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Dentistry — Artificial teeth for dental protheses

Art dentaire — Dents artificielles pour prothèses dentaires



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

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.

ISO 22112 was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 2, *Prosthetic materials*.

This first edition cancels and replaces ISO 3336:1993, ISO 4824:1993 and ISO 4824:1993/Amd. 1:1997 which have been technically revised.

Dentistry — Artificial teeth for dental prostheses

1 Scope

This International Standard specifies the classification, requirements, and test methods for synthetic polymer and ceramic teeth that are manufactured for use in prostheses used in dentistry.

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 483 ¹⁾, *Plastics — Small enclosures for conditioning and testing using aqueous solutions to maintain the humidity at a constant value*

ISO 1567:1999, *Dentistry — Denture base polymers*

ISO 1942 ²⁾, *Dentistry — Vocabulary*

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

ISO 6873:1998, *Dental gypsum products*

ISO 7491:2000, *Dental materials — Determination of colour stability*

3 Terms and definitions

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

3.1

diatoric teeth

teeth designed to be retained by anchorage slots and/or holes

3.2

pin teeth

teeth designed to be retained by headed pins

3.3

set

set of six anterior teeth or eight posterior teeth, as received from the manufacturer

1) To be published. (Revision of ISO 483:1988)

2) To be published. [Revision of ISO 1942 (all parts):1989]

3.4

half-set

three teeth on one side of a set of anterior teeth or four teeth on one side of a set of posterior teeth

3.5

mould chart

chart representing the form, shape and dimensions of all individual teeth of a set

4 Classification

Artificial teeth are grouped in accordance with the following classification:

- a) Type 1: anterior teeth;
- b) Type 2: posterior teeth.

5 Requirements

5.1 General

5.1.1 Biocompatibility

Specific qualitative and quantitative requirements for freedom from biological hazard are not included in this International Standard, but it is recommended that, in assessing possible biological or toxicological hazards, reference be made to ISO 10993-1 and ISO 7405.

5.1.2 Dimensions of teeth

The dimensions of the teeth when examined in accordance with 7.2 shall not differ by more than 5 % for synthetic polymer teeth and 7 % for ceramic teeth from the values shown in the manufacturer's mould chart.

5.1.3 Colour and blending of shades

When tested in accordance with 7.3, sets of anterior and posterior teeth shall exhibit no perceptible colour difference compared with the manufacturer's shade guide (8.2.2) or nominated shade guide. Blended teeth shall show no line of demarcation between incisal and cervical portions on the facial aspects of the teeth.

NOTE This requirement is not intended to disallow especially designed demarcations placed to simulate borders of restorations or enamel imperfections found in natural teeth.

5.1.4 Surface finish

When inspected visually in accordance with 7.1, the teeth as received (excluding retention areas) shall have a smooth, lustrous, non-porous surface.

When ceramic teeth are tested in accordance with 7.4, the processing shall not have impaired the original finish of the teeth, and the teeth shall be capable of being ground and polished.

When synthetic polymer teeth are tested in accordance with 7.5, the teeth shall be capable of being polished to restore the original finish.

5.1.5 Freedom from porosity and other defects

Ceramic teeth shall not show more than a total of 16 pores of diameter greater than 30 µm on the four test surfaces when tested in accordance with 7.6. No more than six of those pores shall have diameters ranging from ≥ 40 µm and ≤ 150 µm. There shall be no pores of diameter greater than 150 µm.

Synthetic polymer teeth, when examined in accordance with 7.7, shall exhibit no porosity or defect, such as rough trimming, rough finish or visible impurities, on the coronal surfaces.

5.2 Ceramic teeth

5.2.1 Radioactivity

When tested in accordance with 7.8, ceramic teeth shall have an activity concentration of no more than $1,0 \text{ Bq}\cdot\text{g}^{-1}$ of uranium-238.

5.2.2 Anchorage

All ceramic diatoric teeth, examined in accordance with 7.9, shall provide a means of positive retention and have holes all of which shall be open and unsealed.

5.2.3 Resistance to thermal shock

Ceramic teeth shall, when tested in accordance with 7.10, show no signs of cracking.

5.3 Synthetic polymer teeth

5.3.1 Bonding to denture base polymers

All synthetic polymer teeth shall be capable of being bonded to heat-polymerized denture-base materials (Type 1), which conform to ISO 1567:1999. 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 7.11.

5.3.2 Resistance to blanching, distortion and crazing

When tested in accordance with 7.12, no teeth shall exhibit blanching or distortion. No teeth shall exhibit crazing with the exception of the ridge lap surfaces and the cervical portion of the teeth up to the cervical line.

5.3.3 Colour stability

When tested in accordance with 7.13, there shall be no perceptible colour change between the exposed and unexposed halves of the tooth and the unexposed tooth.

5.3.4 Dimensional stability

When tested in accordance with 7.14, the dimensional change of a tooth shall be within $\pm 2 \%$ of its original mesio-distal dimension.

6 Sampling

The sample shall consist of six groups, each comprising sets of mandibular and maxillary anterior and posterior teeth (if available).

For comparisons with the manufacturer's shade guide, all available shades of anterior teeth and five shades of available posterior teeth shades shall be included.

Five mould sizes shall be included covering the range of mould sizes shown by the manufacturer's mould chart. The teeth shall be representative of the physical dimensions of the brand and type.

7 Inspection and test methods

7.1 Visual inspection

Visually examine without magnification all the teeth in each set for compliance with the requirements given in 5.1.3 and 5.1.4.

7.2 Dimensions of teeth

7.2.1 Apparatus

7.2.1.1 **Micrometer**, accurate to $\pm 0,01$ mm and fitted with parallel steel face pieces.

7.2.2 Procedure

Measure the maximum mesio-distal dimension of each upper (l_1, l_5) and lower (l_3, l_7) set of teeth (see Clause 6) in the in-line plane for conformity to the mould chart dimensions (see 5.1.2). Measure the maximum mesio-distal (l_2, l_4) and cervico-incisal (h_1, h_2) dimensions of the upper and lower left central incisors (21, 31), and the overall facio-lingual (l_6, l_8) dimensions of the crowns of the upper and lower left first molars (26, 36), using a micrometer (7.2.1.1). See Figure 1 for these dimensions given in parentheses. The numerical tooth designations given in parentheses are in accordance with ISO 3950:1984.

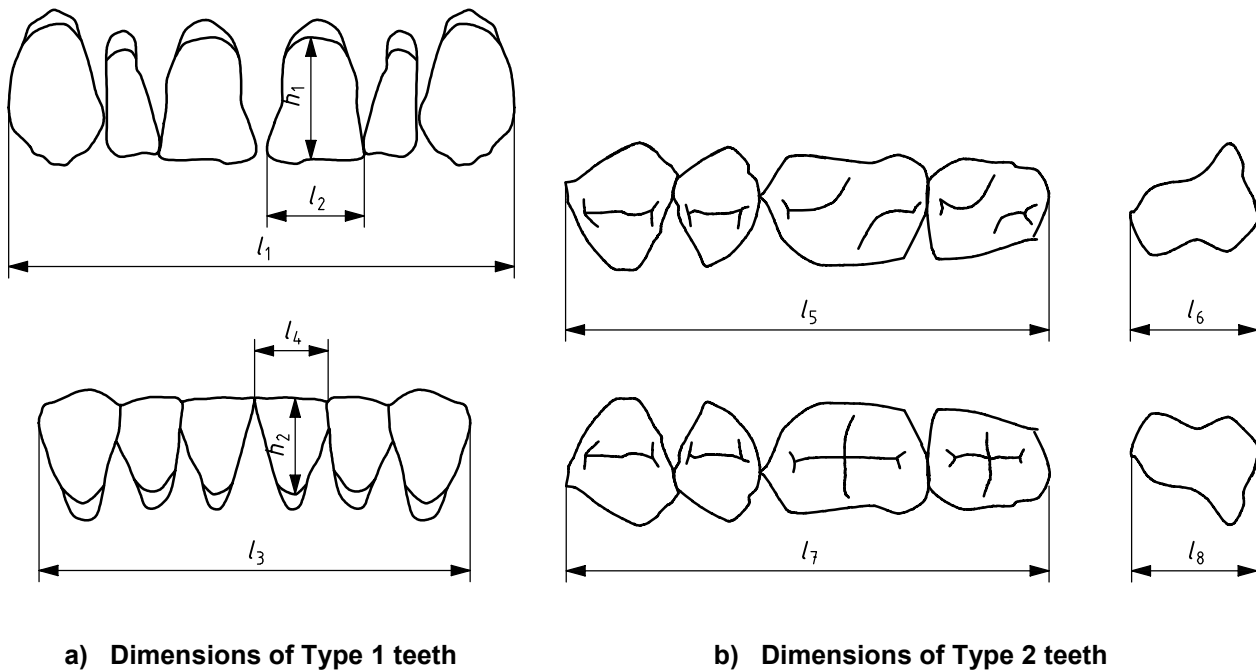


Figure 1 — Dimensions of teeth to be measured

7.3 Comparison with shade guide

Select a maxillary central incisor of all available anterior shades and/or a maxillary premolar tooth (see Clause 6) from each of the five different posterior tooth shades for evaluation. Evaluate in accordance with ISO 7491:2000, 3.2.3. 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 5.1.3 if there is no perceptible colour difference.

7.4 Surface finish of ceramic teeth

7.4.1 Apparatus and materials

- 7.4.1.1 **Denture base polymer**, Type 1, complying with ISO 1567:1999.
- 7.4.1.2 **Dental laboratory equipment**, for denture flasking, processing, finishing and wet polishing.
- 7.4.1.3 **Dental gypsum for investment**, complying with ISO 6873:1998 (Type 2 or Type 3).
- 7.4.1.4 **Dental modelling wax**.
- 7.4.1.5 **Wet 300 grit silicon carbide lathe wheel**, of diameter (63 ± 3) mm and thickness $(4,7 \pm 0,3)$ mm, capable of being rotated at $(1\ 700 \pm 300)$ r/min.

7.4.2 Processing

7.4.2.1 Preparation of specimens

Process a group of three teeth from different moulds of Type 1 teeth and likewise from Type 2 teeth to a denture base polymer (7.4.1.1), using the dental laboratory equipment (7.4.1.2) and accepted denture compression packing techniques, and following the manufacturer's instructions. Use a gypsum product (7.4.1.3) and a suitable modelling wax (7.4.1.4).

7.4.2.2 Procedure

After deflasking, using dental laboratory equipment and techniques, remove any surplus denture base material from those surfaces of the teeth that are normally exposed. Polish the teeth with dental laboratory equipment (7.4.1.2) taking care to keep the polishing tools wet where appropriate.

After polishing, examine the teeth visually for compliance with 5.1.4 and for evidence of any damage suffered in processing, excluding accidental damage by the equipment used in processing.

7.4.3 Grinding

7.4.3.1 Preparation of specimens

Using the lathe wheel (7.4.1.5), carefully grind the occlusal surfaces of posterior teeth or the incisal edges of anterior teeth from the sample of the processed teeth from 7.4.2, removing a layer of ceramic material approximately 1 mm thick. Rotate the wheel at $(1\ 700 \pm 300)$ r/min. Take care to avoid overheating the teeth during grinding.

7.4.3.2 Procedure

Using dental laboratory equipment and techniques (7.4.1.2), polish the ground surfaces and examine for compliance with 5.1.4.

7.5 Surface finish of synthetic polymer teeth

7.5.1 Apparatus and materials

- 7.5.1.1 **Denture base polymer**, Type 1, complying with ISO 1567:1999.
- 7.5.1.2 **Dental laboratory equipment**, for denture flasking, processing, finishing, and wet polishing.
- 7.5.1.3 **Timer**, accurate to ± 1 s.

7.5.1.4 **Precipitated calcium carbonate** (chalk), of a dental polishing grade.

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

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

7.5.1.6 **Silicon carbide wheel** or **silicon carbide impregnated rubber wheel**, of less than 65 μm grit, approximately 20 mm diameter and 5 mm width.

7.5.1.7 **Pumice powder**, medium grain size.

7.5.2 Processing

7.5.2.1 Preparation of specimens

Bond a group of three teeth from different moulds of Type 1 teeth and likewise from Type 2 teeth to a denture base polymer (7.5.1.1), following the manufacturer's instructions for the denture base polymer.

7.5.2.2 Procedure

After curing and deflasking (7.5.1.2) the tooth/polymer specimen, polish the teeth for no longer than 1 min (7.5.1.3) using wet chalk (7.5.1.4) and the muslin wheel (7.5.1.5) 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 5.1.4.

After completion of the first polishing step, grind the occlusal surface of one of the processed posterior teeth or the incisal edge of the processed anterior teeth with the silicon carbide wheel (7.5.1.6) being careful to avoid excessive temperature rise. Then polish the ground surface using pumice powder (7.5.1.7) for 1 min (7.5.1.3). Then polish with chalk (7.5.1.4) and the muslin wheel (7.5.1.5) for no longer than 1 min (7.5.1.3). After polishing, examine the teeth for compliance with 5.1.4.

7.6 Porosity of ceramic teeth

7.6.1 Apparatus and materials

7.6.1.1 **Diamond wheel with lubricant.**

7.6.1.2 **Mounting material** such as autopolymerizing poly(methyl methacrylate) (PMMA).

7.6.1.3 **Equipment for the preparation of polished sections.**

7.6.1.4 **Silicon carbide paper for grinding**, 240 to 600 grit.

7.6.1.5 **Diamond paste or powder**, of 3,0 μm grade.

7.6.1.6 **Optical microscope**, capable of 100 \times magnification, with photographic equipment.

7.6.2 Preparation of specimens

Cut two Type 1 teeth and two Type 2 teeth of a set in their long axis, using a diamond wheel under lubrication (7.6.1.1). Embed the four halves, exposing the cut surfaces, in the mounting material (7.6.1.2). Polish the exposed surfaces (7.6.1.3) by progressively grinding with wet silicon carbide paper (7.6.1.4), commencing with 240 grit and finishing with 600 grit paper. Use 3,0 μm grade diamond paste or powder (7.6.1.5) for the final polish such that a clear definition in each half of the tooth is visible using the optical microscope (7.6.1.6).

7.6.3 Procedure

Examine each of the four specimens in the following way. View the section under the microscope (7.6.1.6) using incident reflected light and select the area with the highest porosity (but not in the region of the core, if present). Prepare a photomicrograph with a final enlargement of approximately 100×; a gauge mark should be included to facilitate determination of pore diameters. Inspect the photomicrograph and again select the region with the highest porosity. Count the pores in a circular area representing 1 mm diameter on the specimen, and record the following:

- a) the number of pores with diameters between 30 µm and 40 µm;
- b) the number of pores with diameters between 41 µm and 150 µm;
- c) whether or not any pore has a diameter greater than 150 µm.

Examine the results for compliance with 5.1.5.

Alternative methods such as scanning electron microscopy or image analysis may be used in place of optical microscopy.

7.7 Porosity of synthetic polymer teeth and other defects

7.7.1 Apparatus and materials

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

7.7.1.2 Abrasive paper, of mean grit particle size 8 µm to 20 µm, corresponding to grit grade 1 000.

7.7.1.3 Micrometer, accurate to $\pm 0,01$ mm and fitted with parallel steel face pieces.

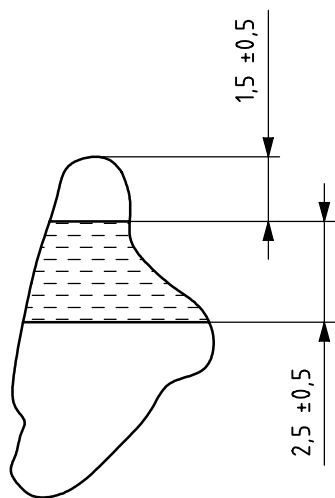
7.7.1.4 Instrument capable of 8× to 10× magnification.

7.7.2 Procedure

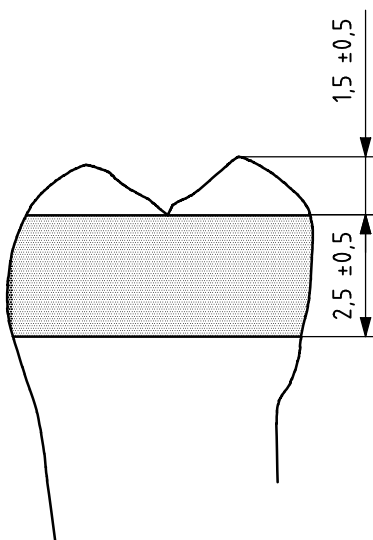
Provide a flat surface ($1,5 \pm 0,5$) mm from the incisal edge or cusp tips of two anterior teeth from different moulds and two posterior teeth from different moulds using either a low-speed cooled saw or by wet grinding (7.7.1.1). Produce another approximately parallel surface, by removal of the lower coronal region and fitting surface, to provide a specimen thickness of ($2,5 \pm 0,5$) mm (see Figure 2) using abrasive paper (7.7.1.2). Measure the dimensions with the micrometer (7.7.1.3).

Examine the tooth specimen surfaces with the magnifying instrument (7.7.1.4) for compliance with 5.1.5.

NOTE Ground surfaces are at right angles to the long axes of the teeth.



a) Anterior



b) Posterior

Figure 2 — Specimen tooth thickness for the porosity test (see 7.7)

7.8 Radioactivity of ceramic teeth

7.8.1 Apparatus

- 7.8.1.1 **Tungsten-carbide mill** or **alumina ceramic mill**.
- 7.8.1.2 **Sieve**, capable of sieving particles less than 75 μm .
- 7.8.1.3 **Equipment for neutron activation**.

7.8.2 Sample preparation

If the ceramic teeth contain pins, crush lightly to remove pins, then continue milling in a tungsten-carbide mill or an alumina ceramic mill (7.8.1.1). Sieve (7.8.1.2) and obtain 10 g of powder with particle size less than 75 μm .

7.8.3 Counting procedure

Use a sample volume of 10 g bulk powder and determine the activity concentration of uranium-238 by neutron activation (7.8.1.3).

7.8.4 Assessment of results

The sample tested shall comply with the requirements in 5.2.1.

Containers and equipment in contact with the ceramic teeth material shall be free of radioactivity when testing.

7.9 Anchorage of ceramic teeth to denture base polymers

7.9.1 Apparatus

- 7.9.1.1 **Stiff wire**, of at least $(1,0 \pm 0,1)$ mm diameter.

A high tensile stainless steel wire is suitable.

7.9.2 Procedure

Visually examine each tooth of two sets of diatoric teeth (16 teeth) and ascertain whether the anchorage slots and/or holes are capable of providing positive retention for the denture base material. If holes are provided, probe with the stiff wire (7.9.1.1) to a depth of at least 0,5 mm. Check for compliance with 5.2.2.

7.10 Resistance of ceramic teeth to thermal shock

7.10.1 Apparatus and materials

- 7.10.1.1 **Cleansing solution**.

A 10 g/l solution of household detergent is suitable.

- 7.10.1.2 **Perforated container**, of non-corrodible metal of suitable capacity to contain at least 28 teeth.

- 7.10.1.3 **Electric oven**, maintained at (100 ± 2) °C.

- 7.10.1.4 **Timer**, accurate to ± 1 s.

- 7.10.1.5 **Metal container**, of ice water at (1 ± 1) °C, sufficiently large to enable the perforated container to be completely immersed.

7.10.1.6 Light source, of minimum illuminance of 1 000 lx.

7.10.1.7 Magnifying glass, of 10× magnification.

7.10.2 Preparation of specimens

Using the cleansing solution (7.10.1.1) thoroughly clean two sets of Type 1 and Type 2 teeth of the same mould and shade, removing all traces of adherent wax. Rinse the teeth with water.

7.10.3 Procedure

Place the teeth in the perforated container (7.10.1.2) and transfer it to the oven (7.10.1.3) at (100 ± 2) °C. After (20 ± 1) min (7.10.1.4), remove the container and immediately (within 3 s) immerse it in the metal container of ice water (7.10.1.5). After immersion for no less than 30 s (7.10.1.4), remove the container and return it to the oven at (100 ± 2) °C for a further (15 ± 1) min. Remove the container and allow to cool to (23 ± 2) °C. Then examine each tooth by high-intensity transillumination (7.10.1.6) with the magnifying glass (7.10.1.7) for compliance with 5.2.3.

7.11 Quality of bonding of synthetic polymer teeth to denture-base polymers

7.11.1 Apparatus and materials

7.11.1.1 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.

7.11.1.2 Dental mounting wax.

7.11.1.3 Normal dental laboratory apparatus, for denture flasking and processing.

7.11.1.4 Denture base polymer, Type 1, complying with ISO 1567:1999.

7.11.1.5 Dental gypsum, for investment, complying with ISO 6873:1998 (Type 2 or Type 3).

7.11.1.6 Water bath(s), capable of being maintained at (70 ± 3) °C and at boiling water temperature (100 ± 1) °C.

7.11.1.7 Timer, accurate to ± 1 s.

7.11.1.8 Tensile-testing apparatus, with the specially designed grips illustrated in Figure 3 c).

7.11.1.9 Tap water.

7.11.2 Procedure

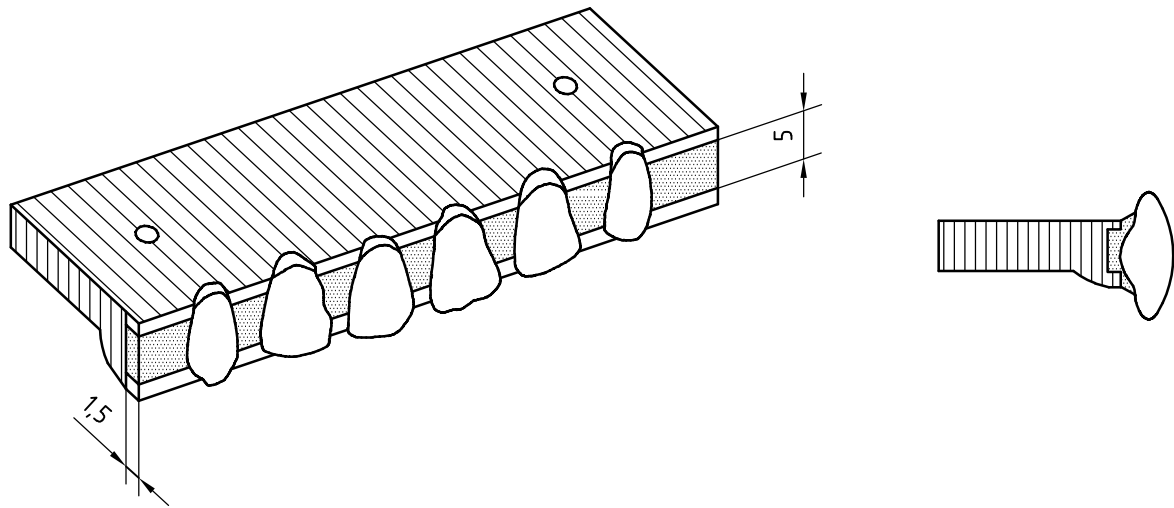
Take six maxillary anterior teeth from at least two different moulds. Mount these teeth on a metal former (7.11.1.1) with wax (7.11.1.2), as illustrated in Figure 3 a), so that about one-half of the lingual surface of the incisal portion of the tooth and about one-half of the tooth projects beyond the metal former. Using a denture flask (7.11.1.3), set the mounted teeth in dental gypsum (7.11.1.5) [see Figure 3 b)]. Remove the metal mount and then flush the wax from the teeth with boiling tap water. Process the denture base polymer (7.11.1.4) to the teeth (see 8.3) after proper plasticity has been reached, submerge the clamped flask in water at (70 ± 3) °C in the water bath (7.11.1.6) for (90 ± 1) min (7.11.1.7) and finally immerse in boiling water in the water bath (7.11.1.6) for (30 ± 1) min (7.11.1.7). When this heating procedure has been completed, cool the flask in the clamp in air until room temperature (23 ± 2) °C is reached. Test the plastics-mounted teeth in a machine (7.7.11.8) designed to permit a direct pull on the incisal part of the lingual surface in a labial direction at a consistent height above the denture base polymer bar [see Figure 3 c)]. Use equipment that 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 mm/min to 10 mm/min, until fracture occurs.

The bond passes the test if the mode of fracture is cohesive within the tooth or the denture base polymer, i.e. there are remnants of tooth remaining bonded to the denture base polymer or there are remnants of denture base polymer remaining bonded to the tooth.

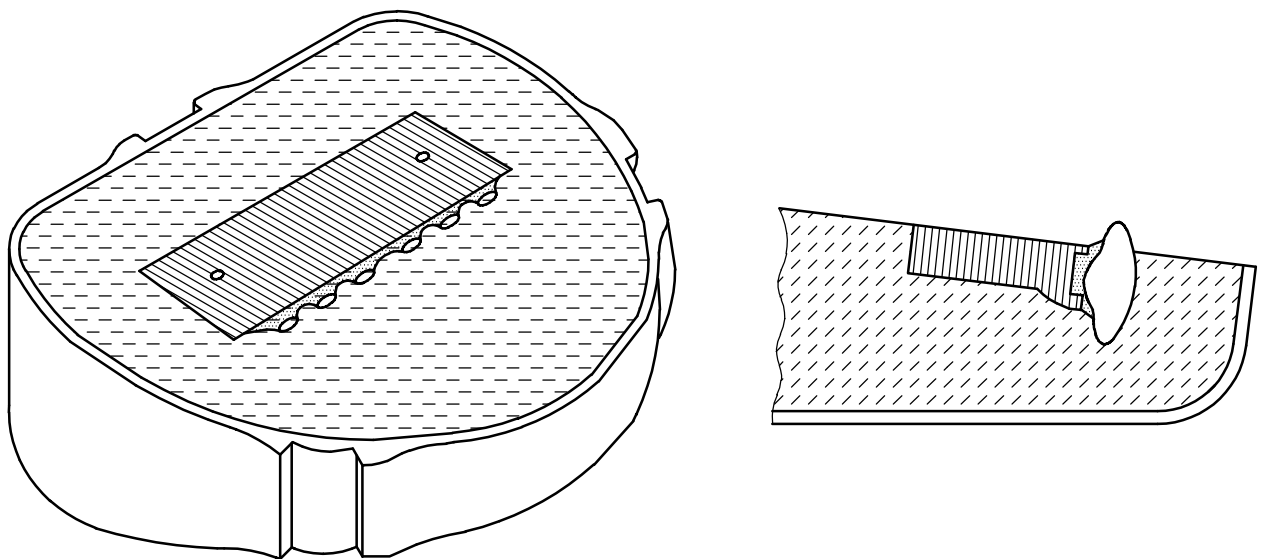
Only pure adhesive interfacial fracture indicates a failure to meet the requirement.

Report the number of teeth for which the bond passes the test and examine for compliance with 5.3.1.

Dimensions in millimetres

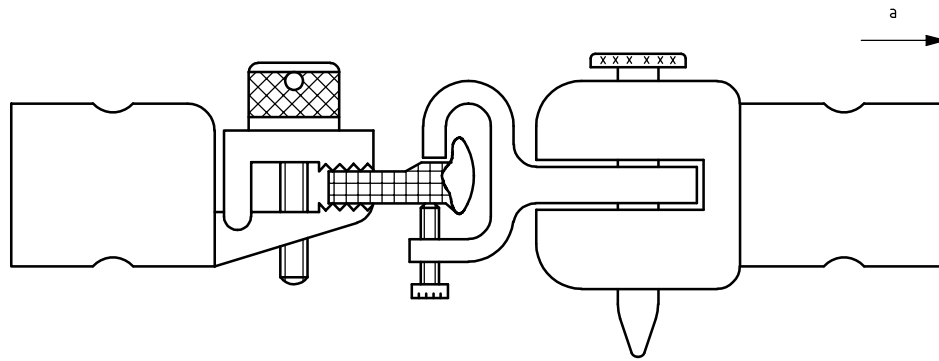


a) Teeth mounted on metal former



b) Mounted teeth set in gypsum

Figure 3 — Apparatus and mould for bonding test (continued)



a Pull.

c) Tensile-testing apparatus

Key

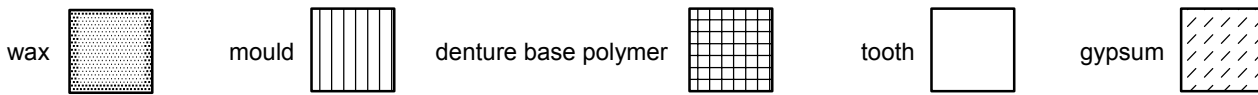


Figure 3 — Apparatus and mould for bonding test

7.12 Resistance to blanching, distortion and crazing of synthetic polymer teeth

7.12.1 Sampling

Select two groups of teeth, one group as a control for the other group. One tooth from each of five different sets of five different shades, as defined in Clause 6, shall comprise one group; the counterpart tooth from each of the same five sets shall comprise the other group. This procedure involves exposure of both the test group and the control group to monomer, but the control group is used in the “as received” condition and the test group is used after the conditioning cycle described in 7.12.3. Before exposure to monomer or conditioning, examine each tooth for blanching, distortion or crazing following the procedure in 7.12.5. Teeth that exhibit blanching, distortion or crazing at this stage shall be judged as failing.

7.12.2 Apparatus and materials

- 7.12.2.1 Large test tube**, with a stand, for immersion in the water bath.
- 7.12.2.2 Water bath**, capable of being maintained at boiling-water temperature $(100 \pm 1) ^\circ\text{C}$.
- 7.12.2.3 Timer**, accurate to ± 1 s.
- 7.12.2.4 Non-absorbent tissue**.
- 7.12.2.5 Desiccator**, charged with a solution capable of maintaining a relative humidity of $(50 \pm 5) \%$, in accordance with ISO 483.

The required conditions may be achieved with a solution of calcium nitrate $[\text{Ca}(\text{NO}_3)_2]$ in the closed desiccator to which an excess of the hydrate $[\text{Ca}(\text{NO}_3)_2 \cdot 4\text{H}_2\text{O}]$ has been added at least 24 h prior to testing and stored at room temperature. A conditioned room or laboratory with controlled relative humidity $(50 \pm 5) \%$ can be used instead of the desiccator.

- 7.12.2.6 Methyl methacrylate monomer** (without cross linking agent).

7.12.2.7 Absorbent paper tissues.

7.12.2.8 Flexible fibre-optic white-light inspection unit.

Lighting units designed as an adjunct to optical microscopy are appropriate.

7.12.2.9 Instrument, capable of $\times 8$ to $\times 10$ magnification.

7.12.3 Conditioning of test specimens

Submerge the second group of five teeth (see 7.12.1) in the water-filled test tube (7.12.2.1) and place in the water bath (7.12.2.2) so that the test tube does not come into contact with the sides of the water bath. Heat the water bath from room temperature to boiling temperature during a period of between 5 min and 20 min, and maintain at this temperature for $(3 \text{ h} \pm 5 \text{ min})$ (7.12.2.3).

In order to control the loss of water from the surfaces of the teeth, allow the specimens to cool gradually in water to $(23 \pm 2) ^\circ\text{C}$, then take the teeth out, remove the water from the surfaces with non-absorbent tissue (7.12.2.4), place them in the desiccator (7.12.2.5) on a perforated plate and immediately close the desiccator. Store the teeth in the desiccator for $(60 \pm 5) \text{ min}$.

7.12.4 Procedure for exposure to monomer

Immerse both groups of five teeth (see 7.12.1) in methyl methacrylate (7.12.2.6) for 5 s (7.12.2.3) and remove them. Immediately wipe any monomer from the surfaces using absorbent tissues (7.12.2.7). After 1 min, again immerse them for 5 s, without the subsequent wiping with absorbent tissues, and then allow them to dry on a non-absorbent towel for $(120 \pm 5) \text{ min}$ at $(23 \pm 2) ^\circ\text{C}$.

7.12.5 Inspection

Examine the teeth for blanching, distortion and crazing. Using two observers, inspect the teeth from a variety of angles with the aid of the light (7.12.2.8) and the magnifying instrument (7.12.2.9) for compliance with the requirements of 5.3.2.

NOTE Some cracks present will only become visible when viewed and illuminated from certain angles.

7.13 Colour stability of synthetic polymer teeth

7.13.1 General

Perform the test in accordance with ISO 7491:2000 with five shades of Type 1 teeth and five shades of Type 2 teeth.

7.13.2 Test specimens

Select two matched pairs of teeth of each shade; store one of each pair in water at $(37 \pm 5) ^\circ\text{C}$ for $(24 \pm 1) \text{ h}$ prior to exposure. Keep the remaining teeth in the dark at $(23 \pm 2) ^\circ\text{C}$ until colour comparison. In order to clamp the teeth in the specimen holder (see ISO 7491:2000, 3.1.3.2), the teeth can be ground on the lingual side.

7.14 Dimensional stability of synthetic polymer teeth

7.14.1 Apparatus and materials

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

7.14.1.2 Dental modelling wax.

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

7.14.2 Procedure

Select an appropriate anterior or posterior tooth. Prepare the tooth for testing by grinding (7.14.1.1) two parallel flat surfaces at the positions of maximum width. Mount the tooth on a (15 ± 5) mm cube of wax (7.4.1.2) with the occlusal surface uppermost and the ridge lap surface embedded in the wax. Measure the maximum mesio-distal dimension of the tooth with the micrometer (7.14.1.3).

After taking this reading, invest the tooth and wax block in dental gypsum and process it to a denture base polymer as specified in 7.11. Again, measure the maximum width of the tooth. Examine the results for compliance with 5.3.4.

8 Marking, labelling, packaging, and information to be supplied by the manufacturer

8.1 Marking, labelling and packaging

The teeth shall be supplied in mounted sets in containers that protect the contents against damage during normal transport, storage and handling. The following information shall be clearly marked on the mounts or packages:

- a) manufacturer's brand name;
- b) mould designation (see 8.2.1);
- c) shade designation (see 8.2.2).

The manufacturer's name or brand name shall appear, in clear and indelible markings, on each container or on a label securely attached to each container.

8.2 Information to be supplied by manufacturer

8.2.1 Mould chart

The manufacturer shall make available a mould chart depicting all the shapes and sizes of teeth (scale 1:1) available with the dimensions in metric units as follows:

- a) Type 1: The overall dimensions (l_1, l_3) of a complete set of maxillary and mandibular teeth. The maximum dimensions (l_2, l_4 and h_1, h_2) of the crowns of the maxillary and mandibular central incisors (21, 31).
- b) Type 2: The overall dimensions (l_5, l_7) of a maxillary and mandibular half set. The maximum dimensions (l_6, l_8) of the crowns of the maxillary and mandibular left first molars (26, 36).

See Figure 1 for these dimensions given in parentheses. The numerical tooth designations given in parentheses are in accordance with ISO 3950:1984.

The mould chart shall include the facio-lingual profile views of the maxillary and mandibular left central incisors (21, 31) and the maxillary and mandibular left premolars (24, 34) for all the individual moulds.

The number of this International Standard, its year of publication, i.e. ISO 22112:2005, and the year of publication of the mould chart shall be indicated on the mould chart.

When the product is not fluorescent, this fact shall be marked on the mould chart.

8.2.2 Shade guide

The manufacturer shall make available a shade guide with the shade guide teeth corresponding in colour to each shade of Type 1 and Type 2 teeth available in the product line.

8.3 Manufacturer's instructions

When special treatment (for example, grinding) is required in order to achieve adequate bonding of synthetic polymer teeth to denture base polymer, guidance on this shall clearly be stated on the mould chart or made available by the manufacturer in separate instructions.

Bibliography

- [1] ISO 3336:1993, *Dentistry — Synthetic polymer teeth*
- [2] ISO 4824:1993, *Dentistry — Ceramic denture teeth*
- [3] ISO 4824:1993/Amd 1:1997, *Dentistry — Ceramic denture teeth — Amendment 1*
- [4] ISO 7405, *Dentistry — Preclinical evaluation of biocompatibility of medical devices used in dentistry — Test methods for dental materials*
- [5] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

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