Is zirconium dioxide biocompatible?

Comment from Dr. Jörg Reinshagen -WIELAND

Zirconium dioxide is increasingly being used for the fabrication of full ceramic crown and bridge work. The zirconium dioxide used for this purpose is a high-performance technical ceramic with exceptionally good physical properties. In particular, it is very strong for a ceramic material and very resistant to cracking. The tooth-like colour and the translucency similar to that of natural dentine make it suitable for the production of highly aesthetic dental restorations **(Fig. 1)**.

Fig. 1: ZENO® Zr bridge

For the manufacture of **ZENO® Zr** and **ZENO® Zr_{eco}** milling blanks **(Fig. 2)** WIELAND process zirconium dioxide partly stabilised with 3 mol-% yttrium oxide (3Y-TZP)[1].

The addition of small amounts (< 0.5 Ma.-%) of aluminium oxide (also known as alumina) makes 3Y-TZP especially resistant to ageing and orally stable. It is then often referred to as 3Y-TZP-A[2].

Fig. 2: Finished **ZENO® Zr** Disc

There are no known allergic reactions. Furthermore, the **ZENO® Zr** zirconium dioxide reveals absolutely no potential for cytotoxicity **(Fig. 3)**.

Its high resistance to physical wear and to the corrosive effect of most acids and alkalis also add to its exceptional biocompatibility of this material. A further advantage is the low thermal conductivity of the material when compared to metals, especially for patients who are sensitive to heat and cold. 3Y-TZP has been in use for more than 20 years as a material for orthopaedic implants in human medicine.

ZERTIFIKAT

Prüfung der Biokompatibilität

Prüfmaterial

Zeno Zr Disc

Dentalkeramik, EN ISO 6872

Zusammensetzung

Zirkoniumoxid		
$ZrO_2 + HfO_2$	Y_2O_3	Al_2O_3
94	5	<1

Massenanteile in %

Hersteller

Wieland Dental + Technik GmbH & Co. KG
Schwenninger Straße 13 · 75179 Pforzheim, Germany

Prüfungen

Wir bestätigen, dass die folgenden Prüfungen zur Bestimmung der Biokompatibilität gemäß den internationalen Normen ISO 10993 „Biological evaluation of medical devices" (EN ISO 10993-1, EN ISO 10993-2, EN ISO 10993-5, EN ISO 10993-12) und EN ISO 7405, „Zahnheilkunde – Prüfmethode Beurteilung der Biokompatibilität von in der Zahnheilkunde verwendeten Medizinprodukten – Prüfverfahren für zahnärztliche Werkstoffe" durchgeführt wurden. Die Untersuchungen erfolgten nach den OECD-Richtlinien „Good laboratory Practice" (GLP) durch das Institut BSL Bioservice Scientific laboratories.
Die Koordination und das Monitoring der Prüfung erfolgte durch Dr. Henning + Co.
Die Prüfkörper wurden nach der Verarbeitungsanweisung der Fa. Wieland Dental + Technik hergestellt.

Zytotoxizität

Die potentielle zelltoxische Wirkung der Dentalkeramik wurde in vitro mit L 929-Fibroblasten untersucht.
Methode: „Test on extracts", Nachweis mit XTT-Färbung, EN ISO 10993-5: 1999, EN ISO 10993-12: 1996 und EN ISO 7405 (5.4.e3).

Testergebnis:

Zeno Zr Disc hatte kein zelltoxisches Potential

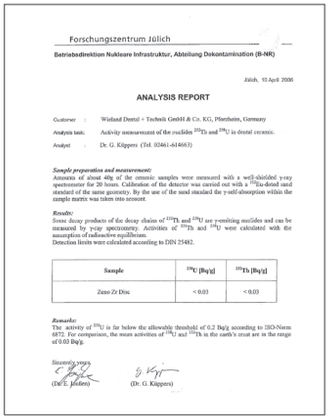
Dr. Henning + Co., Dental Engineering
Unterer Lichtenweg 18 · D-79541 Lörrach

Lörrach, 30. 1. 2006

Fig. 3: Certificate: "Cytotoxic potential of **ZENO® Zr**"

The questions relating to radioactivity which were originally raised have long since been settled. The alpha waves from technical zirconium dioxides used for medical products lie considerably below the exposure from natural sources. The values for **ZENO® Zr** and **ZENO® Zr_{eco}** are many times lower than the threshold values required by standards **(Fig. 4)**. Frivolous claims and publications, including those in the Internet which maintain that zirconium dioxide is toxic or is "an allergising metalloid", or that zirconium dioxide is not a ceramic, are false.

Such misinterpretations are probably due at least in part to the fact that the terms zirconium or zircon are often used as an abbreviation for zirconium dioxide or 3Y-TZP. These abbreviations are incorrect and repeatedly lead to confusion. Zirconium (chemical symbol Zr) is the term for element No. 40 in the periodic table, a heavy metal, whilst zircon is a zirconium-bearing mineral (Zr[SiO4]) which is also known as a gemstone. Zirconia is sometimes used as an alternative expression for zirconium dioxide. In order to avoid misunderstandings, the material should always be referred to as zirconium dioxide or zirconium oxide or better still as 3Y-TZP. The zirconium oxide specially produced for dental applications (3Y-TZP-A) is a structural ceramic offering excellent biocompatibility. To date there are absolutely no clinical studies or publications which indicate the possibility of incompatibility reactions. "Zirconium dioxide is the best material that we currently have at our disposal for the manufacture of full ceramic dental restorations".



Forschungszentrum Jülich

Betriebsdirektion Nukleare Infrastruktur, Abteilung Dekontamination (B-NR)

Jülich, 10 April 2006

ANALYSIS REPORT

Customer : Wieland Dental + Technik GmbH & Co. KG, Pforzheim, Germany
Analysis task: Activity measurement of the nuclides ^{232}Th and ^{238}U in dental ceramic.
Analyst : Dr. G. Klöppers (Tel. 02461-614663)

Sample preparation and measurement:
Amounts of about 40g of the ceramic samples were measured with a well-shielded γ-ray spectrometer for 20 hours. Calibration of the detector was carried out with a ^{152}Eu-doted sand standard of the same geometry. By the use of the used standard the γ-self-absorption within the sample matrix was taken into account.

Results:
Some decay products of the decay chains of ^{232}Th and ^{238}U are γ-emitting nuclides and can be measured by γ-ray spectrometry. Activities of ^{232}Th and ^{238}U were calculated with the assumption of radioactive equilibrium.
Detection limits were calculated according to DIN 25482.

Sample	^{238}U [Bq/g]	^{232}Th [Bq/g]
Zeno Zr Disc	< 0.03	< 0.03

Remarks:
The activity of ^{238}U is far below the allowable threshold of 0.2 Bq/g according to ISO-Norm 6872. For comparison, the mean activities of ^{238}U and ^{232}Th in the earth's crust are in the range of 0.03 Bq/g.

Executed by:
(Dr. E. Jolkes)

(Dr. G. Klöppers)

Fig. 4: Certificate: "Radioactivity of **ZENO® Zr**"