TECHNICAL REPORT

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Implants for surgery — Partial and total hip joint prostheses — Recommendations for simulators for evaluation of hip joint prostheses

Implants chirurgicaux — Prothèses partielle et totale de hanche — Recommandations concernant les simulateurs de marche destinés à l'évaluation des prothèses de hanche

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Contents

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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 main task of ISO technical committees is to prepare International Standards. In exceptional circumstances a technical committee may propose the publication of a technical report of one of the following types:

— type 1, when the necessary support within the technical committee cannot be obtained for the publication of an International Standard, despite repeated efforts;

— type 2, when the subject is still under technical development requiring wider exposure;

— type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical reports are accepted for publication directly by ISO Council. Technical reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standard. Technical reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 9325, which is a technical report of type 2, was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

Annexes A, B and C of this Technical Report are given for information only.

Introduction

These recommendations are concerned with the laboratory evaluation of wear, endurance and friction characteristics of hip joint prostheses and the conditions of loading and environment that approximate to those that are believed to prevail *in vivo* and under which, consequently, a prosthesis will be required to function effectively when implanted in the patient. The loading profile used may be developed from *in vivo* biotelemetry information, or from predictions from external dynamic measurements.

The application to a hip joint prosthesis, for a considerable period of time, of a rigidly controlled cyclic load of the correct magnitude and combination of directional components under accurate temperature control, and in a medium of liquid lubricant, necessitates the use of an apparatus (commonly referred to as a simulator) that is purpose-built, often by the establishment that is conducting the tests, and which will differ to some extent from an apparatus constructed by another centre of expertise. Indeed, a particular design of simulator may well be unique in the way in which the various design considerations have been met.

The present incomplete state of knowledge of the loading system generated in the hip during walking, the largely unproven correlations between conditions *in vivo* and the concepts and detail of apparatus design and test environment, coupled with the difficulties inherent in the precise and accurate determination of hip prosthesis performance and the fact that the quality of measurements can be no better than that of the weakest link in the experimental chain, do not allow the exact specification of the test apparatus or procedure.

For these reasons, it was decided to produce this Type 2 Technical Report which gives recommendations for the conditions that should appertain to a hip joint simulator and the test specimens, in order to improve comparability of results. It is hoped that these recommendations will be adopted by the various centres involved in testing hip joint prostheses and thereby facilitate the future preparation of International Standards dealing with simulators and the testing of hip joint prostheses.

The use or interpretation of experimental results obtained from simulators is not discussed.

Implants for surgery — Partial and total hip joint prostheses — Recommendations for simulators for evaluation of hip joint prostheses

1 Scope

This Technical Report gives recommendations relating to the apparatus, specimens, test conditions and procedures for the evaluation of properties of hip joint prostheses by means of hip joint simulators.

NOTE — Atttention is drawn to ISO/TR 9326 regarding the evaluation of change of form of bearing surfaces of hip joint prostheses.

2 Recommendations for preparation of test specimens

2.1 General

2.1.1 Fabrication

Specimens should be prepared in the same manner, and by the same processes that are or would be used to prepare components for clinical service, in order to produce comparable bulk material properties and surface characteristics. Attention is drawn to the requirements for aspects of fabrication given in ISO 5839 and ISO 7206-1.

2.1.2 Weighing

When studying a hip joint prosthesis that has a large mass and a small wear rate, it may not be possible to determine accurately the change of mass of components using this method of assessment. If a weighing method is employed, weighing should be performed using a balance with a precision of 1 µg. The specimen should be cleaned and dried (see 2.2.4 and 2.3.5) before weighing, and should be handled under dust-free conditions. At least two, and preferably up to ten, weighings should be carried out on the specimen and a mean mass calculated. Further guidance on weighing is given in ISO/TR 9326.

2.1.3 Reference and control specimens

It is essential that reference specimens made of polymeric material used to evaluate the wear properties of experimental counterface materials or components should all be made from the same bar or sheet of material.

It is preferable that reference specimens made of metallic, ceramic or composite materials used to evaluate the wear properties of experimental counterface materials or components should all be of the same batch of components.

For any individual test, it is essential that control specimens, such as those used to determine the water uptake of polymeric materials and those used for loading with no movement in order to determine the amount of creep of polymeric materials, should be made from, and orientated in the same direction relative to, the same bar or sheet of materials as the test specimen or, if this is not possible, be made from the same batch of moulding powder and be part of the same batch of mouldings.

Consideration should be given to the preparation of sufficient numbers of control and reference specimens before the start of a test programme or, if this is not possible, to confirming that the behaviour of reference specimens of heterogeneous origin is not anomalous.

Recommended reference materials are

a) ultra-high molecular weight polyethylene complying with ISO 5834-2;

b) stainless steel of composition D complying with ISO 5832-1;

c) cobalt-chromium-molybdenum alloy complying with ISO 5832-4;

d) titanium alloy complying with ISO 5832-3.

2.2 Test and control specimens made of polymeric material

2.2.1 History

A detailed fabrication history should be prepared or obtained for each specimen and should, if possible, include such information as

a) grade of material;

b) batch number of the material;

c) method of forming the specimen (e.g. extrusion, moulding, machining);

d) details of the forming process (e.g. temperature, time, pressure);

e) details of other treatments (e.g. post-curing, annealing, sterilization).

It is essential for replicate specimens to have been prepared from, and in the same orientation relative to, the same bar or sheet of polymeric material, or be made from the same batch of moulding powder and be part of the same batch of mouldings.

Attention is drawn to ISO 5834-1, ISO 5834-2 and ISO 5839.

Polymeric components should be stored in a cool, dark, dry place, not exposed to ionizing radiation.

2.2.2 Characterization

It is advisable to determine and record various characteristics of the specimen before testing commences. These may include the following. Measurements should be made in a location on the specimen that will not affect the test results.

a) surface hardness of the bearing surface (see ISO 2039-2);

b) density of the material (see ISO/R 1183);

c) molecular mass distribution of the material;

d) degree of crystallinity;

e) characterization of the surface finish of the bearing surface (e.g. surface roughness: see ISO/R 468);

f) form of the bearing surface (e.g. roundness: see ISO 4291);

g) design of component (see ISO 7206-1).

With regard to e), methods that have been used include profilometry, microscopy, photo-microscopy, and replication techniques. Replication techniques should be used with caution because the process can leave a film of replicating agent on the surface of the specimen that can cause spurious results in subsequent testing. Care should be exercised in the selection of reagents that are allowed to contact the surface of the specimen, as any resulting chemical action can also affect test results.

No attempt should be made to improve or alter the surface finish of the specimen by polishing it with abrasives, because particles of abrasive can become embedded in the polymeric material and thereby affect the surface properties. Attention is drawn to ISO 7206-2.

2.2.3 Sterilization

The specimen should be sterilized before testing commences in order to take account of any changes in characteristics caused by the sterilizing process. A number of methods of sterilization (e.g. gamma-ray irradiation, exposure to ethylene oxide, autoclaving) are in current use, and the specimen, if not supplied in the sterile condition, should be sterilized by the same process and under the same conditions that are, or would be, used for a component for clinical service. Replicate specimens should all be sterilized in the same sterilizing equipment at the same time.

2.2.4 Cleaning

Prior to (and during) testing in a simulator, thorough and careful cleaning of the specimen is essential in order to remove particulate matter and other contaminants that could affect the test result. The cleaning procedure should, in its principal elements, resemble that which is, or would be, used for a component for clinical service. The specimen should not be re-machined, as this would affect the properties. An example of a cleaning procedure is given in annex A.

2.3 Test and control specimens made of metallic, ceramic or composite materials

2.3.1 History

A detailed fabrication history should be prepared or obtained for each specimen and should, if possible, include such information as

a) composition and grade of material;

b) batch number of the material;

c) method of forming the specimen (e.g. forging, casting, sintering);

d) details of the forming process (e.g. temperature, pressure);

e) details of other treatments (e.g. annealing, machining).

Components containing polymeric materials should be stored in a cool, dark, dry place, not exposed to ionizing radiation.

2.3.2 Characterization

It is advisable to determine and record various characteristics of the specimen before testing commences. These may include the following. Measurements should be made in a location on the specimen that will not affect the test results.

a) surface hardness of the bearing surface (see ISO/R 1024, ISO 6506, ISO 6507-1);

b) the grain structure of the material;

c) characterization of the surface finish of the bearing surface (e.g. surface roughness: see ISO/R 468);

d) form of the bearing surface (e.g. roundness: see ISO 4291);

e) design of the component (see ISO 7206-1).

Regarding ceramic materials, attention is drawn to ISO 6474.

2.3.3 Surface finish

Surface finish should be typical of that achieved, or expected to be achieved, for a component for clinical service. Attention is drawn to the values for roundness and surface finish given in ISO 7206-2.

2.3.4 Sterilization

The recommendations given in 2.2.3 apply.

2.3.5 Cleaning

Prior to testing, thorough and careful cleaning of the specimen is essential in order to remove particulate matter and other contaminants that could affect the properties being determined. The cleaning procedure should leave the specimen free of particles, oil, grease, and chemical residues. Passivation should have been carried out where applicable.

3 Recommendations for apparatus (simulators) used to effect wear

3.1 Test chambers

The chamber in which the prosthesis is mounted for wear testing should be made entirely of corrosion-resistant material such as polymethylmethacrylate (see ISO 5833-1), titanium or titanium alloy (see ISO 5832-2 and ISO 5832-3), and should be easily removable from the simulator in order to facilitate cleaning. The chamber should be designed so that the bearing surfaces of the test specimens are immersed in lubricant.

If a machine is designed to test more than one specimen simultaneously, the individual chambers should be isolated from one another to prevent contamination of one test specimen with debris from another. Considerable care should be exercised to ensure that conditions in each chamber are as near identical as possible.

3.2 Fixing of test specimen

The method of fixing the specimen in the test chamber should not affect the surface finish or geometry of the specimen and should not interfere with the method selected for the measurement of wear. An example of a suitable method of fixing is the use of a replica of the outer surfaces of the test specimen, which is split into two portions to allow the specimen to be fitted in the replica. The replica, containing the specimen, may be then firmly mounted in the test chamber, taking care that the specimen does not become distorted.

It is essential that the relative orientation of the acetabular and femoral test specimens be maintained, and the fixing system should make provision for this.

The method of mounting should be such that either the specimen can be accurately re-located after removal for cleaning and examination, or the specimen can be examined without removal from the fixing device.

3.3 Movement and loading conditions

The specimen should be mounted in an orientation that resembles the anatomical configuration, in order to allow debris to drain from the acetabular cup. Abnormal wear conditions have been encountered when non-anatomical configurations have been employed. ISO 7206-3 and ISO 7206-4 give details of how femoral components may be set up for testing.

The relative movement between the acetabular and the femoral test specimens should take account of the relative movements occurring in the normal gait. The frequency should be in the range 0,5 Hz to 1 Hz. Ideally, the femoral test specimen should be self-centring in the acetabular test specimen.

The test loading cycle should be applied to the specimen in a manner such that it acts through the centre of rotation of the head of the femoral component. The loading cycle should be physiological and reproducible within and between tests. Instantaneous values of the applied load at the same point in the load cycle should not vary by more than ± 3 % of the intended value throughout the duration of the test.

The maximum applied peak load (representing the maximum load in early stance) should be at least 1 500 N.

3.4 Instrumentation

The apparatus should be equipped with a counter in order to record the number of load cycles applied, and it is recommended that it also incorporates strain gauge instrumentation or other transducers to provide a continuous readout of the forces transmitted across the components during the test.

The test apparatus should be so designed that if failure of the apparatus or the power supply occurs, the load is removed from the test specimen. This will avoid excessive creep or plastic deformation that could occur if the specimen were to be statically loaded for the period before the failure is discovered. The provision of a stand-by power supply, or an automatic restart system fitted with an operation indicator is advantageous.

4 Recommendations for environment in which studies take place

4.1 Lubricant

The test specimens should be lubricated during the test with a lubricant which has properties resembling those of synovial fluid. Bovine serum often forms the basis of such a lubricant and should be stored frozen to avoid deterioration. It should be thawed and then sterilized by filtration immediately prior to use to remove particulate and bacterial contamination. It may be buffered at a physiological pH value and should contain a bacteristatic agent to prevent microbial growth. An example of a lubricant is given in annex B.

The volume, cleanliness and concentration of the lubricant should be held constant during the period of its use in the test chamber. This may be achieved by sealing the test chamber to minimize evaporation and the ingress of contaminants, by replacing lost water by the addition of freshly distilled water, or by continuous addition of fresh lubricant and draining of the excess to waste. It should be noted that the last-mentioned procedure will result in wear particles being removed from the test chamber.

The lubricant should be changed at regular intervals, the length of which will depend on a number of experimental variables and the resistance of the lubricant to degradation of the protein content by microbial or other action.

4.2 Temperature

The temperature of the lubricant should be maintained at 37 °C ± 1 °C during operation of the test apparatus.

4.3 Duration of test

The duration of the test depends on many factors, notably the creep and wear rates of the specimen and the accuracy of the method of their determination. Generally, a minimum of 5×10^6 loading cycles is required. The duration of the test should also take into account the necessity of attaining the required level of statistical significance.

NOTE — A duration of 3 000 h at a frequency of 1 Hz ($10{,}8 \times 10^6$ cycles) corresponds approximately to a 4 year period of use in the human body.

4.4. Number of replicate tests

A sufficient number of replicate determinations should be performed in order to attain the required level of statistical significance.

Annex A
(informative)

Example of procedure for cleaning test specimens

A.1 Principle

The purpose of cleaning the test specimens is to remove all traces of proteinaceous material and particulate matter and any residues from processes used to characterize the specimen. Thorough cleaning is important in order to minimize spurious effects on the properties of the specimen being determined and to establish a uniform condition for the determination of those properties. The cleaning procedure itself should exert a minimal effect on the specimen.

A.2 Procedure

A.2.1 Carefully wipe the specimen to remove all deposits. Check the effectiveness of this step by visual examination using approximately 3X magnification.

A.2.2 Rinse the specimen in a stream of distilled or deionized water.

A.2.3 Digest any protein present by immersing the specimen in a solution of a proteolytic agent that does not affect the material of the specimen.

A.2.4 Rinse the specimen in a stream of distilled or deionized water.

A.2.5 Treat the specimen in an ultrasonic cleaning bath, using the following sequence:

a) Vibrate for 5 min in distilled or deionized water.

b) Rinse in distilled or deionized water.

c) Vibrate for 10 min in an aqueous solution of a cleaning agent that does not affect the specimen.

d) Rinse in distilled or deionized water.

e) Vibrate for 10 min in distilled or deionized water.

f) Rinse in distilled or deionized water.

g) Vibrate for 3 min in distilled or deionized water.

A.2.6 Rinse the specimen in a stream of distilled or deionized water.

A.2.7 Dry the surface of the specimen using dry, filtered air.

A.2.8 Keep the specimen in a dry jar at room temperature for not more than 30 min before weighing.

NOTE — All distilled or deionized water should be freshly prepared and clean.