INTERNATIONAL STANDARD

ISO 14242-4

First edition
2018-05

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

ISO 14242-4:2018
https://standards.iteh.ai/catalog/standards/sist/b3fa6067-1a52-4d56-bf66-891e7418a28f/iso-14242-4-2018

Reference number
ISO 14242-4:2018(E)

© ISO 2018

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 14242-4:2018
https://standards.iteh.ai/catalog/standards/sist/b3fa6667-1a32-4d36-bf66-89fe7418a28f/iso-14242-4-2018

COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

© ISO 2018 – All rights reserved

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Testing conditions **1**
5 Simulator set up **2**
6 Output measurements **3**
7 Reference specimen **4**
8 Test report **4**
Annex A (informative) **Dynamic separation and edge loading** **6**
Bibliography **11**

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 14242-4:2018
https://standards.iteh.ai/catalog/standards/sist/b3fa6667-1a32-4d36-bf66-89fe7418a28f/iso-14242-4-2018

© ISO 2018 – All rights reserved

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

ISO 14242-4:2018
https://standards.iteh.ai/catalog/standards/sist/b3fa6667-1a32-4d36-bf66-80b7448c28f5/iso-14242-4-2018

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

© ISO 2018 – All rights reserved

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;

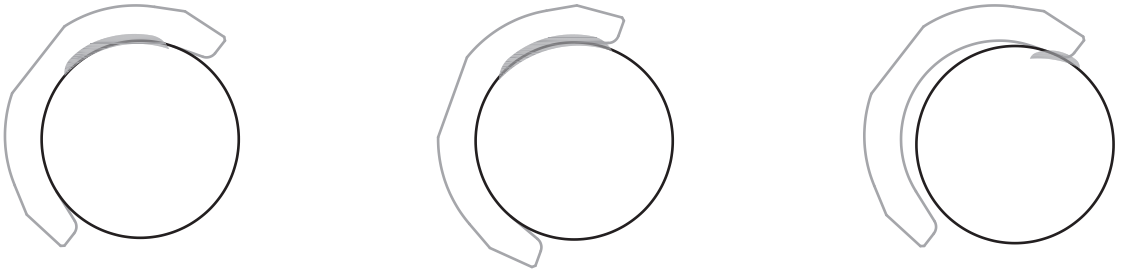
b) Direct edge loading, where the femoral head locates directly on the edge of the acetabular cup (without impingement), which is dependent on component positioning, joint laxity and patients biomechanics.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

This document deals with direct edge loading conditions.

ISO 14242-4:2018
https://standards.iteh.ai/catalog/standards/sist/b3fa6667-1a32-4d36-bf66-89fc7418a281/iso-14242-4-2018

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

© ISO 2018 – All rights reserved

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;

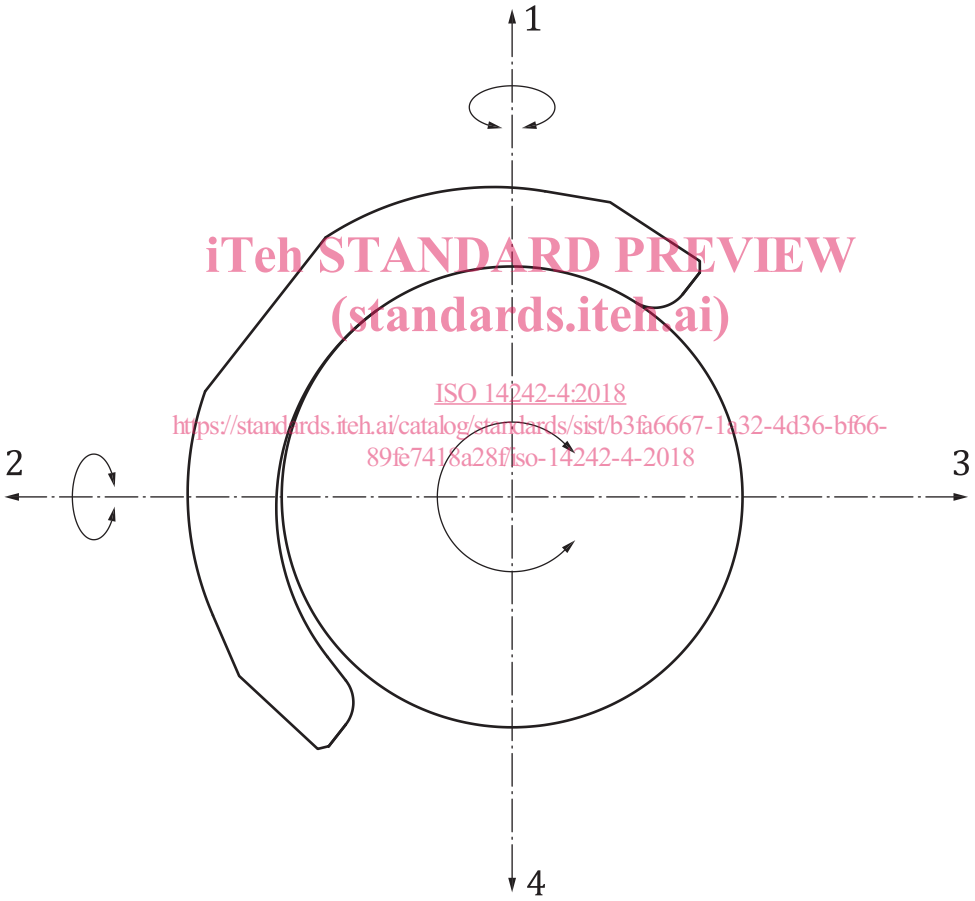
c) the medial lateral axis (Figure 2).

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.



iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 14242-4:2018
https://standards.iteh.ai/catalog/standards/sist/b3fa6667-1a32-4d36-bf66-89fe7418a28f/iso-14242-4-2018

Key

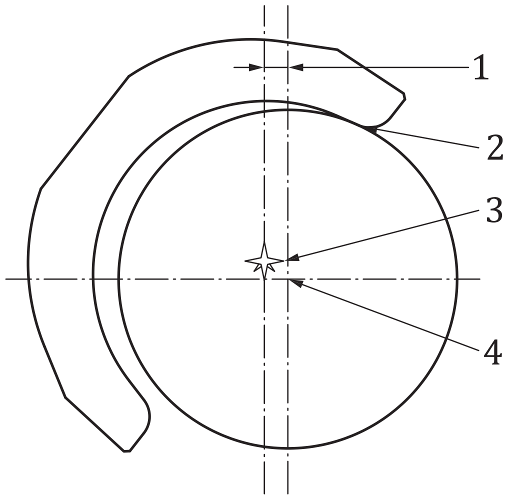
1	superior	3	lateral
2	medial	4	inferior

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

© ISO 2018 – All rights reserved

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

2 edge loading

3 centre of the acetabular cup

4 centre of the femoral head

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 14242-4:2018
https://standards.iteh.ai/catalog/standards/sist/651a6667-1a52-4d30-b1b6-891e7418a28f/iso-14242-4-2018

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

© ISO 2018 – All rights reserved

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 14242-4:2018
https://standards.iteh.ai/catalog/standards/sist/b3fa6667-1a32-4d36-bf66-89fe7418a28f/iso-14242-4-2018

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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 14242-4:2018
https://standards.iteh.ai/catalog/standards/sist/b2f66667-1b22-4d36-b866-89fe7418a28f/iso-14242-4-2018

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.

© ISO 2018 – All rights reserved

Table 1 — Summary of conditions explored in combination with ISO 14242-1 or ISO 14242-3 resulting in two additional different conditions

Acetabular cup inclination angle L as defined in Figure 1d) in ISO 14242-1	Medial-lateral offset/mismatch between the centres of the femoral head and acetabular cup mm	Swing phase load N	Medial-lateral Spring constant N/mm	Condition
55°	0	300	No spring required	ISO 14242-1 with steep acetabular cup inclination angle
	4	70	100	ISO 14242-1 with edge loading due to dynamic separation condition combined with steep cup inclination angle

5 Simulator set up

Set up the machine as specified in ISO 14242-1 or ISO 14242-3.

A mismatch between the centres of the acetabular cup and the femoral head may be achieved as follows:

iTeh STANDARD PREVIEW
(standards.iteh.ai)

a) A minimum of three test components shall be used.

b) Position a spring so it can hold the femoral head or the acetabular cup at the intended input mismatch [Figure 4 a)], when there is no medial-lateral force acting on the acetabular cup and no vertical load on the acetabular cup. During dynamic loading conditions the spring will experience maximum compression during peak loading of stance phase, and the femoral head will articulate on the intended bearing area of the acetabular cup [Figure 4 b)]. During the swing phase with low axial load, the spring compression reduces so the acetabular cup moves medially with respect to the centre of the femoral head and the centres of the femoral head and acetabular cup separate and the femoral head articulates on the edge or rim of the acetabular cup, simulating dynamic separation of the centres. Upon the start of the heel strike the axial load increases and starts to move the acetabular cup back towards the intended articulation position. It is worth noting that during the start of stance phase, an increasing load is applied to the edge of the acetabular cup by the femoral head until the acetabular cup moves back to its intended position.

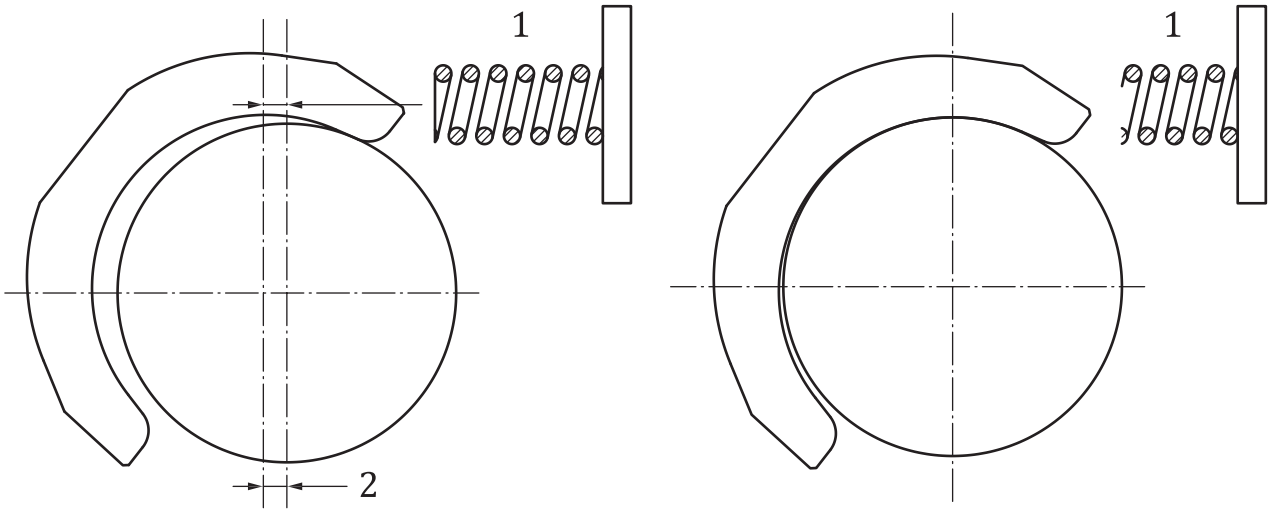
ISO 14242-4:2018
https://standards.iteh.ai/catalog/standards/sist/3b6667d4-42c2-4136-bf6b-80fe7418e28f/iso-14242-4-2018

NOTE The simulation set up described above describes an *in vitro* simulation. Clinically it is recognized that dynamic separation of the centres of the femoral head and acetabular cup occurs in some patients and this results in loading of the femoral head on the edge of the acetabular cup. This is thought to be associated with joint laxity, resulting from inadequate soft tissue tensions post operatively and/or variation in the surgical positioning of the components. It is important to note that the *in vitro* medial-lateral spring force acting on the acetabular cup to move it in the medial direction, described in this simulator set up is not intended to directly represent a soft tissue force, nor does it directly represent other complex time dependent muscle forces or dynamic forces acting in the medial lateral or the anterior posterior direction in joint replacements with laxity in the body. The laboratory simulation mechanism and set up described above simply generates dynamic separation (separation of the centres of the femoral head and acetabular cup, not separation of the bearing surfaces). Edge loading contact, loading of the femoral head on the rim of the acetabular cup occurs during swing phase and the early part of stance phase, with the increasing axial load during the start of stance phase likely to produce the most implant damage/deformation and wear, as the femoral head moves back to its intended articulating position. The method described herein, specifies simulator specific adjustments (medial lateral mismatch between femoral head and acetabular cup centres as well as adding a spring in medial-lateral direction) to allow for an acetabular cup/femoral head reposition procedure within the simulator.

c) Use a spring with a constant of 100 N/mm.

© ISO 2018 – All rights reserved

d) Use a calibrated displacement measurement device such as an LVDT to measure the medial-lateral displacement of the acetabular cup during the gait cycle.



a) The spring at its full length when the offset is applied between the femoral head and acetabular cup

b) The spring when compressed due to the vertical load acting on the femoral head and acetabular cup (none edge loading condition)

Key

1 spring in the medial-lateral direction
2 translational mismatch (offset)

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Figure 4 — Schematic showing a representation of the femoral head, acetabular cup and the spring

ISO 14242-4:2018
https://standards.iteh.ai/catalog/standards/sist/b3fa6667-1a32-4d36-bf66-89fc7418a28f/iso-14242-4-2018

In some simulators, the spring force may also be applied to the femoral head and apply a lateral force to achieve dynamic separation.

6 Output measurements

Edge loading conditions shall be assessed and reported along with the wear results. Two outputs shall be recorded:

a) The magnitude of the dynamic translation (separation) – medial-lateral displacement of the acetabular cup relative to the femoral head (Figure 5). This shall be measured during the operation of the machine using a calibrated displacement measurement device such as an LVDT, detecting the maximum displacement between the femoral head and the acetabular cup in the medial-lateral axis. Station to station variability should be noted.

   The signal of external sensor measurements (for example mounted at the spring system) depends on the machine stiffness. Hence, the correct medial-lateral displacement measured directly at the specimen might deviate from the external sensor measurements. Validation of the external sensor measurements shall be reported.

b) The geometric and/or gravimetric assessment of wear at least after 5×10^5 cycles, 1×10^6 cycles or earlier and, thereafter at least every 1×10^6 cycle until three million cycles of testing (follow ISO 14242-2).

c) If possible, a third output should be recorded: The magnitude of load under edge loading conditions and duration of edge loading conditions during the gait cycle (Figure 5). This should be measured using a calibrated load cell. The start and end points of edge loading depend on the geometry of the acetabular cup and the test conditions. If the dynamic separation is measured using an external

© ISO 2018 – All rights reserved