IPS e.max® Press

Scientific Documentation
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1. **Introduction**

1.1 **Overview of IPS e.max range of products**

IPS e.max is an all-ceramic system that consists of the following five components:

- IPS e.max Press (lithium disilicate glass-ceramic ingot for the press technique)
- IPS e.max ZirPress (fluorapatite glass-ceramic ingot for the press-on technique)
- IPS e.max CAD (lithium disilicate glass-ceramic block for the CAD/CAM technique)
- IPS e.max ZirCAD (zirconium oxide block for the CAD/CAM technique)
- IPS e.max Ceram (fluorapatite veneering ceramic)
1.2 IPS e.max Press

1.2.1 Material/ Manufacture

IPS e.max Press is a lithium disilicate glass-ceramic ingot for use with the press technique (Fig. 1). The ingots are available in two degrees of opacity.

These ingots have been developed on the basis of a lithium silicate glass ceramic (Fig. 2). The ingots are produced by bulk casting. A continuous manufacturing process based on glass technology (casting/pressing procedure) is utilized in the manufacture of the ingots. This new technology uses optimized processing parameters, which prevent the formation of defects (pores, pigments, etc) in the bulk of the ingot.

As lithium disilicate glass ceramic and zirconium oxide (IPS e.max ZirCAD) feature a similar coefficient of thermal expansion, the same layering ceramic (IPS e.max Ceram) can be used in conjunction with both of these materials.

IPS e.max Press is processed in the dental laboratory with the known Empress pressing equipment. This equipment is distinguished for providing a high accuracy of fit.
1.2.2 Coloration
The new manufacturing method does not allow color pigments to be added to the material, as these pigments would melt out when the melting temperature is reached. Instead, polyvalent ions, which are dissolved in the glass, are utilized to provide the desired color. The combination, concentration and valence of the coloration ions play an essential role in this mechanism. The advantage of using an ion-based coloration mechanism is that the color-releasing ions can be homogeneously distributed in the single-phase material. By contrast, color pigments represent imperfections in the microstructure.

1.2.3 Microstructure
The microstructure of IPS e.max Press consists of lithium disilicate crystals (approx. 70%), $\text{Li}_2\text{Si}_2\text{O}_5$, which are embedded in a glassy matrix. Lithium disilicate, the main crystal phase, consists of needle-like crystals (Fig. 3). The crystals measure 3 to 6 µm in length.

![Microstructure of IPS e.max Press (SEM, etched with HF vapor for 30 s)](image)
2. Technical data

IPS e.max Press
Ingots for the ceramic press technique

**Standard composition:**

<table>
<thead>
<tr>
<th>Oxide</th>
<th>Percentage (wt %)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SiO₂</td>
<td>57.0 – 80.0</td>
</tr>
<tr>
<td>Li₂O</td>
<td>11.0 – 19.0</td>
</tr>
<tr>
<td>K₂O</td>
<td>0.0 – 13.0</td>
</tr>
<tr>
<td>P₂O₅</td>
<td>0.0 – 11.0</td>
</tr>
<tr>
<td>ZrO₂</td>
<td>0.0 – 8.0</td>
</tr>
<tr>
<td>ZnO</td>
<td>0.0 – 8.0</td>
</tr>
<tr>
<td>+ other oxides</td>
<td>0.0 – 10.0</td>
</tr>
<tr>
<td>+ coloring oxides</td>
<td>0.0 – 8.0</td>
</tr>
</tbody>
</table>

**Physical properties:**

In compliance with:
ISO 6872 Dental ceramic
ISO 9693 Metal-ceramic dental restorative systems

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexural strength (biaxial)</td>
<td>400 ± 40 MPa</td>
</tr>
<tr>
<td>Chemical solubility</td>
<td>40 ± 10 µg/cm²</td>
</tr>
<tr>
<td>Coefficient of thermal expansion (100 - 400°C)</td>
<td>10.15 ± 0.4 × 10⁻⁶ K⁻¹</td>
</tr>
<tr>
<td>Coefficient of thermal expansion (100 - 500°C)</td>
<td>10.55 ± 0.35 × 10⁻⁶ K⁻¹</td>
</tr>
</tbody>
</table>
3. Material science investigations

3.1 Physical properties

<table>
<thead>
<tr>
<th>Physical property</th>
<th>Value</th>
<th>Investigator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fracture toughness (SEVNB)</td>
<td>2.5 – 3.0 MPam$^{1/2}$</td>
<td>in-house, (Ivoclar Vivadent AG, Schaan)</td>
</tr>
<tr>
<td>Modulus of elasticity</td>
<td>95 ± 5 GPa</td>
<td>in-house (Ivoclar Vivadent AG, Schaan)</td>
</tr>
<tr>
<td>Modulus of elasticity</td>
<td>91.0 GPa</td>
<td>Albakry et al.$^{11}$</td>
</tr>
<tr>
<td>Modulus of elasticity</td>
<td>94.4 GPa</td>
<td>Lohbauer$^3$</td>
</tr>
<tr>
<td>Modulus of elasticity</td>
<td>96.0 GPa</td>
<td>Anusavice$^2$</td>
</tr>
<tr>
<td>Poisson’s ratio, $\nu$</td>
<td>0.23</td>
<td>Albakry et al.$^{11}$</td>
</tr>
<tr>
<td>Vickers hardness</td>
<td>5800 ± 100 MPa</td>
<td>in-house (Ivoclar Vivadent AG, Schaan)</td>
</tr>
<tr>
<td>Hardness</td>
<td>5.5 GPa</td>
<td>Albakry et al.$^{13}$</td>
</tr>
<tr>
<td>Density</td>
<td>2.5 ± 0.1 g/cm$^3$</td>
<td>in-house (Ivoclar Vivadent AG, Schaan)</td>
</tr>
</tbody>
</table>

Table 1: Physical properties

3.2 Flexural strength

3.2.1 Flexural strength of IPS e.max Press (various methods)

Flexural strength values largely depend on the methods used to measure them. Fig. 4 provides an overview of the flexural strength values measured for a single material using different measuring methods.

![Fig. 4: Flexural strength values measured for IPS e.max Press using different methods (see also Table 2)](image-url)
3.2.2 Biaxial flexural strength of different pressable ceramics

Albakry et al.\textsuperscript{11} determined the biaxial flexural strength and Weibull modulus of different pressable ceramic materials of Ivoclar Vivadent AG. Twenty discs were tested for each material; the tests were carried out in compliance with ASTM F 394-78.

![Fig. 5: Biaxial flexural strength and Weibull modulus of selected pressable ceramics (Albakry et al.\textsuperscript{11})](image)

- The strength values of IPS e.max Press and IPS Empress2, which are higher than IPS Empress, are attributable to the composition of these materials (lithium disilicate crystals).
- IPS e.max Press and IPS Empress2 show a higher Weibull modulus than IPS Empress. This means that the values measured for these materials are more reliable and have less variance.

3.2.3 Weibull strength $\sigma_{63.21\%}$

Strength measurements in ceramic materials tend to yield results with a wide distribution. Consequently, what is known as the Weibull strength $\sigma_{63.21\%}$ is often mentioned in conjunction with ceramic materials. The Weibull strength $\sigma_{63.21\%}$ indicates the load at which 63.21\% of all samples measured in a single series of measurements fail. Other terms used for Weibull strength are “characteristic strength” or “mean strength”.

---

<table>
<thead>
<tr>
<th>Examiner</th>
<th>Flexural strength [MPa]</th>
<th>Measuring method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berge et al.\textsuperscript{3}; f)</td>
<td>375.7</td>
<td>Biaxial flexural strength, ISO 6872; test in H$_2$O</td>
</tr>
<tr>
<td>Sorensen et al.\textsuperscript{4}; e)</td>
<td>411.6</td>
<td>Biaxial flexural strength (wet test)</td>
</tr>
<tr>
<td>Sorensen et al.\textsuperscript{4}; a)</td>
<td>455.5</td>
<td>Biaxial flexural strength</td>
</tr>
<tr>
<td>Kappert\textsuperscript{4}; a)</td>
<td>426</td>
<td>Biaxial flexural strength</td>
</tr>
<tr>
<td>Anusavice\textsuperscript{4}; d)</td>
<td>239</td>
<td>4-point flexural strength after 48 hours of storage in H$_2$O</td>
</tr>
<tr>
<td>Ludwig et al.\textsuperscript{5}; b)</td>
<td>426</td>
<td>3-point flexural strength</td>
</tr>
<tr>
<td>Lohbauer\textsuperscript{5}; c)</td>
<td>374.4</td>
<td>Weibull strength $\sigma_{63.21%}$, 4-point flexural strength, DIN EN 843-1</td>
</tr>
<tr>
<td>Marx, Fischer\textsuperscript{5}; b)</td>
<td>466</td>
<td>3-point flexural strength</td>
</tr>
<tr>
<td>Marx et al.\textsuperscript{10}; c)</td>
<td>388</td>
<td>Weibull strength $\sigma_{63.21%}$, 4-point flexural strength, DIN EN 843-1</td>
</tr>
<tr>
<td>Albakry et al.\textsuperscript{11}; a)</td>
<td>440</td>
<td>Biaxial flexural strength</td>
</tr>
<tr>
<td>Guazzato et al.\textsuperscript{12}; b)</td>
<td>303</td>
<td>3-point flexural strength</td>
</tr>
</tbody>
</table>

Table 2: Values and measuring methods shown in Fig. 4
Marx et al.\textsuperscript{9,10} determined the Weibull strength by means of a 4-point flexural strength test (DIN V ENV 843-1), using a sample size of $n=30$.

![Weibull strength comparison](image)

Fig. 6: Weibull strength $\sigma_{93.21\%}$ of selected pressable ceramic materials (Marx et al.\textsuperscript{9,10})

- The Weibull strength of IPS e.max Press is higher than that of IPS Empress 2.

### 3.3 Fracture toughness

The fracture toughness $K_{IC}$ provides a measure of the material's resistance to crack propagation. $K_{IC}$, which is also called critical stress intensity factor or crack toughness, is the critical value for a crack in a material to propagate to failure.

#### 3.3.1 Fracture toughness of IPS e.max Press (various methods)

Various methods can be used to determine the fracture toughness of a material. The results of individual materials can only be compared if the same methods are used to measure the fracture toughness ($K_{IC}$), similar to the flexural strength measurements. It is not the purpose of this documentation to discuss each individual method in detail. Instead, the two methods utilized to determine the fracture toughness of IPS e.max Press are briefly described below.

**IF (indentation fracture technique):**

After the samples have been prepared, different loads are applied to them with a Vickers hardness tester to produce indentation patterns on the surfaces of the samples. The cracks that have formed at the corners of the indentations are measured in an optical microscope. The fracture toughness is calculated as a function of the length of the cracks measured, the indentation load applied and characteristic values of the material (modulus of elasticity, hardness). The material may appear anisotropic in the microscope, depending on the size, shape and orientation of the crystals. This means that the cracks propagate differently, depending on whether they run parallel or perpendicular to the crystals. Consequently, two different values are obtained. These values are indicated as $\text{IF}_{\text{parallel}}$ and $\text{IF}_{\text{perpend}}$ in the present study.

**IS (indentation strength):**

After the samples have been prepared, different loads are applied to them with a Vickers hardness tester to produce indentation patterns on the surface of the samples. Subsequently, the samples are subjected to a strength test (3-point, 4-point or biaxial flexural strength). The fracture toughness is calculated as a function of the strength value measured, the indentation load applied and the characteristic values of the material (modulus of elasticity, hardness).
The large differences in the fracture toughness values measured provide a clue as to how tricky it is to interpret individual values. The fracture toughness values largely depend on the individual methods used to determine them. In addition, the degree to which the individual methods affect the results also depends on the materials tested (see Section 3.3.2). Albakry et al.\textsuperscript{13} refer to a study conducted by Fischer et al\textsuperscript{14}, who described the IF method as inappropriate to determine the $K_{IC}$ value and recommended using this method only for initial rough estimates of a material's fracture toughness.

3.3.2 Fracture toughness: Effect of individual methods on the values measured in selected pressable ceramic materials

Albakry et al.\textsuperscript{13} determined the fracture toughness using different methods.
The fracture toughness values measured for the two lithium disilicate ceramics IPS Empress 2 and IPS e.max Press largely depend on the measuring method used, while the values measured for IPS Empress show only minimal variation. Albakry et al.\textsuperscript{13} surmise that the orientation of the lithium disilicate crystals may have had an effect on the results. The crystals arrange themselves in a specific order of orientation when the material is pressed into samples. Consequently, the samples should be matched to the measuring methods. The size and direction of the crystals have an effect on crack propagation.

4. **In vitro investigations**

4.1 **Fracture strength of anterior bridges**

Ludwig et al.\textsuperscript{7} determined the fracture strength of anterior bridges under static and dynamic loading. The bridges were fabricated and glazed according to the Instructions for Use.

**Methods:**

- **static (n=6):** static load applied to the pontic (at an angle of 30°) up to the point of breaking
- **dynamic (n=12):**
  - up to 300 N: loading in a chewing simulator, including thermocycling
  - as of 300 N: loading in pneumatic loading system, without thermocycling

![Graph showing static and dynamic fracture strength of IPS Empress, IPS Empress 2, and IPS e.max Press](image)

Fig. 9: Static fracture strength and fatigue strength of anterior bridges (Ludwig et al.\textsuperscript{7,15})

- The fatigue strength of IPS e.max Press by far surpasses the maximum load that may be exerted on the material under natural conditions.\textsuperscript{7}
- It can be assumed that three-unit anterior bridges made of IPS e.max Press are long lastingly resistant to fracture, if constructed according to the Instructions for Use.\textsuperscript{15}
4.2 Fracture strength of three-unit posterior bridges

Schröder\textsuperscript{16} examined the static fracture load of three-unit IPS e.max Press frameworks and bridges. Non-veneered and veneered frameworks were tested. The bridges were anatomically pressed and tested with and without glaze.

![Fracture load of three-unit posterior bridges made of IPS e.max Press (Schröder)\textsuperscript{16}}

- The highest fracture strength was measured for anatomically pressed bridges.
- The fracture strength of veneered frameworks is higher than that of frameworks without veneering. This increase in fracture load may be attributed to the size of the cross-section, which is larger in veneered frameworks than in non-veneered ones.
4.3 **Light transmission**

4.3.1 **Light transmission through framework and luting material**

Edelhoff et al.\(^{17}\) determined the light transmission rate in conjunction with various frameworks and luting materials. For this purpose, a cementation material was applied in a layer thickness of 0.1 mm to ceramic discs, which were 0.9 mm in thickness. Uncoated ceramic discs of a thickness of 1.0 mm were used as reference samples. After the samples had been stored in artificial saliva for 30 days, the light transmission rate was determined by means of a spectrophotometer.

![Graph showing light transmission through framework and luting material](image)

Fig. 11: Light transmission through framework and luting material (Edelhoff et al.\(^{17}\))

- Coating the samples with Variolink transparent increased significantly the light transmission.
- Translucent ceramic materials are more affected by the choice of cementation material than other ceramic materials.
4.3.2 Light transmission through framework material and dentin

Edelhoff et al.\textsuperscript{18} measured the light transmission rate in ceramic discs of a thickness of 0.1 mm. The measurements were carried out after the samples had been stored in artificial saliva for 30 days.

![Graph showing light transmission through framework materials and dentin](image)

Fig. 12: Light transmission through selected framework materials and dentin (Edelhoff et al.\textsuperscript{18})

- The light transmission rate increases with longer wavelengths.
- IPS e.max Press exhibited the highest light transmission rate of all materials tested.

4.4 Marginal fit

Stappert et al.\textsuperscript{19} measured the marginal gap widths of three-unit bridges before and after cementation as well as after thermomechanical loading. IPS Empress 2, IPS e.max Press and metal-ceramic bridges as a control group (Metalor V-Classic/Vita Omega Ceramic) were examined. The bridges were luted with Variolink II. Thermomechanical loading was performed in a chewing simulator (120,000 cycles, 49 N, 5 °/55 °C).

![Bar chart showing marginal gap width](image)

Fig. 13 Marginal gap width of three-unit bridges (Stappert et al.)\textsuperscript{19}

- A significant increase in the marginal gap was observed in all groups after the samples had been cemented.
The marginal gap widths were similar in all materials.

Chewing simulation and thermocycling did not have any significant effect on the accuracy of fit of the samples.

All results are within the range of clinically acceptable values.

4.5 Fracture strength of partial crowns

The fracture strength was determined in natural molars, on which various all-ceramic crowns, which had been prepared according to different preparation designs, were placed (Stappert et al.20,21). Teeth with and without MOD inlays were used as control group. The preparations of partial crowns included 1 to 4 occlusal cusps (TK-1, TK-2, TK-3, TK-4). The crowns were placed using an adhesive technique (Variolink II). All test samples were subjected to chewing simulation and thermocycling (1.2 million cycles, 98 N, 5°/55 °C) and subsequently loaded to breaking point in a universal test machine.

![Fracture Strength Graph](image)

**Fig. 14:** Fracture strength of natural molars in conjunction with partial crowns prepared according to various preparation designs (Stappert et al.)20,21

- All groups achieved a 100% *in vitro* survival rate in the chewing simulator.
- Independent of the size of the ceramic restoration, the fracture strength measured in the posterior region did not significantly differ from that of the natural, unprepared teeth.
5. External clinical studies

5.1 University of Aachen

Head of study: PD Dr. Edelhoff, University Aachen

Title: Clinical performance of IPS e.max Press veneered with IPS Eris for E2

Objective: To examine the clinical performance of IPS e.max Press restorations.

Experimental: A total of 139 restorations (121 crowns, 18 bridges) were incorporated in 52 patients. The majority of the restorations were cemented in place using an adhesive technique (Variolink II) and a few restorations were placed using a glass ionomer cement (Vivaglass Cem).

Results: No failures were reported after a mean observation period of 13.84 months (1 to 23 months). Neither framework fractures nor chipping of veneering material occurred.

5.2 University of Kiel

5.2.1 Clinical performance of inlay and crown-retained bridges

Head of study: Prof. Dr. Kern, University Schleswig-Holstein, Kiel

Title: Prospective 5-year study on all-ceramic crown and inlay-retained bridges

Objective: To evaluate and compare the clinical performance of inlay- and crown-retained bridges made of IPS e.max Press.

Experimental: A total of 81 three-unit bridges (36 crown-retained bridges; 45 inlay-retained bridges) were incorporated in 68 patients. Twenty crown-retained bridges were placed using a conventional cementation technique (Ketac Cem). The remaining 16 crown-retained bridges and all inlay-retained bridges were cemented in place adhesively (Variolink II).

As many as 92% of all restorations were placed in the posterior region.

Results: The mean observation period for the inlay-retained bridges was 37 months and for the crown-retained bridges 48 months. A survival rate of 100% was reported for the crown-retained bridges. Six failures occurred in the group of inlay-retained bridges due to debonding (n=3) and a combination of debonding and fracturing (n=3).

The four-year Kaplan-Meier survival rate was 89% for the inlay-retained bridges and 100% for the crown-retained bridges.
5.2.2 Clinical evaluation of marginal gap

Head of study: Prof. Dr. Kern, University, Schleswig-Holstein, Kiel, Germany

Title: Clinical examination of the accuracy of fit of a new experimental all-ceramic system before and after cementation

Objective: To examine the accuracy of fit of inlay and crown-retained bridge anchors.

Experimental: The study included 19 patients. One anchor was examined in each bridge (11 crowns, 8 inlays). Impressions were taken before and after adhesive cementation (Variolink II). The marginal discrepancies were measured in a scanning electron microscope (SEM). The outer profile was divided into sections of 200 µm. The highest value recorded for the individual sections was used in the final evaluation.

Results:

![Graph showing marginal discrepancy before and after cementation](image)

Fig. 15: Marginal gaps of inlays and crowns before and after cementation (Wolfart et al)²²

The marginal gaps in crown-retained bridges were significantly higher after cementation than they were before. Inlay-retained bridges did not show any significant changes in the marginal discrepancy after cementation. The marginal gaps of the crown and inlay-retained bridges fall within the biologically acceptable range.

5.3 University of Florida (Gainesville), University of Texas Health Centre (San Antonio)

5.3.1 Clinical performance of posterior bridges

Head of study: Prof. Dr. Anusavice, University of Florida, Gainesville
Dr. Esquivel-Upshaw, University of Texas Health Center, San Antonio

Title: In vivo behavior of an experimental framework material for posterior bridges
Objective:

- To examine the clinical performance of IPS e.max Press in posterior bridges whose connectors were designed according to the dimensions stipulated in the manufacturer’s direction.
- To examine the effect of the maximum bite force on the survival rate of bridges

Experimental:

Thirty bridges (staining technique, glazed) were incorporated in 21 patients. A conventional (Protec CEM) or adhesive (Variolink II) cementation technique was used. The cross-sections of the connectors were measured in each bridge. The bite force was determined in each patient. These data would later be used in the interpretation of the clinical results.

Results:

5-year results:

If all cases are included, even those in which the manufacturer’s directions regarding the dimensions of the connectors were not followed, the 5-year failure rate was 10% due to fracture (3/30). In addition, a single incidence of secondary caries (3.3%) was observed.

A bite force of 1031N was recorded in conjunction with one of the fractured bridges and in two cases, the minimum dimensions stipulated for the connectors were not observed.

If the above aberrations, i.e. unusually high bite force and faulty connector design (manufacturer’s directions) are excluded from the evaluation, the 5-year failure rate is 3.3%, i.e. a single bridge failed due to fracture.

5.3.2 Clinical performance of posterior crowns

Head of study: Dr. Esquivel-Upshaw, University of Texas Health Center, San Antonio

Title: Evaluation of abrasive behavior of natural enamel and ceramic restorations (crowns) in clinical applications

Objective: To examine the abrasive behavior of the enamel and IPS e.max Press crowns in clinical applications.

Experimental: A total of 36 metal-ceramic and all-ceramic crowns were placed in 29 patients. The crowns were classified into three groups:

- Metal ceramic crowns (IPS d.SIGN; n=12)
- IPS Empress 2 crowns veneered with IPS Eris for E2 (n=12)
- IPS e.max Press crowns veneered with IPS Eris for E2 (n=12)

The all-ceramic crowns were cemented in place using Variolink II. The metal-ceramic crowns were placed with self adhesive conventional cement.

Pictures and impressions were taken of the restorations at baseline to evaluate the degree of abrasion over time.

Results: According to the first interim report, an IPS Empress 2 crown fractured in the first month after placement. Additionally, an IPS e.max Press crown debonded after 4 months.
5.4 **University of Freiburg**

Head of study: Dr. Stappert, University, Freiburg i. Br.

Title: Clinical evaluation of partial lower posterior crowns fabricated using an all-ceramic lithium disilicate or using the Cerec 3 technique

Objective: To evaluate the clinical performance of all-ceramic partial crowns for the posterior region (IPS e.max Press and ProCAD).

Experimental: Crowns/inlays made of IPS e.max Press (n=40) and ProCAD (n=40) were placed. A maximum of 20 non-vital abutment teeth were included in each group. The aim was to stabilize these teeth with an all-ceramic post system.

Results: Both groups have not produced any failures one year into the study.

5.5 **King's College, London**

Head of study: Prof. Dr. Watson, King's College, London

Title: Clinical examination of two commercially available systems against an experimental ceramic system

Objective: To evaluate the clinical performance of posterior crowns. Compare the performance of three ceramic materials, i.e. two all-ceramic and one metal-ceramic system.

Experimental: A total of 90 posterior crowns were placed in 48 patients:
- 30 IPS e.max Press crowns, fully anatomical
- 30 Procera-AllCeram crowns, layered
- 30 metal ceramic crowns (PFM)

The crowns were evaluated according to USPHS criteria in the follow-up examinations.

Results: Evaluation after 54 months:
- No or only minor changes were observed in the IPS e.max Press restorations according to USPHS criteria (discoloration, plaque accumulation, chipping, etc).
- Two Procera-AllCeram crowns fractured.
- Two IPS e.max Press crowns were replaced due to severe crack propagation.

5.6 **University of Innsbruck**

Head of study: Prof. Dumfahrt, University, Innsbruck, Austria

Title: Clinical performance of a new press ceramic system – inlays, onlays, veneers

Objective: To examine the clinical performance of IPS e.max Press when used in inlays, onlays and veneers.
Experimental: A total of 177 restorations (fully anatomical or veneered) were incorporated in 26 patients.

Adhesive cementation (Variolink II)
Number of restorations: 41 inlays, 66 onlays, 24 crowns and 46 veneers.

Results: A survival rate of 100% was reported (after 1 year).
The accuracy of fit was rated excellent.
The handling characteristics were rated excellent by both technicians and clinicians.

5.7 Conclusions

A multitude of data has been gathered in clinical studies on IPS e.max Press and these data have been available for quite some time now. For this reason, it has been possible to define the field of application of this lithium disilicate press ceramic very precisely. Several years of clinical experience have also been gathered with the related IPS Empress 2 ceramic material.

IPS e.max Press can be used effectively in clinical applications if the requirements stipulated in the Instructions for Use are followed.
6. Biocompatibility

6.1 Introduction

All-ceramic materials are known for their high levels of biocompatibility\textsuperscript{27,28}.

6.2 Chemical durability

Dental materials are exposed to a wide spectrum of pH-values and temperatures in the oral environment. Consequently, high chemical durability is an essential requirement of any dental material. According to Anusavice\textsuperscript{29}, ceramic materials are among the most durable dental materials. Chemical durability according to ISO 6872:

<table>
<thead>
<tr>
<th></th>
<th>Chemical solubility [µg/cm(^2)]</th>
<th>Limit value [µg/cm(^2)]</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPS e.max Press</td>
<td>40 ± 10</td>
<td>&lt; 100</td>
</tr>
</tbody>
</table>

(Ivoclar Vivadent AG, Schaan, 2005)

- The chemical solubility of IPS e.max Press is far lower than the maximum level permitted by the relevant standard.

6.3 In vitro cytotoxicity

The \textit{in vitro} toxicity was tested by NIOM, the Scandinavian Institute of Dental Materials, Haslum, Norway by means of a direct cell contact test.

The test was conducted according to ISO 10993-5: \textit{Biological evaluation of medical devices Part 5: Tests for \textit{in vitro} cytotoxicity}.

No cytotoxic potential has been observed in IPS e.max Press under the given test conditions\textsuperscript{30}.

6.4 Sensitization, irritation

Cavazos\textsuperscript{31}, Henry et al.\textsuperscript{32} and Allison et al.\textsuperscript{33} demonstrated that dental ceramics – unlike other dental materials – do not induce a negative response when they come into contact with the oral mucous membrane. Mitchell\textsuperscript{34} as well as Podshadley and Harrison\textsuperscript{35} showed that glazed ceramics, which were used in implant-based trials, caused only very mild inflammatory reactions and had a far less irritating effect than other accepted dental materials, such as gold and composite resin.

As it can virtually be ruled out that ceramic materials cause direct irritation in the cells of the mucous membrane, possible irritations may generally be attributed to mechanical irritation. Such reactions can normally be prevented by following the Instructions for Use of IPS e.max Press.

Ceramic has no – or, compared to other dental materials – very little potential to cause irritation or sensitizing reactions.
6.5 Radioactivity

The radioactivity of IPS e.max Press was determined at the Research Centre Jülich. The value measured for IPS e.max Press was <0.03 Bq/g\textsuperscript{16} and is therefore clearly below the maximum value of 1.0 Bq/g permitted by ISO 6872.

6.6 Conclusions

On the basis of the current data and present level of knowledge, it can be stated that IPS e.max Press does not exhibit any toxic potential. If the material is applied in accordance with the manufacturer’s directions, it does not pose any risk to the health of patients, dental technicians or dentists.
7. References

2. Anusavice (2001), interner Bericht an Ivoclar Vivadent AG
8. Lohbauer (2003), interner Bericht an Ivoclar Vivadent AG
9. Marx, Fischer (2001), interner Bericht an Ivoclar Vivadent AG
15. Ludwig (2001), interner Bericht an Ivoclar Vivadent AG
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