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Dentistry — Polymer-based crown and veneering materials

Médecine bucco-dentaire — Produits à base de polymères pour couronnes et facettes

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Contents

Page

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 procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials.*

This third edition cancels and replaces the second edition (ISO 10477:2004), which has been technically revised.

The main changes compared to the previous edition are as follows:

— the limitation to anterior crowns has been deleted;

— the limitation to metal substructure has been deleted;

— the test for ambient light testing has been deleted.

Introduction

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazards are not included in this document, but it is recommended that, for the assessment of possible biological hazards, reference should be made to ISO 10993-1 and ISO 7405.

Dentistry — Polymer-based crown and veneering materials

1 Scope

This document classifies polymer-based crown and veneering materials used in dentistry and specifies their requirements. It also specifies the test methods to be used to determine conformity to these requirements.

This document is applicable to polymer-based crown and veneering materials for laboratory-fabricated permanent veneers or crowns. It also applies to polymer-based dental crown and veneering materials for which the manufacturer claims adhesion to the substructure without macro-mechanical retention such as beads or wires.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1942, *Dentistry — Vocabulary*

ISO 3696, *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 22674, *Dentistry — Metallic materials for fixed and removable restorations and appliances*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1942 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
polymer-based crown and veneering material
composition of powders and liquids or pastes that may contain monomers, inorganic and/or polymeric fillers and that, when polymerized, is suitable for use as permanent dental veneers or crowns

Note 1 to entry: 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].

Note 2 to entry: The polymer-based crown and veneering materials for laboratory-fabricated permanent veneers or crowns may or may not be attached to a substructure.

3.2
dentine resin
pigmented and slightly translucent *polymer-based crown and veneering material* (3.1) that simulates the natural appearance of dentine

3.3
enamel resin
translucent and slightly pigmented *polymer-based crown and veneering material* (3.1) 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 veneering material* (3.1) 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 veneering material applied in thin layers for masking the underlying material

4 Classification

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

— **Type 1:** polymer-based crown and veneering materials whose setting is effected by mixing initiator(s) and activator(s) ("self-curing" materials);

— **Type 2**: polymer-based crown and veneering materials whose setting is effected by the application of energy from an external source ("external-energy-activated" materials), such as heat and/or radiation (visible or UV range);

  — **Class 1:** polymer-based crown and veneering materials that do not contain a photo-polymerization initiator;

  — **Class 2:** polymer-based crown and veneering materials that contain a photo-polymerization initiator;

— **Type 3**: polymer-based crown and veneering 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 General

The tests required for a crown and veneering material depend on the classification according to Type and Class.

See Table 1 for the necessity of the specific tests described in 5.2 to 5.9.

Table 1 — Test protocol

Subclause	Property	Type 1	Type 2		Type 3
			Class 1	Class 2	
5.2	Depth of cure	—	—	+[a]	—
5.3	Surface finish	+[a]	+[a]	+[a]	+[a]
5.4	Flexural strength	+[a]	+[a]	+[a]	+[a]
5.5	Bond strength	+	+	+	+
5.6 to 5.9	Water sorption, solubility, shade consistency, colour stability	+	+	+	+

\+ carry out test;

— do not test.

[a] If the material is opaque resin, do not test.

5.2 Depth of cure

5.2.1 General

Testing shall be carried out in accordance with 7.3.

5.2.2 Depth of cure, Type 2, Class 2 materials

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

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

5.3 Surface finish

A test specimen polished in accordance with 7.4 shall have a glossy surface.

Testing shall be carried out in accordance with 7.4.

5.4 Flexural strength

The flexural strength shall be at least 50 MPa (see Table 2). This requirement is not applicable to opaque resins.

Testing shall be carried out in accordance with 7.5.

Table 2 — Physical and chemical requirements

Subclause	Property	Requirement
5.2	Depth of cure	Hardness of bottom surface ≥70 % of top surface
5.4	Flexural strength	≥50 MPa
5.5.1	Bond strength	≥5 MPa
5.5.2		≥80 % of the value claimed
5.6	Water sorption	≤40 µg/mm^3
5.7	Solubility	≤7,5 µg/mm^3

5.5 Bond strength

5.5.1 Special bonding system without macromechanical retention

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

Testing shall be carried out in accordance with 7.6.

5.5.2 Values higher than 5 MPa

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 7.6.

5.6 Water sorption

The water sorption of the cured polymer-based crown and veneering material shall be not more than 40 µg/mm^3 (see Table 2).

Testing shall be carried out in accordance with 7.7.

5.7 Solubility

The solubility in water of the cured polymer-based crown and veneering material shall be not more than 7,5 µg/mm^3 (see Table 2).

Testing shall be carried out in accordance with 7.7.

5.8 Shade consistency

The colours of the cured polymer-based crown and veneering material from different batches (according to 6.1 and 6.2) shall show no more than a slight difference with the colour indicated by the manufacturer.

Testing shall be carried out in accordance with 7.8 and ISO 7491.

5.9 Colour stability

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

Testing shall be carried out in accordance with 7.8 and ISO 7491.

5.10 Biocompatibility

See Introduction for guidance on biocompatibility.

6 Sampling

6.1 For all tests

The test sample shall consist of one or more packages of one selected shade, corresponding to the purpose of the test, 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 (5.8 and 7.8) shall consist of the same shade as in 6.1 (approximately 1 ml) but from another batch.

6.3 For test of colour stability

The sample for the test of colour stability (5.9 and 7.8) shall consist of two further shades selected in consideration of its colouring components. The shade of the resin sample shall consist of three different shades each of which correspond to one representative shade of enamel, dentine and cervical resin (approximately 1 ml for each shade).

7 Measurement and 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, Grade 3.

7.1.3 Preparation of test specimens

For the preparation of Type 2 and Type 3 polymer-based crown and veneering materials, reference shall be made to the instruction for use [see 9 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 energy source is fully functional.

Mix or otherwise prepare the polymer-based crown and veneering material in accordance with the instruction for use 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 (7.4 to 7.8), it is important to ensure that the specimens are homogeneous after removal from the mould. There shall be no voids, clefts or air inclusions present by visual inspection without magnification.

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 conformity to Clauses 8 and 9. The colour comparison in 7.8 shall be performed in accordance with ISO 7491.

7.3 Depth of cure

7.3.1 Apparatus

7.3.1.1 Split rings, such as shown in Figure 1, (15 ± 1) mm in diameter and (1 ± 0,1) mm in height.

7.3.1.2 Two polished plates (e.g. metal or glass), measuring approximately 20 mm × 20 mm × 5 mm.

7.3.1.3 Radiation source, as recommended in the instruction for use.

7.3.1.4 Hardness testing instrument, for HV 0,5.

7.3.1.5 Oven, set at (37 ± 1) °C.

7.3.2 Materials

7.3.2.1 White filter paper.

7.3.2.2 Film, colourless, transparent, (50 ± 30) µm thick.

7.3.3 Procedure

Cover one plate (7.3.1.2) with a piece of white filter paper (7.3.2.1) followed by the film (7.3.2.2), and position the split ring (7.3.1.1) upon it. Prepare the polymer-based crown and veneering material according to the instruction for use, and place it into the split ring to a slight excess. Cover the polymer-based crown and veneering material and the split ring with a second piece of film and the second plate (7.3.1.2), and extrude the excess material. Remove the upper plate and irradiate the test specimen in the split ring through the film, in accordance with the instruction for use. Remove the test specimen from the split ring. Grind (wet) the specimen on both sides and polish according to the instruction for use.

Prepare three specimens, and store them in water at (37 ± 1) °C for 24 h. Carry out the hardness test on the upper and lower surfaces of the specimens three times in accordance with ISO 6507-1.

7.3.4 Expression of results

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

All three specimens shall meet the requirement of 5.2. Otherwise the polymer-based crown and veneering material does not comply with the requirement of 5.2.

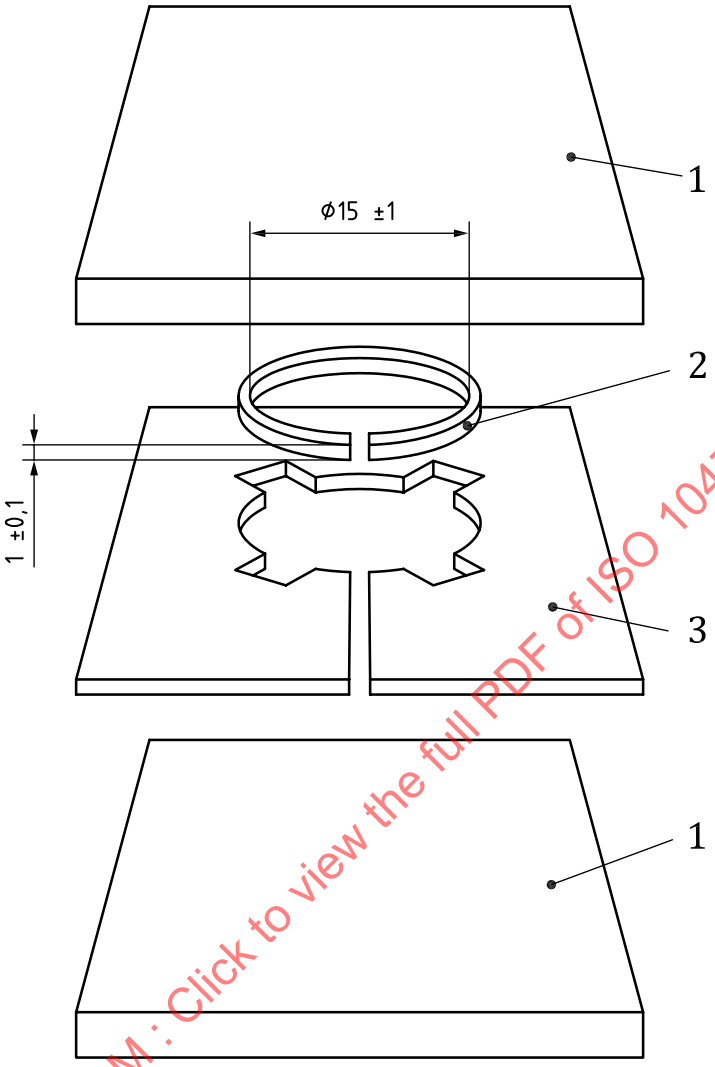
7.4 Surface finish

Polish a test specimen prepared in accordance with the instruction for use. If no specific procedure is given, polish for not longer than 1 min with an 18- to 36-ply muslin wheel at a circumferential speed of (650 ± 350) m/min and with precipitated calcium carbonate. Keep at least 10 mm between the outer diameter of the wheel and the stitching or other reinforcement.

Thoroughly clean the specimen by rinsing with water, blot dry, and visually inspect the surface for conformity to the requirement of 5.3.

NOTE A wheel with a diameter of 70 mm rotating at 1 500 r/min has a circumferential speed of 330 m/min and a 100 mm diameter wheel rotating at 3 500 r/min has a circumferential speed of 1 100 m/min.

Dimensions in millimetres



Key

1 glass or metal plates
2 split ring
3 retaining plate or former

Figure 1 — Mould for the preparation of test specimens for depth of cure, water sorption, solubility, shade consistency and colour stability

7.5 Flexural strength

7.5.1 Apparatus

7.5.1.1 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.

7.5.1.2 Two glass or metal plates, of approximately 30 mm × 30 mm × 2 mm.

7.5.1.3 Small screw clamp.

7.5.1.4 Polymerization apparatus, as recommended in the instruction for use.

7.5.1.5 Oven, set at (37 ± 1) °C.

7.5.1.6 Flexural strength test apparatus, appropriately calibrated, to provide a constant cross-head speed of (1,0 ± 0,3) mm/min. The apparatus consists of two rods (2 mm in diameter), mounted parallel with 20 mm between centres, and a third rod (2 mm in diameter) centred between, and parallel to the other two, so that the three rods in combination can be used to give a three-point loading to the specimen. Other instruments with a constant loading rate of (50 ± 16) N/min may also be used.

7.5.1.7 Micrometer, with an accuracy of 0,01 mm.

7.5.1.8 Timer, accurate to ± 1 s.

7.5.2 Materials

7.5.2.1 White filter paper, as in 7.3.2.1.

7.5.2.2 Film, as in 7.3.2.2.

7.5.2.3 Abrasive paper, between P220 and P320 according to ISO 6344-1.

7.5.2.4 Metal or glass plates, 1 quartz plate for UV photo-initiated material, no less than 30 mm × 10 mm × 2 mm.

7.5.2.5 Water, conforming to ISO 3696, Grade 2.

Dimensions in millimetres

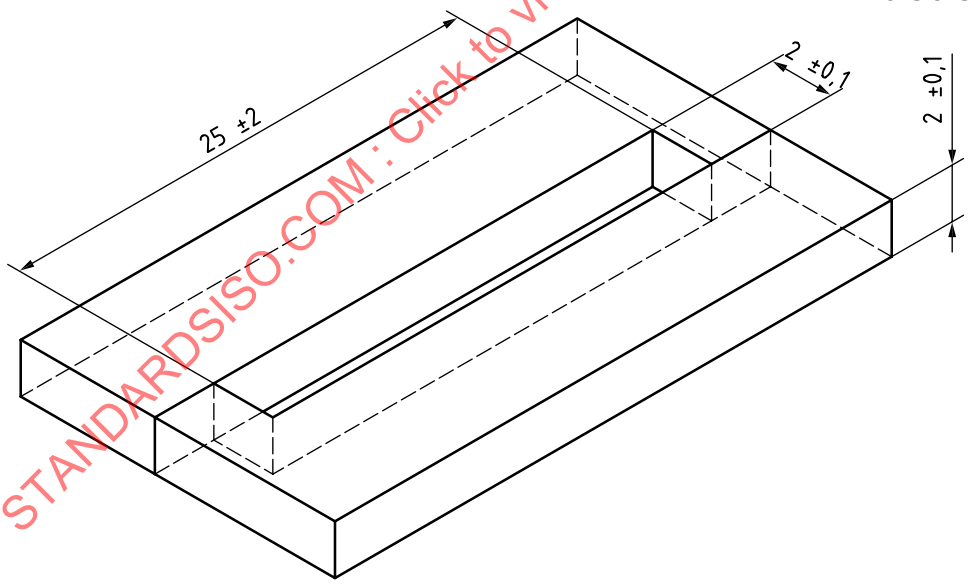


Figure 2 — Split mould for test specimens for the flexural test

7.5.3 Preparation of test specimens

7.5.3.1 Type 1 and Type 2, Class 1 materials

Cover one of the metal or glass plates (7.5.1.2) with the film (7.5.2.2), and position the mould (7.5.1.1) upon it. Prepare the polymer-based crown and veneering material in accordance with the instruction for use and immediately place it in the mould to a slight excess. Place a second piece of film onto the

polymer-based crown and veneering material in the mould and cover this with the second metal or glass plate. Apply pressure to displace excess material by means of the clamp (7.5.1.3).

Polymerize the polymer-based crown and veneering material in accordance with the instruction for use. Fifteen minutes after polymerization, remove the specimen and carefully remove any flash by gently abrading with abrasive paper (7.5.2.3), avoiding touching any other surface. Store the specimen in water (7.5.2.5) at (37 ± 1) °C (7.5.1.5) until the start of testing (7.5.4).

Specimens shall be plane-parallel for flexural testing.

Prepare five specimens.

7.5.3.2 Type 2, Class 2 and Type 3 materials

For light (385 nm to 515 nm) photo-polymerization initiators use glass plates for the bottom and top plates. For photo-polymerization initiator materials use a glass plate as the bottom plate and a quartz plate as the top plate. Cover the bottom plate with the white filter paper (7.5.2.1), followed by the film (7.5.2.2), and position the mould (7.5.1.1) upon it. Prepare the polymer-based crown and veneering material in accordance with the instruction for use and fill the mould with the polymer-based crown and veneering material, as described in 7.5.3.1. Place a second piece of film on the polymer-based crown and veneering material in the mould. For light photo-polymerization initiator materials cover this with a glass plate; for photo-polymerization initiator materials cover this with a quartz plate. Apply pressure to displace excess material by means of the clamp (7.5.1.3).

Polymerize the polymer-based crown and veneering material in accordance with the instruction for use. Irradiate the specimen through the top glass plate, remove both glass plates and the white filter paper. Irradiate the specimen from the other side. Fifteen minutes after polymerization remove the specimen and carefully remove any flash by gently abrading with abrasive paper (7.5.2.3). Store the specimen in water (7.5.2.5) at (37 ± 1) °C (7.5.1.5) until the start of testing (7.5.4).

Specimens shall be plane-parallel for flexural testing.

Prepare five specimens.

7.5.4 Procedure

At 24 h after the start of the preparation of the test specimens, measure the width and the height of the test specimens to an accuracy of 0,01 mm. Apply the load (7.5.1.6) 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. For Type 2, Class 2 and Type 3 materials, the load shall be applied on the first irradiated surface.

7.5.5 Expression of results

7.5.5.1 Calculation

Calculate the flexural strength, σ, in megapascals, from Formula (1):

$$\sigma = \frac{3Fl}{2bh^2} \tag{1}$$

where

F is the maximum applied load, in newtons;

l is the distance, in millimetres, between the supports, i.e. 20 mm;

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

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

7.5.5.2 Treatment of results

If at least four of the results are not less than the lowest value specified in Table 2, the polymer-based crown and veneering material complies with the requirement of 5.4.

If less than three of the results are not less than the lowest value specified in Table 2, the polymer-based crown and veneering material does not comply with the requirement of 5.4.

If three of the results are not less than the lowest value specified in Table 2, repeat the whole test. Only if all results are not less than the lowest values specified in Table 2 on the second occasion, the polymer-based crown and veneering material complies with the requirement of 5.4.

This treatment is summarized in Table 3.

Table 3 — Treatment of results (7.5.5.2, 7.6.5.2, 7.7.5.2)

Number of complying specimens	Conformity to requirement
First test	
4 to 5	Yes
3	Repeat test
0 to 2	No
Second test (repetition)	
5	Yes
0 to 4	No

7.6 Bond strength

7.6.1 Apparatus

7.6.1.1 Mould, of stainless steel with a slightly conical bore having a larger diameter of (5 ± 0,1) mm at one end and a smaller diameter of (4,9 ± 0,1) mm at the other end, and (2,5 ± 0,05) mm high, with sharp edges. The mould may be coated with a separating medium, e.g. a 3 % solution of polyvinylstearyl ether wax in hexane.

7.6.1.2 Five plates, made by conventional dental laboratory or milling techniques of a frame material suitable for crown and veneer constructions. The dimensions of the plate are 9 mm (minimum) × 9 mm (minimum) × (2,0 ± 0,5) mm. The test surface shall be plane and the finish as recommended in the instruction for use. If no specific brand is recommended, then the alloy or metal used shall conform with the alloys or product groups specified in ISO 22674.

7.6.1.3 Polymerization apparatus, as recommended in the instruction for use, as in 7.5.1.4.

7.6.1.4 Apparatus for thermocycling, which automatically exposes the specimen to 5 000 cycles of 30 s to 35 s in water at (5 ± 1) °C and 30 s to 35 s in water at (55 ± 1) °C.

7.6.1.5 Apparatus for testing shear bond strength (e.g. as shown in Figure 3) that allows the application of the force at a distance of (0,5 ± 0,02) mm from the surface of the plate (7.6.1.2).

7.6.1.6 Universal testing machine with a constant cross-head speed of (1 ± 0,3) mm/min and a system to record the force with an accuracy of ± 2 % as in 7.5.1.6. Other instruments with a constant loading rate of (50 ± 16) N/min may also be used.

7.6.1.7 Timer, accurate to ±1 s.

7.6.1.8 Micrometer, with an accuracy of 0,01 mm.

7.6.2 Materials

7.6.2.1 Film, as in 7.3.2.2.

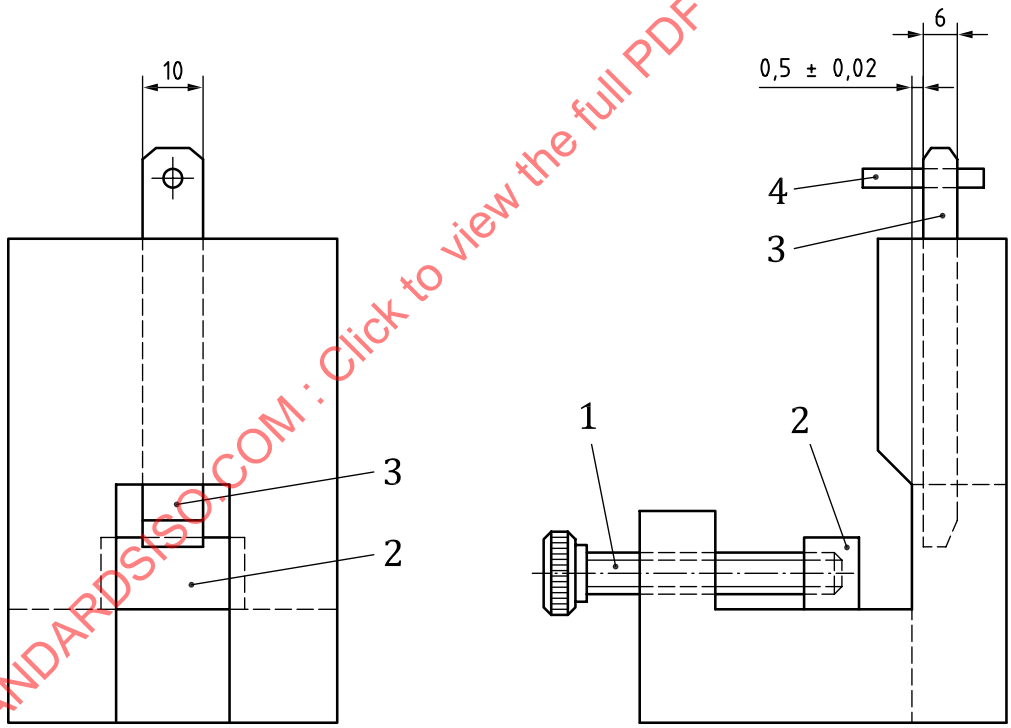
7.6.3 Preparation of test specimens

Treat the plates (7.6.1.2) as recommended by the manufacturer of the bonding system. Apply and cure the opaque resin, if the manufacturer recommends this procedure, to the bonding area as recommended by the manufacturer of the polymer-based crown and veneering material (7.6.1.3). Put the mould (7.6.1.1) with the wider opening against the opaque layer, if recommended. Press the polymer-based crown and veneering material into the mould and cover it with a film (7.6.2.1). Cure the polymer-based crown and veneering material according to the instruction for use.

Prepare five specimens.

It is recommended that the mould (7.6.1.1) be fixed on the plate with the help of a clamp, so that it cannot move when the polymer-based crown and veneering material is pressed into the mould.

Dimensions in millimetres



Key

1 fixation screw
2 fixation plate
3 plunger
4 stop pin

NOTE The distance of (0,50 ± 0,02) mm is a requirement.

Figure 3 — Example for an apparatus for testing shear bond strength

7.6.4 Procedure

After curing the polymer-based crown and veneering material, carefully remove the mould and store the specimens dry at (23 ± 2) °C for (24 ± 2) h. Expose the specimens to 5 000 thermal cycles of 30 s to 35 s in water at (5 ± 1) °C and 30 s to 35 s in water at (55 ± 1) °C (7.6.1.4).

Remove the specimen from the water (7.6.1.4) and measure two diameters of each of the bonded polymer-based crown and veneering material at right angles to each other. Calculate the adhesive surface area, A, using the mean diameter.

Adjust the specimen without drying in the apparatus (Figure 3) for shear testing (7.6.1.5). Take care that the plate contacts the baseplate of the apparatus. Put the apparatus in the universal testing machine (7.6.1.6) and load the specimen with a constant cross head speed of (1 ± 0,3) mm/min or at a loading rate of (50 ± 16) N/min. Record the load, F, at break.

7.6.5 Expression of results

7.6.5.1 Calculation

Calculate the bond strength, B, in megapascals, from Formula (2):

$$B = \frac{F}{A} \tag{2}$$

where

F is the load, in newtons, at break;

A is the bonded surface area, in square millimetres.

7.6.5.2 Treatment of results

Report all values of the bond strength, in megapascals, together with the type and trade name of the material used for the test.

If at least four of the results are ≥5 MPa, the polymer-based crown and veneering material complies with the requirement of 5.5.1.

If less than three of the results are ≥5 MPa, the polymer-based crown and veneering material does not comply with the requirement of 5.5.1.

If three of the results are <5 MPa, repeat the whole test. Only if all results are ≥5 MPa on the second occasion the polymer-based crown and veneering material complies with the requirement of 5.5.1.

This treatment is summarized in Table 3.

If the manufacturer claims a value higher than 5 MPa for the bond strength, then at least four out of five, or eight out of 10 if a second series is necessary as explained above, of the results shall be not less than 80 % of the claimed value, in order to comply with the requirement of 5.5.2.

7.7 Water sorption and solubility

7.7.1 Apparatus

7.7.1.1 Split rings, such as shown in Figure 1, as in 7.3.1.1.

7.7.1.2 Glass or metal plates, as in 7.3.1.2.

7.7.1.3 Small screw clamp, as in 7.5.1.3.

7.7.1.4 Polymerization apparatus, as recommended in the instruction for use, as in 7.5.1.4.

7.7.1.5 Plastic tweezers.

7.7.1.6 Oven, at (37 ± 1) °C, as in 7.5.1.5.

7.7.1.7 Two desiccators, containing silica gel (7.7.2.3).

7.7.1.8 Analytical balance, with an accuracy of 0,05 mg.

7.7.1.9 Timer, accurate to ±1 s.

7.7.1.10 Micrometer, with an accuracy of 0,01 mm.

7.7.2 Materials

7.7.2.1 White filter paper, as in 7.3.2.1.

7.7.2.2 Film, as in 7.3.2.2.

7.7.2.3 Silica gel, freshly dried at 130 °C or higher for at least 3 h.

7.7.2.4 Aluminium oxide grinding powder, with particle size approximately 0,3 µm.

7.7.2.5 Water, conforming to ISO 3696, Grade 2.

7.7.2.6 Felt.

7.7.2.7 Blotting paper.

7.7.3 Preparation of test specimen

Cover one of the glass or metal plates (7.7.1.2) with the white filter paper (7.7.2.1) [for Type 2, Class 2 and Type 3 (if photo-activated dual cure) polymer-based crown and veneering material] followed by the film (7.7.2.2), and position the split ring (7.7.1.1) upon it. Prepare the polymer-based crown and veneering material in accordance with the instruction for use and immediately place it into the split ring to a slight excess, avoiding air inclusions. Place a second piece of film (7.7.2.2) onto the polymer-based crown and veneering material in the mould and cover this with the second glass plate (7.7.1.2). Carefully extrude the excess material with the screw clamp (7.7.1.3). Remove the screw clamp and initiate polymerization of the polymer-based crown and veneering material in accordance with the instruction for use. For Type 2, Class 2 and Type 3 polymer-based crown and veneering materials, first irradiate through the top glass plate, remove both glass plates and the white filter paper, and irradiate the specimen from the other side.

Separate the test specimen from the split ring, wet grind it on both sides and polish it with felt (7.7.2.6) to gloss to a thickness of (1,0 ± 0,2) mm with aluminium oxide (7.7.2.4) suspended in water. To avoid contamination of the specimens, handle them at all times after grinding with the plastics tweezers (7.7.1.5). Make two measurements of the diameter of the specimen at right angles to each other, to an accuracy of 0,01 mm, and calculate the mean diameter. Measure the thickness at the centre and at four equally spaced points on the circumference to an accuracy of 0,01 mm. Calculate the area, in square millimetres, from the mean diameter and, using the mean thickness, calculate the volume, *V*, in cubic millimetres.

Prepare five test specimens.

7.7.4 Procedure

Condition the polished specimens in a desiccator (7.7.1.7) at (37 ± 1) °C in the oven (7.7.1.6). After 22 h place the test specimens in a second desiccator (7.7.1.7) for 2 h at (23 ± 2) °C. Take out one specimen at a time and weigh each to an accuracy of 0,1 mg (7.7.1.8). Continue the drying procedure until the loss of mass of each test specimen is less than 0,1 mg within each 24 h period, and record the final mass as m_1. Store the test specimens in 20 ml water (7.7.2.5) at (37 ± 1) °C in the oven (7.7.1.6) for 7 days. Remove each test specimen separately, wash with water (7.7.2.5) and dab with blotting paper (7.7.2.7) until free from visible moisture. Wave each test specimen in the air for 15 s and weigh 1 min after removal from the water (mass m_2). After weighing, recondition the test specimens in the desiccator to a constant mass until the loss of mass of each test specimen is less than 0,1 mg within each 24 h period using the cycle described above. Record the final mass as m_3.

Replace the silica gel with freshly dried gel after each weighing sequence (7.7.2.3).

NOTE Approximately two to three weeks are necessary to achieve constant mass.

7.7.5 Expression of results

7.7.5.1 Calculation of water sorption

For each of the five specimens, calculate the values for water sorption, ρ_w, in micrograms per cubic millimetre, to the nearest 0,1 µg/mm^3 from Formula (3):

$$\rho_w = \frac{m_2 - m_3}{V} \tag{3}$$

where

m_2 is the mass of the specimen, in micrograms, after immersion in water for 7 days (see 7.7.4);

m_3 is the mass of the reconditioned specimen, in micrograms (see 7.7.4);

V is the volume of the specimen, in cubic millimetres (see 7.7.3).

7.7.5.2 Treatment of results for water sorption

If at least four of the results are ≤40 µg/mm^3, the polymer-based crown and veneering material complies with the requirement of 5.6.

If less than three of the results are ≤40 µg/mm^3, the polymer-based crown and veneering material does not comply with the requirement of 5.6.

If three of the results are ≤40 µg/mm^3, repeat the whole test. Only if all five results are ≤40 µg/mm^3 on the second occasion, the polymer-based crown and veneering material complies with the requirement of 5.7, otherwise it fails.

This treatment is summarized in Table 3.

