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Implants for surgery — Wear of total ankle-joint prostheses — Loading and displacement parameters for wear-testing machines with load or displacement control and corresponding environmental conditions for test

Implants chirurgicaux — Usure des prothèses totales de l'articulation de la cheville — Paramètres de charge et de déplacement pour machines d'essai d'usure avec contrôle de la charge ou du déplacement et conditions environnementales correspondantes d'essai

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Implants for surgery — Wear of total ankle-joint prostheses — Loading and displacement parameters for wear-testing machines with load or displacement control and corresponding environmental conditions for test

1 Scope

This document 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 ankle-joint prostheses in wear-testing machines with load or displacement control.

NOTE This document is based on the method described by ISO 14243-1 and ISO 14243-3 and allows for the use of the same test equipment as for total knee replacement wear testing.

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

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
talar component
total ankle-joint prosthesis component attached to the talus

Note 1 to entry: Component that articulates against the bearing (see Figure 1).

3.2
tibial component
total ankle-joint prosthesis component attached to the tibia

3.3
bearing
total ankle-joint prosthesis component intended for articulating with both tibial component and talar component surfaces

Note 1 to entry: The superior bearing surface supports the tibial internal/external rotation, and the inferior bearing surface supports the talar plantar/dorsiflexion (see Figure 1).

3.4
frontal plane
plane that lies in the medial-lateral direction of the implant

Note 1 to entry: See G in Figure 1.

3.5
sagittal plane
plane that lies perpendicular to the frontal plane

Note 1 to entry: See H in Figure 1.

3.6
talar plantar/dorsiflexion rotation
angular movement of the talar component of the total ankle joint-prosthesis about a medial/lateral axis

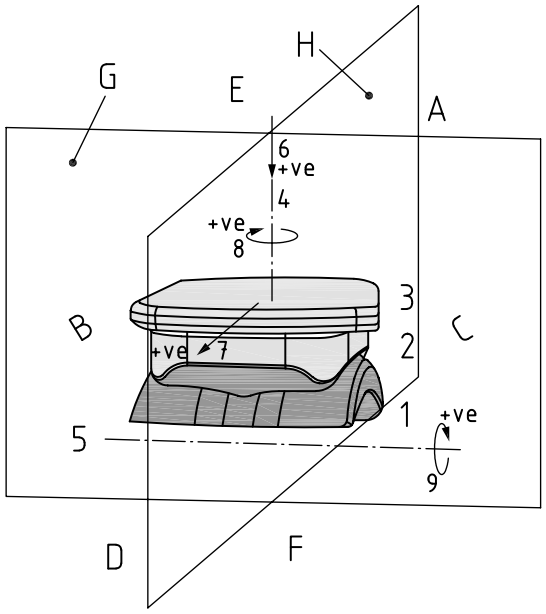
Note 1 to entry: The plantar/dorsiflexion rotation is considered to be zero when the total ankle-joint prosthesis is in the *reference position* (3.13), is positive when the talar component is in dorsiflexion (+ve) and is negative when the talar component is in plantarflexion (see Figure 1).

3.7
plantar/dorsiflexion test axis
nominal axis of rotation of the talar component relative to the tibial component

Note 1 to entry: See 5 in Figure 1.

Note 2 to entry: The test axis is the line parallel to the medial/lateral axis, and intersecting with both the plantar/dorsiflexion talar design axis provided by the manufacturer and the axis of internal/external rotation of the tibial component (see Figure 2).

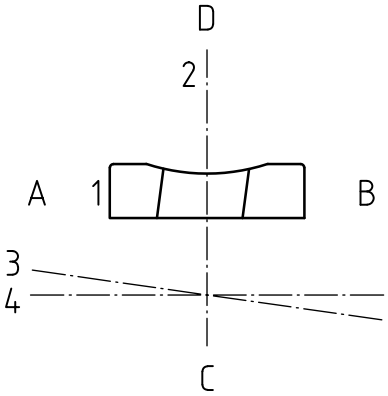
Note 3 to entry: When the talar plantar/dorsiflexion design axis is horizontal, this axis is used as plantar/dorsiflexion test axis.



Key

1 talar component
2 bearing
3 tibial component
4 axis of internal/external rotation for the tibial component, axial force axis
5 plantar/dorsiflexion test axis
6 axial force (on the tibial component)
7 AP displacement by the tibial component, AP force on the tibial component
8 tibial component internal/external rotation, tibial rotation torque
9 talar plantar/dorsiflexion rotation
A posterior
B medial
C lateral
D anterior
E superior
F inferior
G frontal plane
H sagittal plane

Figure 1 — Sign convention for the forces and motions, shown for a left total ankle joint-prosthesis



Key

1 talar component
2 axis of internal/external rotation for the tibial component
3 talar plantar/dorsiflexion design axis
4 plantar/dorsiflexion test axis
A medial
B lateral
C inferior
D superior

Figure 2 — Plantar/dorsiflexion test axis

3.8
anterior posterior (AP) displacement
displacement of the tibial component in the sagittal plane perpendicular to the axial force axis

Note 1 to entry: AP is an abbreviation for anterior posterior.

Note 2 to entry: The displacement is considered to be zero when the total ankle-joint prosthesis is in the *reference position* (3.13) and is considered to be positive (+ve) when the tibial component is moved to an anterior position (see Figure 1).

3.9
anterior posterior (AP) force
force applied to the tibial component in the sagittal plane perpendicular to the axial force axis

Note 1 to entry: AP is an abbreviation for anterior posterior.

Note 2 to entry: The force is considered to be zero when the total ankle joint-prosthesis is in the *reference position* (3.13) and is to be considered to be positive (+ve) when it acts from posterior to an anterior direction on the tibial component (see Figure 1).

3.10
tibial internal/external rotation
rotation of the tibial component of the total ankle-joint prosthesis about the axial force axis

Note 1 to entry: The tibial rotation is considered to be zero when the total ankle-joint prosthesis is in the *reference position* (3.13) and is considered to be positive (+ve) when the tibial component rotates internally (see Figure 1).

3.11
axial force
normal force applied to the ankle-joint prosthesis in a direction parallel to the tibial axis

Note 1 to entry: The axial force is considered to be positive (+ve) when the tibial component is loaded towards the talar component (see Figure 1).

3.12
axial force axis
vertical line of action of the axial force taken to pass through a point on the tibial component of the total ankle-joint prosthesis which is in the centre of the medial-lateral width of the tibial component

Note 1 to entry: See 4 in Figure 1.

Note 2 to entry: The axial force axis coincides with the axis of rotation for the tibial component.

3.13
reference position
angular and linear alignment of the tibial component relative to the talar component which gives static equilibrium of the tibial component when it is loaded against the talar component by a positive axial force applied along the axial force axis, with the most proximal points on the talar bearing surface resting on the highest points on the tibial bearing surface

Note 1 to entry: The reference position is equivalent to the position of 0° talar plantar/dorsiflexion *in vivo.*

Note 2 to entry: For the purpose of determining the reference position, the effect of friction between the tibial and talar components is ignored.

Note 3 to entry: The reference position can be determined by geometrical calculations based on the three dimensional form of the tibial and talar surfaces. For the purpose of these calculations, the form of the tibial and talar surfaces can be taken either from design data or from co-ordinate measurements of an unworn total ankle-joint prosthesis.

Note 4 to entry: In a moderately constrained or flat design of tibial bearing component the lowest points on the tibial bearing surface can span a large (flat) range of anterior-posterior positions, such that there is no distinct lowest point. In such a situation, this definition of reference position cannot apply. In such situations, the prosthesis manufacturer should be consulted to decide what neutral position should be set and this should be noted in detail in the test report.

3.14
tibial axis
nominal longitudinal axis of the tibia, corresponding to the central axis of the medullary cavity of the proximal tibia

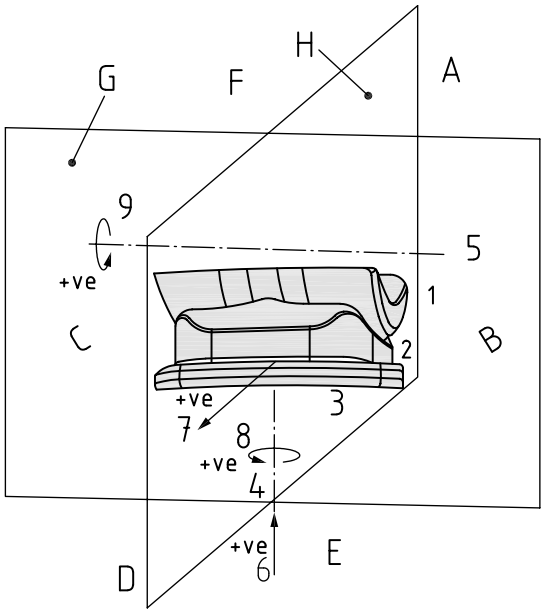
3.15
tibial component rotational torque
torque applied to the tibial component of the total ankle-joint prosthesis around the axial force axis

Note 1 to entry: The tibial component rotational torque is considered to be positive (+ve) when it rotates the tibial component internally (see Figure 1).

3.16
inverted position
inverted orientation of the total ankle joint-prosthesis

Note 1 to entry: To enable testing of a total ankle joint-prosthesis in a knee simulator according to ISO 14243-1 and ISO 14243-3 an inverted position of the implant is required (see Figure 3).

Note 2 to entry: The sign convention shown in Figure 2 is for informative purpose.



Key

1 talar component
2 bearing
3 tibial component
4 axis of rotation for the tibial component, axial force axis
5 plantar/dorsiflexion test axis
6 axial force (on the tibial component)
7 AP displacement by the tibial component, AP force on the tibial component
8 tibial component internal/external rotation, tibial rotation torque
9 talar plantar/dorsiflexion rotation
A posterior
B medial
C lateral
D anterior
E inferior
F superior
G frontal plane
H sagittal plane

Figure 3 — Sign convention for the forces and motions, shown for a left total ankle joint-prosthesis (inverted position)

4 Principle

The total ankle-joint prosthesis is mounted in an apparatus which applies a simultaneous cyclic variation of rotation actions (talar plantar/dorsiflexion rotation and tibial rotational torque) and contact forces (axial and AP forces) to the interface between tibial and talar components, simulating normal human walking.

NOTE Contact force actions were scaled by an assumed body weight of 720 N.

Wear testing of a total ankle-joint prosthesis in a knee simulator according to ISO 14243-1 and ISO 14243-3 requires an inverted position (see 3.16), with the talar component in superior position of

the total ankle-joint prosthesis. The tibial component position as given by ISO 14243-1 and ISO 14243-3 remains the tibial component position of the total ankle-joint prosthesis, and the femoral component position as given by ISO 14243-1 or ISO 14243-3 becomes the talar component position of the total ankle-joint prosthesis.

Great care should be taken not to confuse the directions of the motions because of the inverted position when implementing the curves.

The applied contact forces and rotation actions for wear-testing machines with load control are axial force, anterior posterior (AP) force, talar plantar/dorsiflexion rotation and tibial component rotational torque.

The applied contact forces and rotation actions for wear-testing machines with displacement control are axial force, anterior posterior (AP) displacement, talar plantar/dorsiflexion rotation and tibial component internal/external rotation.

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

5.1 Fluid test medium, calf serum diluted with deionized water to have a protein mass concentration of 20 g/l ± 2 g/l.

Normally the fluid test medium is filtered through a 2 µm filter.

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 g) 5)].

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, constituted by the tibial and talar components and the bearing of the total ankle joint-prosthesis.

These components shall be chosen so that their size combination and design detail represent the worst expected case for wear of the total ankle joint-prosthesis being tested. The user shall provide a justification for why the size combination and design detail represent the worst expected case for wear.

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 without destruction.

The components shall be sterilized in the same way as for clinical use because this might affect the wear properties of the materials. Sterilization of all test and control components within a specific test group should be done simultaneously (in a single container) when possible, to minimize variation.

5.3 Control specimen, identical to test specimen.

5.4 Sample size, at least three test specimens and one loaded soak control specimen shall be tested to represent the wear of each type of prosthesis.

6 Apparatus

6.1 Testing machine, capable of applying the forces and torque prescribed in association with corresponding displacements and rotations (see Figure 1) and operating at a frequency of 1,0 Hz ± 0,1 Hz.

6.2 Means of mounting and enclosing the test specimen, using a corrosion-resistant material, capable of holding tibial and talar 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 testing machine and the atmosphere.

6.3 Means of aligning and positioning the tibial 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 of wear.

6.4 Means of aligning and positioning the talar component of the test specimen in the inferior position so that the same position and orientation can be reproduced after its removal for measurement of wear.

6.5 Axial force control system, capable of generating an axial force following the cycle given in Figure 6 with an accuracy of ±3 % of the cycle time for phasing and maintaining the magnitude of this force to a tolerance of ±5 % of the maximum value specified throughout the cycle. The axial force is applied along the axial force axis by applying the axial force to the tibial component of the total ankle-joint prosthesis (see Figure 1).

6.6 Plantar/dorsiflexion motion control system, capable of generating the plantar/dorsiflexion motion given in Figure 8 with an accuracy of ±3 % of the cycle time for phasing and maintaining the magnitude of this motion to a tolerance of ±5 % of the maximum value specified throughout the cycle.

6.7 AP force control system, capable of generating an AP force following the cycle given in Figure 7 with an accuracy of ±3 % of the cycle time for phasing and maintaining the magnitude of this force to a tolerance of ±5 % of the maximum value of the force specified throughout the cycle. The AP force is applied along the line of action that is perpendicular to both the tibial axis and the flexion/extension axis and which passes through the axial force axis.

6.8 AP motion restraint system, capable of applying a restraining AP force along its line of action (see 6.7). The direction of the restraining AP force is such as to oppose AP movement of the tibial component. It should be 20 N/mm ± 1 N/mm when the total ankle-joint prosthesis is in, or within 6 mm of, the reference position.

At a tibial AP displacement > 6 mm, a tibial restraint of 140 N/mm ± 5 N/mm should be used; at a tibial AP displacement < 0 mm, a tibial restraint of 120 N/mm ± 5 N/mm should be used (see Figure 4).

6.9 AP displacement control system, (for displacement control tests) capable of generating the AP displacement given in Figure 9 with an accuracy of ±3 % of the cycle time for phasing and maintaining the magnitude of this motion to a tolerance of ±5 % of the maximum value specified throughout the cycle.

6.10 Tibial component rotational torque control system, capable of generating a tibial component rotational torque following the cycle given in Figure 10 with an accuracy of ±3 % of the cycle time for

