TECHNICAL REPORT

ISO TR 11175

First edition
1993-08-15

Dental implants — Guidelines for developing dental implants

Implants dentaires — Guide pour le développement d'un implant dentaire

Reference number
ISO/TR 11175:1993(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.

The main task of technical committees is to prepare International Standards, but in exceptional circumstances a technical committee may propose the publication of a Technical Report of one of the following types:

— type 1, when the required support cannot be obtained for the publication of an International Standard, despite repeated efforts;

— type 2, when the subject is still under technical development or where for any other reason there is the future but not immediate possibility of an agreement on an International Standard;

— type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical Reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standards. Technical Reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 11175, which is a Technical Report of type 3, was prepared by Technical Committee ISO/TC 106, *Dentistry*, Sub-Committee SC 8, *Dental implants*.

The intention is to establish general guidelines in a Technical Report for dental implants.

The present document is based on the recommendations of the "Consensus Conference on Dental Implants" sponsored by the National Institutes of Health, held in Washington, USA, in June 1988.

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Printed in Switzerland

Dental implants — Guidelines for developing dental implants

1 Scope

This Technical Report provides general guidelines, principles and concepts relevant to the production of a given type of dental implant: it does not aim to define the ideal dental implant.

This Technical Report includes technical aspects and biological aspects (see 5.1 and 5.2 respectively).

2 References

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

ISO 6018:1987, *Orthopaedic implants — General requirements for marking, packaging and labelling.*

ISO/TR 7405:1984, *Biological evaluation of dental materials.*

ISO 9001:1987, *Quality systems — Model for quality assurance in design/development, production, installation and servicing.*

ISO/TR 9966:1989, *Implants for surgery — Biocompatibility — Selection of biological test methods for materials and devices.*

ISO/TR 10451:1991, *Dental implants — State of the art — Survey of materials.*

3 Definitions

For the purposes of this Technical Report, the definitions given in ISO 1942-1 and the following definitions apply.

3.1 dental implant: Device specially designed to be placed surgically within or on the mandibular or maxillary bone as means of providing resistance to displacement of a *dental prosthesis*.

It can be either transgingival (with part of the implant emerging from gingiva for direct abutment), or fully embedded under the gingiva (only aiming at the support of a removable prosthesis). [ISO 1942-1:1989, definition 1.080]

3.2 transendodontic implant or transradicular implant: Rod specially designed and/or prepared to be inserted through the root canal or through the root into the bone. [ISO 1942-1:1989, definition 1.081]

3.3 endosseous implant: Dental implant placed partly or entirely within bone.

3.4 fully embedded dental implant: Dental implant which is fully covered by gingiva or mucosa.

3.5 transgingival [transmucosal] implant: Dental implant that has extension(s) into the oral cavity through the mucosa for providing resistance to the displacement of a dental prosthesis.

3.6 subperiosteal implant: Dental implant placed between periosteum and the surface of the bone.

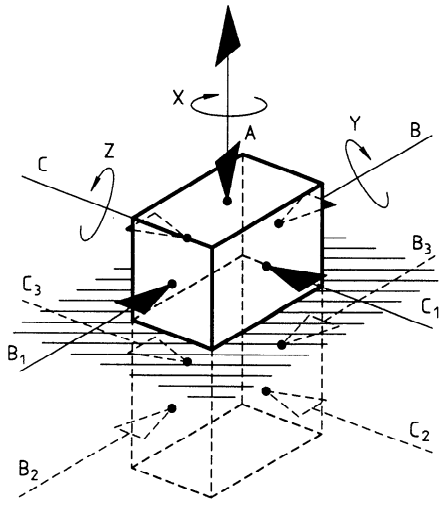
3.7 intramucosal implant: Dental implant placed into the soft tissue lining of the oral cavity.

3.8 transosseous implant: Dental implant that is placed through the superior and inferior border of the mandible, usually through an extra oral incision.

4 Dental implant configuration

4.1 Transmucosal implants have the forces shown in figure 1.

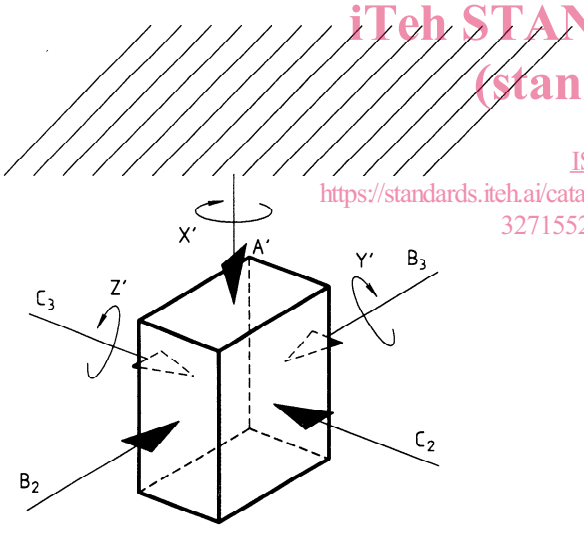
4.2 Fully embedded dental implants have the forces shown in figure 2.



Key

A	= intrusive/extrusive
B/B_1	= mesio/distal within the oral cavity
B_2 /B_3	= mesio/distal within the tissues
C/C_1	= bucco/lingual within the oral cavity
C_2 /C_3	= bucco/lingual within the tissues
X, Y and Z	= rotational

Figure 1 — Schematic force diagram of transmucosal dental implant



Key

A'	= intrusive within the tissues
B_2 /B_3	= mesio/distal within the tissues
C_2 /C_3	= bucco/lingual within the tissues
X', Y' and Z'	= rotational within the tissues

Figure 2 — Schematic force diagram of fully embedded dental implant

5 Recommendations

5.1 Technological

5.1.1 The designer of the implant should integrate all applicable information from research, and clinical and technical experience including

a) biomaterials science and biological behaviour;

b) biomechanics and biological reaction of the surrounding tissues;

c) prosthodontics including dental laboratory technology;

d) oral surgery;

e) periodontology;

f) radiology.

5.1.2 These guidelines should be used in conjunction with the quality systems in ISO 9001, including:

a) design control, including specification of materials, theoretical calculations, qualification tests, clinical trials, manufacturing information [see b)] and design records;

b) manufacturing informative data including procedures for the inspection of materials, in-process product and final product, drawings, work instructions, procedures for packaging, labelling, sterilization and quality records.

5.1.3 The intrinsic properties of the constituent raw materials should be described according to the format in ISO/TR 10451.

5.1.4 Manufacturing procedures relating to the implant including cutting up, machining, finishing surface treatment, sterilization and decontamination should be indicated.

5.2 Biological

5.2.1 These recommendations have three objectives:

a) to recognize the specific needs for safety and efficacy relating to various types of dental implant;

b) to define the methods for evaluating the safety and the efficacy:

— at the level of the constituent materials,

— at the level of the dental implant itself by *in vitro* and *in vivo* tests;

c) to be consistent with good clinical practices.

5.2.2 The establishment of these recommendations will take into account International Standards, and Technical Reports ISO/TR 7405 and ISO/TR 9966.

6 Testing

NOTE 1 Clinical evaluation makes a distinction between the "horizontal standards" formulated by ISO/TC 194/WG4 on clinical investigation protocols and the "vertical standards" to be developed for the testing of dental implants by ISO/TC 106/SC8/WG1 and WG2.

6.1 The test methods should simulate the stresses to which the implant is subjected during insertion as well as in function with added suprastructure in place. The intention is to include fatigue-testing and electrochemical phenomena.

6.2 The holding device used in these tests should provide fixation of the implant in a configuration simulating the insertion situation, and appropriate directional loads should be applied and recorded.

6.3 Test methods should be devised to simulate the behaviour of the implant *in situ*, including fatigue-testing.

7 Marking, labelling, packaging

The manufacturer should provide instructions to the users that include the handling and the insertion of the implant, with required instrumentation in a manner similar to that for other orthopaedic implants as specified in ISO 6018.

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UDC 616.314-089.843

Descriptors: dentistry, medical equipment, surgical implants, dental implants, specifications, materials specifications, operating requirements, biological requirements, tests, marking, general conditions.

Price based on 3 pages