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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

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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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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*

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.