INTERNATIONAL STANDARD

ISO 11491

First edition
2017-07

Implants for surgery — Determination of impact resistance of ceramic femoral heads for hip joint prostheses

Implants chirurgicaux — Détermination de la résistance à l'impact des têtes de fémur en céramique pour les prothèses de la hanche

Reference number
ISO 11491:2017(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

Introduction

Partial and total hip joint prostheses are designed to transmit load and allow movement under high stress conditions. They are intended to replace anatomical structures and to provide function as closely as possible to the attributes of the normal natural joint. Some designs of femoral components of total hip joint prostheses comprise a ceramic femoral head and a metal femoral stem. It is important, therefore, that the ceramic femoral head is of sufficient strength to withstand the static loads as well as the dynamic impact loads likely to be exerted on the prostheses during use. It has been found that the ISO 7206-10 test did not produce the same type of fracture for zirconia heads that were similar to fractures produced clinically, while the test fractures produced on alumina heads were similar to clinical fractures. It is important, specifically in cases of a new ceramic material and/or new taper configurations, to know the behaviour after impact loading such as delayed fracture that may not be detected by a purely static burst test. Hence, this document specifies two alternative test methods to determine the impact strength of ceramic femoral heads.

The fracture mechanisms of ceramic ball heads occurring after an impact load may be either an immediate overload breakage or subcritical crack growth. Subcritical crack growth may then lead to failure at forces lower than the initial static burst load. In ceramic ball heads loaded via the interface between the metal trunnion (neck unit) and the ball head, subcritical crack growth may either be induced by impaction or by incremental load-release cycles with quasi-static forces.

Implants for surgery — Determination of impact resistance of ceramic femoral heads for hip joint prostheses

1 Scope

This document specifies two alternative test methods for determining the impact resistance of ceramic femoral heads for hip joint prostheses.

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 197-1, *Copper and copper alloys — Terms and definitions — Part 1: Materials*

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

ISO 7206-10, *Implants for surgery — Partial and total hip-joint prostheses — Part 10: Determination of resistance to static load of modular femoral heads*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7206-10 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 http://www.iso.org/obp

3.1
impact energy
potential mechanical energy of the falling/drop weight used for applying the impact

3.2
cyclic impact resistance
maximum impact energy without failure of the test specimen, when consecutively increased impacts are applied

3.3
impact load
peak measured force before fracture when impact energy or quasi-static load-release cycles are applied

3.4
impact velocity
falling weight velocity immediately prior to impact

3.5
quasi-static force
force that changes slowly with time so that any mass inertia influence can be neglected

4 Principle

This document can be used for the purpose of material development, material comparison, quality assurance, implant system characterization, reliability analysis and design data generation.

Impact resistance (cyclic strength) is determined by applying impacts of increasing energy to the head/taper construct and identifying the maximum energy that does not result in fracture. Alternatively, the impact load (cyclic strength) may be determined by quasi-static load-release cycles identifying the maximum load that does not result in fracture.

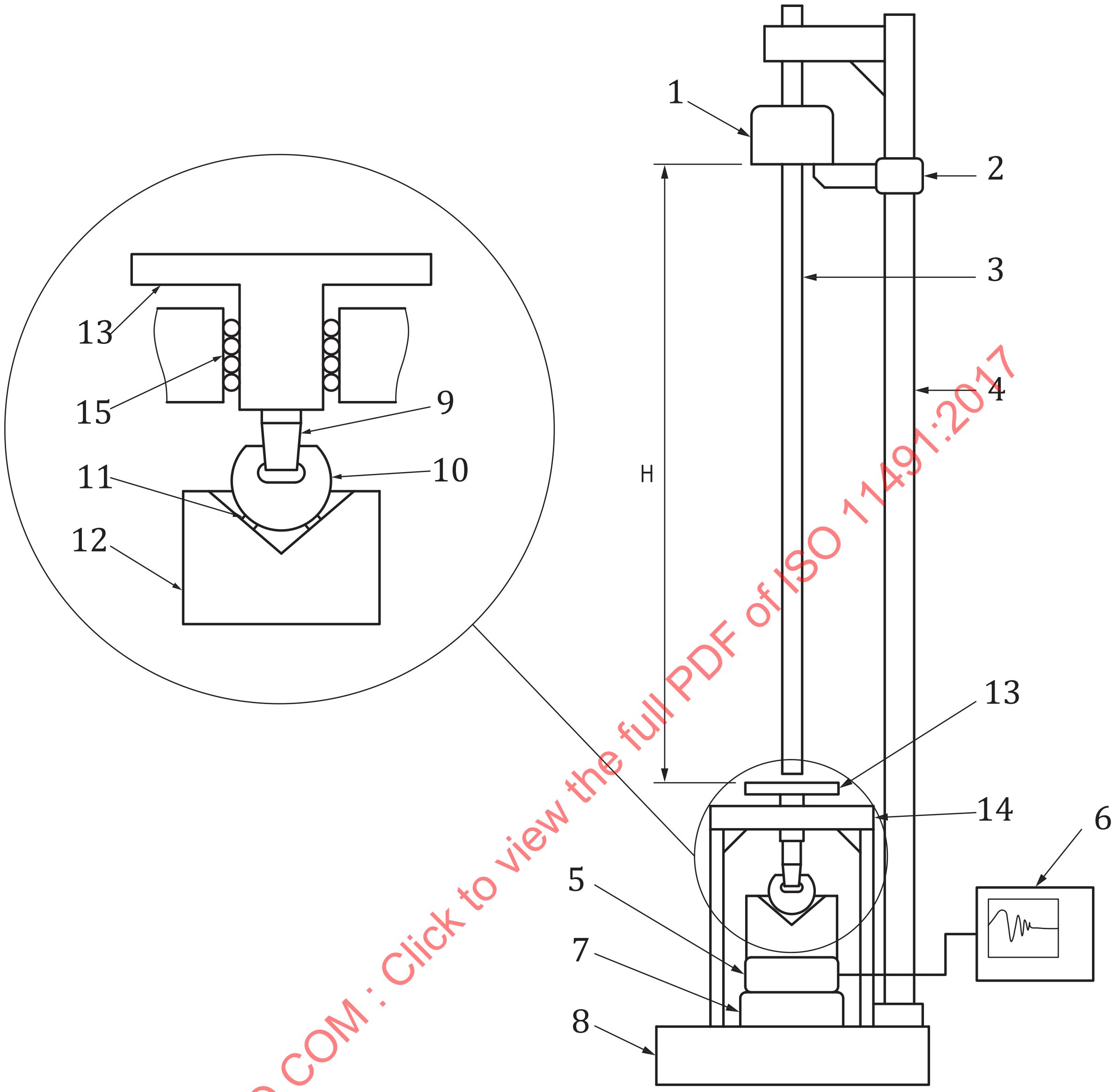
NOTE These test methods are most appropriate for evaluating new types of ceramic ball head material in combination with metal stem tapers as well as new taper design specifications by comparing them with clinically established and proven ceramic ball head and metal stem taper systems.

5 Apparatus and equipment

5.1 Test machine for the impact test.

The test machine shall have a stiff structure capable of applying an impact to a test specimen by a falling/drop weight. The machine shall be firmly mounted on the ground or a heavy, rigid bench (e.g. granite or steel topped measuring table). The machine shall accommodate a weight of adjustable mass to fall onto the sample from adjustable height to allow the application of a range of impact energies. The weight can be guided or free. Any guiding mechanism shall minimize friction. The guiding mechanism should not be in contact with the striking assembly. The test specimen composed of a head and neck unit shall be supported on a holding block mounted on a load cell. The axis of the falling weight, the test specimen, the holding block and the load cell shall be aligned vertically (±1°) and laterally (±1 mm). Fixturing to position the test specimen shall have low mass, but shall be stiff and strong enough to withstand repeated impacts.

One example of the test machine is shown in Figure 1.



Key

1	falling weight assembly	9	neck unit
2	falling weight stopper	10	specimen
3	guiding rail	11	copper ring
4	support column	12	holding block
5	load cell	13	striking plate (neck unit holder)
6	load cell data recorder	14	housing
7	mount	15	sleeve/bearing
8	base	H	falling height

Figure 1 — Example of testing machine

In order to avoid applying the impact load on the specimen/neck unit assembly in malposition, a linear bearing or low friction sleeve shall be installed at neck unit holder. This structure can also prevent the specimen/neck unit assembly from unexpected movement after impact loading. The striking plate (neck unit holder) needs to have stiffness, diameter and thickness appropriate as the target of the falling weight, but should be as small as possible within that context.

5.2 Test apparatus for the impact test.

5.2.1 Falling weight

Impact energy shall be calculated based on the mass of all components of the falling weight assembly. Measurement of mass and drop height shall allow the impact energy to be calculated with an uncertainty of ±2 %.

If impact energy is calculated from the potential energy of the drop weight then, periodically, the kinetic energy at impact shall be verified by measuring impact velocity. Any discrepancy between kinetic and potential energy shall be accounted for within the ±2 % uncertainty.

In order to minimize the friction resistance between the falling weight and guiding rail, a linear bearing or low friction sleeve should be included in falling weight assembly.

Principle or frequency of verification can refer to ISO 148-2.

5.2.2 Neck unit

The neck unit shall be made of the same material, to the same cone dimensions including shape and surface requirements and with the same manufacturing process as the commercial hip prosthesis part (stem) to be engaged with the mating conical bore of the ceramic femoral head, and shall have the shape to be fitted to a testing machine. An unused neck unit shall be used in each test. Care shall be taken that there is no foreign substances on the cone portion of the neck unit that contacts the ceramic femoral head.

5.2.3 Holding jig

The holding jig is composed of a combination of a holding block and a copper ring.

a) Holding block

The holding block shall be made of steel and shall have dimensions and hardness described in ISO 7206-10. The holding block shall be fixed to the base through a mount.

NOTE The dimensions of the holding block are typically approximately 2 times the dimensions of the tested femoral heads in diameter and its height between 1,0 and 1,5 times the tested ball head diameter.

b) Copper ring

A copper ring shall have the shape to match the test specimen diameter as described in ISO 7206-10 but with the tolerance of ±0,1 mm, and shall be made of refined copper, with minimum copper content of 99,85 % (mass/mass), according to ISO 197-1. In testing, an unused copper ring shall be used for each test specimen.

5.2.4 Load cell and the load cell data recorder

5.2.4.1 General

By measuring and recording the force resulting from an applied impact, the forces experienced by the test specimen, as well as any abnormalities of the test, can be detected.

5.2.4.2 Load cell

The load cell shall be an impact load cell (not static) and shall be rigidly mounted as specified by its manufacturer.

5.2.4.3 Load cell data recorder

The load cell data recorder shall have a sampling rate of at least 200 kHz, and shall be able to acquire the data of an impact load from the impact initiation to at least 500 ms thereafter.

5.2.5 Mount and base

The mount and the base shall be made of steel and robust to firmly hold the test setting.

5.3 Test machine, apparatus and setup for the cyclic load-release burst test.

All specifications for the test machine, the apparatus and the test setup shall be according to the static compression test described in ISO 7206-10. The test needs to be performed force-controlled, hence, the test machine shall be capable to perform compressive tests under force control.

5.4 Test specimens.

5.4.1 Geometry and size

Either commercial products of the ceramic femoral head, or test specimens manufactured with the same design and material, through the same process as the intended commercial product may be used.

If the ceramic femoral heads come in a range of diameters, engagement lengths, etc., and there are no requests from submitter, testing shall be performed on “worst-case” sizes.

5.4.2 Sample size

The sample size shall be a minimum of five for each design and/or material combination tested.

6 Procedure

6.1 General

6.1.1 Copper ring shall be cleaned with organic solvent and neutral detergent in order to remove oil, fat and contaminants.

6.1.2 Use a new ceramic femoral head and a new neck unit both cleaned according to the requirements of ISO 7206-10, for each test.

6.1.3 Use a new copper ring load distributing device for each test. A single copper ring shall be used for each test specimen (femoral head) until the test has been completed.

NOTE 1 It is reported that a contamination entrapped within the coupling portion of the conical bore of the ceramic femoral head and the cone of the femoral stem considerably reduces the mechanical strength of the ceramic femoral head[1].

6.1.4 Mount the ceramic femoral head onto the neck unit. Care should be taken to maintain the alignment of the neck unit and ceramic femoral head.

NOTE 2 Adding a rotational movement to the specimen during mounting onto the neck unit is useful to maintain the alignment of the neck unit and the specimen.

6.1.5 Apply an installation force according to ISO 7206-10. If the specimen is damaged for any reason, do not use it for the testing.

6.2 Test method for impact resistance (cyclic strength)

6.2.1 Setting the test specimen

Place the specimen/neck unit assembly in the fixture of the test machine. Align the loading axes of the different components to be vertical (±1°) and adjust their lateral position (±1 mm). Care should be taken not to apply any impact force to the test specimen during the setting.

6.2.2 Applying an impact

An initial impact energy of 20 J shall be applied to the sample by employing the appropriate falling weight mass (M) and falling height (H) of 1 m. This ensures proper seating of the femoral head on the neck unit and deforms the shape of the copper ring to match the shape of the femoral head and holding block.

Apply progressive energy impact steps with increasing energy starting at a level that does not cause fracture.

Increase the energy impact in 10 J steps, increasing the falling mass.

Inspect and correct the alignment of the copper ring and the loading axis of the test specimen between impacts. Wait at least 1 h between impacts. Continue testing steps until the femoral head cracks or fractures.

If a shorter interval time between impacts is used, a rational should be provided as part of the test report.

The interval of at least 1 h between impacts is required because a delayed fracture can occur after a certain period of time in spite of not observing a failure immediately after applying an impact.

6.2.3 Load cell data sampling

The maximum force value (peak force) recorded by the data recorder from the load cell shall be recorded as impact load.

Produce a plot of impact load versus time.

6.3 Test method for the cyclic load-release burst test

6.3.1 Setting the test specimen

The setting of the test specimen shall be done according to ISO 7206-10.

6.3.2 Loading of the specimen

Apply a compressive force up to an initial force of 20 kN (±0,1 kN) at a loading rate of (0,5 ± 0,1) kN/s, taking a record of the force-time behaviour. Keep the load for at least 1 s, then apply subsequent load-release cycles as described in the following.

a) Release the initial force (maximum force) at an unloading rate equal to the loading rate until 0,2 kN ± 0,1 kN (unloaded state).

b) Keep the unloaded state for Δt = 5 min ± 5 s.

c) Increase the force again up to the previous maximum force plus 5 kN ± 0,1 kN with a loading rate of 0,5 kN/±0,1 kN/s (new maximum force). Keep the force for at least 1 s.

d) Go back to a).

