

INTERNATIONAL STANDARD

ISO
10477

First edition
1992-12-15

AMENDMENT 1
1998-04-15

Dentistry — Polymer-based crown and bridge materials

AMENDMENT 1

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

AMENDEMENT 1



Reference number
ISO 10477:1992/Amd.1:1998(E)

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.

Amendment 1 to International Standard ISO 10477:1992 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthodontic materials*.

© ISO 1998

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Organization for Standardization
Case postale 56 • CH-1211 Genève 20 • Switzerland
Internet central@iso.ch
X.400 c=ch; a=400net; p=iso; o=isocs; s=central

Printed in Switzerland

Dentistry — Polymer-based crown and bridge materials

AMENDMENT 1

Page 1

Clause 1 Scope

After the first paragraph, add the following paragraph.

"This International Standard applies to polymer-based crown and bridge materials for which the manufacturer claims adhesion to the metal sub-frame without macromechanical retention, such as beads or wires. It does not apply to denture base polymer and its adhesion to metal alloys, or to ceramic and its bonding to alloys."

Clause 2 Normative references

Add the two following references:

ISO 1562:1993, *Dental casting gold alloys*.

ISO 8891:1993, *Dental casting alloys with noble metal content of 25 % up to but not including 75 %*.

Page 2

Clause 5 Requirements

After subclause 5.2.8 add the following subclause.

5.2.9 Bond strength

5.2.9.1 If the manufacturer recommends a special bonding system without macromechanical retention, the bond strength shall be not less than 5 MPa.

5.2.9.2 If the manufacturer claims a specific value for the bond strength, then the bond strength shall be not less than 80 % of this value.

Testing shall be carried out in accordance with 7.9.

Page 7

Clause 7 Test methods

After subclause 7.8.3 add the following subclause.

7.9 Bond strength

7.9.1 Apparatus

7.9.1.1 Mould, of stainless steel with a slightly conical bore having a large diameter of $(5 \pm 0,1)$ mm and a small diameter of $(4,9 \pm 0,1)$ mm, and $(2,5 \pm 0,05)$ 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.

7.9.1.2 Five metal plates, made of an alloy suitable for crown and bridge technique with the dimensions of (20 ± 1) mm x (10 ± 1) mm x $(2 \pm 0,5)$ mm and made by a conventional dental laboratory technique. The test surface shall be plane and the finish as recommended by the manufacturer. If no specific brand is recommended by the manufacturer, then the alloy or metal used shall conform with the alloys or product groups specified in ISO 1562 or ISO 8891 where available.

7.9.1.3 Polyester film (as in 7.4.1.4).

7.9.1.4 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.

7.9.1.5 Apparatus for testing shear bond strength (e.g. as shown in figure 3) which allows the application of the force at a distance of $(0,5 \pm 0,02)$ mm from the surface of the metal plate (7.9.1.2).

7.9.1.6 Universal testing machine with a crosshead speed of $(1 \pm 0,3)$ mm/min and a system to record the force with an accuracy of ± 2 %.

NOTE Other instruments with a constant loading of (50 ± 16) N/min may also be used.

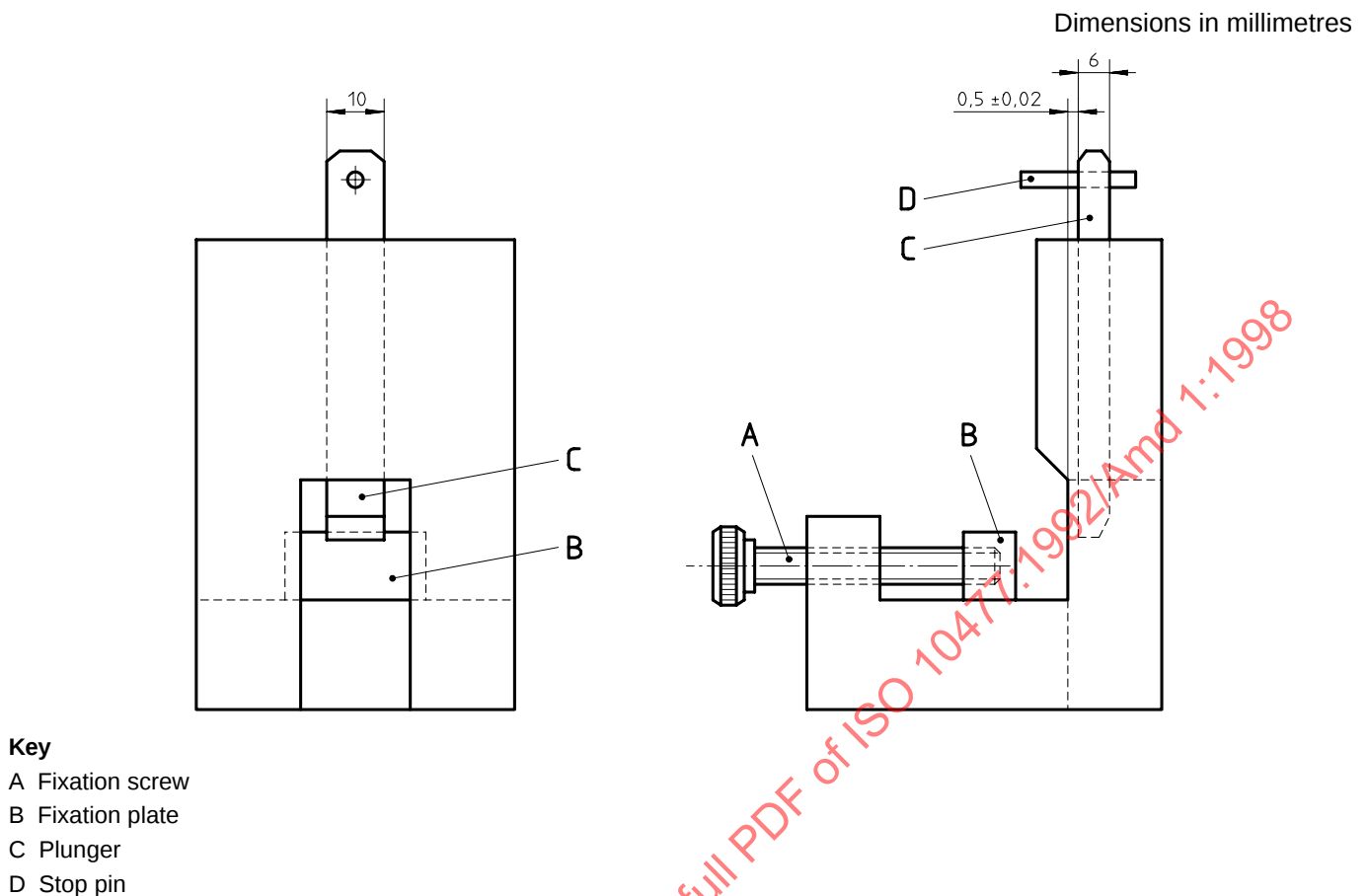


Figure 3 — Apparatus for testing shear bond strength

7.9.2 Preparation of test specimens

Treat the metal plates (7.9.1.2) as recommended by the manufacturer of the bonding system. Apply and cure the opaque resin to the bonding area as recommended by the manufacturer of the crown and bridge material. Put the steel mould (7.9.1.1) onto the opaque layer with the wider opening against the opaque layer. Press the crown and bridge material into the mould and cover it with a polyester film (7.9.1.3). Cure the crown and bridge material according to the manufacturer's instructions. Prepare five specimens.

NOTE It is recommended that the steel mould (7.9.1.1) be fixed on the metal plate with the help of a clamp so that it cannot move when the crown and bridge material is pressed into the mould.

7.9.3 Procedure

After curing the crown and bridge material, carefully remove the steel mould and store the specimens dry at $(23 \pm 2) ^\circ\text{C}$ for (24 ± 2) h. Expose the specimen to 5 000 thermal cycles of 30 s to 35 s in water at $(5 \pm 1) ^\circ\text{C}$ and 30 s to 35 s in water at $(55 \pm 1) ^\circ\text{C}$ (7.9.1.4).

Remove the specimen from the water (7.9.1.4) and measure two diameters of the bonded crown and bridge material at right angles to each other. Calculate the adhesive surface area, S , using the mean diameter.

Adjust the specimen without drying in the apparatus (figure 3) for shear testing (7.9.1.5). Take care that the metal plate contacts the baseplate of the apparatus. Put the apparatus in the universal testing machine (7.9.1.6) and load the specimen with a constant crosshead speed of $(1 \pm 0,3)$ mm/min [or at (50 ± 16) N/min] and record the load F at break.

7.9.4 Calculation and expression of results

Calculate the bond strength B , in megapascals, from the equation

$$B = \frac{F}{S}$$

where

F is the load, in newtons, at break;
 S is the bonded surface area, in square millimetres.

7.9.5 Interpretation of results

Report all values of the bond strength in megapascals, together with the type of alloy used for the test.

If four of the five values are not less than 5 MPa, the crown and bridge material complies with the requirement according to 5.2.9.1.

If three or more of the five values are less than 5 MPa, the crown and bridge material does not comply with the requirement according to 5.2.9.1.

If only three of the five values are not less than 5 MPa, repeat the whole test. If all five values are not less than 5 MPa on the second occasion, the crown and bridge material complies with the requirement according to 5.2.9.1.

If the manufacturer has claimed a specific value for the bond strength then at least four out of five, (or eight out of ten, where a second series is necessary), of the test values shall be not less than 80 % of the claimed value, in order to comply with the requirement according to 5.2.9.2.

Page 8

Clause 8 Manufacturer's instructions and shade guide

After 8.1 u) add the following items:

- v) if the manufacturer claims adhesion between the polymer-based crown and bridge material and the metal without macromechanical retention, then the method of use and treatment of the metal shall be stated;
- w) if the manufacturer claims a specific value for the bond strength, then the measured bond strength shall not be less than the value claimed and shall comply with the requirements in 5.2.9 when tested in accordance with 7.9.