
**Dentistry — Polymer-based crown and
bridge materials**

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

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Published in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

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 10477 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

This second edition cancels and replaces the first edition (ISO 10477:1992), which has been technically revised. It also incorporates the amendment ISO 10477:1992/Amd.1:1998.

The following changes were made:

- a) addition of a bonding test, <https://standards.iteh.ai/catalog/standards/sist/72cb9b85-eae8-45e0-af41-40f5b8c6a43a/iso-10477-2004>
- b) addition of a table for the test protocol and two tables of results.

Introduction

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this International Standard. Assessment of possible biological hazards is covered in ISO 10993-1 and ISO 7405.

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Dentistry — Polymer-based crown and bridge materials

1 Scope

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

This International Standard is applicable to polymer-based dental crown and bridge materials for laboratory-fabricated permanent facings or anterior crowns that may or may not be attached to a metal substructure. It also applies to polymer-based dental crown and bridge materials for which the manufacturer claims adhesion to the metal substructure without macromechanical retention such as beads or wires.

This International Standard is not applicable to polymer-based materials that are used to make crowns, veneers or repairs in the operatory, nor does it cover the application of those materials to stress-bearing areas of posterior teeth.

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 1562, *Dentistry — Casting gold alloys* <http://www.iso.org/standards/sist/72cb9b85-eae8-45e0-af41-40f5b8c6a43a/iso-10477-2004>

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

ISO 6344-1, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 7491, *Dental materials — Determination of colour stability*

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

ISO 8891, *Dental casting alloys with noble metal content of at least 25 % but less than 75 %*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

polymer-based crown and bridge material

composition of powders and liquids or pastes that may contain monomers, inorganic and/or polymeric fillers and that, when polymerized, is suitable for its intended use as permanent dental facings or anterior crowns

NOTE Polymerization is effected by mixing initiator(s) and activator(s) (“self-curing” materials) and/or by external energy activation [by heat (“heat-curing” materials), photoactivated materials, by visible light (“light-curing” materials) and/or by UV radiation].

3.2 dentine resin
pigmented and slightly translucent polymer-based crown and bridge material that simulates the natural appearance of dentine

3.3 enamel resin
translucent and slightly pigmented polymer-based crown and bridge material that is packed in a layer over the dentine resin and that simulates the natural appearance of enamel

3.4 cervical resin
intensely pigmented and slightly translucent polymer-based crown and bridge material with a colour that simulates the natural appearance of dentine of the cervical region of the tooth

3.5 opaque resin
intensely pigmented polymer-based crown and bridge material for masking the underlying metal substructure

4 Classification

The polymer-based crown and bridge materials described in this International Standard shall be classified according to their activation system for polymerization.

- **Type 1** polymer-based crown and bridge materials whose setting is effected by mixing initiator(s) and activator(s) (“self-curing” materials);
- **Type 2** polymer-based crown and bridge materials whose setting is effected by the application of energy from an external source (“external-energy-activated” materials), such as heat and/or light or UV radiation;
 - **Class 1** polymer-based crown and bridge materials that do not contain a light or UV-sensitive initiator;
 - **Class 2** polymer-based crown and bridge materials that contain a light or UV-sensitive initiator;
- **Type 3** polymer-based crown and bridge materials whose setting is effected by mixing initiator(s) and activator(s) and also by the application of energy from an external source (“dual-cure” materials).

5 Requirements

5.1 Biocompatibility

See the Introduction for guidance on biocompatibility.

5.2 Sensitivity to ambient light, Type 2, Class 2 polymer-based crown and bridge materials

The polymer-based crown and bridge materials Type 2, Class 2 shall remain physically homogeneous when exposed to ambient light (see Table 1).

Testing shall be carried out in accordance with 7.3.

NOTE For Type 1, Type 2, Class 1 and Type 3 materials, no requirement is specified.

Table 1 — Test protocol

Subclause	Property	Type 1	Type 2		Type 3
			Class 1	Class 2	
5.2	Sensitivity to ambient light	—	—	+	—
5.3	Depth of cure	—	—	+ ^a	—
5.4, 5.5	Surface finish, flexural strength	+ ^a	+ ^a	+ ^a	+ ^a
5.6	Bond strength	+	+	+	+
5.7 to 5.10	Water sorption, solubility, shade consistency, colour stability	+ ^a	+ ^a	+ ^a	+ ^a
+ carry out test; — do not test. ^a If the material is opaque resin, do not test.					

5.3 Depth of cure, Type 2, Class 2 polymer-based crown and bridge materials

For Type 2, Class 2 polymer-based crown and bridge materials, the hardness of the bottom surface shall be not less than 70 % of that of the top surface.

This requirement is not applicable to opaque resins (see Table 1).

Testing shall be carried out in accordance with 7.4.

NOTE For Type 1, Type 2, Class 1 and Type 3 no requirement is specified.

5.4 Surface finish

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

This requirement is not applicable to opaque resins (see Table 1).

Testing shall be carried out in accordance with 7.5.

5.5 Flexural strength

The flexural strength shall be at least 50 MPa (see Table 2).

This requirement is not applicable to opaque resins (see Table 1).

Testing shall be carried out in accordance with 7.6.

Table 2 — Physical and chemical requirements

Subclause	Property	Requirement
5.5	Flexural strength	≥ 50 MPa
5.6.1	Bond strength	≥ 5 MPa
5.6.2		≥ 80 % of the value claimed
5.7	Water sorption	≤ 40 µg/mm ³
5.8	Solubility	≤ 7,5 µg/mm ³

5.6 Bond strength

5.6.1 If the manufacturer recommends a special metal-bonding system without macromechanical retention, the strength of bond to the metal used for the substructure shall be not less than 5 MPa (see Tables 1 and 2).

Testing shall be carried out in accordance with 7.7.

5.6.2 If the manufacturer claims a value higher than 5 MPa for the bond strength, then the bond strength shall be not less than 80 % of the value claimed.

Testing shall be carried out in accordance with 7.7.

5.7 Water sorption

The water sorption of the cured polymer-based crown and bridge material shall be not more than 40 µg/mm³ (see Table 2).

This requirement is not applicable to opaque resins (see Table 1).

Testing shall be carried out in accordance with 7.8.

5.8 Solubility

The solubility in water of the cured polymer-based crown and bridge material shall be not more than 7,5 µg/mm³ (see Table 2).

This requirement is not applicable to opaque resins (see Table 1).

Testing shall be carried out in accordance with 7.8.

5.9 Shade consistency

The colours of the cured polymer-based crown and bridge material from different batches shall show no more than a slight difference.

This requirement is not applicable to opaque resins (see Table 1).

Testing shall be carried out in accordance with 7.9 and ISO 7491.

5.10 Colour stability

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

This requirement is not applicable to opaque resins (see Table 1).

Testing shall be carried out in accordance with 7.9 and ISO 7491.

6 Sampling

6.1 For all tests

The test sample shall consist of one or more retail packages prepared for retail sale of one randomly selected shade from a single batch and contain sufficient (approximately 20 ml) material to carry out the specified tests, plus an allowance for any necessary repetition of tests.

6.2 For test of shade consistency

The sample for the test of shade consistency (5.9 and 7.9) shall consist of the same shade as in 6.1 but of another batch (approximately 1 ml).

6.3 For test of colour stability

The sample for the test of colour stability (5.10 and 7.9) shall consist of two further randomly selected shades. The whole sample shall represent one shade of enamel, dentine and cervical resin (approximately 1 ml each).

7 Test methods

7.1 General

7.1.1 Test conditions

Test specimens shall be prepared and tested at (23 ± 2) °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 3696:1987, Grade 3.

7.1.3 Preparation of test specimens

For the preparation of Types 2 and 3 polymer-based crown and bridge materials, reference should be made to the manufacturer's instructions [see 9.1 p) and q)] that state the external energy source or sources recommended for the materials to be tested. Care shall be taken to ensure that the source is in a satisfactory condition.

Mix or otherwise prepare the polymer-based crown and bridge material in accordance with the manufacturer's instructions and the test conditions specified in 7.1.1.

Use only the quantity required to prepare one of the corresponding specimens.

If fully cured specimens are required for testing (7.5 to 7.9), it is important to ensure that the specimens are homogeneous after removal from the mould. There should be no voids, clefs or air inclusions present by visual inspection without magnification.

NOTE A separating medium which does not interfere with the setting reaction (e.g. 3 % solution of polyvinylstearyl ether wax in hexane) may be used to facilitate removal of the specimen.

7.2 Visual inspection

Use visual inspection to determine compliance with Clauses 8 and 9. The colour comparison in 7.9 shall be performed in accordance with ISO 7491.

7.3 Sensitivity to ambient light, Type 2, Class 2 polymer-based crown and bridge materials

7.3.1 Apparatus

7.3.1.1 Xenon lamp, or radiation source of equivalent performance (a suitable apparatus is described in ISO 7491) with colour-conversion filter ¹⁾ inserted.

The colour-conversion filter shall be hardened glass of thickness 3 mm and shall have an internal transmittance that matches within ± 10 % that shown in Figure 1.

7.3.1.2 Two glass microscope slides/plates.

7.3.1.3 Illuminance-measuring device, e.g. luxmeter, capable of measuring illuminance of $(8\ 000 \pm 1\ 000)$ lx.

7.3.1.4 Adjustable table.

1) The KR 12 filter supplied by Schott Spezialglas GmbH, Vertrieb Filter, Hüttenstr. 1; D-31073 Grünenplan, Germany, is an example of a suitable product available commercially. This information is given for the convenience of users of this International Standard and does not constitute an endorsement by ISO of this product.