The 3D control elements include bore and cone circularity, bore and cone straightness, cone angle, bore angle, bore and cone concentricity, and bore and cone diameter at a reference point. Different manufacturers have different ways of controlling and measuring the basic design controls and 3D control elements they use in the manufacture of modular head systems. For this test it is required that these parameters are always within the manufacturers requirements. If the implant manufacturers are running the tests, all basic design controls and 3D control elements and tolerances should be reported for the specimens.

6.2 The alignment of the femoral cone and bore axis with the line of force application is important. If the applied force is not in line with the axis of the cone and the bore, it can affect the results of the test. It is more difficult to align the cone section of an actual femoral implant to the line of force application and maintain that alignment under large forces. It is acceptable to produce a simulated cone that has a flat base that makes that alignment easier. Those simulated cones shall be fabricated from the same material in the same metallurgical condition and be produced using the same fabrication methods as the actual femoral implant. They shall have all the same basic design controls and 3D control elements as actual implants. All basic design controls and 3D control elements used in the manufacture of test specimens shall be measured and recorded using the same techniques used in the production of actual implants.

6.3 All heads used in the tests shall be actual implants. The manufacturer shall ensure that the heads tested have all the same basic design controls and 3D control elements as actual implants. If tested under the control of the manufacturer, the basic design controls and 3D control elements for each test head shall be measured and recorded.

6.4 At least five specimens of each type shall be used for each kind of static test.

7 Procedure

7.1 Sampling

7.1.1 Each test specimen will consist of a femoral head assembled on a neck unit.

7.2 Assembly of test specimens

7.2.1 Use new femoral heads and neck units for each test. The head and neck units shall have a cleanliness equivalent to implants intended for clinical use. All test specimens should be permanently marked in a way to maintain traceability to measurement requirements in 6.1.

7.2.2 Fit together the head and the cone by hand by applying gentle rotation during insertion, without forcing, prior to any force being applied, Force shall be applied to the head on the cone using a method

such as that illustrated in Figure 3 or Figure 4, or any other method provided the following requirements are met:

Normal laboratory cleaning procedures should be used to remove any debris or surface contaminants prior to assembling modular components.

a)   the alignment tolerances shown in Figure 2 shall be maintained;

b)   apply an installation force of (2,0 ± 0,2) kN at a loading rate of (0,5 ± 0,1) kN/s or at a stroke rate of (0,04 ± 0,01) mm/s. The installation force of 2 kN can also be directly implemented in the test procedure provided the force is dropped to approximately 0,1 % of the maximum force of the testing machine (between 50 N and 200 N);

c)   inspect the specimen; if it is damaged terminate the test;

d)   if the fixtures used for installation are to be used for the test, inspect them and replace them if they are damaged.

CAUTION — Protect the test operator from injury by fragments in case the specimen should shatter when under load or when disassembling or when storing the specimen after removal of the load from unfractured specimens.

7.3   Static compression test

7.3.1   Load the femoral head through a conical loading bore (5.1.3) according to the testing configurations shown in Figure 3, insuring the alignment tolerances shown in Figure 2. A copper ring (5.1.4) shall be inserted between the femoral head and loading bore (Figure 3) to protect the contact surface of the head and the conical loading bore.

7.3.2   Apply a preload of 0,1 % of the maximum force of the testing machine (or between 50 N and 200 N) to the assembly. The compressive test force shall be applied at a loading rate of (0,5 ± 0,1) kN/s; or at a stroke rate of (0,04 ± 0,01) mm/s taking a record of the force/time, displacement/time, or force/displacement behaviour. It may be possible to shorten the test time by using a copper ring pre-deformed at the appropriate diameter.

7.3.3   Increase the force until one of the following occurs:

a)   the fracture of the head; or

b)   fracture or permanent deformation of the neck; or

c)   the chosen maximum force has been applied.

7.3.4   Record the maximum force applied and explain the reason the test was terminated.

NOTE   A discontinuity could occur during the static compression test, due to stick-slip effects.

7.3.5   Examine the conical loading bore after each test, and discard it if damaged. If a copper ring is used for the contact, replace it for each test.

7.3.6   Determine the range, average and the standard deviation of the maximum forces from the specimens tested, and define the average force as the static resistance to fracture.

7.4 Static tension test

7.4.1 Place the head/neck assembly in a fixture, such as that shown in Figure 5, capable of holding the neck component securely, achieving uniform flat contact around the base of the head, and maintaining the alignment tolerances shown in Figure 5.

The design of the fixture used to pull against the head requires either an opening on one side or a modular design. This fixture should be sufficiently rigid to prevent deformation which might apply a bending moment or torque to the neck.

7.4.2 Load the head by applying to the assembly a tensile force at a stroke rate of (0,04 ± 0,02) mm/s, maintaining the alignment tolerances shown in Figure 5. Faster rates may be used if it can be demonstrated that they do not affect the result.

7.4.3 Terminate the test when the head is suddenly removed from the neck component or the loading force drops below 100 N after a higher peak.

7.4.4 For each specimen, register the maximum tensile force applied and the standard deviation of the maximum tension forces from the specimens tested. Define the average force as the static tension resistance.

8 Test report

The test report shall include the following information:

a) a reference to this document, i.e. ISO 7206-10:2018;

b) the identity of the femoral head test specimen, including the manufacturer's name, manufacturing lot code, femoral head diameter, neck length (standard, long, etc.), and material and if available from the submitter the bore angle, bore diameter at a reference point, and bore surface roughness (Ra and Rz in accordance with ISO 4288) [see Figure 1 a)];

c) the identity of the cone specimen, including the manufacturer's name, the cone material, if available from the submitter, the cone angle, cone diameter, and cone surface roughness (Ra and Rz in accordance with ISO 4288) [see Figure 1 a)];

d) for each compressive test, the load rate or the stroke rate at which the test was conducted, the force at which the test was terminated, the maximum value of the test force applied, and the reason for termination. The range and average static resistance to fracture and the standard deviation for the specimen tested (7.3.6);

e) for each tensile test, the stroke rate at which the test was conducted, the maximum value of force applied, and the reason for termination. The range and average static tension resistance and the standard deviation for the specimens tested (7.4.4);

f) the results of the examination requested by the party submitting the specimen for test, if appropriate.

NOTE Measurements of linearity (or straightness) and circularity (or roundness, conicity, or concentricity) of the head bore and the cone [see Figures 1 a) and 1 b)] can be useful in explaining test results.

9 Disposal of test specimens

9.1 Components that survive the test shall not be used for clinical purposes after testing. Care should be exercised in the use of the components for further mechanical tests, because the loading regime could have altered the mechanical properties. In particular, it is recommended that neither component be used for further tests by the methods described in this document.
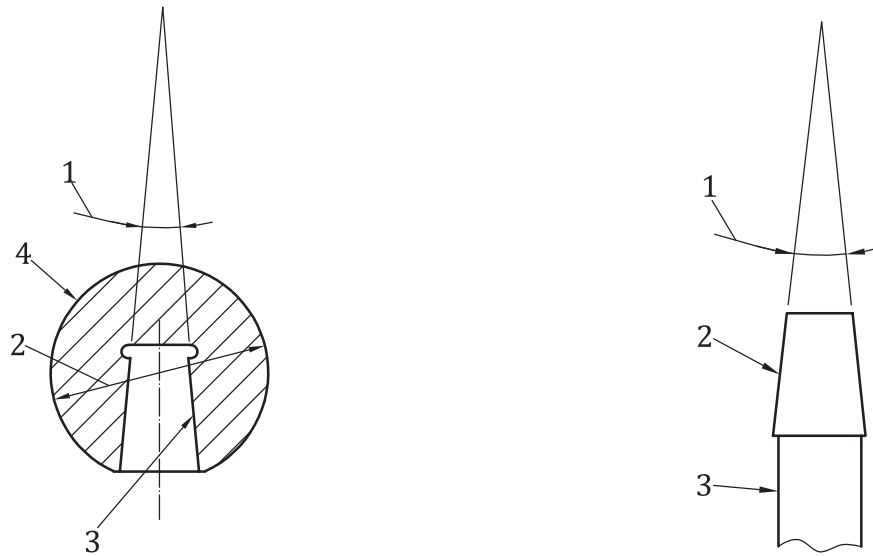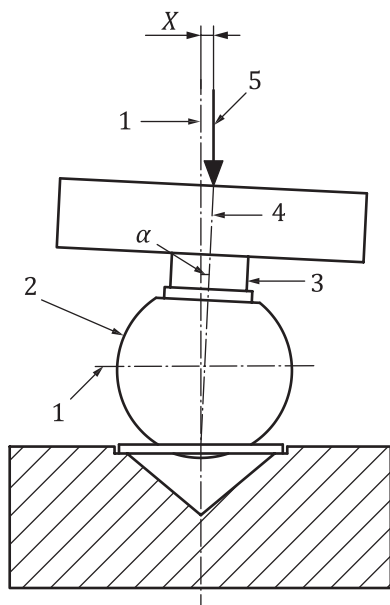

a) Geometrical features on femoral head   **b) Geometrical features on neck specimen**

Key

1	bore angle		1	cone angle
2	head diameter		2	cone
3	bore		3	neck
4	head			

Figure 1 — Geometrical features on mating head and neck specimens

Key

1	centrelines of head	5	load axis
2	head	α	inclination of neck axis to load axis of testing machine = $(0 \pm 1)°$
3	neck	X	offset of load axis from centre of head = $(0 \pm 0,1)$ mm
4	neck axis		

**Figure 2 — Illustration of the alignment tolerances in the compressive loading test**

NOTE   The inclination of the neck axis angle and offset of the load axis in this figure have been exaggerated to make the requirements clear.

Dimensions in millimetres
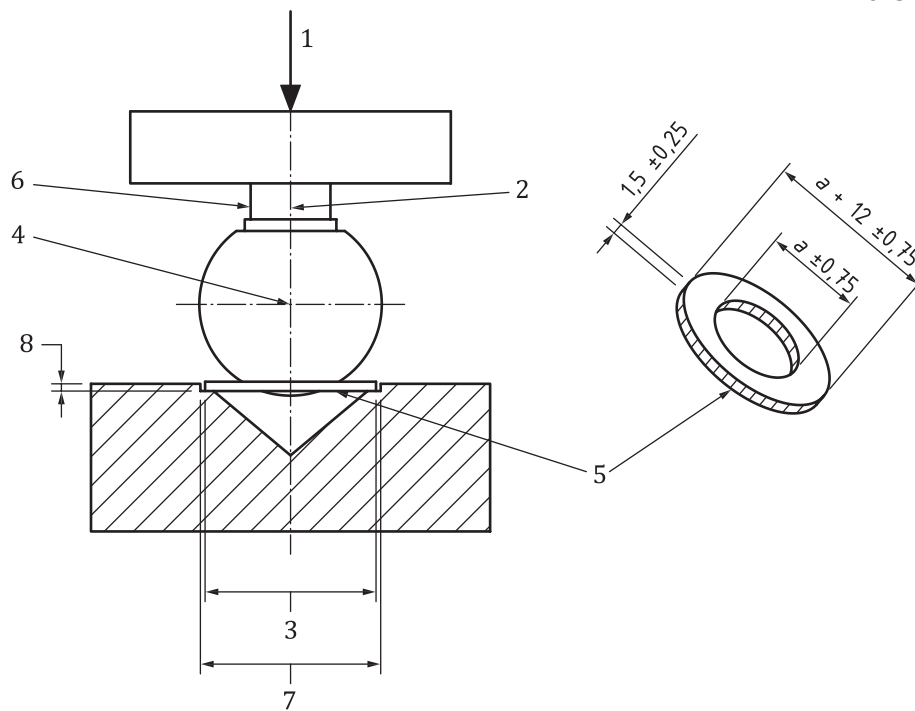
Key

1   load axis
2   neck axis
3   opening diameter of conical holder 0,75 *diameter of head (min.) [mm], 100° ± 1
4   head
5   Ring shall be fabricated from soft annealed copper
6   neck
7   ring alignment diameter ≥ maximum outer diameter of the chosen copper ring (use a clearance fit)
8   ring alignment deep enough to keep the copper ring from slipping off the edge under load
a = 0,643 × diameter of the head −3[mm].

Figure 3 — Example of the loading method in conical metal bore assemblies
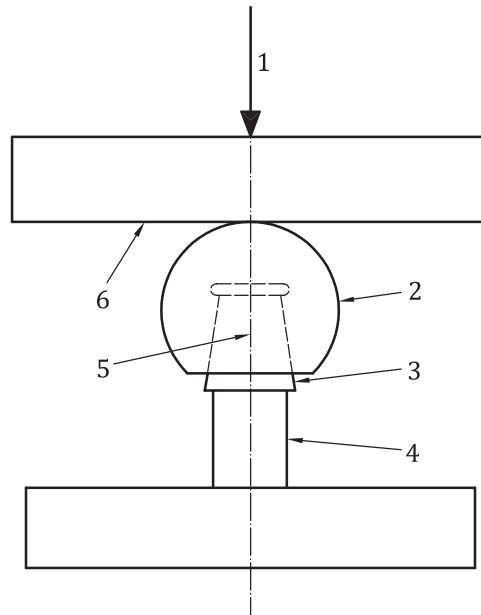
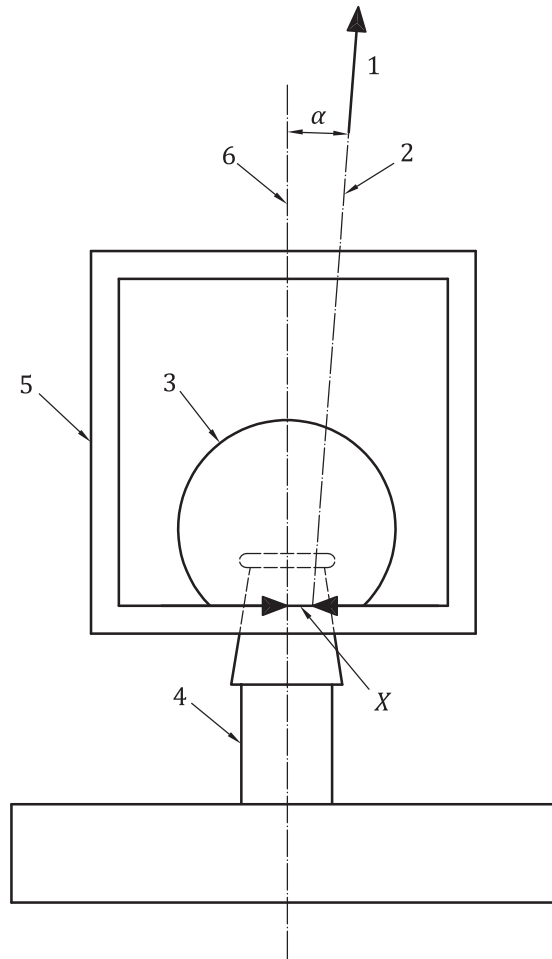**Key**

1	load axis	4	neck
2	head	5	neck axis
3	cone	6	flat plate

The method shown in Figure 3 may also be used.

Figure 4 — Loading method for installing modular head assemblies

Key

1	load	5	disassembly cage
2	load axis	6	neck axis
3	head	α	$(0 \pm 1)°$ loading tolerance
4	neck	X	$(0 \pm 0,1)$ mm loading tolerance

Figure 5 — Illustration of tensile loading method for modular head disassembly and the required alignment tolerances

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