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Implants for surgery — Partial and total hip joint prostheses —

Part 12: Deformation test method for press-fit acetabular components

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

Partie 12: Méthode d'essai de déformation des composants acétabulaires sans ciment

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

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

This second edition cancels and replaces the first edition (ISO 7206-12:2016), which has been technically revised.

The main changes are as follows:

— the third element of the title has been aligned with the scope which states that this test is for press-fit acetabular components;

— the terminology has been aligned with ISO 21535:2023;

— the scope has been revised to clarify that the deformation measurements that are made in this test and how these measurements are then used in an evaluation of risks associated with acetabular cup deformation to determine if acetabular component performance can be adversely affected;

— the term “metal backing deformation” has been changed to “metal shell deformation” and the term “spherical socket deformation” has been deleted in Clause 3;

— a requirement for the clamping jaw material to have a minimum hardness of 60 HRC has been added in 5.1;

— the requirement to test all liner articulating surface materials has been changed to a recommendation and a requirement has been added to justify why each liner material was not tested in 5.2;

— a new subclause, “5.3 Number of samples and testing conditions”, has been added and corresponding information has been moved to this subclause;

— in Clause 6, the starting rotational orientation for symmetric and asymmetric specimens have been clarified and tolerances have been added to the rotational orientations where needed, a minimum loading rate has been added, a clarification has been added regarding the 0,2 % deformation stopping criterion, the steps for testing monobloc and modular acetabular components have been clarified and corresponding procedure steps have been added;

requirements for the year of publication, any unusual observations during testing, and the date of the test have been added, and the requirement to report stiffness of the testing setup has been removed;

— a new Clause, "8 Interpretation of results", has been added to include examples of factors to consider in an evaluation of risks associated with acetabular component deformation under load and plastic deformation after unloading, and, based on the measured deformation test results, a requirement has been added to perform an evaluation to determine whether or not implant performance can be adversely affected.

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Press-fit fixation is currently a common method for implanting a non-cemented acetabular component for total hip joint replacement. In such a press-fit acetabular component, primary fixation is achieved by an interference fit between the acetabular cup and the reamed acetabulum.[1] The interference, diameter difference, leads to a certain amount of pressure between bone and acetabular component that contributes to the amount of fixation, but also causes deformation of both the bone of the acetabulum and the acetabular component. The amount of interference is based on the design of the reamer and acetabular cup, is known by the manufacturer and can be included in the surgical technique manual.

The anisotropic mechanical properties of the acetabular bone, with increased stiffness mainly in the regions of ilium and ischium,[2] and variable geometry of the acetabulum, can create the potential for inhomogeneous deformation of the acetabular component. The local deformation of the acetabular component can be increased in areas where the acetabular component is in contact with bone regions of increased stiffness. Therefore, the deformed acetabular component can be oval in shape when looking onto its frontal 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 outer surface such as fins and grooves.[2][3][4][5] 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 the cup's rotational orientation around its polar axis under loading.

Deformation of a modular acetabular component can affect the proper seating and locking of the articulating liner. Additionally, articulating surface deformation can affect the lubrication and friction properties.[3][4][5][6] Deformation of a monobloc acetabular cup definitely results in articulating surface deformation potentially affecting lubrication and friction properties,[7] potentially resulting in higher wear rates and premature failure of the prosthesis.[3][8][9] Therefore, acetabular component deformation has the potential to affect the hip replacement's performance.

Therefore, it is important to ensure that the deformation of an acetabular component does not significantly affect the hip replacement'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 must be considered that the test conditions described in this document do not exactly reproduce all the factors of the clinical situation.