INTERNATIONAL STANDARD

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Dentistry — Polymer-based crown and bridge materials

Art dentaire — Produits à base de polymère pour couronnes et ponts

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.

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.

International Standard ISO 10477 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Sub-Committee SC 2, *Prosthodontic materials*.

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Introduction

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard but it is recommended that, in assessing possible biological or toxicological hazards, reference should be made to ISO/TR 7405:1984, *Biological evaluation of dental materials*, or any more recent edition.

Although this International Standard does not require manufacturers to declare details of the composition, attention is drawn to the fact that some national or international authorities require details to be provided to them.

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Dentistry — Polymer-based crown and bridge materials

1 Scope

This International Standard covers polymer-based crown and bridge materials for laboratory-fabricated permanent facings or anterior crowns which may or may not be attached to a metal substructure. It excludes polymer-based materials which are used by the dentist to make crowns or veneers, or for repairs at the operatory. Nor does it cover the application of those materials for stress-bearing areas of posterior teeth.

This International Standard classifies polymer-based crown and bridge materials and specifies the requirements: it also specifies the test methods to be used to determine compliance with these requirements.

2 Normative references

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

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

ISO 6507-2:1983, *Metallic materials — Hardness test — Vickers test — Part 2: HV 0,2 to less than HV 5.*

ISO 7491:1985, *Dental materials — Determination of colour stability of dental polymeric materials.*

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 polymer-based crown and bridge material: Composition of powders and liquids or pastes which may contain monomer, polymeric and/or inorganic fillers. The crown and bridge materials polymerize by heat, chemical activation or photoactivation to be suitable for the intended use as permanent facings or anterior crowns.

3.2 dentine resin: Pigmented and slightly translucent polymer-based crown and bridge material with a colour suitable to imitate the natural colour of dentine.

3.3 enamel resin: Translucent and slightly pigmented polymer-based crown and bridge material suitable to imitate the natural colour of the tooth enamel packed in a layer over the dentine resin.

3.4 cervical resin: Intensely pigmented and slightly translucent polymer-based crown and bridge material with a colour suitable to imitate the natural dentine colours of the cervical part of the tooth.

3.5 opaque resin: Intensely pigmented polymer-based crown and bridge material suitable to mask the underlying metal substructure.

4 Classification

The materials described in this International Standard are classified according to their activation system:

Type 1 heat-activated material;

Type 2 chemically activated (self-curing) material;

Type 3 photoactivated- (light and/or UV radiation-activated) material.

5 Requirements

5.1 Components

When a component is supplied in the form of a powder, it shall be free of extraneous matter. When a component is supplied in the form of a liquid, it shall be free of deposits and/or sediment. The viscosity of the liquid shall not increase, and the liquid shall not discolour. When a component is supplied in the form of a paste, it shall be free of extraneous matter.

Testing shall be carried out in accordance with 7.2 and 7.3.

5.2 Polymerized crown and bridge material

5.2.1 Biocompatibility

See the Introduction for guidance on biocompatibility.

5.2.2 Depth of cure

For types 1 and 2, no requirement is specified.

For type 3, the hardness of the bottom surface shall not be less than 70 % of that of the top surface (i.e. the surface towards the radiation) for 1 mm thick specimens of cervical resins and for 2 mm thick specimens of dentine resins and enamel resins.

Testing shall be carried out in accordance with 7.4.

5.2.3 Surface finish

A test specimen polished in accordance with 7.5 shall have a highly polished surface.

Testing shall be carried out in accordance with 7.2 and 7.5.

5.2.4 Flexural strength

The flexural strength, $\overline{\sigma}_B$, in megapascals, shall be at least 50 MPa, and shall be not lower than the value

$$N = (\text{flexural modulus} \times 0{,}0025) + 40 \text{ MPa}$$

Testing shall be carried out in accordance with 7.6.

5.2.5 Water absorption

The water absorption of the polymer-based crown and bridge material shall not exceed 32 $\mu g/mm^3$.

Testing shall be carried out in accordance with 7.7.

5.2.6 Solubility

The solubility of the polymer-based crown and bridge material shall not exceed 5 $\mu g/mm^3$.

Testing shall be carried out in accordance with 7.7.

5.2.7 Colour and translucency

The colour and translucency of the polymer-based crown and bridge material shall match closely the equivalent zone of the manufacturer's shade guide. The colour and translucency of polymer-based crown and bridge material from different batches shall show no more than a slight difference in colour.

Testing shall be carried out in accordance with 7.2 and 7.8.

5.2.8 Colour stability

The polymer-based crown and bridge material shall show no more than a slight change in colour.

Testing shall be carried out in accordance with 7.2 and 7.8.

6 Sampling

The test sample shall consist of one or more retail packages from the same batch with at least two containers of liquid as well as of two other batches of the same shade for the test of colour and translucency (5.2.7) and contain sufficient (approximately 20 ml) material to carry out the specified tests plus an allowance for any necessary repetition of the tests.

7 Test methods

7.1 General

7.1.1 Test conditions

The test specimens shall be prepared and tested at (23 ± 1) °C. The relative humidity shall be not less than 30 %.

7.1.2 Water

Unless otherwise specified, the water to be used shall conform to ISO 3696, Grade 3.

7.1.3 Preparation of test specimens

Mix and process the polymer-based crown and bridge material in accordance with the manufacturer's instructions. Only use the quantity required to prepare one of the corresponding specimens.

Ensure that the apparatus for the polymerization of the polymer-based crown and bridge material is in satisfactory operating condition.

7.2 Visual inspection

Use visual inspection to determine compliance with clauses 5.1, 5.2.3, 5.2.7, 5.2.8, 8, 9 and 10. The colour comparison shall be performed in accordance with 7.8.

7.3 Components

7.3.1 Apparatus

Oven capable of maintaining a temperature of (60 ± 2) °C.

7.3.2 Procedure

An original container of liquid shall be stored in the dark for 24 h at (60 ± 2) °C. A second container of liquid shall be stored under the conditions recommended by the manufacturer. Compare the viscosity and the colour of the two samples.

7.4 Depth of cure: type 3 materials

7.4.1 Apparatus

7.4.1.1 Split rings such as shown in figure 1, (1 ± 0,1) mm or (2 ± 0,1) mm high.

7.4.1.2 Transparent glass plate of approximately 20 mm × 20 mm × 5 mm.

7.4.1.3 Polished metal plate of approximately 20 mm × 20 mm × 5 mm.

7.4.1.4 Colourless, clear, transparent, polyester film, impermeable to oxygen, of (50 ± 30) µm thickness.

7.4.1.5 Radiation source as recommended by the manufacturer.

7.4.1.6 Hardness testing instrument for HV 0,2 for measurements under load.

7.4.2 Procedure

For the neck colour, use the split ring 1 mm high; for all other colours, use the split ring 2 mm high.

Cover the polished metal plate with a piece of the polyester film and place the split ring on top. Pack the polymer-based crown and bridge material prepared in accordance with the manufacturer's instructions, to a slight excess, into the split ring avoiding air bubbles, cover it with the polyester film and the glass plate, and carefully extrude excess material. Irradiate the test specimen in the split ring in accordance with the manufacturer's instructions through the polyester film. Remove the test specimen from the split ring. Prepare three specimens, store them in water at (37 ± 1) °C for 24 h and carry out the hardness test according to ISO 6507-2 three times each on the upper and lower surface of each specimen.

7.4.3 Expression of results

Express the hardness of each surface as the mean of the three values obtained for it.

The determinations for the three specimens shall meet the requirement of 5.2.2.

7.5 Surface finish

Polish a test specimen prepared in accordance with the manufacturer's instructions for not longer than 1 min with a polishing agent used in dentistry and with an 18 to 36 ply muslin wheel at a circumferential speed of (650 ± 350) m/min. (A wheel with a diameter of 70 mm rotating at 1 500 min^{-1} will have a circumferential speed of 329 m/min and a 100 mm wheel rotating at 3 500 min^{-1} will have a circumferential speed of 1 010 m/min.) Keep at least 10 mm between the outer diameter of the wheel and the stitching or other reinforcement. After polishing and thorough cleaning, visually inspect the surface.

7.6 Flexural strength

7.6.1 Apparatus

7.6.1.1 Split stainless steel mould coated with a separating medium (e.g. 3 % solution of polyvinylstearyl ether wax in hexane), as shown in figure 2, in an appropriate mounting device.

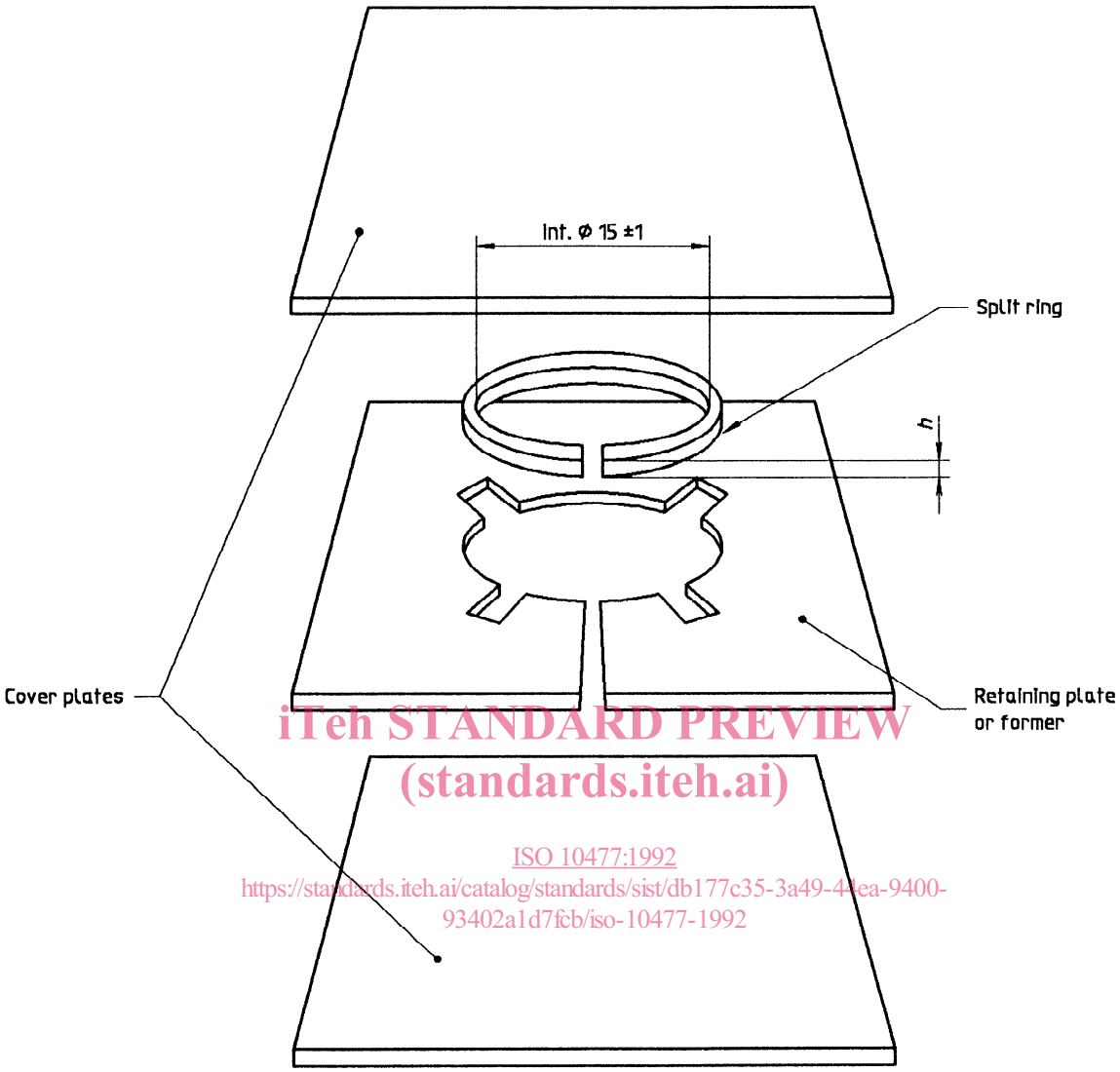
7.6.1.2 Two glass or metal plates of approximately 30 mm × 30 mm × 2 mm coated with a separating medium, e.g. polyester film (for type 3 polymer-based crown and bridge materials of appropriate transparency).

7.6.1.3 Small screw clamp.

7.6.1.4 Polymerization apparatus as recommended by the manufacturer.

7.6.1.5 Oven at (37 ± 1) °C.

Dimensions in millimetres



NOTE — The same mould may be used for the determination of depth of cure, absorption of water, solubility and colour stability; it may be made from metal, e.g. stainless steel alloy. The split ring has the following values for the height, h:

$h = (1 \pm 0,1)$ mm for depth of cure and all other tests

$h = (2 \pm 0,1)$ mm for depth of cure

Figure 1 — Preliminary mould for preparation of test specimens

7.6.1.6 Suitable test equipment with a constant cross-head speed of $(1 \pm 0,2)$ mm/min or at a loading rate of (50 ± 16) N/min and a **bending apparatus** consisting of two parallel supports of 2 mm in diameter in a distance of $(20 \pm 0,1)$ mm and a **third rod** of 2 mm diameter in the middle between the two supports for loading the specimen centrally.

7.6.1.7 Micrometer with an accuracy of 0,01 mm.

7.6.2 Preparation of test specimens

Cover one of the plates with a piece of polyester film and place the mould on top. Pack the polymer-based crown and bridge material prepared in accordance with the manufacturer's instructions, to a slight excess, into the mould avoiding air bubbles, cover with the polyester film and the other plate, and carefully extrude the excess material with the screw clamp. Polymerize the polymer-based crown and bridge material in accordance with the manufacturer's instructions. Separate the test specimen from the

Dimensions in millimetres

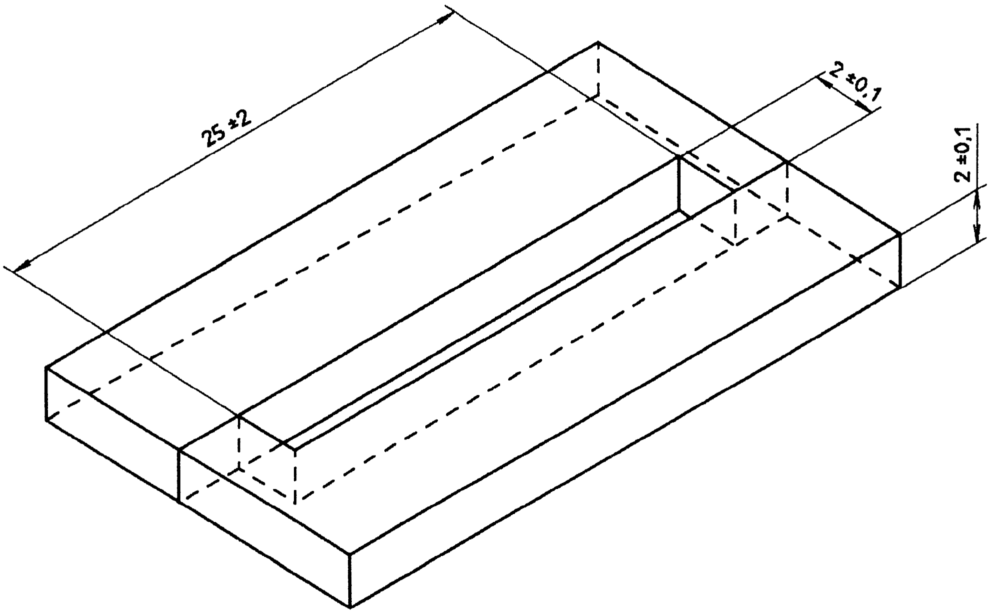


Figure 2 — Split mould for preparation of test specimens for the flexural test, made from stainless steel

mould, remove the flash and store in water at (37 ± 1) °C. Prepare five test specimens.

7.6.3 Procedure

At 24 h after the start of the preparation of the test specimens, measure the breadth and the height of the test specimens to an accuracy of 0,01 mm. Subsequently apply a load at a cross-head speed of (1 ± 0,3) mm/min or at a loading rate of (50 ± 16) N/min until the specimen fractures.

7.6.4 Calculation and expression of results

Calculate the flexural strength, σ_B, in megapascals, from the equation

$$\sigma_B = \frac{3Fl}{2bh^2}$$

where

F is the maximum applied load in newtons;

l is the supporting width, in millimetres, i.e. 20 mm;

b is the breadth of the test specimen, in millimetres;

h is the height of the test specimen, in millimetres.

Using the values for flexural strength, calculate the flexural modulus, E, in megapascals, from the equation

$$E = \frac{l^3 \times F_1}{4fbh^3}$$

where

F_1 is the load, in newtons, at a convenient point in the straight line portion of the trace;

f is the deflection of the test specimen in millimetres at load F_1;

l, b and h are as defined above.

NOTE 1 For greater accuracy the straight line may be extended. Calculate the result for each specimen.

7.6.5 Interpretation of results

If at least four of the results are not less than 50 MPa, the polymer-based crown and bridge material meets the requirement. If less than three of the results are not less than 50 MPa, the material does not meet the requirement. If three of the results are not less than 50 MPa, repeat the whole test. Only if all results are not less than 50 MPa on the second occasion does the material meet the requirement. If four or five out of five specimens or, where a second series was necessary, eight out of ten specimens were not less than 50 MPa, discard the failed results and calculate the mean flexural strength, $\overline{\sigma}_B$, of the successful specimens to three significant figures.

Calculate the flexural modulus, in megapascals of each of the successful specimens and determine the mean value, $\overline{E}$, to three significant figures; using this