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Implants for surgery — Partial and total hip joint prostheses —

Part 12: Deformation test method for acetabular shells

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

Partie 12: Méthode d'essai de déformation des cupules acétabulaires

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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).

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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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 and performance 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 components*

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

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Introduction

Press-fit fixation is currently a common method for implanting non-cemented acetabular component for total hip joint replacement. In such a press-fit system, primary fixation of the acetabular component is achieved by an interference fit between the acetabular hip cup and the reamed acetabular base.[1] The interference, diameter difference, leads to a certain amount of pressure between bone and acetabular component that determines the amount of fixation, but also causes deformation of both the bone of the acetabular base and the acetabular component. The amount of interference is specifically defined for the appropriate acetabular component.

Due to the anisotropic mechanical properties of the acetabular bone, increased stiffness mainly in the regions of ilium and ischium,[4] the deformation of the acetabular component does not occur homogenously. The local deformation of the acetabular component is increased in areas where the acetabular component is in contact with bone regions of increased stiffness. Therefore, the deformed acetabular component tends to get in oval shape when looking onto its front face.

There are design features beside the cup-bone-interference and the bone stiffness that affect the deformation of the acetabular component. These design features include among others the cup diameter, wall thickness, material and anti-rotation elements on the acetabular component's outside as fins and grooves.[3][4][8][9] Screw holes and any kind of asymmetrically positioned cut-outs could also affect the cup's deformation behaviour leading to differences in the amount of deformation depending on load orientation.

Deformation of the acetabular component in a modular acetabular component system can affect the proper seating and locking of the articulating insert, as well as the lubrication and friction properties of the articulating surfaces, if there also occurs a deformation of the articulating spherical socket.[3][4][6][9] Deformation of the acetabular component in a monoblock cup system definitely results in a deformation of the articulating spherical socket potentially affecting lubrication and friction properties of the articulating surfaces, potentially resulting in higher wear rates and premature failure of the prosthesis system.[2][5][7][8] Acetabular component deformation can even then affect the systems performance if the deformation itself is not recognizable for the surgeon.

Therefore, it is important to ensure that the deformation of an acetabular component does not significantly affect the system's functional properties as intraoperative assembly of components, tribology, etc. This method addresses the short-term deformation performed under laboratory conditions. It does not give a quantitative deformation limit as an acceptance criterion because there is no reliable data in the scientific literature to support such a threshold today. It has to be considered that the test conditions described in this part of ISO 7206 do not exactly reproduce all the factors of the clinical situation.

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Implants for surgery — Partial and total hip joint prostheses —

Part 12: Deformation test method for acetabular shells

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1 Scope

This part of ISO 7206 specifies a test method for determining short-term deformation of a press-fit acetabular component for total hip joint replacement under specific laboratory conditions. It also defines the conditions of testing so that the important parameters that affect the components are taken into account and it describes how the specimen is set up for testing. Furthermore, this part of ISO 7206 specifies the test parameters of press-fit acetabular components tested in accordance with this part of ISO 7206.

The described method is intended to be used to evaluate the comparison of various designs and materials used for acetabular components in total hip joint replacement when tested under similar conditions.

The loading of the acetabular components *in vivo* will, in general, differ from the loading defined in this test method. The results obtained here cannot be used to directly predict *in vivo* performance.

This part of ISO 7206 does not cover methods of examining the test specimen.

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 2768-2, *General tolerances — Part 2: Geometrical tolerances for features without individual tolerance indications*

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

ISO 7206-2, *Implants for surgery — Partial and total hip joint prostheses — Part 2: Articulating surfaces made of metallic, ceramic and plastics materials*

ISO 21534, *Non-active surgical implants — Joint replacement implants — Particular requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 7206-1, ISO 7206-2 and ISO 21534 and the following, apply.

3.1
metal backing deformation
amount of geometrical deviation (inner diameter and circularity of metal backing in a defined measurement plane) from design specifications under loading conditions

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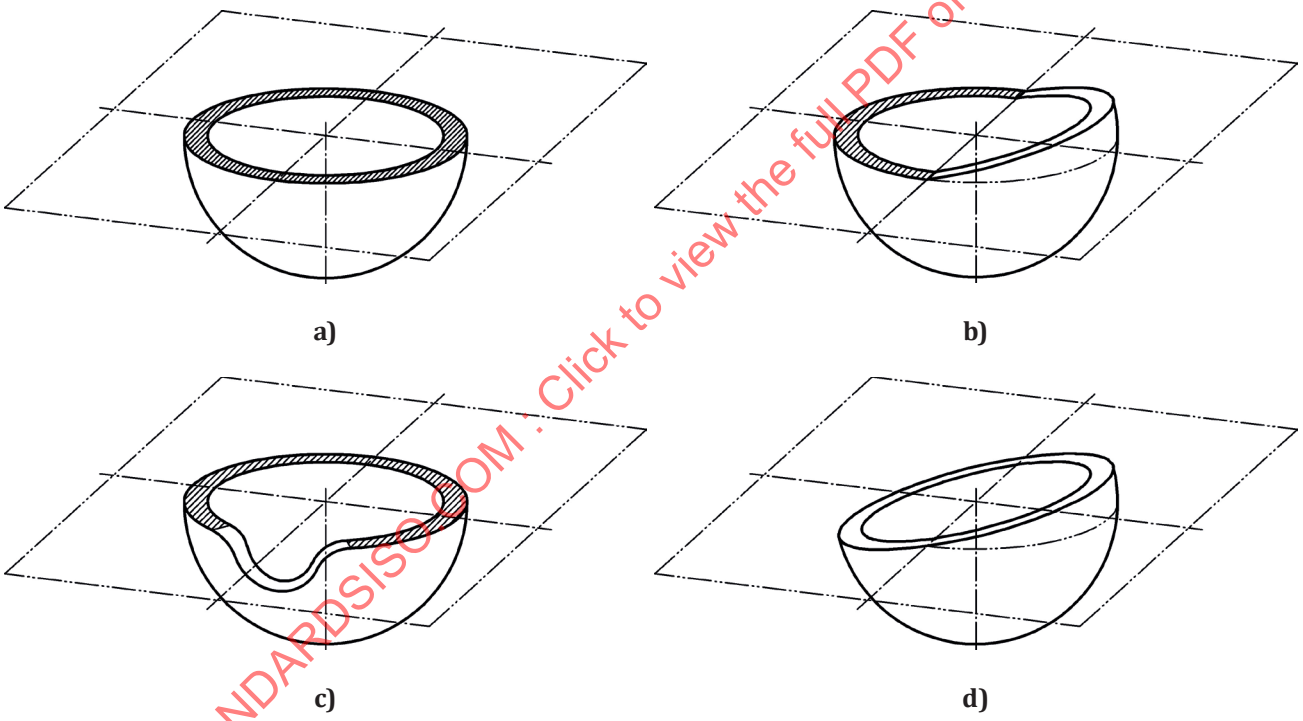
3.2
spherical socket deformation
articulating surface deformation
amount of geometrical deviation (diameter and circularity in a defined measurement plane) from design specifications under loading conditions

3.3
frontal face reference plane
plane, perpendicular to the component polar axis, nominally at the frontal face level (see Figure 1 a))

Note 1 to entry: In case of doubt, the polar axis can be defined as perpendicular to the plane spanning around the contact zone of the acetabular component to the cortical bone, and as containing the centre point of the ball sphere approximating the acetabular component's outer sphere.

Note 2 to entry: In case of an asymmetrically shaped front face, e.g. anatomically shaped acetabular components, the frontal face reference plane can be located at a level, which contains the largest part of the frontal face that is perpendicular to the component polar axis (see Figure 1 b) and c)).

Note 3 to entry: In case that the frontal face does not contain any part perpendicular to the component axis, the frontal face reference plane can be located at that level at the approximated middle between the highest and the lowest point of the frontal face in distal direction (see Figure 1 d)).



NOTE Marked (shaded) areas of the frontal face are located in the reference plane.

Figure 1 — Frontal face reference plane of acetabular components

3.4
loading plane
plane, parallel to the frontal face reference plane and located in an area where the acetabular cup gets in contact with the cortical bone after being properly and fully seated intraoperatively

EXAMPLE For symmetrically shaped acetabular components, Figure 1 a), the loading plane will usually be located close to the frontal face reference plane.

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3.5
measurement plane
plane, parallel to the frontal face reference plane, located with a certain distance to the frontal face reference plane but as close as possible to the frontal face reference plane

Note 1 to entry: The sensitivity of the deformation measurement decreases with increasing distance of the measurement plane from the front face reference plane and with decreasing distance of the measurement plane to the top of the cup.

Note 2 to entry: Within the measurement plane, the measurement points for determining the inner diameter of the test specimen can be captured. Therefore, the measurement plane can be defined so that capturing the measurement points is not disturbed by any design features of the test specimen as holes or cut-outs. The measurement points can be captured at the test specimen directly; they cannot be captured at the load frame.

4 Principle

The test specimen is subjected to diametrically opposite two-point loading. For the determination of short-term deformation, measurements of diameter in loading direction in a defined measurement plane are carried out prior and under loading, as well as after unloading. This deformation measurement procedure is repeated two times after rotating the specimen with rotation angles of itself, of which each rotation angle measures 120° to account for influence of asymmetric design features as fins, holes, etc.

Metal-backed modular acetabular components can deform and affect the seating of the insert. The combination of metal-backing and insert can deform and affect the tribology. So such components shall be tested in two steps: first step, testing of the metal backing alone; second step, testing of the metal backing with the appropriately mounted bearing insert.

Press-fit installation of monoblock acetabular cup components can cause deformation of the articular surface which may affect tribology. Such components shall be tested in only one step.

5 Apparatus

5.1 Loading device

A load frame capable of the following functionality:

a) shall not exhibit any visible and irreversible deformation under loading the test specimen;

b) shall allow reproducible loading and unloading of a test specimen along a defined mechanical axis and measuring loads and distances, respectively;

c) shall be capable of loading acetabular hip cups up to a diameter of 100 mm and a height of 50 mm.

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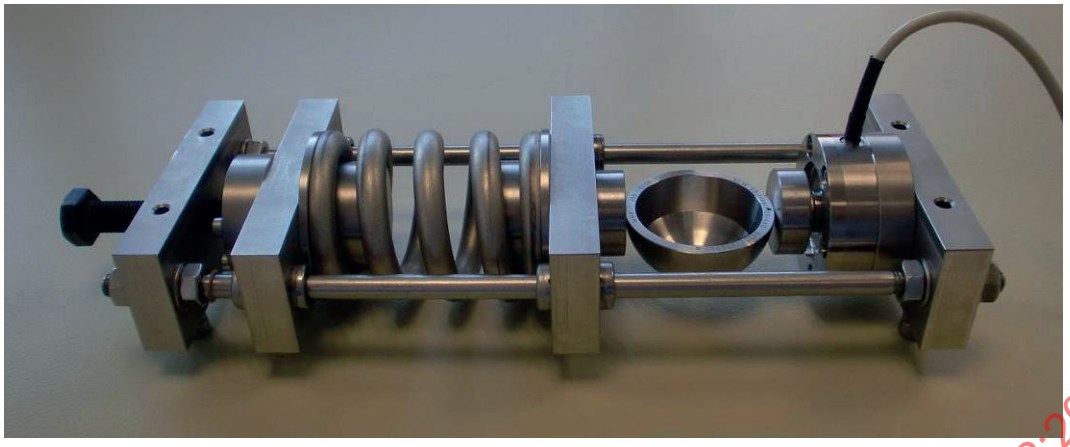
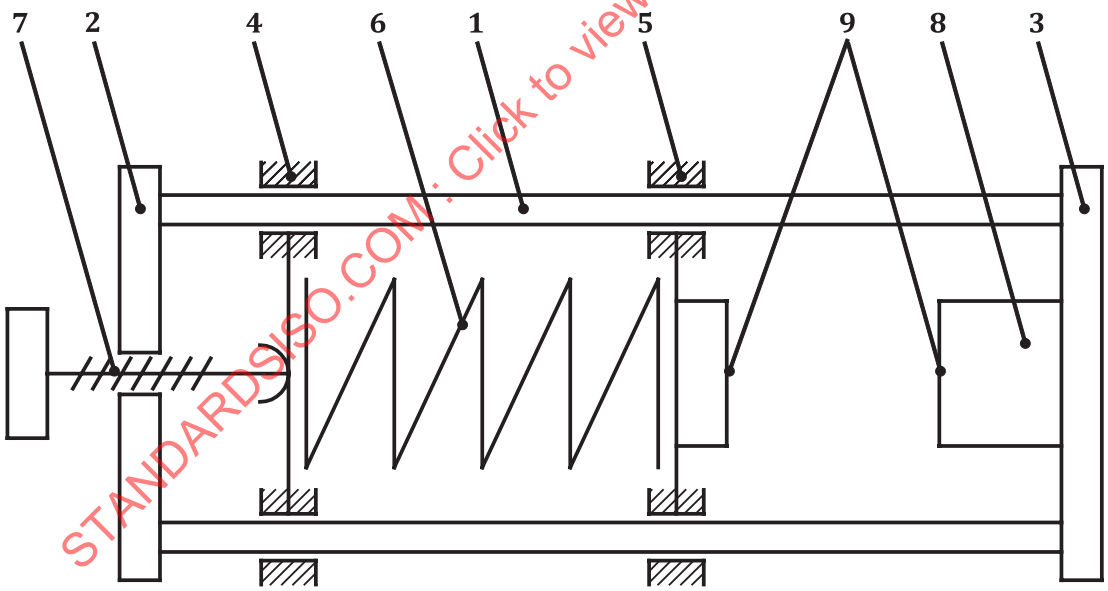


Figure 2 — Example of a load frame for applying a two-point-loading onto an acetabular hip cup or hip cup system, respectively

An example of such a load frame is described in References [1] and [12] and shown in Figure 2. The load frame favourably consists of two cross beams fixed at the beginning and end portion of two parallel guiding rails and two versatile cross beams which can be shifted along the guiding rails (see Figure 3). The load is applied by a load adjustment screw on one of the movable cross beams and transferred to the second movable cross beam by use of a spiral spring.

NOTE The spiral spring lowers the stiffness of the device leading to a larger tolerance against small displacements in loaded state due to the fact that the potential load deviation results from the value of displacement multiplied by the stiffness coefficient of the system.



Key

1 guiding rails
2, 3 fixed cross beams
4, 5 moveable cross beams
6 spiral spring
7 load adjustment screw
8 load cell
9 clamping/loading surfaces

Figure 3 — Principle of load frame

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The clamping jaws holding the test specimen in place during loading shall possess a flat clamping surface (flatness according to ISO 2768-2:1989, K, avoiding cross forces due to tilting or sliding of the test specimen during loading and measuring.

Certain acetabular component designs contain design elements for exceptional purposes such as complex revision surgery or specific patients' demands, e.g. anchoring edges, anatomical shaped rim, etc. In case that such an acetabular component shall be tested, clamping jaws shall be used which are designed in a way that the specimen can be fixed and loaded.

The width of the clamping surface shall be at least 20 % of the outer diameter of the test specimen at the frontal face reference plane allowing the manual centring of the test specimen contact points on the clamping surfaces prior testing. Additional centring features or tools are not necessary. If centring features or tools are provided, ensure that the two-point loading and the deformation of the test specimen are not constrained.

The load cell shall be capable of measuring an axial compressive force with an uncertainty of 1 %.

5.2 Test specimen selection

The test specimen of that size of the acetabular component, which has been identified to be the worst-case size, shall be randomly selected being representative for manufacturing and shall have the same geometry and be made to the same material specification through the same process as the final product.

NOTE In case of modular acetabular components, the worst-case size for the first step of testing (metal backing deformation) may be different from the worst-case size of the second step of testing (articulating surface deformation of the acetabular component).

If there are different articulating surface materials offered for the modular acetabular components, then all insert articulating surface material and sizes shall be evaluated regarding identification of worst-case material and sizes. Design features, such as asymmetrically located screw holes, shall also be considered.

6 Procedure

a) Prior to loading, measure the inner diameter, D_0 [mm], of the specimen for each of the planned loading directions by using a capable measurement device. The diameter shall be measured in the measurement plane inside the spherical socket. An uncertainty of the measurement of <5 µm is required.

   The diameter can additionally be measured at further positions in the same measurement plane, e.g. perpendicular to the loading direction, for acquisition of additional data on the general deformation behaviour of the test specimen.

b) Position the specimen in the testing set-up and apply and maintain an axial force of (1,00 ± 0,01) kN by steady turning the load adjustment screw. Avoid jerky loading. The contact points of the specimen with the loading surfaces of the load frame shall be located within the loading plane.

c) Measure the diameter D_1 (mm) of the specimen in the loading direction, within the same measurement plane and by use of the same measurement device as in a). The deformation of the cup is the difference $D_0 - D_1$.

d) Unload the test specimen.

e) Measure the diameter, D_0' [mm], of the specimen in the direction of c) again by using the same measurement device. If a remaining difference, $D_0' - D_0$, to the initial diameter from a) is determined, which is larger than the uncertainty of the measurement device and which is larger than 2 % of the deformation [$|(D_0' - D_0)/(D_0 - D_1)| > 0{,}02$] determined in c), then a plastic deformation of the specimen occurred. In that case, the test shall be stopped for that specimen and the testing proceeds taking the next specimen and starting at a).

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f) Rotate the cup for 120° with respect to the previous position, using the component polar axis as the centre of rotation. Repeat b) to e). Rotate the cup for another 120° with respect to the previous position, using the component polar axis as the centre of rotation. Repeat b) to e) and proceed with the next specimen.

Testing conditions: assembly and measurements shall be carried out under consistent laboratory conditions.

A sample size of at least three specimen shall be used for the test. For asymmetric specimen, a reference orientation shall be defined and the orientation of the specimen according to a rotation around its polar axis at the beginning of the test shall be shifted from specimen to specimen.

Instead of measuring the diameter of the specimen solely in loading direction, it is also possible to determine the deformation by evaluating the differences in diameter and circularity of the specimen within the appropriate measurement plane.

Some rare acetabular component designs as press-fitted monoblock cups made from plastics cannot withstand the loading defined without irreversible damages even if they are clinically well established. In these cases, the load may be reduced appropriately and the comparison of a newly developed system with a clinically established one may be done by use of test results of both systems under reduced loading.

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7 Report

The test report shall include the following information:

a) a reference to this part of ISO 7206, i.e. ISO 7206-12;

b) the identity and description of all parts of the acetabular component, as stated by the party submitting the specimen for the test and the manufacturer's name and list reference;

c) acetabular component (e.g. cup, insert) dimensions and tolerances for each worst-case design, size and material combination (if applicable);

d) deviations from acetabular component design specification;

e) the material and stiffness of the testing setup, i.e. material and stiffness of the spiral spring;

f) in case of asymmetric cup rim designs, e.g. as shown in Figure 1 b) to d), a description of the cup orientation during the loading in the load frame giving information about the contact of the cup with the loading surfaces, e.g. by photographic pictures;

g) in case of asymmetric cup rim designs, e.g. as shown in Figure 1 b) to d), a description on how the polar axis is defined;

h) in case of asymmetric cup rim designs, e.g. as shown in Figure 1 b) to d), a description on how the frontal face reference plane is defined with regard to the specimen design;

i) the distance between the measurement plane and the frontal face reference plane and how the measurement plane is positioned (distal/ proximal) with regard to the frontal face reference plane;

j) while under load, range and average deformation (standard deviation) (diameter, other measurements) for each worst-case construct (e.g. cup, cup/insert combined), design, size and material combination tested;

k) after loading, range and average plastic deformation (standard deviation) (diameter, other measurements) for each worst-case construct (e.g. cup, cup/insert combined), design, size and material combination tested;

l) the specification of the measurement device (diameter measurements);

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