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PD ISO/TS 11405:2015



BSI Standards Publication

Dentistry — Testing of adhesion to tooth structure

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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.

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 on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT), see the following URL: [Foreword - Supplementary Information](#).

The committee responsible for this document is ISO/TC 106, *Dentistry*, Subcommittee SC 1, *Filling and restorative materials*.

This third edition cancels and replaces the second edition (ISO/TS 11405:2003), which has been technically revised.

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Introduction

Adhesion in restorative dentistry is an important topic. It is the intention of this Technical Specification to describe different laboratory and clinical procedures whereby the effect or quality of a bond between a dental material and tooth structure may be substantiated. By gaining experience with different testing methods, a correlation between laboratory and clinical performance of the materials may be sought.

Adhesive materials are used in many types of restorative and preventive work. Even if the stress on the bond in most circumstances may be defined as either tensile, shear, or a combination of these, there are no specific laboratory or clinical tests which may be valid for all the various clinical applications of adhesive materials.

The relative performance of materials that are claimed to bond to tooth structure has been examined by laboratory assessment of bond strength. While bond strengths may not predict exact clinical behaviour, they could be useful for comparing adhesive materials.

ISO 29022^[1] describes the notched-edge shear bond strength test which is an important publication in the subject.

[Annex A](#) lists several published laboratory methods for tensile bond strength measurement.

Adhesion testing is also common in general materials in science and a publication listing where many systems have been provided with information.^[2]

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Dentistry — Testing of adhesion to tooth structure

1 Scope

This Technical Specification gives guidance on substrate selection, storage, and handling as well as essential characteristics of different test methods for quality testing of the adhesive bond between restorative dental materials and tooth structure, i.e. enamel and dentine. It includes a tensile bond strength measurement test, a test for measurement of marginal gaps around fillings, a microleakage test, and gives guidance on clinical usage tests for such materials. Some specific test methods for bond strength measurements are given for information in [Annex A](#).

This Technical Specification does not include requirements for adhesive materials and their performance.

2 Normative references

The following referenced documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1942:2009, *Dentistry — Vocabulary*

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

ISO 3823-1:1997, *Dental rotary instruments — Burs — Part 1: Steel and carbide burs*

ISO 6344-1:1998, *Coated abrasives — Grain size analysis — Part 1: Grain size distribution test*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

3 Terms and definitions

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

3.1

adhere

to be in a state of *adherence* ([3.2](#))

3.2

adherence

state in which two surfaces are held together by interfacial forces

3.3

adherend

body that is held or is intended to be held to another body by an *adhesive* ([3.5](#))

3.4

adhesion

state in which two surfaces are held together by chemical or physical forces, or both, with the aid of an *adhesive* ([3.5](#))

3.5

adhesive

substance capable of holding materials together