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A practice-based research network on the survival of ceramic inlay/onlay restorations

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ABSTRACT

Objective. To evaluate prospectively the longevity of ceramic inlay/onlay restorations placed in a web-based practice-based research network and to investigate risk factors associated with restoration failures.

Materials and methods. Data were collected by a practice-based research network called Ceramic Success Analysis (CSA). 5791 inlay/onlay ceramic restorations were placed in 5523 patients by 167 dentists between 1994 and 2014 in their dental practices. For each restoration specific information related to the tooth, procedures and materials used were recorded. Annual failure rates (AFRs) were calculated and variables associated with failure were assessed by a multivariate Cox-regression analysis with shared frailty.

Results. The mean observation time was 3 years (maximum 15 years) of clinical service, and AFRs at 3 and 10 years follow up were calculated as 1.0% and 1.6%. Restorations with cervical outline in dentin showed a 78% higher risk for failure compared to restorations with margins in enamel. The presence of a liner or base of glass-ionomer cement resulted in a risk for failure twice as large as that of restorations without liner or base material. Restorations performed with simplified adhesive systems (2-step etch-and-rinse and 1-step self-etch) presented a risk of failure 142% higher than restorations performed with adhesives with bonding resin as a separate step (3-step etch-and-rinse and 2-step self-etch). 220 failures were recorded and the most predominant reason for failure was fracture of the restoration or tooth (44.5%).

Conclusions. Ceramic inlay/onlay restorations made from several glass ceramic materials and applied by a large number of dentists showed a good survival. Deep cervical cavity outline, presence of a glass ionomer lining cement, and use of simplified adhesive systems were risk factors for survival.

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1. Introduction

Restorative work is the core business of dentistry. It is estimated that every year 500 million dental direct restorations are placed worldwide [1], of which most are composite resin restorations [2]. Restorations are placed due to caries, fractures, or tooth wear, and a high number of restorative procedures is indicated to replace restorations that have failed [3,4]. As an alternative for direct restorations, indirect restorations may be placed using metal, composite, and/or ceramic restorative materials. Indirect inlay/onlay restorations provide more control over shape and function, particularly in larger defects in posterior teeth. Due to increased esthetic demands by patients, it is likely that most indirect restorations are currently made from ceramic materials.

Indirect ceramic restorations can be made either by a dental technician in the laboratory or by using CAD/CAM systems to make chairside restorations in a single session. Longevity reports vary between 0 and 7.5% annual failure rate (AFR) for ceramic inlays/onlays [5], while for chairside fabricated restorations (in this case the CEREC® system) this is between 0.8% and 4.8% AFR [6]. Indirect ceramic restorations have shown comparable or slightly better clinical performance than direct composite restorations, especially when taking into account the fact that indirect restorations are generally larger [5,7].

The procedure of placing indirect inlay/onlay restorations includes many steps and a wide variation of ceramic materials and luting cements can be used. Some factors related to the materials, such as ceramic properties or characteristics of the adhesive luting technique, have been investigated extensively *in vitro* [8–10]. Clinical studies with limited sample size also have shown the influence of factors related to patients and operators on the clinical outcome of ceramic inlays/onlays [11–14]. However, there is a lack of clinical studies analysing the combined role of different risk factors on restoration longevity and performance, where each factor might be compensating for another. For such study design, a large sample size is mandatory, which is usually hard to achieve in randomized controlled trials (RCTs).

While RCTs allow us to investigate differences between therapies or materials under ideal circumstances, the general dental practitioner is also interested in the outcome of a therapy under ‘real world’ conditions, i.e. where restoration, patient and practice level factors together influence the results. The sheer number of variables involved in a general practice setting requires a very large number of restorations in a dataset, in order to support a multivariate statistical approach [15–17]. The possibilities of digital data collection offer new opportunities in this respect. In Germany, the initiative was taken in 1994 to start with a longevity survey on indirect ceramic inlay/onlay restorations, mainly using the CEREC system. Since 2008 available as an online platform, dentists can join this group with a certain amount of restorations for which data are uploaded on a website. This resulted in a large data set with information on inlay/onlay restorations placed routinely by dental practitioners and followed up for several years.

The aim of this study was to evaluate prospectively the longevity of ceramic inlay/onlay restorations placed in a web-based practice-based research network and to investigate risk factors associated with restoration failures.

2. Materials and methods

2.1. Practice-based research network

Data for this study were collected by a practice-based research network called Ceramic Success Analysis (CSA). Starting in 1994, the Society for Dental Ceramics (SDC) in Germany invited dentists to make specific recordings on all single ceramic restorations (inlays, onlays, and crowns) that were placed in their dental practices, including CAD-CAM chairside fabricated restorations and restorations manufactured by dental laboratories. In general, dentists who were enrolled in specific continuing education or training courses, especially on CAD-CAM restorations, were invited to join the network and introduce data from their restorations into the database. For becoming a member of the CSA project, each dentist was required to accept security and data protection conditions and had to follow protocols to include cases into the system. Between 1994 and 2007, the dentists used a Microsoft Access programmed databank and sent the data regularly via disc to the SDC. From 2008 onward, data collection was carried out via an internet platform (www.csa-online.net) in several languages, allowing dentists from other countries also to join the network. In total, 167 dentists from six countries (161 from Germany, 2 from Chile, 1 from China, 1 from Spain, 1 from France, and 1 from USA), uploaded data until 2014 on almost 6000 inlay/onlay restorations. Information on operator experience was not collected on this study.

2.2. Data recording

Originally, each professional could initially take part of the study with 50 cases, with a limit of one restoration per patient. Recently, including more than one restoration per patient into the dataset has been made possible. For all restorations recorded data included information such as date of treatment, type of restoration, surfaces included in the preparation, and materials used. Follow up was documented during regular check-up visits in the practice or when a problem occurred. Therefore, this study was a non-interventional trial, which according to guidelines for good clinical practice (Clinical trials – Directive 2001/20/EC), was not subject to Medical Ethical Committee approval. Patient and operator characteristics were analyzed anonymously according to privacy legislation. Dentists placed the restorations using the protocol they considered appropriate for each case with informed consent of the patient. The choice for specific materials, brands, and techniques was at the discretion of the operators.

2.3. Data analysis

The variables that were recorded by the dentists are listed in Table 1 (variables related to teeth and restorative procedures) and Table 2 (variables related to materials used). Both

Table 1 – Distribution of ceramic inlay/onlay restorations according to tooth/restoration variables (N = 5791).

| Variable | Description | Outcome | N | % |
|-----------------------------|---|----------------------|----------------------------------|------|
| Tooth | Type of restored tooth | Molar | 3793 | 65.5 |
| | | Premolar | 1998 | 34.5 |
| Number of restored surfaces | Number of tooth surfaces included in the restoration | 1 | 205 | 3.5 |
| | | 2 | 1359 | 23.5 |
| | | 3 | 2256 | 39.0 |
| | | >4 | 1971 | 34.0 |
| | | Endodontic treatment | Presence of endodontic treatment | Yes |
| Cavity outline | Cervical margins of restoration | Enamel | 3162 | 54.6 |
| | | Dentin | 2629 | 45.4 |
| | | Use of liner or base | Liner or base material | None |
| Rubber dam | Use of rubber dam during cementation | Glass-ionomer | 410 | 7.1 |
| | | Composite | 344 | 5.9 |
| | | Others | 181 | 3.1 |
| | | Yes | 3732 | 64.4 |
| Matrix | Matrix used during cementation | Yes | 3147 | 54.3 |
| Silane | Silane applied to ceramic | Yes | 5542 | 95.7 |
| Ultrasonic cementation | Use of ultrasonic device for cementation | Yes | 3420 | 59.1 |
| Dental flossing | Use of dental floss to remove excess luting agent | Yes | 3603 | 62.2 |
| Oxygen-blocking | Use of oxygen-blocking gel before cement photoactivation | Yes | 2412 | 41.7 |
| Eva instrument | Use of Eva oscillating instrument for finishing interproximal or cervical restoration areas | Yes | 575 | 9.9 |

tables show description of the variable, categorization (when applied), and distribution of inlays/onlays in different variable groups. For adhesives, resin-based luting agents, and ceramics used in the restorative procedure, the dentist recorded the name and brand of products. For the analysis, each material was categorized (Table 2) according to ceramic type, ceramic processing technique, adhesive system, and polymerization characteristic of resin-based luting agents. All restorations with missing data for variables (except for patient age) were excluded from the analysis.

During the observation period, patients attended the same dental practice and maintained routine visits according to their dental treatment needs, without visiting other dentists during the period. In the check-up visits, or when a problem occurred, the restorations were inspected by the dentist in the practice, usually the same person that placed the restoration. When a dentist considered the restoration as clinically unacceptable, i.e. needing intervention, it was considered a failure and date and reason for failure were recorded. As only some dentists also recorded the type of intervention for failed restorations, this information was not included in the study. The date of the last check-up visit was recorded as the censoring date for restorations still in place without failure.

Statistical analyses were performed using STATA 12 software package (StataCorp LP; College Station, TX, USA). Descriptive statistics was used to report the frequency distribution of restorations by independent variables and reasons for failure. Annual failure rates (AFRs) were calculated from life tables according to the formula: $(1 - y)^z = (1 - x)$, in which "y" expresses the mean AFR and "x" the total failure rate at "z" years. The proportional-hazards test was assessed for each variable. Variables associated with failure were assessed by a multivariate Cox-regression analysis with shared frailty, taking into account that observations within the same group (dentist) are correlated, sharing the same frailty. Hazard ratios (HRs) with respective 95% confidence intervals (CIs) were

determined. A significance level of 5% was considered for all analyses.

3. Results

In total, 5791 inlay/onlay restorations placed in 5523 patients by 167 dentists were introduced into the database. The observation time of the restorations varied from one day to 15 years of clinical service, with a mean observation time of 3 years (median 1.8 years). The calculated AFRs at 3, 5, and 10 years of follow up were 1.0%, 1.1%, and 1.6%. A total of 192 restorations were excluded from the analysis due to missing information in some variables. As shown in Tables 1 and 2, most inlays/onlays included in the study were monolithic restorations (98.2%) prepared with feldspathic porcelain (77.3%), placed in molars (65.5%) and involving more than three tooth surfaces (73.0%).

Table 3 shows the results of the multivariate Cox-regression models analysis. The adjusted analysis revealed that restorations with cervical outline in dentin (AFR 1.9% over 10 years) showed a 78% higher risk for failure compared to restorations with margins in enamel (AFR 1.3% over 10 years), as shown in Fig. 1. The presence of a liner or base of glass-ionomer cement resulted in a risk for failure twice as large as that of restorations without liner or base material. Restorations performed with simplified adhesive systems (2-step etch-and-rinse and 1-step self-etch) presented a risk of failure 142% higher than restorations performed with adhesives with bonding resin as a separate step (3-step etch-and-rinse and 2-step self-etch), as shown in Fig. 2. Tooth type, number of surfaces involved in the restoration, presence of endodontic treatment, and several other variables related to procedure did not significantly influence restoration failure. The likelihood-ratio test on the model showed a significant frailty effect ($p < 0.001$), meaning that there is a significant clustering of failures within dentists. The variable 'luting material' was not included in the adjusted model since it violated the proportional hazard assumption.

Table 2 – Distribution of ceramic inlay/onlay restorations according to materials variables (N = 5791).

| Variable | Materials used | Outcome | N | % |
|--------------------------|---|--|------|------|
| Ceramic | FP: CEREC Block C In (Sirona); VITABLOCS® TriLuxe forte, VITABLOCS® RealLife, VITABLOCS® TriLuxe, VITABLOCS® Mark II (VITA) LEU: HeraCeram, HeraCeramSun (Heraeus); IPS Empress CAD, IPS Empress Esthetic, ProCAD (Ivoclar); OPC press (Jeneric Pentron); Imagine PressX (Wieland) LD: IPS e.max CAD, IPS Empress, IPS e.max Press (Ivoclar) | <i>Ceramic type</i> | | |
| | | Feldspathic porcelain (FP) | 4475 | 77.3 |
| | | Leucite glass-ceramic (LEU) | 1076 | 18.6 |
| | | Lithium disilicate glass-ceramic (LD) | 240 | 4.1 |
| | | <i>Processing technique</i> | | |
| | | Monolithic restoration | 5689 | 98.2 |
| | | Veneered restoration | 102 | 1.8 |
| Adhesive | <i>Separate:</i> Xeno III (Dentsply); AdheSE DC, Syntac Classic; Multilink Automix system (Ivoclar); Clearfil SE Bond; Panavia F2.0 system (Kuraray); Contax Bond, LuxaBond (DMG); OptiBond FL (Kerr); Adper™ Scotchbond™ MP (3M ESPE) <i>Simplified:</i> One-Step Plus (Bisco); A.R.T. Bond (Coltene); Adhesive (Cumdente); Adper Scotchbond 1 XT, Pertac Universal Bond, Adper™ Prompt™, Scotchbond™ Universal Adhesive (3M ESPE); CharmBond (DentKist); Prime & Bond 2.1, Prime&Bond NT, XP Bond (Dentsply), ExcITE F (Ivoclar); Futurabond DC (Voco); G-BOND (GC); GLUMA® 2 Bond, I-BOND Total Etch (Heraeus); OptiBond Solo Plus (Kerr); Permaflow DC (Ultradent); VITA A.R.T. Bond (Vita) | <i>Use of separate bonding resin</i> | | |
| | | Separate bonding resin (3-step total-etch or 2-step self-etch adhesives) | 4711 | 81.4 |
| | | Simplified adhesive (2-step total-etch or 1-step self-etch adhesives) | 845 | 14.6 |
| | | Other ^a | 235 | 4.1 |
| Resin-based luting agent | <i>Photoactivated:</i> Adaptic LC (Johnson & Johnson); ApaFill, ApaFlow (Cumdente); Brilliant NG, Synergy Nano Formula (Coltene); Ceram X, SpectrumTPH, X-flow (Dentsply); Charisma, Charisma flow, Durafill VS, Venus Composite (Heraeus Kulzer); Enamel plus HFO (Mycerium); Palfique Estelite LV (Tokuyama); Filtek Supreme, Filtek Supreme XT, Filtek Z100 MP, Filtek Z250 MP, Filtek Z500 (3M ESPE); Pertac (ESPE); Gradia Direct X, Gradia® Direct LoFlo (GC); Herculite XRV, Prodigy, Point 4 (Kerr); Grandio (Voco); Tetric Ceram HB, Tetric EvoCeram, Tetric Evoflow, Heliomolar (Ivoclar) <i>Dual-cured:</i> Bifix QM, Bifix SE (Voco); BisCem, Duo-link Universal (Bisco); Calibra, SmartCem2 (Dentsply); PermaCem Dual Smartmix, Vitique (DMG); Clearfil SA, Clearfil Esthetic Cement EX, Panavia F2.0 (Kuraray); Dual Cement, Multilink Automix, Multilink Sprint, SpeedCEM, Variolink II, Variolink Ultra, Variolink Veneer (Ivoclar); Duo Cement Plus, Duo Cement Plus (Coltene); Fantestic Core DC (R-dental); G-CEM (GC); iCEM Self Adhesive, Twinlook, (Heraeus Kulzer); Maxcem Elite, Nexus 2, NX3 Nexus, Porcelite Dual Cure, (Kerr); RelyX Unicem, RelyX Ultimate, RelyX ARC, 3M Opal (3M ESPE); PermaFlo DC (Ultradent); SonoCem (ESPE); Duo Cement (Vita) | <i>Polymerization mode</i> | | |
| | | Photoactivated luting agent | 3430 | 59.2 |
| | | Dual-cured luting agent | 2361 | 40.8 |

^a Combination of 195 restorations with no specified materials and 40 restorations luted with self-adhesive resin-based luting agents.

Table 4 shows the distribution of reasons for failure of the restorations. The predominant causes of failure were fracture of restoration or tooth (44.5%) and endodontic complications (16.4%). An increasing relative number of failures were observed over time.

4. Discussion

The present practice-based study evaluating the longevity of ceramic inlays and onlays has a unique design, as practitioners from different parts of the world (here most practitioners were working in Germany) uploaded detailed information about restorative treatments and follow up visits onto a website. Therefore, besides discussing the outcomes regarding longevity and risk factors for restoration survival, also the

design in itself has to be evaluated and its advantages and disadvantages have to be addressed.

RCTs are generally considered the most reliable type of clinical research but have disadvantages for evaluating dental restorations, such as biases related to inclusion criteria and performance. RCTs also generate considerable costs, limiting the number of restorations that can be included in the sample. Although a practice-based setting demands a very high sample size, due to the higher treatment variability, this setting usually provides more options for inclusion. Different possibilities for bias make part of practice-based studies. In the present design, for instance, restorations were evaluated by the dentists themselves, not by independent evaluators, resulting in evaluation bias. In addition, restorations were considered clinically acceptable or not during follow ups based on the clinical judgment of the dentists instead of calibrated

Table 3 – Cox-regression analyses on factors related to failure of ceramic inlay/onlay restorations. (Multivariate adjusted analysis includes a shared frailty^a).

| Variable | Crude | | Adjusted | |
|---|------------------|---------|------------------|---------|
| | HR (95% CI) | p-Value | HR (95% CI) | p-Value |
| Tooth (ref = molar) | | 0.310 | | 0.512 |
| Premolar | 0.86 (0.65–1.15) | | 0.91 (0.67–1.22) | |
| Number of restored surfaces (ref = 1) | | 0.179 | | 0.149 |
| 2 | 1.03 (0.47–2.27) | | 1.18 (0.52–2.68) | |
| 3 | 1.47 (0.68–3.17) | | 1.56 (0.70–3.51) | |
| >4 | 1.21 (0.55–2.65) | | 1.12 (0.49–2.55) | |
| Endodontic treatment (ref = no) | | 0.053 | | 0.068 |
| Yes | 1.61 (1.03–2.53) | | 1.54 (0.97–2.45) | |
| Cavity outline (ref = enamel) | | <0.001 | | <0.001 |
| Dentin | 1.79 (1.37–2.33) | | 1.78 (1.31–2.42) | |
| Rubber dam (ref = yes) | | <0.001 | | 0.061 |
| No | 1.67 (1.28–2.19) | | 1.40 (0.98–1.99) | |
| Use of liner (ref = none) | | 0.038 | | 0.014 |
| Glass-ionomer | 1.93 (1.08–3.44) | | 2.05 (1.13–3.70) | |
| Composite | 0.67 (0.41–1.08) | | 0.64 (0.39–1.05) | |
| Others | 1.50 (0.66–3.40) | | 1.75 (0.76–4.01) | |
| Matrix (ref = yes) | | 0.630 | | 0.997 |
| No | 1.07 (0.82–1.40) | | 1.00 (0.56–1.80) | |
| Silane (ref = yes) | | 0.002 | | 0.179 |
| No | 2.10 (1.31–3.36) | | 1.53 (0.82–2.85) | |
| Ultrasonic cementation (ref = yes) | | 0.511 | | 0.467 |
| No | 1.09 (0.84–1.43) | | 0.87 (0.60–1.26) | |
| Dental flossing (ref = yes) | | 0.273 | | 0.366 |
| No | 0.86 (0.65–1.13) | | 0.75 (0.41–1.39) | |
| Oxygen-blocking (ref = yes) | | 0.185 | | 0.137 |
| No | 1.21 (0.91–1.59) | | 1.33 (0.91–1.93) | |
| Eva instrument (ref = yes) | | 0.025 | | 0.078 |
| No | 0.53 (0.30–0.92) | | 0.54 (0.27–1.07) | |
| Ceramic type (ref = feldspathic porcelain) | | 0.486 | | 0.288 |
| Leucite glass-ceramic | 0.86 (0.58–1.28) | | 0.66 (0.39–1.11) | |
| Lithium disilicate glass-ceramic | 1.45 (0.63–3.30) | | 0.87 (0.30–2.48) | |
| Ceramic processing (ref = monolithic) | | 0.063 | | 0.241 |
| Veneered | 2.98 (0.94–9.40) | | 2.15 (0.60–7.69) | |
| Adhesive type (ref = separate bonding resin) | | <0.001 | | 0.002 |
| Simplified adhesive | 2.17 (1.58–2.99) | | 2.42 (1.49–3.91) | |
| Other | 1.53 (0.88–2.66) | | 1.23 (0.59–2.55) | |
| Luting material^b (ref = photoactivated) | | 0.750 | | |
| Dual-cured | 0.95 (0.71–1.28) | | | |

^a Theta value = 0.45 and likelihood-ratio test ≤ 0.001 .

^b Not included in the final model. Test of proportional-hazards ($p \leq 0.05$).

independent evaluators using well-defined criteria. Therefore, the actual number of failed restorations might be a little higher or lower in reality: higher if dentists did not succeed in uploading follow up data or evaluated their own restorations as better than they were in reality; lower if the dentist overestimates failures, resulting in a larger number of interventions. The method of prospectively following up a large set of restorations and evaluation being performed by the treating dentist has been used in other practice-based studies [18,15,19,20].

Due to a lack of calibration, as it happens daily in dental clinical practice, the criteria for clinical failure may have varied between dentists. While the inclusion of hundreds of dentists increase significantly the sample size, it becomes unfeasible to standardize the assessment of restorations. In order to reduce the influence of this variation, a Cox shared-frailty model was used. In this study, a significant frailty effect was found, meaning that the correlation of results within each dentist could not be ignored. In the final model, all results were adjusted by this

operator effect, thus it is justified to conclude that the reported risk factors are independent of operator performance. The same situation could arise for multiple restorations placed in the same patient. However, as most patients had only one restoration placed, such a precaution was not necessary.

The dentists in this study were invited, mainly in specific continuing education or training courses, to join the database with their data on restorations and therefore, this might have resulted in a selection of more motivated dentists. In addition, even with the inclusion of dentist from different parts of the world, more than 95% of them are from Germany. Therefore, these selection limitations have a possible influence on the final results and also do not permit extrapolating the results to worldwide situations. The dentists recorded a large number of variables on restoration and tooth level. However, in the first years after CSA was launched, the professionals often did not include patient variables such as age, gender, caries risk, and bruxism. For the age variable for example, there

Table 4 – Reasons for failure of ceramic inlay/onlay restorations during up to 15 years of follow up.

| Period (years) | Number of restorations | Reasons for failure | | | | | | | | | | Total | Failure (%) |
|----------------|------------------------|----------------------------|-------------------------|----------|-------------|--------------------------|---------------|----------------|-----|--|--|-------|-------------|
| | | Ceramic or tooth fractures | Endodontic complication | Caries | Sensitivity | Periodontal complication | Other reasons | No information | | | | | |
| 0-2 | 5791 | 44 | 19 | 1 | 6 | 2 | 7 | 6 | 85 | | | | 1.47% |
| 2-4 | 2720 | 17 | 6 | 3 | 0 | 0 | 5 | 8 | 39 | | | | 1.43% |
| 4-6 | 1492 | 16 | 6 | 2 | 1 | 0 | 5 | 7 | 37 | | | | 2.48% |
| 6-8 | 911 | 12 | 4 | 1 | 0 | 2 | 5 | 1 | 25 | | | | 2.74% |
| 8-10 | 541 | 5 | 0 | 6 | 0 | 2 | 1 | 6 | 20 | | | | 3.70% |
| 10-15 | 307 | 4 | 1 | 5 | 0 | 0 | 2 | 2 | 14 | | | | 4.56% |
| | Total (%) | 98 (44.5) | 36 (16.4) | 18 (8.2) | 7 (3.2) | 6 (2.7) | 27 (12.3) | 30 (13.6) | 220 | | | | |

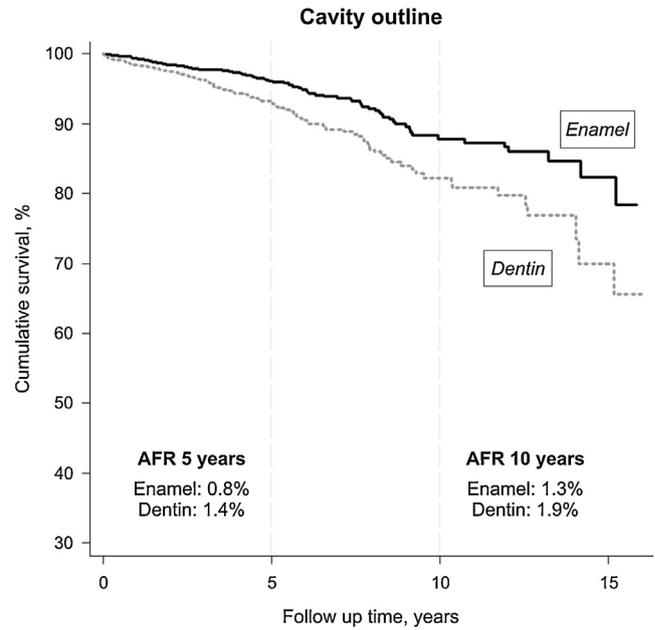


Fig. 1 – Kaplan-Meier survival curves according to cavity outline with annual failure rates (AFRs) for 5 and 10 years of observation.

was missing information in more than 25% of sample, usually involving restorations placed in the first years of study. This omission may reflect the general belief at the time CSA was initiated that restoration survival is mainly dependent on material properties and application techniques. Nowadays it is recognized that factors related to the dentist and particularly the patient (like bruxism and caries risk) have a major influence on restoration survival [21-23]. On this study, the authors expect that most of patients had a high socioeconomic level and good oral hygiene since most of them were

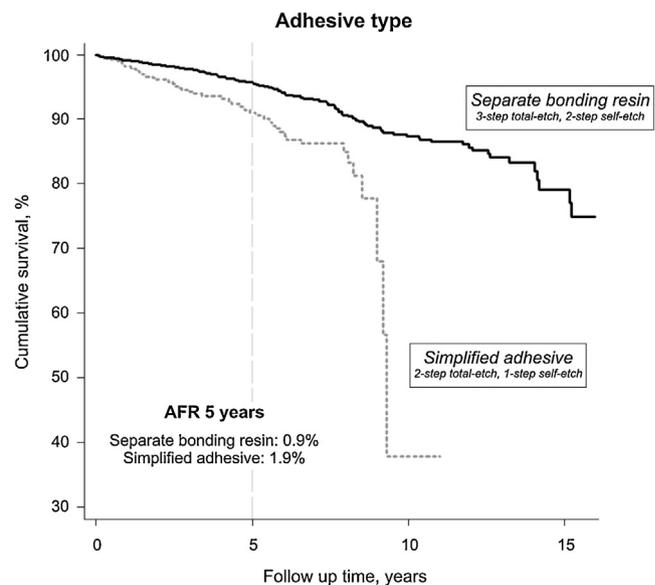


Fig. 2 – Kaplan-Meier survival curves according to adhesive type used with annual failure rates (AFR) for 5 years of observation.

treated in private practice by well-motivated dentist. However, for a future practice-based study design, it is recommended to include these patient-related factors as much as possible when evaluating all types of restorations.

The main finding of the present study is that ceramic inlay/onlay restorations, placed by general practitioners, have good survival rates, which are comparable with other prospective studies on ceramic restorations [24,25,7]. Several risk factors were identified to play a role in the survival of ceramic inlays/onlays. Some variables showed significance in the univariate analysis, but this significance disappeared in the final model due to confounding factors. An example for this is the use of rubber dam when placing the restorations, which was highly significant in the first model but not in the final multivariate model. An explanation may be that restorations with cervical margins in enamel have better survival compared to restorations ending in dentin below the cement–enamel junction (CEJ), for which use of rubber dam is difficult during cementation. Therefore, deep restorations may have been more often placed without rubber dam. Another possibility that cannot be ruled out is the choice of dentist for specific techniques.

In the final model, three risk factors were identified as being of statistical significance: position of restoration cervical outline, use of a glass-ionomer liner, and type of adhesive. The position of the outline below or above CEJ was already discussed and is an obvious risk factor in clinical survival, also found in a study on direct composite and amalgam restorations [26]. This findings may be related to the more reliable bond to enamel compared to dentin, but also to the plain fact that restorations ending below the CEJ are generally larger, teeth are more compromised in terms of tooth substance loss, and restorations are more subject to unfavorable loading.

The use of a glass-ionomer cement lining resulted in a significantly higher risk for failure. This finding is in accordance with another study on ceramic inlays [27] and with a study on posterior composites placed with or without liner [28]. In contrast, a recent meta-analysis [16] and another study on posterior composites [22] were not conclusive on this subject. On one hand, it seems that the less mechanically strong glass-ionomer liner may contribute to more deterioration of the interface and promote fracture, especially considering the very high elastic modulus of the ceramic restorations. On the other hand, the placement of such a liner may also indicate that cavities were more close to the pulp, a variable not recorded nor included in this analysis. Thus, interpretation of this finding should be done with caution.

The use of the so-called gold-standard adhesives (3-step etch and rinse and two step self-etch) resulted in a better ceramic restoration outcome compared to more simplified adhesives. This is in accordance with a clinical study that evaluated the long-term durability of posterior ceramic coverages [29] and a systematic review evaluating retention rates of class-V restorations placed in non-carious cervical lesions [30]. For the analysis, we pooled adhesive systems according to the use or not of a separate bonding resin. This may be a limitation in the interpretation of results, but the above mentioned studies applied the same method for classifying the adhesives. The outcome of the present clinical study therefore confirms that also for Class II inlay/onlay restorations

gold-standard adhesives seem to be preferred. Explanation for this finding is that the hydrophobic layer of gold-standard adhesives increases the stability of the bonds to dental tissues.

The susceptibility to fracture still seems to be the main problem in ceramic restorations failure. As with the present study, most clinical studies evaluating ceramic restorations have shown ceramic and tooth fracture as the predominant reason for failure [27,31,13]. Except limited fracture toughness of the applied ceramic materials a possible explanation for this high frequency of fracture can also be insufficient bonding as the type of adhesive is a risk factor for failure. The low number of failures due to secondary caries founded is also expected for ceramic restorations and may be partially due to the fact that these restorations are often made in motivated patients with a low caries risk. However, it is interesting to emphasize that after 8 years of observation time secondary caries became the predominant reason for failure, which may indicate that deterioration of the cement and adhesive layer after many years of service and cyclic loading may result in a secondary caries wall lesion [26].

Several recorded variables that were expected to be related to restoration success did not lead to significant differences in outcomes. The type of ceramic material (feldspathic porcelain, lithium disilicate or leucite-reinforced ceramic) was not of influence within the present design, as in general all materials performed well. Most of the inlay/onlay restorations were made according to CAD-CAM concept, particularly the CEREC system, that also in other studies showed good clinical survival [32–34], which is in line with indirect placed ceramic restorations. Veneered restorations, which in *in vitro* studies are generally linked with lower mechanical strength, had similar clinical performance to bulk, non-veneered restorations. This finding is probably related to the limited size of inlay/onlay restorations; the mechanical stresses did not build up in the veneered porcelain to the same extent they would in complete crowns. In addition, the mechanical problems in veneered restorations usually arise from the use of very dissimilar ceramic materials (e.g. zirconia and porcelain), which is not the case here.

In the present study also the cement type (dual cured or chemically cured) as well as several technical details in the procedure were not relevant for the outcome. It may well be that all these details in the clinical protocol, as they are so often investigated *in vitro* resulting in certain levels of microleakage and marginal adaptation, have limited relevance for the clinical practice. However, for investigating clinically material and technique influences in a better way, it would be good to limit the amount of material variables in such a dataset by offering the dentist a limited choice of possible materials. The amount of applied materials in this study show the enormous diversity we have in available materials of which the necessity can be doubted. On the other hand, the authors would advise to pay more attention to patient related variables in future study designs.

5. Conclusion

Within the limitations of this practice-based study, it can be concluded that ceramic inlay/onlay restorations made from

several glass ceramic materials and applied by a large number of dentists have a good survival with AFR of 1% up to 15 years of observation time. The risk factors for survival were deep cervical cavity outline, presence of a glass ionomer lining cement, and use of simplified adhesive systems.

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