

INTERNATIONAL
STANDARD

ISO
3336

Second edition
1993-08-15

Dentistry — Synthetic polymer teeth

*Produits et matériel pour l'art dentaire — Dents en polymères
synthétiques*

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Reference number
ISO 3336:1993(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.

International Standard ISO 3336 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Sub-Committee SC 2, *Prosthetic materials*.

This second edition cancels and replaces the first edition (ISO 3336:1977).

The main changes are as follows:

- a) revision, in accordance with ISO 7491:1985, of the procedure for the determination of colour stability;
- b) inclusion of a requirement for manufacturers to provide guidance when special treatment is required in order to achieve adequate bonding of the teeth to denture-base polymers;
- c) inclusion of a requirement for manufacturers to provide details of the dimensions of the teeth, especially the width, in order to facilitate the selection of teeth by clinicians;
- d) the hardness test for teeth has been omitted, as the crazing test (6.8) serves to identify inadequate crosslinking of the polymer.

It is proposed that at the next revision changes in the procedure in 6.6 for the determination of the quality of bonding will be considered.

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International Organization for Standardization
Case Postale 56 • CH-1211 Genève 20 • Switzerland

Printed in Switzerland

Introduction

Specific qualitative and quantitative requirements of freedom from biological hazard 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 10993-1:1992, *Biological evaluation of medical devices — Part 1: Guidance on selection of tests* and ISO/TR 7405:1984, *Biological evaluation of dental materials*, or any more recent editions.

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Dentistry — Synthetic polymer teeth

1 Scope

This International Standard specifies a classification, requirements and test methods for teeth which are composed of synthetic polymers such as poly(methyl methacrylate) and its copolymers, and which are manufactured for use in prostheses used in dentistry.

Terms used are in accordance with the definitions in ISO 1942-1 and ISO 1942-2.

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 483:1988, *Plastics — Small enclosures for conditioning and testing using aqueous solutions to maintain relative humidity at constant value.*

ISO 1567:1988, *Dentistry — Denture base polymers.*

ISO 1942-1:1989, *Dental vocabulary — Part 1: General and clinical terms.*

ISO 1942-2:1989, *Dental vocabulary — Part 2: Dental materials.*

ISO 3950:1984, *Dentistry — Designation system for teeth and areas of the oral cavity.*

ISO 6873:1983, *Dental gypsum products.*

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

3 Classification

Synthetic polymer teeth are grouped in accordance with the following classification.

— Type 1: anterior teeth

— Type 2: posterior teeth

4 Requirements

4.1 Dimensions of teeth

When measured in accordance with 6.2, the dimensions shall be within 5 % of those stated by the manufacturer (see 7.3).

4.2 Colour and blend

Sets of anterior and posterior teeth, representing each shade from the same manufacturer, shall exhibit no perceptible colour difference between each other and the manufacturer's shade guide (7.2.1), when tested in accordance with 6.3.

4.3 Freedom from biological hazard

See the Introduction for guidance on biological hazard.

4.4 Freedom from porosity and other defects

When examined in accordance with 6.4 (but see 7.2.3), the teeth shall exhibit no porosity or defect, such as rough trimming and rough finish, on the coronal surfaces.

4.5 Surface finish

4.5.1 Retention of finish

After processing and reprocessing, the teeth shall be capable of being polished in accordance with 6.5 to restore the original finish.

4.5.2 Repolishing

The teeth shall be capable of being ground and repolished to a finish that is equivalent to their original appearance, using the dental polishing methods specified in 6.5.

4.6 Quality of bonding to denture-base polymers

The teeth shall be capable of being bonded to heat-polymerized denture-base materials (type I) which conform to ISO 1567. For five out of the six test specimens, the bond formed between the ridge lap portion of the teeth and the denture-base polymer shall pass the test described in 6.5.

When the manufacturer of the teeth recommends special treatments to achieve adequate bonding, the treatments shall be noted in the instructions (7.4).

4.7 Colour stability

There shall be no perceptible colour change in the exposed tooth when tested in accordance with 6.7.

4.8 Resistance to blanching, distortion and crazing

When tested in accordance with 6.8, no tooth shall exhibit blanching or distortion. Four of five test teeth shall not exhibit crazing with the sole exception of the ridge lap surfaces. The remaining tooth shall exhibit no more than very slight crazing, seen only with difficulty.

4.9 Dimensional stability

When tested in accordance with 6.9, the dimensional change of a tooth shall be within ± 2 % of its original mesio-distal dimension.

5 Test sample

The sample consists of five groups, each comprising sets of maxillary and mandibular anterior and posterior teeth (28 teeth), as follows: each group of 28 teeth of a different shade and with a different mould for each set of six anterior teeth and, wherever possible, different moulds for the five different sets of posterior teeth.

The shade guide, mould chart and instructions (see 7.2 to 7.4) are required.

6 Test methods

6.1 General conditions and specimen preparation procedures

6.1.1 Ambient conditions

The teeth and other required materials and equipment shall be kept conditioned at (23 ± 2) °C and at a relative humidity of (50 ± 10) %, except as otherwise required in 6.5.2, 6.6.2, 6.7.2, 6.8.3 and 6.9.2.

6.1.2 Specimen preparation procedures

Conduct overall width measurements of dimensions l_1 , l_3 , l_5 and l_7 (see figure 1) and prepare the teeth for testing as follows. Remove the teeth from the mount, flush the wax from the teeth with boiling tap-water containing a detergent and rinse with boiling tap-water.

6.2 Inspection and conformity to mould chart

6.2.1 Apparatus

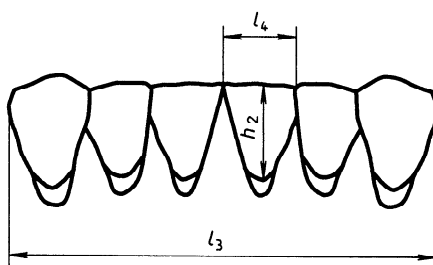
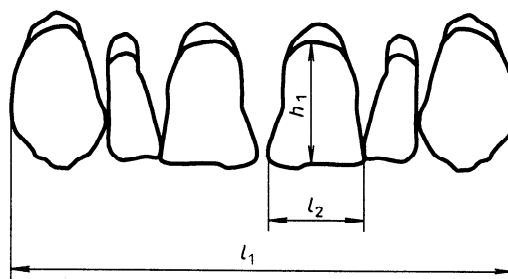
6.2.1.1 Micrometer or dial calliper accurate to 0,01 mm and fitted with parallel anvils.

6.2.2 Procedure

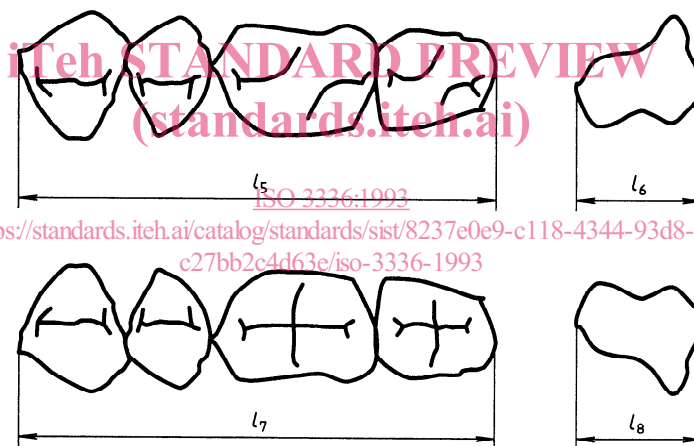
Inspect each set of teeth, cleaned according to 6.1.2, and report whether

- they are type I or type II;
- their shapes are in conformity with the mould chart (7.3);
- their colour and blend is consistent within the set (4.2 and 7.2); and
- their surface finish and packaging conforms with the requirements of 4.5 and 7.1.

With reference to figure 1, and using a micrometer (6.2.1), measure the maximum dimension of each maxillary and mandibular set of anterior teeth (l_1 and l_3) in the in-line plane, for conformity to the mould chart dimensions (4.1). Measure the maximum dimensions (l_2 , h_1 and l_4 , h_2) of the maxillary and mandibular left central incisors, (21, 31: see ISO 3950:1984). For the posterior teeth, measure the overall dimensions of the set (l_5 , l_7) and the maximum dimensions (l_6 , l_8) of the crowns of the maxillary and mandibular left first molars (26, 36).



a) Dimensions of type I teeth



b) Dimensions of type II teeth

Figure 1 — Dimensions of teeth to be measured

6.3 Comparison with shade guide

Select the cleaned maxillary central incisor (see 6.1.2) from each of the five different shades for evaluation. Evaluate in accordance with ISO 7491:1985, subclause 3.2.2. Compare the labial surfaces of each tooth to be tested to the shade guide by holding the tooth alongside and in the same plane as the corresponding shade guide tooth, with the test tooth first on one side of the shade guide tooth and then on the other. The tooth complies with 4.2 if there is no perceptible colour difference.

6.4 Porosity and other defects

6.4.1 Apparatus

6.4.1.1 Instrument capable of $\times 8$ to $\times 10$ magnification.

6.4.1.2 Abrasive paper of mean grit particle size $8\ \mu\text{m}$ to $20\ \mu\text{m}$, corresponding to grit grade 1 000.

6.4.1.3 Low-speed cooled saw or wet-grinding equipment.

6.4.2 Procedure

Provide a flat surface ($1,5 \pm 0,5$) mm from the incisal edge or cusp tips of two anterior and two posterior teeth using either a low-speed cooled saw or by wet grinding (6.4.1.3). Produce another approximately parallel surface, by removal of the lower coronal region and fitting surface, to provide a specimen thickness of ($2,5 \pm 0,5$) mm (see figure 2).

Examine the tooth specimen surfaces with the magnifying instrument (6.4.1.1) and report the presence or absence of porosity on each prepared surface.

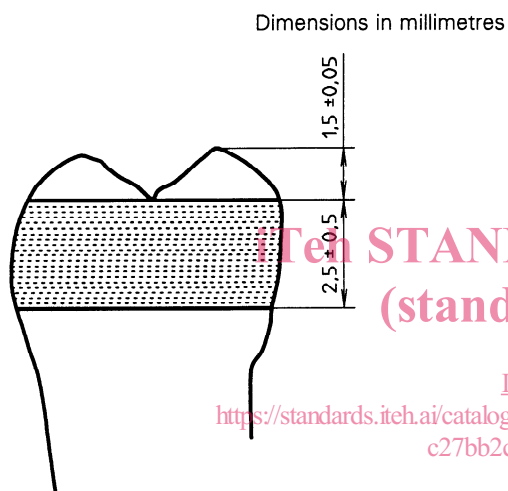


Figure 2 — Tooth thickness

6.5 Surface finish

6.5.1 Apparatus

6.5.1.1 Dental laboratory equipment for denture flasking, processing, finishing and wet polishing.

6.5.1.2 Soft 18 to 36 ply muslin wheel capable of rotating at a circumferential speed of (650 ± 350) m/min.

NOTE 1 A wheel with a diameter of 70 mm rotating at 1 500 r/min will have a circumferential speed of 330 m/min.

6.5.1.3 Silicon carbide wheel or silicon carbide impregnated rubber wheel of less than $65 \mu\text{m}$ grit, approximately 20 mm diameter and 5 mm width.

6.5.1.4 Dental gypsum for investment, complying with ISO 6873:1983.

6.5.1.5 Precipitated calcium carbonate (chalk) of a dental polishing grade.

6.5.1.6 Denture-base polymer, type I, complying with ISO 1567:1988.

6.5.2 Procedure

Bond three teeth to a denture-base polymer, following the manufacturer's instructions for the denture-base polymer. After curing and deflasking the tooth/polymer specimen, polish the teeth for no longer than 1 min using wet chalk (6.5.1.5) and the muslin wheel (6.5.1.2) at a circumferential speed of (650 ± 350) m/min. Maintain a distance of at least 10 mm between the outer diameter of the wheel and the stitching or other reinforcement. Examine the teeth for compliance with 4.5.1.

After completion of the first polishing step, grind the surface of one of the processed teeth with the silicon carbide wheel (6.5.1.3) being careful to avoid excessive temperature rise. Then polish the ground surface using pumice powder and chalk (6.5.1.5) successively with muslin wheels, for no longer than 1 min at each step. After polishing, examine the teeth for compliance with 4.5.2.

6.6 Quality of bonding to denture-base polymers

6.6.1 Apparatus

6.6.1.1 Metal former of the design illustrated in figure 3 a) which incorporates a trough 5 mm wide by 1,5 mm deep for use in mounting the teeth.

6.6.1.2 Normal dental laboratory apparatus for denture flasking and processing.

6.6.1.3 Denture-base polymer, type I, complying with ISO 1567:1988.

6.6.1.4 Tensile testing apparatus with the specially designed grips illustrated in figure 3 c).

6.6.1.5 Dental mounting wax.

6.6.2 Procedure

Take a set of six maxillary anterior teeth. Mount these teeth on a metal former with wax, as illustrated in figure 3 a), so that about one-half of the lingual surface of the incisal portion of the tooth and about one-half of the tooth projects beyond the metal former. Using a denture flask, set the mounted teeth in dental gypsum, [see figure 3 b)]. Remove the metal mount and then flush the wax from the teeth with boiling

tap-water containing a detergent, followed by rinsing with boiling tap-water. Process acrylic resin denture-base material (6.6.1.3) to the teeth after proper plasticity has been reached, submerge the clamped flask in water at $(70 \pm 1) ^\circ\text{C}$ for 90 min and finally immerse in boiling water $(100 \pm 1) ^\circ\text{C}$ for 30 min. When this heating procedure has been completed, cool the flask in the clamp in air.

Test the plastics-mounted teeth in a machine (6.6.1.4) designed to permit a direct pull on the incisal part of the lingual surface in a labial direction at a consistent height above the acrylic bar [see figure 3 c)]. Use equipment which does not permit lateral deflection or change of position.

Load each tooth, as illustrated in figure 3 c), at a displacement rate in the range $0,5 \text{ mm/m}^{-1}$ to 10 mm/m^{-1} , until fracture occurs.

The bond passes the test if the fracture path does not occur cleanly along the interface between the tooth surface and the denture-base polymer. Thus either tooth remnants shall remain bonded to the denture-base polymer and/or denture-base polymer shall remain firmly bonded to the detached tooth.

NOTE 2 Only pure adhesive interfacial fracture indicates a failure to meet the requirement. Cohesive fracture in either the tooth or the denture base is required for a satisfactory bond.

Report the number of teeth for which the bond passes the test.

Dimensions in millimetres

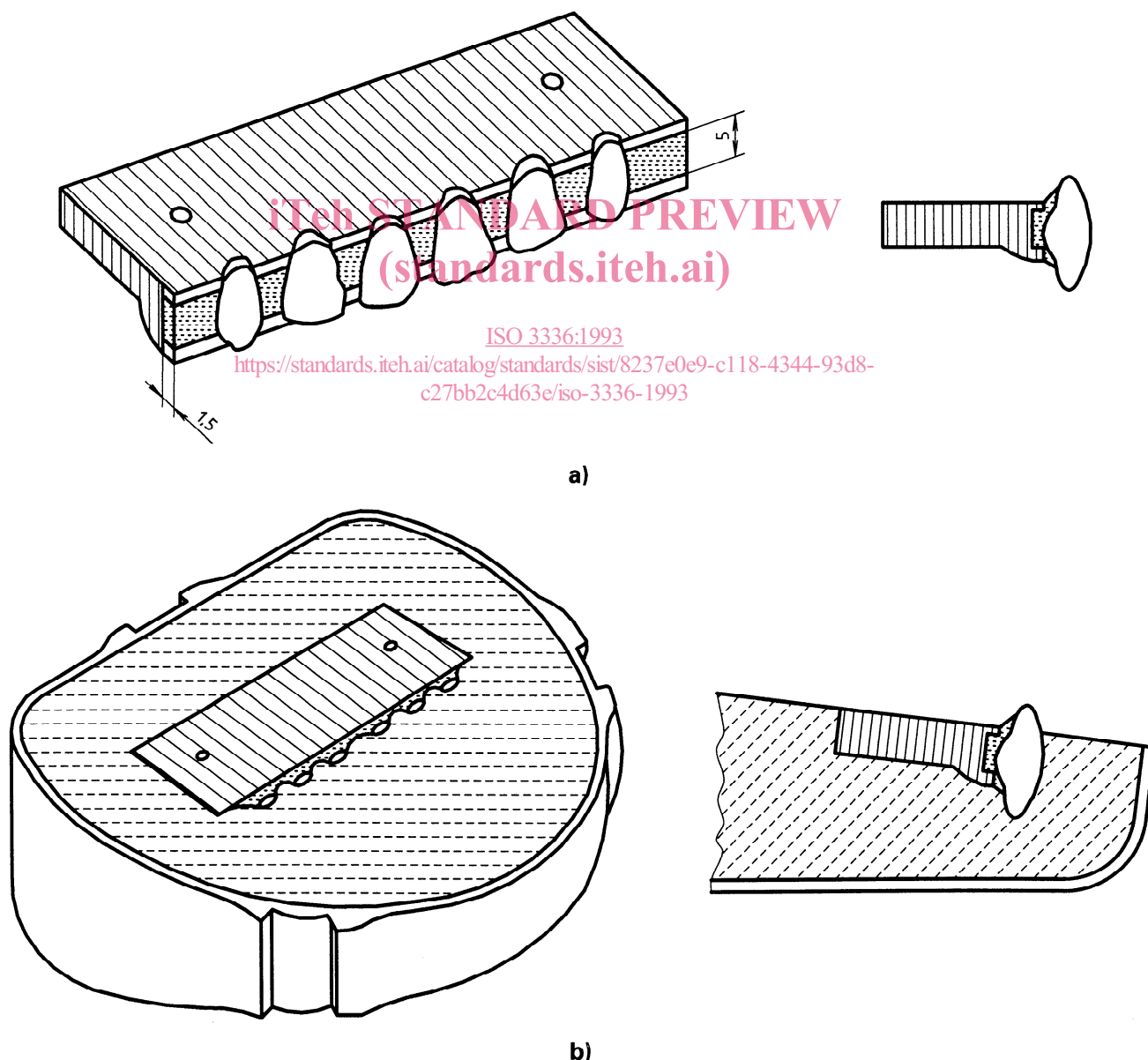


Figure 3 — Apparatus and mould for bonding test