

Scientific Documentation

IPS InLine®

Metal-ceramic materials for
more flexibility in your lab.



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1 Indirect Restorations

Indirect restorations are restorations for replacing missing tooth structure that are fabricated outside the oral cavity. Crowns, bridges, inlays, onlays and veneers are typical examples. Many indirect restorative materials are available, which differ in terms of composition, mechanical properties, processing methods, esthetics and price. All characteristics need to be considered in determining which material best suits which clinical case. Materials in modern use - range from high noble alloys such as gold - with one of the longest uses in dentistry, to base metal alloys, layered metal-ceramic combinations, resin-based composites, zirconia and various all-ceramic materials.

The biggest innovative strides lie within the esthetic, high-end digital side of all-ceramics, however traditional "analog" metal-ceramic restorations remain highly popular and creative, customized esthetics in this field have improved enormously over recent years.

1.1 Metal-ceramics

Metal-ceramic constructions, are often interchangeably referred to as "porcelain fused to metal" (PFM) restorations - referring logically to various metal framework materials that are then veneered with a ceramic "porcelain" material. A highly pigmented opaquer material is used between the metal and ceramic to mask the dark colour of the metal. Metal-ceramics combine the strength and durability of a metal alloy core with the esthetic natural tooth appearance of a ceramic exterior.

Several studies report very low (2-5%) failure rates with conventional metal-ceramic units^{1, 2} and the longevity of standard metal-ceramic crowns and bridges is considered virtually equivalent to that of cast metal restorations.³ Metal-ceramic combinations are often the materials of choice for long span bridges.

1.1.1 Historical background to metal-ceramics

As "all ceramics" represent the current state of the art, one might assume that metal-ceramics were introduced first. This is not however the case. Porcelain (all ceramic) jacket crowns that fit over teeth like a jacket were introduced in the early 1900s by Charles H. Land and were a huge esthetic improvement on earlier tooth replacement methods. They were modernized and used up until the 1950s but lacked durability and often cracked. The late 1950s heralded a breakthrough in dental ceramics with the successful veneering of a metal substructure with porcelain.⁴ In comparison to earlier dental constructions, lost wax-fabricated metal copings improved on the fit of the traditionally constructed jacket crowns and overall cracks were reduced by the bond between the metal and porcelain. Until this time dental porcelain had a much lower coefficient of thermal expansion (CTE) than gold alloys. This thermal mismatch meant cracking of the porcelain during fabrication/cooling and difficulties in attaining a bond between the two materials. It was found however that the CTE of gold could be lowered and better matched to the porcelain by adding platinum and palladium to the alloy.⁴ The first metal-ceramic constructions with balanced thermal expansion were patented and introduced by Weinstein M, Katz and Weinstein A⁵ and Weinstein and Weinstein in 1962.^{6,7}

The Weinstein patents were based on a gold alloy formulation and feldspathic porcelain, whereby the porcelain was shown to bond adequately to the metal oxide with minimum tensile stresses developing in the porcelain during cooling.³ Initial esthetics with metal ceramics despite the opaque metal block-out layer, were however not ideal and visible metallic cervical margins were a common issue. Enormous esthetic strides have been made in recent decades.

1.1.2 Requirements of metal-ceramic restorations

Nowadays metal-ceramic restorations have to fulfil esthetic expectations and look like natural teeth. The alloy must have a high melting temperature - substantially higher than the firing temperatures of the veneering ceramic. The ceramic must wet the alloy when applied as a slurry in order to avoid voids forming at the interface and create a good bond. The coefficient of thermal expansion (CTE) of the ceramic must be compatible with standard alloys used as frameworks i.e. the premise of the Weinstein patents holds true - the CTE of the alloy must be similar to or slightly higher than the CTE-range of the veneering ceramic.^{4,8} This is necessary to ensure that the veneering ceramic is spared tensile stresses that would lead to cracking. If the CTE of the metal is slightly higher than the porcelain it places the veneering ceramic in compression (where it is stronger) following cooling. The ceramic must fuse at relatively low temperatures such that no sagging or distortion of the framework takes place during sintering. The restorations must also age well, resist discoloration and exhibit low abrasiveness to antagonist teeth.

1.1.3 Dental alloys for metal ceramics

Various metal alloys are used for metal-ceramic restorations each with inherent advantages and disadvantages. Most importantly the CTE value of the alloy must be compatible with the veneering ceramic. Gold-platinum-palladium (Au-Pt-Pd) alloys were the earliest type of alloy used for fusing to porcelain and other combinations of gold, palladium, and silver, sometimes with gallium or copper, round out the elements added to high noble and noble alloys for metal-ceramic restorations.^{9, 4, 10} The low CTE of palladium relative to other noble metals makes it highly compatible with a variety of ceramics, and is a common element in noble alloys used in metal-ceramic systems.⁴ The use of noble alloys decreased with the event of more economical base-metal alloys such as cobalt chrome (CoCr) and nickel chrome (NiCr). Commonly used in metal-ceramic constructions, they are either cast traditionally or fabricated digitally using discs such as Colado CAD CoCr4/Ivoclar. Although titanium is well-known as a highly biocompatible material in dental prostheses, results as a metal-ceramic alloy have been mixed, with casting issues, evidence of low bond strengths.^{9, 4} and generally mis-matched CTE values.

1.1.4 Metal-ceramic bond

One of the most important prerequisites for a successful metal-ceramic restoration is the lasting connection between the ceramic and the metal alloy (and their thermal compatibility). The oxidation level of the alloy to a great extent determines its ability to form a lasting bond with the ceramic: alloys that produce a solid oxide layer during the degassing process can also produce a reliable bond to the ceramic. In contrast, alloys with a weak oxide layer form poor bonds with the ceramic.

Good wettability of the alloy surface by the opaquer (which is very viscous at high temperatures), is also necessary for an optimal bond.

The metal-ceramic bond is however largely based on adhesion i.e. the bonding effect between a solid interface (metal surface) and a second phase (the ceramic). The most important of these adhesive mechanisms are described below:

Adhesion by mechanical bond: The ceramic bonds mechanically to the metal surface by filling depressions and/or enclosing protruding structures and anchor points, present on the metal surface following metal-conditioning. In addition to this mechanical bond, the ceramic demonstrates a certain compressive strain, as its coefficient of thermal expansion is lower than that of the alloy.

Adhesion by chemical bond: Various processes including chemical reactions, dissolution, redox processes, diffusion and precipitation result in the formation of a characteristic transition area at the interface between a metal and a ceramic. Particularly in the presence of non-precious alloy components, a certain saturation of both metal and ceramic with metal oxides occurs. Ideally, this results in the formation of an oxide monolayer, which is a component of both the metal and the ceramic. The resulting bond energies and electronic structures are then identical at each point of the interface. The prerequisite for this behaviour is an oxide layer that is formed on the metal surface during oxide firing.

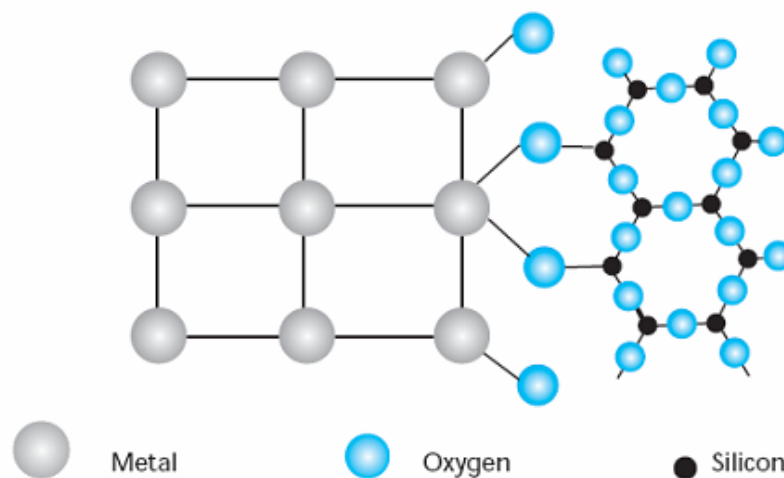


Fig. 1: Model depicting chemical bonding mechanism due to oxide layer formation. Adapted from Schnettger A. Diploma thesis 2005 ²⁹

The chemical bond is initiated by oxygen atoms that are present in both the metal surface layer and the ceramic, and thus link the two materials.

Adhesion by intermolecular forces: Their contribution to the overall adhesive bond is smaller than that of the mechanical and chemical bond, however short-range Van der Waals forces (relating to the distance-dependent attraction of atoms, molecules and surfaces) also act between the alloy and ceramic.

2 Basic Materials Science of feldspathic Ceramics

2.1 Conventional feldspathic ceramics vs. stoneware

Conventional dental ceramics are based on a ternary materials system consisting of three materials: kaolin (clay), feldspar and quartz i.e. the components required to manufacture porcelain. Ternary diagrams represent a mixture of three components expressed as a percentage, whose sum must be 100%. Each apex with its named material corresponds to 100% with the opposite side corresponding to 0% of the material (See Fig 3). The simplified diagram below, indicates how feldspathic dental ceramics differ substantially from household porcelain and earthenware used e.g. in crockery. Dental ceramics traditionally have a high feldspar and low kaolin content, whereas the reverse is true of household ceramics. Nowadays clay/kaolin features only in low concentrations, if at all in dental ceramics thus using the term "porcelain" for such products is quite misleading.

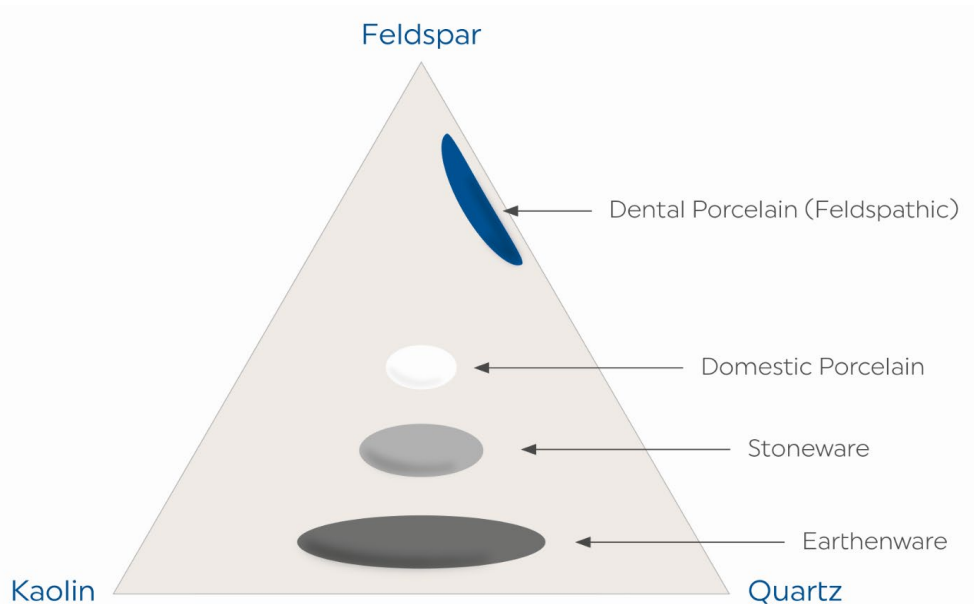
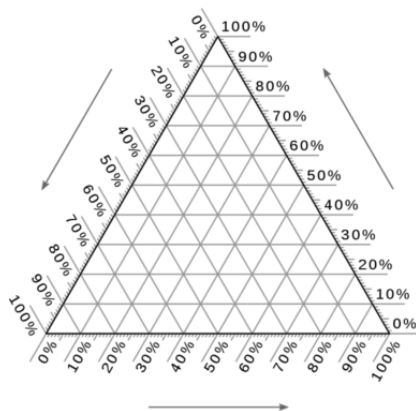


Fig. 2: Ternary materials system: Clay - Feldspar – Quartz. Adapted and simplified from Claus¹²



To interpret the diagram, the amount of feldspar corresponds to percentages written on the right side of the triangle running 0-100% i.e. horizontal lines bottom to top. The other components and sides work in the same way with angled parallel percentage lines running towards each apex. The feldspathic dental porcelain in Fig 2. thus contains approx. 60-80% feldspar (scale on right), 20-40% quartz (bottom scale) and 0-10% kaolin/clay (scale on left).

Fig. 3: Diagram showing percentage scales for ternary style diagrams

2.2 Feldspathic ceramic components

Feldspathic ceramics that are often used in metal-ceramic combinations, are based partly on naturally occurring raw feldspar materials, such as potassium feldspar and sodium feldspar. These are based on oxidic components of alkaline metals: potash (K_2O) or sodium (Na_2O), aluminium (Al_2O_3) and silicon (SiO_2) components.⁴ Dental ceramics usually contain a higher proportion of potassium feldspar. The simplified ternary diagram below shows the approximate composition of feldspathic porcelain products used for metal-ceramic veneering.

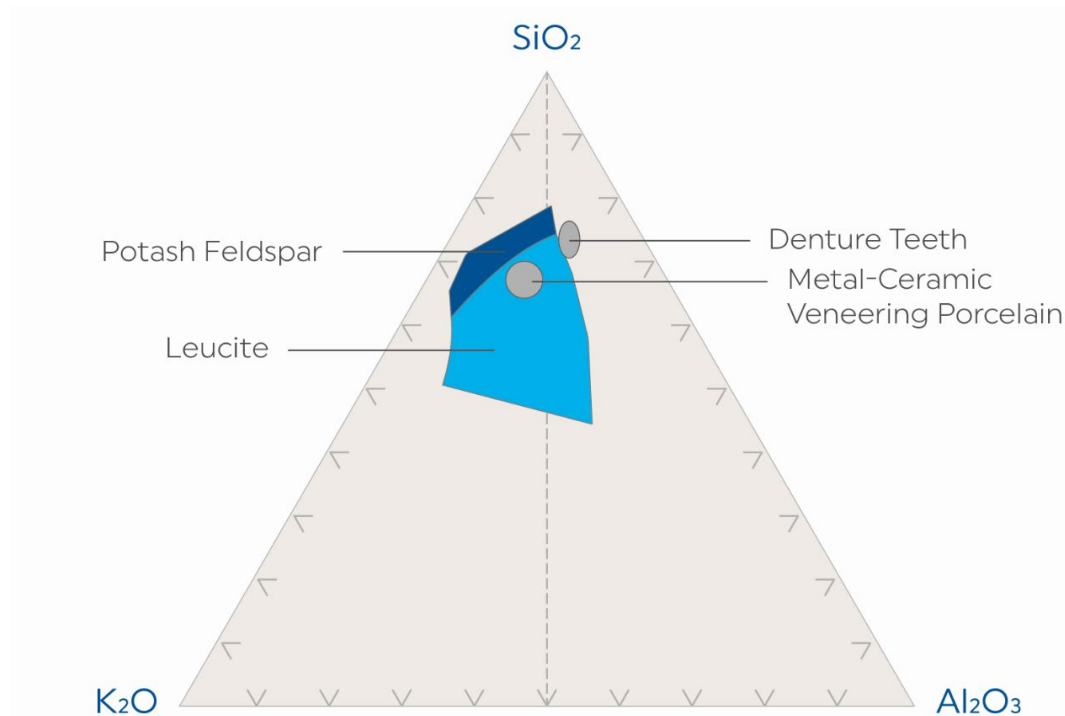


Fig. 4: Ternary phase equilibrium diagram of the Potash-Alumina-Silica ($K_2O-Al_2O_3-SiO_2$) system showing principal phase fields of feldspathic ceramics. Adapted and simplified from Mrazova¹⁴

2.2.1 Incongruent melting

Leucite is a potassium-aluminium-silicate mineral with a large coefficient of thermal expansion compared to feldspar glasses. When (potassium) feldspar is mixed with various metal oxides and fired to high temperatures ($1150^{\circ}C-1530^{\circ}C$), it undergoes incongruent melting and forms leucite crystals in a glass phase that softens and flows slightly, allowing a coalescing of powder-particles i.e. liquid-phase sintering which forms a dense solid.⁴ Incongruent melting refers to the process by which one material melts to form a liquid plus a different crystalline material - rather than forming just one homogenous type of melted material. The leucite crystals form exactly where the feldspar grains once were i.e. along their boundaries. The leucite crystals increase the strength of the material and slow/arrest the propagation of cracks as the crystalline phase is able to absorb fracture energy.

This very tendency of feldspar to form leucite via incongruent melting is used to advantage in the manufacturing of metal-ceramic veneering porcelains - simultaneously effecting an increase in ceramic-strength and CTE - all imperative for combining with metal alloy frameworks.

2.3 Fabrication of feldspar ceramics

Conventional feldspar ceramics thus utilise naturally occurring feldspar as a base material. In contrast, synthetic leucite ceramics (as feldspar is not essential as a precursor to the formation of leucite) ⁴ do not – but are formed by adding synthetic leucite.

Natural feldspar and glass-forming chemicals (oxides/carbonates), such as those illustrated in the diagram below, are milled, mixed and melted. Quenching this melt results in the formation of a glass with the desired chemical composition. Renewed milling of the glass (possibly in combination with other glass powders) produces a glass powder which is the basis for further processing of the final leucite ceramic. The glass powders are mixed and treated according to a procedure which is subsequently defined via sintering/tempering. Alternatively, feldspar can be introduced in its vitrified form as a high melting glass.

The final leucite-content of the end product is controlled by the overall procedure including the quenching of the material mixture at a specific time – stopping the leucite precipitation process. The final products (powders for creating the layering pastes) are obtained by further grinding and sieving.

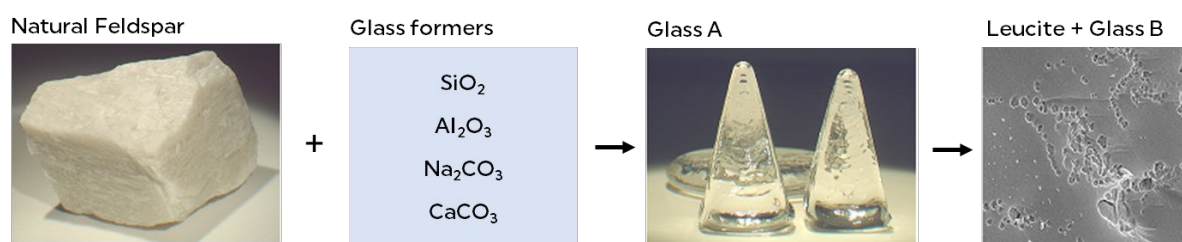


Fig. 5: Fabrication of feldspar ceramics

2.4 Ivoclar product development in metal-ceramics

Feldspathic porcelains were the first all-ceramic restoration material. They exhibited high translucency but were inherently brittle,^{4, 15} with low flexural strength (50 – 100MPa). Beginning in the 1950s the use of feldspathic ceramics was extended to the metal-ceramic field (and fused to metal) to create stronger restorations.¹⁶

The first Ivoclar metal-ceramic, Vivodent PE Porcelain was introduced in 1976 and various products evolved and followed. Ivoclar currently offers three different metal-ceramic systems. **IPS Classic** the long proven feldspar ceramic for metal alloys, introduced in 1989, **IPS InLine** including **IPS InLine One** – two feldspar-leucite ceramics introduced in 2005 and 2010 respectively and **IPS Style**, a material that was introduced in 2015 and is based on glass-ceramics containing leucite, fluorapatite and oxyapatite.

This Scientific Documentation concerns the feldspathic metal-ceramic IPS InLine range: IPS InLine and IPS InLine One.

3 IPS InLine

IPS InLine and IPS InLine One are all-round veneering ceramics. Both are feldspar-based leucite ceramics designed for the layering technique over suitable alloy materials. The classic multi-layer IPS InLine was introduced to the market in 2005, followed by the one-layer IPS InLine One in 2010. The materials are available in powder form which are then mixed with various coordinated liquids. IPS InLine System Opaquer materials are available either as a paste or powder.



IPS InLine

IPS InLine is a conventional metal-ceramic for the multi-layer technique. Enhanced manufacturing processes and a specific grain size distribution formed the basis of its development. It is suitable for use with the most popular dental alloys, with coefficients of thermal expansion (CTE) in the range of $13.8 - 15.0 \times 10^{-6}/K$ (25-500°C) which are fired at temperatures higher than 900°C/1652°F. IPS InLine can be used to create metal ceramic crowns, 3-14-unit bridges and also veneers on refractory dies. IPS InLine features good firing stability, low shrinkage and easy processing for the fabrication of highly esthetic restorations.



IPS InLine One

IPS InLine One is a metal-ceramic for the one-layer technique. These one-layer materials are based on the same raw materials as used in IPS InLine and are also suitable for use with the most popular dental alloys, with coefficients of thermal expansion (CTE) in the range of $13.8 - 15.0 \times 10^{-6}/K$ (25-500°C) which are fired at temperatures higher than 900°C/1652°F. The products combine the dentin and incisal materials in one (along with their corresponding chroma and translucency properties) and are called "Dentcisal" materials. The single layer allows users to create lifelike restorations very quickly and efficiently. IPS InLine One can be used to create metal ceramic crowns, and 3-14-unit bridges.



IPS Ivocolor

Both IPS InLine and IPS InLine One are characterized using IPS Ivocolor. IPS Ivocolor is a range of universal stains and glazes suitable for the individualized surface-staining and characterization of Ivoclar CAD, Press and layered metal-ceramics such as IPS InLine. The materials are based on very fine-grained glass powders, which are sintered at low temperatures. The glaze material comprises pure, unpigmented powders, whereas the shades and stains contain colour pigments. IPS Ivocolor is used post-sintering for adding individuality with natural features such as mamelons, halo effects and enamel cracks. The material is fired following application and is suitable for use with ceramic materials that fall within a CTE range of 9.5 and $16.6 \times 10^{-6}/K$.

3.1 System Concept

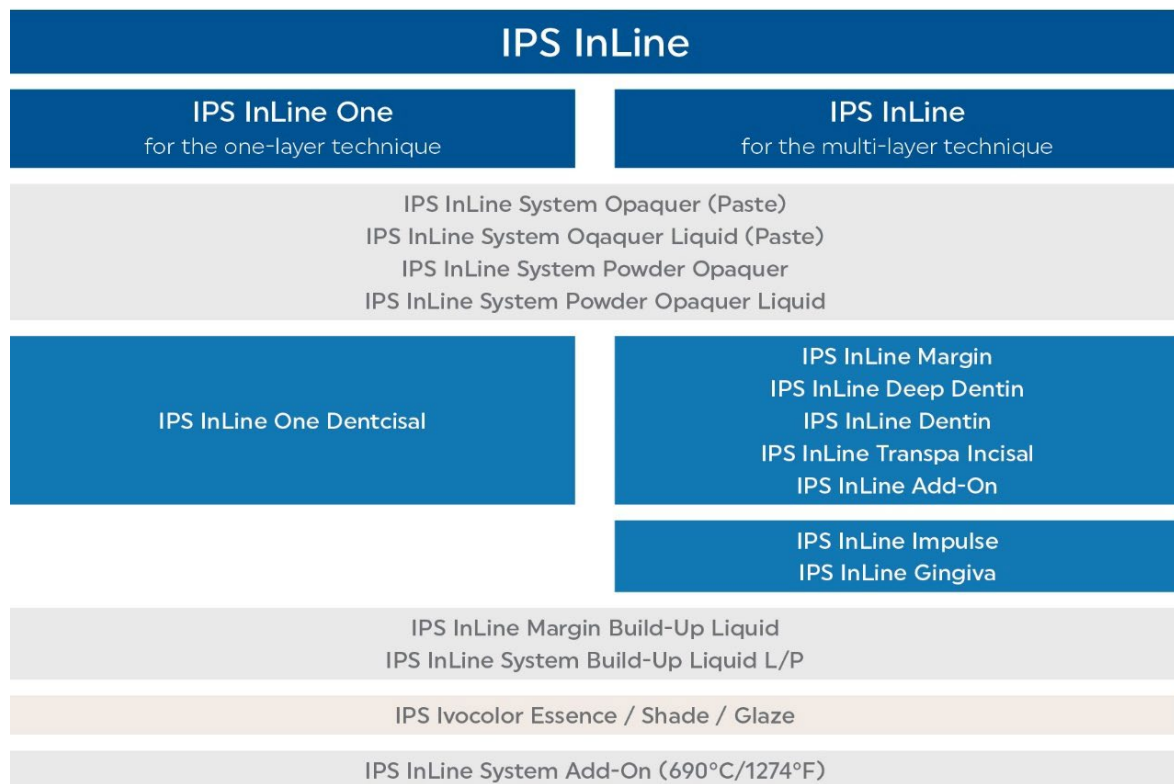


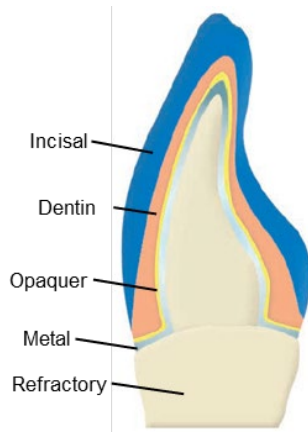
Table 1: Overview of IPS InLine product range

3.2 Workflow: IPS InLine & IPS InLine One

Metal-ceramic restorations consist of a metallic substructure (coping), on which different functional ceramic components are manually applied/layered and fused.

IPS InLine is a ceramic veneering material, used in the fabrication of such restorations. The materials are available in powder form that are mixed to a paste with organic Build-Up Liquids, or they are supplied in paste form (e.g. IPS InLine System Opaquer Paste) which are stable suspensions of ceramic powder in an organic matrix.

A suitable metal alloy is chosen, and a cast or digital metal substructure framework is produced to cover the remaining tooth structure. This metal structure is conditioned according to the alloy-manufacturer's instructions and IPS InLine System Opaquer (Paste) or IPS InLine System Powder Opaquer is then applied either as a paste or as a powder/liquid mix and fired. The opaquer is a ceramic modified with opacifying oxides in order to mask the darkness of the oxidized metal framework for the necessary esthetics. This thin opaque layer also contributes to the metal-ceramic bond. The dentin and incisal areas of the restoration are then built up to represent the natural tooth shape and translucency using either IPS InLine or the technique-simplified IPS InLine One i.e. either multi or single layers of slurry-material are built up over the opaquer layer. Components like IPS InLine Margin, Deep Dentin, and Impulse materials can be applied to enhance esthetics and create more sophisticated restorations, however, even high-end restorations consist of about 80 to 90 wt.-% opaquer, dentin, and incisal materials.



Cross-section of an IPS InLine-type metal-ceramic restoration, built over a refractory die

Fig. 6: Illustration of metal-ceramic crown

The materials are then fired once more with the build-up always larger than the final result, to compensate for shrinkage. The materials are re-applied and fired if necessary to achieve the correct size and shape. As a final step, restorations are individually characterized and glazed using IPS Ivocolor Stains and Glazes. Overall two firing cycles plus glazing are required to finish a standard restoration, though more are possible depending e.g. on the expertise of the dental technician and/or complexity of the restoration. The entire restoration is then fired in e.g. a G2 Programat furnace: P710, P510 or P310. IPS InLine restorations can be cemented either conventionally or adhesively. IPS InLine materials can also be used to fabricate veneers on refractory dies. The missing parts are layered on a copied die made of a refractory material and fired in the furnace. Subsequently, the veneers are finalized with IPS Ivocolor Stains and Glaze. The refractory material must be removed from the finished veneer with a sandblaster. Before cementation at the dentist, the inner aspect of the veneer is conditioned with IPS Ceramic etching gel. The standard workflow for a bridge is depicted below.

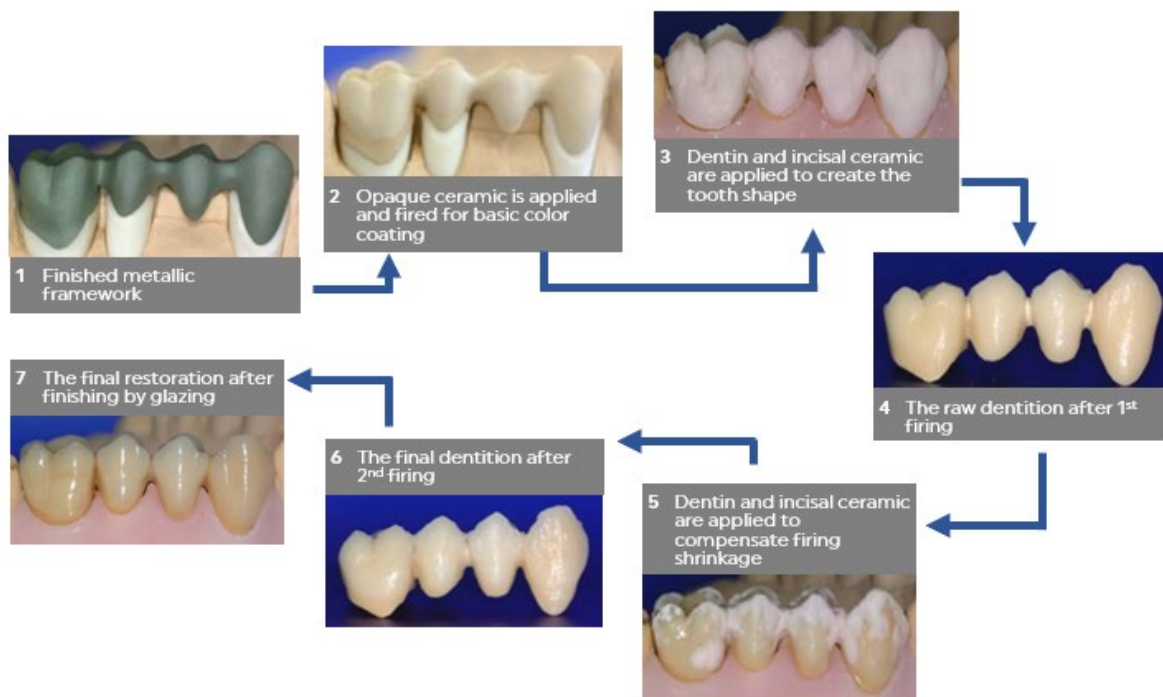


Fig 7: Basic workflow for producing a metal-ceramic bridge restoration

3.3 Material description

The IPS InLine ceramics are based on leucite-forming glasses, some of which are produced from naturally sourced, raw feldspar materials. These demonstrate excellent chemical resistance due to their composition. IPS InLine and IPS InLine One are formed with various glass-forming oxides - potassium, sodium, aluminium and silicon. The appropriate mixing with other metal oxides (as described in section 2.3) and targeted firing at high temperature leads to the formation of leucite crystals of a defined grain-size distribution within the glass matrix. A veneering material of uniform/isotropic microstructure results, which is not just antagonist-friendly, but also provides high strength and convincing optical properties.

The IPS InLine range consists of a wide range of different layering and characterization materials that perform a specific function within the metal ceramic restoration. They are all based on a similar principle of a single glass, glass ceramic powder or mixture thereof dyed with inorganic pigments and provided either as a powder or a paste.

IPS InLine materials correspond to Type I materials of the standard EN ISO 6872:2015+A1:2018.

3.4 IPS InLine microstructure

The microstructure of IPS InLine consists of a glassy matrix and leucite crystals. The SEM images below of polished and etched surfaces reveal the microstructure of the material. Depending on the magnification, different phases (glass/crystal), grain sizes, grain boundaries and defects like pores/cracks are discernible. Leucite is the result of surface crystallization from feldspar and the leucite crystals that form are thus located along the former feldspar grain boundaries. The following magnified pictures show this positioning clearly for both IPS InLine and IPS InLine One. The special etching technique dissolves the surface of the leucite crystals more quickly than the surrounding glass making their positions easily visible.

IPS InLine: Dentin

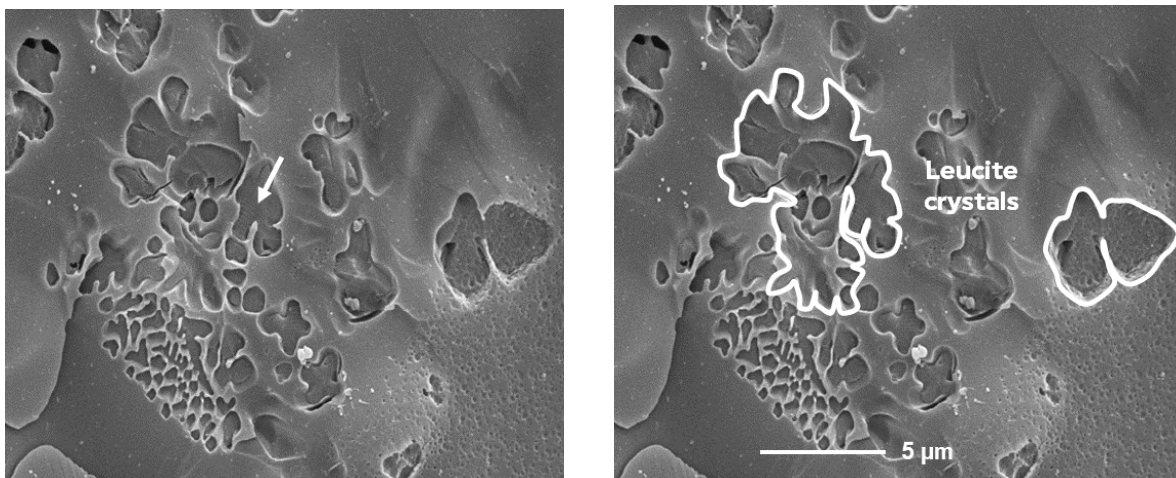


Fig. 8a & b: SEM of etched IPS InLine (Dentin A3). Mag. 5000x. Ivoclar R&D

The diagrams above depict the same section of material – whereby the positions of leucite crystals within the glass matrix are marked in the right-hand picture 8b.



Fig. 8c: Mid-section of Fig. 7a (magnified) showing striations in dissolved area of leucite crystal

The section shown by the white arrow in Fig 8a is magnified further in SEM photo 8c, showing the distinct striation markings within the dissolved areas, indicating the lamellar structure of the leucite crystals resulting from dendritic growth.

IPS InLine: Incisal & IPS InLine One: Dentcisal

In the following SEM pictures, the former grain boundaries are clearly visible in both the IPS InLine and IPS InLine One material. The small leucite crystals are arranged like strings of pearls at the former grain boundaries. Larger crystals are also shown in the SEM picture for IPS InLine One.

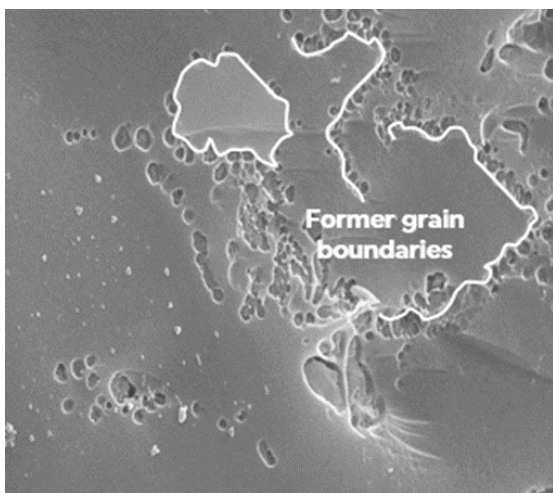


Fig. 9 : SEM of etched IPS InLine (Transpa Incisal 1) Mag. 5000x

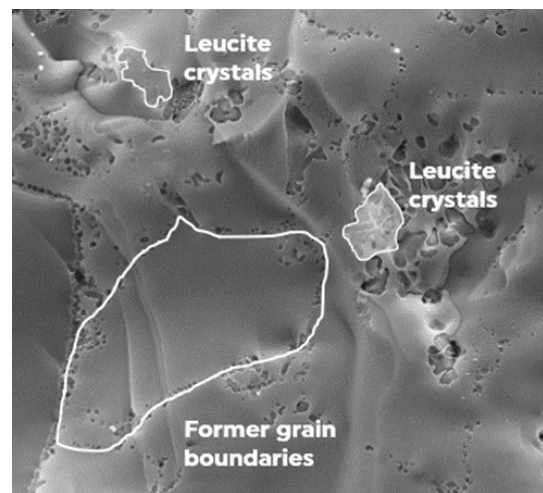


Fig. 10: SEM of etched IPS InLine One (Dentcisal 3) Mag. 1000x

3.5 Metal-ceramic bond with IPS InLine system

A metal-ceramic restoration is a material composition, based on the durable bond between an alloy and a ceramic material. IPS InLine and IPS InLine One are both compatible with the most popular dental alloys in the CTE range of $13.8\text{-}15.0 \times 10^{-6} \text{ K}^{-1}$ ($25\text{-}500^\circ$).¹¹

The interface between metal and ceramic is formed by the opaquer, which, if carefully applied and fired, creates a sound bond between the two materials. The image below clearly shows the homogenous transition areas between the alloy, opaquer and layering ceramic for a high-gold alloy together with IPS InLine. The fine-grain structure of the opaquer is clearly visible and the alloy margin-surface appears rough and covered with depressions that are filled with ceramic material. This depicts the important role of mechanical bonding, as described in section 1.1.4.

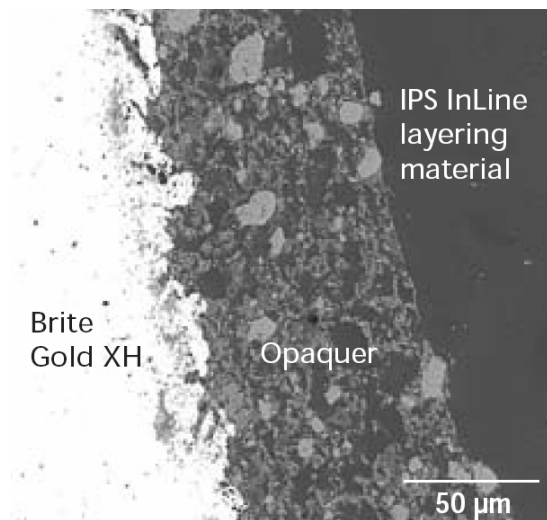


Fig. 10 : Metal-ceramic bond: Brite Gold XH alloy fused with IPS InLine. Ivoclar R&D

4 Technical Data

4.1 Chemical composition of IPS InLine product components

Powders & pastes		Ingredients
Opaquer	IPS InLine System Opaquer IPS InLine Gingiva Opaquer	Leucite glass ceramics Glass Zirconium dioxide Inorganic pigments Glycols (Butanediol, Glycerol) Polyvinylpyrrolidone Hydrophilic fumed silica
	IPS InLine System Powder Opaquer IPS InLine System Intensive Powder Opaquer IPS InLine Gingiva Powder Opaquer	Leucite glass ceramics Zirconium dioxide Inorganic pigments
Margin	IPS InLine Margin	Leucite glass ceramics Inorganic pigments
Deep Dentin	IPS InLine Deep Dentin	Leucite glass ceramics Opalescent glass Inorganic pigments
Dentcisal	IPS InLine One Dentcisal	Leucite glass ceramics Opalescent glass Inorganic pigments
Dentin	IPS InLine Dentin	Leucite glass ceramics Opalescent glass Inorganic pigments
Incisal	IPS InLine Incisal IPS InLine Transpa Incisal	Leucite glass ceramics Opalescent glass Inorganic pigments
Impulse	IPS InLine Cervical Incisal	Leucite glass ceramics
	IPS InLine Cervical Dentin	
	IPS InLine Occlusal Dentin	
	IPS InLine Mamelon	Opalescent glass
	IPS InLine Transpa	
	IPS InLine Gingiva IPS InLine Intensiv Gingiva	Inorganic pigments

Chemical composition of IPS InLine product components – *continued*

Powders & pastes (cont.)		Ingredients
Impulse	IPS InLine Opal Effect	Opalescent leucite glass ceramics Opalescent glass Inorganic pigments
Add-On	IPS InLine Add-On	Leucite glass ceramics Glass Inorganic pigments
	IPS InLine Margin Add-On	Leucite glass ceramics Inorganic pigments
	IPS InLine System Add-On 690 °C	Leucite glass ceramics Glass Inorganic pigments

Ceramic liquids	Ingredients
IPS InLine System Opaquer Liquid	Glycols (Butanediol, Glycerol) Polyvinylpyrrolidone
IPS InLine System Powder Opaquer Liquid	Water Glycol (Propanediol) Inorganic salt Carboxylic acid
IPS InLine Margin Build-Up Liquid	Water Cellulose derivative
IPS InLine System Build-Up Liquid P	Water Polyethyleneglycol Inorganic salt
IPS InLine System Build-Up Liquid L	Water Polyethyleneglycol Inorganic salt

4.2 Characteristics and performance attributes of IPS InLine components

Characteristics	Specification							
	Radioactivity		Flexural strength		Chemical solubility		Debonding / Crack initiation strength	
Unit	[Bq/g U ²³⁸]		[MPa]		[µg/cm ²]		[MPa]	
Notes	A ¹⁾	B ²⁾	A ¹⁾	B ²⁾	A ¹⁾	B ²⁾	C ³⁾	B ²⁾
Product component								
IPS InLine System Opaquer IPS InLine Gingiva Opaquer	≤ 1.0	<< 1.0	> 50	170	< 100	28	> 25	40
IPS InLine System Powder Opaquer IPS InLine System Intensive Powder Opaquer IPS InLine Gingiva Powder Opaquer	≤ 1.0	< 0.03	> 50	127	< 100	28	> 25	43
IPS InLine Margin	≤ 1.0	<< 1.0	> 50	98	< 100	23	N/A	N/A
IPS InLine Deep Dentin	≤ 1.0	<< 1.0	> 50	89	< 100	12	> 25	40
IPS InLine One Dentsisal	≤ 1.0	<< 1.0	> 50	89	< 100	12	> 25	40
IPS InLine Dentin	≤ 1.0	<< 1.0	> 50	89	< 100	12	> 25	40
IPS InLine Incisal IPS InLine Transpa Incisal	≤ 1.0	<< 1.0	> 50	89	< 100	12	> 25	40
IPS InLine Cervical Incisal IPS InLine Cervical Dentin IPS InLine Occlusal Dentin IPS InLine Mamelon Masse IPS InLine Transpa IPS InLine Gingiva IPS InLine Intensiv Gingiva	≤ 1.0	<< 1.0	> 50	89	< 100	12	> 25	40
IPS InLine Opal Effect	≤ 1.0	<< 1.0	> 50	90	< 100	10	N/A	N/A
IPS InLine Add-On	≤ 1.0	<< 1.0	> 50	92	< 100	10	N/A	N/A
IPS InLine Margin Add-On	≤ 1.0	<< 1.0	> 50	94	< 100	12	N/A	N/A
IPS InLine System Add-On 690 °C*)	≤ 1.0	<< 1.0	> 50	108	< 100	20	N/A	N/A

**The product meets the relevant performance criteria as defined in:
ISO 6872:2015 + AMD 1:2018 and ISO 9693:2019**

¹⁾A: Acceptance criterion according to ISO 6872:2015 + AMD 1:2018 *g*

²⁾B: Typical measured values (mean values)

³⁾C: Acceptance criterion according to ISO 9693:2019

Characteristics and performance attributes of IPS InLine components - *continued*

Characteristics	Specification				
	Linear thermal expansion (CTE)			Glass transition temperature	Thermal shock testing
	2-firings	4-firings	Mean value		
Unit	[10 ⁻⁶ /K]	[10 ⁻⁶ /K]	[10 ⁻⁶ /K]	[°C]	N/A
Notes	1)	2)	3)		
IPS InLine component					
IPS InLine System Opaquer IPS InLine Gingiva Opaquer	13.5 ± 0.5	13.7 ± 0.5	13.6 ± 0.5	605 ± 20	Standard-compliant
IPS InLine System Powder Opaquer IPS InLine System Intensive Powder Opaquer IPS InLine Gingiva Powder Opaquer	13.2 ± 0.5	13.4 ± 0.5	13.3 ± 0.5	605 ± 20	Standard-compliant
IPS InLine Margin	13.2 ± 0.5	13.5 ± 0.5	13.4 ± 0.5	600 ± 20	Standard-compliant
IPS InLine Deep Dentin	12.4 ± 0.5	13.2 ± 0.5	12.8 ± 0.5	580 ± 20	N/A
IPS InLine One Denticisal	12.4 ± 0.5	13.2 ± 0.5	12.8 ± 0.5	580 ± 20	N/A
IPS InLine Dentin	12.4 ± 0.5	13.2 ± 0.5	12.8 ± 0.5	580 ± 20	Standard-compliant
IPS InLine Incisal IPS InLine Transpa Incisal	12.4 ± 0.5	13.2 ± 0.5	12.8 ± 0.5	580 ± 20	Standard-compliant
IPS InLine Cervical Incisal IPS InLine Cervical Dentin IPS InLine Occlusal Dentin IPS InLine Mamelon Masse IPS InLine Transpa IPS InLine Gingiva IPS InLine Intensiv Gingiva	12.4 ± 0.5	13.2 ± 0.5	12.8 ± 0.5	580 ± 20	N/A
IPS InLine Opal Effect	12.6 ± 0.5	13.5 ± 0.5	13.1 ± 0.5	595 ± 20	N/A
IPS InLine Add-On	12.3 ± 0.5	12.8 ± 0.5	12.6 ± 0.5	455 ± 20	N/A
IPS InLine Margin Add-On	13.3 ± 0.5	13.7 ± 0.5	13.5 ± 0.5	585 ± 20	N/A
IPS InLine System Add-On 690 °C*)	12.6 ± 0.5	13.3 ± 0.5	13.0 ± 0.5	440 ± 20	N/A

**The product meets the relevant performance criteria as defined in:
ISO 6872:2015 + AMD 1:2018 and ISO 9693:2019**

¹⁾ CTE 2-firings, measuring range 25 – 500 °C

²⁾ CTE 4-firings, measuring range 25 – 500 °C

³⁾ CTE mean value (2 x/4 x fired), measuring range 25 – 500 °C

^{*)} The CTE values refer to a temperature range of 25 to 400 °C, as the glass transition temperature is below 500°C.

5 Materials Science & in vitro Investigations

Numerous materials science and in vitro investigations are conducted during the development phase of a dental product. Though not capable of predicting clinical success directly, they are useful indicators and allow comparisons with comparable products of established clinical performance.

5.1 Biaxial flexural strength

The biaxial flexural strength of the IPS InLine range of products was determined according to the relevant standard: EN ISO 6872. The minimum value stipulated by the standard is > 50 MPa. The information in the Technical Data of section 4 shows that all IPS InLine products way exceed this threshold. These values are depicted below for a some of the principle IPS InLine materials.

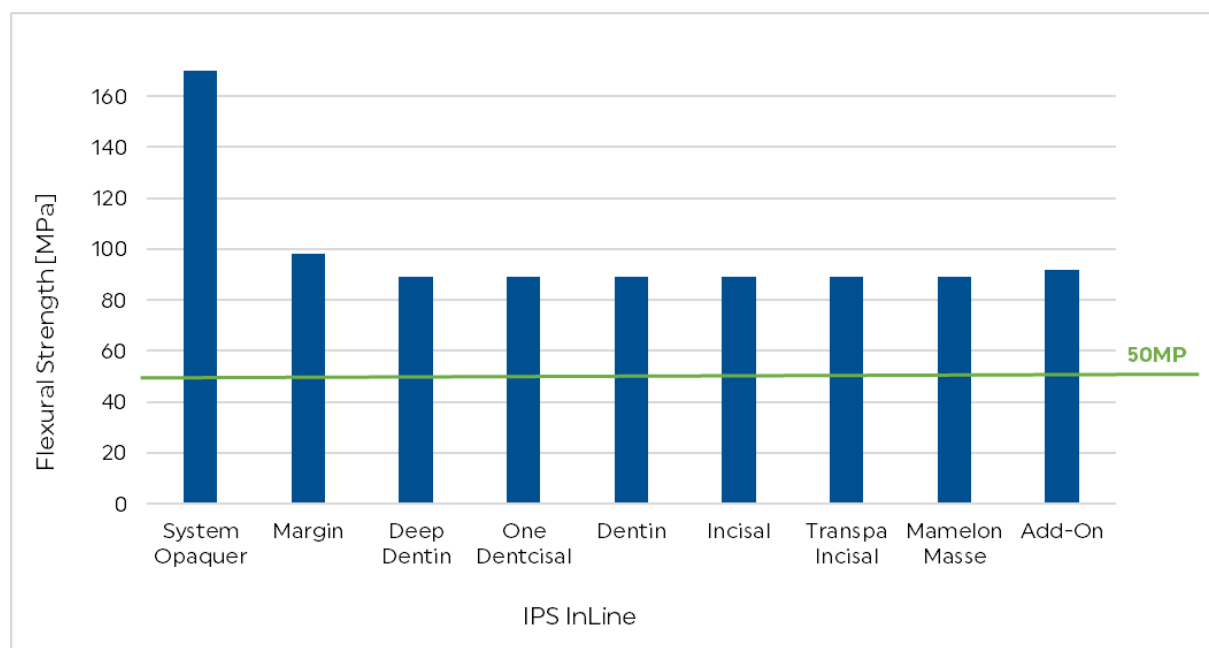


Fig. 12: Mean biaxial flexural strength values of various IPS InLine products. Ivoclar R&D, 2022

The biaxial flexural strength of IPS InLine and several other ceramic materials was also studied by Sinmazisik et al (2006). They compared results when powders were mixed with either distilled water or their corresponding modelling liquid.

IPS InLine powders are indicated for use with their respective material liquids.

Physical properties and microstructural characterization of dental porcelains mixed with distilled water and modeling liquid.¹⁷

Sinmazisik G, Ovecoglu ML. Marmara University, Turkey

Objectives: The authors examined the microstructure and physical properties of six ceramic veneering materials prepared by mixing with distilled water or with their modelling liquid.

Materials and methods: IPS Classic/Ivoclar, IPS d.SIGN (discontinued Ivoclar product), Vita VMK95/Vita Zahnfabrik, Vita OMEGA 900/Vita and Ceramco III/Ceramco-Dentsply were used as starting powders.

Each porcelain powder was mixed with distilled water and with its own modeling liquid. Disc specimens were sintered in accordance with each manufacturer's instructions. Specimens were evaluated using X-ray diffraction (XRD), optical microscopy and SEM analysis and their physical properties such as bulk density, microhardness and biaxial flexural strength were determined.

Results: The sintered dental porcelains premixed with modeling liquid had density, biaxial flexural strength and microhardness values slightly higher than those premixed with distilled water. Mixing with distilled water and modeling liquid caused statistically significant differences between the density values of Vita VMK 95 and microhardness values of IPS d.SIGN and IPS InLine. The XRD and SEM investigations revealed the coexistence of tetragonal leucite (1-3 microm) and hexagonal fluorapatite crystals (0.4-1.2 microm) in a feldspathic glassy matrix in the microstructure of IPS d.SIGN and only leucite crystals (3-6 microm) in the microstructures of other porcelains.

Conclusions: Mixing with distilled water or modeling liquid prior to sintering had no effect on the sintered crystalline microstructure but some significant differences were found for the physical properties of some porcelains

Below the results of the flexural strength values and hardness measurements (see section 5.2) of sintered test samples are shown for materials mixed with their respective modelling liquids.

Flexural strength: Seven test samples per material were investigated by means of a universal testing machine.

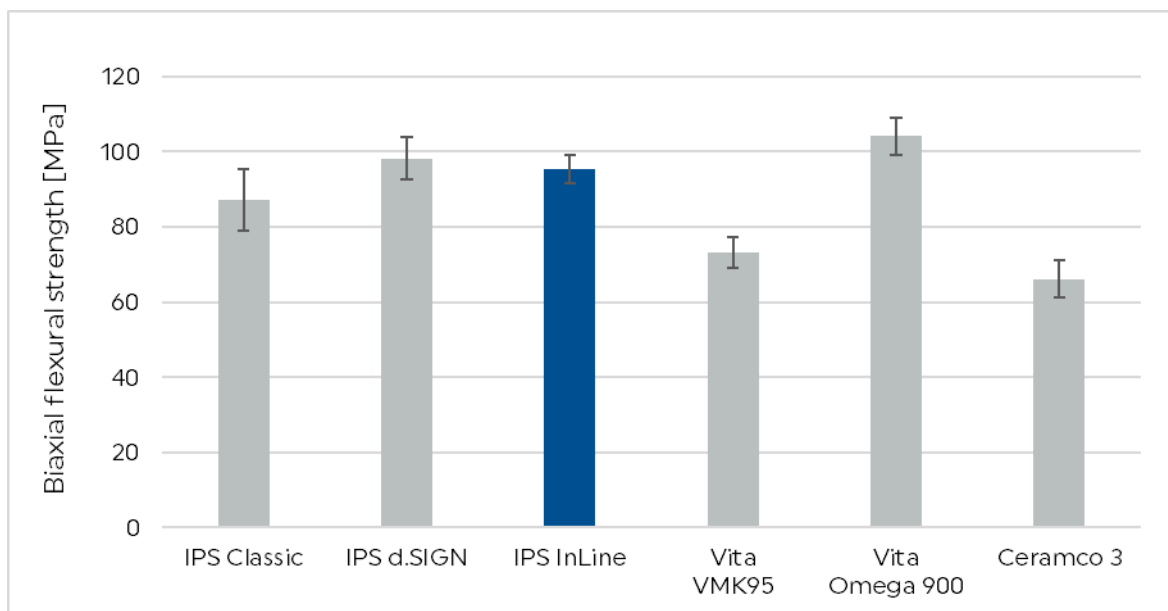


Fig. 13: Biaxial flexural strength values of various ceramic veneering materials.¹⁷

In comparison to the values of other products, the biaxial flexural strength values found for IPS InLine were in the upper range and above the EN ISO 6872 threshold of > 50 MPa.

5.2 Microhardness

The hardness was also measured by Sinmazisik et al ¹⁷ in a microhardness testing unit. A load of 500 g was applied by means of a Vickers diamond indenter for 20s. Ten to 12 impressions were produced in 4 test samples per material to determine hardness.

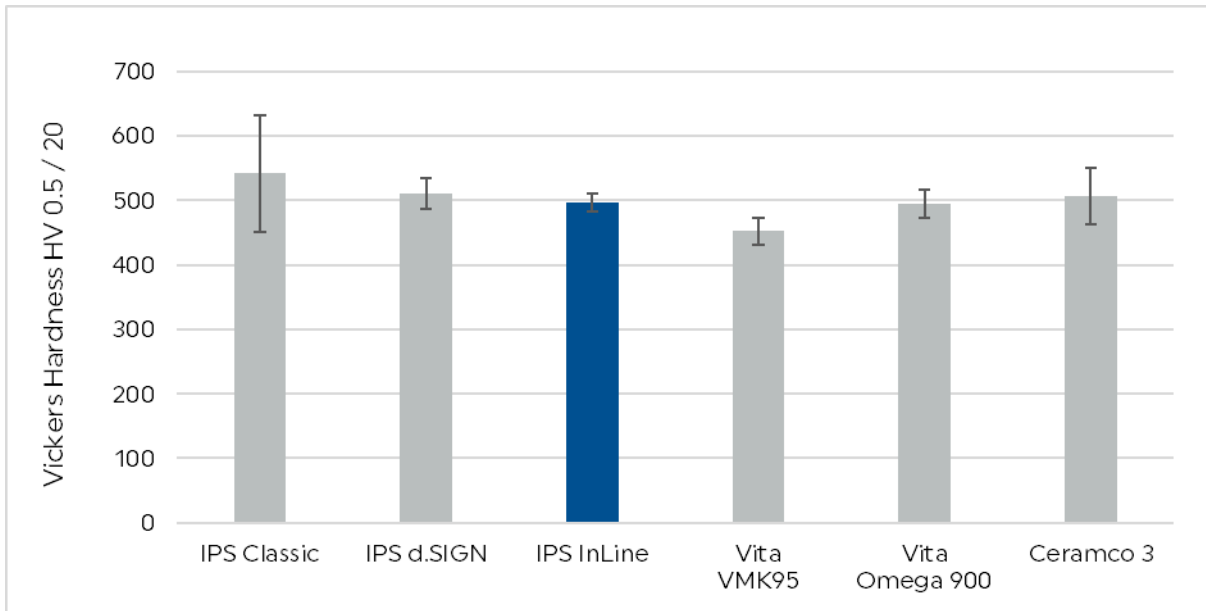


Fig. 14 : Vickers hardness values of various ceramic veneering materials. ¹⁷

The variation in hardness is relatively wide. This is partly due to the testing method but results also depend on the homogeneity and grain size of the microstructure. IPS InLine indicated the smallest amount of variation - as indicated by the minimal standard deviation.

5.3 Volumetric shrinkage

Objects consisting of pressed ceramic powders, shrink when they are sintered at high temperatures. The powder-particles fuse together, and porosity is reduced considerably.

Volumetric shrinkage (ΔV), is calculated as follows: $\Delta V (\%) = (V - V') / V \times 100$

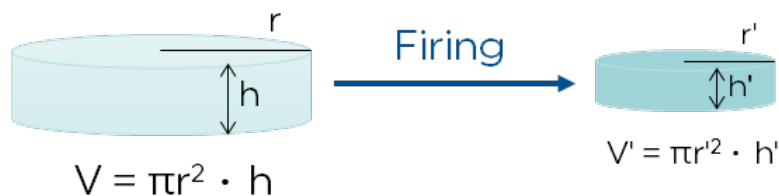


Fig. 15: Schematic representation of volumetric shrinkage resulting from sintering

The volumetric shrinkage of IPS InLine, IPS Classic and three competitor materials was measured in an internal investigation.

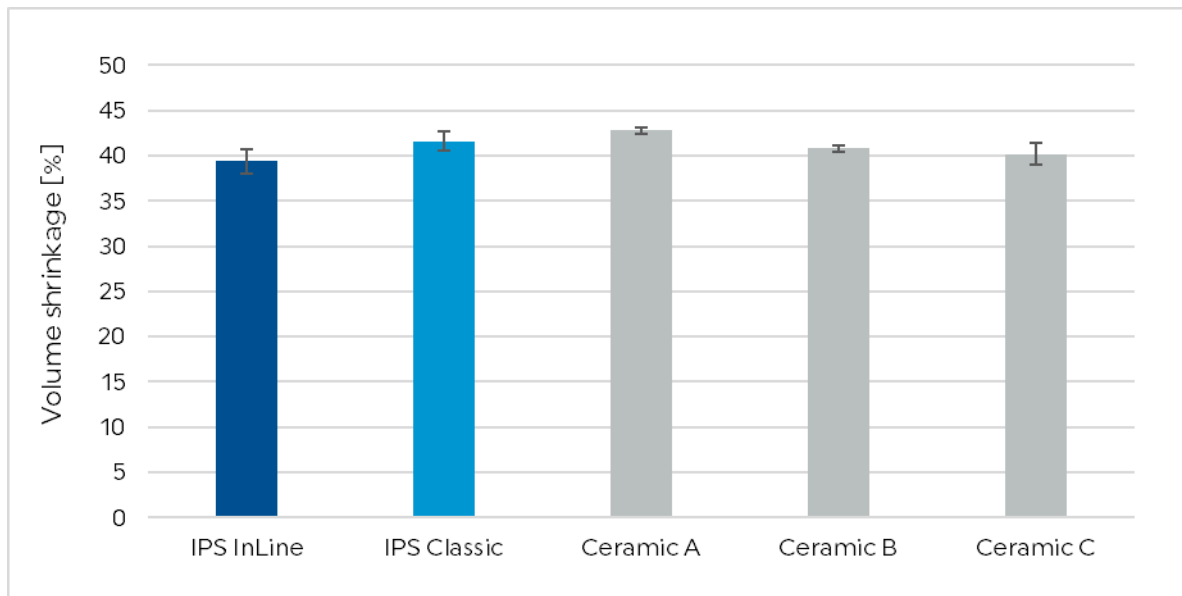


Fig. 16: Volumetric shrinkage of various ceramics. Ivoclar R&D, 2004

Shrinkage is unavoidable and expected. IPS InLine features optimum shrinkage with values similar to and in the range of other well-established layering ceramics.

5.4 Thermal expansion

5.4.1 The linear coefficient of thermal expansion (CTE)

The linear thermal expansion of a material is determined by means of a dilatometer. The specimen is continuously heated/cooled, and the linear dimensional change recorded. The resulting dimensional change can be continuous or erratic. A jump in the curve can be seen if a phase transition occurs in the material. The linear coefficient of thermal expansion (CTE) is determined per unit length for 1 degree change in temperature (1 Kelvin). The CTE largely depends on the temperature range within which it is measured. Therefore, the temperature range must be stated at all times.

The CTE for dental ceramics is analysed in the range up to the glass transition temperature T_G . The CTE serves to assess the possible loading of the ceramic in combination with the framework/layering material. Glass-ceramics at temperatures above the T_G value are soft and the stress is dissipated by the flow of the material. The unit of the CTE is $[10^{-6} \cdot K^{-1}]$ according to ISO 9693. However, $[1 \mu m/m \cdot K]$ is also commonly used.

5.4.2 CTE of ceramic and metal

As mentioned previously (see sections 1.1.1 and 1.1.2), the thermal expansion of the ceramic is decisive for its compatibility with various metal framework materials. Ceramic materials are less sensitive to compressive stresses than to tensile stresses. In dental restorations therefore, the ceramic has to be applied in such a way that it is subjected to compressive stress in the restoration. This is achieved by choosing the CTE of the ceramic to be about one unit $/(1 \times 10^{-6} \cdot K^{-1})$ lower than the CTE of the alloy.

The CTE of the ceramic changes via thermal treatment (e.g. number of firing cycles) because structural changes occur with temperature changes such as grain growth and precipitation of a greater amount of leucite.

5.4.3 Influence of thermal treatment on the CTE

The IPS InLine materials are suitable for alloys in the CTE range of $13.8-15.0 \times 10^{-6} \cdot K^{-1}$ (25/500°C). The CTE of the ceramic can be adjusted to the alloys in a certain range by thermal treatment, e.g. by several firing cycles, long-term cooling or tempering (holding at an increased temperature). For an optimum restoration result, it is imperative to observe the manufacturer recommendations regarding the alloy and thermal treatment specifications.

The CTE values shown in the technical data of section 4 are depicted graphically in the following diagram showing the slight increase in CTE with an increasing number of firings (i.e. Influence of thermal treatment) for the principal IPS InLine and IPS InLine One materials.

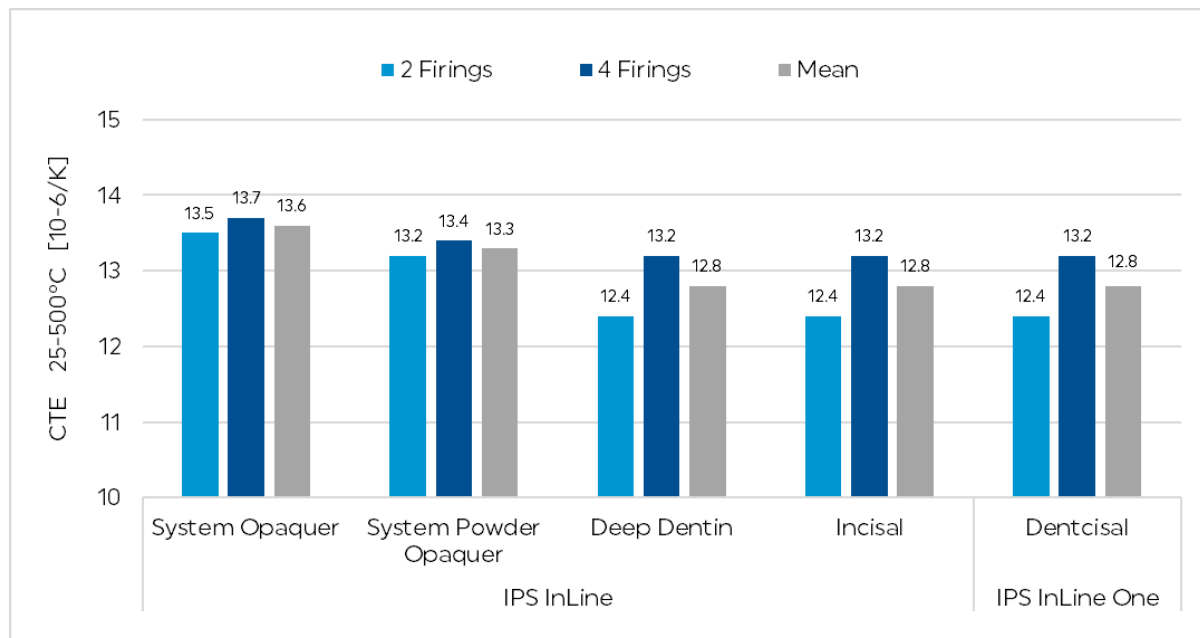


Fig. 17: CTE of IPS InLine materials with 2 and 4 firings at 25-500°C. Ivoclar R&D, 2022

The change in the CTE via thermal treatment depends on the ceramic type and material.

5.5 Wear of IPS InLine

The vertical wear of the IPS InLine material along with a number of competitor products (was tested via means of the Willytec chewing machine. Incisal materials were used for all products as these materials are logically most subjected to wear.

Standardized molar crowns with IPS d.SIGN 30 Gold as the framework were bonded to PMMA dies with Multilink and metal primer and stored dry at 37°C for 24 hours prior to chewing simulation testing. The materials were subjected to 120,000 masticatory cycles at a load of 50N.

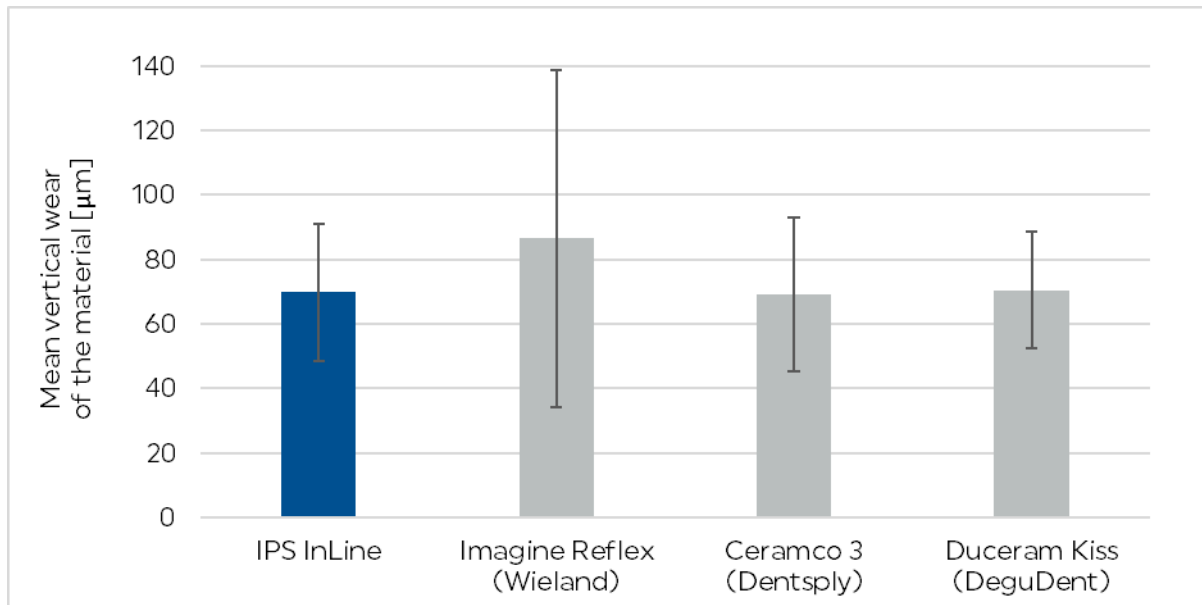


Fig. 18: Mean vertical wear of various ceramic veneering materials. Ivoclar R&D, 2005

The wear of antagonist teeth was also simulated using the palatal enamel cusps of natural upper molars.

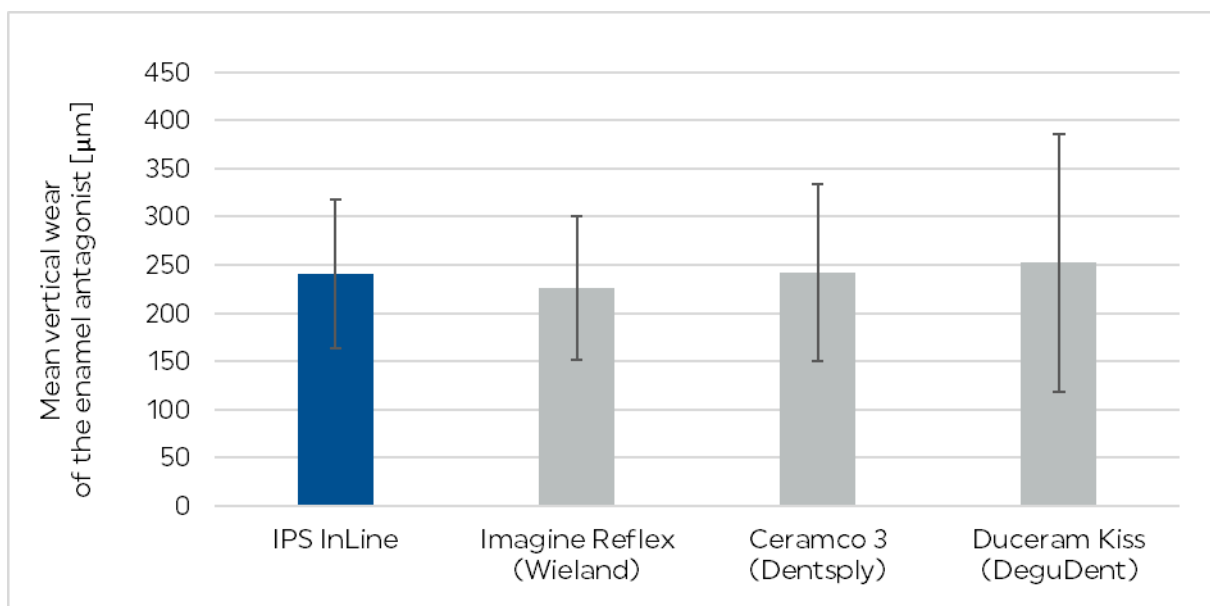


Fig. 19: Mean vertical wear of enamel antagonists. Ivoclar R&D, 2005

Both the material and antagonist wear of IPS InLine was comparable to the values of competitive products. There was no statistically significant difference between the materials with regard to either value.

5.6 Metal-ceramic bond

The metal-ceramic bond of IPS InLine together with various alloys was determined by Schnettger et al, as part of a diploma thesis and the results were also published in 2006. The ceramic was bonded to the alloy specimen by conducting two opaquer firings, two dentin firings and a glaze firing. At the time of the study the alloys involved were Ivoclar Vivadent products.

Testing the bond strength of metal-ceramic systems.¹¹

Schnettger A, Zylla I, Kappert H. Dortmund/Osnabrück Germany

Objectives: To evaluate the bonding quality of IPS InLine to various alloys.

Materials & Methods: Three experiments were conducted to evaluate the bonding quality of the IPS InLine metal-ceramic with 31 alloys. The bond strength was determined using a three-point bending test according to Schwickerath using six standard test specimens according to the standard EN ISO 9693. Essentially, a metal plate of the alloy to be tested is fabricated and the ceramic material is fired onto it. This sample is then loaded (as shown below) into a universal testing machine and a downward force is applied.

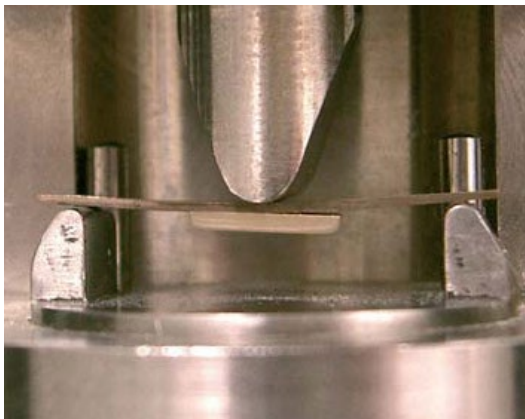


Fig.20: Experimental set-up of bond strength measurement

The force at which delamination/crack formation occurs is determined and this resulting force can be used to calculate the strength of the metal-ceramic bond.

Results: The results in MPa for all 31 alloys is shown below.

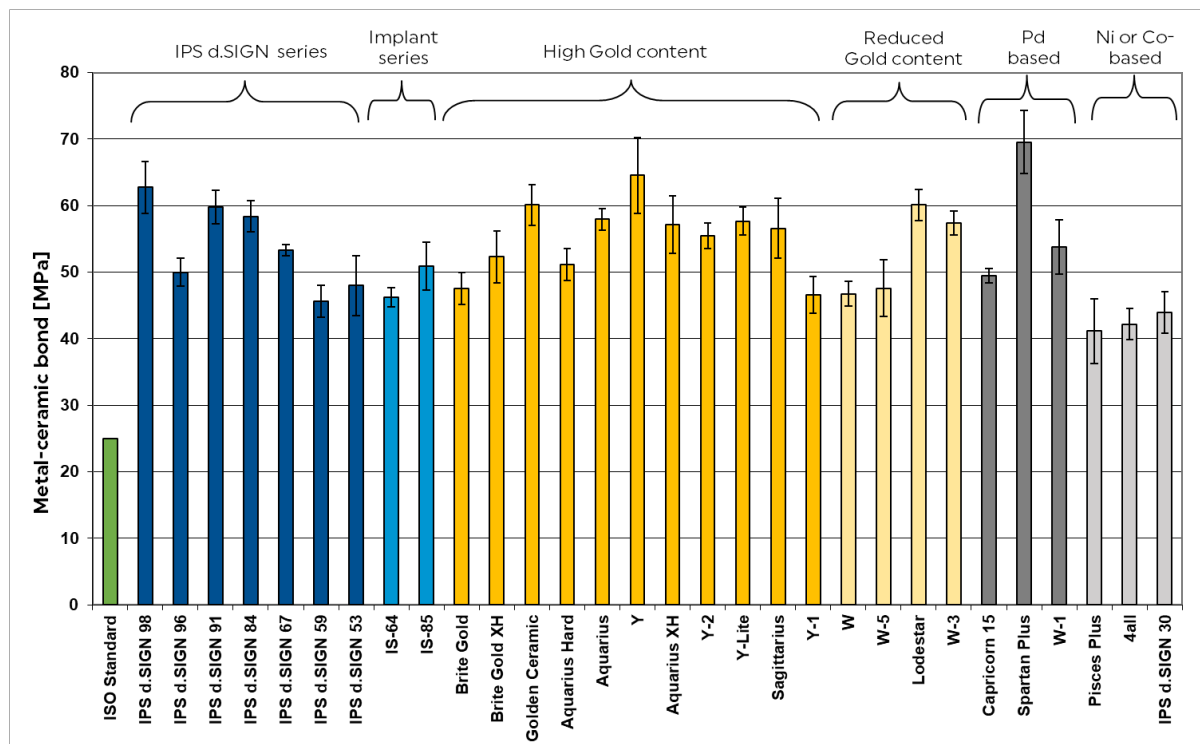


Fig. 21: Mean value and standard deviation of metal-ceramic bonds (number of samples per alloy: n=6) in conjunction with IPS InLine on different alloys. ¹¹

Conclusions: The metal-ceramic bond values of all the investigated alloys were clearly above the minimum value of 25 MPa, stipulated in the ISO standard 9693.

5.6.1 Metal ceramic bond with Colado CAD CoCr4

IPS InLine is also used with digital disc alloy materials. The results below show the results of bond strength testing with the digital disc Colado CAD CoCr4 and Ivoclar the veneering materials IPS InLine and IPS Style Ceram.

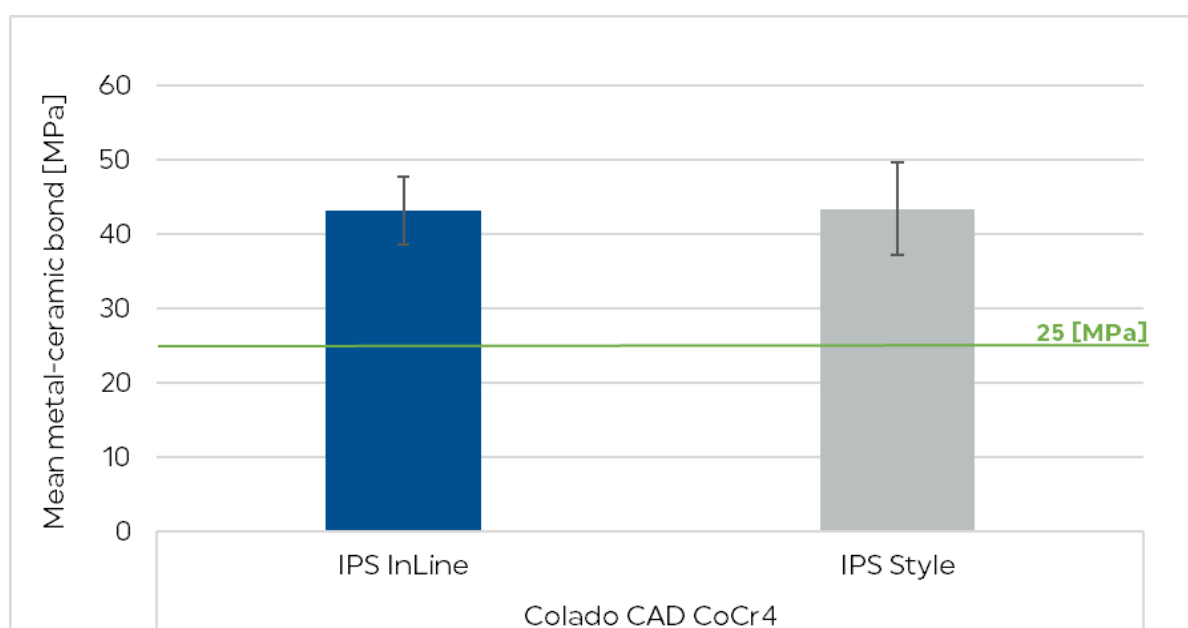


Fig. 22: Bond strength testing (Schwickerath) with Colado CAD CoCr4 and IPS InLine. Ivoclar R&D, 2017

The mean values with 3 different batches (3 x n=6) of the cobalt chrome alloy involving 18 samples per ceramic are shown above. The mean bond strength for IPS InLine was 43.1 ± 4.5 MPa and 43.4 ± 6.2 MPa for IPS Style. The bond strength of 25 MPa required by EN ISO 9693-1 is well exceeded for both veneering materials.

5.6.2 Metal-ceramic bond on re-cast alloys

The re-melting and re-casting of precious or non-precious alloys is a common practice in dental laboratories – mainly practiced for economic reasons and to prevent wastage. The effect of re-casting on the metal-ceramic bond was tested at the Ohio State University, USA. Contrary to common practice, a minimum amount of 50% new alloy was not added in this investigation.

The effect of metal recasting on porcelain-metal bonding: A force-to-failure study

*Liu R, Johnston W M, Holloway J A, Brantley W A, Dasgupta T. Ohio State University, Columbus, Ohio, USA.*¹⁸

Objectives: To evaluate if re-casting up to three times affected the metal to ceramic bond strength for 3 noble alloys (high gold, gold-palladium and palladium-silver), in combination with IPS InLine.

Material & Methods: IPS InLine was tested in combination with different (previously Ivoclar) alloys: Brite Gold XH (Au-Pt), W-5 (Au-Pd-Ag) and IPS d.SIGN 53 (Pd-Ag).

The alloys were cast into metal plates using torch melting. After oxide firing, IPS InLine was fused onto the centre of the metal plate. The same sample assemblies were fabricated from the same alloys after a second and third re-casting - without adding any fresh alloy. Each of the 9 test groups comprised 12 samples. The fracture load and bond strength values were determined according to the standard EN ISO 9693.

Results:

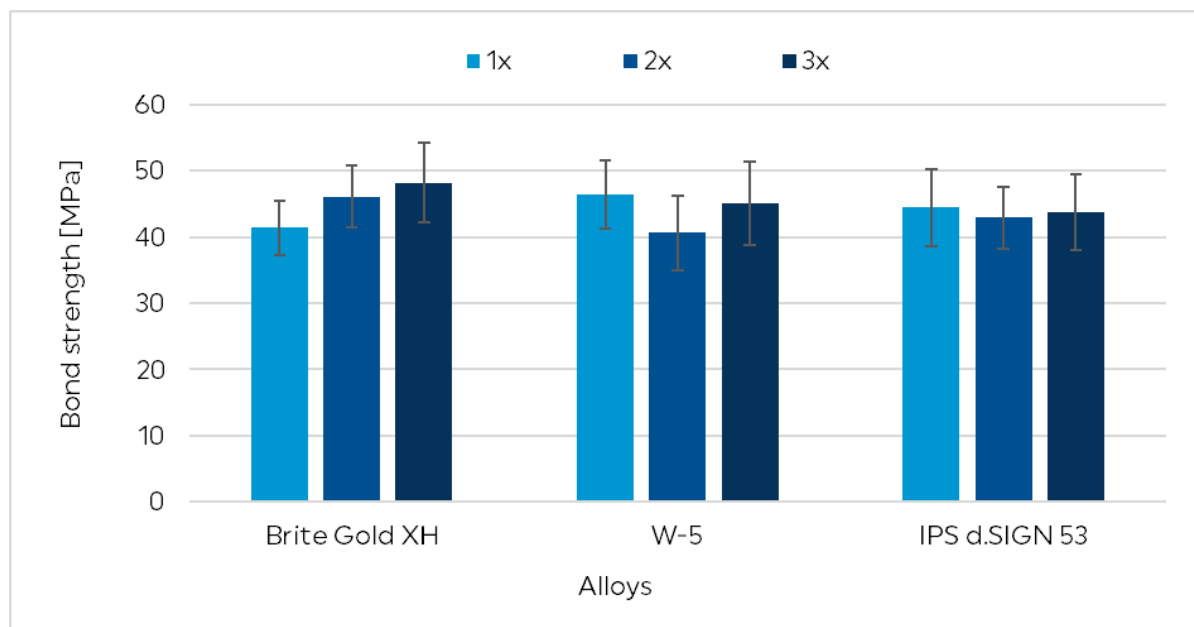


Fig. 23: Bond strength values of IPS InLine on precious alloys, cast 1-3 times¹⁸

The mean values for the specimen groups ranged from 40.6 MPa to 48.2 MPa and there were no significant differences among the 3 alloys after the first casting. In the Brite Gold XH group the difference between the first and third casting was significantly different i.e. higher.

Conclusions: All three noble alloys showed satisfactory bonding compatibility with IPS InLine, after all three castings. The repeated casting of W-5 and IPS d.SIGN 53 had no significant effect on the metal-ceramic bond. With Brite Gold XH the bond strengths were significantly higher after the 3rd casting. The authors hypothesize here that the recasting may have increased the oxidation of the high noble alloy which in turn increased the bonding compatibility. All bond strength values for all products, after all castings were also clearly above the minimum 25 MPa value stipulated by the standard.

6 Clinical Investigations

6.1 Systematic reviews and survival rates

Several reviews of the clinical performance and longevity of metal-ceramics have been conducted. Survival rates tend to be consistently high. For ceramic veneered metal crowns, Reitemeier et al described a survival rate of 88.8% over 8 years and a 77.3% over 10 years.¹⁹ A systematic review by Pjeturssen et al on implant-supported single crowns, estimated (via meta-analysis) a 5 year survival rate of 98.3%.²⁰ Sailer et al detailed a survival rate of ceramic metal crowns of 94.7% over a 5 year period.²¹

Leucite-containing veneering ceramics have been in clinical use together with alloys for many years and their clinical success is well documented.^{22, 23} The IPS InLine system for metal-ceramic restorations is a standard well-established product in this field. The following section details important clinical (in vivo) investigations carried out with the IPS InLine veneering materials for metal ceramics.

6.2 Clinical performance of IPS InLine

Evaluation of the esthetic quality and clinical performance of metal-ceramic IPS InLine crowns and bridges on different metal frameworks.²⁴

Benelli L, Temperani M. Prato & Florence, Italy

Objective: To evaluate the clinical quality of IPS InLine single crowns and bridges (made with different metal frameworks) from a physical, esthetic and biological respect.

Materials & Methods: In a multi-centre trial, 46 different restorations were placed in 32 patients. A total of 92 restoration elements (made up of single crowns and bridges) on different alloy bases were examined and the qualitative and quantitative changes were assessed one week, one month, six months and one year after cementation. The restorations were placed on endodontically treated as well as vital teeth. Two luting cements were used: Ketac Cem Automix glass ionomer cement/3M ESPE and the self-curing Multilink luting composite/Ivoclar were used. For the fabrication of the crown copings and bridge frameworks, four different metal alloys were used: High gold: IPS d.SIGN 98 / CTE 14.3, Reduced gold: W-5 / CTE 14.0, Palladium-based Spartan / CTE 14.3 and Non-precious IPS d.SIGN 30 / CTE 14.5. The following criteria were evaluated – periodontal parameters including bleeding on probing and the plaque index, prosthetic parameters including the presence of cracks, loss of adhesion, antagonist wear and a radiological examination was undertaken. These checks were carried out at baseline, after one week and six months following cementation.

Results: Forty-six restorations placed in thirty-two patients (comprising a total of ninety-two restoration elements) were monitored for one year. The distribution of restorations was as follows:

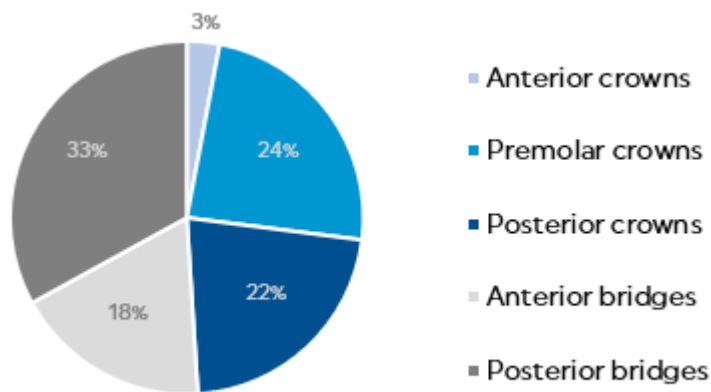


Fig. 24: Type of IPS InLine metal-ceramic restorations evaluated. ²⁴

There were two 6-unit, three 5-unit, two 4-unit and four 3-unit bridges. The total cumulative working time was 1440 months, corresponding to an average working time of 1 year and 3.5 months (15.69 months) per element. Over the study period, no fractures, cracks, chipping, secondary caries, gingival pathology or excessive wear of opposing teeth was observed. All restorations showed optimal proximal contacts, a smooth surface and optimal gingival health, independent of whether the restoration had been placed on vital or non-vital teeth. Excellent aesthetic results could be achieved with the IPS InLine veneering ceramic. One debonding case occurred whereby an adhesively luted single posterior crown had been placed on an endodontically treated tooth with a composite post and core build-up, The clinical assessment was very favourable.

Conclusion: The authors conclude that the ceramic properties were well-coordinated with those of the alloys, the clinical assessment was favourable and excellent esthetic results were achieved with good resistance to occlusal stress and surface wear.

10-year clinical comparative study of ceramic and composite veneered metal crowns. ²⁵

Bacher H, Schweyen R, Olms C, Arnold C, Setz J, Hey J. Marti-Luther Uni Halle-Wittenberg, Germany

Objective: To clinically compare composite vs. ceramic veneered metal-supported crowns.

Materials & Methods: This study was conducted between May 2006 and November 2017. The ceramic IPS InLine based crowns were considered the control in this study.

19 patients with an average age of 49, with at least 2 suitable adjacent natural teeth for crowning, were treated with 64 high noble alloy crowns. Two different alloys both with high gold content were used: IPS d.SIGN for the ceramic group and Academy Gold for the composite group.

The adjacent crowns were veneered with either ceramic (IPS InLine) or a composite veneering material (SR Adoro/Ivoclar). This product has been discontinued.

Follow-up examinations were carried out at baseline (14 days following placement), after 6 months, 18 months, 30 months, 42 months and 10 years - whereby crowns were investigated for mechanical defects, periodontal parameters and discoloration. Crowns were considered successful if in situ without any mechanical defects

Results: The complete patient cohort could be examined up to 30 months and at the 10-year recall, 15 patients were available. The overall 10-year survival rates were high in both groups, at 87.1% and 87.9% for the ceramic and composite-veneered restorations respectively. However the success rates differed. Defects (largely chipping) occurred earlier in the composite group compared to the ceramic IPS InLine group and the survival rates without any mechanical defects (success) after 10 years were 83.9% and 51.5% for the ceramic and composite groups respectively. No significant differences between the groups were found for periodontal parameters, however discoloration was significantly worse in the composite group.

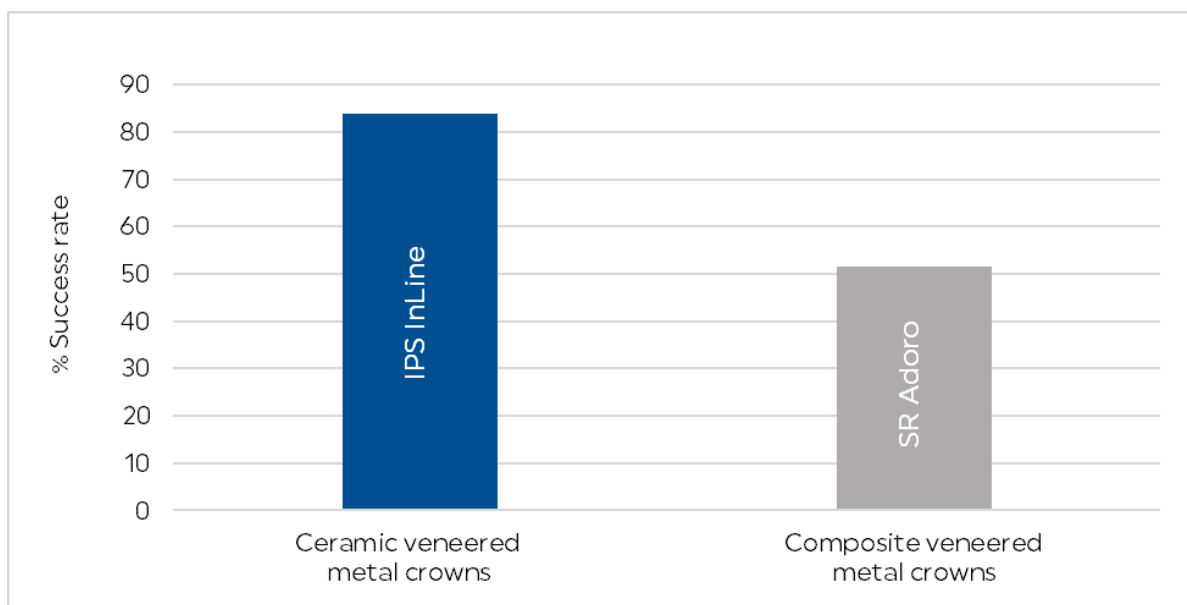


Fig. 25: Comparison of the survival rates without any mechanical defects (success) for ceramic vs. composite veneered metal crowns after 10 years.²⁵

Conclusions: The survival and success rates after 10 years for the ceramic group fabricated with IPS InLine were 87.1% and 83.9% respectively. The authors concluded here that ceramic veneering remains the gold standard for metal crowns. After 10 years, discolorations and mechanical defects were considerably higher in the composite group compared to the ceramic.

6.3 Clinical case with IPS InLine



Fig. 26: Clinical case replacing unesthetic crown with IPS InLine crown. Ivoclar R&D, 2004

An anterior crown was fabricated to replace an old overly opaque metal-ceramic crown on tooth 21. The IPS InLine crown was pre-treated with metal primer, dried and luted adhesively to the tooth stump with a labial ceramic shoulder preparation.

The above case clearly shows the improved esthetics achieved after treatment with an IPS InLine metal-ceramic crown.

7 Biocompatibility

Biocompatibility can be defined as the ability of a substance/material to be in contact with a living system without producing an adverse effect. When developing new products, Ivoclar strives to use well-established raw materials that have already proven safe in vivo – in order to minimize biocompatibility risks from the outset.

Ceramic materials used in dentistry are highly resistant to acid and corrosive attack and are therefore regarded as exceptionally biocompatible.²⁶ The conditions of the oral cavity (pH and temperature changes) are also not severe enough to dissolve components from dental ceramics. Nevertheless, in theory mechanical destruction and chemical reactions (erosion) could have an effect on the constituents of the ceramic. Mechanical abrasion, however, does not affect biocompatibility as broken fragments do not remain in the mouth/body for long and there is no change in material composition. Chemical reactions and the associated dissolution of components could also theoretically lead to problems, but the composition of dental ceramics is biologically harmless, and the amounts of dissolved material would be so small, that they would not pose any biocompatibility-risk.

Medical device standards

Medical devices are subject to strict requirements, which are designed to protect patients and operators from any potential biological risks. ISO 10993 "Biological evaluation of medical devices" defines how the biological safety of a medical device is to be evaluated. Furthermore, dental medical devices are subject to ISO 7405 "Evaluation of biocompatibility of medical devices used in dentistry" and standard risk management requirements as set out in ISO 14971 "Medical devices – Application of risk management to medical devices". ISO 6872: Dentistry – Ceramic Materials, also prescribes how the *evaluation of chemical solubility* should be carried out on ceramic materials.

The biocompatibility of the IPS InLine system materials was evaluated according to these standards with a series of different tests plus literature and database searches.

Chemical durability

Dental materials are exposed to a wide range of pH-values and temperatures (through eating and drinking) in the oral cavity. Chemical stability is therefore a prerequisite for dental materials. According to Anusavice, ceramics are amongst the most durable of all dental materials.²⁶

Chemical solubility (tested in 4% acetic acid) according to ISO 6872 should be < 100 µg/cm² of total mass loss:

IPS InLine product component	Chemical solubility [µg/cm ²]	Threshold value according to standard [µg/cm ²]
IPS InLine System Opaquer	28	< 100
IPS InLine Gingiva Opaquer		
IPS InLine System Powder Opaquer	28	
IPS InLine System Intensive Powder Opaquer		
IPS InLine Gingiva Powder Opaquer		
IPS InLine Margin	23	
IPS InLine Deep Dentin	12	
IPS InLine One Dentsisal	12	
IPS InLine Dentin	12	
IPS InLine Incisal	12	
IPS InLine Transpa Incisal		
IPS InLine Cervical Incisal	12	
IPS InLine Cervical Dentin		
IPS InLine Occlusal Dentin		
IPS InLine Mamelon Masse		
IPS InLine Transpa		
IPS InLine Gingiva		
IPS InLine Intensiv Gingiva		
IPS InLine Opal Effect	10	
IPS InLine Add-On	10	
IPS InLine Margin Add-On	12	
IPS InLine System Add-On 690 °C*)	20	

Table 2: Chemical solubility of IPS InLine products. *R&D Ivoclar*

The chemical solubility of IPS InLine products is well below the relevant standard threshold.

Cytotoxicity / Irritation

As part of the biological evaluation, the *in-vitro* cytotoxicity of IPS InLine was assessed via means of an XTT assay. Under the selected test conditions, none of the tested samples showed cytotoxic potential. These results were also used/transferred to conclude that the risk of potential irritation or intracutaneous effects was very low.

Radioactivity

Concern regarding the potential radioactivity of dental ceramics dates back to the 1970s, when small amounts of radioactive fluorescent substances^{27,28} were employed in various metal-ceramic systems. Nowadays the current standards (EN ISO 6872; EN ISO 9693; ISO 13356) for ceramic materials prohibit the use of radioactive additives and stipulate the maximum level of radioactivity permissible in ceramic materials.

The radioactivity levels in IPS InLine were measured by means of γ -spectrometry for the nuclides ²³⁸U and ²³²Th. In all cases the levels were way below the specified threshold of 1.0 Bq/g

Testing regime and summary

Various biocompatibility assessments were conducted on the IPS InLine materials including cytotoxicity (potential damage to cells) and genotoxicity (potential to damage/alter genetic material) tests. Test samples of IPS InLine were investigated in the finished (glass ceramic) state - representing the most relevant long-term situation for the patient. On the basis of the biological evaluation on the products and long-standing world-wide clinical use of these and similar materials, it can be concluded that:

- IPS InLine extracts are not cytotoxic
- IPS InLine has a negligible sensitizing potential
- IPS InLine is not irritant
- IPS InLine holds no risk for acute, sub-acute, sub-chronic or chronic toxicity
- IPS InLine is not genotoxic
- IPS InLine is not carcinogenic
- IPS InLine reveals negligible radioactivity

8 Conclusion

Dental ceramics are largely bioinert and offer outstanding biocompatibility. Allergic reactions are extremely rare. The dental technician is exposed to the highest risk potential, as ceramic materials are frequently ground in the laboratory. The fine mineral dust created in the process should not be inhaled. This potential risk can be eliminated by using standard suction equipment and a protective mask. The dentist, who handles the completed restoration, is unlikely to face any risk at all and the biological risk posed to the patient is exceptionally low.

In view of the present data and today's level of knowledge, it can be concluded that the IPS InLine materials do not represent a toxicological risk for patients or dental professionals. IPS InLine metal ceramics restore oral esthetics and reconstruct chewing function. Provided that the instructions for use are adhered to, the benefits to patients can be expected to exceed any potential risks.

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