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Implants for surgery — Ceramic materials —

Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement

Implants chirurgicaux — Produits céramiques —

Partie 2: Matériaux composites à matrice alumine de haute pureté renforcée par des grains de zircone

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Foreword

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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 6474-2 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

ISO 6474 consists of the following parts, under the general title *Implants for surgery — Ceramic materials*:

— *Part 1: Ceramic materials based on high purity alumina*

— *Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement*

Introduction

No known surgical implant material has ever been found to be completely free of adverse reactions in the human body. However, long-term clinical experience of use of alumina and zirconia (the main components of the material referred to in this part of ISO 6474) as biomaterials has shown that an acceptable level of biological response can be expected when the material is used in appropriate applications.

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Implants for surgery — Ceramic materials —

Part 2:
Composite materials based on a high-purity alumina matrix with zirconia reinforcement

1 Scope

This part of ISO 6474 specifies the characteristics of, and corresponding test methods for, a biocompatible and biostable ceramic-bone-substitute material based on a zirconia-reinforced, high-purity alumina matrix composite for use as a component in orthopaedic joint prostheses.

This part of ISO 6474 is intended for composite materials which are based on an alumina matrix, i.e. alumina as the dominating phase in the composite with a mass fraction of > 60 %, similar to the material described in ISO 6474-1, but extended by means of a certain amount of zirconia and other defined ingredients.

NOTE The required properties in this part of ISO 6474 differ from those in ISO 6474-1 with respect to strength and fracture toughness. Furthermore, there are requirements specifically applicable for zirconia-containing materials (see ISO 13356).

In the material composition as defined in this part of ISO 6474, additional additives are listed. Typical additives for alumina or zirconia ceramics are Mg, Y, Ce and others. Such additives can be useful in order to improve the mechanical properties and/or the chemical stability of the alumina-zirconia composite material. This part of ISO 6474 does not cover the biocompatibility (see ISO 10993-1) of these inorganic additives in the human body. It is the responsibility of the manufacturer to evaluate the biocompatibility of the specific ceramic composite material which is produced within the framework of this part of ISO 6474.

2 Normative references

The following 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 12677, *Chemical analysis of refractory products by X-ray fluorescence (XRF) — Fused cast bead method*

ISO 13356, *Implants for surgery — Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)*

ISO 14242-1, *Implants for surgery — Wear of total hip-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test*

ISO 14243-1, *Implants for surgery — Wear of total knee-joint prostheses — Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test*

ISO 14704, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for flexural strength of monolithic ceramics at room temperature*

ISO 14705, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for hardness of monolithic ceramics at room temperature*

ISO 15732, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for fracture toughness of monolithic ceramics at room temperature by single edge precracked beam (SEPB) method*

ISO 16428, *Implants for surgery — Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices*

ISO 17561, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for elastic moduli of monolithic ceramics at room temperature by sonic resonance*

ISO 18754, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Determination of density and apparent porosity*

ISO 18756, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Determination of fracture toughness of monolithic ceramics at room temperature by the surface crack in flexure (SCF) method*

ISO 20501, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Weibull statistics for strength data*

ISO 22214, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Test method for cyclic bending fatigue of monolithic ceramics at room temperature*

ISO 23146, *Fine ceramics (advanced ceramics, advanced technical ceramics) — Test methods for fracture toughness of monolithic ceramics — Single-edge V-notch beam (SEVNB) method*

CEN/TS 14425-5, *Advanced technical ceramics — Test methods for determination of fracture toughness of monolithic ceramics — Part 5: Single-edge V-notch beam (SEVNB) method*

EN 623-2, *Advanced technical ceramics — Monolithic ceramics — General and textural properties — Part 2: Determination of density and porosity*

EN 623-3:1993, *Advanced technical ceramics — Monolithic ceramics — General and textural properties — Part 3: Determination of grain size and size distribution (characterized by the Linear Intercept Method)*

EN 843-1, *Advanced technical ceramics — Monolithic ceramics — Mechanical properties at room temperature — Part 1: Determination of flexural strength*

EN 843-2, *Advanced technical ceramics — Mechanical properties of monolithic ceramics at room temperature — Part 2: Determination of Young's modulus, shear modulus and Poisson's ratio*

EN 843-4, *Advanced technical ceramics — Mechanical properties of monolithic ceramics at room temperature — Part 4: Vickers, Knoop and Rockwell superficial hardness*

EN 843-5, *Advanced technical ceramics — Mechanical properties of monolithic ceramics at room temperature — Part 5: Statistical analysis*

ASTM C1161, *Standard Test Method for Flexural Strength of Advanced Ceramics at Ambient Temperature*

ASTM C1198, *Standard Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Sonic Resonance*

ASTM C1239, *Standard Practice for Reporting Uniaxial Strength Data and Estimating Weibull Distribution Parameters for Advanced Ceramics*

ASTM C1259, *Standard Test Method for Dynamic Young's Modulus, Shear Modulus, and Poisson's Ratio for Advanced Ceramics by Impulse Excitation of Vibration*

ASTM C1327, *Standard Test Method for Vickers Indentation Hardness of Advanced Ceramics*

ASTM C1331, *Standard Test Method for Measuring Ultrasonic Velocity in Advanced Ceramics with Broadband Pulse-Echo Cross-Correlation Method*

ASTM C1421, *Standard Test Method for Determination of Fracture Toughness of Advanced Ceramics at Ambient Temperature*

ASTM C1499, *Standard Test Method for Monotonic Equibiaxial Flexural Strength of Advanced Ceramics at Ambient Temperature*

3 Classification

3.1 Material types

The material shall be classified as either Type X or Type S:

— Type X: extra-high strength;

— Type S: standard high strength.

Ceramic materials of Type X are intended for applications where extra-high strength of the material is required (e.g. thin-walled bearings for hip or knee joint replacements).

Ceramic materials of Type S are intended for applications where an improved strength in comparison to pure alumina is recommended (e.g. standard hip joint replacement).

In particular, the strengths of ceramic materials of type X and type S are higher than for materials according to type A as defined in ISO 6474-1.

3.2 Test categories

3.2.1 General

The required tests shall be distinguished in category 1 and category 2.

3.2.2 Category 1: required tests representative for periodical production control

The following tests shall be performed for periodical production control:

a) bulk density (see 5.1);

b) chemical composition (see 5.2);

c) microstructure (see 5.3);

d) strength (see 5.4);

e) radioactivity (see 5.5).

3.2.3 Category 2: required tests representative for the general material specification

The manufacturer shall define the general material specification. In addition to all the tests listed in 3.2.2, the following tests shall be performed for qualification of the material specification:

a) fracture toughness (see 5.6);

b) hardness (see 5.7);

c) Young's modulus (see 5.8);

d) cyclic fatigue (see 5.9);

e) accelerated ageing, including strength, cyclic fatigue and wear (see 5.10).

3.3 Material properties

To fulfil the requirements of this part of ISO 6474, the material shall meet the limits for material properties as specified in Tables 1 and 2.

Table 1 — Limits for material property category 1

Property	Unit	Property category	Requirement		Subclause	References
			Type X	Type S		
Average relative bulk density	%	1	≥ 99	≥ 99	5.1	ISO 18754 EN 623-2
Chemical composition:						
Alumina, Al_2O_3	% mass fraction	1	60 to 90	60 to 90	5.2	ISO 12677
Zirconia, $ZrO_2 + HfO_2$	% mass fraction	1	10 to 30	10 to 30		
Amount of HfO_2 in ZrO_2	% mass fraction	1	≤ 5	≤ 5		
Intended additives	% mass fraction	1	≤ 10	≤ 10		
Total amount of impurities	% mass fraction	1	≤ 0,2	≤ 0,2		
Microstructure:						
Alumina linear intercept grain size	µm	1	≤ 1,5	≤ 1,5	5.3	EN 623-3
Zirconia linear intercept grain size	µm	1	≤ 0,6	≤ 0,6		
Standard deviation alumina	%	1	≤ 25	≤ 25		
Standard deviation zirconia	%	1	≤ 40	≤ 40		
Material strength; alternative 1) or 2):					5.4	
1 a) Mean biaxial flexural strength	MPa	1	≥ 600	≥ 450	5.4.2	ASTM C1499
1 b) Weibull modulus		1	≥ 8	≥ 8	5.4.4	ISO 20501 EN 843-5 ASTM C1239
2 a) Mean 4-point flexural strength	MPa	1	≥ 1 000	≥ 750	5.4.3	ISO 14704 EN 843-1 ASTM C1161
2 b) Weibull modulus		1	≥ 8	≥ 8	5.4.4	ISO 20501 EN 843-5 ASTM C1239
Radioactivity (measured on raw materials)						
Zirconia Other intended additives	Bq/kg	1 See 5.5	≤ 200	≤ 200	5.5	ISO 13356

Table 2 — Limits for material property category 2

Property	Unit	Property category	Requirement		Subclause	References
			Type X	Type S		
Fracture toughness, alternatives 1) to 3)					5.6	
1) SEVNB	MPa $\sqrt{m}$	2	≥ 4,0	≥ 3,5	5.6.2	ISO 23146 CEN/TS 14425-5
2) SEPB	MPa $\sqrt{m}$	2	≥ 4,0	≥ 3,5	5.6.3	ISO 15732
3) SCF	MPa $\sqrt{m}$	2	≥ 4,0	≥ 3,5	5.6.4	ISO 18756 ASTM C1421
Hardness, Vickers HV1	GPa	2	≥ 16,0	≥ 15,5	5.7	ISO 14705 EN 843-4 ASTM C1327
Young's modulus	GPa	2	≥ 320	≥ 320	5.8	ISO 17561 EN 843-2 ASTM C1331 ASTM C1198 ASTM C1259
Cyclic fatigue limit: Cyclic loading in 4-point bending, 10^7 cycles		2	No failure at 400 MPa	No failure at 300 MPa	5.9	ISO 22214
Accelerated ageing: 10 h in autoclave (0,2 MPa, 134 °C) after autoclaving:					5.10	
Strength		2	Degradation ≤ 20 % in comparison to value before autoclaving *and* conformity with values given in Table 1		5.10.2	See 5.4
Cyclic loading in 4-point bending, 10^7 cycles		2	No failure at 320 MPa	No failure at 240 MPa	5.10.3	See 5.9
Wear		2	Increase ≤ 20 % in comparison to value before autoclaving		5.10.4	ISO 14242-1 ISO 14243-1 or other tests

4 Preparation of specimens

Specimens shall be produced in a similar way to the regular production of implants. The same feedstock and comparable shaping technology, high-temperature process and hard machining shall be applied. The shaping and surface finishing of the specimens shall be accomplished according to the requirements of the test.

The manufacturer shall declare and justify that the production of the specimens is equivalent to the regular production.

Finished products or portions of them can be used for the evaluation of material properties. However, due to geometric restrictions and to the risk of damage during specimen preparation, it is not recommended to produce specimens as portions of finished products for evaluation of the following material properties:

— strength (5.4);

— fracture toughness (5.6);

— cyclic fatigue (5.9).

5 Test methods

5.1 Bulk density

5.1.1 General

The bulk density shall be determined in accordance with ISO 18754 or EN 623-2. The benchmark of the bulk density depends on the selected composition of the composite. It is given as a relative density $\rho_r \geq 99$ %.

The relative density ρ_r shall be calculated in accordance with Equation (1):

$$\rho_r = \frac{\rho_m}{\rho_u} \tag{1}$$

where

ρ_m is the measured density, in g/cm^3;

ρ_u is the ultimate density, in g/cm^3.

ρ_u shall be determined either by calculation or empirically.

5.1.2 Calculation of ultimate density

For the calculation of the ultimate density ρ_u, the mass fraction and the density of each phase have to be known exactly. The ultimate density is then calculated in accordance with Equation (2):

$$\rho_u = \frac{100\ \%}{\frac{m_i}{\rho_i} + \ldots + \frac{m_n}{\rho_n}} \tag{2}$$

where

ρ_i, ρ_n are the densities of the individual components (alumina, zirconia, others);

m_i, m_n are the relative mass fractions of the components, in %.

The value of $m_i + \ldots + m_n$ is necessarily 100 %.

The theoretical density of each component for the application of Equation (2) shall be determined. Impurities can be neglected for the calculation of the theoretical density if their amount has a mass fraction of ≤ 0,2 %.

5.1.3 Empirical determination of the ultimate density

If the ultimate density cannot be calculated to a sufficient reliability, it is recommended that the ultimate density be empirically determined in accordance with the following procedure.

a) Choose a powder batch with a representative inorganic composition.

b) Produce at least 10 test pieces by sintering and hot isostatic pressing. Choose the sintering and hot isostatic pressing conditions according to the experience of the manufacturer in order to achieve the highest possible density.

c) Analyse the microstructure after this process for any evidence of residual pores.

d) If no pores can be detected, measure the density according to ISO 18754. The outer surface of the test pieces shall be ground or polished.

e) Round off the density of each test piece to two digits (x,xx g/cm^3).

f) Declare the highest value of all individual density values as the ultimate density.

5.2 Chemical composition

The chemical composition shall be determined either by X-Ray fluorescence in accordance with ISO 12677 or by Inductively Coupled Plasma-Optical Emission Spectroscopy (ICP-OES) or Inductively Coupled Plasma-Mass Spectroscopy (ICP-MS).

If applicable, the manufacturer shall document all inorganic additives which are intentionally added to the composition. Upper and lower limits for these additives shall be defined by the manufacturer. The total amount of these additives is limited to a mass fraction of 10 %.

The manufacturer shall identify elements that have an adverse impact on the properties of the composite as “impurities”. The upper limit of the total amount of these impurities has a mass fraction of 0,2 %.

It is recommended that the manufacturer define the upper and lower limits for the amount of alumina and zirconia which shall be measured in accordance with the definition of category 1 (see 3.2.2).

5.3 Microstructure

Method B of EN 623-3:1993 shall be applied for the determination of microstructure. The linear intercept grain size of the alumina grains and zirconia grains shall be determined. The grain size determination of other phases is not required.

NOTE The linear intercept method reveals a nominal average grain size for the selected position of the micrograph, not the distribution of the size of individual grains.

For selection, preparation and evaluation of the specimen, the following guidelines shall be followed:

a) the wall thickness of the selected specimens shall represent the maximum and minimum of the manufacturer’s products;

b) the position of the micrographs shall represent regions at the centre and at the skin of the selected specimens;

c) the specimen selection shall reflect the possibility of temperature deviation in the furnace;

d) using regular products as specimens for microstructure evaluation is recommended; if other specimens are used, they shall be produced in an equivalent manner to the normal manufacturing of the products;

e) the requirement for linear intercept grain size given in Table 1 shall be met at each selected position of the micrographs;

f) the standard deviation of the linear intercept grain size shall be determined from the data of all selected micrographs; the standard deviation shall meet the requirement given in Table 1.

The determination of linear intercept grain size shall be organized such that homogeneity of the regular production can be assessed to a sufficient statistical relevance. The manufacturer shall justify the organization of grain size determination for his specific manufacturing process. It is recommended that the manufacturer analyse the reliability, repeatability and maintenance of the manufacturing process with respect to microstructure (e.g. validation) and utilize these data for the organization of the regular production control. If this detailed analysis is accomplished successfully, the regular production control of the microstructure can be performed with a reduced amount of specimens and micrographs.

NOTE 1 ASTM E112 cannot be applied as it is not intended for composite materials.

NOTE 2 The linear intercept grain size is inevitably smaller than the genuine grain size. Further details and references to literature are given in EN 623-3.

For improved contrast and grain boundary detection of zirconia and alumina, it is recommended that a secondary electron detector in a scanning electron microscope (SEM) at a high acceleration voltage be used.

5.4 Strength properties

5.4.1 General

The strength properties shall be determined using either the biaxial flexural strength test described in 5.4.2 or the 4-point bending strength test (see 5.4.3). A total of at least 30 specimens for each test shall be used. The data shall be analysed in accordance with Weibull statistics (see 5.4.4).

It is recommended that the surface finish which was used for the test for ease of data interpretation in terms of the product's intended use be specified.

For an as-fired surface, specify whether the surface was made by pressing or green machining.

5.4.2 Biaxial flexural strength

The biaxial flexural strength test shall be performed in accordance with ASTM C1499. The surfaces of the specimen can be either as fired, ground or polished. Within the scope of this part of ISO 6474, the dimensions of the specimen and test rig specified in Table 3 shall be used.

Table 3 — Dimensions of biaxial flexural strength specimens and test rig

Dimensions in millimetres

Dimension	Value	Tolerances	Abbreviation
Circular specimen diameter	36	±1,0	D
Specimen thickness	2	±0,1	h
Support ring diameter	30	±0,1	D_S
Load ring diameter	12	±0,1	D_L
Radius of contact ring	2	±0,2	r
NOTE The abbreviations are in accordance with ASTM C1499.			

5.4.3 4-point flexural strength

The 4-point flexural strength shall be determined in accordance with ISO 14704, EN 843-1 or ASTM C1161. The surfaces of the specimen shall be either ground or polished. Within the scope of this part of ISO 6474, the dimensions of the specimen and test rig specified in Table 4 shall be used.

Table 4 — Dimensions of 4-point flexural specimens and test rig

Dimensions in millimetres

Dimension	Value	Tolerances	Abbreviation
Specimen width	4	±0,2	b
Specimen thickness	3	±0,2	d
Specimen length	≥45	—	L_T
Support span	40	±0,1	L
Loading span	20	±0,1	L_i
NOTE The abbreviations are in accordance with ISO 14704.			

5.4.4 Weibull modulus

The strength data from the biaxial flexural tests or the 4-point flexural tests shall be analysed in accordance with ISO 20501, EN 843-5 or ASTM C1239 using Weibull statistics. For the test report, the mean strength and the Weibull modulus shall be used. These parameters shall meet the limits given in Table 1.

5.5 Radioactivity

The radioactivity shall be determined in accordance with ISO 13356. Other methods are also acceptable if sufficient accuracy and reliability is provided. As test specimens, the raw material powders shall be used, i.e. the materials before mixture of other ingredients. All components shall meet the limits given in Table 2.

Radioactivity is particularly expected for zirconia. Other raw materials used by the manufacturers could also be expected to show radioactivity. It is thus required that the radioactivity of these raw materials be determined in accordance with the requirements of test category 1.

Alumina and most additives for technical ceramics do not show any radioactivity. For these raw materials, no analysis of radioactivity is necessary.

5.6 Fracture toughness

5.6.1 General

The fracture toughness of the material shall be determined using one of the methods referred to in 5.6.2 to 5.6.4. A minimum of 5 specimens for each test shall be used. The required value refers to the mean value of the test series.

5.6.2 SEVNB

The single edge V-notch bending test method (SEVNB) in accordance with ISO 23146 or CEN/TS 14425-5 shall be used. The notch tip radius shall be minimized, preferably to less than 10 µm.

5.6.3 SEPB

The single edge precracked beam test method (SEPB) in accordance with ISO 15732 shall be used.

5.6.4 SCF

The surface crack in flexure test method (SCF) in accordance with ISO 18756, ASTM C1421, EN 843-4 or ASTM C1327 shall be used.

5.7 Hardness

For the characterization of the hardness of the material, the Vickers hardness method in accordance with ISO 14705 shall be used. A test load of 9,81 N (HV1) shall be applied.

The hardness depends on the amount of zirconia and other additives in the alumina matrix. Thus, a limit is defined in Table 2 which is representative for a ceramic composite with a high zirconia content. It is recommended that the manufacturer identify a typical value and define an appropriate lower limit for his specific composition.

5.8 Young's modulus

Young's modulus shall be determined in accordance with ISO 17561, EN 843-2, ASTM C1331, ASTM C1198 or ASTM C1259.

Young's modulus depends on the amount of zirconia and other additives in the alumina matrix. Thus, a limit is defined in Table 2 which is representative for a ceramic composite with a high zirconia content. It is recommended that the manufacturer identify a typical value and define an appropriate lower limit for his specific composition.

5.9 Cyclic fatigue

For the characterization of the cyclic fatigue behaviour of the material, the cyclic flexural fatigue method shall be used in accordance with ISO 22214. The same test specimen and test rig geometry as described in 5.4.3 (4-point flexural strength) shall be used.

The test conditions shall be defined as described in Table 5.

Table 5 — Conditions of cyclic fatigue test

Test condition	Value
Environment	Physiological saline solution [a], 18 °C to 40 °C
Cyclic rate	≤ 20 Hz
σ_{max}	See Table 1
Stress ratio	0,1 ($\sigma_{min}/\sigma_{max}$)
Waveform	Sinusoidal
Test cycles	≥ 10^7
Number of specimens	≥ 5

[a] In accordance with ISO 16428.

5.10 Accelerated ageing

5.10.1 General

This test describes the stability of the material in a hydrous environment. In particular, the test conditions simulate the interaction of zirconia with water at an elevated temperature. The test is useful for determining any material degradation due to hydrothermal ageing.

The test shall be carried out using a suitable autoclave in water vapour at (134 ± 2) °C for a period of 10 h. The autoclave used for this test shall achieve a nominal pressure of 0,2 MPa at this temperature. Specimens shall be used as described in 5.4, 5.9 and 5.10.4, respectively.

In order to assess the effect of material degradation due to hydrothermal ageing, the tests specified in 5.10.2 to 5.10.4 shall be performed after autoclaving.

5.10.2 Strength

Strength tests shall be performed as described in 5.4 and the limits given in Table 2 shall be met after autoclaving.

5.10.3 Cyclic fatigue limit

Cyclic fatigue tests shall be performed as described in 5.9 using a reduced stress level in accordance with Table 2.

5.10.4 Wear resistance

Within the scope of this part of ISO 6474, it is assumed that the wear behaviour could be affected by surface degradation of the material due to hydrothermal ageing, which is considered to be a specific material property. It is thus required that wear behaviour be tested before and after accelerated hydrothermal ageing of the ceramic components.

The wear test shall be selected in accordance with the intended application, in particular considering the materials used for the wear couple of the implant. Either a simulation of the intended application [e.g. ISO 14242-1 (hip) or ISO 14243-1 (knee)] or a simplified wear test (e.g. ring on disc, pin on disc) shall be used.

The wear performance shall be determined quantitatively, e.g. the wear volume or weight loss of both components of the wear couple. If there is an increase in wear after accelerated ageing, the limits given in Table 2 shall be met.

In ISO 13356, the accelerated ageing test is combined with measurement of the monoclinic phase content. An upper limit of monoclinic phase content after ageing is defined for pure zirconia materials. Such a limit is not required within the scope of this part of ISO 6474 because the total volume of zirconia in the composite is approximately 20 % or less. This applies also to the theoretical case where all the zirconia is monoclinic, in which case the total proportion of the monoclinic phase in the composite is $\leq$ 20 %. However, it is recommended that the manufacturer also analyse the monoclinic-phase content after ageing and discuss the results with respect to the mechanical test results.

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Bibliography

[1] ISO 6474-1, *Implants for surgery — Ceramic materials — Part 1: Ceramic materials based on high purity alumina*

[2] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

[3] ASTM E112, *Standard Test Methods for Determining Average Grain Size*

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