First edition
2016-07-01

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

Reference number
ISO 7206-13:2016(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

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 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.