



American National Standard/American Dental Association
Specification No. 53

Polymer-Based Crown and Bridge Materials

Modified adoption of ISO 10477:2004, *Dentistry – Polymer-based crown and bridge materials*.

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Scientific Affairs

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AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 53 FOR POLYMER-BASED CROWN AND BRIDGE MATERIALS

The Council on Scientific Affairs of the American Dental Association has approved American Dental Association Specification No. 53 for Polymer-based Crown and Bridge Materials. This and other specifications for dental materials, instruments and equipment are being formulated by working groups of the ADA Standards Committee on Dental Products (formerly Accredited Standards Committee MD156 for Dental Materials, Instruments and Equipment). The Committee has representation from all interests in the United States in the standardization of materials, instruments and equipment in dentistry. The Council has adopted the specifications, showing professional recognition of their usefulness in dentistry, and has forwarded them to the American National Standards Institute with a recommendation that the specifications be approved as American National Standards. The American National Standards Institute granted approval of ADA Specification No. 53 as an American National Standard on October 14, 2008.

The Council thanks the working group members and the organizations with which they were affiliated at the time the specification was developed:

P.L.Fan (chairman), American Dental Association, Chicago, IL;

Clyde Ingersoll, CEI Enterprises, Ltd., Tonawanda, NY; and

Michael Ryan, Food and Drug Administration, Rockville, MD.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 53 FOR POLYMER-BASED CROWN AND BRIDGE MATERIALS**FOREWORD**

(This Foreword does not form a part of ANSI/ADA Specification No. 53 for Polymer-based Crown and Bridge Materials).

This specification is a modified adoption of ISO 10477:2004, Dentistry – Polymer-based crown and bridge materials. ADA SCDP Working Group No. 2.11 on Artificial Teeth, Crown and Bridge Resin examined the international standard and found it acceptable for adoption as revised ANSI/ADA Specification No. 53 with the following modifications.

A 5.9 Shade consistency

Deleted: "This requirement is not applicable to opaque resins."

Rationale: The shade consistency of the opaque is the primary controller for shade uniformity.

B 5.10 Color stability

Deleted: "This requirement is not applicable to opaque resins."

Rationale: The color stability of the opaque is the primary controller for color stability.

C 6.1 For all tests

Deleted, the words "from a single batch," from: "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."

Rationale: By eliminating this requirement, consistencies of product can more optimally be verified or questioned.

D 8.2.2 Labeling of outer pack

Added: Placement of nationally required hazard identifiers (such as MSDS diamonds).

E 8.2.3 Labeling of containers

Added: Placement of nationally required hazard identifiers (such as MSDS diamonds).

Specific qualitative and quantitative requirements for freedom from biological hazards are not included in this specification. Assessment of possible biological hazards is covered in ANSI/ADA Specification No. 41, ISO 10993-1 and ISO 7405.

Addendum to the Foreword for this Reaffirmation:

In 2012, the ADA Standards Committee on Dental Products approved a change in the terminology used for standards. ADA standards will no longer utilize the term Specification; standards will now be named as ADA Standards.

With this notice, this ADA Specification is now termed an ADA Standard. Where the term "specification" is used, it should be considered as "standard." It will be re-named as an ADA Standard in its next revision.

AMERICAN NATIONAL STANDARD/AMERICAN DENTAL ASSOCIATION SPECIFICATION NO. 53 FOR POLYMER-BASED CROWN AND BRIDGE MATERIALS

1 SCOPE

This specification 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 specification 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 specification 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 22674, *Dentistry – Metallic materials for fixed and removable restorations and appliances*

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 color stability*

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

(ISO standards for dentistry are available from the American Dental Association, Department of Standards, 211 E. Chicago Ave., Chicago, IL 60611 or www.adacatalog.org. Other ISO standards are available from the American National Standards Institute, 25 W. 43rd St., New York, NY 10036 or www.ansi.org).

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 color 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 specification 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 Foreword 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	Water sorption	+ a	+ a	+ a	+ a
5.8	Solubility	+ a	+ a	+ a	+ a
5.9	Shade consistency	+	+	+	+
5.10	Color stability	+	+	+	+
+ 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 $\mu\text{g}/\text{mm}^3$
5.8	Solubility	≤ 7.5 $\mu\text{g}/\text{mm}^3$

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 $\mu\text{g}/\text{mm}^3$ (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 $7.5 \mu\text{g}/\text{mm}^3$ (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 colors of the cured polymer-based crown and bridge material from different batches shall show no more than a slight difference.

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

5.10 Color stability

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

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 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 color stability

The sample for the test of color 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 $(23 \pm 2) ^\circ\text{C}$. 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.