Ceramic inlays bonded with two adhesives after 4 years

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Glass ceramics; Dentin bonding agents; Etch-and-rinse; Self-etch; Clinical trial

Summary  Objective. The aim of the present study was to clinically evaluate the effect of two different adhesive/resin composite combinations for luting of IPS Empress inlays.

Methods. Ninety-four IPS Empress restorations were placed in 31 patients in a controlled prospective clinical split-mouth study. The restorations were luted with EBS Multi/Compolute (3M Espe) or with Syntac/Variolink II low (Ivoclar Vivadent) without lining. At baseline and after 0.5, 1, 2, and 4 years, the ceramic restorations were examined according to modified USPHS codes and criteria.

Results. Two patients including four restorations missed the 4 years recall (drop out). After 4 years of clinical service, four restorations in two patients (three luted with Compolute, one with Variolink II) had to be replaced due to hypersensitivities, 90 inlays and onlays were acceptable (failure rate 4%; Kaplan–Meier survival analysis). Between the five recalls, a statistically significant deterioration was found for the criteria marginal adaptation and inlay fracture (Friedman 2-way ANOVA; \( p < 0.05 \)). Between the adhesives no statistical difference was found. At baseline, 95% of the restorations revealed luting composite overhangs. After 4 years, 55% of cases had overhangs and 38% showed marginal ditching. No differences were found for surface roughness, color matching, integrity tooth, proximal contact, hypersensitivity, and satisfaction (\( p > 0.05 \)).

Conclusion. For luting of ceramic inlays, no difference between the two luting systems was detectable. The overall failure rate after 4 years was 4%.

Introduction

Since the late 1980s, several ceramic inlay systems were introduced on the market [1–3]. The heat-pressed, leucite-reinforced glass ceramic system
IPS Empress (Ivoclar Vivadent, Schaan, Principality of Liechtenstein) was marketed in 1990 and became very popular among dentists all over the world [4–8]. Regarding ceramic inlays, meanwhile a few prospective clinical studies give evidence about clinical long-term performance of different inlay systems [9–12], encouraging data have been published especially for IPS Empress [13,14]. Plenty of data are available for CAD/CAM ceramic inlays [15–18], e.g. an observation of 1011 Cerec inlays (Vita Mark II, Vita Zahnfabrik, Bad Säckingen, Germany) over 12 years revealed a 8% fracture rate [19]. Another report computed a survival analysis of 95% after 5 years being representative of other Cerec investigations [12,16,17].

Luting ceramic inlays is predominantly characterized by two main clinical problems. (1) Caused by the brittleness of ceramics, bulk fractures are still the predominant reason for failures [20]. However, optimization of luting and polishing procedures lead to acceptable rates of fractures [9,21–23]. (2) Postoperative hypersensitivities are still reported to be between 3 and 5% in recent clinical studies observing tooth-colored inlays [7,24–26].

Both concerns (1) and (2) are reflected by the present study design. Therefore, EBS Multi (3M Espe, Seefeld, Germany) as etch-and-rinse adhesive should be compared with Syntac (Ivoclar Vivadent, Schaan, Principality of Liechtenstein) as self-etch adhesive for luting with dual-cured resin composites (Compolute, Variolink II low) in a prospective clinical split-mouth long-term trial. The null hypothesis was that there would be no difference in clinical outcome when the different adhesives were used for bonding of ceramic inlays.

Materials and methods

Patients selected for this study met the following criteria:

(1) absence of pain from the tooth to be restored
(2) possible application of rubber dam during luting of restoration
(3) no further restorations planned in other posterior teeth
(4) high level of oral hygiene
(5) absence of any active periodontal and pulpal disease
(6) restorations required in two different quadrants (split mouth design).

All patients were treated in the Department of Operative Dentistry and Periodontology, University of Erlangen-Nuremberg, by six different clinicians (assistant professors) being experienced with placing ceramic inlays and onlays. All patients were required to give written informed consent. The study was conducted according to EN 540 (Clinical investigation of medical devices for human subjects, European Committee for Standardization), and inspected and approved by an ethics committee (International ethics committee Freiburg, Germany). The patients agreed to a recall programme of 4 years consisting of five appointments.

Ninety-four inlays (MO/OD: n=34; MOD: n=51) and onlays (n=9) were placed in 31 patients (9 male, 22 female; age 24–54 years, mean 31 years). Ten percent of the restorations were placed (n=9) in maxillary molars, 46% (n=43) in maxillary premolars, 15% (n=14) in mandibular molars, and 30% (n=28) in mandibular premolars.

The preparations of the cavities were performed slightly divergent without bevelling of the margins using 80 μm diamond burs (Inlay Prep-Set, Intensiv, Viganello-Lugano, Switzerland), and finished with 25 μm finishing diamonds. The minimum depth of the cavities was 1.5 mm with rounded occluso-axial angles. Full-arch impressions were taken using a polyvinyl-siloxane material (Permagum High Viscosity, 3M Espe, Seefeld, Germany) and washed with a syringeable low-viscosity material (Permagum Garant, 3M Espe) to record preparation details.

Two dental ceramists produced all the inlays and onlays according to the manufacturer’s instructions and recommendations within 2 weeks after impression taking.

The intraoral fit was evaluated under rubber dam. Internal adjustments were performed using finishing diamonds. Interproximal contacts were assessed using waxed dental floss and special contact gauges (YS Contact Gauge, YDM-Yamaura, Tokyo, Japan). Prior to insertion, the thickness of the inlays and onlays was recorded using a pair of tactile compasses (Schnelltaster, Kroeplin, Schluechtern, Germany) with an accuracy of 0.01 mm. The minimum thickness between deepest fissure and fitting surface, minimal width in the isthmus region for inlays, and the minimum thickness of the cuspal coverage in onlays were measured.

The inlays were luted adhesively under rubber dam. The prepared teeth were thoroughly cleaned with pumice slurry. In the Compolute group, enamel and dentin were etched simultaneously for 20 s with 32% orthophosphoric acid (MiniTip Etching gel, 3M Espe), rinsed for 20 s and dried. EBS Multi Primer was rubbed onto the dentin for 20 s and thoroughly dried to evaporate the water as carrier
of the monomers. EBS Multi Bond was applied, rubbed for 20 s, air-thinned with an air syringe and left uncured. Compolute Aplitip was mixed for 10 s in a Rotomix mixing apparatus (3M Espe) and applied into the pre-treated cavity.

In the Variolink group, enamel margins were selectively etched with 37% phosphoric acid gel (Email Preparator GS, Ivoclar Vivadent) for 30 s and rinsed for 30 s. Syntac classic was applied as per manufacturer’s recommendations [Primer 15 s, Adhesive (i.e. 2nd primer) 10 s, Heliobond applied and immediately air-thinned]. Variolink II Low was mixed by hand for 30 s and consequently applied into the cavity.

The internal surface of the restorations was etched with 4.5% hydrofluoric acid (IPS Ceramic etching gel, Ivoclar Vivadent) for 60 s, rinsed, dried, and then silanated (EspeSil, 3M Espe). After application of the silane coupling agent, the solvent was evaporated with compressed air.

Polymerization of the luting agents was performed by light curing for a total of 120 s from different positions (40 s in each direction). The used curing light was Elipar II (3M Espe). The intensity of the light was checked periodically with a radiometer (Demetron Research Corp., Danbury, CT, USA) to ensure that 650 mW/cm² was always delivered during the experiments.

Prior to polymerization, the luting composite in the luting gap was covered with glycerine gel to prevent the formation of an oxygen inhibited layer. After light-curing and examining the luting areas for defects, the rubber dam was removed. Centric and eccentric occlusal contacts were adjusted using diamond finishing burs (Intensiv, Viganello-Lugano, Switzerland) prior to Soflex discs (3M, St. Paul, MN, USA). Overhangs were removed and polished in the same way, proximally with interdental diamond strips (GC Dental Industrial Corp., Tokyo, Japan) and interdental polishing strips (3M, St Paul, MN, USA). Final polishing was conducted using felt discs (Dia-Finish E Filzscheiben, Renfert, Hilzingen, Germany) with polishing gel (Brinell, Renfert, Hilzingen, Germany). Following placement of a restoration, the restored tooth was covered with a fluoride solution (Elmex Fluid, GABA, Lörrach, Germany) for 60 s [27].

At initial recall (baseline), and after 0.5, 1, 2, and 4 years, all available restorations were assessed according to modified United States Public Health Service (USPHS) criteria (Tables 1 and 2) by two independent investigators using mirrors, probes, bitewing radiographs, and intraoral photographs [28]. Recall assessments were not performed by the clinician who had placed the restorations.

The statistical analysis was computed with SPSS for Windows 95/V11. The statistic unit was one ceramic restoration, differences between the groups were evaluated pair-wise with the Mann-Whitney test (level of significance 0.05).

### Results

Two patients (including four restorations) did not attend the recall examinations \( n = 4 \); drop out).

### Table 1 Features of the restorations investigated.

<table>
<thead>
<tr>
<th>Feature</th>
<th>Description</th>
<th>Analogous USPHS criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surface roughness</td>
<td>Perfect</td>
<td>‘alpha’</td>
</tr>
<tr>
<td>Color match</td>
<td>Slight deviations from ideal performance, correction possible without damage of tooth or restoration</td>
<td>‘bravo’</td>
</tr>
<tr>
<td>Marginal integrity</td>
<td>Few defects, correction impossible without damage of tooth or restoration. No negative effects expected</td>
<td>‘charlie’</td>
</tr>
<tr>
<td>Integrity tooth</td>
<td>Severe defects, prophylactic removal for prevention of severe failures</td>
<td>‘delta’</td>
</tr>
<tr>
<td>Integrity inlay</td>
<td>Immediate replacement necessary</td>
<td></td>
</tr>
<tr>
<td>Proximal contact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changes in sensitivity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complaints</td>
<td></td>
<td></td>
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<tr>
<td>Radiographic check</td>
<td></td>
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<tr>
<td>Subjective contentment</td>
<td></td>
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</tr>
</tbody>
</table>

### Table 2 Modified USPHS criteria.

<table>
<thead>
<tr>
<th>Modified criteria</th>
<th>Description</th>
<th>Analogous USPHS criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>‘excellent’</td>
<td>Perfect</td>
<td>‘alpha’</td>
</tr>
<tr>
<td>‘good’</td>
<td>Slight deviations from ideal performance, correction possible without damage of tooth or restoration</td>
<td>‘bravo’</td>
</tr>
<tr>
<td>‘sufficient’</td>
<td>Few defects, correction impossible without damage of tooth or restoration. No negative effects expected</td>
<td>‘charlie’</td>
</tr>
<tr>
<td>‘insufficient’</td>
<td>Severe defects, prophylactic removal for prevention of severe failures</td>
<td>‘delta’</td>
</tr>
<tr>
<td>‘poor’</td>
<td>Immediate replacement necessary</td>
<td></td>
</tr>
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</table>
The recall rate until the 4 years investigation was 91%. The majority \((n=27)\) of the patients were subjectively satisfied with their restorations, two patients were dissatisfied due to persisting hypersensitivity of four restorations (one luted with Variolink Low, three luted with Compolute). So altogether eight restorations could not be examined after 4 years due to failure \((n=4)\) and patient drop out \((n=4)\). Over the whole observation period, the remaining 86 investigated restorations revealed no statistically significant differences as regards. Surface roughness, color matching, proximal contact, sensitivity, complaints, radiographic check (Fig. 1) and subjective contentment (Table 3).

Comparing the data collected at the recall appointments, significant differences were found for marginal integrity. The rating 'alpha' dropped from 98% at baseline to 58% after 4 years. The main reason for the judgement 'alpha2' was initially 'composite overhang' \((95\%, \text{see Fig. 2})\) and changed over time (4-year recall) to mainly 'marginal ditching' \((59\%)\) and 'discoloration' \((16\%)\). No statistically significant differences were computed for the different luting systems \((p>0.05, \text{Mann-Whitney test, Table 3})\).

The absence of cervical enamel in proximal boxes \((n=10)\) did not have any influence on marginal performance or secondary caries of the inlays and onlays.

In relation to tooth integrity, significant differences were detected between the baseline and the 4-year recall data. After 4 years, 43% of the restored teeth showed small enamel cracks with an increase of 50% from the time of insertion of the restorations. 12% of the restored teeth suffered enamel cracks directly after insertion of the restoration (Tables 4 and 5).

The incidence of inlay fracture over time increased from 4% at baseline to 19% after 4 years, and 40% after 6 years which was mainly chipping in occlusal-proximal contact areas was observed. Accurate comparisons with clinical photographs revealed that these fractures mainly occurred in areas which had been subjected to rotary occlusal adjustment (Fig. 3).

Four inlays had to be replaced until the 4-year recall. The survival rate computed with the Kaplan-Meier algorithm was 96% after 4 years (Fig. 4).

The average dimensions measured prior to insertion have been 1.4 mm below the deepest fissure, 3.5 mm buccal-lingually at the isthmus, and 2.0 mm below reconstructed cusps of onlays. There was no statistically significant correlation between dimensions of the inlay and observed fractures \((p>0.05)\).

Discussion

The present prospective clinical split-mouth study investigated the 4-year performance of adhesively luted IPS Empress ceramic inlays and onlays. Due to the fact that clinical data concerning the clinical outcome of IPS Empress inlays and onlays have already been published \([21,29,30]\), particular attention was directed to the two different adhesive/luting composite combinations used (Syntac/Variolink Low, EBS Multi/Compolute). Therefore, a well-suited protocol of a previous prospective study was applied \([31]\). Compared to the previous study, in the course of this study any lining with conventional cements was avoided to preserve a maximum of adhesion area in dentin. Including the complete dentin surface of cavities into the whole adhesive concept is controversially discussed to be beneficial due to the larger bonding area involved \([32,33]\). Comparing the present results with an identically planned study with glass ionomer cement lining \([31]\), no clear beneficial effect of total bonding was detectable, at least until the 4 years investigation.

When indirect restorations are demanded, the cavities are often extended below the CEJ, especially when large amalgam restorations are
replaced [29]. This, furthermore, explains the importance of a durable dentin bonding behavior of luting composites mediated by dentin bonding agents. The main problem in this context is to create a tight contact of the hydrophobic resin-based luting composite to the hydrophilic dentin surface. During the last decade, mainly two adhesion approaches were discussed in the literature in the field. Self-etch adhesives seem to be favorable due to the absence of ‘wet bonding’ characteristics and prerequisites leading to potentially less technique sensitivity [34,35]. On the other hand, etch-and-rinse systems provide an effective hybridization of the demineralized dentin surface, having been repeatedly reported to be effective both in vitro and in vivo [36–38]. Both approaches to bond to dentin are characterized by micromechanical interlocking with demineralized intertubular and peritubular dentin and opened dentin tubules. Therefore, the smear layer has to be dissolved/modified (Syntac) or completely removed (EBS Multi). Nowadays, self-etching systems become stronger in the market, because problems with postoperative hypersensitivities after the etch-and-rinse procedure have been reported not only from general dental practitioners [35]. To compare the described concepts in the present investigation, some selection criteria had to be determined before the start of the treatment:

1. Positive vitality of restored tooth
2. Absence of symptoms relating to restored tooth
3. Sufficient distance from the deepest point of the cavity to the pulp (ensured by bitewings prior to treatment)
4. No pulp exposure during caries excavation
5. Split mouth design possible.

### Table 3

<table>
<thead>
<tr>
<th>Date investigation</th>
<th>Criterion</th>
<th>Baseline (n=94 in %)</th>
<th>6 Months (n=88 in %)</th>
<th>12 Months (n=87 in %)</th>
<th>24 Months (n=87 in %)</th>
<th>48 Months (n=86 in %)</th>
<th>60 Months (n=85 in %)</th>
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<tr>
<td></td>
<td></td>
<td>A1</td>
<td>A2</td>
<td>B</td>
<td>A1</td>
<td>A2</td>
<td>B</td>
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<tr>
<td></td>
<td></td>
<td>2.2 weeks</td>
<td>0.56 years</td>
<td>1.03 years</td>
<td>2.06 years</td>
<td>4.07 years</td>
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<tr>
<td>Baseline (n=94 in %)</td>
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<td>99</td>
<td>1</td>
<td>97</td>
<td>3</td>
<td>99</td>
<td>1</td>
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<tr>
<td>6 Months (n=88 in %)</td>
<td></td>
<td>96</td>
<td>4</td>
<td>96</td>
<td>4</td>
<td>96</td>
<td>4</td>
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<tr>
<td>12 Months (n=87 in %)</td>
<td></td>
<td>95</td>
<td>3</td>
<td>96</td>
<td>7</td>
<td>99</td>
<td>1</td>
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<tr>
<td>24 Months (n=87 in %)</td>
<td></td>
<td>93</td>
<td>7</td>
<td>95</td>
<td>3</td>
<td>99</td>
<td>1</td>
</tr>
<tr>
<td>48 Months (n=86 in %)</td>
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<td>92</td>
<td>1</td>
<td>99</td>
<td>3</td>
<td>96</td>
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<tr>
<td>60 Months (n=85 in %)</td>
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<td>7</td>
<td>99</td>
<td>5</td>
<td>99</td>
<td>1</td>
</tr>
<tr>
<td>Alpha 1</td>
<td></td>
<td>1</td>
<td></td>
<td>1</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Alpha 2</td>
<td></td>
<td></td>
<td>1</td>
<td>1</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Bravo</td>
<td></td>
<td></td>
<td>1</td>
<td>1</td>
<td></td>
<td>1</td>
<td></td>
</tr>
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</table>

Figure 2 IPS Empress inlays luted with Compolute after 4 years of clinical service. The upper left first premolar still reveals an overhang mesially. The second premolar exhibits typical deterioration of the occlusally loaded luting space.
### Table 4  Results of the clinical investigation of the Compolute group (Alpha 1 = excellent, Alpha 2 = good, Bravo = sufficient).

<table>
<thead>
<tr>
<th></th>
<th>Baseline ($n=50$) in%</th>
<th>6 Months ($n=47$) in%</th>
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<td>A1</td>
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<tr>
<td>Marginal integrity</td>
<td>6</td>
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<td>4</td>
<td>98</td>
<td>2</td>
</tr>
<tr>
<td>Integrity tooth</td>
<td>52</td>
<td>46</td>
<td>2</td>
<td>62</td>
<td>38</td>
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<tr>
<td>Integrity inlay</td>
<td>96</td>
<td>2</td>
<td>2</td>
<td>96</td>
<td>4</td>
</tr>
<tr>
<td>Change of sensitivity</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Hypersensitivity</td>
<td>94</td>
<td>6</td>
<td>4</td>
<td>96</td>
<td>4</td>
</tr>
<tr>
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<td>28</td>
<td>4</td>
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</table>

### Table 5  Results of the clinical investigation of the Variolink group (Alpha 1 = excellent, Alpha 2 = good, Bravo = sufficient).

<table>
<thead>
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<th></th>
<th>Baseline ($n=14$) in%</th>
<th>6 Months ($n=41$) in%</th>
<th>12 Months ($n=41$) in%</th>
<th>24 Months ($n=40$) in%</th>
<th>48 Months ($n=40$) in%</th>
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<td>100</td>
<td>100</td>
<td>2</td>
<td>96</td>
<td>6</td>
</tr>
<tr>
<td>Integrity tooth</td>
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<td>66</td>
<td>42</td>
<td>58</td>
<td>47</td>
</tr>
<tr>
<td>Integrity inlay</td>
<td>98</td>
<td>2</td>
<td>98</td>
<td>2</td>
<td>86</td>
</tr>
<tr>
<td>Change of sensitivity</td>
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<td>2</td>
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<td>100</td>
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<tr>
<td>Hypersensitivity</td>
<td>93</td>
<td>7</td>
<td>98</td>
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<td>100</td>
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<tr>
<td>Radiographic assessment</td>
<td>61</td>
<td>36</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
The results of the present study showed no difference concerning the adhesive potential of both adhesive concepts having been under investigation. In a numerical manner, the etch-and-rinse system EBS Multi resulted in more postoperative hypersensitivity, however, not being statistically significant. On the other hand, it seems to be questionable if the selective enamel etching technique (Syntac) is always correctly performable in the clinical situation. In most of the clinical cases, unintentional etching of the adjacent dentin might occur, being a risk factor for postoperative hypersensitivities, too. Due to the use of different luting composites in the course of the present study, no exact determination in terms of comparing the different bonding approaches could be carried out. Altogether, the null hypothesis of the present study was confirmed by the clinical results.

Besides the focus on adhesive performance of the different luting methodologies, characteristic observations for the involved IPS Empress ceramic were made which can be compared to the already existing knowledge in this field of operative dentistry. One major parameter for clinical success is an acceptable handling of luting composites. An important aspect in this context is overhang control [39]. Directly after placement of indirect ceramic restorations, high viscosity luting composites were reported to exhibit significantly less overhangs compared to low viscosity materials [40]. Analogously, the present study revealed clinically (up to 93%, Fig. 2) as well as radiologically (32%) detected overhangs at baseline. Due to prophylactic matters, any overhangs having been detected radiographically in proximo-cervical areas had to be removed in due course. Due to the fact that the next radiographic assessment was carried out at the end of the clinical observation period, this effect could not be documented directly after the baseline assessment (Fig. 1). These additional corrections, however, explain the improvement of the criterion 'radiographic assessment'.

Changes regarding marginal integrity were similar to previous reports in the literature [14,41]. Also the present study revealed marginal ditching for both luting composites after 4 years of clinical service ranging between 29% (rating 'alpha 2') and 40% (rating 'bravo').

Another reason for failure of adhesive restorations is an insufficient adhesive performance regarding the bond between restorative material and tooth substrates, especially adjacent enamel. In the present study, marginal fractures were not observed, this should be attributed to the twofold treatment of the internal ceramic surface by etching and silanating [2,7,42] and the adhesive luting being superior to glass ionomer cementing [43]. However, clinical evaluations alone may be insufficiently accurate for detecting differences of the small luting space [44]. This particular point will be part of a separate investigation concerning semiquantitative evaluation of luting gap wear (in preparation).

The tendency to fracture is one of the major problems of ceramic inlays [24]. In the present study, the fractures and cracks significantly increased from baseline to the 1 year assessment ('integrity inlay' alpha 1: baseline 97%, 1 year 86%, and 4 years 80%, Fig. 3). These findings are comparable to other studies with leucite-reinforced ceramic IPS Empress [5,13]. Analyzing clinical photographs revealed that in each case of chipping, rotary occlusal adjustments had been performed potentially weakening the ceramic [45,46]. Over the 4 years period, five inlays suffered chipping fractures, especially at proximal ridges (rating 'bravo'). The thickness of the inlays did apparently not influence these findings.

![Figure 3](typical_chipping_of_an_ips_empress_inlay_after_4_years_in_the_area_of_the_lateral_ridge_14_mesial_the_marked_contact_points_showing_the_occlusal_load_distribution.png)

![Figure 4](survival_analysis_kaplan_meier_algorithm.png)

**Figure 3** Typical chipping of an IPS Empress inlay after 4 years in the area of the lateral ridge (14 mesial). The marked contact points showed the occlusal load distribution.

**Figure 4** Survival analysis (Kaplan-Meier algorithm).
Conclusions

Totally bonded IPS Empress restorations revealed a 4% failure rate after 4 years of clinical service. Between the bonding/luting systems no difference was observed.

Acknowledgements

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References


