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МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

Implants for surgery — Partial and total hip joint prostheses —

Part 3 :

Determination of endurance properties of stemmed femoral components without application of torsion

Implants chirurgicaux — Prothèses partielles et totales de l'articulation de la hanche —

Partie 3 : Détermination des propriétés d'endurance des tiges fémorales sans application de torsion

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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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 7206-3 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

ISO 7206 consists of the following parts, under the general title *Implants for surgery — Partial and total hip joint prostheses* :

- *Part 1 : Classification, designation of dimensions and requirements.*
- *Part 2 : Bearing surfaces made of metallic and plastics materials.*
- *Part 3 : Determination of endurance properties of stemmed femoral components without application of torsion.*
- *Part 4 : Determination of endurance properties of stemmed femoral components with application of torsion.*

Annexes A and B do not form an integral part of the standard.

Introduction

The following principles have been adopted in the development of the test method for determining the endurance properties of stemmed femoral components of hip joint prostheses described in this part of ISO 7206 :

- a) the anatomical axis of the femur has been assumed to be at an angle of 10° to the load line, when viewed perpendicular to the plane that includes the stem and neck;
- b) because of the complexity of the dynamic loading pattern in the patient, the diverse geometry of hip joint prostheses and the operative technique at implantation, certain factors (notably, the anteversion angle introduced at implantation, moment arm, maximum bending moment, calcar support and swing phase loading) are not referred to in this part of ISO 7206;
- c) the test conditions are based on the assumption that the stem of the prosthesis has become unsupported through breakdown of the proximal cement or bone, and therefore no account can be taken of any features of a femoral component that are intended to prevent cement breakdown or to aid implantation of the component in the optimum position.

Experience in clinical practice has shown that failure of femoral components is most likely to occur at a distance of between 25 mm and 90 mm below the centre of the head of the component. It is thought that this observation reflects a combination of factors such as placement of the prosthesis, bone resorption, stem loosening and bone cement breakdown.

For reproducibility of location of the prosthesis in the test rig, the embedding depth ($80 \text{ mm} \pm 2 \text{ mm}$) has been related to point C of the component, as designated in ISO 7206-1, i.e. the centre of the head of the prosthesis.

This part of ISO 7206 describes a test method for obtaining the endurance properties of the prosthesis under a constant loading range. It is generally felt that the important factors are the application of cyclic stress, the value of the mean stress, the environment and the orientation of the femoral component in relation to the applied load. It is believed that the waveform has very little effect on specimen life. A loading system has been selected comprising a mean load together with a sinusoidal dynamic load. The loading frequency has been selected to give an acceptably low cyclic rate and a reasonable duration of testing [5×10^6 cycles requires 139 h (approximately 6 days) at 10 Hz or 278 h (approximately 11,5 days) at 5 Hz].

This part of ISO 7206 does not specify the loading range to be applied to the test prosthesis nor the number of load cycles.

It is imperative that, after testing, the prosthesis should not be used for clinical purposes.

Implants for surgery — Partial and total hip joint prostheses —

Part 3 :

Determination of endurance properties of stemmed femoral components without application of torsion

1 Scope

This part of ISO 7206 describes a test method for determining the endurance properties, under specified laboratory conditions, of stemmed femoral components of total hip joint prostheses and stemmed femoral components used alone in partial hip joint replacement, without the application of torsion. It also defines the conditions of testing so that the important parameters that affect the components are taken into account, and describes how the specimen is set up for testing.

This test method has been developed for prostheses that have a plane of symmetry, and may not be suitable for other designs of prosthesis, e.g. those having preformed anteversion or double curvature of the stem.

This part of ISO 7206 does not cover methods of examining and reporting of the test specimen; these should be agreed between the test laboratory and the party submitting the specimen for test.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7206. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7206 are encouraged to investigate the possibility of applying the most recent editions of the standards listed below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 3696 : 1987, *Water for analytical laboratory use — Specifications and test methods*.

ISO 4965 : 1979, *Axial load fatigue testing machines — Dynamic force calibration — Strain gauge technique*.

ISO 5833 : 1979, *Implants for surgery — Acrylic resin cements — Part 1 : Orthopaedic applications*.

ISO 7206-1 : 1985, *Implants for surgery — Partial and total hip joint replacements — Part 1 : Classification, designation of dimensions and requirements*.

ISO 7500-1 : 1986, *Metallic materials — Verification of static uniaxial testing machines — Part 1 : Tensile testing machines*.

3 Definitions

For the purposes of this part of ISO 7206, the definitions given in ISO 7206-1 apply.

4 Principle of the test method

Embedding of the lower portion of the test specimen in a solid medium. Partial immersion of the protruding part of the test specimen in a fluid test medium. Application of a cyclic load to the head of the test specimen until the specimen exhibits failure or until the chosen number of cycles has been attained. Subsequent examination of the specimen for defects caused by the loading regime.

5 Reagents and materials

5.1 Fluid test medium

Solution of analytical grade sodium chloride
[$\rho(\text{NaCl}) = 9 \text{ g/l}$], continuously aerated, in distilled or deionized water of grade 3 as specified in ISO 3696.

5.2 Embedding medium

A casting medium, which should

- not be affected by the fluid test medium (5.1);
- not crack or break under the load applied during testing;
- not exhibit excessive deformation or creep;
- be reproducible in strength and other characteristics.

Three media that appear satisfactory are acrylic bone cement (see ISO 5833-1), epoxy casting resin and high-alumina cement (see annex A which contains guidance on a satisfactory composition of high-alumina cement).