
**Implants for surgery — Acrylic resin
cement — Flexural fatigue testing of
acrylic resin cements used in
orthopaedics**

*Implants chirurgicaux — Ciment à base de résine acrylique — Essais de
fatigue flexurale des ciments à base de résine acrylique utilisés en
orthopédie*

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Foreword

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The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 16402 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

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Implants for surgery — Acrylic resin cement — Flexural fatigue testing of acrylic resin cements used in orthopaedics

1 Scope

This International Standard applies to resin cements based on poly(methacrylic acid esters) and specifies the procedure for determining the fatigue behaviour of the polymerized cement.

This International Standard does not cover the hazards associated with the use of the cement in respect of either the patient or the user of the cement.

2 Normative references

The following referenced documents are indispensable for the application 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 5833:2002, *Implants for surgery — Acrylic resin cements*

ISO 16428, *Implants for surgery — Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices*

3 Test method

The tests make use of rectangular bar-shaped test specimens. The method for preparing these specimens is described in Clause 5.

The bending strength of the resulting test specimens is determined by means of a four-point bend test under quasi static and cyclic loading conditions. Under cyclic loading conditions two test methods are described. The first one follows the Wöhler method (S/N curve method) and determines the behaviour over the full range of stress levels. The second one (low stress method) determines the behaviour at lower stress levels only. These lower stress levels, which are specified, are thought to correspond to stress levels expected to be encountered in clinical use.

4 Apparatus

4.1 Equipment for mixing cement, as recommended by the cement manufacturer.

4.2 Moulds, made of a suitable material to produce rectangular bar-shaped specimens directly in their final shape with the dimensions of 75 mm length, 10 mm width and 3,3 mm depth. If preferred, one or more moulds to produce plates of 3,3 mm thickness may be used and the specimens subsequently cut to size using a saw. All surfaces of the moulds which come into contact with the cement shall be finely finished with 400 grade emery paper.

NOTE Materials with sufficient stiffness, as for example aluminium alloys or stainless steel, have been found to be suitable.

4.3 Flat, smooth plates, (two for each mould) of a suitable material and size to cover the upper and lower surfaces of the moulds (4.2).

4.4 Mould release agent, to facilitate separation of the specimens from the moulds.

NOTE Teflon-spray, vacuum grease or beeswax have been found to be suitable.

4.5 Polyester film, to cover the plates of the mould.

4.6 C-clamp(s) or other device(s), for clamping the mould(s) between the top and bottom plates.

4.7 Bend test machine, capable of applying loads up to 200 N which optionally can increase linearly or can cycle sinusoidally over a range of loads between 0 N and the selected value at a frequency of 5 Hz, and which is equipped with a device for measuring, controlling and recording the load to an accuracy of ± 2 N.

4.8 Four-point bend test rig, having the dimensions shown in Figure 1 (corresponding to ISO 5833:2002, Annex F) with means of preventing initial misalignment, changes of alignment and walking-off of the test specimen on the supports during the test. The loading points should be of the rolling type and have a diameter of 3 mm. The test rig should be such that equal loads are applied to all loading points.

4.9 Water bath, to maintain the test specimen and the loading fixtures at a temperature of (37 ± 1) °C.

4.10 Saw.

4.11 Emery paper, 400 grade.

5 Preparation of test specimens

5.1 General conditions

The mould(s) (4.2), plates (4.3), mixing equipment (4.1) and the cement to be used (both powder and liquid components) shall be maintained at (23 ± 2) °C for at least 2 h before casting the test specimen(s). The specimen(s) shall be cast at (23 ± 2) °C.

5.2 Preparation procedure

5.2.1 Cover the surfaces of the mould which come into contact with the cement, with a thin film of the mould release agent (4.4).

5.2.2 Cover the bottom plate of the mould with polyester film (4.5). Place the mould on top of the film-covered plate.

5.2.3 Mix the components of cement, following the manufacturer's instructions. Use a sufficient quantity of cement to make the required number of specimens.

NOTE A good procedure is the following: obtain a large batch of cement powder and a large batch of cement liquid from the manufacturer. Subdivide these batches into smaller units of powder and liquid, then store. Mix the number of these smaller units which is needed to make the required number of specimens. If possible, make all the specimens to be tested from a single batch of cement powder and a single batch of cement liquid. If this is not possible, use the minimum possible number of cement batches. In both cases record the batch numbers.

5.2.4 Fill the mould(s) with the cement immediately after the mixing is completed, cover with a sheet of the polyester film, add the top plate and clamp the top and bottom plates to the mould(s).

5.2.5 After approximately 1 h remove the clamp(s) (4.6), the top plate and the top polyester film and apply a mark to the top of the specimen near one end, to identify the top surface. Remove the specimen(s) from their mould(s). Wet grind the edges and the faces of the specimens which were in contact with the mould or which result from cutting with a saw (4.10), using 400 grade emery paper (4.11). The rectangular bar-shaped test specimens shall have a length of $(75 \pm 0,2)$ mm, width of $(10 \pm 0,2)$ mm, and thickness of $(3,3 \pm 0,2)$ mm.