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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

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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

Reference number
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Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
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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*.

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ISO 14242 consists of the following parts, under the general title *Implants for surgery — Wear of total hip-joint prostheses*:

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— *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*

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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

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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.

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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).

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3.3
inward rotation
outward rotation
component of internal/external motion

NOTE 1 The OBM hip simulator does not apply an independent “inward/outward” motion to the hip (i.e., about the long axis of the femur.) However, Saikko et al.[8] pointed out that the anti-rotation lever that is connected to each test chamber of an OBM machine induces a component of internal-external rotation to the motion path, effectively converting the OBM into a 3-axis machine. The mechanism of the OBM simulator induces a crossing-path component to the relative motion of the bearing surfaces. Because of this, as was demonstrated in detail by Wang et al.[13], the magnitude of the shear stress and the amount of change of direction of this stress during the loaded part of the gait cycle are comparable to that which occurs in a hip replacement *in vivo.*

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

3.4
polar axis
axis of the acetabular component, which intersects the centre of the spherical articulating surface and is perpendicular to the plane of the flange or, if no flange is present, perpendicular to the plane of the entry diameter

4 Principle

The femoral and acetabular components of a test specimen are placed in position in their normal configuration and the apparatus transmits a specified time-dependent force between the components together with specified relative angular displacements. A control specimen, if polymers are the object of investigation, is subjected to the same time-dependent force to determine the creep of the test specimen and/or the amount of mass change due to fluid transfer. The test takes place in a controlled environment simulating physiological conditions.

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5 Reagents and test specimens

5.1 Fluid test medium, calf serum approximately 25 % volume fraction diluted with de-ionized water (balance).

The fluid test medium should be filtered through a filter of pore size 2 µm and have a protein mass concentration of not less than 17 g/l.

To minimize microbial contamination, the fluid test medium should be stored frozen until required for test. An anti-microbial reagent (such as sodium azide) may be added. Such reagents can be potentially hazardous.

Routine monitoring of the pH of the fluid test medium can be undertaken. If it is, the values should be included in the test report (see Clause 8).

NOTE The use of a fluid test medium of non-biological origin can be considered when performance requirements relating to this test method are being decided.

5.2 Test specimen, femoral head and acetabular components.

The acetabular component shall have the articulating surface attached by its normal immediate backing (for example bone cement or a machined replica of the inner surface of the backing) unless this is impractical due to physical features of the implant system. If the component forming the articulating surface is fixed to the backing by a rim/snap-fit system the machined replica shall provide the same fixation conditions. If it is not practical to use the normal backing or cement fixation due to physical features of the implant system, the support system for the acetabular component should represent normal design features and conditions of use but should allow removal of the component for measurement of wear without destruction.

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Consideration should be given to the condition of the test specimen. This condition should represent the final sterile implanted condition where possible unless processing effects are under investigation.

NOTE It can be useful to characterize specimens prior to testing. Profilometry, hardness, photomicrography and other analytical techniques can be used.

5.3 Control specimen, identical to test specimen.

Consideration should be given to the condition of the control specimen. This condition should represent the final sterile implanted condition where possible unless processing effects are under investigation.

NOTE It can be useful to characterize specimens prior to testing. Profilometry, hardness, photomicrography and other analytical techniques can be used.

6 Apparatus

6.1 Testing machine, capable of producing the angular displacements prescribed in Figures 1 and 2 in association with the corresponding forces prescribed in Figures 1 and 3 and operating at a frequency of 1 Hz ± 0,1 Hz.

6.2 Means of mounting and enclosing the test specimen, using a corrosion resistant material, capable of holding femoral and acetabular components, using attachment methods comparable to the intended anatomical fixation and an enclosure that is capable of isolating the test specimen to prevent third body contamination from the test machine and the atmosphere.

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NOTE Consideration should be given to the support material used to mount femoral and acetabular components to ensure representative force transfer and stress conditions.

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6.3 Means of aligning and positioning the femoral component of the test specimen, in the inferior position so that its axis is situated at the centre of the axes of rotation of the test machine and so that the same position and orientation can be produced following removal of the component for measurement or cleaning, if required.

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NOTE For a modular component, the stem of the implant can be replaced by a support that has an identical cone and assures reproducible positioning of the head.

6.4 Means of aligning and positioning the acetabular component, of the test specimen so that its axis is situated at the centre of the axes of rotation of the test machine and so that the same position and orientation can be reproduced following removal of the component for measurement.

6.5 Motion control system, capable of generating the angular movements of the femoral component given in Figures 1 and 2 with an accuracy of ± 3° at the maxima and minima of the motion and ± 1 % of the cycle time for phasing.

6.6 Force control system, capable of generating a force whose direction is shown in Figure 1 and which varies as shown in Figure 3 and maintaining the magnitude of the maxima and minima of this force cycle to a tolerance of ± 3 % of the maximum force value for the cycle and ± 1 % of the cycle time for phasing.

6.7 Lubrication system, capable of maintaining the contact surfaces immersed in the fluid test medium and having a minimum available lubricant volume of 200 ml.

NOTE The use of sealed enclosures can prevent evaporation.

6.8 Temperature control system, capable of maintaining the temperature of the fluid test medium (5.1) at 37 °C ± 2 °C.

NOTE There can be temperature effects on test medium properties.

6.9 Control station(s), capable of applying the loading regime shown in Figures 1 and 3 without the angular displacements shown in Figures 1 and 2 and incorporating the provisions of 6.2, 6.3, 6.4, 6.6, 6.7 and 6.8.

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