IPS e.max®

ZirCAD

Scientific Documentation

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Contents

1 IPS e.max System

IPS e.max is an innovative all-ceramic system covering all indications ranging from thin veneers to multi-unit bridges.

It consists of a reliable lithium disilicate glass-ceramic (IPS e.max Press and IPS e.max CAD), an innovative zirconium oxide ceramic (IPS e.max ZirCAD) and a coordinated veneering ceramic (IPS e.max Ceram). IPS e.max ZirPress, a press-on fluorapatite ceramic supplements the versatile system. With the highly esthetic, high-strength IPS e.max materials, all indications for fixed restorations, ranging from thin veneers to multi-unit bridges, can be realized. Hybrid restorations are also possible.

Figure 1: IPS e.max range (clockwise) – IPS e.max ZirCAD discs and blocks, IPS e.max CAD, IPS e.max ZirPress, IPS e.max Press and IPS e.max Ceram.

IPS e.max ZirCAD comprises materials for the universal creation of zirconium oxide restorations. A coordinated product portfolio utilizing modern CAD/CAM techniques leads to efficient fabrication processes and reproducible, esthetic results.

IPS e.max CAD is a versatile and reliable lithium disilicate glass-ceramic for the CAD/CAM technique. It is used to fabricate single-tooth restorations, hybrid abutments and 3-unit bridges (premolar region).

IPS e.max Press is a versatile and reliable lithium disilicate glass-ceramic for the press technique. It is used to fabricate single restorations, hybrid-abutment constructions and three-unit bridges (premolar region).

IPS e.max ZirPress is a fluorapatite glass-ceramic for the rapid and efficient press-on technique onto zirconium oxide frameworks (i.e. IPS e.max ZirCAD).

IPS e.max Ceram is a highly esthetic fluorapatite layering ceramic, which is used to characterize and veneer substructures made of lithium disilicate and zirconium oxide.

2 IPS e.max ZirCAD

IPS e.max ZirCAD is a versatile and innovative zirconium oxide material with a wide indication range. It is suitable for fabricating copings and frameworks as well as full-contour crowns and bridges. Dental professionals benefit from the material's high performance and, versatility. IPS e.max ZirCAD is the material of choice when high strength, thin restoration walls and natural-looking esthetics are required.

IPS e.max ZirCAD is available in both disc and block format. IPS e.max ZirCAD discs are available in three levels of translucency: medium opaque (MO), low translucency (LT) and medium translucency (MT) and as polychromatic Multi discs which offer a lifelike transitional translucency (MT Multi). The different translucencies are suitable for a range of different indications – an overview of which is given in Figure 2 and section 2.1. The LT and MO blocks[1] supplement the assortment.

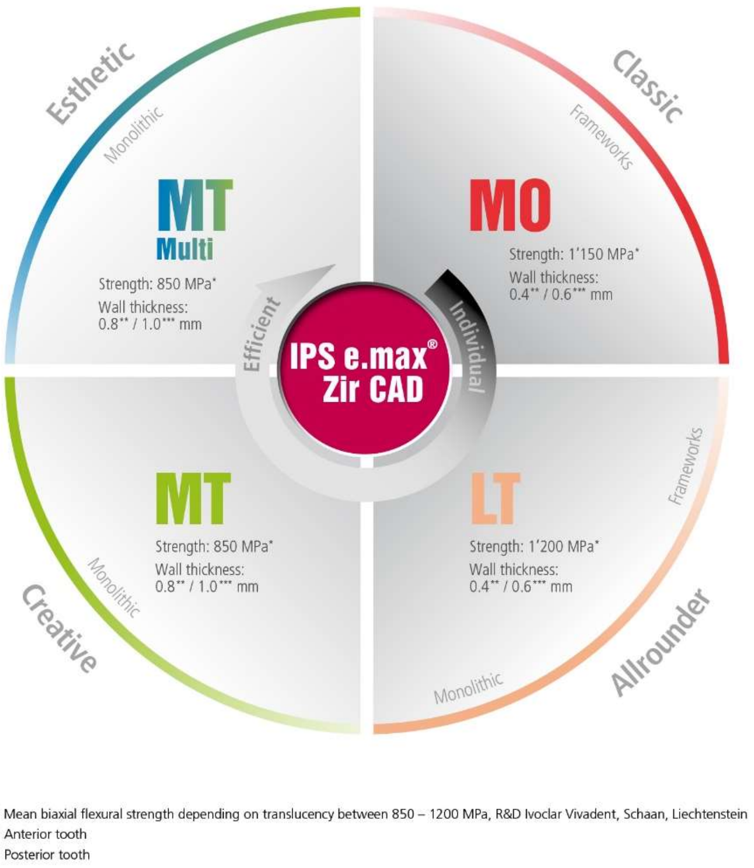

Figure 2: IPS e.max ZirCAD range by translucency (MO, LT, MT, MT Multi) and indication.

[1] *depending on the respective range for authorized CAD/CAM systems.*

2.1 IPS e.max ZirCAD – LABSIDE

Indications:

Translucency level	Indications				
	Full-contour crowns	Full-contour 3-unit bridges	Full-contour, 4- to multi-unit bridges with max. 2 pontics	Crown frameworks	3- to multi-unit bridge frameworks with max. 2 pontics
MT Multi Medium Translucency with shade gradation	✓	✓*			
MT Medium Translucency	✓	✓*			
LT Low Translucency	✓	✓	✓**	✓	✓**
MO Medium Opacity				✓	✓**

* IPS e.max ZirCAD MT and IPS e.max ZirCAD MT Multi are discs for the fabrication of restorations consisting of a maximum of three units.
** In Canada, bridge indications are limited to 6 units with a maximum of 2 connected pontics.

Contraindications:

IPS e.max ZirCAD MT / MT Multi	IPS e.max ZirCAD LT / MO
• Veneering of MT Multi with IPS e.max Ceram	• Bridge constructions with more than two connected bridge pontics
• Bridge reconstructions consisting of more than 3 units	• Patients with severely reduced residual dentition
• Patients with severely reduced residual dentition	• Bruxism, for veneered IPS e.max ZirCAD LT / MO restorations
• Bruxism	• Two or more connected extension units
• Any other use not listed in the indications	• Any other use not listed in the indications
• Temporary seating	• Temporary insertion

2.2 IPS e.max ZirCAD - CHAIRSIDE

IPS e.max ZirCAD LT blocks are now available for the fabrication of "single visit" zirconium oxide restorations at the dental practice. Monolithic restorations can be produced chairside by the dentist. The low translucency blocks allow the fabrication of esthetic restorations without the need for further veneering techniques.

The LT blocks are monochromatic, pre-shaded and are available in 7 A–D shades as well as 1 Bleach (BL) shade. They are available in block sizes C17 and B45.

Indications:
- Full-contour crowns in the anterior and posterior region
- Full-contour 3-unit bridges in the anterior and posterior region

Suitable for wet and dry processing

Contraindications:
- Patients with severely reduced residual dentition
- Any other uses not listed in the indications
- Temporary seating

2.3 IPS e.max ZirCAD Colouring Liquids

IPS e.max ZirCAD Colouring Liquids are used for brush infiltration of restorations before the sintering process. There are two different types available: IPS e.max ZirCAD MT Colouring Liquids are used for the shading of IPS e.max ZirCAD MT BL restorations, whereas the IPS e.max ZirCAD LT Colouring Liquids are used for shading IPS e.max ZirCAD LT. Both colouring liquids are available in 16 A-D tooth shades and 5 Effect liquids.

The colouring liquids are aqueous solutions of nitrates of transition metals and rare earth metals (staining ions). The colouring liquids can be diluted with the Colouring Liquid Diluter, which is a strongly diluted aqueous nitric acid solution. The shade indicators are aqueous solutions of dyes, which may be added to the colouring liquids, to make the brush infiltration process visible. These dyes are burned out without residue during the sintering process. The colouring liquids penetrate the surface of the restoration. The cations remain in the zirconium oxide matrix after sintering and cause the staining of the finished restoration. They are definitively bound within the zirconium oxide matrix and cannot be leached out as confirmed by chemical solubility tests in accordance with ISO 6872:2015 (see chapter 7.1). Because the staining ion content is very low, the crystallographic structure of the frameworks is not affected. In comparison to non-shaded zirconium oxide, the crystallite size tends to be smaller. The reduction in the size of the grains, however, has no significant effect on the physical properties

Indications:

IPS e.max ZirCAD Colouring Liquids are ready-to-use, aqueous metallic salt solutions for colouring unsintered restorations made of IPS e.max ZirCAD MT BL and LT with the brush infiltration technique.

Contraindications:

Any other use not listed in the indications.

3 Material description

Humans have long been aware of the medical and esthetic benefits of tooth replacements. Over 3500 years ago, the ancient Egyptians attempted to close gaps in dentition by carving false teeth out of mulberry wood and tying them to adjacent teeth with gold wire. Guided by this principle, the Etruscans produced more esthetic tooth replacements using bovine teeth. Until the beginning of the 19th century, ivory and natural human teeth taken from fallen soldiers at the battlefields of the time ("Waterloo teeth") were used to fabricate dentures. The first porcelain teeth were developed in 1709. However, it wasn't until 1837, that the industrial production of porcelain teeth began in England. With the fabrication of the first sets of dentures based on rubber and porcelain teeth (1846), a new era in denture prosthetics was ushered in [1; 2].

The suitability of ceramic materials for durable tooth replacements was limited because of their brittleness and susceptibility to fracture. Attempts to overcome these limitations by using metal frameworks were undertaken as early as 1733. However, it wasn't until the nineteen-sixties that metal-ceramics became available in dentistry, with the patented use of gold alloys for the porcelain fused to metal technique. To date, the range of dental alloys has grown considerably and base metal alloys have also become available [3].

Advances were made with dental ceramics and because of their natural, tooth-like appearance and extraordinary biocompatibility; more and more patients began to choose metal-free restorations. As a dental ceramic, zirconia offers a wide range of indications due to its high flexural strength and fracture toughness. For more than 15 years, zirconia has been used in dental laboratories for fabricating frameworks and more recently full-contour restorations [4]. More recently, interest (and ability) has grown in using zirconia for monolithic restorations, due to the development of various generations of the material, incorporating a spectrum of optical and mechanical properties.

3.1 Zirconium – Zircon – Zirconia: What's the difference?

Pure zirconium (Zr) is a rather soft and ductile shiny-silvery metal, optically similar to stainless steel. Zirconium occurs in nature only as a mineral, mostly as "zircon" ($ZrSiO_4$) and very rarely as "baddeleyite" (ZrO_2). These two minerals are used to produce zirconium metal and other zirconium compounds via complex production and purification processes. For dental zirconia only synthetic powder components are used and no natural minerals. The raw material for dental zirconia is derived from zircon which is chemically purified and converted into synthetic zirconium precursors that are transformed into ZrO_2 through thermal and mechanical processes. Most zirconium compounds contain hafnium (Hf) as an impurity. It is very difficult to separate Hf from zirconium during the purification process, because of its similarity to zirconium. Other impurities include traces of thorium, which could cause minor radioactivity in zirconium oxide. This is not an issue however, as dental ceramics must be produced according to the standard EN ISO 6872 (see chapter 7.4) which specifies the acceptable level of radioactivity [5; 6].

Zirconia (ZrO_2), an oxide of the metal, has been used since the end of the 19th century as a fireproof material in glass making [5]. Nowadays it is used for knives, golf putter heads and is famous in its cubic crystal phase as a gemstone for diamond-like jewellery [7]. Since the 1970s, zirconia has been used in medicine and dentistry, due to its favourable properties such as low cytotoxicity, corrosion potential and low propensity to bacterial adhesion [8].

3.2 Zirconia is not Zirconia

Although the raw material of dental zirconia is synthetic, the crystal structure and crystallographic processes can be derived from the natural mineral baddeleyite. Zirconia is polymorph, meaning the same elements exist in three different crystal structures depending on temperature and pressure. The crystal structures or phases are monoclinic (m), tetragonal (t) and cubic (c) (Figure 3). At room temperature, pure zirconia is present in the most stable phase, the monoclinic. As the temperature rises to about 1170°C, the monoclinic phase transforms into the tetragonal phase, accompanied by a shrinkage in volume of approximately 4-5%. The tetragonal phase converts into the cubic phase at about 2370°C, with only minimal changes in volume. [5; 8-10].

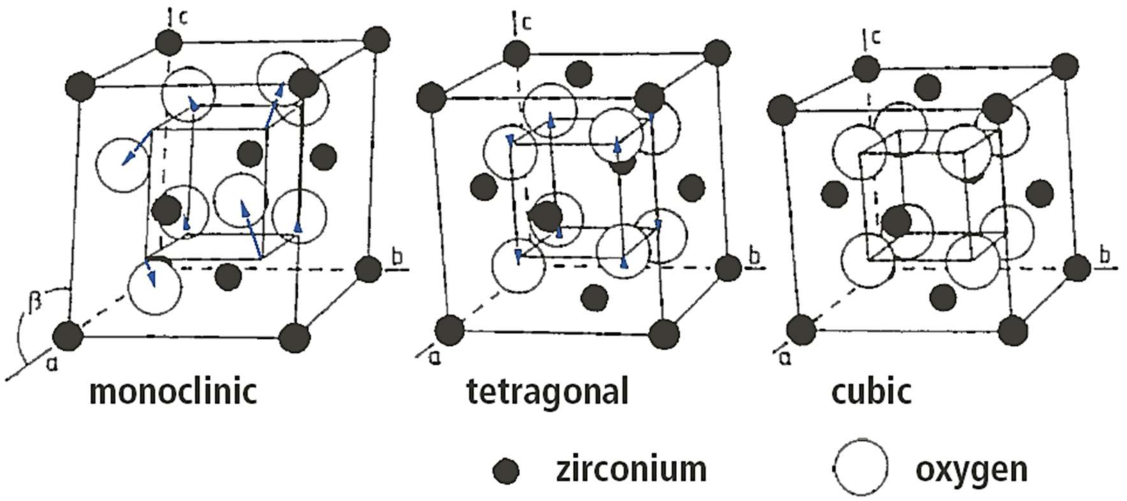

Figure 3: Three crystal structures of zirconia: monoclinic, tetragonal and cubic. The transformation from the cubic to tetragonal phase is associated with a stretching of the position of the oxygen ions along the c-axis. The tetragonal phase transforms into the monoclinic phase by an additional shearing of those ions (see direction of arrows) (adapted from [5]).

These reversible lattice transformations (Figure 4) are (1) diffusion-less (i.e. without transport of atoms); (2) occur within a temperature range, not at a specific temperature (i.e. athermal) and (3) involve shifts in the coordination of lattice positions. These kinds of changes are characteristic of *martensitic transformations* as in austenite-martensite transformation in steels [5; 9].

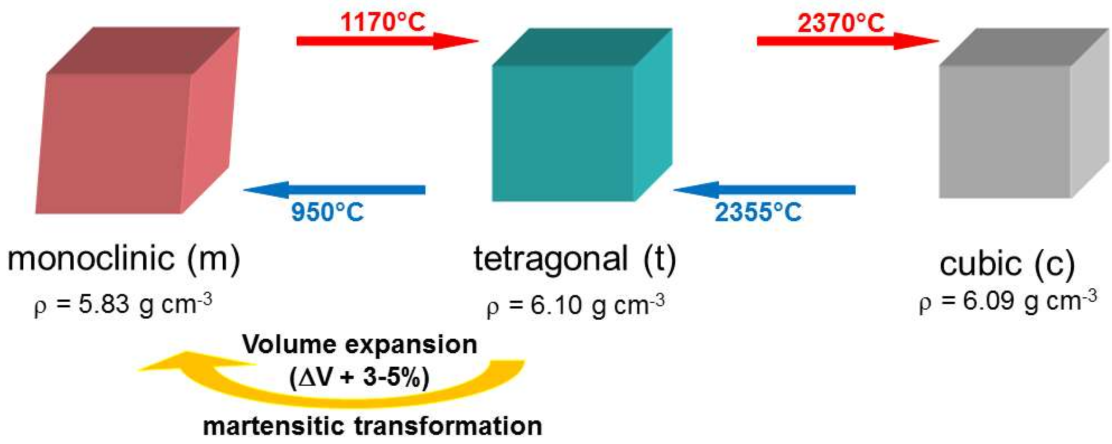

Figure 4: Correlation between temperature and volume change due to lattice transformation of the phases of zirconia.

Cooling results in volume expansion, especially for the t-to-m transformation. It is therefore, impossible to use pure zirconia for biomedical applications, where undamaged structures are imperative. The cooling process itself leads to further stress, caused by the rigidity of the lattice that cannot adjust to the associated abrupt increase in volume. Either immediate damage/fracture of the sintered ceramics or residual stress would promote crack formation over time.

It was discovered however, that by incorporation of components like yttrium oxide (Y_2O_3), calcium oxide (CaO) or magnesium oxide (MgO) into the ZrO_2-lattice, the monoclinic phase is disfavoured at room temperature. These stabilizing dopants stabilize the tetragonal and the cubic phase at room temperature as metastable phases. By adding different amounts of dopant (the quantity also depends on the type of stabilizer), partially or fully stabilized zirconia is formed [4; 5; 8-10]. Fully stabilized zirconia is achieved by adding either 8 mol% Y_2O_3 or 16 mol% MgO or CaO. Smaller amounts of the same dopants lead to partially stabilized zirconia with mainly metastable tetragonal and cubic phases [10]. During the stabilization mechanism, the lower valence dopant ions (Y^{3+} in Figure 5) substitute Zr^{4+} in the lattice, leading to oxygen vacancies. The metastability of the tetragonal phase and therefore the stabilization of zirconia is mostly attributed to the existence of these oxygen vacancies. They allow relaxation of anions and cations depending on their distance to the vacancies [9].

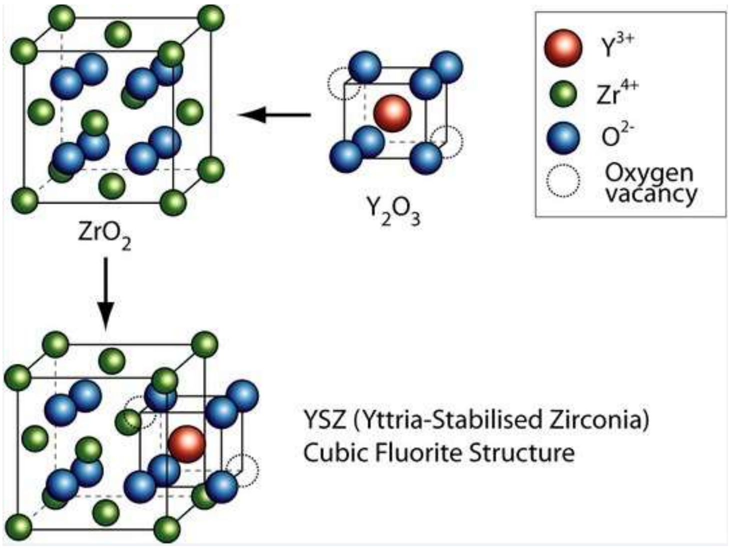

Figure 5: Stabilization mechanism and formation of oxygen vacancies by doping ZrO_2 with Y_2O_3 [2].

Due to the addition of stabilizers, ceramics with remarkable properties like high flexural strength and toughness, high hardness and chemical resistance can be achieved. Parameters like particle size and shape, content of dopant and temperature will influence the t-to-m transformation. The tetragonal phase can only be preserved at room temperature in partially stabilized zirconia (2-3 mol% Y_2O_3), when particle size ranges between 0.2 -1 µm [10].

Partially **s**tabilized **z**irconia (PSZ) is widely studied and commercially used. The ceramics consist mainly of cubic phase with tetragonal intra-granular zirconia precipitates generated during tempering while cooling. The stabilizer utilized is stated as a prefix in the name e.g. Mg-PSZ for MgO or Y-PSZ for Y_2O_3 as a stabilizer. The adjusted cooling procedure leads to the formation of a tetragonal phase of a defined size with a homogenous distribution within the cubic-matrix. If metastable tetragonal particles are too small or too big, they will lose the ability of transformation or transform immediately into the monoclinic phase. Furthermore, during processing, a reduction of porosities and defects is essential in order to achieve final ceramics of sufficient strength [5; 9].

Sintered material of **y**ttria stabilized-**t**etragonal **z**irconia **p**olycrystals (Y-TZP) consists mainly (~98%) of metastable tetragonal phase with 96-99.8% theoretical density. TZP ceramics are mostly made of ultra-pure fine raw material powders. The quantity of utilized dopant is mentioned in front of the abbreviation like 3Y-TZP when 3 mol% Y_2O_3 is used (see Table 1). It was discovered that high strengths go along with high tetragonal phase content, whereas a high amount of monoclinic phase leads to low strengths. The ability of transformation and the corresponding temperature are grain-size controlled. Targeted grain-size adjustment is therefore essential. If the grain size shrinks below a critical size, the material loses its ability for t-to-m transformation during crack development and therefore its toughness decreases. The stabilizer and its concentration control these size-dependent effects. Yttria arises as the strongest stabilizer in a specific concentration and grain size region [5; 9].

[2] https://www.doitpoms.ac.uk/tlplib/fuel-cells/printall.php (11.05.2017)

	3Y-TZP	4Y-TZP	5Y-TZP
mol% Y_2O_3	3	4	5
wt% Y_2O_3	5.35	7.10	8.80

Table 1: Correlation between mol% of Y_2O_3 used and corresponding weight percent (wt%).

3.2.1 Benefits of Transformation – Transformation Toughening

Although the t-to-m transformation is detrimental in pure ZrO_2, it provides a decisive advantage in stabilized zirconia products. Garvie et al. [11] reported in 1975 on their findings, that the t-to-m transformation in partially stabilized zirconia, results in an increased strength and toughness of the material. They compared this strengthening mechanism with the stress and strain induced mechanism known from strengthened steel (austenite-martensite transformation). The group used the term "ceramic steel" for partially stabilized zirconia because of features similar to strengthened steel: three allotropes, the metastable phases and the martensitic transformation [9].

Remarkable aspects resulting from transformation of the metastable tetragonal phase to the monoclinic phase are (1) transformation toughening and (2) increased crack resistance. These features of stabilized zirconia are of outstanding benefit for biomedical applications, where crack propagation is a crucial issue. Residual or applied stress close to the crack tip (within the frontal zone in Figure 6) will result in t-to-m transformation and its associated volume expansion. The transformation leads to the formation of a transformation zone (mix of red and blue grains in Figure 6) initially close to the crack tip and later developing as a crack feature. The size and microstructure (e.g. grain size) of the transformation zone controls the toughening. In Y–TZP material the zone is typically in the range of some µm. Due to the increase in volume and accompanying intrinsic tension, the transformation zone is under compressive stress, which suppresses or even closes the crack and prevents any further growth. Due to the consumption of energy by this process (energy that is otherwise required for crack growth), fracture toughness (K_{IC}) of the material increases. Overall, the process inhibits crack propagation and increases material fracture toughness. [5; 8-10]

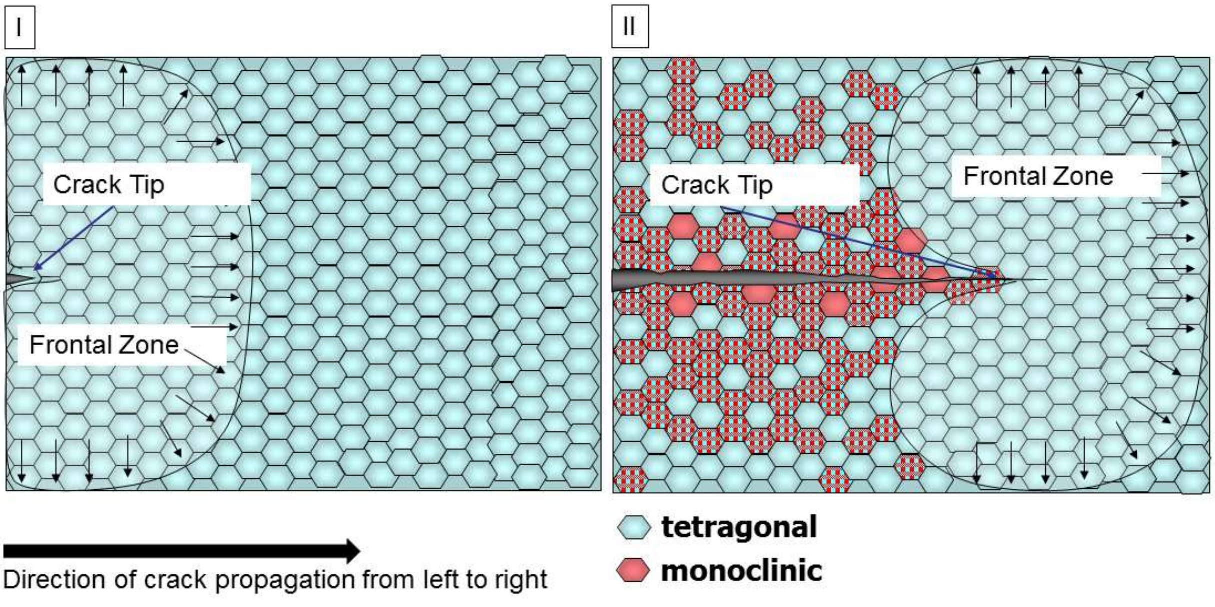

Figure 6: Scheme of transformation toughening in Y-TZP due to initial crack formation.

Crack deflection is an additional toughening mechanism in ceramics. Hereby, a crack changes its direction after clashing with pore or grain boundaries [10].

3.2.2 Aging process - Low temperature degradation

Owing to some problems in orthopaedics in the early 2000s, it is well known that zirconia is susceptible to aging or so called low temperature degradation (LTD). During this ageing process the metastable tetragonal phase converts by a slow transformation into the stable monoclinic phase, starting at the surface in the presence of water at relatively low temperatures [9; 12]. Impacts of LTD are surface degradation, like pull-outs and micro-cracks, leading to strength degradation [13]. The process is schematically depicted in Figure 7.

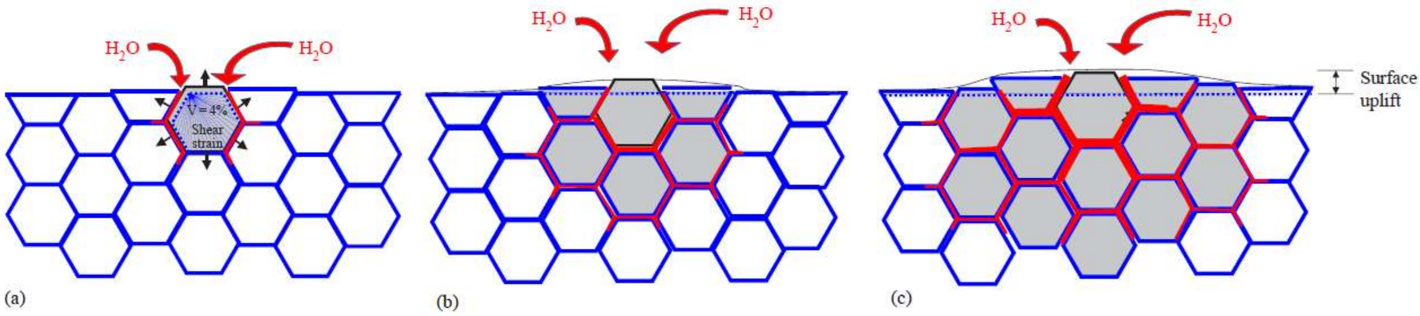

Figure 7: Schematic representation of the aging process. Starting from a single grain at the surface (a) followed by a cascade of transformations neighbour-to-neighbour (grey zone), leading to micro-cracking (water penetration along the red track) and surface roughening (b and c) (adapted from [12]).

Aging starts by transforming a single grain (Figure 7(a)) at the surface via a stress-induced mechanism. This is supported by characteristics or issues that are disadvantageous for the stability of the tetragonal phase like residual stress, large grain size, low yttria content or the presence of cubic phase. The transformation leads to the typical volume increase that induces stress in the neighbouring grains and micro-cracks. This results in a cascade of transformations, which increases the transformed zone (grey in Figure 7). The micro-cracks offer a way (red in Figure 7) through which water can further penetrate into the bulk and the aging process continues to progress. These LTD-generated transformed zones cause surface roughness and may lead to pull-outs due to wear. [9; 12]

Strategies to reduce the risk of LTD in 3Y-TZP are particle-size reduction, increasing the yttria content, addition of Al_2O_3 and changing the chemical synthesis route to gain ZrO_2 raw particles. One has to keep in mind, that machining can introduce stress or tension to the surface, which can enhance susceptibility to LTD. [10]

3.3 Generations of Zirconia

For dental all-ceramic fixed prosthetic restorations, different types of medical grade zirconia are used that can be distinguished by their chemical composition and notably via the content of the stabilizer Y_2O_3. Up until 2014, only high-strength 3Y-TZP was used for fabricating restorations - from single crowns to multi-unit implant-supported bridges. Nowadays various types of zirconia are used, offering improved translucency for esthetic full-contour (monolithic) restorations but lowered mechanical properties. This reduction in strength and fracture toughness, yields certain limitations with regard to indications, wall thickness and connector dimensions.

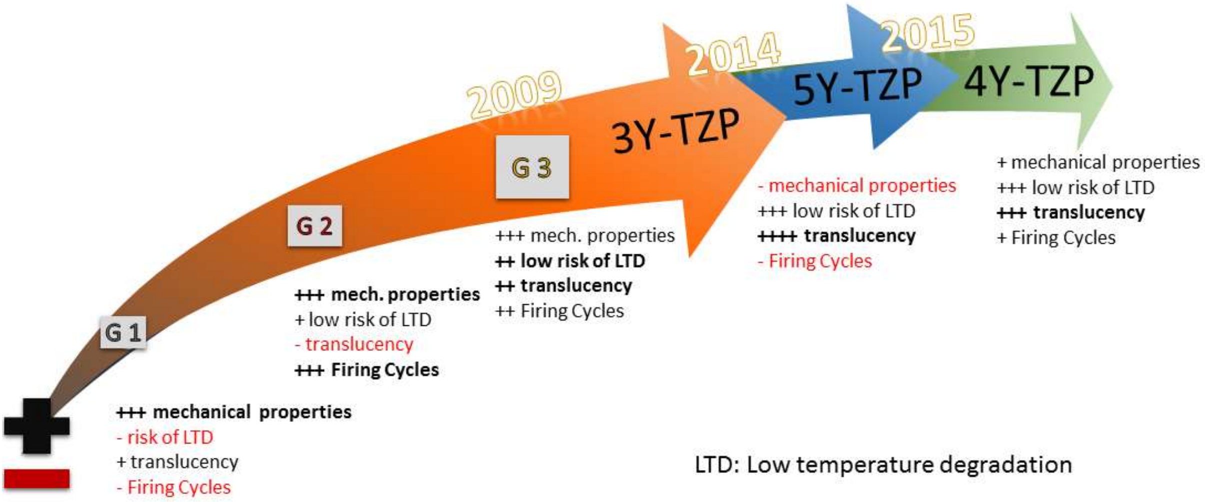

Figure 8: Evolution and characteristics of dental zirconia types: different generations of 3Y-TZP until 2014. After 2014 the 5Y-TZP materials were introduced to the dental market. Low temperature degradation (LTD) describes the aging sensitivity of zirconia.

IPS e.max ZirCAD discs and blocks can be divided into 2 groups: the strong 3Y-TZP materials IPS e.max ZirCAD LT and MO and the translucent 4Y-TZP products with lower mechanical properties (IPS e.max ZirCAD MT Multi and MT).

Figure 9: IPS e.max ZirCAD products are available as pre-sintered discs and blocks for CAD/CAM technology.

There is an influence (see Figure 10) of increasing yttria content on grain size (in the microstructure) and the coefficient of thermal expansion. It controls the major physical properties. This influence on mechanical and optical properties is described in detail in the following chapters.

		ZirCAD MT Multi	
	ZirCAD MO / LT 3Y-TZP/4.5–6.0 wt% Y_2O_3 tetragonal phase and **no cubic** phase	**ZirCAD MT** 4Y-TZP/6.5–8.0 wt% Y_2O_3 tetragonal and **some cubic** phase (25%)	**«Zirconia Anterior»** 5Y-TZP/9.0–10.0 wt% Y_2O_3 tetragonal and **more cubic** phase (50%)
Grain size [µm]	0.50	0.65	0.85
Thermal Expansion CTE [µm/m*K]	10.5	10.4	9.8 – 10.1

Figure 10: Overview of used types and characteristics of TZP materials within the IPS e.max ZirCAD portfolio.

3.3.1 3Y-TZP

The first generations of dental zirconia were all 3Y-TZP based. **Y**ttria stabilized-**t**etragonal **z**irconia **p**olycrystal is made of fine grain zirconia with small amounts of Y_2O_3 as dopant. These fully crystalline 3Y-TZP ceramics (IPS e.max ZirCAD LT and MO) have the following composition:

Component	**Content**
Zirconium oxide (ZrO_2)	88.0 - 95.5 wt%
Yttrium oxide (Y_2O_3)	> 4.5 - ≤ 6.0 wt%
Hafnium oxide (HfO_2)	≤ 5.0 wt%
Aluminium oxide (Al_2O_3)	≤ 1.0 wt%
Other oxides for colouring	≤ 1.0 wt%

Table 2: Typical composition of 3Y-TZP.

After sintering, it consists of around 98% metastable tetragonal phase. The transformation tendency is grain size dependent, which is why good 3Y-TZP ceramics are developed with grains of homogeneous shape and size (see Figure 11). Due to adequate temperature conditions during sintering, the typical grain size is 0.5 µm. If the grain size shrinks below a critical size (< 0.3 µm) the material loses the ability for t-to-m transformation at crack development and therefore toughness decreases.[5; 9]

Compared to glass ceramics, zirconia in general has certain optical disadvantages due to its relatively high refractive index, which causes a high grade of total reflection. The refractive index changes depending on the orientation of the tetragonal crystals of the zirconia, which can cause birefringence[3]. The high reflectability leads to a mirror-like surface that is shinier than natural teeth resulting in poor esthetics. Furthermore, the high number of small crystalline grains, possible pores and precipitated Al_2O_3 grains lead to an enormous number of interfaces. These interfaces scatter passing light and cause a loss in transmitted light, leading to a further deterioration in translucency and therefore esthetics. Higher yttria content leads to reduction in birefringences and increased grainsize. Hence, 3Y-TZP materials are more opaque than zirconia ceramics, which have a higher amount of Y_2O_3 (e. g. 4Y-/5Y-TZP).

These poor esthetic characteristics make additional veneering with suitable products like IPS e.max Ceram and IPS e.max ZirPress necessary or desirable. Veneering materials are not as strong however as zirconia, and this may lead to surface chipping. Differences in the CTE (**c**oefficient of **t**hermal **e**xpansion) of zirconia and the veneering material plus poor fitting of the framework and veneer can lead to additional intrinsic stresses, which can cause fracture of the restoration. [4]

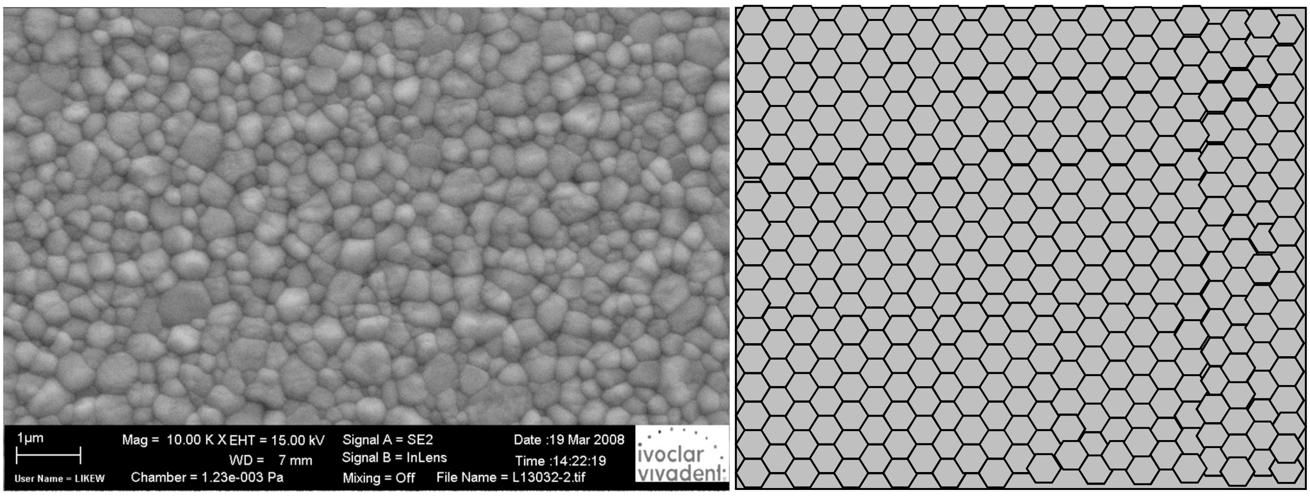

Figure 11: Micrograph of 3Y-TZP material and schematic illustration of uniform grains.

Some features of 3Y-TZP were improved through the development of new 3Y-TZP generations. On the one hand, the amount and size of the Al_2O_3 grains were minimized, leading to increased translucency, improved strength and long-term stability. [4] On the other hand, the processing of the raw material was optimized, leading to more suitable raw powder particles. The improvements in optical characteristics were however insufficient, making the use and the associated drawbacks of veneering materials still necessary.

3.3.2 4Y-TZP and 5Y-TZP

To avoid disadvantages such as high opacity and the risk of chipping, new generations of ZrO_2 were necessary. The new translucent dental zirconias involved increasing the content of Y_2O_3, resulting in two crystalline materials: 4Y-TZP (4 mol% Y_2O_3) and 5Y-PSZ (5 mol% Y_2O_3). Due to the increased Y_2O_3 content, cubic phase occurs alongside metastable tetragonal phase. The quantity of the cubic phase (see Figure 12) increases from around 25% in 4Y-TZP

[3] Birefringence is the ability of double refraction of light in optically anisotropic materials. In this case, a light beam is split into two beams with slightly different paths due to the refractive index, which is dependent on the orientation of the crystals.

materials to up to 50% in 5Y-TZP materials. The latter sometimes contains the cubic phase as the main phase (more than 50%) which is why 5Y-TZP is sometimes referred to as **p**artially **s**tabilized **z**irconia (5Y-PSZ). The grains in 4Y-TZP and 5Y-TZP are larger than in 3Y-TZP, resulting in fewer grain boundaries, less birefringence and scattering of light. The material is thus more translucent than 3Y-TZP.

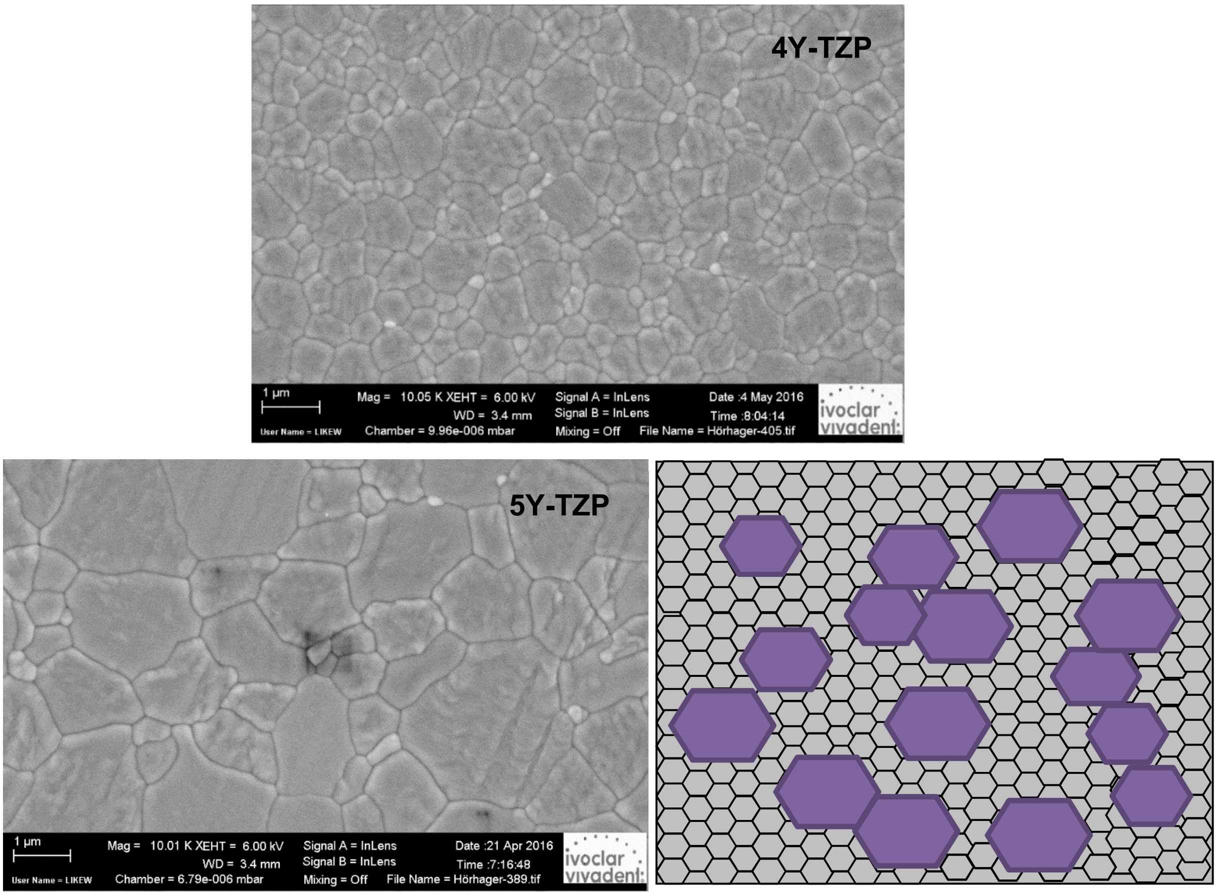

Figure 12: Micrograph of 4-Y-TZP (upper graph) and 5Y-TZP material and schematic illustration (lower graphs). The schematic illustration shows the 50:50 composition of tetragonal (grey) and cubic (purple) phase in 5Y-TZP.

A certain disadvantage of these new translucent ZrO_2 materials is the lower fracture toughness compared to 3Y-TZP. The translucent materials have smaller amounts of tetragonal phase (75% in 4Y-TZP and ~50% in 5Y-TZP), leading to a reduced possibility of t-to-m transformation and therefore less transformation toughening. Furthermore, the CTE decreases with increasing Y_2O_3 content. The resulting variety of CTE values for the different zirconia products may lead to problems with veneering materials that are not specifically designed for a particular type of zirconia, in terms of adjusted CTE differences between framework and veneering.

Material	LiS_2	3Y-TZP	4Y-TZP	5Y-TZP
Biaxial flexural strength [MPa]	500 ± 60	1000± 200(*)	750± 100(*)	600± 50(*)
Fracture toughness [MPa√m]	2.25 ± 0.25	5.00 ± 0.25	3.75 ± 0.25	2.40 ± 0.25
Thermal expansion [µm/m*K]	10.15 ± 0.25	10.50 ± 0.25	10.40 ± 0.25	9.95 ± 0.25

Table 3: Material characteristics of lithium disilicate glass-ceramic (LiS_2) and 3Y-/4Y- and 5Y-TZP. (*) By grinding/polishing of the specimens, the strength values can be increased by up to 40% due to the compressive stress formation within the surface.

Blended mixtures of powders can lead to an increase in fracture toughness. One must keep in mind however, that the strength is controlled by the weakest part of the microstructure, such as pores or conglomerates of large grains.

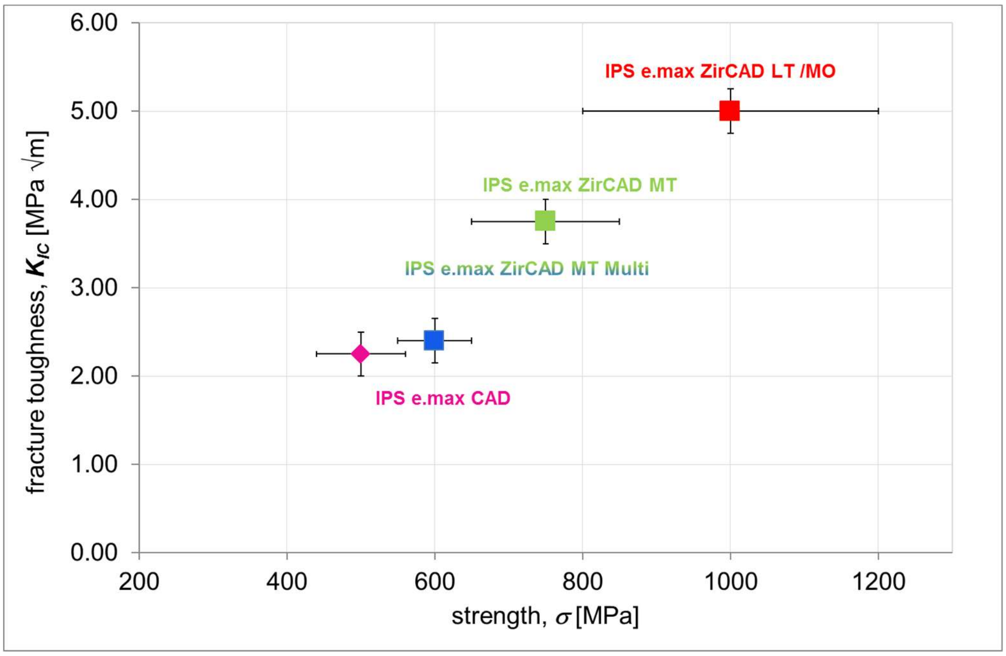

Figure 13: Comparison between different zirconia types (blue, green and red squares) and IPS e.max CAD (pink square). The influence of increasing yttria content on fracture toughness and strength is evident.

Due to this reduction of fracture toughness and strength in highly translucent products, the indications are limited to full-contour crowns and full-contour 3-unit bridges with higher wall thicknesses.

4 Technical Data

Product / Produkt / *Producto*	**Product category** / Produkt Kategorie / *Categoría del producto*
IPS e.max ZirCAD	**Zirconium oxide for processing with CAD/CAM technology** Zirkoniumoxid für die CAD/CAM Technologie *Óxido de circonio para la tecnologia CAD/CAM*

Characteristics[4] Eigenschaften *Características*	*Note(s)*	**Specification/** Spezifikation/*Especificación*		**Unit** Einheit *Unidad*
		MO, LT [5]	**MT** [6]	
Flexural strength Biegefestigkeit *Resistencia a la flexión*	[7]	≥ 900	≥ 700	MPa
Linear thermal expansion (CTE) Wärmeausdehnungskoeffizient (WAK) *Coeficiente de expansion termal*		10.0 ≤ CTE* ≤ 11.0 *(*span 25/100-500°C)*	9.9 ≤ CTE* ≤ 10.9 *(*span 25-500°C)*	$10^{-6}K^{-1}$
Chemical solubility Chemische Löslichkeit *Solubilidad química*		< 100	< 100	$\mu g \cdot cm^{-2}$
Glass transition temperature (T_g) Glasübergangstemperatur *Temperatura de transición vitrea*		N/A		°C
Radioactivity (^{238}U) Radioaktivität *Radioactividad*		≤ 1		$Bq\ g^{-1}$

The product meets the relevant performance criteria as defined in

Das Produkt erfüllt die relevanten Leistungskriterien wie beschrieben in

Se cumplen los criterios de desempeño que se han definido en la norma

EN ISO 6872:2015 - Dentistry – Ceramic materials (ISO 6872:2015)

[4] Physical and Mechanical properties / Propiedades físicas y mecánicas

[5] Class 5 Type II according to EN ISO 6872:2015

[6] Class 4 Type II according to EN ISO 6872:2015. Includes MT Multi

[7] Biaxial

5 Materials Science Investigations (*in-vitro*)

Although the results of *in-vitro* examinations cannot be directly applied to the clinical application of a material, they provide important information about how the product will behave under certain test conditions. These values are not to be interpreted in an absolute manner; rather, they should be seen and interpreted within the context of the test arrangements and conditions.

5.1 Flexural strength

ISO 6872:2015 stipulates a minimum value of 500 or 800 MPa for flexural strength, depending on the class of dental ceramic material.

Product	LOT	Flexural Strength [MPa] *biaxial strength, Piston on three balls (according to DIN EN ISO 6872:2015), as fired*		Type / class *according to DIN EN ISO 6872:2015*
IPS e.max ZirCAD MT Multi (dentine zone) (4.25Y-TZP)	W01746	**865**	SD 115	II / 4
IPS e.max ZirCAD MT (4.25Y-TZP)	VM9002	**881**	SD 135	II / 4
IPS e.max ZirCAD LT (3Y-TZP, 0.05% Al2O3)	V45910	**1224**	SD 144	II / 5
IPS e.max ZirCAD MO (3Y-TZP-A, 0.25% Al2O3)	S13271	**1201**	SD 72	II / 5
BruxZir Anterior	Z0815434	**721**	SD 132	II / 5 (*)
NexxZr T	HVXBD	**1013**	SD 174	II / 5 (*)
NexxZr +	TAAABE	**834**	SD 121	II / 5 (*)
Zenostar MT	U33257	**1093**	SD 56	II / 4 (*)
Zenostar T	V15659	**1184**	SD 248	II / 5 (*)

Table 4: Comparison of strength values of various IPS e.max ZirCAD products and competitor materials (SD: standard deviation) (*) As specified by manufacture, sometimes without year. (R&D Ivoclar Vivadent AG, Schaan, FL).

The measured values are depicted in Figure 14:

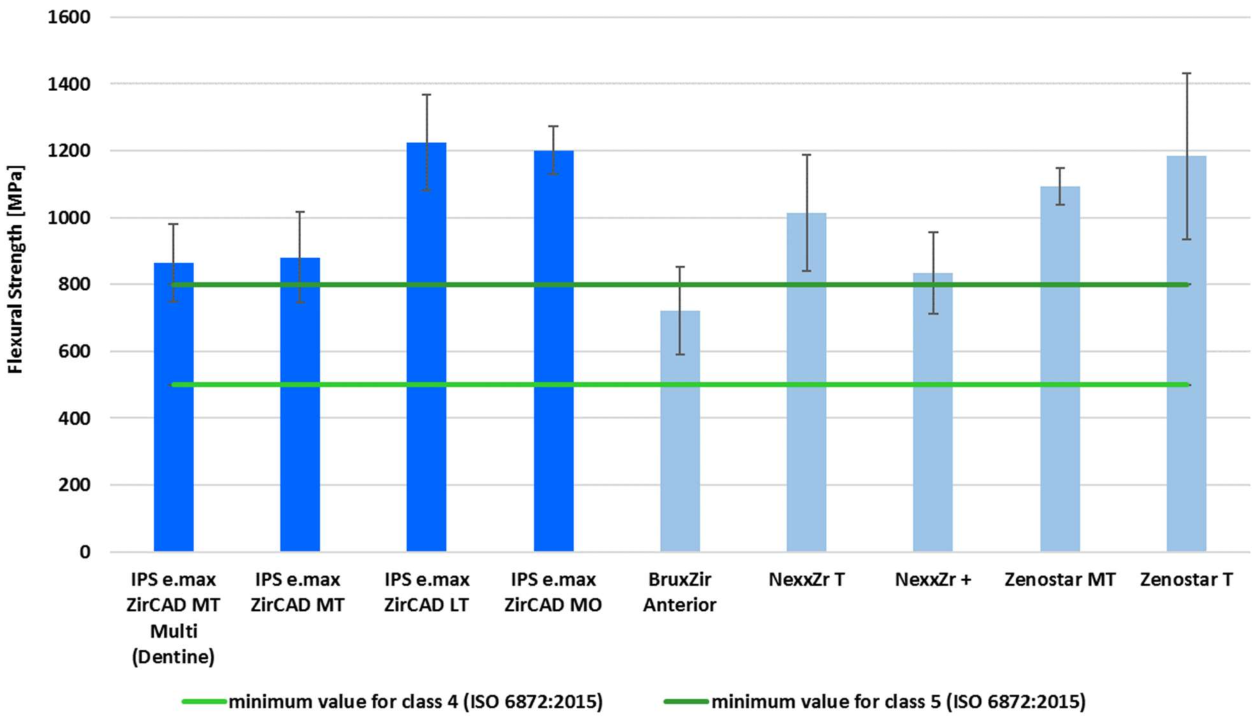

Figure 14: Comparison of flexural strength values of various IPS e.max ZirCAD products and competitor materials. The minimum values according to ISO 6872:2015 are shown as green lines.

► The biaxial flexural strengths of the various IPS e.max ZirCAD products are clearly above the minimum values of 500 MPa (for class 4) or 800 MPa (for class 5) stipulated in the standard.

5.2 Fracture toughness

In ISO 6872:2015 fracture toughness is merely informative and a threshold value has therefore not been defined. Nevertheless, fracture toughness is an important feature of dental ceramic materials, because it can be used to draw conclusions on other properties such as the strength.

Product	LOT	Fracture Toughness [MPa √m]	
		Vickers Indendation Toughness	
IPS e.max ZirCAD MT Multi (Dentine)	V52128	**3.6**	SD 0.2
IPS e.max ZirCAD MT	VM9002	**3.6**	SD 0.15
IPS e.max ZirCAD LT	V45910	**5.1**	SD 0.1
IPS e.max ZirCAD MO	P79043	**5.1**	SD 0.1
BruxZir Anterior	Z0815434	**2.4**	SD 0.1
Katana UTML	DMSYE	**2.2**	SD 0.05
Pritimulti Disc	5YZ-L65-080515-W-007-18-014	**3.2**	SD 0.1
NexxZr T	XXBAF	**4.9**	SD 0.05
NexxZr +	XXAAD	**5.1**	SD 0.1

Table 5: Comparison of fracture toughness values of various IPS e.max ZirCAD products and competitor materials (SD: standard deviation). (R&D Ivoclar Vivadent AG, Schaan, FL).

In Figure 15, the measured values are depicted:

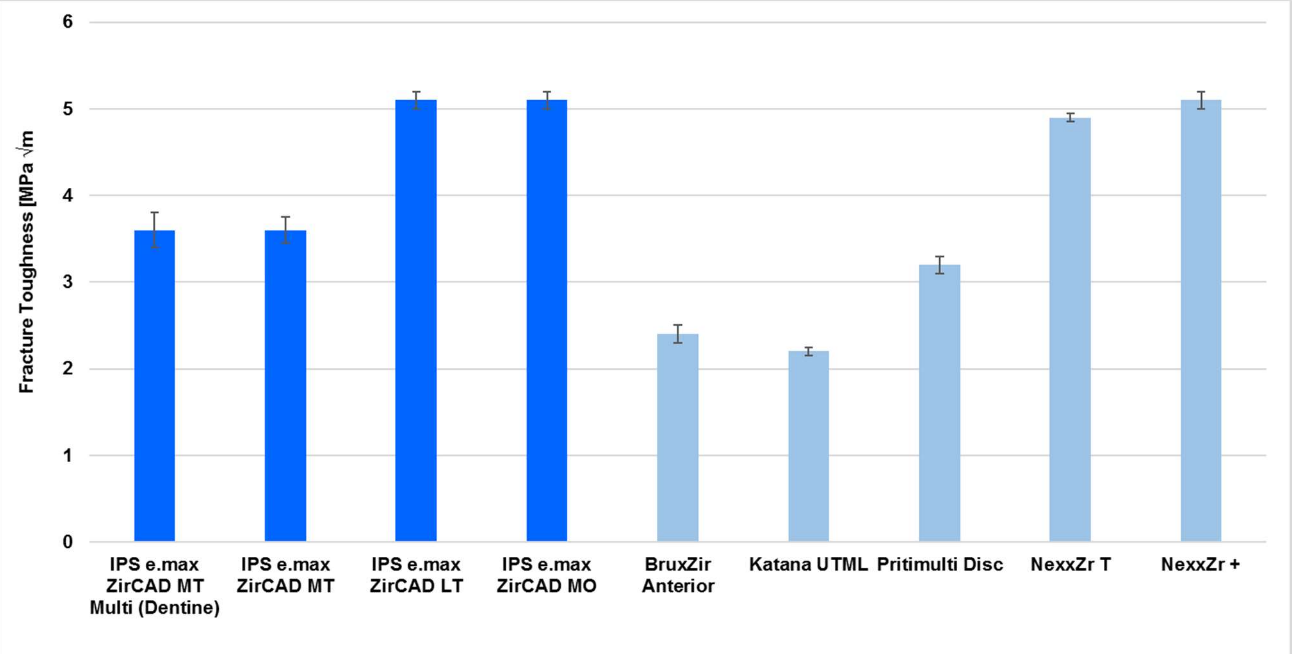

Figure 15: Comparison of fracture toughness values of various IPS e.max ZirCAD products and competitor materials.

5.3 Optical properties

The goal of the IPS e.max ZirCAD MT development was initially to use the highly translucent pure 5Y-TZP raw material to be able to offer a highly translucent full-contour zirconia material. During development however, the limits of a high translucency raw material become clear. At a cervical wall-thickness of about 1.5 mm, the translucency was so high such that a discoloured die could not be covered properly and a tremendous loss of brightness in the oral environment was noticed. Therefore, mixtures of 5Y-TZP with 3Y-TZP were tested to find an optimal opacity for full-contour zirconia crowns that could be used for anterior restorations, as well as having a wall thickness of about 1.5 mm.

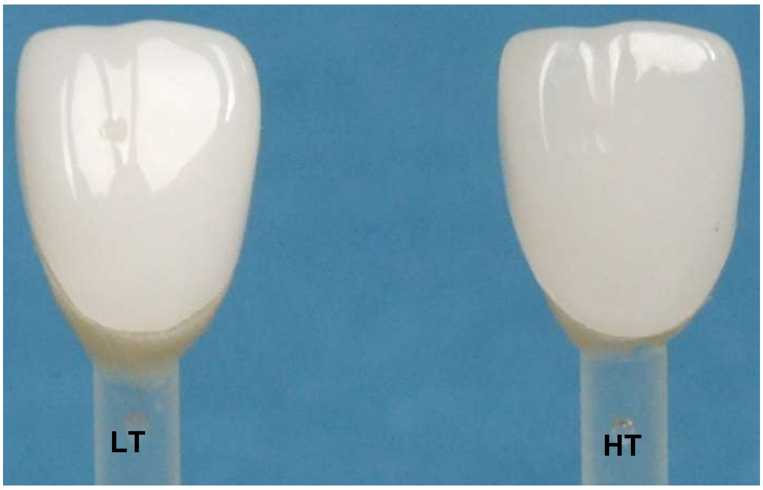

Figure 16: Comparison of low translucent (LT, left side) vs high translucent (HT, right side) zirconia anterior restorations. The HT material does not properly cover the die and seems somewhat grey. The translucency is too high in the cervical part of the crown.

Based on the picture above, it becomes obvious that opacity must be adjusted in order to fit the clinical indication. On the one hand a discoloured tooth or abutment must be covered properly, so as not to lose too much brightness from the restoration; on the other hand, the opacity needs to be low enough such that the occlusal/incisal area still looks esthetically similar to a natural tooth. This is dependent on the wall thickness of the desired restoration.

Since the wall-thickness is determined by the mechanical properties, the right opacity level has to be realized for the various products. Figure 17 shows the dependence between opacity and wall-thickness. The higher the wall thickness, the higher the opacity. This correlation varies depending on the raw material that is applied. The lower the wall thickness the more similar the different zirconia materials become, with respect to opacity.

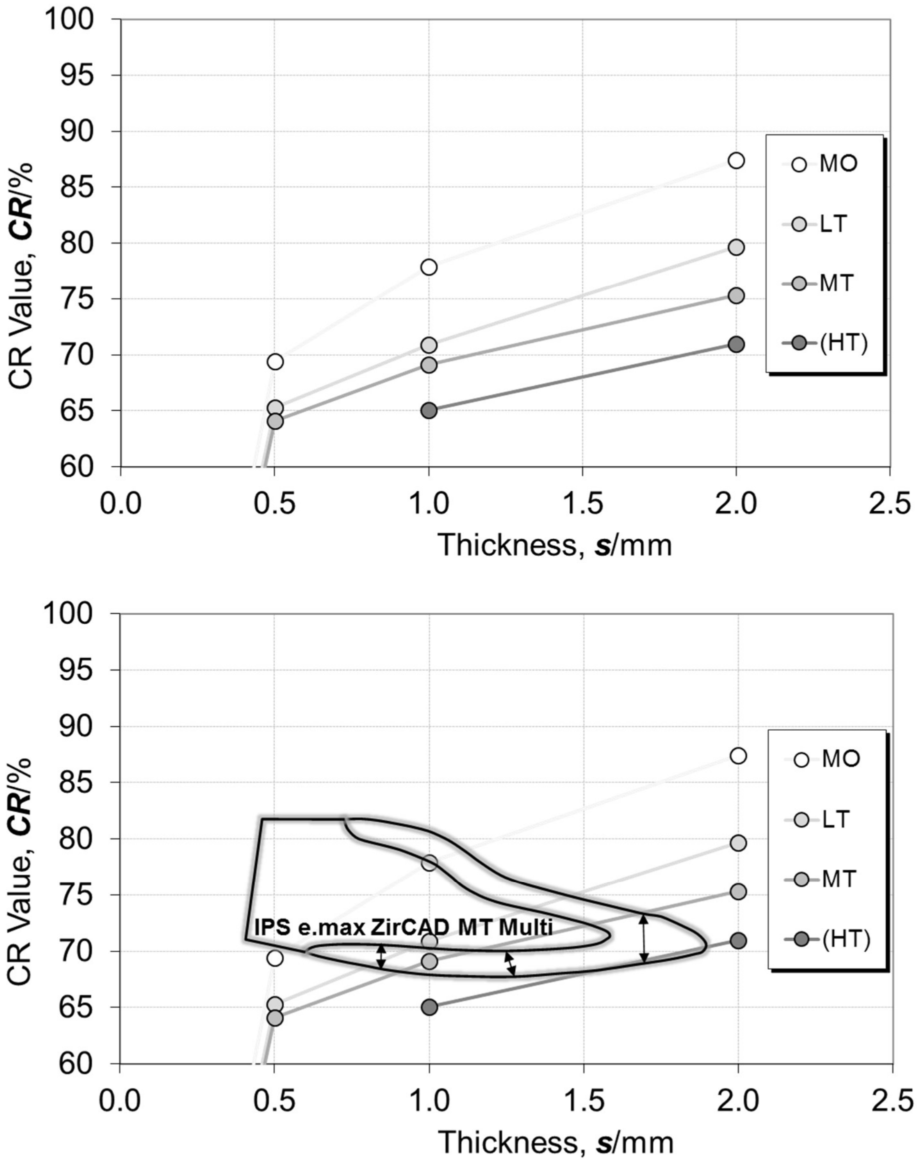

Figure 17: Dependence between opacity CR and wall thickness. In the lower graph, the cross section of an anterior IPS e.max ZirCAD MT Multi crown indicates the concept of the translucency gradient. MO = medium opacity, LT = low translucency, MT = medium translucency and HT = high translucency.

Results achieved from restorations made of IPS e.max ZirCAD MT showed that in the oral environment very esthetic restorations can be made with a cervical/circular wall thickness of 1 mm and an opacity of about 68%. Therefore, IPS e.max ZirCAD MT Multi uses the MT raw material in the cervical part (see lower graph of Figure 17). In the incisal part, where the wall thickness naturally increases to 1.5 – 2 mm the same opacity is achieved with the HT material (5Y-TZP). Hence, the IPS e.max ZirCAD MT Multi has a gradient of the composition starting from 4Y-TZP up to 5Y-TZP, which leads to a natural appearance in the oral environment. The incisal part in particular is characterized by natural light transmission so that IPS e.max ZirCAD MT Multi can be used for anterior restorations without any layering and/or applying veneering ceramics. IPS e.max ZirCAD LT (LT material) can be used as a full-contour zirconia with good esthetics assuming a wall-thickness of 0.5 – 0.8 mm. For IPS e.max ZirCAD LT, thicker walls > 0.9 mm make the restoration look too opaque and too bright. Therefore, minimal layering is recommended in the occlusal or incisal parts, when using IPS e.max ZirCAD LT.

5.4 Wear: Monolithic materials - Ceramic and antagonist wear

Traditionally the main difficulties experienced with zirconia-based restorations, related to chipping of the veneering ceramic. This led to the introduction of techniques such as the CAD-on technique whereby an IPS e.max ZirCAD framework is veneered with IPS e.max CAD and the introduction of more translucent fully anatomic zirconia restorations.

The popularity and use of zirconia-based ceramics has increased in recent years. The clinical success of zirconia-based crowns and fixed dental prostheses has also been demonstrated in several studies [14-18]. The use of CAD/CAM monolithic zirconia restorations with more esthetic translucency have also become more popular [14].

As zirconia is considerably harder than many other ceramic materials this led to concerns about the wear effects on antagonist teeth. In their clinical evaluation, Stober et al. [14], concluded that although monolithic zirconia crowns cause more antagonistic wear than natural teeth, they cause less than other dental ceramics. In summarizing the results of *in vitro* studies, they also note that the consensus is that well-polished zirconia does not lead to excessive wear or damage of opposing enamel and in fact results in less antagonistic wear than other ceramics [19-24]. Polishing of the surface of fully anatomic (monolithic) zirconia restorations is therefore recommended as the effect on the wear of antagonist natural teeth is favourable [19; 25].

5.5 IPS e.max ZirCAD and different veneering techniques

The following studies investigated the fracture, fatigue, reliability and shear bond strength of IPS e.max ZirCAD restorations veneered using the various possible techniques, from layering with IPS e.max Ceram to heat pressed veneers with IPS e.max ZirPress and CAD-on veneered restorations using IPS e.max CAD.

5.5.1 Veneering technique effect on fatigue reliability of zirconia-based all-ceramic crowns.

P. Guess, P. Coelho, V. Thompson. College of Dentistry, New York University, USA [26]

Objective: To evaluate the difference in reliability and failure modes of Y-TZP crowns veneered using the press-on, hand-layering, or the IPS e.max CAD-on technique. The null hypothesis assumed no difference in reliability or failure mode between techniques.

Method: 63 multilayer crown specimens with an IPS e.max ZirCAD core were fabricated according to the 3 techniques: **press-on** using IPS e.max ZirPress, **layering** using IPS e.max Ceram and **IPS e.max CAD-on** using IPS e.max CAD. Each group comprised 21 specimens.

All crowns were fabricated using a standard coping design of a lower molar (0.5 mm thick) with identical dimensions for the IPS e.max ZirCAD framework and veneering ceramic. Metal Zirconia Primer was applied to the internal surfaces, with all crowns cemented with Multilink Automix to aged (water-stored for a minimum of 60 days) resin-based composite dies (Tetric EvoCeram A2). 3 crowns from each group provided single load to failure data. 18 crowns provided mouth-motion step-stress fatigue data using a sliding tungsten carbide indenter machine (r = 3.18 mm) 0.7 mm (lingually) down the disto-buccal cusp with increasing stress levels applied sequentially until failure. Failure constituted chip fractures of the veneering ceramic and or cone cracks reaching the veneer framework interface.

Results I: Single Load to Failure (n = 3 per group)

Press-on and hand-layered crowns all revealed fractures limited to the veneering structure, IPS e.max CAD veneered crowns withstood significantly higher load levels (2699 ± 243 N) until fracture of the veneering structure and framework ceramic occurred (see Figure 18).

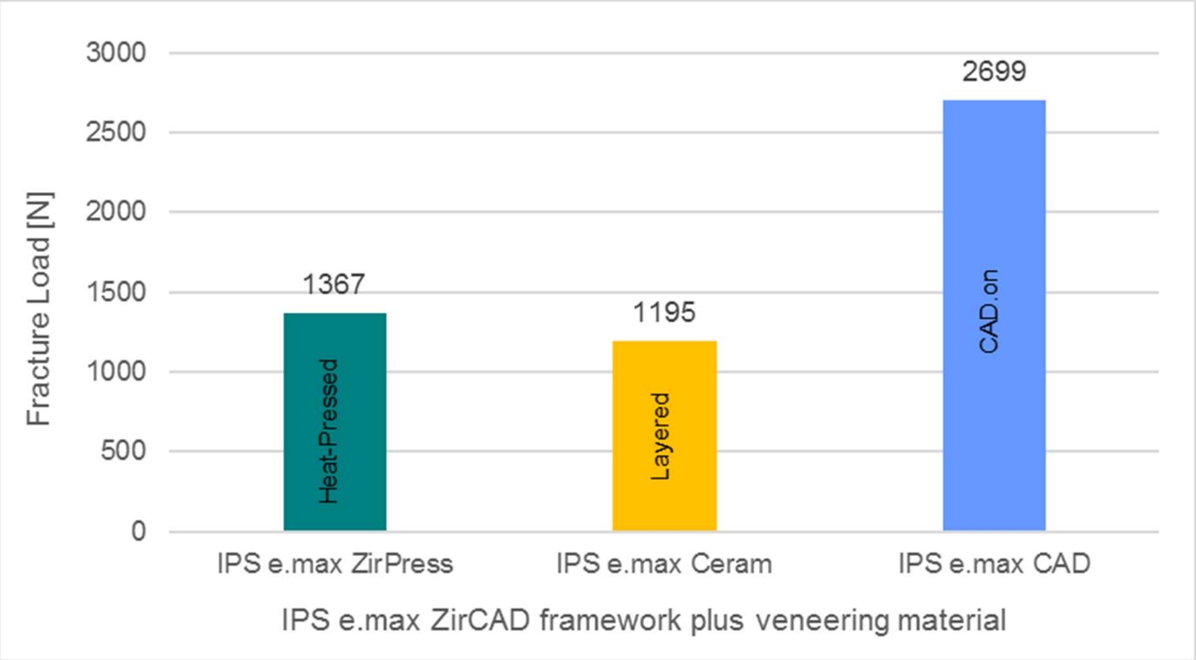

Figure 18: Single load to failure results of IPS e.max ZirCAD framework with different ceramic veneering structures applied using the press-on, layering and IPS e.max CAD-on techniques.

Results II: Mouth-motion Step Stress Fatigue (n = 18 per group)

49% of the hand layered crowns showed crack initiation before catastrophic failure in the form of chip-off fractures of the veneer. Extensive cracks prior to failure were however, not observed in the press-on group. No cracks of the IPS e.max ZirCAD framework were observed in any group. IPS e.max CAD-on crowns showed no actual fractures. All IPS e.max CAD-on crowns were considered survivors as there were no failures at the chosen cut off load of 900 N and after a maximum of 170 K cycles.

Results III: Reliability data (Table 6), calculated at 50,000 cycles and 200 N load indicates that the cumulative damage would lead to veneer failure (due to chipping) in 2% of the IPS e.max ZirPress, 5% of the IPS e.max Ceram and none of the IPS e.max CAD veneers.

Veneer Material	IPS e.max ZirPress	IPS e.max Ceram	IPS e.max CAD
Upper 90% CI	0.99	0.99	1.0
Value	**0.98**	**0.95**	**1.0**
Lower 90% CI	0.91	0.80	1.0
Survivors	0	0	18

Table 6: Reliability comparison of various veneering techniques.

Conclusion: CAD/CAM fabricated lithium-disilicate veneering structures fused to zirconia frameworks resulted in highly fatigue resistant crowns, showing no susceptibility to mouth-motion step stress fatigue at 900 N. Crowns manufactured using the IPS e.max CAD-on technique were more reliable indicating no risk for chipping.

5.5.2 Effect of veneering techniques on bond strength of zirconia-based systems

T. Yilmaz, and F. A. Selcuk University, Konya, Turkey [27]

Objective: The aim of this study was to compare the shear bond strength (SBS) of a zirconia framework material veneered using different fabrication techniques.

Methods: Sixty IPS e.max ZirCAD sample discs were cut and sintered (15 x 11 x 3 mm). Specimens were then divided into three different veneering groups (n=20): Heat-pressed with IPS e.max ZirPress, layered with IPS e.max Ceram or veneered using IPS e.max CAD i.e. CAD-on technique. The layered and heat-pressed groups were coated with ZirLiner (Ivoclar Vivadent). Specimens were subjected to shear force using a universal testing machine. Load was applied at a crosshead speed of 0.5 mm/min until failure. Mean SBSs (MPa) were analyzed with One-Way ANOVA and Tukey tests ($P<0.05$). The failed specimens were examined under a stereomicroscope at x40 to classify the mode of failure as cohesive, mixed or adhesive.

Results: The mean SBS values were 12.23 (±3.04) MPa for the heat-pressed group, 14.27 (± 4.45) MPa for the layered group; and 31.89 (± 5.83) MPa for the CAD-on group. ANOVA and Tukey tests revealed that the CAD/CAM-veneering group showed significantly higher SBS values in all test groups ($P=0.00$). There was no significant difference between the layered and heat-pressed groups ($P=0.347$).

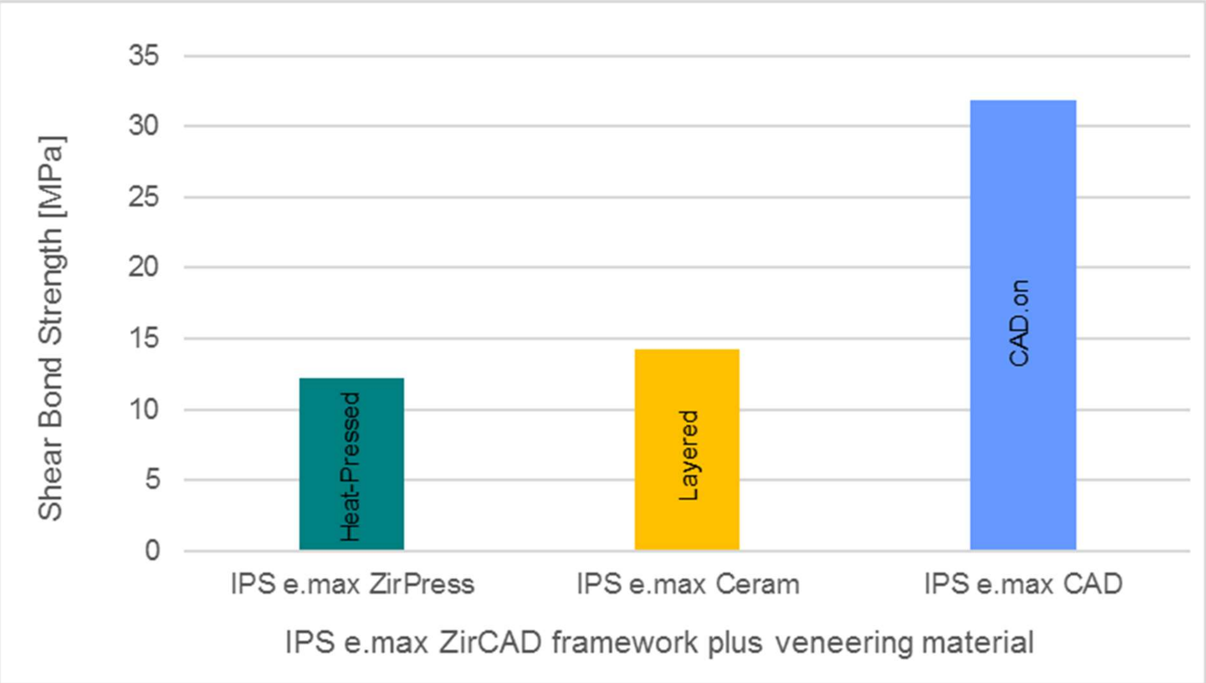

Figure 19: Shear bond strength of IPS ZirCAD frameworks with varying veneering structures.

The mixed type failure mode was observed most in all groups. Cohesive failures within ceramic were found in both layering and heat-pressing groups. Adhesive failures between zirconia and ceramic were only observed in the CAD/CAM-veneering group.

Conclusions: The CAD/CAM-veneering technique showed the highest bond to zirconia framework. This technique may prevent ceramic delamination and chipping in zirconia-based restorations.

5.6 Monolithic Zirconia - Wall thickness and resistance to fatigue

As seen in the previous studies, zirconia restorations have traditionally been veneered in some way due to their lack of translucency. More recently, monolithic all-ceramic zirconia products have been introduced in more translucent shades. Monolithic zirconia offers a number of advantages from the overall strength of the material, elimination of potential chipping, and a reduction in the amount of occlusal space required.

An internal investigation to simulate oral aging was carried out with monolithic molar crowns fabricated from IPS e.max ZirCAD MT discs which are indicated for use at a minimum thickness of 0.8 mm. The crowns in this study were produced with an even thinner constant wall-thickness of 0.5 mm. After milling, the connectors were removed and each crown was glazed twice with IPS Ivocolor. The zirconia crowns were then luted adhesively to PMMA abutments using the Multilink Automix system. The abutments were sandblasted (110 µm) at 2 bar and the inner side of the crowns were sandblasted (50 µm) at 1 bar. Multilink Primer A and B was applied to the PMMA and Monobond Plus to the inner side of the crown. The luted crowns were then stored in dry conditions for at least 24 hours at 37°C. The crowns were placed in a chewing simulator with a steel antagonist for 200,000 cycles (0.9 Hz) at a load of 150 N (n=4) and 170 N (n=4) and evaluated for cracks or fractures. Thermocycling was carried out with regular temperature alterations from 5°C to 55°C. Crowns were checked for damage 4 x a day.

As clinical studies have shown that the chewing load of natural teeth lies between 100 and 150 N [28].The IPS e.max ZirCAD MT crowns in this study withstood similar or higher loads (150N / 170 N) with no fractures observed at either level. As the study was carried out using crowns with an even lower wall thickness than that recommended, this study represents the "worst case scenario" and all crowns survived intact.

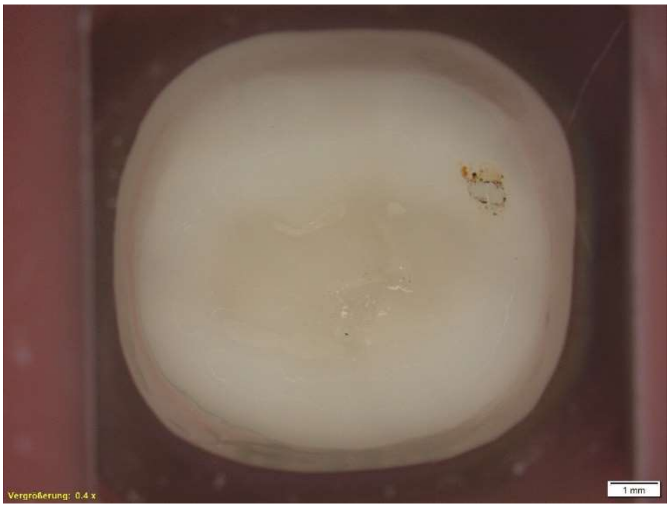

Figure 20: IPS e.max ZirCAD MT molar crowns after 200,000 dynamic loading cycles at 170N.

It can therefore be concluded that IPS e.max ZirCAD MT crowns with a minimum wall thickness of 0.8 mm offer more than adequate resistance to fatigue.

6 Clinical Investigations with IPS e.max ZirCAD

6.1 IPS e.max ZirCAD crowns and bridges veneered with IPS e.max Ceram

Prospective study of zirconia-based restorations: 3-year clinical results Beuer F, Stimmelmayr M, Gernet W, Edelhof D, Güth J-F, Naumann M. [29]

Objectives: To evaluate the clinical performance of crowns and bridges made of IPS e.max ZirCAD veneered with IPS e.max Ceram.

Methods: 38 patients received 68 restorations (18 bridges and 50 single crowns). Zirconia substructures were milled using CAD/CAM technology and veneered with IPS e.max Ceram using the traditional layering technique. All restorations were cemented with glass ionomer. Baseline evaluation was performed 2 weeks after cementation with recall examinations at 12, 24 and 36 months by calibrated investigators. SEM was performed on replicas of all restorations. Survival probabilities according to Kaplan Meier were calculated.

Results: The mean service time was 35 (+/- 14) months. After 3 years of clinical service, three biological and five technical failures were recorded. All failures occurred in the bridge group. One bridge was removed after biological failure of one abutment tooth. The Kaplan-Meier survival probability was 88.2% after 35 months for all types of failures and 98.5% concerning restorations in service. No difference in the gingival parameters measured on restored and control teeth was observed.

Conclusions: IPS e.max ZirCAD veneered with IPS e.max Ceram seem to be a reliable treatment option.

6.2 IPS e.max ZirCAD veneered with IPS e.max CAD or IPS e.max Ceram

Three-unit posterior zirconia-ceramic fixed dental prostheses (FDPs) veneered with layered and milled (CAD-on) veneering ceramics: 1-year follow-up of a randomized controlled clinical trial.

Grohmann P, Bindl, A, Hammerle C, Mehl A, Sailer I. University of Zürich, Switzerland.[30]

Objectives: The aim of this multicenter, randomized controlled clinical trial was to compare zirconia-ceramic fixed dental prostheses (FDPs) veneered with either a CAD/CAM lithium disilicate veneering ceramic (CAD-on) or a manually layered veneering ceramic with respect to survival, technical and biological outcomes.

Methods: Sixty patients in need of one posterior three-unit bridge (FDP) were included. The zirconia (IPS e.max ZirCAD) frameworks were produced with a CAD/CAM system (Cerec inLab 3D/Cerec inEOS inLab). Thirty FDPs were then veneered with a CAD/CAM lithium disilicate veneering ceramic (IPS e.max CAD HT) using the CAD-on technique (test group). The other thirty were veneered with a layered zirconia veneering ceramic (IPS e.max Ceram) (control group). For the clinical evaluation at baseline, 6, and 12 months, the United States Public Health Service (USPHS) criteria were used. The biological outcome was judged by comparing the plaque control record (PCR), bleeding on probing (BOP), and probing pocket depth (PPD). Data were statistically analyzed.

Results: Fifty-six patients were examined at a mean follow-up of 13.9 months. At the 1-year follow-up the survival rate was 100% in the test and in the control group. No significant differences of the technical outcomes occurred. Major chipping occurred in the control group (n = 3) and predominantly minor chipping in the test group (minor n = 2, major n = 1). No biological problems or differences were found.

Conclusions: Both types of zirconia-ceramic FDPs exhibited very good clinical outcomes without differences between groups. Chipping occurred in both types of FDPs in small amounts, yet the extension of the chippings differed. The CAD-on FDPs exhibited predominantly minor chipping, and the control FDPs major chipping.

6.3 IPS e.max ZirCAD veneered with IPS e.max ZirPress or IPS e.max Ceram

A randomized controlled clinical trial of 3-unit posterior zirconia-ceramic fixed dental prostheses (FDP) with layered or pressed veneering ceramics: 3-year results.

Naenni, N, Bindl, A, Sax C, Hammerle C, Sailer I. University of Zürich, Switzerland. [31]

Objectives: The aim of this study was to test whether or not posterior zirconia-ceramic fixed dental prostheses (FDPs) with pressed veneering ceramic exhibit less chipping than FDPs with layered veneering ceramics.

Methods: Forty patients in need of one maxillary or mandibular three-unit FDP in the second premolar or molar region were recruited and treated at two separate centers at the University of Zurich according to the same study protocol. The frameworks were milled from Y-TZP partially sintered zirconia ceramic blocks (IPS e.max ZirCAD) using a CAD/CAM system (Cerec Sirona, Bensheim, Germany). The patients were then randomly assigned to either the test group (zirconia frameworks veneered with pressed ceramic; IPS e.max ZirPress, n=20) or the control group (layered veneering ceramic; IPS e.max Ceram, n=20). All FDPs were adhesively cemented and evaluated at baseline (i.e. at cementation), at 6 months and at 1 and 3 years of clinical service. The survival of the reconstruction was recorded. The technical outcome was assessed using modified United States Public Health Services (USPHS) criteria. The biological parameters were analyzed using abutment teeth and analogous non-restored teeth included probing pocket depth (PPD), plaque control record (PCR), bleeding on probing (BOP), and tooth vitality (CO_2). Data was descriptively analyzed and survival was calculated using Kaplan-Meier statistics.

Results: 36 patients with 18 test and 18 control FDPs were examined after a mean follow-up of 36 months. Group comparison was carried out via cross tabulation, showing an even distribution of the restored teeth amongst the groups. Survival rate was 100% for both test and control FDPs. Chipping of the veneering ceramic tended to occur more frequently in test (n=8; 40%) than in control (n=4; 20%) FDPs, however this was not significant (p=0.3). No further differences of the technical or biological outcomes of test and control FDPs were found.

Conclusions: Zirconia FDPs with pressed and layered veneering ceramics exhibited similar outcomes at 3 years. A trend to more chipping of the pressed veneering ceramic, however, was observed.

6.4 IPS e.max ZirCAD: Monolithic or veneered vs. IPS e.max CAD and IPS Empress CAD

Fracture rates and lifetime estimations of CAD/CAM all-ceramic restorations. Belli R, Petschelt A, Hofner B, Hajto J, Scherrer SS, Lohbauer U. [32]

Objective: To utilize a large dataset from an industry-scale machining centre in Germany pertaining to the fracture and survival of various CAD/CAM all-ceramic posterior restorations.

Methods: The fracture/replacement data for 34,911 restorations (machined, processed and polished at the same company, according to the same guidelines for each restorative system) were analyzed retrospectively. The fractures of bridges, crowns, onlays and inlays fabricated from different all-ceramic systems over a period of 3.5 years were released for analysis. The following restorative systems were included: Monolithic Zenostar, CAD-on (IPS e.max ZirCAD veneered with IPS e.max CAD), IPS e.max ZirCAD – traditionally veneered, IPS e.max CAD and IPS Empress CAD. The Zenostar and CAD-on systems involved crowns and bridges; the veneered IPS e.max ZirCAD involved only bridges. IPS e.max CAD restorations included crowns, onlays and inlays and IPS Empress CAD was use for onlays and inlays.

Data was anonymous regarding patients and dental practices and was filtered according to restoration-type only. Fixed single-unit (crowns, onlays and inlays) and multi-unit constructions (3, 4, 5-unit bridges) on natural teeth in the posterior region were included. Over the time period 491 fractures were reported. Survival statistics and lifetime estimations based on the fracture distributions were then calculated.

Results: A total of 34,911 restorations were analyzed from which 491 (1.4%) fracture events were recorded.

Comparison of restoration types: In summary, no fractures occurred in the monolithic Zenostar group. IPS e.max CAD-on bridges and veneered IPS e.max ZirCAD bridges showed no significant difference in survival. The CAD-on crowns performed significantly better than monolithic IPS e.max CAD crowns in this study. For onlays and inlays IPS e.max CAD performed significantly better in terms of survival, than IPS Empress CAD.

Comparison of material type: The CAD-on restorations performed significantly better when used as crowns than as bridges. The survival of the IPS e.max CAD restorations performed better as inlays or onlays than as crowns. IPS e.max CAD showed significantly better performance than the leucite based IPS Empress CAD for onlays and inlays. There were no fracture events for the IPS e.max ZirCAD veneered bridges and very few (n=3) fracture events involving Zenostar monolithic restorations.

Conclusions: This study has certain limitations in that patients moving away and potentially visiting new dentists with other dental technicians are not included; nevertheless large numbers of patients are difficult to recruit and observe over long periods of time therefore this study offers an unconventional but useful method for analyzing larger datasets.

The overall fracture rate was very low across all materials (1.4%). Regarding zirconium oxide, no fracture was reported for IPS e.max ZirCAD bridges however it can be assumed that chipping events may have occurred but that their consequences did not result in their being replaced and therefore reported to the machining centre. Monolithic zirconia prostheses (Zenostar) showed promising clinical performance with no failures within the first 8.5 months of placement. Overall, all the evaluated restorative systems showed very good clinical performance.

6.5 IPS e.max ZirCAD veneered with IPS e.max CAD: 4 year results

4 years' clinical behaviour of CAD-on restorations (Lithium disilicate fused to zirconium-oxide- framework).

R. Watzke, S. Huth, L. Enggist, A. Peschke. R&D Dental Clinic, Ivoclar Vivadent, Schaan, Liechtenstein. [33]

Objective: Clinical evaluation of all-ceramic lithium-disilicate fused to zirconium-oxide-framework (IPS e.max CAD Veneering Solutions) restorations after 4 years of observation.

Method: 25 CAD-on-restorations (IPS e.max CAD HT fused to IPS e.max ZirCAD), were manufactured using CAD/CAM-methodology (Cerec v.3.80, Sirona, Germany) in combination with an innovative ceramic–fusing-process (Ivomix and IPS e.max CAD Crystall./Connect). The restorations included tooth- and implant retained crowns (n=20) and 3-unit-bridges (n=5). All CAD-on-restorations were cemented conventionally and examined after a clinical observation period of 4 years by means of FDI criteria for evaluation of indirect restorations. [34] The evaluation covered esthetic (A), functional (B) and biological (C) properties.

Results: After 4 years of clinical observation all CAD-on-restorations were scored “excellent” to “good” relative to the esthetic, functional and biological properties which were examined. One crown could not be examined due to a loosening of a core build-up of an endodontically treated tooth, i.e. there was one drop out. A case with a 3-unit-bridge is shown below at both baseline and after 4 years.

Figure 21: Clinical example of CAD-on technique - IPS e.max ZirCAD / IPS e.max CAD HT veneer as 3-unit bridge on teeth 35-37. Left: At baseline. Right: After 4 years.

Conclusion: The clinical study showed that CAD-on restorations combine high strength with natural appearing esthetics. No chipping or fracture was detected, which stands in direct contrast to relatively high chipping rates reported in the literature for conventionally veneered zirconium-oxide-frameworks [35]. Due to occlusal adjustment after cementation and 4 years of occlusal function, 67% of the restorations showed small areas with silk-mat luster (scored “good”). These surfaces could only be detected by closer examination. In summary, all-ceramic CAD-on-restorations fabricated with IPS e.max CAD fused to IPS e.max ZirCAD seemed perfectly indicated for tooth- and implant retained crowns and 3-unit-bridges. These findings were in accordance with the 12, 24 and 36 month data.

6.6 IPS e.max ZirCAD inlay retained bridges veneered with IPS e.max ZirPress

Clinical Behavior of All-Ceramic Inlay-Retained Bridges after 18 Months

R. Watzke, A. Peschke, J-F. Roulet. Dental Clinic, R&D Dental Clinic, Ivoclar Vivadent, Schaan, Liechtenstein [36]

Objective: To evaluate the clinical behaviour of all-ceramic inlay-retained bridges (IRB) after an average observation period of 18 months.

Method: 20 all-ceramic 3-unit IRBs (IPS e.max ZirCAD framework plus IPS e.max ZirPress veneer), were adhesively cemented (total etch technique) and clinically evaluated after an average observation period of 18 months using the FDI evaluation criteria for indirect restorations [37]. The criteria include esthetic, functional and biological properties. A SQUACE evaluation (semi quantitative clinical evaluation) of each restoration was also carried out.

Results: After a mean observation time of 18 months all IRBs were functional.

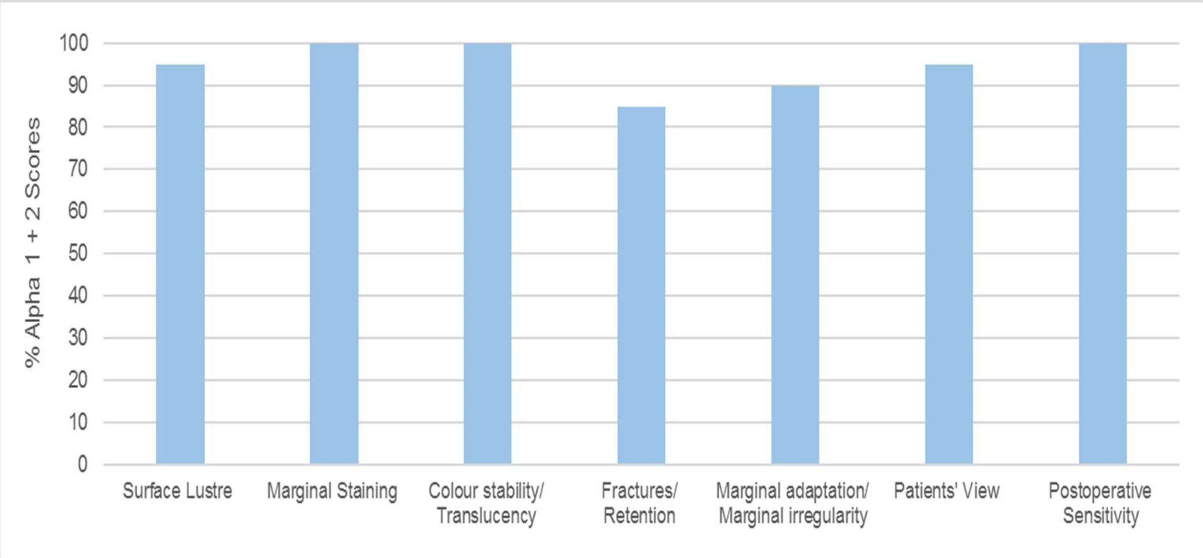

Figure 22: Percentage Alpha 1 and 2 scores for various characteristics of all-ceramic IRBs.

The graph shows the percentage of restorations scoring Alpha 1 (excellent/very good) or 2 (good/after correction very good) for various characteristics. 100% of the restorations scored Alpha 1 or 2 for marginal staining, colour stability and postoperative sensitivity. In one case, the veneering material fractured (including the margin). The restoration was repaired and the IRB is still in function. Two restorations (10%) were rated Beta (sufficient, no unacceptable effects) for marginal adaptation.

The SQUACE evaluation revealed mean values for marginal staining of 1.75% (±2.45) and marginal irregularities for 7.25% (±7.52) of the IRB`s total margin length.

Conclusion: After an average time of 18 months clinical service, 95% of the 3-unit all-ceramic IRBs presented with excellent to very good clinical behavior. All-ceramic IRBs made of IPS e.max ZirCAD/ZirPress seem reliable as a defect-oriented alternative for posterior single tooth replacement.

7 Biocompatibility

Biocompatibility (*bios* [Greek] = life) refers to "the ability of a material to perform with an appropriate biological response in a specific situation". Biocompatibility is therefore concerned with the interaction between the patient and a material and its function. Biocompatibility involves an ongoing dynamic process and is complex to assess. Biocompatibility assessments require an extensive schedule of *in vitro* and *in vivo* investigations. *In vitro* investigations on biocompatibility involve tests in artificial environments, e.g. in cell culture dishes. By contrast, *in vivo* investigations are performed on the living organism in the form of clinical studies [38].

Ceramic materials are highly resistant to acid and corrosion attacks and are therefore regarded as exceptionally biocompatible. The conditions found in the oral cavity (pH and temperature changes) are not severe enough to dissolve components from dental ceramics. Nevertheless, mechanical destruction and chemical reactions (erosion) may have an effect on the constituents of the ceramic. Mechanical abrasion, however, does not affect biocompatibility because the fragments do not remain in the mouth/body for long and the composition of the ceramic does not change if pieces break off. Chemical reactions and the associated dissolution of components would lead to problems, but the composition of dental ceramics is biologically harmless and the amounts of dissolved material would be so small, they would not be a risk to biocompatibility. ISO 6872 prescribes the *evaluation of chemical solubility* to provide proof of the safety of ceramic materials in terms of their solubility [39].

The biocompatibility of IPS e.max ZirCAD and colouring liquids was evaluated with a series of different tests as well as via literature and database searches. The materials were examined for potential cell-damaging effects (cytotoxicity) or harmful effects on genetic material (genotoxicity). Chemical durability was approved by measuring chemical solubility and the radioactivity was determined according to the requirements of the ISO 6872 standard.

7.1 Chemical durability

Dental materials are exposed to a wide range of pH-values and temperatures in the oral cavity. Chemical stability is therefore an essential prerequisite for dental materials. According to Anusavice [40], ceramics are amongst the most durable of all dental materials. Chemical durability according to ISO 6872:

	Chem. solubility [µg/cm^2]	**Limit value according to standard [µg/cm^2]**
IPS e.max ZirCAD MO 0 (Blocks)	1.0	< 100
IPS e.max ZirCAD MO 2 (Blocks)	8.0	
IPS e.max ZirCAD LT BL (Blocks)	10.0	
IPS e.max ZirCAD MT 0	4.6	
IPS e.max ZirCAD MT0 + A4 Colouring Liquid	1.8	
IPS e.max ZirCAD MT0 + B4 Colouring Liquid	0.8	
IPS e.max ZirCAD MT0 + C4 Colouring Liquid	2.7	

IPS e.max ZirCAD MT0 + orange Colouring Liquid	0.9	
IPS e.max ZirCAD MT A3 (Disc)	1.0	
IPS e.max ZirCAD MT Multi A3 (Dentin) (Disc)	6.0	
IPS e.max ZirCAD MT Multi A3 (total) (Disc)	18.0	

Table 7: Chemical solubility of various IPS e.max ZirCAD products. (R&D Ivoclar Vivadent AG, Schaan, FL)

The chemical solubility of all IPS e.max ZirCAD products uncoloured, preshaded and infiltrated with the most intensive colouring liquids (A4, B4, C4 and orange) is far below the limit value according to the relevant standard (ISO 6872.)

7.2 Cytotoxicity

Cytotoxicity refers to the capability of a substance to damage cells. The XTT assay is used to determine whether or not the substance being investigated inhibits cell proliferation or even causes cell death. The resulting XTT_{50} value refers to the concentration of a substance sufficient to reduce the cell number by half.

The cytotoxicity of zirconium oxide has been examined by various authors. Josset *et al.* [41] investigated the biocompatibility of two implant materials, zirconium oxide and aluminium oxide, in osteoblast cell cultures. No toxic potential was found in either one of the two materials. A similar result was reported for cytotoxicity in cell cultures [41].

Furthermore, Ivoclar Vivadent commissioned cytotoxicity tests on coloured Y-TZP materials (IPS e.max ZirCAD).

The *in-vitro* cytotoxicity of the deeply coloured IPS e.max ZirCAD MT 0 + A4 colouring liquid, IPS e.max ZirCAD MT 0 + B4 colouring liquid, IPS e.max ZirCAD MT 0 + C4 colouring liquid, IPS e.max ZirCAD MT 0 + orange colouring liquida and IPS e.max ZirCAD MT 0 + Zenostar MT Color violet were examined with an XTT test. For this examination, the worst case scenario was chosen, where the samples were immersed into the colouring liquids. The result was that none of the samples possessed any cytotoxic potential [42-48].

The *in-vitro* cytotoxicity of the deeply coloured IPS e.max ZirCAD MO4 and IPS e.max ZirCAD MO2, was examined with an XTT test. A cytotoxic potential was not determined for IPS e.max ZirCAD MO4 and MO2 [49; 50].

7.3 Genotoxicity

Genotoxicity refers to the capability of substances or external influences to damage or alter the genetic material of cells.

Josset *et al.* [41] carried out genotoxicity tests on zirconium oxide and aluminium oxide implant materials to assess if these materials cause harm to the DNA. For this purpose, osteoblast cell cultures were used. A genotoxic potential was not found in either one of the two materials. A microbial mutagenicity assay (AMES test) did not show any indication of genotoxic potential for either materials [41]. An AMES test performed by [51] showed the same results.

Ames tests, with extracts of deeply coloured zirconium oxide products were performed at the independent test facility Envigo CRS GmbH in Rossdorf/Germany. It can be stated that during these mutagenicity tests and under the experimental conditions in these tests, the extracts of the test items did not induce gene mutations by base pair changes or frameshifts in the genome of the strains used. Therefore, deeply coloured IPS e.max ZirCAD MT 0 + A4 colouring liquid, IPS e.max ZirCAD MT 0 + B4 colouring liquid, IPS e.max ZirCAD MT 0 + C4 colouring liquid, IPS e.max ZirCAD MT 0 + orange colouring liquid and IPS e.max ZirCAD MT 0 + Zenostar MT Color violet are considered to be non-mutagenic in this *Salmonella typhimurium* and *Escherichia coli* reverse mutation assay (AMES test) [52-58].

7.4 Radioactivity

Concerns have been raised regarding the possible radioactivity of dental ceramics. The origin of these concerns dates back to the seventies, when small amounts of radioactive fluorescent substances [59-61] were employed in various metal-ceramic systems. In this regard, possible radiation levels were measured in relation to ceramic materials used in the oral cavity [62]. Several alternatives for creating fluorescence in dental materials without using radioactive additives, have become available since the eighties. We may therefore assume that all the major manufacturers stopped using radioactive ingredients in their materials from this time onwards. Nonetheless, possible sources of radioactivity cannot be so easily ruled out. Minute impurities of uranium or thorium in raw materials, which are sometimes used in their natural state, or in pigments are difficult to remove [59]. Consequently, the standards covering ceramic materials (EN ISO 6872, EN ISO 9693, ISO 13356) forbid the use of radioactive additives and stipulate the maximum level of radioactivity permissible in ceramic materials.

In the examination report of Rieger [51], an activity ^{238}U of 0.003 Bq/g was recorded for zirconium oxide bio-ceramics. The following radioactivity levels, which are all far below the limit value, were measured for the IPS e.max ZirCAD products using γ-spectrometry:

	^{238}U [Bq/g]	^{232}Th [Bq/g]	Reference
IPS e.max ZirCAD MO 4	< 0.03	< 0.03	[63]
IPS e.max ZirCAD LT A3	< 0.03	< 0.03	[64]
IPS e.max ZirCAD MT Multi A3 (Incisal)	< 0.03	< 0.03	[65]
Threshold value according to ISO 6872:2015	1.000		-

► **Conclusion:**

In view of the present data and today's level of knowledge, it can be stated that IPS e.max ZirCAD including colouring liquids do not feature a toxic potential. A health risk for patients can be excluded, provided IPS e.max ZirCAD and its associated colouring liquids are used according to the instructions of use.

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