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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
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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

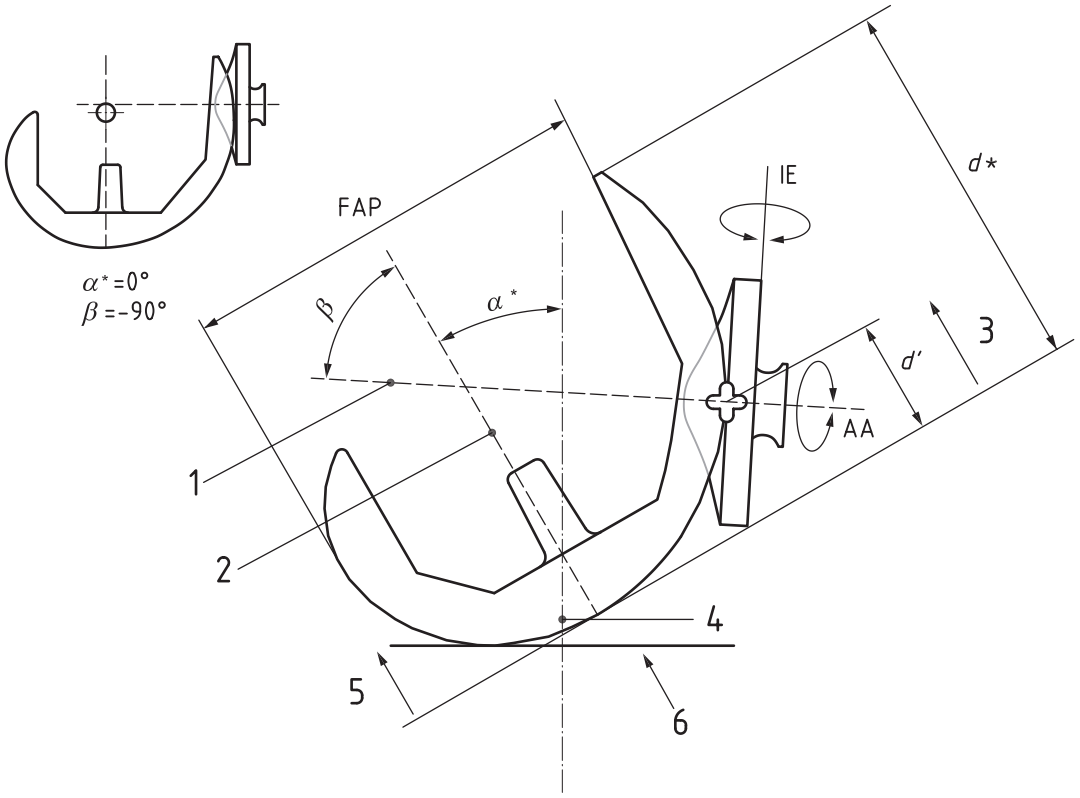
For the purposes of this document, the terms and definitions given in ISO 7207-1 and the following apply.

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.

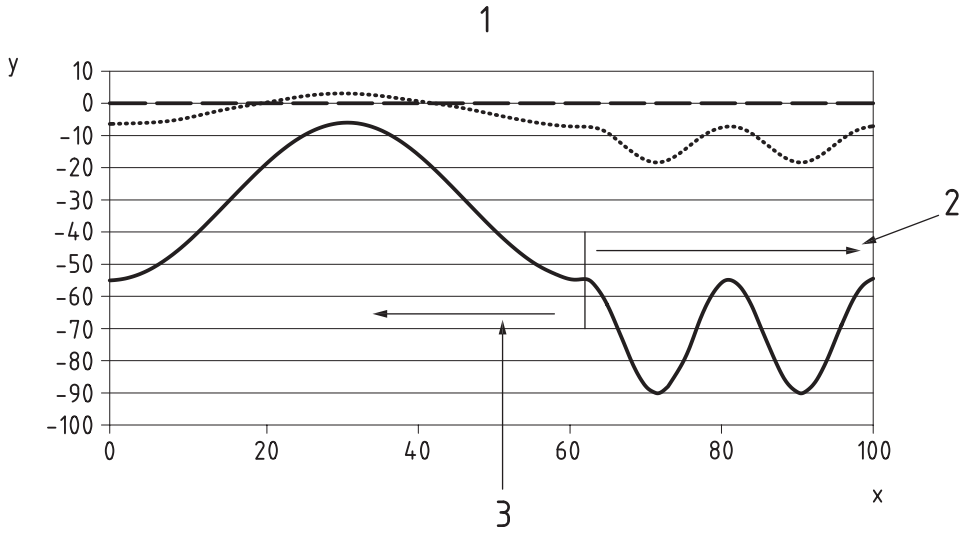
NOTE Common contemporary testing machines do not all function in the same manner with the same coordinate systems. It is the responsibility of the user to understand their own coordinate systems and make the appropriate adjustments.

7.2 Means of mounting and enclosing the test specimens, using corrosion resistant materials, capable of holding the patellar and femoral components and using fixation methods comparable to the intended anatomical fixation.

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

7.3 Means of aligning and positioning the femoral and patellar component, so that the correct nominal position and orientation can be produced, and the same position and orientation can be reproduced following the removal of the test specimens for observation.

7.4 Patellofemoral flexion/extension (FE) rotation control system, capable of generating the angular movements of the femoral component according to Formula (2) in 8.3 (example in Figure 2) while maintaining the magnitude of this motion to a tolerance of ±5 % of the maximum angular value and ±3 % of the full cycle time for phasing.



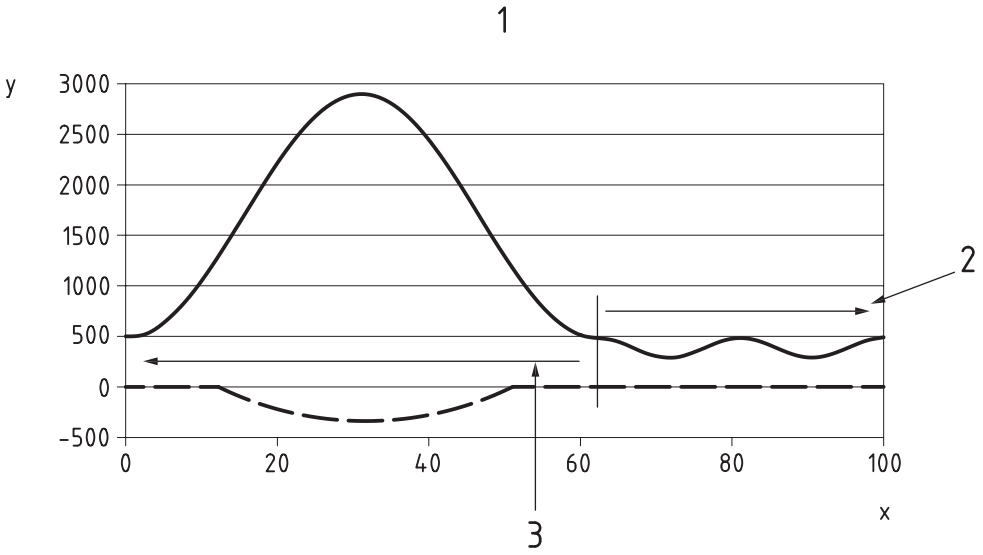
Key

1	kinematics	x	cycle (%)
2	low flexion sub-cycles	y	β and AA (degree), Y (mm)
3	squat sub-cycle		
———	β, patellofemoral angle	– – –	AA, abduction/adduction
.....	Y, translation along the anterior femoral flange		

Figure 2 — Example kinematic waveforms (based on a simulator that performs translation by moving the femoral component)

7.5 Patellofemoral compression force (F) control system, capable of generating a force between the patellar and femoral components according to Formula (4) in 8.5 (example in Figure 3) while

maintaining the magnitude of this force to a tolerance of ±5 % of the maximum force value and ±3 % of the full cycle time for phasing. The force is acting in the direction of the patellar axis.



Key

1	kinetics	x	cycle (%)
2	low flexion sub-cycles	y	force (N)
3	squat sub-cycle		
———	compressive load	– – –	approximate resultant shear load

Figure 3 — Example kinetic waveforms using the adjustable screw method (M-L force may have the opposite sign depending on coordinate system)

7.6 Patellofemoral translation control system, capable of generating a linear translation of the patellar component such that its position relative to the femoral component changes. The steps to determine the waveform for this linear translational motion are described in 8.7. The translational motion magnitude should be maintained to a tolerance of ±5 % of the maximum displacement value and ±3 % of the full cycle time for phasing.

7.7 Patellofemoral abduction/adduction (axial rotation) control system, capable of generating a patellofemoral abduction/adduction (axial rotation) maintaining the magnitude of this rotation to a tolerance of ±5 % of the maximum angle value and ±3 % of the full cycle time for phasing. The recommended waveform is described in 8.8.

NOTE The user might want to apply different abduction/adduction waveforms than indicated in 8.8

7.8 Patellofemoral mediolateral (M-L) force mechanism, capable of generating a shear force acting from lateral to medial on the patella corresponding to 10 % of the maximum compressive force simultaneously with the maximum compressive force.

NOTE 1 Contemporary simulators do not typically provide all of the axes to explicitly control an M-L force in conjunction with performing all other required forces or translations. A mechanical fixture is likely necessary to induce the M-L force; two such examples are illustrated in Figures 4 and 5 and described as following.

Method One allows for the shear force to increase with increasing tibiofemoral flexion while the peak M-L shear force occurs at the maximum tibiofemoral flexion angle and compressive force (Figures 3 and 4). Using this method, at lower tibiofemoral flexion angles (α^* = 0°), the patella tracks more medially within the trochlear groove, which relieves the M-L force induced by the adjustment screw. At higher tibiofemoral flexion angles, the patella tracks laterally within the trochlear groove until it reaches the condyles. This method requires manual adjustment of a screw while monitoring the M-L force until

it meets 10 % ± 1 % of the peak compressive force between the femur and patella. Using this method requires the monitoring of the M-L force, and the screw needs to be adjusted as the polyethylene deforms.

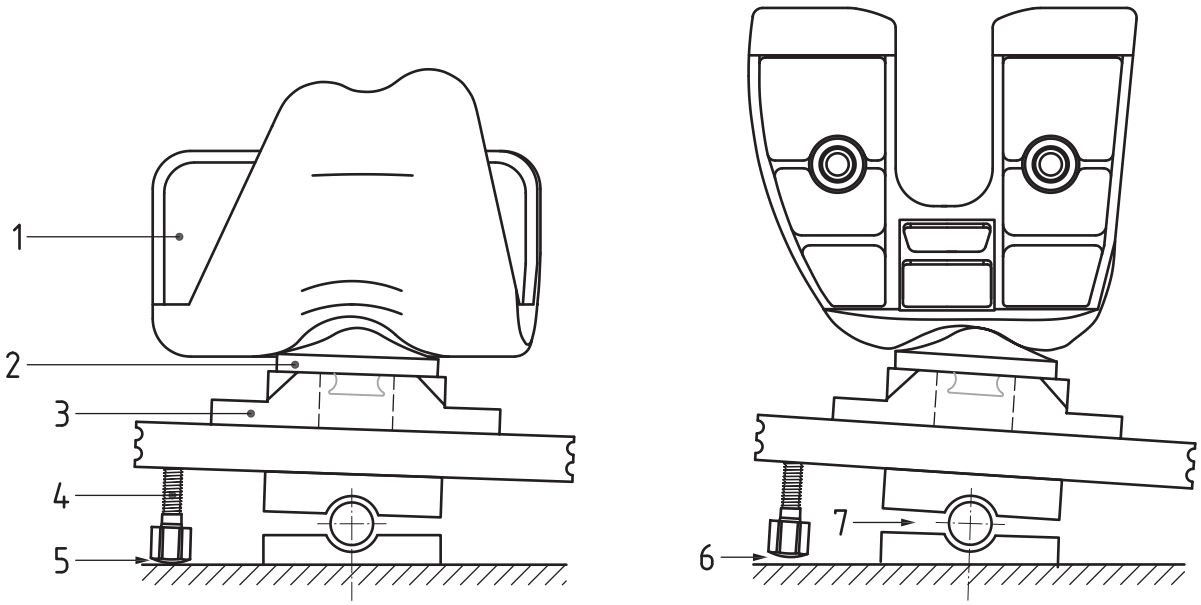
Method Two allows for a constant 10 % M-L shear force to occur continuously throughout the entire cycle (Figures 3). This method uses a thrust bearing inclined at an angle.

Verify the performance of the medial-lateral force imposing fixtures by measuring the medial-lateral force generated by the patellofemoral compression force (Method Two). The measured medial-lateral force has to be 10 % ± 1 % of the patellofemoral compression force.

NOTE 2 The user might want to design an adjustable angulation of the thrust bearing as shown in Figure 5 and monitor the M-L force.

NOTE 3 The user might want to measure the M-L shear force to ensure low friction of the thrust bearing.

NOTE 4 The system illustrated in Figure 4 allows passive internal and external rotation while constraining medio-lateral translation, while the system illustrated in Figure 5 does not allow internal and external rotation, but it does not constrain medio-lateral translation. Both systems satisfy 7.9.



$\alpha^* = 120°$
$\beta = -6°$

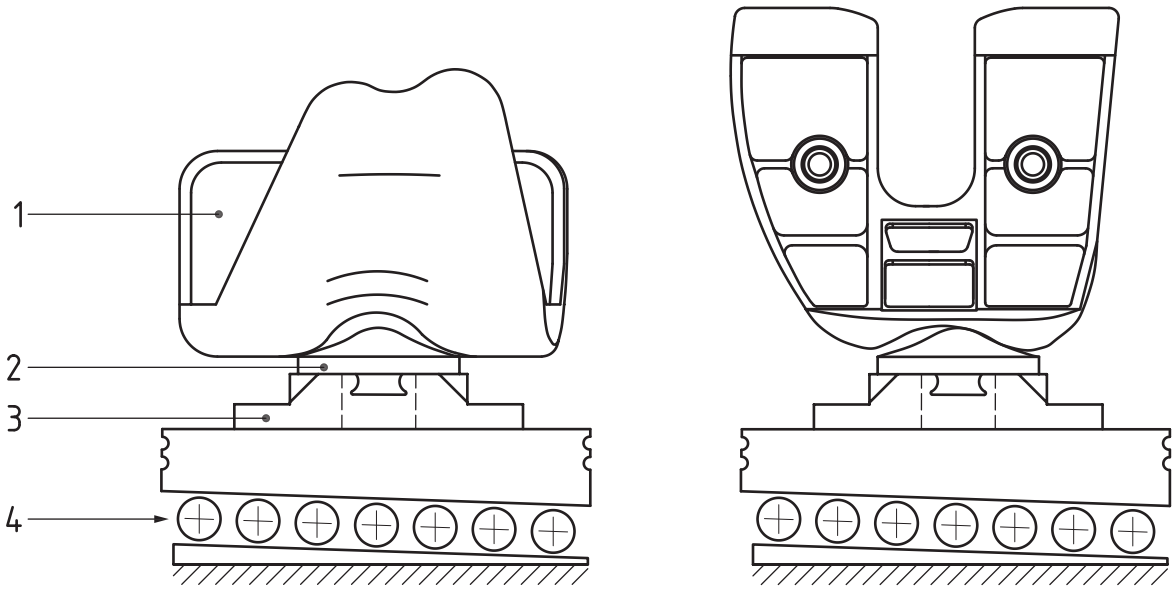
$\alpha^* = 0°$
$\beta = -90°$

Key

1 femoral component
2 patellar component
3 rigid metal or polymeric baseplate
4 adjustment screw
5 contact during higher angles of tibiofemoral flexion
6 no contact during lower angles of tibiofemoral flexion
7 bearing

α^* tibiofemoral flexion angle
β patellofemoral angle

Figure 4 — Example of a screw-type M-L force mechanism for a left knee (for illustration purposes only)



Key

1	femoral component	α^*	tibiofemoral flexion angle
2	patellar component	β	patellofemoral angle
3	rigid metal or polymeric baseplate		
4	angled thrust bearing		

Figure 5 — Example of an inclined bearing type M-L force mechanism for a left knee (for illustration purposes only)

7.9 Patellofemoral mediolateral displacement system, capable of allowing the required passive mediolateral translation of the patellar component to track within the trochlear groove. Mediolateral translation is not an explicitly controlled parameter in this document; it may be included where determined relevant.

NOTE 1 Figure 4 illustrates a system that allows passive internal and external rotation in combination with constrained mediolateral translation.

NOTE 2 Figure 5 illustrates a system that does not allow internal and external rotation, and it does not constrain mediolateral translation.

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

7.11 Temperature control system, capable of maintaining the temperature of the fluid medium (5.1) at 37 ± 2 °C. The test shall be closely monitored for evidence of excessive temperatures and corrective measures taken if needed. These can include stopping the test periodically to allow the bearing and lubricant to cool, and cooling the lubricant bath by, for example, circulating it through a cooling apparatus.

8 Procedure

8.1 Determine the worst-case condition

Determine the worst-case condition for choice of implant design and size (see Clause 6).

8.2 Age the polyethylene patellar component according to ASTM F2003

The patellar component shall be artificially aged in an oxygen environment according to ASTM F2003 if appropriate (see Clause 6).

8.3 Determine the flexion/extension waveform

The machine flexion/extension waveform shall be based on the tibiofemoral flexion angles, and the minimum and maximum angles for walking and squatting. Typically, the values for $\alpha^*_{\text{walk,min}}$, $\alpha^*_{\text{walk,max}}$, and $\alpha^*_{\text{squat,max}}$ are 0°, 58°, and 120°, respectively. Therefore, when these values are plugged into Formula (1), the results for $\beta_{\text{walk,min}}$, $\beta_{\text{walk,max}}$, and $\beta_{\text{squat,max}}$ are −90°,−49,4°, and −6°, respectively. The machine flexion-extension waveform is then generated from Formula (2). Any deviation from these values shall be justified; Formula (2) already includes the frequency differences between the squat and low flexion sub-cycles.

$$\beta(t)=\left\{\begin{array}{l}\dfrac{\beta_{\text{squat,max}}-\beta_{\text{walk,max}}}{2}\sin\left(\dfrac{2}{3}\pi t-\dfrac{\pi}{2}\right)+\dfrac{\beta_{\text{squat,max}}+\beta_{\text{walk,max}}}{2};0\le t\le 3\\ \dfrac{\beta_{\text{walk,max}}-\beta_{\text{walk,min}}}{2}\sin\left(\dfrac{11}{5}\pi t-\dfrac{\pi}{10}\right)+\dfrac{\beta_{\text{walk,min}}+\beta_{\text{walk,max}}}{2};3\le t\le 4{,}82\end{array}\right\} \tag{2}$$

The units of measure for β and α is degrees and t is seconds. The sine term is evaluated in radians. An example plot of what may result as a waveform for $\beta(t)$ is shown in Figure 2.

8.4 Determine the body weight

The recommended body weight (BW) is determined according to Formula (3) but shall not be less than 870 N. The FAP is illustrated in Figure 1.

$$BW=14{,}3\cdot FAP+40{,}8 \tag{3}$$

The unit of measure for BW is newtons, and the unit of measure for FAP is millimetres. Any deviation from the body weight specified herein shall be justified.

8.5 Determine the patellofemoral force waveform

After determining the body weight according to 8.4, the force waveform as a function of time is determined from Formula (4). This equation already includes the frequency differences between the squat and walking sub-cycles.

$$F(t)=\left\{\begin{array}{l}\dfrac{5}{4}BW\sin\left(\dfrac{2}{3}\pi t-\dfrac{\pi}{2}\right)+\dfrac{7}{4}BW;\ 0\le t\le 3\\ \dfrac{1}{10}BW\sin\left(\dfrac{11}{5}\pi t-\dfrac{\pi}{10}\right)+\dfrac{2}{5}BW;\ 3\le t\le 4{,}82\end{array}\right\} \tag{4}$$

The unit of measure for F and BW is newtons and t is seconds. The sine term is evaluated in radians. An example plot of what may result as a waveform for $F(t)$ is shown in Figure 3.

8.6 Determine the location of the flexion/extension axis

The location of the flexion-extension axis is based on the characteristic dimensions of the femoral component. The recommended location for the flexion-extension axis is determined by:

— consider the condyles of the femoral component to be in contact with the plane of the tibial axis when the femoral component is 0° and when it is 60° of flexion;

— each condyle now has two contacting normals which can be extended until they intersect;

— the flexion-extension axis is the line which connects the two intersection points associated with each condyle.

Any divergence from this recommendation shall be justified.

NOTE 1 This axis location differs from the method described in ISO 14243-1 and ISO 14243-3.

NOTE 2 For a hinged knee, the flexion-extension axis is the hinge axis.

8.7 Determine the patellar translation along the femur

The relationship which describes the translation along the anterior flange $Y(\beta)$ is unique to each knee design, and a custom waveform shall be developed, which depending on the geometry of the implants, may differ from that shown in Figure 2 by both the shape of the waveform and/or its magnitude. If the relationship between Y and β is linear, the waveform derived will be similar to that shown in Figure 2. The patellar translation along the anterior flange can be defined by the following steps:

1) Using CAD, mate the patella and femur for a specified β and d' using Formula (5). In the sagittal view, the location where the patellar axis crosses the external geometry of the femoral component is the location of function of d' (Figure 6).

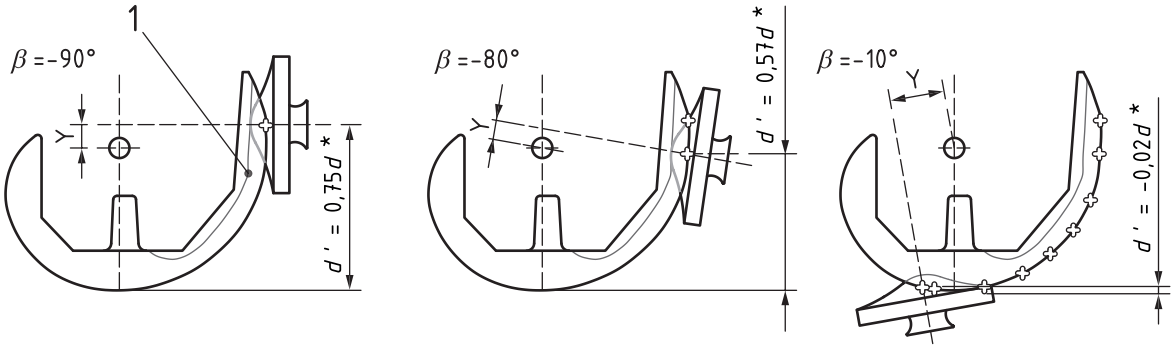
$$\frac{d'}{d^*} = \left[1{,}22\times10^{-4}\left(\beta+90\right)^2 - 0{,}019\ 4\left(\beta+90\right)+0{,}75\right];\ -90 \le \beta \le -6 \tag{5}$$

   At lower tibiofemoral flexion angles, mate the patella within the trochlear groove, and at higher tibiofemoral flexion angles mate the patella at the midpoint between the condyles.

2) The patellar translation waveform, $Y(\beta)$, is the measure between the patellar axis and the flexion-extension axis measured orthogonally to the patellar axis (Figures 6 and 7).

   Depending on the anterior flange design, the sign of Y changes when β is between approximately −30° and −40°. This shall be taken into account and adapted appropriately according to whether the simulator translates the femoral component or patellar component.

3) Repeat for β ranging from −90° to −6° at minimum intervals of 10°.

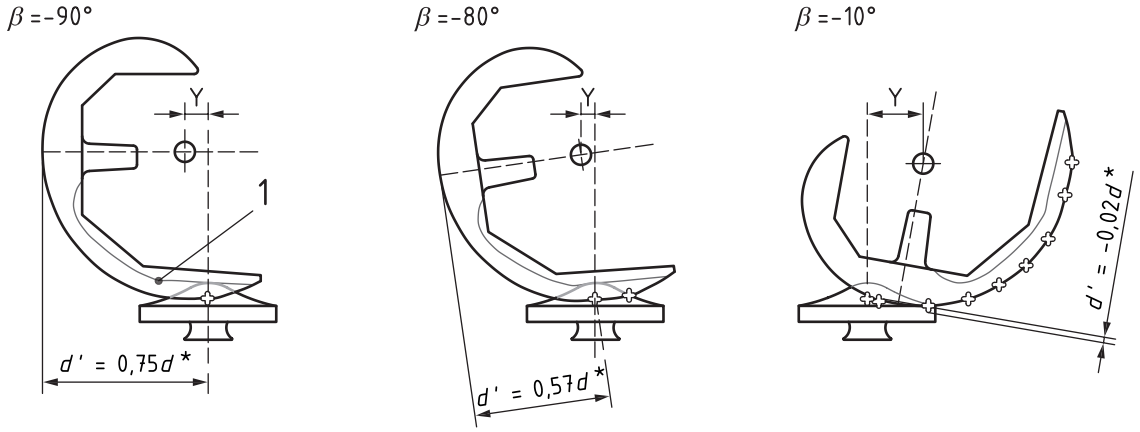


Key

1 trochlear groove
β patellofemoral angle
d' patellar location
d^* femoral height
Y translation along the anterior femoral flange

Figure 6 — Steps to determine $Y(\beta)$

NOTE Typically, the patellar component is held similarly to the tibial component described in ISO 14243-1 and ISO 14243-3. Therefore, a more intuitive setup is illustrated in Figure 7 with the patellar component being held horizontally.



Key

1 trochlear groove
β patellofemoral angle
d' patellar location
d^* femoral height
Y translation along the anterior femoral flange

Figure 7 — Steps to determine $Y(\beta)$, alternate view

8.8 Determine the abduction/adduction (axial rotation) waveform.

This parameter shall be held to 0°. Any deviation from this value shall be justified.

8.9 Prepare the test specimens, and perform any necessary initial analysis, and calibrate each test station if necessary.

8.10 Clean the specimens.

Clean the test specimen as specified in ISO 14243-2.

If weight measurements are performed before and after testing, they shall be performed according to ISO 14243-2.

8.11 Fixture all components to the simulator submersed in the fluid test medium, and begin the test. A visual observation (photographs) shall be performed at minimum intervals of 5, 10, 15, 20, 25 and 50 thousand cycles. The test may be stopped at 50 000 cycles. Photographs of the patellar component shall be taken at each inspection.

If the fixture design requires complete disassembly of the implants, use appropriate alignment fixtures during reassembly.

8.12 Adjust the mediolateral force mechanism.

This is only applicable when using Method 1 for the patellofemoral mediolateral force mechanism. Take great caution while performing this! Within the first 5 000 cycles, the chosen mediolateral force mechanism needs to be monitored while the patella deforms (either by plastic deformation or creep). After the settling in period the monitoring frequency can typically be reduced.

If using the adjustment screw design, the screw should have a hexagonal head so that it can be manipulated from the side using a standard wrench.

8.13 Testing finish.

Continue the test until one of the following occurs:

a) completion of 50 000 cycles (cycle limit) or failure of the patellar component, whichever comes first.

NOTE 1 Failure is described in 8.14.

NOTE 2 At the request of the party submitting the specimen, the test can be continued beyond this limit. If the test is continued after 50 000 cycles, it is advisable that the number of cycles at which the test was stopped be disclosed to the submitter of the implant.

b) failure of the testing machine to maintain the force and displacement parameters within the given tolerances (see 7.4 to 7.8).

8.14 Failure and damage patterns.

8.14.1 General

Potentional failure modes may include, but are not limited to, the following.

8.14.2 Plastic deformation

This damage pattern is regarded as a common finding for patellar components and might be regarded as acceptable if the results are not worse than for a similar device.

8.14.3 Adhesive wear

This damage pattern is regarded as a common finding and is regarded as acceptable.

8.14.4 Abrasive wear

This damage pattern is regarded as a common finding and is regarded as acceptable.

8.14.5 Delamination

This damage pattern might be regarded as acceptable if the results are not worse than for a similar device.

8.14.6 Cracking

This damage pattern might be regarded as acceptable if the results are not worse than for a similar device.

8.14.7 Breakup of the articulating surface

This damage pattern is regarded as not acceptable.

8.14.8 Failure of the interlocking mechanism between the polymeric patella component and its fixation (e.g. metal backing)

This damage pattern is regarded as not acceptable.

9 Test report

The test report shall include the following information:

a) a reference to this document, e.g. ISO 14243-5:2019;

b) the identity of the test specimens, including size material, type, manufacturer, batch code (lot number);

c) sterilization method and its parameters such as radiation type, dose, and time;

d) the aging protocol used;

e) description of the test machine, type of system used for generating motions and forces, range of motions and forces, type of system used for measuring motions and forces, arrangement for mounting specimen, arrangement for lubrication of articulating surfaces, arrangement for temperature control, fluid test medium, and arrangement for the exclusion of contaminant particles;

f) waveforms if different from the waveforms described in this document;

g) a statement of results, including:

   1) The number of cycles each implant combination successfully completed;

   2) the reason for terminating the test for the specific sample;

   3) failure mode and location of the failure on the patella (if any, otherwise state this explicitly);

   4) description (photographs) of the damage to the patellar component incurred over the course of the entire test

10 Disposal of test specimen

No part of the test specimen shall be used for clinical purposes after testing.

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