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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

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

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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.

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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*

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3 Terms and definitions

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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

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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.

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

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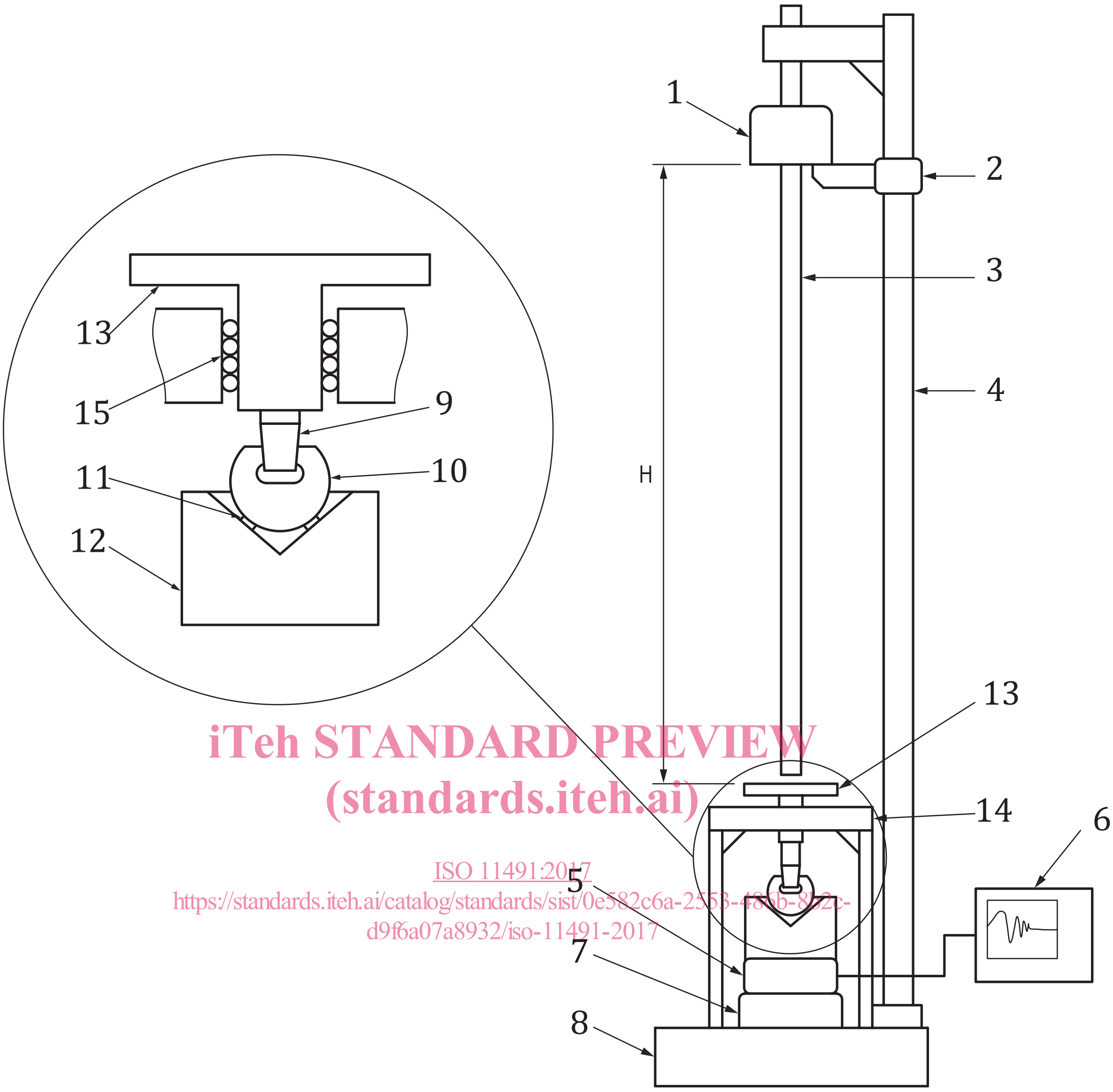

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Key

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

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