INTERNATIONAL STANDARD

ISO 14243-5

First edition
2019-05

Implants for surgery — Wear of total knee prostheses —

Part 5: Durability performance of the patellofemoral joint

Implants chirurgicaux — Usure des prothèses totales du genou — Partie 5: Performance de durabilité de l'articulation fémoro-patellaire

Reference number
ISO 14243-5:2019(E)

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Published in Switzerland

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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.

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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

A list of all parts in the ISO 14243 series can be found on the ISO website.

The main changes compared to the previous edition are as follows:

— In Clause 4, Principle:Total number of cycles has been changed from 220 000 to 50 000;

— 3.14, 3.15 and 3.16 have been changed;

— Figures have been renumbered;

— Failure and damage pattern (8.14) has been updated;

— a Typo in Formula (2) has been corrected.

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.

Introduction

This document is applied for the qualitative visual assessment of durability of an ultra-high molecular weight polyethylene patella when articulating against a femoral component by observing the occurrence of delamination, cracking, or other damage characteristics that occur as a result of the specified displacement and loading inputs.

This standard test method is comprehensive, but it needs to be noted that it is complex to implement - maybe the most complex in its particular field. The reader/user needs to note that:

1) The main compressive force waveforms are to be calculated to suit the individual implant (size).

2) The waveforms for the kinematics on two testing actuators are calculated to suit the particular geometry of the implant tested involving sophisticated CAD measurements, and in each case thorough care is needed when using degrees or radians for the angle computations in setting up the test.

3) Intricate friction sensitive medial-lateral force imposing fixtures are involved, with measurement needed of such force to be provided on the testing machines.

Implants for surgery — Wear of total knee prostheses —

Part 5: Durability performance of the patellofemoral joint

1 Scope

This document specifies the relative angular movement between articulating patellofemoral joint components, the pattern of the applied force, speed and duration of testing, sample configuration and test environment to be used for the durability testing of total knee-joint prostheses in wear-testing machines with load control and displacement.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 5833, *Implants for surgery — Acrylic resin cements*

ISO 7207-1, *Implants for surgery — Components for partial and total knee joint prostheses — Part 1: Classification, definitions and designation of dimensions*

ISO 14243-1, *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*

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

ISO 14243-3, *Implants for surgery — Wear of total knee-joint prostheses — Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test*

ASTM F2003, *Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air*

3 Terms and definitions

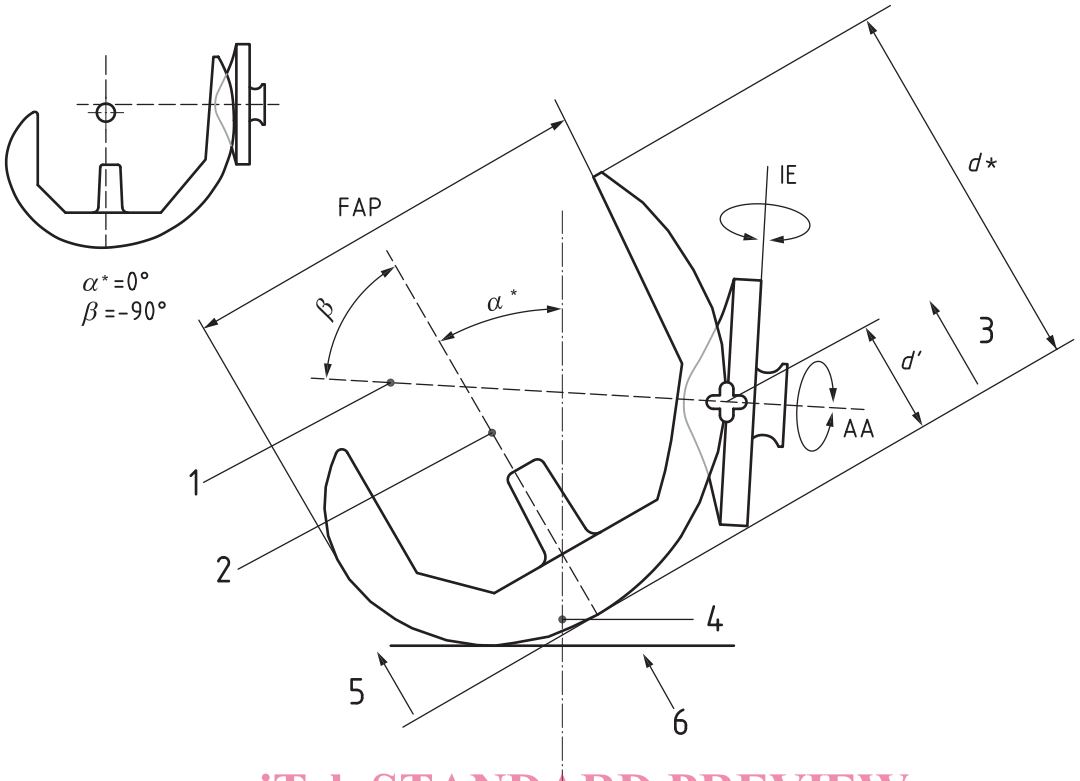
For the purposes of this document, the terms and definitions given in ISO 7207-1 and the following apply.

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/

Applied nomenclature is illustrated in Figure 1.



Key

1	patellar axis	α^*	tibiofemoral flexion angle
2	femoral axis	β	patellofemoral angle
3	positive values for d'	d^*	femoral height
4	tibial axis	d'	patellar location
5	negative values for d'	IE	internal/external rotation
6	tibial plane	AA	abduction/adduction
		FAP	functional A-P

Figure 1 — Nomenclature

3.1
femoral axis
imaginary line that is orthogonal to the tibial plane and bisects the midpoint of the line that connects the deepest (most distal) points of both condyles at 0° tibiofemoral flexion

3.2
patellar axis
imaginary line, orthogonal to the patellar component backface plane, passing though the peak of the articulation surface of the patellar component

3.3
tibial axis
nominal longitudinal axis of the tibia, corresponding to the central axis of the medullary cavity of the proximal tibia

Note 1 to entry: At 0° tibiofemoral flexion, the tibial axis is parallel with the femoral axis

3.4
tibial plane
imaginary plane orthogonal to the tibial axis

3.5
tibiofemoral flexion angle
α^*
angle in the sagittal plane between the tibial axis and the femoral axis

Note 1 to entry: This value is considered to be positive in the direction of tibiofemoral flexion and negative in the direction of tibiofemoral hyperextension.

Note 2 to entry: The unit of measure for the tibiofemoral flexion angle is degrees.

3.6
patellofemoral angle
β
angle in the sagittal plane between the patellar axis and the femoral axis

Note 1 to entry: The machine flexion-extension waveform is based on the patellofemoral angle.

Note 2 to entry: The coordinate system that describes this parameter is non-intuitive, since the *in vivo* rotation centre is not static. For simplicity when being applied as the machine flexion-extension angle the patellofemoral angle is defined mathematically in Formula (1), and its unit of measure is degrees.

$$\beta = 0{,}7\alpha^* - 90 \tag{1}$$

3.7
femoral height
d^*
overall height of the femoral component

Note 1 to entry: It is the distance between the most proximal point of the anterior flange and the most distal condylar point. For a bi compartmental knee, the femoral height is the sum of parameters *d* and *g*, according to ISO 7207-1.

Note 2 to entry: The unit of measure for the overall height of the femoral component is millimetres.

3.8
patellar location
d'
distance to translate the patella fixture on the test simulator to complement the femoral component rotation to achieve effective wrapping of the patella around the femoral component during knee flexion

Note 1 to entry: d' is an offset distance between the perceived intersection of the femoral component articulating surface and the patellar axis in the sagittal plane when the patella is contacting the femoral component either in the trochlear groove or between the condyles.

Note 2 to entry: d' changes in sign when the patella and femoral axis line up, such that positive values of d' occur when the patella is located anteriorly to the femoral axis; while negative values of d' occur posteriorly to the femoral axis.

Note 3 to entry: The unit of measure for the patellar location is millimetres.

3.9
functional A-P
FAP
distance in the anterior-posterior direction orthogonal to the femoral axis of the femoral component, between the most proximal, interior point of the anterior flange and the most posterior point along the condyle

Note 1 to entry: The unit of measure for the FAP dimension is millimetres.

3.10
patellar internal/external rotation
rotation about an axis that is orthogonal to the patellar axis and is parallel to the tibial and femoral axes at 0° tibiofemoral flexion

3.11
patellar abduction/adduction rotation
rotation around the patella axis

Note 1 to entry: Rotation is positive (abduction) for a left knee when the patella rotates clockwise when viewed from anterior. It is positive (abduction) for a right knee when the patella rotates counter clockwise when viewed from anterior.

3.12
cycle limit
number of cycles at which the test is terminated if no functional failure has occurred

3.13
mediolateral force
force acting parallel to the femoral flexion-extension axis

3.14
patellar translation
Y
measure between the patellar axis and the flexion extension axis measured orthogonally to the patellar axis (see 8.7)

Note 1 to entry: The unit of measure for Y is millimetres.

3.15
femoral flexion/extension axis
nominal axis of rotation of the femoral component

3.16
similar device
device that is defined as a legally marketed device with significant human clinical experience and for which there is evidence showing it has performed well in clinical use (absence of product-related recalls and/or statistically-significant number of failures) and that has the same intended use, similar materials, and similar design (for example, fixation, modularity, features, key dimensions, surface treatment, etc.)

Note 1 to entry: Identification of a similar device is at the discretions of the manufacturer in accordance with the regulatory requirements in the jurisdictions where the device is marketed.

4 Principle

This document describes a durability testing method which uses cyclic waveforms that simulate the patellofemoral kinetics and kinematics by combining a squatting sub-cycle with two low flexion sub-cycles based on individual knee design characteristics. Loading and displacement waveforms are performed until delamination, cracking, or another identified failure mode occurs. If the implants do not demonstrate any failure modes (8.14) by 50 000 cycles, the test can be stopped. The value of 50 000 is based on laboratory experience gained by comparing the results of delaminated components with retrieved components. The squatting sub-cycle simulates up to 120° of tibiofemoral flexion at a rate of 1/3 Hz with a compressive load range from 0,5 to 3 times body weight. The low flexion (walking) sub-cycles simulate 0° to 58° of tibiofemoral flexion at a rate of 1,1 Hz ± 0,1 Hz and ranges from 0,3 to 0,5 times body weight. The resulting cycle time is 4,82 s. The low flexion sub-cycles challenge the dome of the patella whereas the squat sub-cycle challenges the periphery of the patella.

5 Reagents and materials

5.1 Fluid test medium, in accordance with ISO 14243-1 and ISO 14243-3.

To minimize microbial contamination, the fluid test medium should be stored frozen until required. An antimicrobial reagent (such as sodium azide) may be added. Additionally, a chelating agent (such as EDTA) may be added as well. Such reagents can be hazardous. It is recommended to filter the solution of additives and deionized water through a 2 µm filter. Additionally, routine monitoring of the pH of the fluid medium may be undertaken. If it is, the values should be included in the test report.

5.2 Test specimen, patellar and femoral components.

5.3 Acrylic resin cement, in accordance with ISO 5833.

5.4 Rigid metal or polymeric fixture, manufactured according to the patellar component design for fixing the patellar component on the test machine support.

6 Test specimen and number of samples

Dimensional specifications of the knee joint shall represent the worst-case conditions. It is defined as the combination between a femur and patella component, which results in the highest contact stress and subsurface shear stress. This combination is typically the largest femur used in conjunction with the smallest patella for patellae that do not share the load with surrounding tissues (i.e. not an inset patella).

The size of the components that result in the worst-case scenario shall be justified. This could be a theoretical analysis, finite element analysis (FEA), or a suitably chosen and reported experimental procedure (e.g. repeated testing). The analysis or testing should include contact locations for lower tibiofemoral angles, as well as higher tibiofemoral flexion angles using the appropriate setup parameters described in Clause 7.

If the flange geometries are different within a product family among patient solutions (i.e. posterior stabilizing (PS), cruciate retaining (CR), ultra-congruent (UC), or any other femur type), they should be evaluated separately.

The patellar component should be mounted by fastening or cementing with polymethylmethacrylate (PMMA, resin cement) (5.3) to a suitable rigid (metal or polymeric) fixture (5.4) so as to neither cushion nor artificially increase the sub-surface shear stresses during testing. The choice of fixture and fastening/cementing method need to be explained in the report, with reference to how the patella component design is inserted and fixed *in vivo*.

The polyethylene patellar component shall be artificially aged in an oxygen environment according to ASTM F2003 if appropriate i.e. would negatively affect mechanical properties of the polyethylene. If this artificially ageing protocol could potentially improve the mechanical properties of the polyethylene then the patella shall not be artificially aged.

At least 5 polymeric knee joint patellar components should be tested for this qualitative durability assessment.

7 Apparatus

7.1 Testing machine, capable of producing the angular and translational displacements determined according to 8.3 and 8.7 in conjunction with the corresponding loading determined according to 8.5.

NOTE Common contemporary testing machines do not all function in the same manner with the same coordinate systems. It is the responsibility of the user to understand their own coordinate systems and make the appropriate adjustments.