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Implants for surgery — Wear of total hip-joint prostheses —

Part 4: Testing hip prostheses under variations in component positioning which results in direct edge loading

Implants chirurgicaux — Usure des prothèses totales de l'articulation de la hanche —

Partie 4: Essai des prothèses de hanche par variation du positionnement des composants pour induire un chargement direct de bord

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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, *Bone and joint replacements*.

A list of all parts in the ISO 14242 series can be found on the ISO website.

Introduction

Evaluation of the wear of hip joint replacement bearings plays an important role in the development of bearing materials and designs and in the continual assessment of current products. The test conditions outlined in ISO 14242-1 and ISO 14242-3 assume that components are placed at the intended acetabular cup inclination (e.g. 30° as measured between the cup polar axis to the load line), without dynamic separation, and patient range of motion and loading limited to normal walking gait.

However, research findings have shown that for various reasons including differences in hip bearing designs and materials, unintended implant positioning, soft tissue laxity, additional patient range of motion, increased loads, etc., unintended conditions such as edge loading can occur clinically and the consequence can be severe, possibly leading to implant failure.

Many factors contribute to the occurrence of edge loading condition. The test conditions are defined to enable pre-clinical evaluation of performance of devices under edge loading conditions due to variations in rotational and translational positioning and to allow comparison with a control or reference device that has a clinical history.

Edge loading

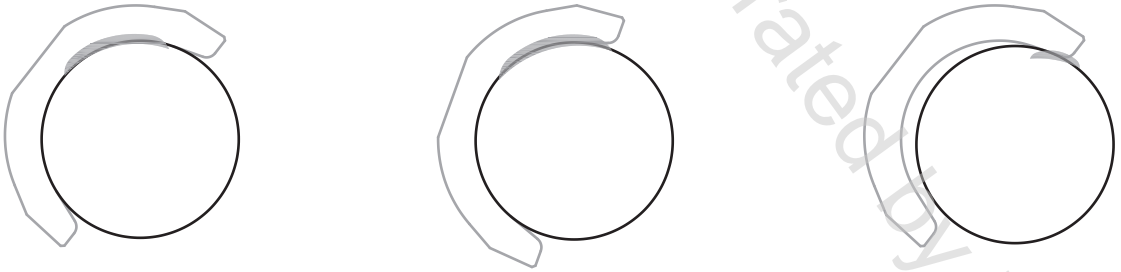
Edge loading is a complex phenomenon influenced by many variables. There are two main types of edge loading:

a) Indirect edge loading which occurs following impingement and lever out of the femoral head;

b) Direct edge loading, where the femoral head locates directly on the edge of the acetabular cup (without impingement), which is dependent on component positioning, joint laxity and patients biomechanics.

This document deals with direct edge loading conditions.

Intended normal (non-edge) loading conditions are when the contact area lies between the intended bearing surface of the femoral head and the acetabular cup [Figure 1 a)]. This is the condition tested in ISO 14242-1 and ISO 14242-3. Edge loading is the contact between the femoral head and the non-spherical bearing surface of the acetabular cup (i.e. rim, or chamfer, or where the geometry deviates from the bearing surface). Edge loading occurs when the contact area [Figure 1 a)] moves away from the intended bearing surface during part or all the gait cycle, as illustrated due to the steep inclination of the acetabular cup in relation to the patient's anatomy influences [Figure 1 b)] or when dynamic separation between the centres of the femoral head and acetabular cup occurs [Figure 1 c)].



a) Under none edge loading condition **b) Under edge loading condition** **c) Under edge loading condition**

Figure 1 — Contact area between the femoral head and the acetabular cup

Rotational positioning

Rotational positioning of the acetabular cup can be split into the rotations around the following three anatomical axes:

a) the anterior posterior axis;

b) the superior inferior axis;

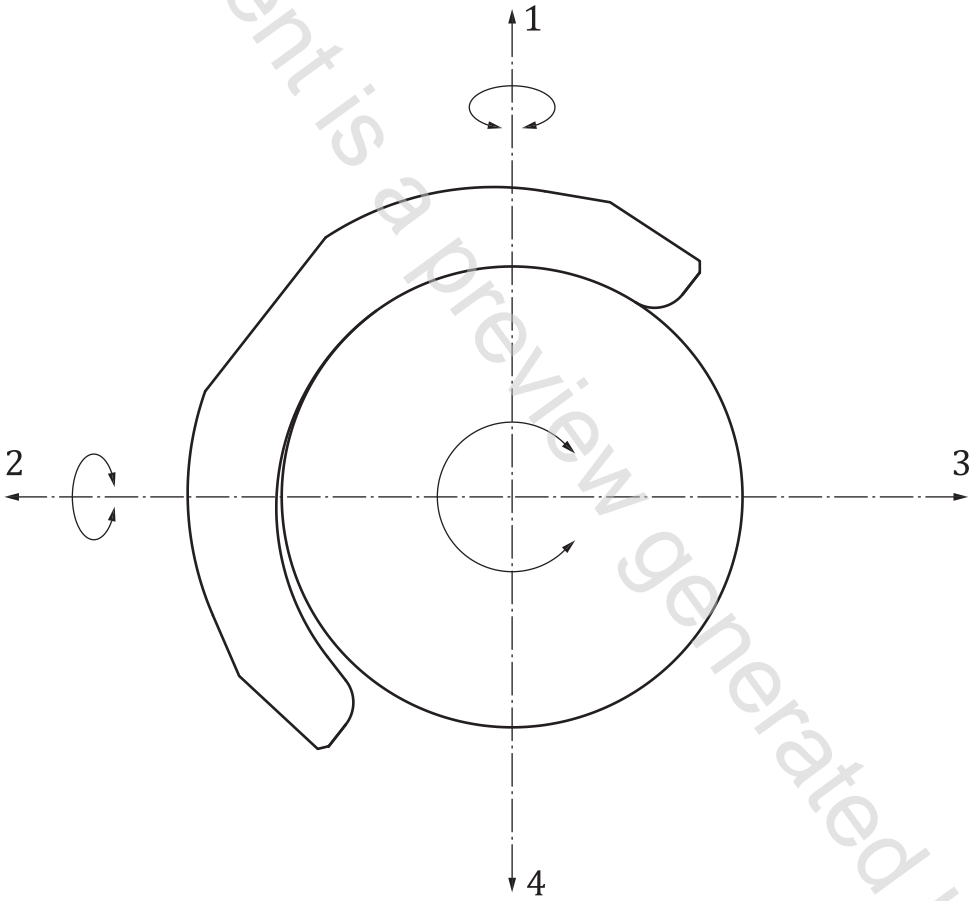
c) the medial lateral axis (Figure 2).

The angular rotations about the three anatomical axes are:

a) Inclination: rotation about the anterior-posterior (A-P) axis;

b) Version: rotation about the superior-inferior (S-I) axis;

c) Tilt: rotation about the medial-lateral (M-L) axis.



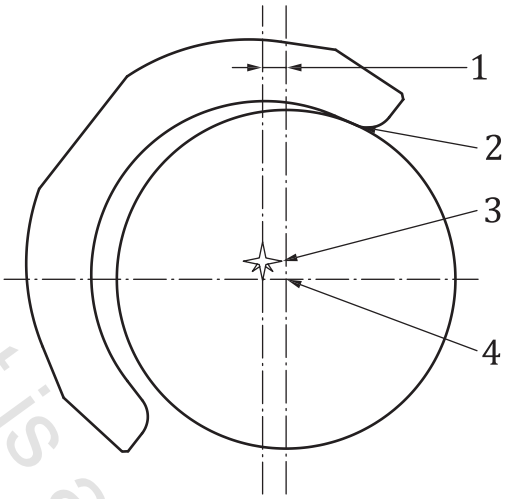
Key

1	superior	3	lateral
2	medial	4	inferior

Figure 2 — Schematic showing frontal view of a left hip with the axes of rotation around the medial-lateral, anterior-posterior (not visible in this frontal view) and superior-inferior axes. Acetabular cup movement- lateral: negative, medial: positive

Translational positioning

The translational position of the femoral head and the acetabular cup is defined as the position of the centres of the rotations of the acetabular cup and femoral head relative to each other along the axes shown in Figure 3. A translational position mismatch can be along the medial-lateral (Figure 3), anterior-posterior and superior-inferior axes. The mismatch between the femoral head and acetabular cup centres in the simulator is needed to replicate *in vivo* separation.



Key

1	translational mismatch in the centres of rotation of the femoral head and acetabular cup	3	centre of the acetabular cup
2	edge loading	4	centre of the femoral head

Figure 3 — Schematic showing a medial-lateral translational mismatch (offset) between the femoral head and acetabular cup where the centre of rotation of the acetabular cup was positioned medially and superiorly to the centre of the femoral head

Implants for surgery — Wear of total hip-joint prostheses —

Part 4: Testing hip prostheses under variations in component positioning which results in direct edge loading

1 Scope

This document specifies the test conditions to simulate edge loading in hip prostheses due to steep acetabular cup inclination angle and dynamic separation conditions.

This document is used in conjunction with ISO 14242-1 or ISO 14242-3.

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 14242-1:2014, *Implants for surgery — Wear of total hip-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test*

ISO 14242-2, *Implants for surgery — Wear of total hip-joint prostheses — Part 2: Methods of measurement*

ISO 14242-3, *Implants for surgery — Wear of total hip-joint prostheses — Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test*

3 Terms and definitions

No terms and definitions are listed in this document.

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

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

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

4 Testing conditions

Two testing conditions summarized in Table 1 are considered in this document. Examples of the assessment of edge loading are given in Annex A. Use lubricant and loaded soak control specimens as specified in ISO 14242-1 or ISO 14242-3.