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Implants for surgery — Wear of total intervertebral spinal disc prostheses —

Part 3: Impingement-wear testing and corresponding environmental conditions for test of lumbar prostheses under adverse kinematic conditions

Implants chirurgicaux — Usure des prothèses totales de remplacement des disques intervertébraux lombaires —

Partie 3: Essai d'incidence d'usure et conditions environnementales correspondantes pour l'essai de prothèses lombaires sous conditions cinématiques défavorables

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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 5, *Osteosynthesis and spinal devices*.

A list of all parts in the ISO 18192 series can be found on the ISO website.

Implants for surgery — Wear of total intervertebral spinal disc prostheses —

Part 3:
Impingement-wear testing and corresponding environmental conditions for test of lumbar prostheses under adverse kinematic conditions

1 Scope

This document defines a test procedure to simulate and evaluate lumbar spinal disc prostheses wear under adverse impingement conditions.

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 4965-1, *Metallic materials — Dynamic force calibration for uniaxial fatigue testing — Part 1: Testing systems*

ISO 18192-1, *Implants for surgery — Wear of total intervertebral spinal disc prostheses — Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test*

ISO 23788, *Metallic materials — Verification of the alignment of fatigue testing machines*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 18192-1 and the following apply.

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

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

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

3.1
impingement
point at which two opposing components collide or restrict motion usually indicated by a sharp change in force or moment

3.2
range of motion
ROM
amount of angular displacement that a total disk replacement prosthesis can undergo from the device neutral position to the point at which impingement occurs around a defined global axis

Note 1 to entry: If an implant impinges at 15° from the implant neutral position in flexion and 20° from the implant neutral position in extension, the implant range of motion can be defined as +15°/-20° in flexion/extension.

3.3
distance between centre of rotation and point of impingement
DCI
distance between the point of impingement and the nominal centre of rotation for the flexion, extension or lateral bending motions

3.4
axial load during impingement
ALI
axial load applied to the device in newtons while the device is in an impinged condition

3.5
point of impingement
point of contact between two opposing components that results in impingement

4 Principle

Based on current clinical evidence, lumbar spinal disc prostheses have experienced impingement in extension/flexion, lateral bending, axial rotation and combinations thereof with extension being the most commonly reported mode for the lumbar spine.

Adverse impingement testing conditions are determined based on available clinical data, engineering analysis and other relevant information in the literature.

An axial load and a time-varying angular displacement are applied to the test specimens to simulate repeated contact between design features of the specimens.

Four possible individual impingement scenarios have been identified in the literature:

a) flexion;

b) extension;

c) lateral bending;

d) combined flexion and lateral bending.

In addition, combined axial rotation with any of the aforementioned motion modes should be considered, if necessary to achieve a clinically relevant impingement wear scar and/or worst case impingement scenario.

A load soak 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.

The fluid test medium consisting of calf serum diluted with de-ionized water (balance) to a concentration of 20 g ± 2 g protein/l shall be prepared according to ISO 18192-1. If routine monitoring of the pH of the fluid test medium is undertaken, the values shall be included in the test report [see Clause 8, m) 6)] as an increase in pH could indicate an increase in microbial activity[1].

5.2 Test and control specimen.

Between the inferior and superior components shall be the articulating surface of the inferior and superior components, attached by its normal immediate backing (for example, bone cement or a machined replica of the inner surface of the backing), unless this is impractical due to physical features

of the implant system. If the component forming the articulating surface is fixed to the backing 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 inferior and/or superior component should represent normal design features and conditions of use but should allow removal of the component for measurement of wear without destruction.

It is recommended that six specimens be tested for the impingement-wear test. If less than six specimens are tested, appropriate justification shall be given.

NOTE The number of specimens tested can be the subject of national legislation.

If polymers are the object of investigation, a load soak control specimen is to be subjected to the same axial load to determine the creep of the test specimen and/or the amount of mass change due to fluid transfer. The test should take place in a controlled environment of test medium to simulate physiological conditions (see 5.1).

In the test cases where surrounding fluid is not absorbed by the specimens, test specimens shall be weighed prior to testing with an instrument having a precision of 0,1 mg.

The tested implant size should be selected by an engineering analysis including theoretical, computational, or experimental methods. If computational methods are used, experimental verification that considers the point of impingement, the materials in contact and the range of motion of the specimens is recommended. The point of impingement and the centre of rotation of the bearing are detected in all testing directions. The combination of implant components with the highest contact stress in the tested direction is selected for the test. If the materials in contact during impingement change with size, then tests with different implant sizes should be considered. The number of test specimens of each size should not be less than three with no less than six test specimens in total.

6 Apparatus

For the kinematical analysis the following testing configuration shall be applied. Deviation from this testing configuration shall be justified.

6.1 Test machine, in accordance with ISO 4965-1 and ISO 23788, as specified in ISO 18192-1 for lumbar prosthesis, and capable of associating and replacing the required corresponding angular displacements and forces (see Clause 7) for each specific protocol of movement.

6.2 Means of mounting and enclosing the test specimen, as specified in ISO 18192-1 for lumbar prosthesis.

6.3 Means of aligning and positioning, as specified in ISO 18192-1 for lumbar prosthesis.

6.4 Motion control system, capable of generating the required angular movements of the inferior component with an accuracy of ±1° at the maxima and minima of the motion and ±5 % of cycle time phasing. For multi-station test systems, capabilities shall be assessed with all stations active.

6.5 Force control system, capable of generating a force in the z-direction (see Figure 1), which varies for each specific protocol of movement, and capable of maintaining the magnitude of the maxima and minima of this force cycle to a tolerance of ±5 % of the maximum force value for the cycle and ±5 % of the full cycle time for phasing. For multi-station test systems, capabilities shall be assessed with all stations active.

6.6 Lubrication system, as specified in ISO 18192-1 for lumbar prosthesis.

6.7 Temperature control system, as specified in ISO 18192-1.

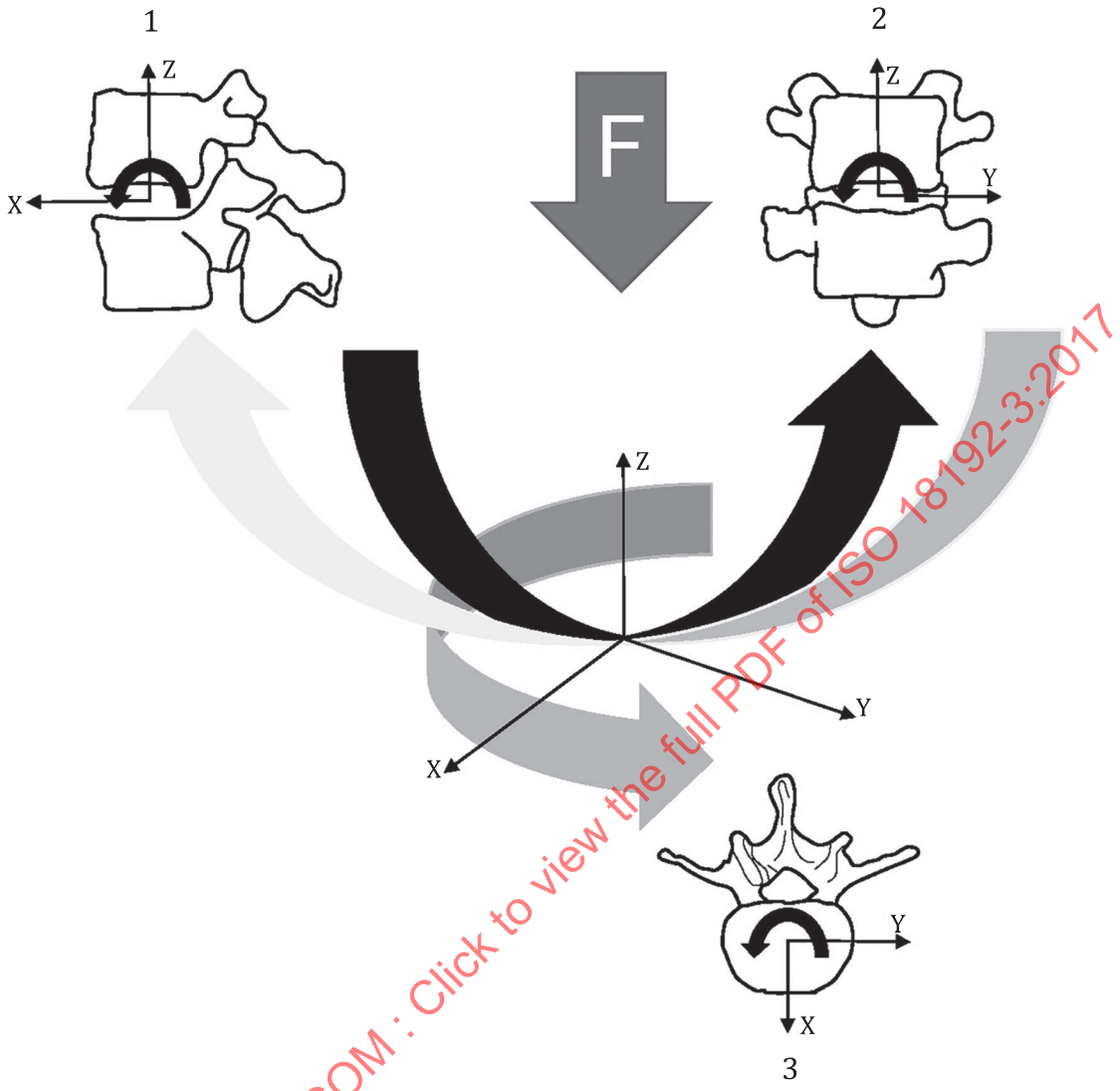
6.8 Control station(s), capable of applying the loading regime for specific protocol of movement and incorporating the requirements given in 6.1, 6.2, 6.5, 6.6 and 6.7.

6.9 The origin of the fixed coordinate system of the test machine (which is consistent with the centre of rotation of the implant) shall be the intersection of the axis for lateral bending, flexion extension and axial rotation. The machine's former sequence shall be the Euler sequence used for coordinate transformation. The coordinate system of the test machine shall coincide with the coordinate system of the upper endplate. All other parts of the specimens shall move relative to this coordinate system (see Figure 1).

The axial load vector shall be perpendicular to the flexion (Y) and lateral bending (X) axis and shall coincide with axial rotation (Z) axis in a fixed coordinate system.

The superior endplate may translate along the Z axis and in the XY plane (to avoid shear forces). The inferior endplate may rotate around all three axis.

The intended movement shall be applied via the inferior endplate. The load shall be applied via the superior endplate.



Key

1 flexion/extension
2 lateral/bending
3 axial rotation

Figure 1 — Coordinate system of the test machine

7 Impingement wear testing methods

7.1 General

Extension, flexion, and lateral bending impingement boundary conditions shall be analysed to determine the worst case clinically relevant conditions to be tested. In addition, the manufacturer should consider combining axial rotation with any of the aforementioned motion modes, if necessary to achieve a clinically relevant impingement wear scar and worst case impingement wear or damage.

The nominal device centre of rotation in flexion, extension, lateral bending and axial rotation shall be determined.

The points of impingement in all testing directions shall be detected and the respective perpendicular distance between each point of impingement and the nominal centre of rotation (DCI) determined.

The load and displacement profile shall be developed prior to running the test.

During impingement testing, the device range of motion shall be exceeded by at least 2° in the impingement direction. In addition, the impingement region shall be offloaded completely each cycle.

The angular displacements applying flexion/extension, lateral bending and/or rotation should be sinusoidal.

Establish the pattern of load and movement for each selected movement protocol. An example of development of load and displacement profiles for extension impingement protocol is presented in 7.2.

7.2 Example of development of load and displacement profiles for extension impingement protocol

Figure 2 shows an example of an impingement load and displacement profile in extension that is based on applying a moment of 7,5 Nm to the device during impingement. In this example, the test starts with the device in the 0-point position and progresses 3° in flexion. Subsequently the motion progresses back through the neutral position to 2° beyond the device range of motion in extension. In this example, lateral bending and axial rotation are held at neutral.

For some bearing combination, force overshoot can be observed at the point of impingement. Force overshoot should be minimized.

To apply a 7,5 Nm extension moment, the horizontal distance between the centre of the device and DCI should be measured. The ALI necessary to apply the 7,5 Nm impingement motion mode moment during impingement shall be determined by dividing 7,5 Nm by the DCI, expressed in metres (m).

NOTE 1 The extension moment value is justified in Reference [2].

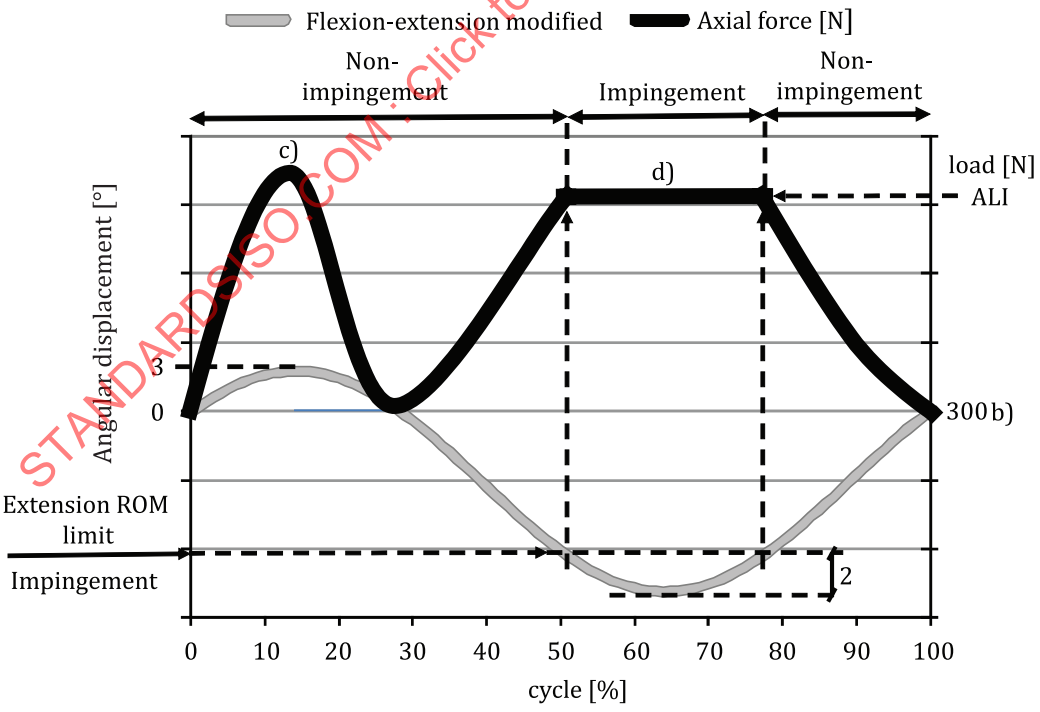


Figure 2 — Example of load and displacement profile for a lumbar spine extension impingement wear test

The loading conditions for this example are as follows:

a) sinusoidal axial loading is used except for the impingement loading interval;

b) a minimum axial load of 300 N is used to engage the sample at the neutral position;

NOTE 2 The minimum axial load value in ISO 18192-1 is 600 N. In certain designs, a 600 N load will exceed the 7,5 Nm moment. Therefore, a 300 N minimum axial load force was selected for this example.

c) the maximum ALI from all tested motions is used to define the non-impingement sinusoidal load profile;

d) during impingement, the axial load is constant and equal to ALI as determined above.

NOTE 3 In the context of this example, to "offload" means changing the angular displacement to eliminate impingement,

7.3 Procedure

7.3.1 Prior to testing, clean the implant specimen and characterize the surface conditions with photographs using up to 10 times magnification. A typical ultrasonic cleaning regime is established in A.2.4.

7.3.2 Mount the specimen in the testing machine, ensuring the required alignment.

7.3.3 Fill the test chamber such that the test specimen is fully immersed in the fluid test medium.

7.3.4 In accordance with accepted wear-test procedures, replace the fluid test medium completely at least every 5×10^5 cycles, or every seven days, whichever is the shorter. If the objective of the test is to characterize particle or ion release, one volume of test medium may be used without changing the test medium until the protocol is complete.

7.3.5 Run the test with the load and displacement profiles developed for the protocol. See 7.2 and Figure 2 for example load and displacement profiles. For any control specimens, run the test with the same load profile without displacement. Operating the testing machine at a frequency of 1 Hz is recommended. An accuracy of ±0,1Hz is required.

7.3.6 Stop the machine after $1{,}25 \times 10^5$ cycles, $2{,}5 \times 10^5$ cycles, 5×10^5 cycles and 1×10^6 cycles. Remove the test specimen from the machine. Clean the specimen. Characterize the contact pattern with light microscopy with appropriate magnification.

NOTE Use of 50 times magnification has been used successfully in some laboratories for impingement wear characterization.

7.3.7 Gravimetric analyses of the specimen shall be performed at the beginning of the test and at each of the intervals defined in 7.3.6 according to Annex A. Additionally, the fluid test medium may be analysed for wear particles and ion-concentration. If particle analysis is to be conducted, the fluid test medium should be frozen and stored.

7.3.8 In case larger deformations are observed during specimen inspection at the point of impingement which allow no further contact between implant components as intended for the test, the displacement waveform has to be adjusted to again run the specimen to 2° beyond the ROM.

7.3.9 Continue the test until one of the following occurs.

a) Completion of the cycle limit. The cycle limit shall be 1×10^6 cycles unless the submitter of the specimen requests a different cycle limit, which may be used with appropriate justification.

NOTE 1 The number of cycles tested can be the subject of national legislation.

NOTE 2 The 1×10^6 cycles has been shown to create impingement damage consistent with clinical retrievals[9].

b) Functional or user-defined failure modes may be specified by the user based on the design of the implant.

c) Failure of the testing machine to maintain the force and displacement parameters within the given tolerances (see Clause 6).

8 Test report

The test report shall include the following information:

a) a dated reference to this document, i.e. ISO 18192-3;

b) the identity of the test specimens, as stated by the submitter of the specimens for test, including size, material, type and manufacturer;

c) a description of the testing machine, including number of stations, type of systems used for generating motions and forces, range of motions and forces, type of systems used for measuring motions and forces, arrangement for mounting specimen (see 6.3), arrangement for lubrication of articulating surfaces, arrangement for temperature control and arrangement for the exclusion of contaminant particles;

d) a description of the testing protocol, including load and displacement profiles with a summary of the engineering analysis used to ensure the profiles are sufficient to generate impingement;

e) the test frequency including a justification if a frequency other than 1 Hz has been used;

f) the inclination angle of the device and a justification of the selection in regard to the motion of the articulating surfaces (see ISO 18192-1 for a definition of the inclination angle);

g) the number of specimens and a justification if less than six specimens (excluding the soak specimen) have been tested;

h) the addition or avoidance of EDTA and a justification for doing so;

i) the addition or avoidance of an antimicrobial reagent and a justification for doing so;

j) the selection of the centre of rotation based on the implant design;

k) whether control specimens were used and, if not, the reference to the tests from which the control data were taken;

l) the cycle limit, including a justification if a cycle limit of other than 1×10^6 cycles was used;

m) a statement of results, including

   1) the total number of cycles applied,

   2) reason for terminating the test, if fewer cycles than the designated cycle limit were applied,

   3) description of the surfaces of all components at which relative movement has occurred,

   4) description of the condition of the interfaces between subcomponents, if the components are of modular construction,

   5) description of the failure mode, functional or user-defined (see 7.3.8), if a failure has occurred, and

   6) pH values, if routine monitoring was undertaken (see 5.1);

7) comparison of results with ISO 18192-1.

n) details of the method of measurement of wear and the results obtained (as specified in Annex A), namely

1) gravimetric method of wear measurement,

2) change in mass (W_n) for each measurement,

3) the mean wear rate (a_G),

4) descriptive statistics, including standard deviation, and

5) graphic presentation of wear as a function of cycle count;

o) any deviations made from the original test protocol, including the corresponding rationale;

p) any photographic records.

9 Disposal of test specimen

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

Annex A
(normative)

Wear of spinal disc prostheses — Gravimetric measurement method

A.1 General

This annex establishes a method for assessment of wear of the spinal disc prosthesis components, tested according to Clause 7, using gravimetric techniques.

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 annex, but cleaning techniques adopted should be suitable for the soils produced.

A.2 Procedure

A.2.1 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 spinal disc prostheses simulator. A loaded, non-articulating control specimen is intended to allow for fluid sorption and undergoes the same procedure for reference purposes.

A.2.2 Reagents and materials

A.2.2.1 **Fluid test medium**, in accordance with 5.1.

A.2.2.2 **Test and control specimens**, in accordance with 5.2.

A.2.2.3 **Propan-2-ol**.

A.2.3 Apparatus

A.2.3.1 **Balance**, with an accuracy of ±0,1 mg, of sufficient capacity for the mass of the implant specimen components.

A.2.3.2 **Ultrasonic cleaner**.

A.2.3.3 **Vacuum drying system**, capable of achieving a vacuum of at least 13,33 Pa.

A.2.3.4 **Filtered inert-gas jet**, e.g. nitrogen.

A.2.4 Preparation of test specimen for gravimetric measurements

A.2.4.1 Soak the test specimen and control specimen in the fluid test medium (A.2.2.1) for (48 ± 4) h.

A.2.4.2 Remove the test specimen and control specimen from the fluid test medium (A.2.2.1) and clean in the ultrasonic cleaner (A.2.3.2).

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 (A.2.3.3).

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

A.2.4.3 Dry the test specimen and control specimen with a jet of filtered inert gas (A.2.3.4).

A.2.4.4 Soak the test specimen and control specimen in propan-2-ol (A.2.2.3) for 5 min ± 15 s.

A.2.4.5 Dry the test specimen and control specimen with a jet of filtered inert gas (A.2.3.4), then dry further in a vacuum of better than (13,3 ± 0,13) Pa for at least 30 min.

A.2.4.6 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.

A.2.4.7 Repeat A.2.4.2 to A.2.4.6 at intervals until the incremental mass change of the specimen over 24 h is less than 10 % of the previous cumulative mass change.

A.2.4.8 Record the average increase in mass *S* of the control specimen.

A.2.4.9 Take photographic records of all the articulation and fixation surfaces of the test specimen.

A.2.4.10 Mark the test specimen with reference points so that after the wear test, the location of the worn surfaces can be identified relative to the axes of the test specimen.

A.2.5 Procedure for gravimetric measurement

A.2.5.1 Record the mass of the specimens.

A.2.5.2 Mount the test specimens in the testing machine and conduct the wear test and the control test in accordance with 7.3.

A.2.5.3 On each occasion when the test specimen and control specimen are removed from the wear-testing machine, repeat the following procedures:

a) A.2.4.2 to A.2.4.8, A.2.5.1 and A.2.5.2 for intermediate stopping test;

b) A.2.4.2 to A.2.4.9 for finishing test.

A.2.5.4 Calculate the gravimetric wear as shown in Formula (A.1):

$$W_n = W_{an} + S_n \tag{A.1}$$

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.

A.2.5.5 Calculate the average wear rate a_G using Formula (A.2) for the least squares linear fit relationship between W_n and the number of loading cycles n:

$$a_G = W_n \cdot n + b \tag{A.2}$$

where

W_n is the net loss in mass after n cycles;

b is a constant.

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