INTERNATIONAL STANDARD

ISO 14242-2

First edition
2000-09-15

Implants for surgery — Wear of total hip-joint prostheses —

Part 2: Methods of measurement

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

Partie 2: Méthodes de mesurage

Reference number
ISO 14242-2:2000(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

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 3.

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 part of ISO 14242 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14242-2 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*

Implants for surgery — Wear of total hip-joint prostheses —

Part 2:
Methods of measurement

1 Scope

This part of ISO 14242 specifies methods of assessment of wear of the acetabular component of total hip-joint prostheses using gravimetric techniques and changes in dimensional form of components tested in accordance with ISO 14242-1.

NOTE Some investigators have experienced problems with organic deposits affecting the results of measurements, especially with hard/hard combinations. No specific precautions are included in this part of ISO 14242, but cleaning techniques adopted should be suitable for the soils produced.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 14242. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 14242 are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 14242-1, *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.*

3 Term and definition

For the purposes of this part of ISO 14242, the following term and definition applies.

3.1
wear
material loss from components of the prosthetic joint due to combined movement and loading

4 Gravimetric method

4.1 Principle

The test specimen is soaked in a lubricant. It is repeatedly removed from the lubricant, cleaned, dried and weighed until a steady rate of fluid sorption is established. The test specimen is assessed subsequently for wear by testing for loss in mass in a knee-hip simulator. A loaded, non-articulating control specimen is intended to allow for fluid sorption and undergoes the same procedure for reference purposes.

4.2 Reagents and materials

4.2.1 **Fluid test medium**, in accordance with ISO 14242-1.

4.2.2 **Control specimen**, in accordance with ISO 14242-1.

4.2.3 **Propan-2-ol.**

4.3 Apparatus

4.3.1 **Balance**, with an accuracy of ± 0,1 mg, of sufficient capacity for the mass of the test specimen.

4.3.2 **Ultrasonic cleaner.**

4.3.3 **Vacuum drying system**, capable of achieving a vacuum of at least 13,33 Pa.

4.3.4 **Filtered inert-gas jet**, e.g. nitrogen.

4.4 Preparation of test specimen for gravimetric measurements

4.4.1 Soak the test specimen and control specimen in the fluid test medium (4.2.1) for 48 h ± 4 h.

4.4.2 Remove the test specimen and control specimen from the fluid test medium (4.2.1) and clean in the ultrasonic cleaner (4.3.2).

A typical cleaning regime in the ultrasonic cleaner is as follows:

a) vibrate for 10 min in deionized water;

b) rinse in deionized water;

c) vibrate for 10 min in a mixture of ultrasonic cleaning detergent in deionized water at the concentration recommended by the detergent manufacturer;

d) rinse in deionized water;

e) vibrate for 10 min in deionized water;

f) rinse in deionized water;

g) vibrate for 3 min in deionized water;

h) rinse in deionized water;

i) dry in a vacuum drying chamber (4.3.3).

Care should be taken to avoid abrasion in the ultrasonic cleaner which could lead to change in mass.

4.4.3 Dry the test specimen and control specimen with a jet of filtered inert gas (4.3.4).

4.4.4 Soak the test specimen and control specimen in propan-2-ol (4.2.3) for 5 min ± 15 s.

4.4.5 Dry the test specimen and control specimen with a jet of filtered inert gas (4.3.4), then dry further in a vacuum of better than 13,3 Pa ± 0,13 Pa for at least 30 min.

4.4.6 Weigh the test specimen and control specimen on the balance twice in rotation within 90 min of removal from the vacuum. If the two readings per specimen are not identical within 100 µg, continue taking readings in rotation until at least two readings per specimen are identical within 100 µg. Store the test specimen and control specimen in a sealed dust-free container between weighings.

4.4.7 Repeat 4.4.2 to 4.4.6 at intervals until the incremental mass change of the specimen over 24 h is less than 10 % of the previous cumulative mass change.

4.4.8 Record the average increase in mass S of the control specimen.

4.5 Procedure for gravimetric measurement

4.5.1 Mount the test pieces in the testing machine and conduct the wear test in accordance with ISO 14242-1.

4.5.2 Record the mass of the specimens.

4.5.3 On each occasion when the test specimen and control specimen are removed from the wear-testing machine, repeat the procedures 4.4.2 to 4.4.8, 4.5.1 and 4.5.2.

4.5.4 Calculate the gravimetric wear as follows:

$$W_n = W_{an} + S_n$$

where

W_n is the net mass loss after n cycles of loading;

W_{an} is the average uncorrected mass loss;

S_n is the average increase in mass of the control specimen over the same period.

4.5.5 Calculate the average wear rate a_G using the equation for the least squares linear fit relationship between W_n and the number of loading cycles n:

$$W_n = a_G \cdot n + b$$

where W_n is the net loss in mass after n cycles and b is a constant.

The zero time point shall not be used in this calculation.

5 Dimensional change method

5.1 Principle

A coordinate measuring machine is used to map the articulating surface of a total hip prosthesis relative to a reference position, direction and plane prior to the start of the wear test and at suitable intervals during the test. From these data the volumetric change between measurements is determined. Loaded non-articulating controls are intended to allow the effects of plastic flow, mainly occurring in the first 5×10^5 cycles, to be separated from material loss.

5.2 Apparatus

5.2.1 Three-dimensional coordinate measuring machine, with maximum axial-position error of measurement D, in micrometres, of:

$$D = 4 + 4l \times 10^{-6}$$

where l is the numerical value of the dimension, expressed in metres.

5.2.2 Ultrasonic cleaner.

5.3 Procedure for dimensional change measurement

5.3.1 Select a point of reference, an origin and a plane on the test specimen. Maintain this reference system throughout the procedure.

5.3.2 Clean the specimens.

5.3.3 To ensure dimensional stability, retain the test specimen at the measurement temperature ± 2 °C (measured at the normal points of the metrology laboratory) for at least 48 h.

5.3.4 At the beginning of a series of tests, check that relocation of the test specimen does not affect the measured volume by more than 0,05 %.

NOTE This may be achieved by the use of fixturing or the recognition of features in software, for example.

5.3.5 Start the measurement machine and produce a full three-dimensional contour mesh of the articulating surface of the test specimen. Ensure the mesh spacing is no greater than 1 mm in the horizontal plane or along any arc.

5.3.6 Calculate the volume V_n of the acetabular cavity, where n is the number of wear cycles which have been applied.

5.3.7 Express the wear as the volume change after n loading cycles, ΔV_n, as follows:

$$\Delta V_n = V_n - V_0$$

where V_0 is the original volume.

5.3.8 Insert the test specimen and any control specimen in the testing machine and conduct the tests in accordance with ISO 14242-1.

5.3.9 On each occasion when the test specimen and the control specimen are removed from the testing machine, repeat procedures 5.3.2 to 5.3.7.

5.3.10 Calculate the wear rate, a_V, using the equation for the least squares linear relationship between ΔV_n and n as:

$$\Delta V_n = a_V \cdot n + b$$

where b is a constant, using a least squares fit.

When controls are provided, the slope of the line, representing the rate of creep, should be calculated including the zero time point. The zero time point shall not be used in the slope calculation for the wear rate a_V.

6 Test report

The test report shall include the following information:

a) a reference to this part of ISO 14242;

b) the identity of the test specimens, as stated by the party submitting the specimen for test;

c) the method of wear measurement (i.e. gravimetric or dimensional change);

d) the value W_n for each measurement using the gravimetric method, or the value ΔV_n for each measurement using the dimensional change method;

e) the wear rate, a_G or a_V (gravimetric or dimensional change method);

f) a reference to the wear test method used from ISO 14242-1.