# Not of the data

Vol. 03 / 2001-2017 English





# IPS e.max\* | SCIENTIFIC REPORT | Vol. 03 / 2001–2017 TABLE OF CONTENTS

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Dr Thomas Hirt



Dr Arnd Peschke

IPS e.max comprises highly esthetic lithium disilicate and high-strength zirconium oxide products for use with both the Press and CAD/CAM techniques. Through linking material and processing technologies, the IPS e.max system has undeniably changed the dental market and enabled the breakthrough of full contour, metal-free restorations. A combination of outstanding esthetics, excellent mechanical properties and impressive processing-tolerance has led to exceptional clinical results, and in turn highly satisfied customers.

Achieving this success, required excellence in several areas, along with a clear vision of how the market could evolve with this product system. The various technical hurdles that occurred were overcome with intensive developmental work over many years. Broad-based patenting and technically sophisticated production processes ensured lvoclar Vivadent's unique market position. Together with the specially developed Programat oven range, luting materials and corresponding technical equipment, a comprehensive, robust system was created, covering a wide range of applications. IPS e.max set new standards regarding efficient, esthetic, minimally invasive all-ceramic restorations.

The IPS e.max system underwent systematic expansion, with new clinical indications added according to customer demand. Along with an ever-expanding choice of colours and translucencies, product improvements include the IPS e.max Press Multi (the world's first polychromatic press ingot), the IPS e.max Abutment Solutions - for fabricating individual abutments and abutment crowns and the IPS e.max ZirCAD MT Multi disc that combines high strength with a shade and translucency gradient.

Long-standing support from dental technicians, dentists, opinion leaders and university professors from all over the world was essential for the success of these product developments and market-penetration. With this in mind, we would like to thank everyone who has had an enthusiastic hand in improving and distributing IPS e.max.

The IPS e.max system has had a lasting impact on the dental market and its components will serve as reference materials in dentistry for long to come. Hardly any other dental material is as clinically well-documented as IPS e.max. This Scientific Report presents the most important results from these studies.

Best regards

Dr Thomas Hirt Chief Technology Officer

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Dr Arnd Peschke Director R&D Clinic

# INTRODUCTION

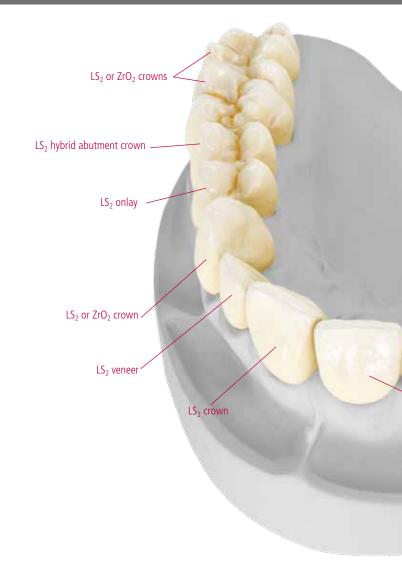
# IPS e.max<sup>®</sup> lithium disilicate

- High material-stability and reliability confirmed by clinical studies
- Outstanding flexural strength of 500 MPa\*
- Exceptional esthetics notably for the anterior region
- Comprehensive range of translucencies and shade
- Minimally invasive restorations such as thin veneers (≥ 0.3 mm) or adhesively cemented crowns (≥ 1 mm)

\*Mean biaxial flexural strength measured over 10 years, <u>R&D lvocl</u>ar Vivadent, Schaan, Liechtenstein

The IPS e.max<sup>®</sup> system is an innovative all-ceramic system that covers all indications ranging from thin veneers to multi-unit bridges. It comprises lithium disilicate glass-ceramic materials for both Press and CAD/CAM techniques (IPS e.max Press and IPS e.max CAD), an innovative zirconium oxide ceramic in disc and block form (IPS e.max ZirCAD), a coordinated veneering ceramic (IPS e.max Ceram) and a press-on fluorapatite ceramic (IPS e.max ZirPress).

- **IPS e.max Press** is a highly esthetic, reliable and versatile lithium disilicate glass-ceramic for the Press technique. It is used to fabricate single restorations, hybrid-abutments and 3-unit bridges (premolar region).
- IPS e.max CAD: is a highly esthetic, reliable and versatile 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 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 ZirPress** is a fluorapatite glassceramic for the rapid and efficient PRESS-ON technique onto zirconium oxide frameworks (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.

Introduction

# IPS e.max<sup>®</sup> zirconium oxide

- Robust and long-lasting
- Strength of 850 to 1200 MPa\*\* dependent on translucency level
- Multi-unit bridges and crowns
- Polychromatic Multidiscs for impressive esthetic results
- Low wall thickness for minimally invasive restorations

\*\*Typical mean value of biaxial flexural strength, R&D Ivoclar Vivadent, Schaan, Liechtenstein



ZrO<sub>2</sub> bridge

LS<sub>2</sub> or ZrO<sub>2</sub> bridge

From the development of the IPS e.max materials to the present, their use has been investigated extensively by the scientific community and many renowned experts have contributed to the expanding body of literature evaluating their clinical performance. This plus the ever-growing demand for highly reliable, esthetic restorative materials, are testament to the success of the IPS e.max system.

This 3<sup>rd</sup> version of the Scientific Report for IPS e.max, summarizes the most important *in vivo* and *in vitro* studies from 2001 to 2017.





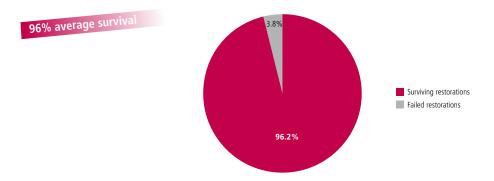
# **IPS e.max® Materials – Clinical Performance**

IPS e.max<sup>®</sup> Materials – Clinical Performance

# **Summary survival statistics**

#### IPS e.max<sup>®</sup> Press (LS<sub>2</sub>)

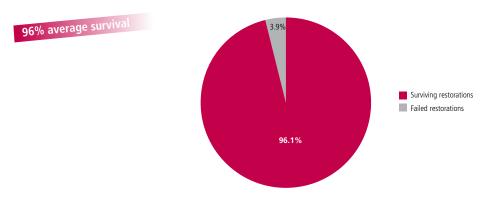
There are currently clinical studies, with up to 12 years of evaluated data for IPS e.max Press (Schmitz et al. 2017), however this study evaluates IPS Empress 2 and IPS e.max Press restorations together. Therefore, the following shows the basic average survival rate as calculated from that reported by the following six external clinical studies involving IPS e.max Press: Malament 2017, Kern et al. 2012, Gehrt et al 2012b, Guess et al. 2014, The Dental Advisor 2010 & 2012, Böning et al 2006.



The studies covered study time period periods from 3 years to 10 years and involved both crowns and/or bridges, which were luted either adhesively, self-adhesively or conventionally depending on the study. Further details of the studies can be found in the IPS e.max Press *in vivo* studies section.

#### IPS e.max<sup>®</sup> CAD (LS<sub>2</sub>)

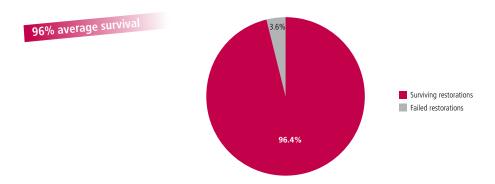
There are currently clinical studies, with up to 10 years of evaluated data for IPS e.max CAD. The following shows the basic average survival rate as calculated from that reported by the following six external clinical studies: Fasbinder et al. 2017a, Rauch et al. 2017, Spies et al. 2017, Beuer et al 2011a, Reich et al. 2014, Nathanson et al. 2008.



The studies covered study time period periods from 3 years to 10 years and involved both crowns and/or bridges, which were luted either adhesively or self-adhesively depending on the study. Further details of the studies can be found in the IPS e.max CAD *in vivo* studies section.

#### IPS e.max<sup>®</sup> ZirCAD (ZrO<sub>2</sub>)

The following diagram summarizes clinical studies, with up to 5 years of evaluated data for IPS e.max ZirCAD. The basic average survival rate is calculated from that reported by the following six external clinical studies: Beuer et al. 2011b, Gehrt et al. 2012, Stanford 2009, Sorensen et al. 2009a, Fasbinder et al. 2009, Christensen et al. 2008.



The studies covered study time period periods from 2 years to 5 years and involved standard crowns and/ or bridges, depending on the study. Further details of the studies can be found in the IPS e.max ZirCAD *in vivo* studies section.

# **Comparison with the literature:**

Metal ceramic restorations are still considered the industry gold standard. IPS e.max all-ceramic restorations provide an excellent highly esthetic alternative to metal ceramics for various indications and provide similarly positive survival rates. (Pjetursson et al. 2007, Schley et al. 2010, Kern et al.

2012, Sailer et al. 2015).







in vivo studies in vitro studies IPS e.max<sup>®</sup> Lithium Disilicate (LS<sub>2</sub>) – IPS e.max<sup>®</sup> Press

# in vivo Studies

## Reflections on modern dental ceramics

Study location:	Private practice / Tufts University School of Dental Medicine, Boston, USA	
Study time period:	32 years / All glass ceramics: 1983–2015	
	10 years / IPS e.max CAD/Press: 2005–2015	
Study author(s):	K. A. Malament	

#### Method:

In a review of modern dental ceramics, Malament details the long-term survival of over 6000 all-ceramic restorations placed at a Boston practice since 1983. Four different types of ceramic are described: Dicor/Dentsply Sirona (n = 1504), In-Ceram/Vita (n = 330), IPS Empress (n = 2133) and IPS e.max Press or CAD (n = 2364). Records of Dicor were made from 1983, of In-Ceram from 1990, of IPS Empress since 1992 and IPS e.max from 2005.

#### **Results:**



Percentage of surviving glass ceramic restorations by product, after varying time periods

#### Summary:

Though the period of observation was the shortest at just over 10 years (128 months), this large-scale overview showed the lithium disilicate restorations to have the lowest failure rate.

#### **Conclusion:**

Of all the glass ceramic materials placed, IPS e.max CAD/Press (lithium disilicate), with a survival rate of 99.75%, was the most versatile and successful, having according to the author, met or exceeded almost all of the clinical requirements considered "ideal" for a dental ceramic used in the clinical practice.

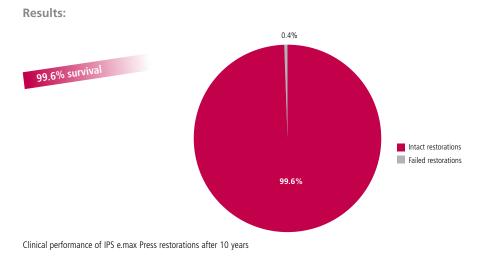
Reference: Malament (2015)

## Survival of lithium disilicate glass ceramic dental restorations over ten years

Study location:Private practice / Tufts University School of Dental Medicine, Boston, USAStudy time period:10 years / 2005–2015Study author(s):K. Malament

#### Method:

Starting in 2005, 556 patients aged 17 to 97 were recruited to take part in a study of the long-term survival of IPS e.max Press – lithium disilicate restorations. Restorations included single crowns, 3-unit fixed partial dentures, cantilevered anterior restorations and foundation restorations. All were placed by the same experienced prosthodontist. Both monolithic and bi-layered restorations were included in the study. All restorations were luted with Variolink II. A restorative failure constituted any fracture of the restoration that necessitated replacement. Chips of less than 1 mm that could be re-shaped and polished were not considered failures.



#### Summary:

After 10 years, 7 failures were recorded from the 1960 restorations. The survival rate was calculated as 99.6% at 10.4 years. There was no significant difference between the survival of mandibular and maxillary restorations. There were 1410 monolithic restorations and 550 bi-layered. The 7 failures all occurred in the monolithic group. The total time at risk computed for the monolithic units was 3380 years providing an estimated risk of 0.2% per year. With no failures, over a total time at risk of 1733 years for the bi-layered units, the estimated risk was 0% per year.

#### **Conclusion:**

IPS e.max Press lithium disilicate restorations showed excellent survival over the 10.4 year study period. The 7 failures occurred during a cumulative monitoring period of 5113 years, providing an estimated risk of failure of 0.14% per year.

Reference: Malament (2017)

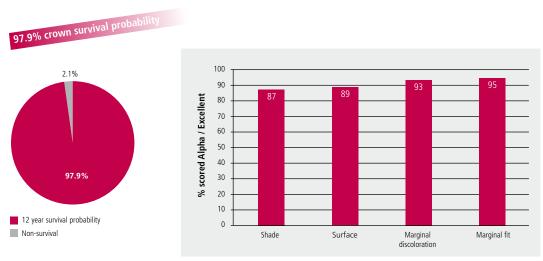
Monolithic lithium disilicate complete single crowns with feather-edge\* preparation design in the posterior region: A multicentric retrospective study up to 12 years

Study location:	Private practices in Milan, Riccione, Modena, Pordenone / Italy
Study time period:	Up to 12 years / 2004-2015
Study author(s):	J. H. Schmitz, D Cortellini, S. Granata, M Valenti

#### Method:

The clinical success of monolithic, posterior lithium disilicate single crowns fabricated with feather-edge margins, was evaluated in a non-randomized retrospective study. 627 pressed IPS Empress 2 or IPS e.max Press restorations (110 first premolars, 151 second premolars, 240 first molars, 121 second molars, 5 third molars) were placed in 335 patients at 4 different dental practices, between January 2004 and July 2015. The mean follow-up time was 4 years, ranging from 6 months to 12 years. Modified California Dental Association criteria were used to evaluate restorations at the 3 to 6 month recalls. Survival time was defined as the period starting at baseline and ending when the clinician estimated that an irreparable failure of the crown had occurred.

#### **Results:**



Survival probability and percentage of remaining crowns (n=614) evaluated as excellent for various criteria

#### Summary:

There were 13 failures (2 in vital teeth and 11 in endodontically treated teeth). Nine of these crowns were replaced over the follow-up period due to bulk fracture of the material and 4 teeth were extracted due to tooth fracture or endodontic failure. The overall Kaplan Meier survival rate was 97.9% up to 12 years. No other technical or biological failure was observed.

#### Conclusion:

In this retrospective evaluation of restorations placed in a standard clinical setting, monolithic lithium disilicate crowns with feather-edge margins yielded clinical outcomes similar to those reported with other margin designs and materials. Following the same clinical protocol, crowns on second molars showed lower survival rates when compared to restorations on other posterior teeth.

Reference: Schmitz et al. (2017), Valenti et al. (2015)

\*Feather edged preparation is not recommended in the Instructions for Use for IPS e.max Press

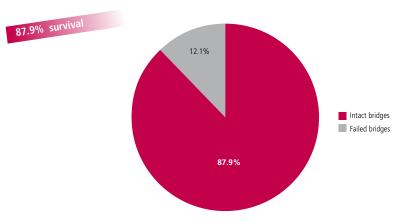
# 10-year results for 3-unit bridges made of monolithic lithium disilicate

Study location:University Clinic Schleswig-Holstein, Kiel, GermanyStudy time period:10 years / 2001–2011Study author(s):M. Kern, S. Wolfart

#### Method:

36 three-unit IPS e.max Press bridges were seated in 28 patients. Just over half of the crown-retained bridges were placed using a conventional cementation technique. All other bridges were cemented adhesively with Variolink II. Approximately 90% of all the restorations were placed in the posterior region.

#### **Results:**



Clinical performance of IPS e.max Press lithium disilicate bridges after 10 years

#### Summary:

The 4-year survival rate according to Kaplan Meier was 100%. No fractures of the bridges occurred after a mean observation period of 48 months.

Two bridges fractured, and chipping of the veneering material occurred in two others (6%) after 8 years. The eight-year survival rate according to Kaplan Meier was 93%. With regard to periodontal parameters, the comparison of the pocket depth, bleeding upon probing and tooth mobility showed no significant differences between the test and comparison teeth (P >0.05 Wilcoxon Signed-Rank Test).

After 10 years (121 months), a total of 3 fractures (in the molar region) occurred, and another restoration was lost due to the extraction of a tooth for biological reasons. Chipping occurred in 6.1% of the restorations. The 10-year survival rate according to Kaplan Meier was 87.9%.

#### **Conclusion:**

Three-unit bridges made of IPS e.max Press (lithium disilicate) glass-ceramic proved their clinical efficacy in the posterior region (premolars) with both adhesive and conventional cementation. The survival rate was comparable to that of metal-ceramics and better than that of other ceramic systems.

Reference: Wolfart et al. (2005), Wolfart et al. (2009), Kern et al. (2012)

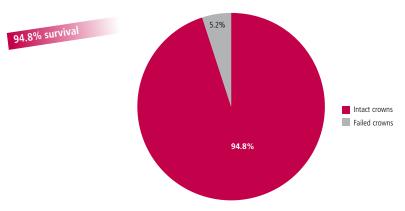
# Clinical examination of veneered IPS e.max Press crowns

Study location:University Clinic Aachen, Aachen, GermanyStudy time period:9 years / 2002–2012Study author(s):D. Edelhoff

#### Method:

A total of 104 IPS e.max Press restorations (82 crowns in the anterior region and 22 crowns in the posterior region) were placed in 41 patients. The majority of the restorations (69.2%) were cemented using an adhesive technique (Variolink II) and roughly one third of the restorations (30.8%) were placed using a glass ionomer cement (Vivaglass CEM). All teeth received a 1mm-wide chamfer or rounded shoulder preparation win an occlusal/incisal reduction of 1.5-2.0mm. Frameworks were laminated with a prototype of a veneering material and an experimental glaze. Recalls were conducted after 6 months and then annually. The need to replace a restoration was considered a failure.

#### **Results:**



Clinical performance of IPS e.max Press crowns after 8 years in terms of cumulative Kaplan-Meier survival

#### Summary:

Four patients with 10 crowns were defined as dropouts. For the remaining 94 crowns, the mean observation time was 6.6 years, ranging from approximately 3 to 9 years. The Kaplan Meier survival rate was 97.4% at 5 years and 94.8% after 8 years. Four severe complications were rated as failures: Two fractures occurred, one restoration failed due to secondary caries and another due to endodontic complications. Repairable chipping of the veneering material occurred in 3 crowns (3.3%) and 2 crowns required endodontic treatment with the crowns remaining *in situ*.

#### **Conclusion:**

Crowns made of veneered IPS e.max Press (lithium disilicate) glass-ceramic proved their clinical efficacy in both the anterior and posterior regions with both adhesive and conventional cementation.

Reference: Gehrt et al. (2010), Gehrt et al. (2013)

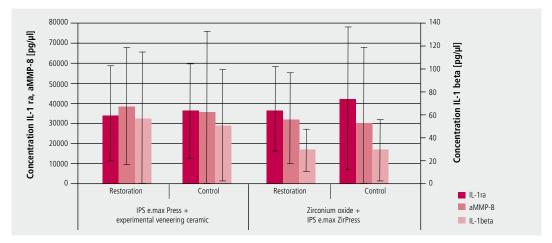
## Biocompatibility of all-ceramic restorations based on inflammatory parameters.

Study location:	RWTH Aachen University, Aachen, Germany	
Study time period:	8 years / IPS e.max Press: 2013	
	3 years / ZrO <sub>2</sub> + IPS e.max ZirPress: 2013	
Study author(s):	K. Seibicke, H. Schiffer, B. Plümäkers, L. Rink, S. Wolfart	

#### Method:

Two groups of patients were compared. They were treated with either at least 1 restoration made of lithium disilicate (IPS e.max Press veneered with an experimental ceramic material; n=26, Group A) or 1 zirconium oxide restoration veneered with IPS e.max ZirPress (n=11, Group B). After a mean wear period of 103 months (Group A) or 36 months (Group B), samples of the sulcus liquid of treated and non-treated control teeth were taken. The concentrations of the inflammatory parameters IL1-B, IL-1ra and aMMP-8 were measured by means of ELISA. Furthermore, the pocket depth (PD) and bleeding index (BOP) were determined. Professional tooth cleaning was performed 7 days before that.

#### **Results:**



Concentrations of inflammatory parameters (IL-1ra, aMMP-8, IL-1beta) in the sulcus liquid

#### Summary:

There were no significant differences in the concentrations of the inflammatory parameters, neither between the lithium disilicate group and the zirconium oxide group, nor between restored teeth and the control teeth. The pocket depth and bleeding index also showed no differences.

#### **Conclusion:**

All-ceramic restorations do not induce inflammation. The biocompatibility of lithium dislicate ceramic does not differ from that of zirconium oxide.

Reference: Seibicke et al. (2012)

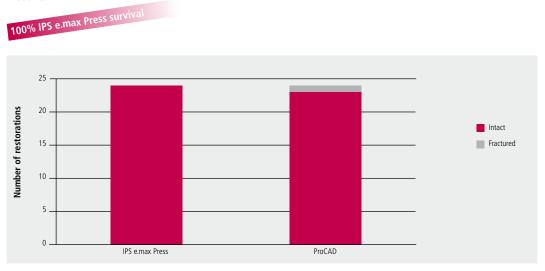
# Prospective clinical split-mouth study of pressed and CAD/CAM all-ceramic partial coverage restorations: 7-year results

Study location:University Clinic Freiburg, Freiburg, GermanyStudy time period:7 years / 2005–2012Study author(s):P. C. Guess, C. F. Selz, Y-N. Steinhart, S. Stampf, J. R. Strub

#### Method:

To investigate the long term performance of pressed and CAD/CAM all ceramic (adhesively luted) partial coverage restorations (PCRs), 40 IPS e.max Press (lithium disilicate) and 40 ProCAD (leucite glass ceramic) restorations were placed using a split mouth design in 25 patients. Patients required two to four PCRs in either first or second vital molars. Restorations were examined for postoperative hypersensitivity, fractures and evaluated according to modified USPHS criteria at baseline and annually for 7 years.

#### **Results:**



Clinical performance of IPS e.max Press and ProCAD crowns after 7 years

#### Summary:

Eleven of the 25 patients were lost during the 7-year follow-up for reasons unrelated to the dental treatment. 24 IPS e.max Press and 24 ProCAD restorations in 14 patients could be evaluated after 7 years. The 7-year Kaplan Meier survival rate was reported as 100% for IPS e.max Press and 97% for ProCAD restorations.

#### Conclusion:

Although a significant reduction in Alpha ratings for all USPHS criteria in both material types was seen over the period, all-ceramic partial crowns, whether pressed or CAD/CAM-fabricated, represented a reliable treatment option for restoring larger defects in the posterior region.

Reference: Guess et al. (2013)

# Retrospective clinical study of single-retainer, cantilever IPS e.max Press bridges: Mean follow up of 6 years

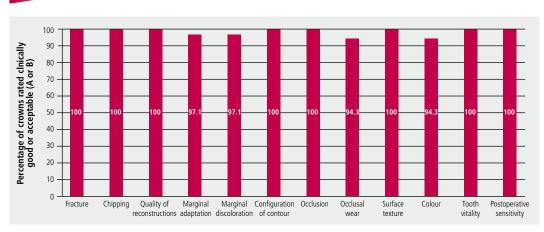
Study location:	Private practice / University of Zurich, Zurich, Switzerland
Study time period:	6 years (mean) and up to 13 years / 2000–2013
Study author(s):	I. Sailer, T. Bonani, U. Brodbeck, C. H. F. Hämmerle

#### Method:

To establish the survival rates and performance of single-retainer, cantilever glass ceramic, resin bonded bridges/fixed dental prostheses (FDPs), 49 FDPs were placed in 40 patients and evaluated retrospectively. 46 of the FDPs (94%) were made of IPS e.max Press (lithium disilicate). Just 3 FDPs were fabricated using IPS Empress material (leucite reinforced glass ceramic). The restorations were evaluated according to modified USPHS criteria. An outcome was rated "A" when no problems were found and "B" when small but clinically acceptable defects were found. Recalls took place twice a year for patients with a high caries risk and once a year for those with a low risk.

#### **Results:**

100% survival



Percentage of IPS e.max Press/IPS Empress FDPs (n=35) rated as A or B according to USPHS criteria for various characteristics

#### Summary:

28 patients with 35 FDPs could be evaluated at the final recall. The mean follow-up period was 6 years. The 6-year survival rate was 100%. No catastrophic failures occurred and none of the restorations had to be removed due to biological or technical complications. No debonding was recorded. Chipping was recorded for 5.7% of the bridges (B rating) which could be repaired.

#### **Conclusion:**

The 6-year survival rate for single-retainer, cantilever FDPs made of IPS e.max Press (94%) and IPS Empress (6%) was 100%.

Reference: Sailer et al. (2013)

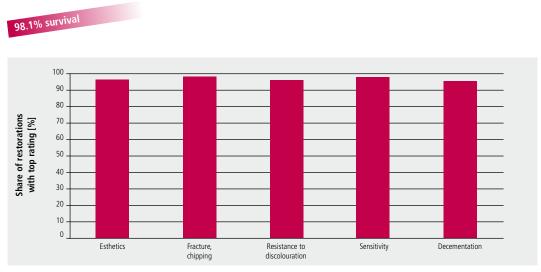
# IPS e.max Press: Clinical efficiency after 5 years

Study location:USAStudy time period:5 years / 2006 - 2012Study author(s):The Dental Advisor

#### Method:

Four dentists placed 671 IPS e.max Press restorations in 282 patients. 381 restorations were examined at recall (maximum period of wear was 5 years). Of these restorations, 46% were molar crowns, 38% premolar crowns, 8% anterior crowns, 5% inlays/onlays and 3% bridges. A self-adhesive or adhesive cement was used for cementation.

#### **Results:**



Evaluation of clinical parameters after 5 years - for IPS e.max Press restorations

#### Summary:

Out of 381 restorations, 7 were replaced due to fractures, corresponding to a fracture rate of less than 2%. Chipping was observed in only 1.5% of the restorations, which could be remedied by polishing. IPS e.max Press was rated excellent also with regard to marginal discoloration and esthetics.

#### Conclusion:

IPS e.max Press is a highly esthetic material exhibiting high strength and excellent clinical performance over 5 years.

Reference: The Dental Advisor (2010) and (2012)

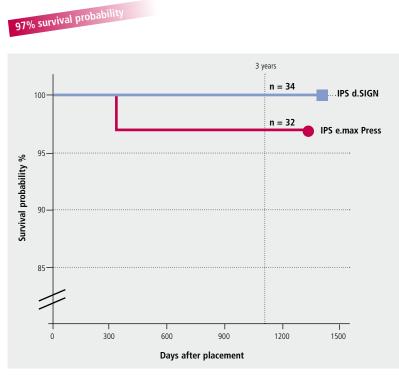
## Performance of a new press glass-ceramic

Study location:Technical University Dresden, Dresden, GermanyStudy time period:3 years / 2003 – 2006Study author(s):K. Böning

#### Method:

39 IPS e.max Press crowns (test group) and 40 metal-ceramic crowns made of the d.SIGN 96 highgold alloy and the IPS d.SIGN fusable ceramic (control group) were placed in a total of 63 patients. All restorations were conventionally cemented with glass-ionomer cement.

#### **Results:**



Survival probability of IPS e.max Press and IPS d.SIGN crowns after 3 years

#### Summary:

After an observation period of 3 years, a survival probability of 97% for the test group and 100% for the control group was determined. The log rank test did not show any significant difference.

#### Conclusion:

All-ceramic crowns made of IPS e.max Press performed almost as well as crowns made of metal-ceramic.

Reference: Böning et al. (2006)

# Clinical comparison of three different restorative materials for crowns

Study location:King's College, London, Great BritainStudy time period:2 years / 2001 – 2008Study author(s):T.F. Watson, M.K. Etman

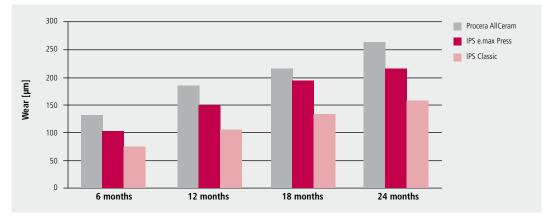
#### Method:

The clinical behaviour of posterior crowns with regard to abrasion was examined. Three different types of ceramic/ metal-ceramic materials were compared:

- 30 IPS e.max Press crowns, fully anatomical
- 30 Procera-AllCeram/Nobel Biocare crowns, layered
- 30 IPS Classic metal-ceramic crowns

The 90 posterior crowns were placed in 48 patients. Impressions were taken at regular intervals over a 2 year period, whereby wear was determined.

**Results:** 



Wear of different ceramic crowns at 6 month intervals

#### Summary:

Measurements after 2 years showed that IPS e.max Press crowns demonstrated less wear than Procera AllCeram crowns. The abrasion of the opposing tooth was also lower. After 7 years, the abrasion of enamel opposing IPS e.max Press crowns was still lower than that caused by Procera AllCeram crowns (only published as an abstract).

#### **Conclusion:**

Procera AllCeram and IPS e.max Press performed similarly well under clinical conditions. IPS e.max Press however, performed better with regard to abrasion. Even if wear can be measured it is usually not noticed by patients or dentists. The phenomenon should therefore not be overrated under normal circumstances (i.e. in patients without bruxism or increased masticatory pressure). If materials are processed correctly, the wear of glass-ceramic crowns is so low that the esthetic and biological advantages over metal /metal-ceramic restorations prevail.

Reference: Etman et al. (2001), Etman and Woolford (2008), Etman and Woolford (2010)

### in vitro Studies

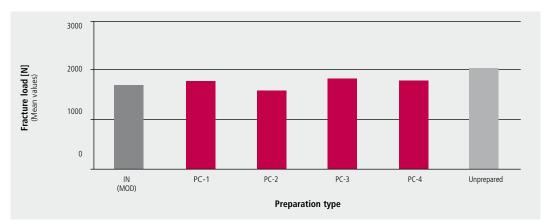
Survival rate and fracture load of all-ceramic partial crowns with different preparation designs after thermocycling and masticatory simulation.

Study location:University Clinic, Freiburg im Breisgau, GermanyStudy time period:2002, 2006Study author(s):C. F. Stappert, W. Att, T. Gerds, J.R. Strub

#### Method:

The fracture load of natural molars with all-ceramic monolithic IPS e.max Press partial crowns, with different preparation designs was determined. Teeth with and without MOD inlay preparation were used as control groups. The partial crown preparations included 1 – 4 occlusal cusps (PC-1, PC-2, PC-3 and PC-4). The partial crowns were adhesively cemented (Variolink II). All test specimens were subjected to masticatory simulation and thermocycling (1.2 million cycles, 98 N, 5°/55°C) and subsequently loaded to breaking point in a universal testing machine.

#### **Results:**



Fracture load of natural molars with partial crowns - in various preparation designs

#### Summary:

All specimens achieved a 100% *in vitro* survival rate in the masticatory simulator. Irrespective of the size of the ceramic IPS e.max Press restoration, the fracture load values achieved in the posterior region did not differ significantly from that of natural, unprepared teeth.

#### Conclusion:

All specimens achieved a 100% in vitro survival rate in the masticatory simulator.

Reference: Stappert et al. (2002), Stappert et al. (2006)

All-ceramic partial crowns on premolars. Cavity-preparation design, reliability and fracture load upon fatigue.

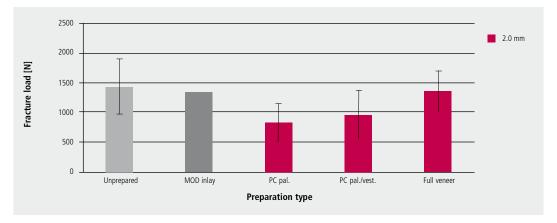
Study location:University Clinic, Freiburg im Breisgau, GermanyStudy time period:2005Study author(s):C. Stappert, P.C. Guess, T.A. Gerds, J.R. Strub

#### Method:

In natural upper premolars, the effect of various preparation designs and layer thicknesses on the fatigue behaviour and fracture load was determined in all-ceramic partial crowns and veneers made of IPS e.max Press. Teeth with and without MOD inlay preparation were used as control groups. The partial crowns were adhesively cemented (Variolink II). All test specimens were subjected to masticatory simulation and thermocycling (1.2 million cycles, 49 N, 5°/55°C) and subsequently loaded to breaking point in a universal testing machine.

The following preparation designs were tested (n=16 per design version):

- Unprepared teeth
- MOD inlays
- Partial crowns with palatal cusp reduced by 2.0 mm
- Partial crowns with the palatal (pal.) and vestibular (vest.) cusp reduced by 2.0 mm
- Full veneers: Reduction of the entire masticatory surface and veneer preparation of the facial segment (occlusal layer thickness 2.0 mm / facial segment 0.8 mm)



#### **Results:**

Mean fracture load values (after masticatory simulation) of upper premolars with variously prepared partial crowns and full veneers

#### Summary:

The survival rate after more than 1.2 million cycles in the mastication simulator was 100% for all the partial premolar crowns tested. The fracture load of the partial palatal crowns (PC pal.) did not differ significantly from that of the partial crowns for which the entire occlusal surface was reduced (PC pal./vest.). Neither the fracture load of MOD inlay preparations, nor full veneers (with an occlusal layer thickness of 2.0 mm and a facial segment of 0.8 mm) significantly differed from that of unprepared natural premolars.

#### Conclusion:

All specimens achieved a 100% in vitro survival rate in the masticatory simulator.

Reference: Stappert et al. (2005)

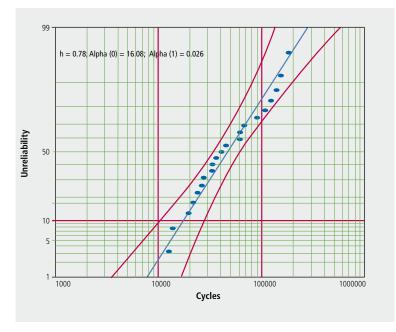
## Reliability and failure types of a new ceramic abutment prototype

Study location:	New York University, New York, USA
Study time period:	2012
Study author(s):	V.P. Thompson, P. Coelho, N.R.F.A. Silva

#### Method:

Implants (Implant Direct 4.3 mm/Nobel Biocare) were placed in a cylindrical polycarbonate mould filled with PMMA at a 30° angle and polymerized. 24 IPS e.max Press hybrid abutments cemented onto a titanium sleeve with Multilink Hybrid Abutment (n=24) were manually screwed on with the help of a torque wrench. IPS e.max Press crowns were cemented onto the abutment using Multilink Automix. The test samples were then stored in water at 37°C for at least 7 days. Three specimens were loaded until fracture in a universal testing machine. The load of 0.5 mm/min. was constantly applied with a tungsten carbide piston (6.25 mm) 2 mm cervical to the lingual incisal edge with a mesiodistal sliding motion of 0.7-1.0 mm. The reliability of the remaining 21 test specimens was tested with a three-stage stress test. After which, specimens were inspected for damage under a stereo microscope.

#### **Results:**



Weibull probability curve for implants with abutments made of IPS e.max Press at a load of 200N

#### Summary:

All the hybrid abutments and hybrid abutment crowns made of IPS e.max Press were able to withstand a load of 280 N. The weak point of the system was always the implant screw. It fractured before any damage to the crown or abutment occurred.

#### **Conclusion:**

Hybrid abutment restorations made of IPS e.max Press were able to withstand higher forces than the implant screws used in this test.

Reference: Thompson et al. (2012)

IPS e.max<sup>®</sup> Lithium Disilicate (LS<sub>2</sub>) – IPS e.max<sup>®</sup> CAD

#### in vivo Studies

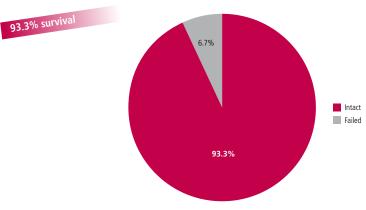
Clinical evaluation of a glass ceramic material for chairside CAD/CAM crowns

Study location:School of Dentistry, University of Michigan, Ann Arbor, USAStudy time period:10 years and 7 years / 2006–2017Study author(s):D. Fasbinder, G. Neiva, D. Heys, R. Heys

#### Method:

A longitudinal clinical trial was conducted to assess the performance of monolithic, chairside CAD/CAM fabricated lithium disilicate crowns. 100 IPS e.max CAD crowns were placed in the premolars or molars of 55 patients by one clinician at one-appointment sittings: 62 single IPS e.max CAD crowns were placed in 43 patients from 2006 to 2007 and these restorations could be evaluated over a ten-year period. An extra group of 38 crowns was added to the study in 2009 – for which the 7-year recall has been conducted. This involved an additional 12 patients and some of the original group received a second crown. The first 62 crowns were cemented with the self-etching bonding agent Multilink Automix (n=23) or an experimental self-adhesive cement (n=39). The extra 38 crowns were all cemented with SpeedCEM. Two independent evaluators scored the crowns at placement using modified USPHS criteria for various characteristics.

#### **Results:**



Clinical performance of chairside IPS e.max CAD crowns after up to 10 years

#### Summary:

There was an 84% (52/62) recall rate after 10 years for the first group of crowns and 100% (38/38) for the second group. 90 of 100 crowns could be evaluated overall. Mild sensitivity was reported in 15% of the teeth at week 1 but all cases had resolved after 4 weeks and no treatment was required. Two crowns required replacement due to fracture. There was no chipping reported, however one other crown presented with a linear craze line fracture that did not require replacement. Four crowns debonded after 3 years, 3 with the experimental cement and one with Multilink Automix – however all could be re-cemented with Multilink Automix and have remained functional. A further crown debonded after 9 years which had to be replaced as the patient lost it. The diagram depicts the survived (n=84) and failed (n=6) crowns as calculated from the pooled 10 year and 7 year data groups. Failed referring to crowns that required replacement due to fracture (n=2), root canal failure (n=1), core/pin fracture (n=1), secondary caries (n=1), missing crown after decementation (n=1).

#### **Conclusion:**

Only 2 crowns fractured requiring replacement. The IPS e.max CAD crowns performed exceptionally well up to 10 years of clinical service.

Reference: Fasbinder et al. (2010), Fasbinder et al. (2017a)

in vivo Studies

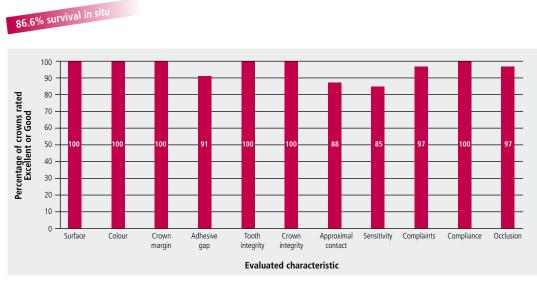
# Long-term clinical performance of chairside fabricated IPS e.max CAD LT crowns: 10-year results

Study location:	Universität Leipzig, Leipzig, Germany
Study time period:	10 years / 2006/2007–2017
Study author(s):	A. Rauch, S. Reich, L. Dalchau, O. Schierz

#### Method:

Between June 2006 and February 2007 forty-one posterior (31 molars and 10 premolars) full contour lithium disilicate (IPS e.max CAD LT) crowns were placed in 34 patients using a chairside CAD/CAM technique. Thirteen patients were male and 21 female, with an average age of 46.5 years. Twenty teeth were successfully endodontically treated before insertion. Crowns were luted with Multilink Sprint/Ivoclar Vivadent and were evaluated according to modified USPHS criteria at baseline and after 6, 12, 24, 36, 48, 60, 72 and 120 months. Clinical characteristics were rated from A1=1, A2=2, B=3, C=4, D=5 relating to Excellent, Good, Sufficient, Insufficient, Poor respectively.





Percentage of crowns rated excellent or good after 10 years in situ

#### Summary:

After 10 years, 33 crowns (80% of the original 41 crowns) could be evaluated in 26 patients. The survival rate *in situ* was reported as 86.6%. Five failures occurred over the time period, involving one crown-fracture at 2 years, an apical infection and a carious lesion under a core build up at 6 years, a lengthwise root fracture at 7 years and a new crown at 10 years due to a carious lesion. When further complications such as decementation were included in the calculation, the survival rate reduced to 76.3% after ten years. As shown in the diagram, the surface of the restorations, colour, crown margin, tooth integrity, crown integrity and compliance (how positively the patient rated the overall treatment experience), were all rated excellent or good.

#### **Conclusion:**

Chairside crowns made of IPS e.max CAD LT proved clinically efficient over a period of 10 years and can be recommended. The survival rate (86.6%) was comparable to that recorded with other ceramic materials after ten years.

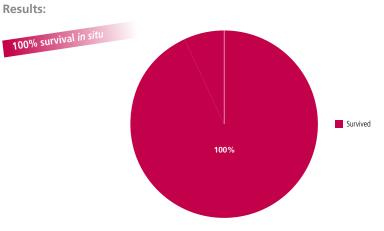
Reference: Rauch et al. (2017)

# 8 years' clinical behaviour of adhesively luted all-ceramic single-unit restorations

Study location:	Ivoclar Vivadent AG, Schaan, Liechtenstein
Study time period:	8 years / 2007–2016
Study author(s):	L. Enggist, A. Peschke, S. Huth, R. Watzke

#### Method:

Fifty-five single-unit lithium disilicate restorations (IPS e.max CAD / Press) were adhesively luted with Multilink Automix. 33 crowns, 13 partial coverage crowns and 9 inlays were placed by two operators. After a mean observation-time of 7.9 years in clinical function, 49 restorations could be assessed according to selected FDI-criteria.



Survival of IPS e.max CAD or Press single unit restorations after 8 years

#### Summary:

Overall, there were 6 drop-outs: 3 patients could no longer be reached, 1 crown fractured because the occlusal minimal thickness was not respected and 2 teeth were extracted due to vertical root fracture or post-endodontic failure. Of the 49 assessed restorations, the longest period in situ was 9 years and 1 month and the shortest was 7 years and 2 months.

After 7.9 years all of the restorations remained in situ, and most exhibited "excellent" to "good" clinical performance. 17% of the total length of all margins showed slight discoloration (FDI grade 2) and 16% of the margins showed minor irregularities.

#### **Conclusion:**

After almost eight years of clinical service, most IPS e.max CAD / Press restorations (cemented with Multilink Automix), exhibited outstanding clinical performance.

Reference: Peschke et al. (2013), Enggist et al. (2016)

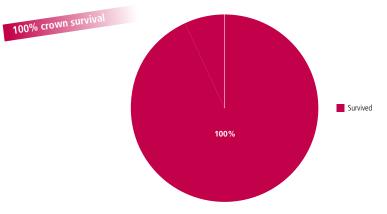
# CAD/CAM-fabricated, ceramic implant-supported single crowns made from lithium disilicate: Final results of a 5-year prospective cohort study

Study location:	Department of prosthetic dentistry, University of Freiburg, Germany
Study time period:	5 years / 2017
Study author(s):	B. C. Spies, S. Pieralli, K. Vath, R-J. Kohal

#### Method:

24 patients were included in a study, to evaluate the clinical and patient-reported outcomes of monolithic IPS e.max CAD (LT) crowns on zirconia-implants. All participants received a one-piece ceramic implant in the anterior (n=4) and posterior regions (n= 20). Lithium disilicate crowns were then adhesively luted to the implants using Multilink Automix. Evaluations were carried out at recalls every year for 5 years. Crowns were evaluated as regards survival and clinical performance using modified USPHS criteria. Clinically relevant defects that were repairable intraorally were accepted for survival. Restorations graded alpha or bravo were also considered successful.





Clinical performance of IPS e.max CAD crowns on zirconia implants after 5 years

#### Summary:

22 implant supported crowns could be investigated after 55.2 +/- 4.2 months. Two patients dropped out due to death/ moving away. No failures were observed. The survival rate was 100%, however as 2 crowns had to be re-polished (rated Charlie) due to major roughness issues, the Kaplan Meier success rate was calculated as 92%. All the crowns were rated Alpha or Beta for fracture (just one minor chipping = beta), marginal integrity, contour, esthetics and marginal discoloration.

#### Conclusion:

After 5 years, no implant-supported IPS e.max CAD LT restoration needed to be replaced, resulting in a survival rate of 100%. The Kaplan Meier success rate was calculated as 92%.

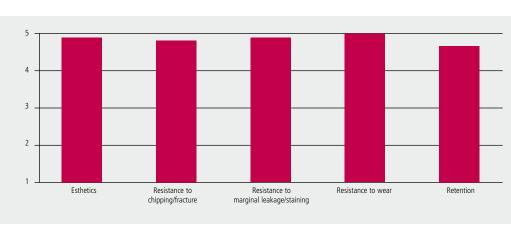
Reference: Spies et al. (2017)

## IPS e.max CAD: 5 year clinical performance

Study location:The Dental Advisor, Biomaterials Research Center, Ann Arbor, Michigan, USAStudy time period:5 years / 2006–2015Study author(s):The Dental Advisor

#### Method:

To establish the long-term clinical performance of IPS e.max CAD, 1079 IPS e.max CAD restorations were placed between June 2006 and August 2015. Recall data was available for 758 restorations, of which 734 were crowns, 15 inlays and 9 onlays. Overall 48% of the restorations were in service up to 3 years, 30% between 3 and 5 years and 22% were in service for 5 years or more.



#### **Results:**



#### Summary:

At the 5 year recall, various clinically relevant attributes as shown above, were measured on a scale of 1-5 (1=poor, 2=fair, 3= good, 4= very good, 5= excellent). Esthetics: 96% of the IPS e.max CAD restorations received an excellent rating for esthetics. Chipping/Fracture: 95% received an excellent rating. Two percent of the restorations chipped but did not require replacement. Four crowns fractured and were replaced one of which was due to bruxism. Marginal discoloration: 96% had no visible marginal discolorations and were rated excellent. Wear resistance: No replacements were necessary. Retention: 11 restorations debonded and were recemented – this was not deemed to be due to any particular cement.

#### Conclusion:

IPS e.max CAD offers excellent esthetics and wear resistance and was rated highly for resistance to chipping/fracture and resistance to microleakage and staining. Retention was excellent and no wear was reported for any restoration. IPS e.max CAD received a clinical performance rating of 98% at 5 years.

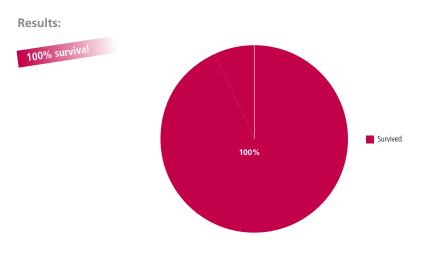
Reference: The Dental Advisor (2016)

# Clinical efficiency of CAD/CAM-fabricated lithium disilicate restorations: 4-year report

Study location:Ludwig Maximillian University (LMU), Munich, GermanyStudy time period:4 years / 2007–2011Study author(s):F. Beuer

#### Method:

A total of 38 fully anatomical and partially reduced IPS e.max CAD restorations were fabricated using KaVo Everest (36 crowns, 2 anterior bridges) and veneered with IPS e.max Ceram. The restorations were self-adhesively cemented with Multilink Sprint or adhesively cemented with Multilink Automix.



Clinical performance of IPS e.max CAD crowns and bridges after 4 years

#### Summary:

No restorative failures were reported, after a mean observation period of 4 years.

#### **Conclusion:**

Crowns and anterior bridges made of IPS e.max CAD, proved their clinical efficiency over a period of 4 years.

Reference: Richter et al. (2009), Beuer (2011a)

# Three-unit CAD-CAM-fabricated lithium disilicate bridges after a mean observation period of 46 months

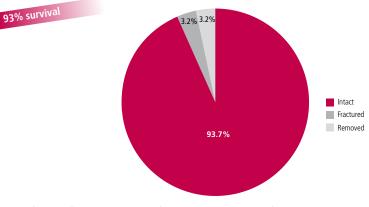
Study location:	Multi-center study in Berlin, Buchholz i. d. Nordheide, Zwickau and Aachen, Germany,
	under the direction of the RWTH Aachen, Germany
Study time period:	4 years / 2008–2012
Study author(s):	S. Reich, L. Endres, C. Weber, K. Wiedhahn, P. Neumann, O. Schneider, N. Rafai,
	S. Wolfart

#### Method:

A total of 38 three-unit bridges, for seating no further back than the second premolar as the last abutment tooth, were fabricated from IPS e.max CAD LT and placed in 33 patients. Fifteen bridges were layered with IPS e.max Ceram after cut-back. Twelve bridges were fabricated chairside. Cementation was performed with Multilink Automix.

#### **Results:**

For patients who received more than one bridge, only one bridge was selected at random for evaluation. One female patient also did not appear for the recall because she had moved away. Thus after 48 months, 32 bridges in 32 patients could be evaluated. Two bridges were rated as failures. One of them had fractured in the connector area and the other had to be removed due to unexplained, continuous pain. Two minor cases of repairable chipping were observed after 3 years. Furthermore, three endodontic complications occurred in two bridges after 1.3 and 1.6 years (one of these bridges was removed after 3 years, as described above, due to pain). The survival rate according to Kaplan-Meier was 93%.



Clinical performance of IPS e.max CAD crowns after a mean observation period of 46 months

#### Summary:

Only one fracture was reported after a mean observation period of 46 months. This fracture occurred within one year after placement and was caused by failing to observe the recommended connector dimensions.

#### **Conclusion:**

Bridges made of IPS e.max CAD up to the 2<sup>nd</sup> bicuspid proved their clinical efficacy over a period of approximately 4 years.

Reference: Reich et al. (2014)

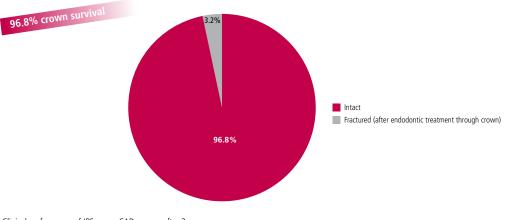
## Clinical efficiency and accuracy of fit of milled ceramic crowns

Study location:Boston University, Boston, USAStudy time period:3 years / 2005–2008Study author(s):D. Nathanson

#### Method:

Thirty-one IPS e.max CAD crowns (23 anterior and 8 posterior crowns) were placed in 14 patients by two operators. The restorations were veneered with IPS e.max Ceram and cemented using Multilink or Multilink Automix. Marginal accuracy and clinical performance was assessed at the time of placement and thereafter at 6 months and at yearly recalls.

#### **Results:**



Clinical performance of IPS e.max CAD crowns after 3 years

#### Summary:

Clinical fit was ranked alpha for all restorations. Three anterior single crowns required re-fabrication for improved colour. 17 restorations (55% of total) were evaluated at 2–3 years. One (posterior) restoration fractured after requiring a root canal through the crown after 12 months.

#### **Conclusion:**

After an observation period of up to 3 years, only one crown fractured after endodontic treatment through the crown. No other adverse findings were noted throughout the recall process. Crowns made of IPS e.max CAD proved their clinical efficiency over a period of 3 years.

Reference: Nathanson (2008)

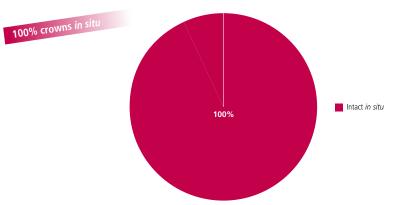
Survival rate and clinical quality of CAD/CAM fabricated posterior crowns made of lithium disilicate ceramic. A prospective clinical study.

Study location:University of Zurich, Zurich, SwitzerlandStudy time period:3 years / 2007–2011Study author(s):A. Bindl

#### Method:

In order to establish the survival rate and clinical quality of self-adhesively luted lithium disilicate CAD/CAM crowns, 42 IPS e.max CAD LT monolithic crowns were placed in 37 patients. Recalls were carried out after 1, 2 and 3 years. At the 3-year recall, 37 crowns in 31 patients could be investigated. Crowns were evaluated according to USPHS criteria.





Clinical performance of IPS e.max CAD crowns after a mean observation period of 46 months

#### Summary:

At the follow-up examination after 2 years, 37 crowns were evaluated. Neither fractures nor chipping had occurred, but one crown was affected by decementation. The crown was fully intact and was re-cemented using Multilink Automix. This crown appears amongst the 37 crowns evaluated as part of the 3 year recall – explaining the 100% in situ situation at 3 years. After 3 years all the crowns were evaluated Alpha or Bravo for crown integrity, marginal adaptation, anatomical form, occlusal contact, changes to sensitivity, secondary caries, surface characteristics. With regard to colour, one crown was rated Charlie as it was too light and also due to tooth migration of a neighbouring tooth one crown was rated Charlie regarding approximal contacts.

#### **Conclusion:**

Posterior crowns made of IPS e.max CAD proved their clinical efficiency over a period of 3 years.

Reference: Bindl (2011), Bindl (2012)

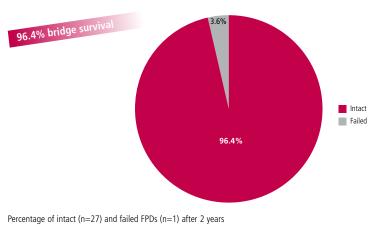
# Clinical evaluation of chairside CAD/CAM lithium disilicate fixed partial dentures: 2-year report

Study location:	University of Michigan School of Dentistry, Michigan, USA
Study time period:	2 years / 2017
Study author(s):	D. J. Fasbinder, G. Neiva, D. Heys, R. Heys

#### Method:

A longitudinal clinical trial was conducted to assess the performance of chairside fabricated IPS e.max CAD bridges. Patients had a missing premolar or anterior tooth that was appropriate for replacement with a fixed partial denture (FPD)/bridge. Patients received one 3-unit bridge only, which included just one missing tooth. The second premolar was the most distal missing tooth acceptable for inclusion in the study. Abutment teeth had a healthy periodontal status and were asymptomatic prior to treatment. Endodontically treated teeth were acceptable for one of the abutments. Two clinicians placed 30 IPS e.max CAD bridges in 30 patients. Scans were carried out chairside. The digital impression was used in the CEREC 4.3 software program/Dentsply Sirona, for the full contour design of the FPD. The designed FPD was milled in a MCX milling unit/Dentsply Sirona and crystallized in the Programat CS2. The bridges were cemented using Multilink Automix. Clinical evaluation using modified USPHS criteria was carried out at baseline, six months, one year and two years.

**Results:** 



# Summary:

After two years, 2 patients could not be contacted and were assigned as drop-outs. One bridge failed after 2 years due to extensive recurrent caries associated with health and medication issues causing xerostomia. The overall survival rate (27/28) was therefore 96.4%. Mild sensitivity was reported in 6 patients after the first week, which had all resolved by 4 weeks. The USPHS scores were overwhelmingly Alpha for all FPDs.

#### Conclusion:

After 2 years, the survival rate of chairside-fabricated IPS e.max CAD bridges was 96.4% with no structural complications of the material recorded.

Reference: Fasbinder et al. (2017b)

IPS e.max<sup>®</sup> Lithium Disilicate (LS<sub>2</sub>) - IPS e.max<sup>®</sup> CAD

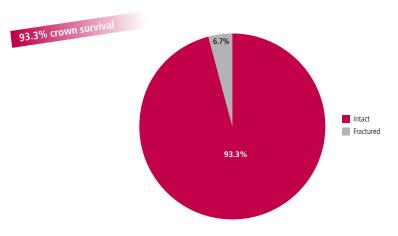
# Clinical study on IPS e.max CAD posterior crowns

Study location:	Pacific Dental Institute, Portland, USA
Study time period:	2 years / 2006-2009
Study author(s):	J.A. Sorensen, R. Trotman, K. Yokoyama

#### Method:

Thirty IPS e.max CAD crowns were veneered with IPS e.max Ceram and placed in 27 patients using an adhesive cementation protocol with Multilink.

#### **Results:**



Clinical performance of IPS e.max CAD crowns after 2 years

#### **Summary:** After an observation period of 2 years, two crowns had fractured.

#### Conclusion:

Lithium disilicate crowns made of IPS e.max CAD proved their clinical efficiency over a period of 2 years.

Reference: Sorensen et al. (2009b)

in vivo Studies

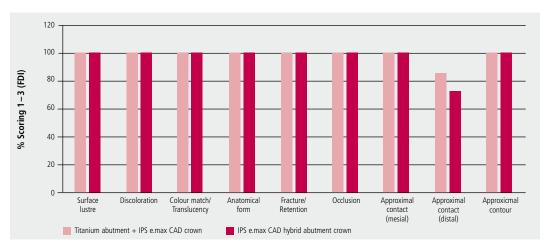
Prospective randomized controlled study of monolithic, chairside, implantsupported crowns made of CAD/CAM lithium disilicate: Baseline Report

Study location:Clinic for dental prosthetics, University Clinic Aachen, GermanyStudy time period:Baseline / 2017Study author(s):S. Reich, S. Wolfart

#### Method:

In order to evaluate the long-term performance of one-piece hybrid-abutment-crowns for implants, 41 patients received 57 implants/restorations - either a monolithic IPS e.max CAD hybrid abutment crown (Group E/n= 29) or an individualized titanium abutment with a cemented IPS e.max CAD crown (Group A/n=28). The latter group served as a control. 27 patients received 1 implant (A or E), 12 patients received 2 implants (A + E) and 2 patients received 3 implants (A + E + E). The choice of implant type was randomized in each group. FDI grading was used for the clinical evaluation with grades 1-3 considered clinically satisfactory or better.





Percentage of (Titanium abutment + IPS e.max CAD crown vs. IPS e.max CAD hybrid abutment crown) restorations scoring 1 – 3 (clinically satisfactory) according to FDI criteria, for various characteristics

#### Summary:

Patient satisfaction, the condition of the peri-implant tissues and the clinical performance of the implant superstructure are to be evaluated. At the baseline stage, patients' satisfaction after the treatment showed no real difference between the IPS e.max CAD hybrid abutment crown group or the titanium abutment plus IPS e.max CAD crown group in terms of perceived strain of the treatment, expectations, satisfaction with the esthetics, colour or form, chewing and speaking. With regard to peri-implant tissues, no significant group differences were noted. The baseline clinical evaluation according to FDI criteria shown in the graph above indicated a clinically satisfactory situation in both groups for all characteristics except distal approximal contacts (in both Group A and E), where in some cases the contacts were slightly too wide.

#### Conclusion:

At baseline the monolithic, chairside IPS e.max CAD hybrid abutment crown, exhibited similar characteristics to an individualized titanium abutment with a cemented IPS e.max CAD crown.

Reference: Reich et al. (2017)

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IPS e.max<sup>®</sup> Lithium Disilicate (LS<sub>2</sub>) – IPS e.max<sup>®</sup> CAD

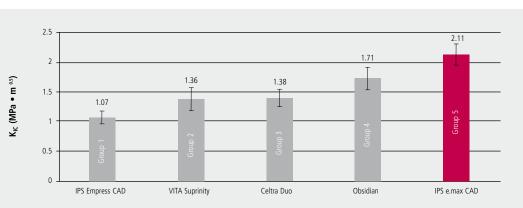
### *in vitro* Studies

### Fracture toughness of five CAD/CAM glass-ceramics

Study location:Ivoclar Vivadent, Amherst NY, USA.Study time period:2016Study author(s):T. Hill, G. Tysowsky

#### Method:

Using the V-notched beam test, the fracture toughness ( $K_{IC}$ ) of five commercially available CAD/CAM glass-ceramics was tested. The glass-ceramic materials (n=8) included: Group 1: IPS Empress CAD/lvoclar Vivadent (leucite), Group 2: VITA Suprinity/Vita (lithium silicate), Group 3: Celtra Duo/Dentsply Sirona (lithium silicate/lithium disilicate), Group 4: Obsidian/Glidewell Dental (lithium silicate), and Group 5: IPS e.max CAD/lvoclar Vivadent (lithium disilicate). Each material was sectioned into bars (3 mm x 4 mm x 17 mm) using an IsoMet saw. Group 1 was fired using a glaze cycle, groups 2–5 were fired according to the manufacturer's instructions. An initial V-notch was cut into the bars at a depth of 0.5–0.7 mm, using an Amann diamond saw at low speed with copious amounts of water. The V-notch was finished to a depth of between 0.9–1.1 mm, using a razor blade and 6, 3, 1µm diamond paste. After cleaning in an ethanol bath for 10 minutes, the specimens were loaded to failure in a three-point testing fixture (span-15 mm) at a crosshead speed of 0.5 mm/min in an Instron testing machine. Notch depths were measured at three evenly spaced points, using a microscope at 50x magnification. The average and relative depth lengths were calculated and checked that the maximum and minimum values did not vary by more than 0.1mm. The pre-cracked beam method was used to calculate fracture toughness ( $K_{IC}$ ). Pf is failure load; s is span; t is thickness; w is width; and a is average V-notch depth:



$$\begin{split} K_{IC} &= g * [(P_f * Sx 10^6) / (t * w^{3/2})] * [(3(a/w)^{1/2}) / (2(1-a/w)^{3/2})] \\ g \text{ is } \{1.99 - [(a/w)(1-a/w)] * [2.15 - 3.93(a/w) + 2.7 * (a/w)^2] / [1 + 2(a/w)] \end{split}$$

### Results:

Fracture toughness ( $K_{IC}$ ) of five different glass ceramics

#### Summary:

Fracture toughness is inherent to a material and can be used to predict other properties such as strength. For the materials examined, fracture toughness increased with increased crystal volume fraction for the lithia based materials. A statistical difference was found between all the groups except Groups 2 and 3.

#### **Conclusion:**

IPS e.max CAD exhibited the highest fracture toughness.

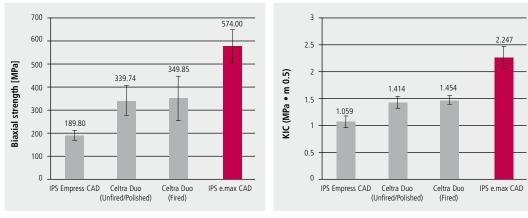
Reference: Hill et al. (2016)

# Evaluation of biaxial flexural strength and fracture toughness of a zirconia – reinforced dental ceramic

Study location:College of Dental Medicine, Columbia University, New York, USA/Ivoclar Vivadent,<br/>Amherst, New York, USAStudy time period:2017Study author(s):W. Randi, A. Randi, T. Hill

#### Method:

The study compared the biaxial strength and fracture toughness of the lithium disilicate material IPS e.max CAD, the leucite reinforced glass ceramic IPS Empress CAD and the zirconia reinforced lithium silicate Celtra Duo (fired and unfired/polished)/Dentsply Sirona. 14 disc samples of each material were prepared for biaxial flexural strength testing and 15 of each for the fracture toughness tests. For the biaxial tests, discs with a radius of 12–16 mm and thickness of 1.2 mm (+/- 0.2 mm) were prepared and polished (30 um grit) according to ISO 6872:2015(E). The specimens were broken over three concentrically supporting balls with the load applied to the centre of the test piece. The single edge V-notched beam method was used for fracture toughness, following ISO 6872:2015(E) guidelines. Bars (3 mm x 4 mm x 17 mm) were fabricated and prepared with a V-notch ranging from 0.8–1.2 mm using a razor blade with diamond paste. V-notch depth measurements were made after specimens were fractured using a stereomicroscope. Fracture toughness was calculated using the same formula as detailed in the previous study by Hill et al. (2016).



#### **Results:**

#### Summary:

Lithium disilicate (IPS e.max CAD) met the ISO standard recommendation of a minimum fracture toughness of 2.0 for single unit crowns with a value of 2.247 in this study. IPS e.max CAD exhibited the highest biaxial strength and fracture toughness values.

#### **Conclusion:**

IPS e.max CAD exhibited significantly higher biaxial strength and fracture toughness values compared to the other materials. There was little difference between the fired and unfired-polished Celtra Duo material and no clinical advantages for zirconia reinforced lithium silicate over lithium disilicate were found.

Biaxial strength and fracture toughness of various dental ceramics

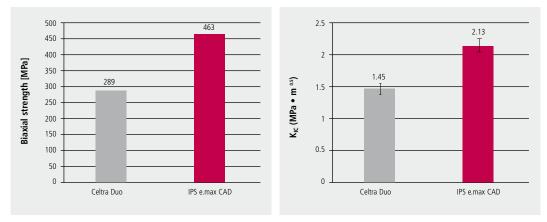
# Biaxial strength and fracture toughness of IPS e.max CAD and Celtra Duo glass-ceramics

Study location:New York College of Dentistry, New York, USA.Study time period:2017Study author(s):Y. Zhang

#### Method:

Five samples each of IPS e.max CAD/Ivoclar Vivadent (lithium disilicate) and Celtra Duo/Dentsply Sirona (lithium silicate) were tested. Biaxial flexural strength tests were carried out using a piston on 3-ball apparatus. The single-edged V-notched beam method (SEVNB), was used to test fracture toughness ( $K_{IC}$ ), with each material sectioned into bars (3mm x 4mm x 17mm) using an IsoMet saw. Specimens were polished and an initial V-notch was cut into the bars. Specimens were then loaded to failure in a three-point testing fixture. Notch/pre-crack lengths were measured with optical and scanning electron microscopes.

#### **Results:**



Biaxial flexural strength (left) and fracture toughness (right) of two different glass ceramics

#### Summary:

IPS e.max CAD exhibited higher biaxial strength than Celtra Duo at 463 MPa compared to 289 MPa, and also significantly higher fracture toughness.

#### **Conclusion:**

IPS e.max CAD exhibited higher biaxial strength and fracture toughness than Celtra Duo – mainly due to the higher crystalline content of IPS e.max CAD relative to Celtra Duo.

Reference: Zhang (2017/2018), Zhang (2017)

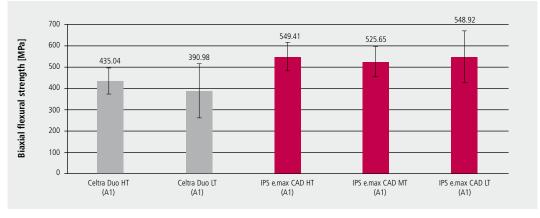
# Mechanical characteristics of a zirconia-reinforced lithium silicate CAD/CAM restorative material

Study location:Department of Prosthodontics, Louisiana State University, New Orleans, USAStudy time period:2017Study author(s):K. Vu

#### Method:

Specimens of IPS e.max CAD and Celtra Duo/Dentsply Sirona were sectioned from their CAD/CAM blocs via section saw. Specimens were fired according to manufacturer-instructions then fixed to a metal cylinder whereupon the testing surface was smoothed and polished. The flexural strength and flexural modulus were calculated using the piston on 3-balls configuration according to the ISO standard 6870. Both products were tested in shade A1 and in high and low translucency (HT, LT) for Celtra Duo and high, medium and low translucency (HT, MT, LT) for IPS e.max CAD – creating five (n=10) study groups.

#### **Results:**



Biaxial flexural strength of Celtra Duo and IPS e.max CAD in shade A1 with different translucencies

#### Summary:

The flexural strength of IPS e.max CAD exceeded 500 MPa for all translucencies and was significantly higher than that of Celtra Duo. The two translucencies of Celtra Duo exhibited greater variation in flexural strength than the three translucencies of IPS e.max CAD.

#### Conclusion:

The flexural strength of IPS e.max CAD exceeded that of Celtra Duo for all translucencies.

Reference: Vu (2017)

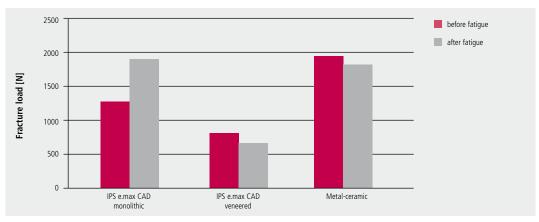
Monolithic and veneered CAD/CAM lithium disilicate bridges vs. metalceramic: Comparison of the fracture load values and failure modes upon fatigue

Study location:	University Clinic, Freiburg im Breisgau, Germany
Study time period:	2012
Study author(s):	S. Schultheis, J.R. Strub, T.A. Gerds, P.C. Guess

#### Method:

A total of 96 extracted human molars and premolars were divided into 3 groups. Full-contour bridges were milled from IPS e.max CAD using CEREC/Dentsply Sirona and either cemented as a monolithic restoration or manually veneered. Metal-ceramic bridges were used as a control group. The fracture load was determined before and after fatigue tests.





Mean fracture load of monolithic or veneered bridges made of IPS e.max CAD - compared to metal-ceramic after fatigue testing

#### Summary:

All bridges survived the fatigue test. Veneered bridges made of IPS e.max CAD fractured at lower forces than monolithic bridges made of IPS e.max CAD, which achieved fracture loads comparable to metal-ceramic. Bridges made of IPS e.max CAD fractured in the connector area. Chipping was not observed in the lithium disilicate bridges, while this was the only type of failure in metal-ceramic bridges.

#### **Conclusion:**

Monolithic bridges made of IPS e.max CAD tolerate loads comparable to those of bridges made of metal-ceramic – the gold standard.

Reference: Schultheis et al. (2013)

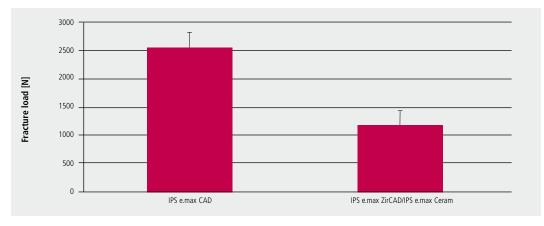
### Monolithic CAD/CAM lithium disilicate compared to veneered Y-TZP crowns: Comparison of the failure types and reliability after fatigue

Study location:	New York University, New York, USA	
Study time period:	2010	
Study author(s):	P.C. Guess, R.A. Zavanelli, N.R.F.A. Silva, E.A. Bonfante, P.G. Coelho, V.P. Thompson	

#### Method:

The fatigue behaviour and reliability of monolithic IPS e.max CAD crowns were investigated.

- Method I: 19 fully anatomical crowns were constructed and milled with a CAD/CAM system. The crowns were etched with 5% hydrofluoric acid for 20 seconds, silanated with Monobond Plus, and adhesively cemented onto aged, dentin-type composite dies using Multilink Automix. The test specimens were stored in water for at least seven days prior to the fatigue tests. During the fatigue tests, the crowns were subjected to a tungsten carbide piston that moved from the disto-buccal cusp 0.7 mm in the lingual direction in order to simulate occlusal movements. Three different stress levels were used, with the highest load amounting to 1000 N. After the tests, the crowns were inspected for damage under a stereo microscope with polarized light.
- Method II: In the second part of the investigation, the crowns were subjected to a "staircase ratio fatigue" stress test involving 1 million cycles. The loads varied from 90 to 900 N, 95 to 950 N, 100 to 1000 N and 110 to 1100 N.



#### **Results:**

Fracture load of IPS e.max CAD compared to IPS e.max ZirCAD veneered with IPS e.max Ceram

#### Summary:

Only at rather high forces, did IPS e.max CAD crowns demonstrate fractures with cracks down to the composite die (2576  $\pm$  206 N). In contrast, IPS e.max ZirCAD exhibited fractures exclusively in the IPS e.max Ceram veneering ceramic (1195  $\pm$  221 N).

#### **Conclusion:**

Fully anatomical IPS e.max CAD crowns showed to be resistant against fatigue in cyclic fatigue tests. In comparison, crowns made of zirconium oxide failed by fractures in the veneering material at clearly lower loads.

Reference: Guess et al. (2010a)

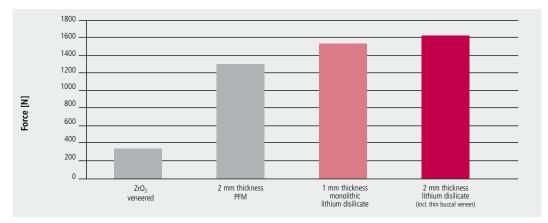
## Reliability of IPS e.max CAD crowns with thin layer thickness and thinly veneered IPS e.max CAD crowns Reliability: Crowns with reduced layer thickness and thinly veneered lithium disilicate compared with PFM and Y-TZP crowns

Study location:New York University, New York, USAStudy time period:2010Study author(s):N.R.F.A. Silva, V.P. Thompson

#### Method:

The fatigue behaviour and reliability of monolithic CAD/CAM-fabricated crowns made of IPS e.max CAD were investigated in comparison with veneered crowns made of zirconium oxide (Y-TZP) and conventional porcelain fused to metal-ceramic (PFM). The study included monolithic lithium disilicate crowns with an occlusal thickness of 1 mm and lithium disilicate crowns comprising a 1.5 mm framework plus a thin 0.5 mm buccal veneer i.e. 2 mm thickness overall. Twenty-one crowns per group were constructed, milled with a CAD/CAM system and subsequently glazed. The crowns were adhesively cemented onto an aged, dentin-type composite die using Multilink Automix. The test specimens were stored in water for at least seven days prior to fatigue testing. During the fatigue tests, the crowns were subjected to a tungsten carbide piston that moved from the disto-buccal cusp 0.7 mm in the lingual direction in order to simulate occlusal movements. Three different stress levels were used. After testing, the crowns were inspected for damage under a stereo microscope with polarized light.

#### **Results:**



Force upon failure after fatigue testing in masticatory simulator

#### Summary:

The fracture load of 1 mm monolithic lithium disilicate restorations (IPS e.max CAD) was 1535 N, and 1610 N for 2 mm IPS e.max CAD with a thin veneer. These values are comparable to those of metal-ceramics (1304 N) and higher than those of veneered zirconium oxide (371 N) (see graph). The fractures observed were complete fractures for IPS e.max CAD and chipping for the two other materials. The IPS e.max CAD material was most reliable.

#### Conclusion:

In this investigation, IPS e.max CAD crowns exhibited values comparable to those of the gold standard – metal-ceramics.

Reference: Martins et al. (2011)

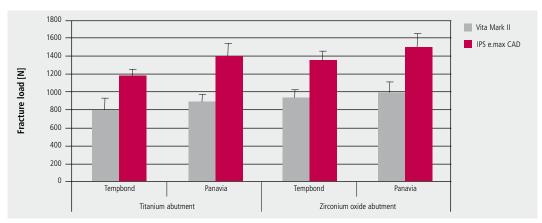
# Compressive strength, fatigue and fracture load of implant-retained ceramic crowns

Study location:	Ain Sham University, Cairo, Egypt/University of Toronto, Toronto, Canada	
Study time period:	2010	
Study author(s):	A. El-Dimeery, T. Salah, A. Hamdy, O. El-Mowafy, A. Fenton	

#### Method:

A total of 64 implant replicas were divided into 8 groups. Various ceramic materials (VITA Mark II/Vita, IPS e.max CAD), various abutment materials (titanium, zirconium oxide), as well as different cementation materials (Temp-Bond/Kerr Dental, Panavia/Kuraray Noritake) were compared. Molar crowns were cemented to the implant replicas and stored in water at 37°C for 24 hours, before an underwater fatigue test at 55–550 N for 500,000 cycles was conducted. The surviving test specimens were subjected to fracture testing.

#### **Results:**



Fracture load of implant-retained crowns made of IPS e.max CAD or Vita Mark II on titanium or zirconium oxide abutments

#### Summary:

During the fatigue test, two Vita Mark II crowns fractured (1 on a titanium abutment, 1 on a zirconium abutment, both of which were cemented with Temp-Bond). All the other test specimens survived. IPS e.max CAD crowns exhibited higher fracture load values than Vita Mark II in all groups.

#### **Conclusion:**

The groups with the IPS e.max CAD crowns achieved statistically significantly higher fracture load values than the groups with Vita Mark II crowns.

Reference: El-Dimeery et al. (2011)





# IPS e.max® Zirconium Oxide (ZrO<sub>2</sub>)

in vivo studies in vitro studies IPS e.max<sup>®</sup> Zirconium Oxide (ZrO<sub>2</sub>) – IPS e.max<sup>®</sup> ZirCAD

### in vivo Studies

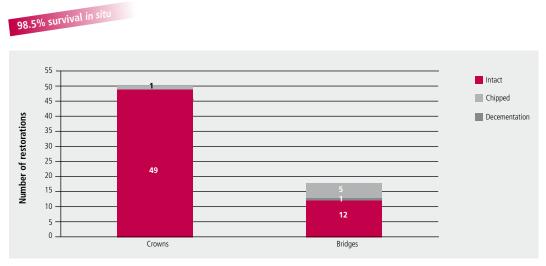
Clinical study on all-ceramic restorations made of zirconium oxide ceramic veneered with a new veneering ceramic

Study location:Ludwig Maximillian University (LMU), Munich, GermanyStudy time period:5 years / 2005–2009Study author(s):F. Beuer, W. Gernet

#### Method:

To evaluate the clinical performance of zirconium oxide restorations veneered with IPS e.max Ceram, 38 patients received 68 restorations: 50 crowns and 18 (3 to 4 unit) bridges made of IPS e.max ZirCAD, veneered with IPS e.max Ceram. All restorations were cemented with glass ionomer cement. Baseline examination was carried out after 2 weeks and recalls were performed after 1, 2 and 3 years by calibrated investigators.

#### **Results:**



Clinical efficiency of IPS e.max ZirCAD crowns and bridges veneered with IPS e.max Ceram after 5 years

#### Summary:

After an observation period of up to 5 years, no crown failures occurred, only one case of chipping of the veneering ceramic. For the bridges, 5 cases of chipping were reported. Furthermore, there was one case of repeated decementation, which resulted in the bridge being newly fabricated, thus counting as failure. 98.5% of the restorations were still in clinical use after 5 years.

#### **Conclusion:**

Crowns and bridges made of IPS e.max ZirCAD veneered with IPS e.max Ceram, exhibited excellent clinical performance; none of the restorations fractured during the study period of 5 years.

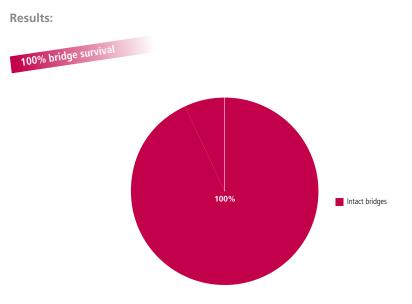
Reference: Beuer et al. (2010), Beuer (2011b)

# CAD/CAM single retainer zirconia-ceramic resin-bonded fixed dental prostheses: Clinical outcome after 5 years

Study location:Christian Albrechts University of Kiel, GermanyStudy time period:5 years / 2006–2013Study author(s):M. Sasse, M. Kern

#### Method:

Thirty anterior single-retainer zirconia-ceramic (IPS e.max ZirCAD veneered with IPS e.max Ceram) resin bonded bridges were placed in 25 patients. Five patients received 2 restorations. 16 restorations were bonded with a phosphate monomer containing resin (Panavia 21 TC/Kuraray Noritake) and 14 with Multiliink Automix.



Clinical performance of single-retainer, adhesively luted IPS e.max ZirCAD crowns after 5 years

#### Summary:

Over a mean observation period of 64.2 months, one debonding occurred in each group. Both debondings were however due to traumatic oral impact events (e.g. a hit to the chin) unrelated to the materials. Both IPS e.max ZirCAD restorations remained intact and could be rebonded successfully - resulting in a five-year survival rate of 100%.

#### **Conclusion:**

Independent of the bonding system, cantilevered bridges made of IPS e.max ZirCAD showed promising results over five years.

Reference: Sasse et al. (2013)

#### Heat pressed veneered zirconia crowns: 4-years' clinical performance

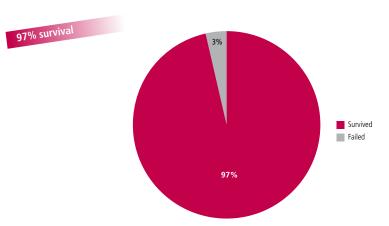
Study location: Study time period: 4 years / 2005-2012 Study author(s):

RWTH Aachen University, Aachen, Germany M. Gehrt, J. Tinschert, J. Schley, S. Wolfart

#### Method:

106 posterior crowns (33 premolars, 73 molars) made of IPS e.max ZirCAD (n=37), Lava Systems/3M Espe (n=35) or DC Zirkon/Dental Concept Systems (n=34) were pressed-over with IPS e.max ZirPress and placed in 46 patients.





Clinical performance (with Kaplan Meier survival rate) of zirconium oxide crowns pressed over with IPS e.max ZirPress, after 5 years

#### Summary:

After a mean observation period of 50.8 months, 92 crowns were examined. Two biological complications occurred (1 endodontic infection, 1 root fracture), which required the extraction of the abutment tooth. Technical complications were reported for 5 cases (1 decementation and 4 chippings). However, none of these required crown replacement. The Kaplan-Meier survival rate after 5 years was 97%.

#### **Conclusion:**

Zirconium oxide restorations pressed over with IPS e.max ZirPress performed well, irrespective of the framework material used.

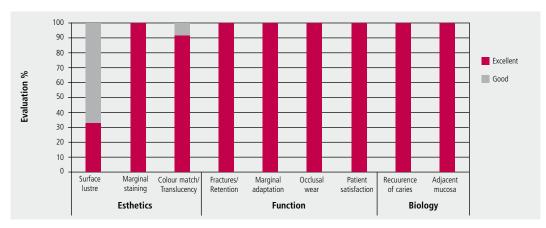
Reference: Gehrt et al. (2012)

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

Study location:R&D Dental Clinic, lvoclar Vivadent, Schaan, LiechtensteinStudy time period:4 years / 2009–2013Study author(s):R. Watzke, S. Huth, A. Peschke

#### Method:

In order to evaluate the clinical performance of lithium-disilicate fused to zirconium-oxide-frameworks, 25 CAD-onrestorations (IPS e.max CAD HT fused to IPS e.max ZirCAD), were manufactured using CAD/CAM-methodology 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 (Hickel 2010). The evaluation covered esthetic (A), functional (B) and biological (C) properties.



#### Results:

#### Summary:

After 4 years of clinical observation all CAD-on-restorations were scored "excellent" to "good" relative to the esthetic, functional and biological properties 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. Neither chipping nor fractures were detected. Due to occlusal adjustment after cementation and 4 years of occlusal function, 67% of the restorations showed small areas with silk-mat lustre (scored "good"). These surfaces could only be detected by close examination.

#### **Conclusion:**

After four years, IPS e.max CAD-on restorations combined high strength with natural appearing esthetics and seemed perfectly indicated for tooth and implant retained crowns and 3-unit-bridges.

Reference: Watzke et al. (2014)

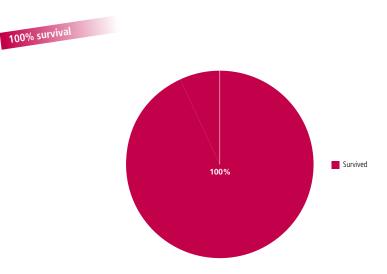
Clinical performance of IPS e.max CAD-on crowns and bridges after 4 years' observation

### Clinical performance of IPS e.max Ceram on IPS e.max ZirCAD

Study location:Pacific Dental Institute, Portland, USAStudy time period:4 years / 2004–2009Study author(s):J.A. Sorensen

#### Method: Incorporation of 20 IPS e.max ZirCAD bridges, veneered with IPS e.max Ceram.

#### **Results:**



Clinical performance of bridges made of IPS e.max ZirCAD veneered with IPS e.max Ceram

#### Summary:

No absolute failures were reported in an observation period of  $46.7 \pm 5$  months. The survival rate was 100%. Two small (cohesive) chippings within the veneering ceramic were reported.

#### **Conclusion:**

With a survival rate of 100%, the clinical performance of IPS e.max ZirCAD bridges veneered with IPS e.max Ceram was excellent.

Reference: Sorensen et al. (2009a)

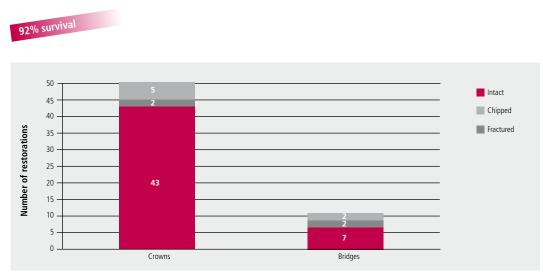
### Clinical performance of IPS e.max Ceram on IPS e.max ZirCAD

Study location:Dental Clinical Research Center, University of Iowa, Iowa City, USAStudy time period:3 years / 2005–2009Study author(s):C. Stanford

#### Method:

Incorporation of 50 crowns and 11 bridges made of IPS e.max ZirCAD, veneered with IPS e.max Ceram.

#### **Results:**



Clinical performance of IPS e.max ZirCAD/Ceram-veneered restorations after 36 months

#### Summary:

After an observation period of 36 months, 2 fractures and 5 cases of repairable (via polishing) chipping of the veneering material occurred in the crowns. For the bridges, 2 fractures (one of which was a decementation requiring new fabrication) and 2 cases of chipping were reported – which were also repairable in situ via polishing.

#### Conclusion:

Restorations made of IPS e.max ZirCAD, veneered with IPS e.max Ceram proved clinically efficacious.

Reference: Stanford (2009)

# Clinical evaluation of CAD/CAM-fabricated zirconium oxide ceramic crowns and bridges

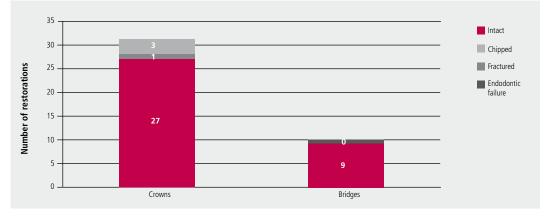
Study location:University of Michigan, Ann Arbor, USAStudy time period:3 years / 2005–2009Study author(s):D.J. Fasbinder

#### Method:

31 crowns and 10 bridges made of IPS e.max ZirCAD, press-veneered with IPS e.max ZirPress were placed.

#### **Results:**





Clinical performance of IPS e.max ZirCAD crowns and bridges, press-veneered with IPS e.max ZirPress after 3 years

#### Summary:

After an observation period of up to three years, the framework of one crown failed/fractured, requiring replacement. Three chippings of the veneering material of the crowns were also reported. In the bridge group, one failure caused by endodontic treatment occurred. In total, there were 2 absolute failures requiring restorative replacement.

#### **Conclusion:**

Restorations made of IPS e.max ZirCAD press-veneered with IPS e.max ZirPress showed excellent clinical behaviour.

Reference: Fasbinder et al. (2009)

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

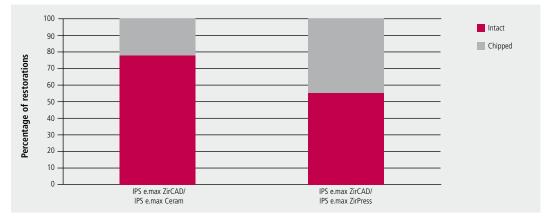
Study location:	University of Zurich, Switzerland	
Study time period:	3 years / 2005–2012	
Study author(s):	N. Naenni, A. Bindl, C. Sax, C Hämmerle, A. Mehl, I. Sailer	

#### Method:

40 patients in need of a 3-unit bridge were each fitted with an IPS e.max ZirCAD framework. Twenty restorations were veneered with IPS e.max Ceram (layered) and 20 with IPS e.max ZirPress (pressed). All FDPs were cemented adhesively and evaluated at baseline and after 6 months, 1 and 3 years of service. The technical outcome was assessed using modified USPHS criteria. Biological parameters were analyzed using abutment teeth and analogous non-restored teeth included pocket depth, plaque control record, bleeding on probing and tooth vitality. Survival was calculated via Kaplan Meier.

#### **Results:**

# 100% survival



Clinical performance of IPS e.max bridges veneered with IPS e.max Ceram and IPS e.max ZirPress

#### Summary:

36 patients with 18 test (pressed) and 18 control (layered) FDPs could be examined after a mean follow-up of 3 years. No framework fractures occurred thus the survival rate for both groups was 100%. Chipping of the veneer occurred more frequently in the test group but the difference was not significant. All chips could be repaired without replacing the restoration. No further differences in technical or biological outcomes of test and control FDPs were found.

#### **Conclusion:**

Bridges made of IPS e.max ZirCAD were clinically efficient over a period of 3 years, with both layered and pressed-on veneers.

Reference: Naenni et al. (2015)

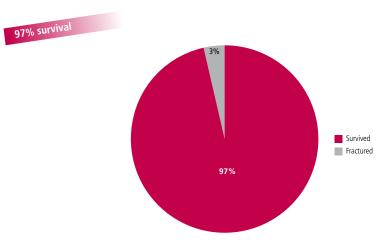
# Clinical efficiency of three-unit porcelain fused to metal (PFM), zirconium oxide and aluminium oxide posterior bridges

Study location:	CR Foundation, Provo, USA	
Study time period:	2 years / 2006-2008	
Study author(s):	R.P. Christensen	

#### Method:

293 three-unit bridges with metal or ceramic frameworks were veneered, (amongst other materials) with IPS e.max ZirPress (n=33), and placed by 116 dentists. The restorations were examined with regard to esthetic and functional parameters at regular recalls.

#### **Results:**



Clinical efficiency of IPS e.max ZirCAD restorations over-pressed with IPS e.max ZirPress after 2 years

#### Summary:

Of the 33 bridges made of IPS e.max ZirCAD and veneered with IPS e.max ZirPress, 1 bridge had to be replaced due to major veneer-fracture after an observation period of 2 years. A number of minor chipping cases which could be repaired in situ, also occurred. These did not require replacement of the restoration. (Note: Numerous cases of chipping also occurred in zirconium oxide restorations from other manufacturers in this study).

#### **Conclusion:**

The survival rate of IPS e.max ZirCAD veneered with IPS e.max ZirPress was 97% after 2 years.

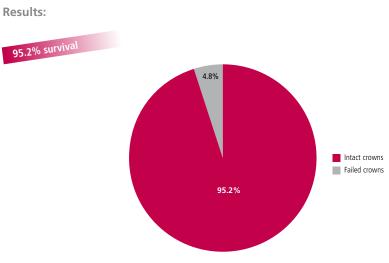
Reference: Christensen et al. (2008)

# Clinical evaluation of a self-adhesive luting composite in conjunction with all-ceramic crowns

Study location:The State University of New York, Buffalo, USAStudy time period:2 years / 2006–2009Study author(s):C. A. Muñoz

#### Method:

42 IPS e.max ZirCAD crowns veneered with IPS e.max Ceram or IPS e.max ZirPress were cemented with the selfadhesive luting composite Multilink Sprint.



Clinical efficiency of IPS e.max ZirCAD crowns

#### Summary:

After 2 years, 2 crowns failed in that they had to be replaced due to veneer fractures.

#### **Conclusion:**

The study confirms the clinical suitability of veneered IPS e.max ZirCAD as a crown material.

Reference: Muñoz (2009)

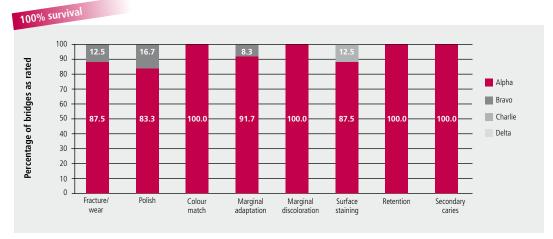
### Prospective clinical study with all-ceramic CAD-on posterior bridges: 2-year Report

Study location:	School of Dental Medicine, University of Pennsylvania, Philadelphia, USA		
Study time period:	2 years / 2010–2014		
Study author(s):	M. Blatz, N. Saleh, F. Mante, K. Hariton-Gross, F. Ozer, A. Atlas, M. Bergler		

#### Method:

To determine the clinical efficacy of posterior, 3-unit bridges made of IPS e.max ZirCAD veneered with IPS e.max CAD (IPS e.max CAD-on technique), 25 patients with an average age of 55.6 were recruited. All patients required at least one 3-unit bridge to replace either a missing 2nd premolar or 1st molar. All bridges were cemented using a resin modified glass-ionomer cement. The restorations were evaluated using modified Ryge clinical criteria at baseline and at the 6, 12 and 24-month recalls.

#### **Results:**



Clinical evaluation of IPS e.max CAD-on restorations after 2 years in situ, according to modified Ryge criteria

#### Summary:

Of the 25 patients, 24 could be followed up for 24 months. One patient dropped out after the 6-month follow-up for unknown reasons. All bridges were in situ at 24 months without any major adverse events having occurred – suggesting a survival rate of 100%. All bridges scored excellently i.e. Alpha for colour match, marginal discoloration, retention and secondary caries. Some surface wear (Bravo scores) was found in 3 (12.5%) of the 24 bridges. Bravo ratings were also seen for polish and marginal adaptation. 3 (12.5%) Charlie ratings were noted for surface staining.

#### **Conclusion:**

IPS e.max CAD-on bridges performed well after 24 months, exhibiting a 100% survival rate.

Reference: Blatz et al. (2014)

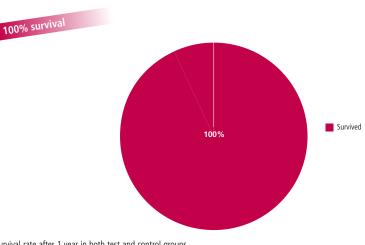
Three-unit posterior zirconia-ceramic fixed dental prostheses (FDPs) veneered with layered and milled (CAD-on) veneering ceramics: 1-year follow-up of a randomized controlled clinical trial.

Study location:	University of Zurich, Switzerland	
Study time period:	1 year / 2015	
Study author(s):	P. Grohmann, A. Bindl, C. Hämmerle, A. Mehl, I. Sailer	

#### Method:

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 - 60 patients in need of one posterior three-unit bridge (FDP) were included in the study. Thirty IPS e.max ZirCAD FDPs were 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 veneering ceramic (IPS e.max Ceram) (control group). For the clinical evaluation at baseline, 6, and 12 months, 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).

**Results:** 



Survival rate after 1 year in both test and control groups

#### Summary:

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 both the test and 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.

#### **Conclusion:**

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.

Reference: Grohmann et al. (2015)

IPS e.max<sup>®</sup> Zirconium Oxide (ZrO<sub>2</sub>) – IPS e.max<sup>®</sup> ZirCAD

#### *in vitro* Studies

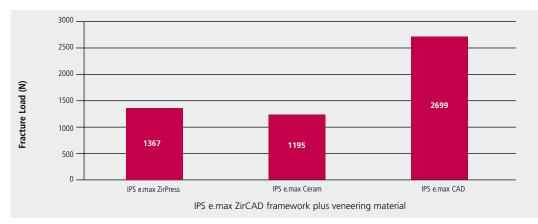
Veneering technique effect on fatigue reliability of zirconia-based all-ceramic crowns.

Study location:	New York University, USA
Study time period:	2010
Study author(s):	P. Guess, V. Thompson

#### Method:

To evaluate the difference in reliability and failure modes of zirconia crowns with different veneering techniques, 63 multilayer crown specimens with an IPS e.max ZirCAD core were fabricated using 3 techniques: Press-on – IPS e.max ZirPress, Layering – IPS e.max Ceram and IPS e.max CAD-on using IPS e.max CAD. Each group comprised 21 specimens. 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. Failure constituted chip fractures of the veneering ceramic and or cone cracks reaching the veneer framework interface.

#### **Results:**



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

#### Summary:

Single Load to Failure: 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  $\pm$  243 N).

Mouth motion Step Stress fatigue: 49% of 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.

#### **Conclusion:**

No cracks of the IPS e.max ZirCAD framework were observed in any group. IPS e.max CAD-on crowns showed no fractures. Crowns manufactured using the IPS e.max CAD-on technique were most reliable, indicating no risk for chipping.

Reference: Guess et al. (2010b)

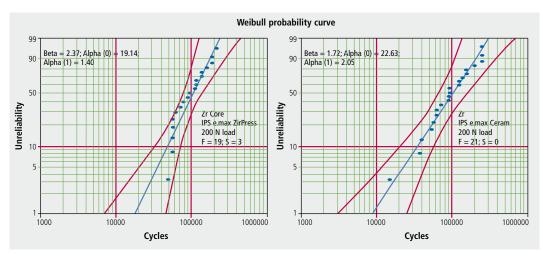
# Influence of veneering techniques on the failure behavior and fatigue strength of Y-TZP three-layer systems

Study location:New York University, New York, USAStudy time period:2009Study author(s):P.C. Guess, Y. Zhang, V.P. Thompson

#### Method:

IPS e.max ZirCAD specimens ( $12 \times 12 \times 0.7 \text{ mm}$ ) were veneered using either the lost-wax press technique (IPS e.max ZirPress; test group, n=24) or the layering technique (IPS e.max Ceram, control group, n=24). After adhesive cementation onto composite blocks ( $12 \times 12 \times 4 \text{ mm}$ , Z-100), the test specimens were stored in water for seven days before fatigue testing. The three-layered test specimens were subjected to a chewing simulation – step stress test with a ball-shaped tungsten carbide antagonist (R=3.18) with three different profiles (EL-3300 Bose/ Enduratec) until the cracks reached the bonding interface between the veneering and framework ceramics. All test specimens were arranged at a 30° off-axis angle to simulate the cusp inclination in the posterior region. The step stress profiles were determined on the basis of the initial fracture toughness.

#### **Results:**



Weibull probability curve for IPS e.max ZirCAD veneered with IPS e.max ZirPress (left) or IPS e.max Ceram (right) Blue dots = data dots. Red line = 2-sided 90% confidence intervals 19 IPS e.max ZirPress and 21 IPS e.max Ceram test specimens failed (F)

#### Summary:

The fatigue strength of veneered IPS e.max ZirCAD (pressed or layered) was comparable in step stress profiles. Only superficial fractures in the veneer were observed. Framework fractures did not occur.

#### **Conclusion:**

The fatigue strength of IPS e.max ZirCAD is not dependent on the type of veneer (pressed-on or layered).

Reference: Guess (2009)

IPS e.max<sup>®</sup> Zirconium Oxide (ZrO<sub>2</sub>) – IPS e.max<sup>®</sup> ZirCAD

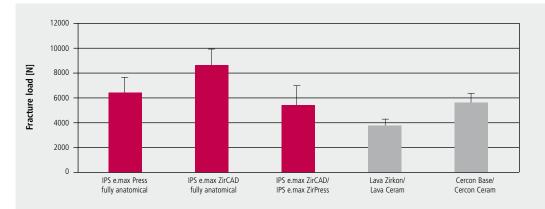
### Fracture load of all-ceramic crowns

Study location:	Christian Albrechts University, Kiel, Germany	
Study time period:	2011	
Study author(s):	M. Steiner, M. Sasse, M. Kern	

#### Method:

A model die was fabricated, onto which a model crown was waxed, and subsequently scanned. The crown had a standardized, anatomical occlusal surface with an occlusal layer thickness of 2.0 mm (cusps) and 1.5 mm (fissures). Several identical crown models were milled from an acrylate resin and used for the fabrication of lithium disilicate press crowns (IPS e.max Press). The CAD-milled zirconia crowns (IPS e.max ZirCAD, Lava Zirconia/3M Espe, Cercon Base/ Dentsply Sirona) were all fabricated in the same manner by scanning and milling from the respective materials. For the fabrication of veneered crowns, the occlusal thickness of the veneering material was 1.0 mm and 0.8 mm. Veneering with Lava Ceram/3M Espe, Cercon Ceram/Dentsply Sirona and pressing-over with IPS e.max ZirPress were carried out according to the instructions of the respective manufacturer. The crowns were adhesively cemented on metal dies using Multilink Automix. The test specimens were stored in water at 37 °C for 3 days before stress testing. 8 test specimens per material group were then mounted in the Willytec chewing simulator and subjected to cyclic load. The weight load was increased every 100,000 cycles (3, 5, 9, 11 kg) for a total number of cycles of 400,000. All intact test specimens were then loaded in a universal testing machine until complete failure.

#### **Results:**



Fracture load of all-ceramic crowns made of different materials

#### Summary:

No chipping occurred during dynamic loading. The fracture load of fully anatomical IPS e.max Press was in the same range as that of veneered zirconium oxide.

#### **Conclusion:**

The IPS e.max materials not only withstood the physiological forces of the posterior region, which range between 300 and 1000 N, but they also offer a certain safety-margin beyond this.

Reference: Steiner et al. (2011)

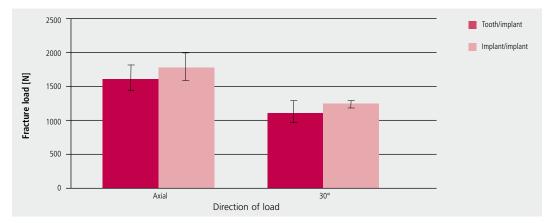
in vitro Studies

### Fracture load and chipping of implant-retained all-ceramic restorations

Study location:	University Clinic Heidelberg, Heidelberg, Germany		
Study time period:	2012		
Study author(s):	A. Alkharrat, M. Schmitter, S. Rues, P. Rammelsberg		

#### Method:

A standardized model of a 3-unit bridge for replacement of the first molar was fabricated. 32 IPS e.max ZirCAD frameworks were fabricated and split between 2 groups. 16 for implant/implant retained bridges and 16 for tooth/implant retained bridges. The frameworks were veneered using IPS e.max CAD to create IPS e.max CAD-on restorations. Half of the restorations of each group were subjected to axial loading, whilst the other half were subjected to loading at a 30° angle. Thermocycling with 10,000 cycles at 6.5°C/60°C and 1.2 million masticatory cycles at a force of 100 N were performed. Subsequently, all surviving bridges were loaded until fracture in a universal testing machine.



#### **Results**:

Mean fracture toughness of differently supported (Tooth/Implant or Implant/Implant) IPS e.max CAD-on molar bridges after masticatory simulation

#### Summary:

The type of substructure (implant/implant or tooth/implant) did not influence the fracture resistance of CAD-on bridges. Loading at a 30° angle, however, resulted in a decrease in fracture load.

#### **Conclusion:**

The forces of >1500 N tolerated by CAD-on bridges mean that the restorations are well able to withstand the usual forces of the posterior region.

Reference: Alkharrat et al. (2013)

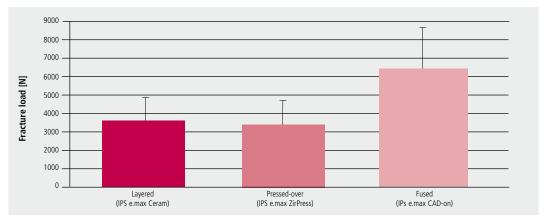
# High-strength CAD/CAM-fabricated veneering material sintered into zirconium oxide frameworks: A new fabrication method for all-ceramic restorations

Study location:	Ludwig Maximillian University (LMU), Munich, Germany	
Study time period:	2009	
Study author(s):	F. Beuer, J. Schweiger, M. Eichberger, H.F. Kappert, W. Gernet, D. Edelhoff	

#### Method:

A 360° chamfer preparation with a shoulder of 1.2 mm, was prepared on a second upper molar and doubled 15 times with a cobalt-chromium alloy. Forty-five zirconium oxide copings were fabricated of IPS e.max ZirCAD and divided into 3 groups. The first group was conventionally veneered using IPS e.max Ceram in the layering technique, the second group was pressed-over with IPS e.max ZirPress, while a high-strength, anatomically shaped full veneer was CAD/ CAM-fabricated from IPS e.max CAD and fused onto the IPS e.max ZirCAD (IPS e.max CAD-on restoration). All crowns were conventionally cemented and loaded in a universal testing machine until clinical failure.

#### **Results:**



Fracture load of variously veneered IPS e.max ZirCAD crowns

#### Summary:

The fracture load values of the layered and pressed-over crowns were similar, while the values of the IPS e.max CAD-on crowns were higher.

#### Conclusion:

The IPS e.max CAD-on crowns were superior to the layering and press-on technique with regard to fracture load.

Reference: Beuer et al. (2009)



# Biocompatibility Definition of Terms Literature

# 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. Tests indicate the reactivity or tolerance of cells to soluble compounds of a material. Biocompatibility tests may include in vitro investigations (conducted in artificial environments such as petri/cell culture dishes) such as cytotoxicity, mutagenicity, irritation and sensitivity tests. These tests are useful but have limited significance. Only in vivo investigations (performed in the living organism) i.e. clinical experience, can provide a final and definitive evaluation of biocompatibility.

In order to minimize biocompatibility risks from the outset, Ivoclar Vivadent strives to use well-established raw materials that have already proven safe in vivo – in the development of new products.

The biocompatibility of lithium disilicate glass-ceramic and zirconium oxide has been assessed on the basis of toxicity data from various institutes, plus data found in literature. In these tests, neither lithium disilicate nor zirconium oxide showed excessive solubility, cytotoxicity, genotoxicity or any significant radioactivity.

### Chemical durability/solubility

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 also not extreme enough to dissolve components from dental ceramics. The standard ISO 6872 prescribes guidelines for chemical solubility testing.

#### Lithium disilicate

The chemical solubility of IPS e.max lithium disilicate (IPS e.max Press and IPS e.max CAD) was evaluated according to ISO 6872. The values found were clearly below the limit of 100 µg/cm<sup>2</sup>. An analysis of ions (dissolved in artificial saliva and acetic acid) from IPS e.max Press and IPS e.max CAD specimens demonstrated a low ion content. Concentrations were in the same range as those of other dental ceramics.

#### Zirconium oxide

IPS e.max ZirCAD blocks, discs and colouring liquids were similarly tested for chemical solubility according to ISO 6872. All values were also well below the limit of 100  $\mu$ g/cm<sup>2</sup>.

#### 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 viability by half. The lower the  $XTT_{50}$  concentration, the more cytoxic. Numerous tests were carried out on both lithium disilicate and zirconium oxide and neither showed cytotoxic potential.

#### Lithium disilicate

- RCC Report In vitro cytotoxicity test evaluation of materials for medical devices (direct cell contact assay) CCR Project 571100 (28 October 1996)\*
- RCC Report In vitro cytotoxicity test evaluation of materials for medical devices (direct cell contact assay) CCR Project 590001 (24 June 1997) \*
- RCC Report In vitro cytotoxicity test evaluation of materials for medical devices (direct cell contact assay) CCR Project 590002 (24 June 1997) \*
- RCC Report Cytotoxicity Assay in vitro: Evaluation of materials for Medical Devices) RCC-devices with e.max Press (XTT Test) RCC-CCR study number 1165602 (March 2008)\*
- NIOM; Test Rep.; #012/04 (4 March 2004)\*
- NIOM; Test Rep.; #004/04 (4 February 2004) \*
- Grall, F. Toxicon Final GLP Report: 10-1251-G1. Agar Diffusion Test ISO. April 2010.\*

#### Zirconium oxide

In a "worst case" testing scenario, the in vitro cytotoxicity of the MT O (bleach) discs (immersed in various colouring liquids) was evaluated. None of the samples possessed any cytotoxic potential:

- Roth M. Cytotoxicity assay in vitro (XTT-Test). Envigo Report No. 1716001. 2015.\*
- Roth M. Cytotoxicity assay in vitro (XTT-Test). Envigo Report No. 1716007. 2015.\*
- Roth M. Cytotoxicity assay in vitro (XTT-Test). Envigo Report No. 1716005. 2015.\*
- Roth M. Cytotoxicity assay in vitro (XTT-Test). Envigo Report No. 1716003. 2015.\*

- Roth M. Cytotoxicity assay in vitro (XTT-Test). Envigo Report No. 1734305. 2016.\*
- Roth M. Cytotoxicity assay in vitro (XTT-Test). Envigo Report No. 1734303. 2016.\*
- Roth M. Cytotoxicity assay in vitro (XTT-Test). Envigo Report No. 1734301. 2016.\*

The *in-vitro* cytotoxicity of the pre-shaded discs: IPS e.max ZirCAD MO4 and IPS e.max ZirCAD MO2, was also examined via XTT test. No cytotoxic potential was determined:

- Meurer K. Cytotoxicity assay in vitro: Evaluation of materials for medical devices (XTT-test). RCC-CCR Report No. 1015500. 2006.\*
- Heppenheimer A. Cytotoxicity assay in vitro: Evaluation of materials for medical devices (XTT-Test). RCC-CCR Report No. 1120101. 2007. \*

#### Genotoxicity

Genotoxicity refers to the capability of substances or external influences to damage or alter the genetic materials of cells. Ames tests were carried out with lithium disilicate and (deeply coloured) zirconium oxide samples. Neither material showed mutagenicity.

Lithium disilicate

- RCC Report Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay with e.max Press (Ames Test) RCC – CCR study number 1165601 (May 2008)
- Devaki S, Toxikon Final GLP Report: 10-1251-G3: Salmonella typhimurium and Escherichia coli reverse mutation assay – ISO. April 2010.

Zirconium oxide

- Sokolowski A. Salmonella typhimurium and Escherichia coli reverse mutation assay. Envigo Report No. 1716009. 2015. \*
- Sokolowski A. Salmonella typhimurium and Escherichia coli reverse mutation assay. Envigo Report No. 1716015.
  2015. \*
- Sokolowski A. Salmonella typhimurium and Escherichia coli reverse mutation assay. Envigo Report No. 1716013.
  2015. \*
- Sokolowski A. Salmonella typhimurium and Escherichia coli reverse mutation assay. Envigo Report No. 1716011.
  2015.\*
- Sokolowski A. Salmonella typhimurium and Escherichia coli reverse mutation assay. Envigo Report No. 1734313.
  2016.\*
- Sokolowski A. Salmonella typhimurium and Escherichia coli reverse mutation assay. Envigo Report No. 1734315.
  2016. \*
- Sokolowski A. Salmonella typhimurium and Escherichia coli reverse mutation assay. Envigo Report No. 1734317.
  2016.\*

#### Radioactivity

The standards EN ISO 6872, EN ISO 9693 and IS13356 forbid the use of radioactive additives and stipulate the maximum level of radioactivity permissible in ceramic materials. Tests are made for minute levels of thorium or uranium which may be present in raw materials or pigments. Radioactivity levels in lithium dislocate and zirconium oxide were all far below the allowable threshold of 1Bq/g (ISO 6872).

Lithium disilicate

- Laugs O. Activity measurement of the nuclides 232Th and 238U in dental ceramic with Pulver e.max Press Multi A3.5. Forschungszentrum Jülich. 2014.\*
- Küppers G. Activity measurement of the nuclides 232Th and 238U in dental ceramic with IPS e.max CAD MO4.
  Forschungszentrum Jülich. 2013.\*
- Küppers G. Activity measurement of the nuclides 232Th and 238U in dental ceramic with IPS e.max CAD HT C4.
  Forschungszentrum Jülich. 2013. \*
- Küppers G. Activity measurement of the nuclides 232Th and 238U in dental ceramic with IPS e.max CAD LT D4.
  Forschungszentrum Jülich. 2013.\*

Biocompatibility

Zirconium oxide

- Küppers G. Activity measurement of the nuclides 232Th and 238U in dental ceramic with EAM591. Forschungszentrum Jülich. 2006.\*
- Laugs O. Activity measurement of the nuclides 232Th and 238U in dental ceramic with Probe 1298-1 PU ZirCAD LT.
  Forschungszentrum Jülich Report No. 17-10064. 2017. \*
- Laugs O. Activity measurement of the nuclides 232Th and 238U in dental ceramic with Probe 1298-2 PU ZirCAD Schneide. Forschungszentrum Jülich Report No. 17-10065. 2017. \*

#### Conclusion

The IPS e.max lithium disilicate and zirconium oxide ceramics were examined for their toxicological potential with regard to their use as medical products. Dental ceramics are generally known and accepted as highly biocompatible, numerous studies were conducted which confirm this. In addition, the scientific literature and a decade plus of clinical use are testament to the safety of these materials.

It can be concluded that the IPS e.max ceramics pose no health hazard if used correctly, and the benefits of their use outweigh any residual risk.

\* Reports of investigations commissioned by Ivoclar Vivadent AG are not published or for distribution

# **Studies**

Studies are conducted to forecast or examine the behaviour of materials when used for the intended application. Aspects of functionality, reliability, safety, compatibility or user-friendliness are often of most interest.

#### • In vitro studies

*In vitro* means "in glass". These examinations are conducted in a laboratory outside of their normal biological context. Many materials science or toxicological tests are carried out *in vitro*, since they cannot be conducted on human beings for practical or ethical reasons. Moreover *in vitro* studies have the advantage that researchers can work under standardized conditions – plus they are often quicker and less expensive than *in vivo* studies

#### • In vivo studies

*In vivo* means "in the living object". Such studies are carried out within the biological context i.e. in human beings. The advantage is that results are more meaningful as the investigations are conducted under real conditions. They are however complex due to a wealth of possible influencing factors. They require exact planning, systematic methods and statistically correct evaluation. Randomized controlled studies are considered the gold standard.

#### • Prospective study

A study planned to be conducted in the future in order to test a certain hypothesis, such as material A is as good as material B. After preparation of a test plan, the patients are recruited and the material used. The test subjects are observed over a certain period of time and the results are subsequently evaluated.

#### • Retrospective study

Analysis of data collected in the past. For example - all cases of bridge fractures that occurred in a dental office are examined to find out if the fractures happen more frequently with one material than with another.

# **Clinical Evaluation Techniques for Restorations**

#### Cvar and Ryge/USPHS Criteria

(Cvar & Ryge 1971 and 2005)

Cvar and Ryge developed their much used measurement scale over 40 years ago. This method of evaluation is i nterchangeably referred to as Cvar & Ryge criteria, Ryge criteria or USPHS criteria. The criteria were drawn up for evaluating amalgam or resin based direct restorations. Various authors modified the criteria as restoratives improved over time in terms of longevity. These are referred to as modified Ryge or modified USPHS criteria. The criteria used the Alpha, Bravo, Charlie, Delta evaluation scale. These scores have different meanings depending on the criteria being assessed however in general: Alpha = excellent/optimal, Bravo = acceptable, Charlie = unacceptable/insufficient and Delta = needs replacing.

#### Hickel/FDI Criteria

#### (Hickel et al, 2007 and 2010)

Hickel et al as part of the FDI World Dental Federation Science Committee, published a paper in 2007 outlining a proposal for a more modern clinical evaluation of both direct and indirect restorations. They present evaluation criteria related to the original Ryge criteria. These are evaluated as follows: Score 1 = Excellent, Score 2 = Very good but not ideal, Score 3 = Sufficient with minor shortcomings, Score 4 = Unacceptable but repairable, Score 5 = Unacceptable and needs replacing. Hickel et al compare their scoring system with Cvar and Ryge as follows:

Cvar & Ryge	Hickel/FDI
Alpha	Scores 1 & 2
Bravo	Score 3
Charlie	Score 4
Delta	Score 5

In 2010 a number of changes and improvements to the 2007 guidelines were added.

## Mechanical properties and in vitro tests

In materials science, there are numerous test methods to determine the mechanical properties of materials. The object of mechanical testing in dentistry, is to make estimates about the clinical efficacy of a material. However, standard test methods frequently test isolated stress conditions, whereas the effects on a material are much more complex in clinical reality. Nevertheless materials science examinations in the laboratory do permit the comparison of different materials when tested in exactly the same way.

#### Fracture Load

The fracture load indicates the value at which a component fractures. Values are mostly indicated in N (Newton).

#### **Flexural Strength**

The flexural strength indicates the flexural stress value that, when exceeded, causes the test specimen to fracture. There are several different methods to determine the flexural strength. Examples of frequently used methods are the biaxial strength (disc-shaped test specimens), 3-point flexural strength, 4-point flexural strength (bar-shaped test specimens). Flexural strength is highly dependent on the measuring method used and the surface texture e.g. polished or ground. Data can only be compared if the methodology is the same. The strength is indicated in MPa (megapascal).

#### Fracture Toughness

Fracture toughness ( $K_{IC}$ ) is a unit of measure for the ability of a material to resist crack propagation.  $K_{IC}$ , which is also called stress intensity factor or crack toughness, is the critical value at which a catastrophic failure of the component occurs and the stored energy is released in the form of new surfaces, heat and kinetic energy. Various methods can be used to determine the fracture toughness of a material. Similarly to flexural strength values, results of individual measurements can only be compared if the same methods of measurement are used. Typical methods are described briefly below.

#### **IF (Indentation Fracture) method**

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 under the microscope, depending on the size, shape and orientation of the crystals.

#### IS (Indentation Strength) method

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. 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).

#### SEVNB (Single Edge V-Notched Beam) method

Once the specimens are prepared, a defined notch is placed by means of a diamond bur, razor blade and polishing paste. The test specimens are then subjected to a strength test. The  $K_{IC}$  value is calculated in accordance with ISO 6872:2008.

#### Hardness

The hardness of a material is the resistance of a material to the penetration by another body. Various methods can be used to determine hardness, such as Vickers, Knoop, Brinell and Rockwell. In the Vickers method, for example, the surface of a material is loaded with a fine point in the form of a pyramid. The deeper the point penetrates, the less hard the material is considered to be. When indicating hardness, the corresponding method and ideally the load and duration of the load application, should be indicated. Values can only be compared when the method is identical.

#### Modulus of elasticity

The modulus of elasticity describes the stiffness of the material, that is, its resistance against elastic (temporary) deformation when a stress is applied. The stiffer the material the higher the elastic modulus.

#### Thermocycling / Chewing simulation / Fatigue

During the development of new materials, it is important to determine how susceptible they are to fracture under the expected stress conditions in the oral cavity. In vitro chewing simulation / fatigue tests are often used, as results are available quickly and materials can be tested and compared under standardized conditions. Test specimens are usually adhesively cemented to standardized PMMA dies and subjected to cyclic, eccentric loading with a pointed steel antagonist in a water bath. The load is increased in steps, e.g. 100,000 cycles with approximately 80 N, then 100,000 cycles with approximately 150 N, followed by 100,000 cycles with approximately 220 N (0.8Hz). Test specimens are simultaneously subject to thermocycling of 105 s each at 5°C and 105 s at 55°C. The number of cycles before fracturing or chipping occurs is measured.

#### Dynamic stress test

In a dynamic fatigue test, the fatigue behaviour of test specimens is tested in a force- or distance-controlled testing machine. In a test of implants and implant superstructures according to ISO 14801, the test specimens are typically subject to 2 million cycles (2 Hz, water at 37°C).

#### Cohesive/adhesive delamination

Delamination such as chipping is cohesive if the fracture surface is within a material, e.g. within a veneer. In contrast, a fracture is adhesive, if it occurs between two materials, e.g. at the interface between the framework material and veneer.

#### Weibull theory / Weibull statistics

Compared to other materials, ceramics exhibit special strength behaviour. Ceramic fractures originate from imperfections in the component. The number of imperfections therefore greatly influences strength values, and can cause relatively wide scattering of the measured data. Strength values also depend on the size of the component, i.e. the smaller the component, the fewer imperfections that are present and consequently - the higher the strength. Weibull statistics take these aspects into consideration.

The Weibull modulus "m" makes a statement about the reliability of a material; the higher "m" is, the more reliable the measured strength values (more narrow scattering).

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

Strength measurements in ceramic materials tend to yield results that scatter widely. Consequently, the Weibull strength  $\sigma_{_{63,21\%}}$  value is often utilized. This indicates the load at which 63.21% of all samples of a test series fail . Other terms used for Weibull strength are "characteristic strength" or "mean strength".

### **Survival Rates**

#### Kaplan-Meier survival rate

The Kaplan-Meier survival rate is used in studies to present and calculate the probability that a certain (mostly undesired) incident does not occur for a test specimen. In studies involving dental ceramics, the incident is most frequently the failure of the restoration. A special characteristic of these survival curves is that they take dropouts into account which depending on the study may mean patients and/or restorations. These are then represented on the Kaplan Meier curve as a sudden drop.

## **Cementation / Luting**

Dental cements or luting agents are materials used for cementing/luting indirect restorations to the remaining tooth structure/core. Both adhesive and non-adhesive materials are available.

#### **Conventional cementation**

Zinc phosphate, carboxlate and glass ionomer cements are all conventional materials. Most consist of a powder plus a liquid component, which are manually mixed. Some are available in mixing capsules. The chemical setting process starts immediately after mixing and does not involve additional initiation. No special pre-treatment of the prepared tooth is needed in conjunction with these materials. Usually, the restoration is simply placed as delivered by the dental laboratory. Complete isolation of the prepared tooth is not required. However, a retentive preparation design is necessary which may entail considerable loss of healthy tooth structure. Conventional cements usually have a grey-opaque appearance and, are therefore visible if the cement joint is exposed. Glass-ionomer cements have been further developed to produce a new group of materials known as hybrid cements. In addition to glass-ionomer components, hybrid cements contain monomers, so that both a cement setting reaction and polymer cross-linking occurs to ensure a complete cure. These luting materials feature better mechanical properties but also lack an adhesive bond to the tooth structure.

#### Adhesive luting composites

Adhesive composite-based luting materials are resins, composed of monomers and inorganic fillers. These materials can establish a sound chemical bond with the dental hard tissues and allow minimally invasive techniques. They are classified into self-curing, light-curing and dual- curing materials. By carefully selecting the pigments and colour additives, tooth-coloured luting composites are not visible if the cement joint is exposed. Enamel and dentin are pre-treated as prescribed by the adhesive luting protocol and the glass-ceramic material to be luted is usually etched with hydrofluoric acid and treated with a silane coupling agent. The clinical success of glass-ceramic restorations would have been unthinkable without composite luting materials.

#### Self-adhesive luting composites

These combine the advantages of conventional and adhesive luting materials. Although adhesive luting composites have many advantages, their application involves effort (isolation, application of additional steps and products such as dentin adhesives and primers), whereas conventional cements are simpler to use. Self-adhesive luting composites bond, both to the tooth structure and the restorative material, reducing the number of steps involved in their application and so also eliminating potential sources of error.

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