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Implants for surgery — Partial and total hip joint prostheses —

Part 13: Determination of resistance to torque of head fixation of stemmed femoral components

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

Partie 13: Détermination de la résistance au couple de la fixation des têtes des tiges fémorales

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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

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Foreword

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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

ISO 7206 consists of the following parts, under the general title *Implants for surgery — Partial and total hip joint prostheses*:

- *Part 1: Classification and designation of dimensions*
- *Part 2: Articulating surfaces made of metallic, ceramic and plastics materials*
- *Part 4: Determination of endurance properties of stemmed femoral components*
- *Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components*
- *Part 10: Determination of resistance to static load of modular femoral heads*
- *Part 12: Deformation test method for acetabular shells*
- *Part 13: Determination of resistance to torque of head fixation of stemmed femoral components*

Introduction

Some designs of stemmed femoral components of total hip joint prostheses comprise a stem/neck component and a bearing head component, which is commonly in the form of a partial sphere incorporating a female fixation feature for attachment to the neck of the stem. Such heads are generally produced using metal or ceramic material. It is important that after assembly, whether by the manufacturer or by the surgeon in the operating theatre, the head subsequently remains immobile on the neck, because movement of a metal or a ceramic femoral head component on a metal stem/neck component will cause the metal components to wear, while metal-on-metal movement may lead to severe fretting corrosion (see Reference [1]).

It is essential, therefore, that the strength of the fixation between the head and the neck is sufficient to withstand the torque likely to be transmitted through the prosthesis in use. The maximum torque applied to the interface connection depends on several design, material, and manufacturing specific parameters, e.g. pairing of bearing materials, bearing diameter, and clearance, surface finish, etc. (see Reference [2]).

The locking strength of the interface connection depends on several design, material, and manufacturing specific parameters for the taper geometry of the mating components, as taper angle and tolerances, taper clearance, surface finish, etc. In consequence, the torsional locking strength of nominal identical taper fixations might vary significantly (see Reference [3]) and needs to be determined prior to clinical use.

Clinical failure of taper connections is related to particle generation by interface micromotion, fretting, and fatigue failure (see Reference [4]). Torsional interface stability is essential for stable fixation of taper connections in order to limit the above listed adverse effects.

Implants for surgery — Partial and total hip joint prostheses —

Part 13: Determination of resistance to torque of head fixation of stemmed femoral components

1 Scope

This part of ISO 7206 describes a method of determining the torque required, under specified laboratory conditions, to loosen the fixation of the head of hip joint prostheses in which the head is not intended to rotate relative to the neck. It applies to the femoral component of total or partial hip joint replacements in which the head and neck/stem (in the following referred to as cone) are secured together by a locking conical taper or any other means and in which the head and cone are separate components, and which are made of metallic or non-metallic materials.

This part of ISO 7206 does not cover methods of examining the test specimens; these should be agreed between the test laboratory and the party submitting the specimen for test.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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

ISO 7500-1, *Metallic materials — Verification of static uniaxial testing machines — Part 1: Tension/compression testing machines — Verification and calibration 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 ISO 7206-10 apply.

4 Principle

A static torque is applied to the head/cone assembly of the hip-joint prosthesis and increased until the connection between the head and the cone fails or until the chosen maximum torque has been applied without occurrence of failure.

5 Apparatus

5.1 Testing machine, according to ISO 7500-1 requirements, shall have the following characteristics:

— ability to apply an axial compressive force through the axis of the head/cone for assembly, with an accuracy of 1 % of full scale reading;

— ability to apply an axial force to a certain point of a lever arm mounted onto the cone unit or capable of directly applying a torque to the cone unit without needing a lever arm, with an accuracy of 1 % of full scale reading;

— instrumentation to register the values of the applied loads and the angular displacements of the test specimen to a tolerance of ±0,5°.

5.2 Cone unit, comprises a cone of the type to which the head is to be mounted in service or a replica having the same dimensions and being made of the same material, by the same manufacturing process and to the same specification.

5.3 Loading fixtures, shall be capable of sustaining expected loads and designed so that the line of action of the external torque is collinear to the centre line of the head/cone assembly as indicated in Figure 2.

6 Procedure

6.1 Test specimen and sample size

To determine the torque required to loosen the fixation of a head of hip joint prostheses, a minimum of five test specimens shall be tested for each cone unit to which the head is to be mounted. Each test specimen shall consist of a head and a neck of the intended fixation of the head of hip joint prostheses. Test specimens may consist of real implants or coupon components.

6.2 Assembly of test specimen (installation)

Assembly of ball head and cone unit is done according to ISO 7206-10.

6.3 Head fixation

6.3.1 Preparation of the head by flattening it in the equatorial region resulting in two parallel and plane surfaces with nearly the same perpendicular distance to the ball head centre as indicated in Figure 1.

The two surfaces represent an engagement for a kind of flat wrench fixation of the ball head against axial torque loading. The perpendicular distance of the parallel surfaces should be in a range of 30 % to 70 % of the ball head mean diameter. Its remaining wall thickness at the flat surfaces should be at least 2,0 mm.

NOTE For a 28 mm ball head, a perpendicular distance of 19,0 mm ± 0,5 mm has been found to be suitable.

6.3.2 Alternatively, preparation of the head by gluing it into a spherical calotte of a metal fixture so that the calotte covers at least 140° of the head's hemisphere.

The breakaway torque of the bonding should exceed the expected breakaway torque of the head/cone assembly. If the bonding interface breaks before expected rotation of the head, this fact has to be recorded in the test report. An additional sample shall be tested.

NOTE Epoxy resin glues have been found to be suitable for gluing the head into the fixture.

6.3.3 Alternatively, preparation of the head by embedding it into an embedding fixture using a cast resin.

The breakaway torque of the embedding/head coupling should exceed the expected breakaway torque of the head/cone assembly. If the bonding interface breaks before expected rotation of the head, this fact has to be recorded in the test report. An additional sample shall be tested.

NOTE Cast resins (e.g. Technovit®4071)[1)] have been found to be suitable for fixing the head.

6.4 Torque of head fixation

6.4.1 Mount the head/cone assembly into the fixture as described in 6.3.

Alignment of head/cone axis, head fixture axis, and the axis of the loading torque is essential for avoiding additional constraints that could bias the results. The test set-up has to provide axes alignment not only while mounting the head/cone assembly into the set-up but also while the torque load is applied until the breakaway limit is reached. Ideally, this is realized by ensuring a Degree of Freedom (DOF) of 5 for the fixed head/cone assembly, i.e. fixture blocks only rotation around head/cone axis, rotation and movements in other directions are free within a certain range (see Figure 2).

6.4.2 Apply an increasing torque to the cone unit at a loading rate of 20 Ncm/s ± 4 Ncm/s; or if this is not possible, at a rotation angle rate of 0,05 °/s ± 0,01 °/s continuously recording the torque/time or angle/time applied.

6.4.3 Increase the load until the following occurs:

a) peaking and later decrease in the recorded load profile;

b) a torque limit of 50 Nm is reached which assumes that the specimen is strong enough;

c) an angle limit of 20° is reached which signifies that the test should be terminated. If it could be shown that such rotation has occurred within the machine fixtures or between those fixtures and the specimen (e.g. fixation glue), then that individual test shall not count towards the five specimens.

6.4.4 Remove the head/cone assembly from the testing machine and fixtures and examine the test specimen regarding damages especially of the taper areas of male and female taper.

6.4.5 Report the torque resistance and the displacement angle achieved at test termination and the reason for it (see 6.4.3).

6.5 Performance criteria

The party submitting the specimen for test (customer) shall define the acceptance criteria for the test as a torque equal to or greater than that of an existing, clinically successful hip head/cone assembly. The acceptance criteria should contain both a lower limit for the mean torque and a lower torque limit for each sample tested.

6.6 Test report

The test report shall include the following information:

a) a reference to this part of ISO 7206, i.e. ISO 7206-13;

b) the identity of the femoral head test specimen, including the manufacturer's name, femoral head diameter, cone length, and material as stated by the party submitting the specimen for test;

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