INTERNATIONAL STANDARD

ISO 14243-1

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

Part 1:
Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test

Implants chirurgicaux — Usure des prothèses totales de l'articulation du genou —

Partie 1: Paramètres de charge et de déplacement pour machines d'essai d'usure avec contrôle de la charge et des 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 3.

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 part of ISO 14243 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14243-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 4, *Bone and joint replacements*.

ISO 14243 consists of the following parts, under the general title *Implants for surgery — Wear of total knee-joint prostheses*:

— *Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test*

— *Part 2: Methods of measurement*

Annex A of this part of ISO 14243 is for information only.

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

Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test

1 Scope

This part of ISO 14243 specifies the 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 wear testing of total knee-joint prostheses in wear-testing machines with load control.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 14243. 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 14243 are encouraged to investigate the possibility of applying the most recent editions of the normative documents 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 7207-1:1994, *Implants for surgery — Components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions*

ISO 14243-2:2000, *Implants for surgery — Wear of total knee-joint prostheses — Part 2: Methods of measurement*

3 Terms and definitions

For the purposes of this part of ISO 14243, the terms and definitions given in ISO 7207-1 apply, together with the following.

3.1
anterior posterior displacement
AP displacement
offset of the axial force axis from the flexion/extension axis, measured in a direction which is perpendicular to both of these axes

NOTE The displacement is considered to be zero when the total knee-joint prosthesis is in the **reference position** (3.7) and is considered to be positive when the axial force axis is anterior to its position with the total knee-joint prosthesis in the reference position (3.7).

3.2
AP force
force applied to the tibial component along a line of action which is perpendicular to both the tibial axis and the flexion/extension axis and which passes through the axial force axis

NOTE The force is considered to be positive when it acts from a posterior to an anterior direction.

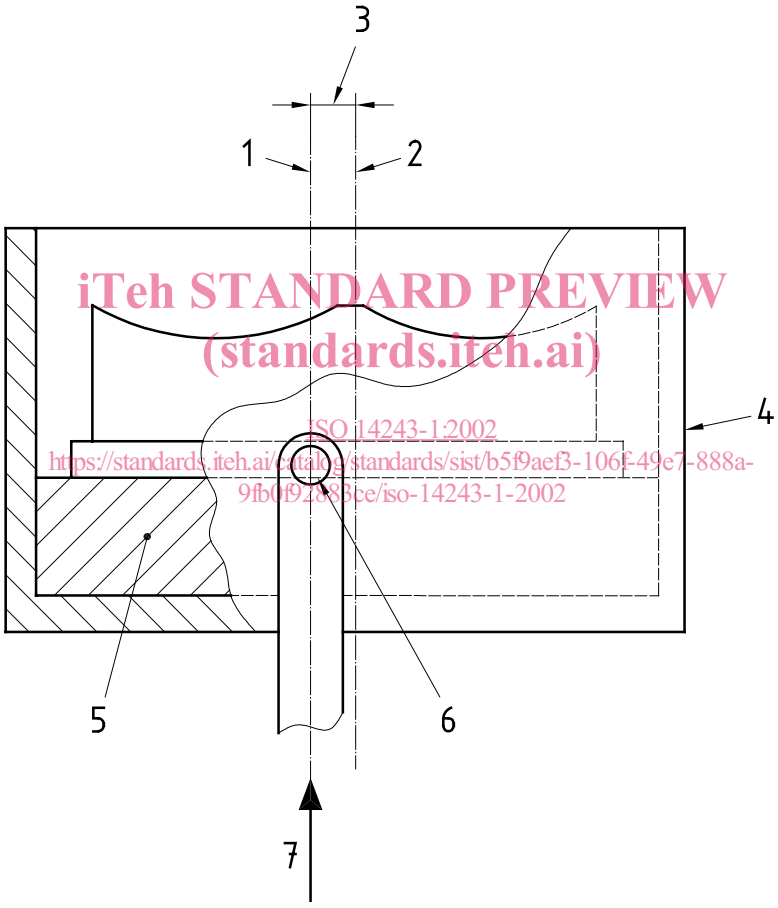
3.3
axial force
force applied to the tibial component of the knee-joint prosthesis in a direction parallel to the tibial axis

NOTE The force is considered to be positive when it acts in an inferior-to-superior direction (see Figure 1).

3.4
axial force axis
line of action of the axial force taken to pass through a point on the tibial component of the knee-joint prosthesis which is offset by $0{,}07w \pm 0{,}01w$ in the medial direction from the tibial axis, where w is the overall width of the tibial component measured in accordance with ISO 7207-1

See Figure 1.

NOTE The value of $0{,}07w$ offset is equivalent to 5 mm offset for a tibial component of average width, i.e. 74 mm.



Key

1 Axial force axis
2 Tibial axis
3 $0{,}07w$ offset
4 Holder of tibial component
5 Cement mounting for tibial component
6 Axial force applied through free-turning pivot(s)
7 Force

Figure 1 —Test specimen configuration

3.5
condylar centres
centres of two circles which are a best fit to the sagittal sections through the curved surfaces of the posterior regions of the two condyles of a condylar or meniscal total knee-joint prosthesis

3.6
flexion/extension axis
nominal axis of rotation of the femoral component relative to the tibial component

NOTE 1 For hinged knees, the flexion/extension axis is the hinge axis.

NOTE 2 For condylar and meniscal knees, the flexion/extension axis may be determined by:

— considering the condyles of the femoral component to be in contact with an imaginary plane perpendicular to the tibial axis when the femoral component is at 30° and when it is at 60° of flexion; and then

— visualizing four lines (contact normals) perpendicular to the imaginary plane running through the points where the two femoral components would contact the plane at each of these flexion angles.

The flexion/extension axis is then the line intersecting all four contact normals.

NOTE 3 The axis of rotation of the femoral component relative to the machine frame does not necessarily coincide with the flexion/extension axis.

3.7
reference position
angular and linear alignment of the tibial component relative to the femoral component which gives static equilibrium of the tibial component when it is loaded against the femoral component by a positive axial force applied along the axial force axis, with the most distal points on the femoral bearing surface resting on the lowest points on the tibial bearing surface

NOTE 1 The reference position is equivalent to the position of 0° flexion (i.e. full extension) *in vivo.*

NOTE 2 For the purpose of determining the reference position, the effect of friction between the tibial and femoral components is ignored.

NOTE 3 The reference position may be determined by geometrical calculations based on the three-dimensional form of the tibial and femoral surfaces. For the purpose of these calculations, the form of the tibial and femoral surfaces may be taken either from design data or from coordinate measurements of an unworn total knee-joint prosthesis.

3.8
tibial axis
nominal longitudinal axis of the tibia, corresponding to the central axis of the medullary cavity of the proximal tibia

3.9
tibial rotation
rotation of the tibial component of the knee-joint prosthesis about an axis parallel to the tibial axis

NOTE The rotation is considered to be zero when the total knee-joint prosthesis is in the **reference position** (3.7). For a right-sided total knee-joint prosthesis, the tibial rotation is positive when a plan view onto the tibial component shows the tibial component rotated anti-clockwise from its position with the total knee-joint prosthesis in the reference position.

3.10
tibial rotation torque
torque applied to the tibial component of the total knee-joint prosthesis about an axis parallel to the tibial axis

NOTE From a plan view onto the tibial component, the axial torque is positive when it acts clockwise on a left-sided total knee-joint prosthesis and positive when it acts anti-clockwise on a right-sided total knee-joint prosthesis.

4 Principle

The total knee-joint prosthesis is mounted in an apparatus which applies a cyclic variation of flexion/extension angle and contact force to the interface between tibial and femoral components, simulating normal human walking. The tibial component is free to move relative to the femoral component under the influence of the applied contact forces, this motion having all degrees of freedom except for the flexion/extension angle which follows a specified cyclic variation.

The applied contact force actions are axial force, anterior posterior (AP) force and tibial rotation torque. The axial force follows a specified cyclic variation. The AP force comprises two components, one being a specified cyclic variation and the other being proportional to, and in the opposite direction to, AP displacement. Similarly the tibial rotation torque comprises two components, one being a specified cyclic variation and the other being a rotation torque which is proportional to the amount of and in the opposite direction to tibial rotation. The load actions which are proportional to the AP displacement and tibial rotation correspond to the tensions transmitted by anatomical ligaments in normal knee-joint function.

The contacting surfaces of the femoral and tibial components are immersed in a fluid test medium simulating human synovial fluid. A control specimen, if polymers are the object of investigation, is subjected to the same time-varying 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.

5 Reagents and materials

5.1 Fluid test medium: calf serum (25 % ± 2 %) diluted with deionized water (balance).

Normally the fluid test medium is filtered through a 2 µm filter, and has 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 may be undertaken. If it is, the measured values should be included in the test report (see clause 8).

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

5.2 Test specimen. Femoral and tibial component: the tibial component should have the articulating surface attached by its normal immediate backing (for example bone cement or a machined replica of the inner surface of the tibial tray) unless this is impractical due to physical features of the implant system. If the component forming the articulating surface is fixed to the tibial tray 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 tibial component should represent normal design features and conditions of use but should allow removal of the component for measurement of wear (if required) without destruction.

5.3 Control specimen, identical to test specimen.

6 Apparatus

6.1 Testing machine, capable of applying the forces and torque specified in association with corresponding displacements (Figure 2) 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 tibial components using attachment methods comparable to the intended anatomical fixation.

An enclosure shall be provided which is capable of isolating the test specimen to prevent third-body contamination from the test machine and the atmosphere.

6.3 Means of aligning and positioning the femoral component of the test specimen in the reference position, so that the same position and orientation can be reproduced following the removal of the tibial component for measurement.

6.4 Means of aligning and positioning the tibial component of the test specimen in the inferior position, so that the same position and orientation can be reproduced following removal for measurement.

6.5 Axial force control system, capable of generating an axial force following the cycle given in Figure 2 b) and maintaining the magnitude of this force to a tolerance of ± 5 % of the numerical value specified, throughout the cycle and ± 3 % of the cycle time for phasing. The axial force is applied along the axial-force axis to the tibial component of the total knee-joint prosthesis (see Figure 1).

6.6 Motion control system, capable of generating the flexion/extension motion given in Figure 2 a) and maintaining the magnitude of this motion to a tolerance of ± 5 % of the numerical value specified throughout the cycle and ± 3 % of the cycle time for phasing. The flexion/extension motion is measured about the flexion/extension axis as a relative angular motion between the femoral and tibial components. Provision shall be included for the adjustment of the zero position of the motion control system so that when the applied flexion/extension motion reaches zero flexion angle, as shown in Figure 2, the total knee-joint prosthesis is at the designed fully extended state.

NOTE For total knee-joint prostheses which include a positive extension stop, a device may be included to limit the extension moment which can be applied by over-extension.

6.7 AP force control system, capable of generating an AP force following the cycle given in Figure 2 c) and maintaining the magnitude of this force to a tolerance of ± 5 % of the numerical value of the force specified throughout the cycle and ± 3 % of the cycle time for phasing. The AP force is applied along the line of action which is perpendicular to both the tibial axis and the flexion/extension axis and which passes through the axial force axis.

6.8 Tibial torque control system, capable of generating a tibial torque following the cycle given in Figure 2 d) and maintaining the magnitude of this torque to a tolerance of ± 5 % of the numerical value specified throughout the cycle and ± 3 % of the cycle time for phasing. The tibial torque is applied about the tibial axis.

6.9 AP motion restraint system, capable of applying a restraining AP force along its **line of action** (6.7). The magnitude of the restraining AP force is proportional to the AP displacement of the tibial component, the magnitude of the constant of proportionality being 30 N/mm ± 1,5 N/mm. The direction of the restraining AP force is such as to oppose AP movement of the tibial component and is zero when the total knee-joint prosthesis is in the reference position.

NOTE The restraining AP force may be generated by an elastic spring element.

6.10 Tibial rotation restraint system, capable of applying a restraining tibial rotation torque about the same axis as that of the tibial torque (6.8). The magnitude of the restraining tibial rotation torque is proportional to the tibial rotation, the magnitude of the constant of proportionality being (0,6 ± 0,03) N·m per degree. The direction of the tibial rotation torque is such as to oppose rotation of the tibial component and is zero when the total knee-joint prosthesis is in the reference position.

NOTE The restraining torque may be generated by an elastic spring element.

6.11 Lubrication system, capable of maintaining the contact surfaces immersed in the fluid test medium.

NOTE The use of sealed enclosures may prevent evaporation.

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