

METROLOGICAL SUPPORT OF ZIRCONIA BASED CERAMIC MATERIALS DUE TO ISO STANDARDS

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Advanced zirconia ceramic materials have great potential to replace traditional materials in many biomedical applications. The biocompatibility of zirconia is well documented, with in vitro and in vivo tests using Y-TZP showing good biocompatibility with no adverse reactions with cells or tissues. There is a need to extend the specification of the ISO standard. Therefore, ISO 13356 specifies requirements and appropriate test methods for biocompatible and biostable ceramic bone substitute materials based on yttria-stabilized tetragonal zirconia (polycrystalline tetragonal yttria-zirconia, Y-TZP) for use as surgical implant materials. ISO 13365 refers to general standards for ceramic materials and provides additional guidance on sample preparation, sample number and sample size. While these additional instructions are detailed for some tests, there is some flexibility for others. Modern zirconia biomaterials and products used as surgical (implant) materials should meet the requirements described by the International Organisation for Standardisation (ISO) 13556, represented in table 1. Table 1. Requirements according to ISO 13356

Property	Unit	Requirement
Bulk density	g cm ⁻³	≥ 6
Chemical composition ZrO ₂ + HfO ₂ + Y ₂ O ₃ Y ₂ O ₃ HfO ₂ Al ₂ O ₃ other oxides	mass%	≥ 99.0 > 4.5 to ≤ 6.0 ≤ 5 ≤ 0.5 ≤ 0.5
Microstructure grain size amount of monoclinic phase	μm mol%	0.4 ≤ 20
Strength 4-point bending Weibull modulus	MPa	≥ 800 ≥ 8
Young's modulus	GPa	≥ 200
Hardness	GPa	≥ 11.8
Cyclic fatigue limit stress at 10 ⁶ cycles	MPa	≤ 200
Radioactivity	Bq kg	-1 ≤ 200
Accelerated ageing maximum amount of monoclinic phase residual biaxial strength	mol % MPa	≤ 25%
residual 4-point bending strength	MPa	Δ < 20% ≥ 800 MPa, Δ < 20%

To conclude, the current ISO requirements for the long-term stability and surface condition of Y-TZP samples should be updated according to the current understanding of aging phenomena. Advanced specifications are required to ensure the long-term stability and success of Y-TZP biomedical devices.

References 1. Vagkopoulou T, Koutayas SO, Koidis P, Strub JR. Zirconia in dentistry: Part 1. Discovering the nature of an upcoming bioceramic. *Eur J Esthet Dent.* 2009 Summer;4(2):130-51. PMID: 19655651. 2. SIST EN ISO 13356:2015 - Implants for surgery - Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP) (ISO 13356:2015) 3. Test strategy for material qualification of AM produced ceramics for implants and dental applications © 2021 by T. Lube, S. Endt, M. Schwentenwein, J. Rabitsch is licensed under CC BY-NC-ND 4.0.