
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

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

Partie 3: Paramètres de charge et de déplacement pour machines d'essai d'usure du type orbital de maintien et conditions environnementales correspondantes d'essai



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 14242-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

ISO 14242 consists of the following parts, under the general title *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*
- *Part 2: Methods of measurement*
- *Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test*

Introduction

The orbital bearing hip wear simulator (OBM) is widely used and has been successful in evaluating the wear properties of Total Hip Arthroplasty (THA) articulating surfaces. These test results have been shown to correlate well with clinical experience. Since this type of test machine is widely used, it is important that the parameters be standardized to make the results more uniform and comparable between laboratories.

This test method differs from that in ISO 14242-1 in the articulating motion of the test. Although the motion of the OBM is simpler and less anatomic than the motion described in ISO 14242-1, OBM hip simulators have been used to evaluate the wear of THA articulating components for more than 25 years. The equipment is used globally for wear testing of THA components, and has been very successful in reproducing the types and amounts of wear that occur *in vivo* with a wide variety of bearing materials, including polyethylene, metals and ceramics. Because of this, tests on OBM machines have provided very accurate predictions of the subsequent clinical performance of newly developed materials. This is particularly true for the new crosslinked polyethylenes. Several recent reports with more than five years of follow up have shown percent reductions in wear, compared to historical polyethylene, that are very close to those that were predicted as much as ten years earlier in tests run on OBM hip simulators.

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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

1 Scope

This part of ISO 14242 specifies relative angular movement between articulating components, the pattern of the applied force, speed and duration of testing, sample configuration and test environment to be used for the orbital bearing type wear testing of total hip joint prostheses.

2 Normative references

The following referenced documents are indispensable for the application 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 14242-2, *Implants for surgery — Wear of total hip joint prostheses — Part 2: Methods of measurement*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

abduction

adduction

motion about an axis arranged in an anterior-posterior direction through the hip joint

NOTE 1 Movement of the femur away from the midline of the torso is termed abduction. Movement of the femur toward the torso midline is known as adduction.

NOTE 2 Angular movement is shown in Figure 1 a).

3.2

flexion

extension

motion that occurs about a transverse axis through the hip joint

NOTE 1 Movement at a joint, which decreases the angle between the torso and the femur, is termed flexion. The opposite action is termed extension, where the angle between the torso and the femur is increased.

NOTE 2 Angular movement is shown in Figure 1 b).