ISO/FDIS 5139:2023(E)
ISO TC 106/SC 9/WG 6
Secretariat: JISC

Dentistry — Polymer-based composite machinable blanks

First edition
Date: 2022-~~11-24~~01-06

~~FDIS stage~~

Contents

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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 106, *Dentistry*, Subcommittee SC 9, *Dental CAD/CAM ~~system~~systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 55, *Dentistry,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Specific qualitative and quantitative test methods for demonstrating freedom from unacceptable biological hazards are not included in this document, but it is recommended that, for the assessment of possible biological hazards, reference should be made to ISO 10993--1 and ISO 7405.

Requirements for the materials properties of polymer-based composite machinable blanks are not included in this document, but these requirements will be included in a future ~~revision~~edition of ISO 10477.

The test method to determine the bonding properties between blank and holding jig is not included in this document, but it is recommended to adopt the test procedure given in Annex C when measuring the bonding properties between blank and holding jig.

Dentistry — Polymer-based composite machinable blanks

1 Scope

This document specifies the characteristics of polymer-based composite machinable blanks with respect to the milling process and provides the test methods that address the clinical issues specific to those materials. In addition, this document specifies the items to be described on the packaging and materials, as well as descriptions to be included in the instructions for use.

The polymer-based composite machinable blanks covered in this document are blanks that are used for fabricating permanent dental restorative appliances (e.g. single crowns or inlays) by milling processes. They do not include large-sized blanks (e.g. discs) that allow for fabrication of two or more units of crowns or bridges from one blank or materials for temporary use.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1942, *Dentistry — Vocabulary*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods*

ISO 4049:2019, *Dentistry — Polymer-based restorative materials*

ISO 6344-3, *Coated abrasives — Determination and designation of grain size distribution — Part 3: Micrograt sizes P240 to P5000*

ISO 6872:2015, *Dentistry — Ceramic materials*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 18675:2022, *Dentistry — Machinable ceramic blanks*

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
polymer-based composite machinable blank
piece of solid *polymer-based composite* (3.2) that is subjected to subtractive methods to remove material from the piece leaving the final desired part

3.2

polymer-based composite
polymer-based dental material including either organic filler or inorganic filler, or both fillers that have been treated by a coupling agent to ensure chemical bonding with the polymeric matrix

3.3
holding jig
mandrel
jig that attaches a composite resin block to be mounted for milling machine

4 Characteristics

4.1 Requirement

Measure five product blanks in accordance with the method described in 6.2. The dimensions of all blanks shall not be smaller than 0,25 mm nor larger than 1,00 mm than the size specified in Clause 8 d).

4.2 Recommendations

4.2.1 Machining damage

The machining damage of blanks should be evaluated in accordance with the methods described in 6.3.

4.2.2 Machinability

The machinability of blanks should be evaluated using the test method for merlon fracture test given in ISO 18675:2022, Clause 8.

4.2.3 Bonding properties between blank and holding jig

The bonding properties between blank and holding jig should be evaluated. An example of the test method for bonding properties is described in Annex C.

5 Sampling

The test sample shall consist of one or more packages for retail of one selected shade, corresponding to the purpose of the test, from a single batch and contain sufficient material to carry out the specified tests, plus an allowance for any necessary repetition of tests.

6 Test methods

6.1 General

Test specimens shall be prepared and tested at (23 ± 2) °C. The relative humidity shall be not less than 30 %.

6.2 Size of blanks

6.2.1 Apparatus

Micrometer, with an accuracy of 0,01 mm.

6.2.2 Procedure

Measure five blanks using a micrometer at the points where the size is specified by the manufacturer in the instructions for use Clause 8 d).

6.3 Machining damage

6.3.1 General

Perform machining damage test in accordance with the method described in ISO 18675:2022, Clause 7. Specifically, measure the three-point flexural strength for the control specimen fabricated by cutting and grinding and for the machined specimen fabricated using a milling machine, and compare the results between these specimens.

6.3.2 Apparatus

6.3.2.1 Oven, set at (37 ± 1) °C.

6.3.2.2 Universal mechanical testing machine, capable of a crosshead speed of (1 ± 0,5) mm/min; for example, see ISO 7500-~~-~~1.

6.3.2.3 Fixture for three-point bending, consisting of support rollers (1,5 mm to 2 mm in diameter, tolerances are ~~±~~ ± 0,2 mm) positioned with their centres (12 ± 0,1) mm apart. The load shall be applied at the midpoint between the supports by means of a third roller (1,5 mm to 2 mm in diameter, tolerances are ~~±~~ ± 0,2 mm). Rollers shall be made from hardened steel or other hard material having a hardness greater than 40 HRC (Rockwell C-scale) and have a smooth surface with a roughness less than 0,5 µm Ra. It is recommended to measure the actual spacing between the centres of the support rollers (*l*) to ensure it is (12 ± 0,1) mm.

6.3.2.4 Micrometer, with an accuracy of 0,01 mm.

6.3.2.5 CAD/CAM milling machine

6.3.3 Water

Water shall conform to ISO 3696:1987, Grade 2.

6.3.4 Preparation of test specimens

6.3.4.1 Test specimen dimensions

~~Width:~~The width is *w* = (4 ± 0,2) mm (dimension of the side at right angles to the direction of the applied load~~)~~).

~~Thickness:~~The thickness is *b* = (1,2 ± 0,2) mm (dimension of the side parallel to the direction of the applied load~~)~~).

Lengths shall be at least 2 mm longer than the test span (12 ± 0,1) mm.

When the edge chamfer is necessary, it shall be prepared in accordance with the method described in ISO 6872:2015, 7.3.1.2.1.

NOTE The dimensions of test specimen specified in this document are not verified for the measurement of flexural strength absolute values for composite resin materials. There are some published scientific papers in which flexural strength test of composite machinable blanks were performed at this size.

6.3.4.2 Test parameters

The test span~~:~~ is *l* = (12 ± 0,5) mm (centre-to-centre distance between support rollers).

6.3.4.3 Control specimen

Prepare test specimens from blanks. Polish the surface of specimen until the required thickness is reached. Perform the final polishing using P1000 or finer silicon carbide waterproof abrasive paper. Confirm the absence of chipping in the centre portion.

Specimens shall be plane-parallel for bending test. Prepare five specimens. Store the specimen in water at (37 ± 1) °C for 7 d ± 4 h until the start of testing.

NOTE An example of detailed method is shown in Annex A.

6.3.4.4 Machined specimen

Fabricate test specimens of the abovementioned dimensions by the milling machine.

It is desirable to adopt a milling design and processing path that avoids bending test specimens during milling. It is also desirable to arrange appropriate supports in the milling design for this purpose. When setting the supports, ensure that the supports are located on the outer area of the test specimen for the three-point bending test.

After the machining process, cut off the support portion using an appropriate method (e.g. diamond disks).

Prepare five specimens having plane-parallel surfaces. Report the number of specimens that cannot be tested due to machining failure.

Store the specimen in water at (37 ± 1) °C for 7 d ± 4 h until the start of testing. The test specimens are subjected to the bending test without further surface polishing as is used for the control specimens.

NOTE Annex B gives an example of a specific milling design for test specimens from blanks.

6.3.5 Procedure

Measure the cross-sectional dimensions of each test specimen to ±0,01 mm. Then, place a test specimen centrally on the supports of the test machine so that the load is applied to a 4 mm wide face along a line perpendicular to the long axis of the test specimen and determine the maximum load required to break the test specimen. Use a crosshead speed of (1 ± 0,5) mm/min. Repeat the procedure with the remaining test specimens.

6.3.6 Expression of results

6.3.6.1 Calculation

Calculate the flexural strength, σ, in megapascals:

$$\sigma = \frac{3Fl}{2wb^2} \quad (1)$$

where

F is the maximum applied load, in newtons;

l is the distance, in millimetres, between the supports, i.e. 12 mm;

w is the width of the test specimen, in millimetres;

b is the thickness of the test specimen, in millimetres.

Calculate the mean and standard deviation of the flexural strength values for control and machined specimens, followed by the percentage of change in flexural strength of the machined group as compared with that of the control group.

6.3.6.2 Test report

Test report for machining damage should be in accordance with ISO 18675:2022, 7.3. The documentation of the test shall include at least the following information:

a) name of manufacturer, brand name, shade – if applicable;

b) size of the blank(s);

c) lot-number of the blank(s);

d) fabrication conditions of the control specimens including sectioning methodology and finishing of the surface;

e) length, width, and height of the bar test specimens;

f) characterization (manufacturer, brand name, accuracy, etc.) of the micrometer gauge or another appropriate device used to perform all necessary dimension measurements;

g) characterization (manufacturer, brand name, accuracy, etc.) of the milling machine used to fabricate the specimens as a well as machining conditions (bur size, bur grit, feed rate if known) and software (manufacturer and version) used for machining;

h) instruments (manufacturer, brand-name, accuracy, etc.) used for mechanical testing and conditions of the test (such as crosshead speed, load cell);

i) flexural strength values of each specimen as well as mean and standard deviation of each group – control and machined;

j) percentage of change in flexural strength of the machined group as compared to the control group;

k) number of specimens that cannot be tested due to machining failure;

l) appropriate statistical analysis to determine significant differences;

m) International Standard used (including its year of publication);

n) any deviation from recommended test procedure and unusual features observed;

o) date of test.

7 Packaging and labelling

7.1 Packaging

The components of the polymer-based composite machinable blank shall be supplied in such containers that the contents are adequately protected and the quality of the polymer-based composite machinable blank is not adversely altered before the expiry date marked on the package and the container [see 7.2.2 f)].

7.2 Labelling

7.2.1 General

The relevant information shall be provided on the outer pack, polymer-based composite machinable blank, or included in the instructions for use.