INTERNATIONAL STANDARD

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Dentistry — Synthetic polymer teeth

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

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, *Prosthodontic 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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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

a) they are type I or type II;

b) their shapes are in conformity with the mould chart (7.3);

c) their colour and blend is consistent within the set (4.2 and 7.2); and

d) 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).