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## A new testing protocol for zirconia dental implants

Clarisse Sanon<sup>a,b</sup>, Jérôme Chevalier<sup>a,c,\*</sup>, Thierry Douillard<sup>a</sup>,  
Maria Cattani-Lorente<sup>d</sup>, Susanne S. Scherrer<sup>d</sup>, Laurent Gremillard<sup>a</sup>

<sup>a</sup> INSA-Lyon, UMR CNRS 5510 (MATEIS), 7 avenue Jean Capelle, 69621 Villeurbanne Cedex, France

<sup>b</sup> University Lyon 1, Faculty of Odontology, Department of Biomaterials, 11, Rue Guillaume Paradin, 69372 Lyon Cedex 08, France

<sup>c</sup> Institut Universitaire de France, 103 bd Saint-Michel, Paris 75005, France

<sup>d</sup> University of Geneva, School of Dental Medicine, Department of Prosthodontics-Biomaterials, 19 rue Barthélémy-Menn, CH 1205 Geneva, Switzerland

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### ABSTRACT

**Objectives.** Based on the current lack of standards concerning zirconia dental implants, we aim at developing a protocol to validate their functionality and safety prior their clinical use. The protocol is designed to account for the specific brittle nature of ceramics and the specific behavior of zirconia in terms of phase transformation.

**Methods.** Several types of zirconia dental implants with different surface textures (porous, alveolar, rough) were assessed. The implants were first characterized in their as-received state by Scanning Electron Microscopy (SEM), Focused Ion Beam (FIB), X-Ray Diffraction (XRD). Fracture tests following a method adapted from ISO 14801 were conducted to evaluate their initial mechanical properties. Accelerated aging was performed on the implants, and XRD monoclinic content measured directly at their surface instead of using polished samples as in ISO 13356. The implants were then characterized again after aging.

**Results.** Implants with an alveolar surface presented large defects. The protocol shows that such defects compromise the long-term mechanical properties. Implants with a porous surface exhibited sufficient strength but a significant sensitivity to aging. Even if associated to micro cracking clearly observed by FIB, aging did not decrease mechanical strength of the implants.

**Significance.** As each dental implant company has its own process, all zirconia implants may behave differently, even if the starting powder is the same. Especially, surface modifications have a large influence on strength and aging resistance, which is not taken into account by the current standards. Protocols adapted from this work could be useful.

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\* Corresponding author at: INSA-Lyon, UMR CNRS 5510 (MATEIS), 7 avenue Jean Capelle, 69621 Villeurbanne Cedex, France.  
E-mail address: [jerome.chevalier@insa-lyon.fr](mailto:jerome.chevalier@insa-lyon.fr) (J. Chevalier).

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## 1. Introduction

Oral implants offer an effective treatment for replacement of missing teeth. Since the pioneering works of Brånemark in the 60's [1], several millions of titanium implants have been produced. It is reported that the oral implant number will grow at a rate of 6% per year from 2010 to 2015, since there is a tendency to propose more and more implants to patients to improve their quality of life (aesthetic, but also mastication and long-term stability) [2]. Current long-term clinical investigations (more than 10 years of follow-up) report very favorable survival rates, which places titanium and its biomedical alloys as the gold standard [3]. However, in some cases, the greyish color of a titanium implant may be perceived through the peri-implant mucosa causing some aesthetic drawbacks [4]. Furthermore, in rare cases, metals (including titanium) may induce sensitization or allergic reactions [5,6]. Finally, some patients also ask for completely metal-free dental reconstructions. Thus, implants fabricated with ceramic materials are gaining popularity and might have a certain clinical and industrial success if they prove to be strong enough, stable over time and well integrated in the jawbone. Especially, yttria-doped zirconia ceramics (often referred as 3Y-TZP, standing for 3 mol.% Yttria doped Zirconia Tetragonal Polycrystals) are often presented as the alternative to titanium [7]. These ceramics possess good mechanical strength [8], excellent tissue compatibility and show osseointegration comparable to that of titanium [9]. A further advantage of zirconia is the reduced formation of plaque [10]. Moreover, the white-opaque  $ZrO_2$  ceramic better resembles the tooth in terms of color, and thus provides good esthetics even with a thin gingiva or with soft-tissue recessions.

Worldwide, there are more than 10 companies producing zirconia dental implants and each manufacturer develops its process, its implant design and its own surface features to promote osseointegration. It is generally accepted that rough surfaces improve osseointegration and favor mechanical anchorage with bone. Several strategies are explored to process rough or porous surface implant i.e. machining, acid etching, sandblasting, molding or coating with a porous layer [11–13]. Although zirconia has good initial mechanical properties (high fracture toughness and bending strength), it remains a ceramic material with a significant sensitivity to surface defects. The above-mentioned surface treatments may generate cracks and/or defects which could be detrimental for mechanical properties of these zirconia implants. Moreover, screw design allows mechanical anchorage of dental implant into the bone but is challenging for ceramics material because of stress concentration at sharp edges [14]. All these aspects are poorly documented in the recent literature on zirconia dental implants. It has also to be recalled at this stage that 3Y-TZP was introduced as an implant biomaterial (femoral heads) in orthopedics over 30 years ago, but was abandoned after 15 years of use, after a series of failures in specific batches manufactured with a new process [15]. Zirconia is a complex material because it is meta-stable at room temperature. On the one hand, its excellent mechanical properties (the best of oxide ceramics) are due to the transformation of metastable tetragonal grains to the monoclinic phase under stress (for

example in the vicinity of a crack). The development of this transformation zone is accompanied by an increase of crack resistance, which is known as phase transformation toughening [16]. On the other hand, this meta-stability leads to a possible transformation of grains in contact with water (or body fluids) with time. This phenomenon is often referred as to Low Temperature Degradation (LTD) or aging. Aging is a progressive tetragonal to monoclinic transformation at the surface triggered by the presence of water [16], which often results in surface roughening and micro cracking and thereby potentially decreases the device physicochemical and mechanical properties. The experience of zirconia in orthopedics field gave some important indications on how aging may proceed, on the potential impact of the transformation and on the conditions by which it may be triggered. The transformation proceeds from the surface in contact with water to the bulk of the material. The kinetics by which the transformation occurs is highly dependent on process conditions and resulting microstructure [17].

Surface modifications for example may have a positive effect on bone apposition and bone in-growth, but also could facilitate the water penetration into the bulk and/or lead to a modification of the stability of the tetragonal phase under humid atmosphere. Except few recent works, including one from the authors of the current paper [18], the risk of lifetime reduction associated to surface modification of implants is barely discussed. There is today no standardized protocol that allows assessing the mechanical properties of the implant, to determine the aging kinetics and the effects of aging on the mechanical properties for a given type of implant. The only ISO standard [19] concerning medical grade zirconia is based on mechanical strength and aging kinetics measured on bending bars or discs, which are polished and therefore not relevant for dental implants. To bridge this gap, we aim at proposing a protocol to validate the functionality and safety of zirconia implants prior their clinical use. The protocol is designed to account for the specific brittle nature of ceramics (sensitive to surface defects and slow crack growth) and the specific behavior of zirconia in terms of phase transformation.

## 2. Materials and method

### 2.1. Implant description

For this research, Axis Biodental provided two types of 3Y-TZP dental implants processed by injection molding, with either a structured rough surface, which will be referred as 'Axis-rough' or with an additional proprietary porous zirconia coating here referred as 'Axis-alveolar' in relation with their surface texture. Axis-rough surface was obtained after surface treatment of the mold inner and the alveolar one, after deposition and sintering of a mixture of zirconia powder and polymer beads (patent application EP 1924300 B1). Only the 'Axis-rough' implants were commercial implants, while 'Axis-alveolar' were prototypes in the development phase.

Nobel Biocare provided zirconia implant prototypes with a porous surface (ZiUnite®). The porous surface was achieved after sintering, by coating the endosseous part of the implants with a slurry containing zirconia powder and a pore former

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