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ORIGINAL ARTICLE

Polymer-infiltrated ceramic CAD/CAM inlays and partial coverage restorations: 3-year results of a prospective clinical study over 5 years

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Abstract

Objective The aim of this prospective clinical 5-year study was to evaluate the long-term behavior of monolithic computer-aided design and computer-aided manufacturing (CAD/CAM)-fabricated minimally invasive polymer-infiltrated ceramic network (PICN) inlays and partial coverage restorations (PCR).
Material and methods Posterior teeth of 47 patients were restored with 103 restorations (45 inlays, 58 PCRs). After defect-oriented preparations, monolithic PICN restorations of VITA Enamic were fabricated with a CAD/CAM system (inEoS blue/CEREC inLab MCXL) and adhesively bonded (Variolink II). Clinical reevaluations were so far performed at baseline and 6, 12, 24, and 36 months after insertion according to modified United States Public Health Service (USPHS) criteria. Absolute failures were demonstrated by Kaplan-Meier survival rate and relative failures by Kaplan-Meier success rate. A logistic regression model was adjusted for modified USPHS criteria to investigate time and restoration effects ($p < 0.05$).
Results After an observation time of 3 years, survival rates were 97.4% for inlays and 95.6% for PCRs. Three restorations had to be replaced due to clinically unacceptable fractures. Secondary caries and debonding were not observed. The 3-year Kaplan-Meier success rate was 84.8% for inlays and 82.4% for PCRs. The decrease in marginal adaption ($p = 0.0005$), increase in marginal discoloration ($p < 0.0001$), and surface roughness ($p = 0.0005$) over time were significant. Color match and anatomic form were excellent. No significant differences were found between both types of restorations for survival ($p = 0.716$) and success rate ($p = 0.431$).
Conclusions Minimally invasive PICN restorations showed a favorable clinical performance over an observation period of 36 months. However, clinical long-term data have to be awaited.
Clinical relevance PICN restorations are a suitable treatment option for posterior inlays and PCRs.

Keywords Dental ceramics · Polymer-infiltrated ceramic · PICN · CAD/CAM material · Clinical trial · Survival · Longevity

Introduction

In 1985, the first computer-aided design and computer-aided manufacturing (CAD/CAM) system was developed to provide patients with esthetic and long-lasting reliable prosthetic restorations in one single treatment session. At that time, mainly CAD/CAM feldspar blocks were used to restore patients [1]. Nowadays, clinicians are able to choose out of a wide variety of different esthetic, natural-looking, and tooth-colored materials for minimally invasive dentistry. Until now, this indication has been mostly covered by high-performance composites or glass ceramics. New treatment modalities opened up with the commercial launch of innovative CAD/CAM resin-matrix ceramics, which combine the

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positive material properties of both composites and ceramics [2, 3].

According to their chemical composition and polymerization mode, resin-matrix ceramics or hybrid materials may be further subdivided into HT (high temperature) polymerized CAD/CAM resin composites with dispersed fillers and a predominately organic phase and HT/HP (high temperature/high pressure) polymerized polymer-infiltrated ceramic network (PICN) materials, with a predominately inorganic phase [4]. The flexural strength of resin-matrix materials ranges between feldspar and leucite-reinforced ceramics. In vitro studies measured flexural strengths of 150–240 MPa for resin-matrix ceramics [2, 3, 5, 6]. The high amount of polymer fillers and low brittleness enable the machinability of thin restoration margins for minimal invasive dentistry [3, 7].

The PICN material VITA Enamic (VITA Zahnfabrik, Bad Säckingen, Germany) is composed of a ceramic network infiltrated by a polymer mixture (TEGDMA and UDMA) and was developed to mimic the biomechanical properties of natural teeth [2]. The elastic modulus of Enamic (30–32 GPa) is much lower than most all-ceramic materials and resembles dental hard tissues [8]. Furthermore, the material exhibits an increased resistance to crack initiation and growth, due to the low modulus of elasticity and its hardness [8, 9], and reveals a higher damage tolerance to bur adjustments [10, 11].

Nearly all resin-matrix ceramics cover the same indication of single-tooth restorations, such as veneers, inlays, onlays, crowns, and implant crowns.

Minimally invasive glass-ceramic inlays and partial coverage restorations (PCR) are widely used as a reliable alternative to direct fillings, especially in larger carious and restorative defects [12, 13]. The long-term success of CAD/CAM feldspathic and lithium disilicate ceramics for inlays and overlay restorations is scientifically well documented in the dental literature [13–16].

However, there are currently no controlled clinical studies available, which describe the long-term performance of polymer-infiltrated ceramics. So far, only a few case series are retrievable on PubMed [17, 18]. Just recently, 2-year results of a clinical study on Lava Ultimate (3M Espe, Neuss, Germany) partial crowns were published [19].

To the authors' knowledge, this is the first prospective investigation that reports on the clinical performance of polymer-infiltrated ceramics. Therefore, the aim of this prospective clinical study over 5 years was to evaluate the survival rate and clinical behavior of CAD/CAM minimally invasive posterior PICN inlays and partial coverage restorations. The present data describes the follow-up period of up to 36 months after insertion.

Material and methods

Study group

This prospective clinical trial included 47 patients, which were provided with 103 minimally invasive restorations in the posterior region. Patients with carious lesions, insufficient fillings, or inlay restorations were recruited form the patient collective of the Department of Prosthodontics of the University Hospital Freiburg and treated by clinicians experienced with all-ceramic CAD/CAM restorations. The patient cohort was assigned in two study groups according to their defect extension (58 PCR restorations and 45 inlays). The inclusion criteria were as follows: adult patients (age > 18) with at least one or more vital abutment teeth or a sufficient endodontic treatment (all endodontically treated teeth (ETT) were later restored with PCRs), good oral hygiene and periodontal health (probing depth < 4 mm, and tooth mobility and furcation involvement < degree II) (Fig. 1a). Patients with parafunction (e.g., bruxism), alcohol or drug abuse, or life-threatening diseases (American Society of Anesthesiologist classification) [20] were excluded from the study. Possible parafunctions were diagnosed via a comprehensive clinical functional analysis, which included palpation of muscles, registration of jaw mobility, movement pain, and auscultation of noises in the temporomandibular joint (TMJ).

The prospective clinical therapy study was conducted according to the Declaration of Helsinki for clinical trials and was inspected and approved by the local ethics committee of the Albert-Ludwigs-University, Freiburg, Germany (Registration Number 241/101 10628). Oral and written explanation of the study protocol was provided for each patient. Informed consent form was obtained from each participant.

Prosthodontic treatment sequence

If necessary, the selected abutment teeth received endondontical treatment and adhesive core built-ups (Clearfil Core/New Bond, Kuraray Co. Ltd., Chiyoda, Japan) to block out defect related undercuts to maintain a standardized preparation protocol. All procedures were performed under rubber dam. Subsequently, the selected abutment teeth received inlay or non-retentive minimally invasive PCR preparations following the guidelines for all-ceramic preparations [21] (Fig. 1b, c). Depending on the defect size and residual wall thickness (< 1.5 mm), occlusal surfaces and cusps were shortened following the occlusal anatomy resulting in defect-oriented PCR preparation designs. Cavities for inlay preparation were slightly divergent with an overall preparation angle of 6° towards the occlusal aspect. Proximal boxes of inlays ended all above the cemento enamel junction. Beveled preparation margins and thin feather-edges were omitted. The restrictions of manufacturer's minimum

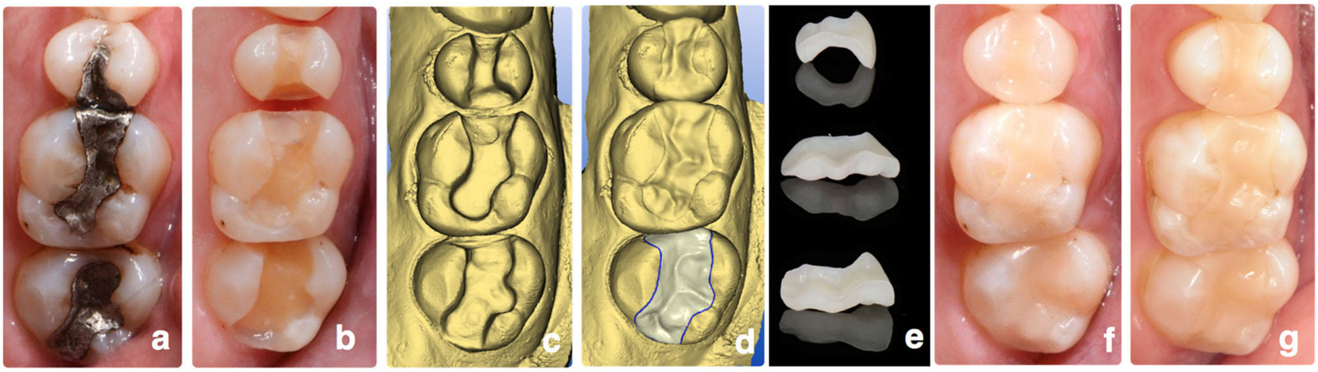

Fig. 1 CAD/CAM workflow. **a** Initial situation: insufficient amalgam fillings on teeth 25–27 (FDI). **b** Minimal invasive inlay preparations 25, 26, and 27. **c** Optical scans of the preparations. **d** Digital design of Enamic restorations. **e** Final restorations. **f** Clinical situation immediately after adhesive cementation. **g** PICN inlays after 36 months of clinical service

material thickness (occlusally 1.0–1.5 mm and axially at least 0.8 mm) were strictly maintained during preparation. All inner angles were rounded. Temporary restorations were fabricated chairside with a silicone key and an acrylic self-curing provisional material (Luxatemp Automix Plus, DMG, Hamburg, Germany). The shade of the restorations was determined by using a shade guide (VITA Toothguide 3D-Master, VITA Zahnfabrik). Impressions were taken with a vinylsiloxanether impression material (Identium, Kettenbach, Eschenburg, Germany) by using the double-cord technique (Ultrapack, Ultradent Products Inc., South Jordan, USA) to control bleeding and expose preparation margins. Master models were made with type 4 dental stone (GC Fujirock EP, GC Europe, Leuven, Belgium) and digitally scanned (inEoS Blue, Dentsply Sirona, York, USA). After acquisition of the digitalized master models, inlays and partial crowns were CAD/CAM designed (inLab SW 4.0, Dentsply Sirona) (Fig. 1d) and milled (CEREC inLab MCXL milling unit, Dentsply Sirona) out of PICN blocks (VITA Enamic, VITA Zahnfabrik) (Fig. 1e).

After milling, the restorations were polished according to manufacturer's recommendation (VITA Enamic Polishing Set, VITA Zahnfabrik, Fig. 1 e). Further individualization of the Enamic restorations with the staining technique (VITA Enamic Stains Kit and VITA Enamic Glaze) was not performed.

All inlays and PCRs were adhesively bonded under rubber dam (Roeko Flexi Dam, Coltene, Altstätten, Switzerland). The prepared teeth were thoroughly cleaned with a polishing brush and a fluoride-free cleaning paste (SuperPolish, Kerr, Orange, USA), sprayed with water and air-dried. Dental hard tissues were etched with a 37% phosphoric acid (Total-etch, Ivoclar Vivadent, Schaan, FL), enamel for 40 s and dentine for 15 s, rinsed with water, and gently air-dried. Subsequently, a primer (Syntac Primer, Ivoclar Vivadent) was applied for 15 s and blown dry after a reaction time of 10 s. A second primer (Syntac Adhesive, Ivoclar Vivadent) was then applied with an exposure time of 10 s, followed by a light-curing bonding agent (Heliobond, Ivoclar Vivadent) and blown to a thin layer. As recommended by the manufacturer, Heliobond was not light cured to avoid misfit for indirect restorations.

Simultaneously, the Enamic restorations were first cleaned with 99% isopropanol and the intaglio surface was etched with 4.9% hydrofluoric acid (IPS Ceramic Etching Gel, Ivoclar Vivadent) for 60 s. The pretreated surface was carefully rinsed with water, dried, and followed by application of a silane (Monobond S, Ivoclar Vivadent). After a reaction time of 60 s, the surface was dried with oil-free compressed air. A dual-curing adhesive resin cement (Variolink II, Ivoclar Vivadent) was used for cementation. The restorations were seated slowly with increasing pressure (ca. 5–10 N). Excess cement was immediately removed with foam pellets and dental floss in all margin areas. To prevent an oxygen inhibition layer, a glycerin gel (Liquid Strip, Ivoclar Vivadent) was applied. Each cement interface was then light cured for 40 s (Bluephase C8 with 800 mW/cm^2, Ivoclar Vivadent) from every direction. Residual cement surpluses were removed with a 15c scalpel (Gebr. Martin, Tuttlingen, Germany). Static and dynamic occlusal contacts were checked and if necessary adjusted with fine diamond burs. A two-step PICN polishing kit (VITA Enamic Polishing Set, Fig. 1f) was used for the final intraoral polishing procedure.

Clinical evaluation

Clinical evaluation was performed at baseline (after insertion of PICN restorations) and 6, 12, 24, and 36 months after insertion. All restorations were classified according to the modified United States Public Health Service (USPHS) criteria by two independent investigators who were not involved in the patients treatment [22] (Fig. 1g). The present report describes the 36 months data of an ongoing 5-year study. Restorations were visually examined by dental mirror and dental probe and clinically inspected with a waxed dental floss. Any mismatch in color, restoration form, and contour as compared to baseline were notified and documented with

Table 1 Modified USPHS criteria (United States Public Health Service)

Criteria	Rating	Characteristic
Secondary caries	Alpha	No evidence of caries contiguous with the margin of the restoration
	Bravo	Caries evident contiguous with the margin of the restoration
Marginal adaptation	Alpha	No visible evidence of crevice along margin; no catch or penetration of explorer
	Bravo	Visible evidence of crevice and/or catch of explorer; no penetration of explorer
	Charlie	Visible evidence, penetration of explorer
Marginal discoloration	Alpha	No discoloration on the margin between the restoration and the tooth structure
	Bravo	Superficial discoloration on the margin between the restoration and the tooth structure; does not penetrate in pulpal direction
	Charlie	Discoloration has penetrated along the margin of the restorative material in pulpal direction
Surface roughness	Alpha	Visual fine polished glossy surface, no palpable roughness
	Bravo	Slight, visible and palpable roughness
	Charlie	Coarse, visible and palpable roughness
Color match	Alpha	No mismatch in color, shade, and/or translucency between restoration and adjacent tooth
	Bravo	Mismatch between restoration and tooth structure within the normal range of color, shade, and (or translucency (< 1 shade off; Vita shade guide)
	Charlie	Mismatch between restoration and tooth structure outside the normal range of color, shade, and/or translucency (> 1 shade off; Vita shade guide)
Anatomical form	Alpha	The restoration is continuous with tooth anatomy
	Bravo	The restoration is not continuous with tooth anatomy. The restoration is slightly under- or over-contoured
	Charlie	The restoration is not continuous with tooth anatomy. Restoration material is missing; a surface concavity is ascertainable

digital photography. Pulp sensitivity was verified with CO_2 test (Frisco Spray, Arztbedarf, Frechen, Germany).

Each PICN restoration was furthermore analyzed for cracks, fractures, and debonding. Restorations that showed no deviation to baseline were rated "Alpha." Inlays and PCRs that showed little deviations in color match and anatomical form were rated "Bravo." All restorations that showed fractures, major defects, or restorations that had to be replaced were rated "Charlie."

Statistical analysis

Clinical measured data were evaluated and analyzed with SAS 9.2 (SAS Institute GmbH, Heidelberg, Germany) and STATA 13 (StataCorp LP, College Station, Texas, USA). Based on absolute and relative failures, Kaplan-Meier survival and success rates were calculated and graphically displayed [23]. Absolute failures were defined as clinically unacceptable fracture, which required replacement of the restorations, inacceptable (= "Charlie" rating) marginal discoloration, marginal adaptation, and secondary caries or debonding. Relative failures were defined as minimal cohesive fractures and minor cracks, which were clinically acceptable, as well as minor marginal stains and minor deviations in marginal fit.

The Cox proportional hazard model was applied to test differences in terms of restoration type and success rate. A mixed logistic regression model with a random intercept by using the SAS 9.2 procedure PROC GLIMMIX was adapted for the modified USPHS criteria (Table 1) to investigate time and restoration effects. The level of significance was set to a p value of less than 0.05.

Results

This clinical study encompassed a total of 47 patients, 31 (66%) female, and 16 (34%) male patients with a mean age

Table 2 Distribution of Enamic restorations: inlays ($n = 45$) and PCRs ($n = 58$) by localization

	Premolars ($n = 40$)			Molars ($n = 63$)			Total ($n = 103$)
	PCRs	Inlays	Total	PCRs	Inlays	Total	
Maxilla	11 (27.5%)	14 (35%)	25 (62.5%)	21 (33.3%)	15 (23.8%)	36 (57.1%)	61 (59.2%)
Mandible	9 (22.5%)	6 (15%)	15 (37.5%)	17 (27%)	10 (15.9%)	27 (42.9%)	42 (40.8%)

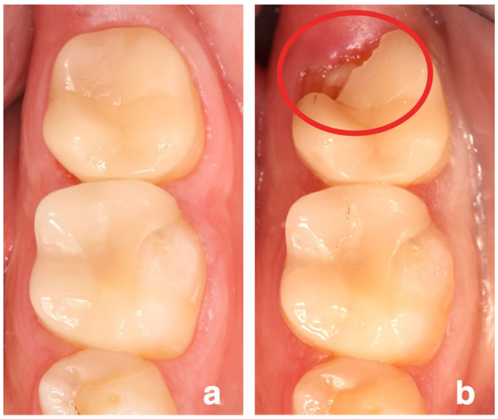

Fig. 2 Occlusal view of Enamic PCR on tooth 37 (FDI). **a** After 12 months. **b** Clinically unacceptable fracture disto-lingual after 23.9 months of service

of 47.6 ± 10.7 years. Table 2 gives an overview of the distribution of inserted Enamic restorations by localization.

Within the observed recall period a total of three absolute failures were recorded. Two partial crowns (after 23.9 and 28.9 months) and one inlay (after 19.4 months) had to be replaced due to clinically unacceptable bulk fractures (Fig. 2). None of the affected teeth were endodontically treated. Neither biological complications nor secondary caries or debonding were notified. Thus, the estimated Kaplan-Meier survival probability for all minimally invasive PICN restorations was 96.4% after 3 years—95.6% for PCRs and 97.4% for inlays, respectively (Fig. 3 and Table 3). No statistically significant difference for type and extent of restorations (p = 0.716) could be detected for survival rates. Severe marginal discoloration or clinically unacceptable marginal adaptation (Charlie rating) was not observed during the given follow-up period (Table 4).

Four PCRs demonstrated minimal cohesive fractures (chipping), which were clinically acceptable. The fractures occurred 11.4, 16.3, 36.9, and 38.2 months after insertion and were limited to the PICN material (Fig. 4). Due to the small extension of the fractures, the restorations could remain in situ and the minimal defects were corrected with a composite (Tetric EvoCeram, Ivoclar Vivadent). The small areas of cohesive fractures were first cleaned and roughened with a fine bur (#379EF.314.023, Komet Dental, Gebr. Brasseler, Lemgo, Germany), followed by the application of an adhesive system (Syntac classic system as mentioned above) and a composite material (Tetric EvoCeram). The chipping areas were investigated in the subsequent recalls, and no further changes could be recorded.

The estimated Kaplan-Meier success rate was 82.4% for PCRs and 84.8% for inlays (Table 5 and Fig. 5). No statistically significant correlation was detected between success rate and type and extent of restorations ($p = 0.431$). An increase of Bravo ratings in marginal adaptation and marginal discoloration were observed as most frequent events after 36 months and contributed to a decrease of the success rates for inlays and PCRs (Table 4).

A significant decrease of Alpha rankings for the USPHS criteria of surface roughness ($p = 0.0005$), marginal adaptation ($p = 0.0005$), and marginal discoloration ($p < 0.0001$) were detected over the given service time. Whereas the USPHS criteria of surface roughness was predominately recorded with Alpha at baseline (69.9% of all restorations), only 17.5, 10.0, and 3.6% of the restorations showed Alpha ratings at 6, 12,

Fig. 3 Enamic restorations on tooth 24 and 25 (FDI); clinical acceptable cohesive fracture on tooth 25. **a** Clinical situation after 24 months. **b** Occlusal crack after 38.2 months before repair with composite

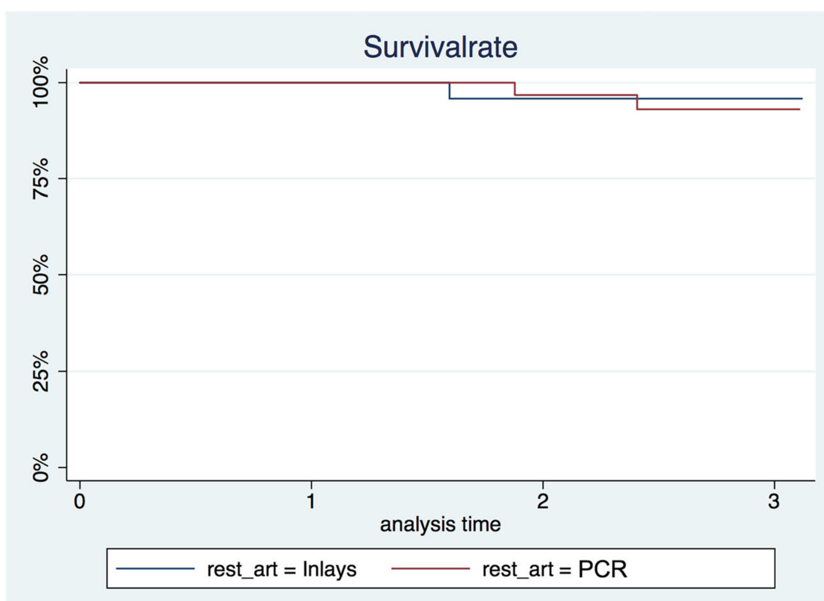

Table 3 Kaplan-Meier survival probability and confidence interval (95% CI)

Service time in years	Number of followed restorations (patients)			Survival probability (95% CI)		
	PCRs	Inlays	Total	PCRs	Inlays	Total
0.50	55 (31)	42 (24)	97 (44)	100% (−)	100% (−)	100% (−)
1.00	50 (30)	40 (23)	90 (43)	100% (−)	100% (−)	100% (−)
2.00	47 (28)	37 (20)	84 (39)	97.9% (86.1–99.7%)	97.4% (82.8–99.6%)	97.7% (91–99.4%)
3.00	44 (26)	35 (19)	79 (37)	95.6% (84.5–98.9%)	97.4% (82.8–99.6%)	96.4% (89.3–98.8%)

and 24 months, respectively. This deterioration continued until the 3-year recall: 97.5% of all Enamic restorations were evaluated with Bravo and only 2.5% with Alpha (Table 4). There was no difference in surface roughness between both types of restorations ($p = 0.5295$). None of the restorations revealed severe degradation in surface roughness (Charlie rating). The observed surface roughness occurred mainly in fissures as well as in functionally stressed areas, such as occlusal contact points or masticatory cusps. Color match and anatomic form of the restorations were consistently good. At baseline, five PCRs were non vital and received sufficient root canal treatments (Table 6). One abutment tooth (PCR) showed endodontic complications after insertion of the PICN restoration and needed a root canal treatment. The access cavity was sealed with composite. The restoration could be left in situ and was further evaluated within the given observation time. Yet, no changes or fractures occurred.

Ten patients with 24 PICN restorations (ten inlays and 14 PCRs) did not reach the 3-year follow-up. This leads to a dropout rate regarding restorations of 23.3% and a patient dropout rate of 21.3%. Two patients (one inlay and two PCRs) revealed absolute failures and were therefore excluded from the study. For the other eight patients, no dental complications were responsible for the dropout. Three of them (a total of five inlay and five PCRs) moved to other countries and could not attend the follow-up examinations. Further four patients (with a total of three inlay and five PCR restorations) were not retrievable by phone or mail. One patient (with one inlay and two PCRs) did not want to participate in the study due to personal reasons.

Discussion

Over the mean observation period of 3 years minimally invasive polymer-infiltrated ceramic VITA Enamic inlays and partial coverage restorations showed promising results with survival rates of 97.4 and 95.6%, respectively.

As there are no controlled clinical trials of VITA Enamic in the literature available yet, comparisons to other clinical studies are only possible to a limited extent. Variations in material selection, as well as clinical treatment procedure and study design have to be taken into account.

The number of restorations that were investigated in the present study correlates with the current literature [19, 24–27].

Just recently, 24 months results of a clinical trial on HT CAD/CAM resin composite PCRs were published [19]. Calibrated dental students inserted 42 partial crowns of Lava Ultimate in the posterior dentition. Two tooth fractures (4.8%) and three debondings (7.1%) were observed, resulting in an overall survival rate of 85.7% after 2 years. In contrast to that, the clinical behavior of the PICN restorations within the present investigation is superior. However, it has to be noticed that the observed results in the study by Zimmermann et al. [19] refers to dental students.

Comparable short-term clinical results were reported after 3 years in a clinical trial on 40 CAD/CAM feldspar inlays (VITA Mark II, VITA Zahnfabrik) and 40 CAD/CAM resin composite inlays (Paradigm, 3M ESPE, Neuss, Germany) [24]. Three fractures (one feldspar inlay and two resin composite inlays) occurred, resulting in a survival rate of 95% for Paradigm and 97.5% for VITA Mark II restorations [12]. Similar survival rates of 95% for Cerec 3D inlays (VITA Mark II) were also reported after an observation time of 3 years [25]. However, depending on the cementation protocol, VITA Mark II partial crowns revealed lower survival rates of 87.6% (self-adhesive composite cement with selective enamel etching) and 72.9% (without) after 3 years [26].

CAD/CAM leucite ceramic (ProCAD) partial coverage restorations revealed comparable results with survival rates of 97% after 3 years [27] and 94.6% for IPS Empress CAD (Ivoclar Vivadent) PCRs [28] after 4–5 years.

A recently published systematic review [16] indicated cohesive fractures (4%) as the most frequent failure for both composites and ceramic inlays, onlays and overlays. Moreover, restorations on vital teeth showed better survival rates than on devitalized teeth [16]. In the present study, unacceptable fractures occurred after 23.9 and 28.9 months for PCRs and after 19.4 months for inlays past insertion resulting in an overall fracture rate of 3.8% after 36 months. The affected abutment teeth were all vital. Other clinical studies observed similar fracture rates of 1.6–3% for all-ceramic

Table 4 Modified USPHS criteria (United States Public Health Service) and clinical evaluation of Enamic restorations at baseline and after a mean follow-up period of 6, 12, 24, and 36 months (number of patients and restorations, USPHS criteria, and clinical evaluation in %)

USPHS criteria and clinical evaluation		Baseline (0 month)			1. Recall (6 months)			2. Recall (12 months)		
		PCR ($n = 58$)	Inlays ($n = 45$)	Total ($n = 103$)	PCR ($n = 55$)	Inlays ($n = 42$)	Total ($n = 97$)	PCR ($n = 50$)	Inlays ($n = 40$)	Total ($n = 90$)
Number of patients		33	26	47	31	24	44	30	23	43
Secondary caries	Alpha	100% (58)	100% (45)	100% (103)	100% (55)	100% (42)	100% (97)	100% (50)	100% (40)	100% (90)
	Bravo	–	–	–	–	–	–	–	–	–
Marginal adaption	Alpha	100% (58)	100% (45)	100% (103)	96.4% (53)	90.5% (38)	93.8% (91)	94% (47)	90% (36)	92.2% (83)
	Bravo	–	–	–	3.6% (2)	9.5% (4)	6.2% (6)	6% (3)	10% (4)	7.8% (7)
	Charlie	–	–	–	–	–	–	–	–	–
Marginal discoloration	Alpha	100% (58)	100% (45)	100% (103)	100% (55)	97.6% (41)	98.9% (96)	96% (48)	92.5% (37)	94.4% (85)
	Bravo	–	–	–	–	2.4% (1)	1.1% (1)	4% (2)	7.5% (3)	5.6% (5)
	Charlie	–	–	–	–	–	–	–	–	–
Surface roughness	Alpha	62.1% (36)	80% (36)	69.9% (72)	14.5% (8)	21.4% (9)	17.5% (17)	6% (3)	15% (6)	10% (9)
	Bravo	37.9% (22)	20% (9)	30.1% (31)	85.5% (47)	78.6% (33)	82.5% (80)	94% (47)	85% (34)	90% (71)
	Charlie	–	–	–	–	–	–	–	–	–
Color match	Alpha	91.4% (53)	97.8% (44)	94.2% (97)	90.9% (50)	97.6% (41)	93.8% (91)	90% (45)	97.5% (39)	93.3% (84)
	Bravo	8.6% (5)	2.2% (1)	5.8% (6)	9.1% (5)	2.4% (1)	6.2% (6)	10% (5)	2.5% (1)	6.7% (6)
	Charlie	–	–	–	–	–	–	–	–	–
Anatomical form	Alpha	100% (58)	100% (45)	100% (103)	98.2% (54)	100% (42)	98.9% (96)	98% (49)	100% (40)	99% (89)
	Bravo	–	–	–	1.8% (1)	–	1.1% (1)	2% (1)	–	1% (1)
	Charlie	–	–	–	–	–	–	–	–	–

USPHS criteria and clinical evaluation		3. Recall (24 months)			4. Recall (36 months)		
		PCR ($n = 47$)	Inlays ($n = 37$)	Total ($n = 84$)	PCR ($n = 44$)	Inlays ($n = 35$)	Total ($n = 79$)
Number of patients		28	20	39	26	19	37
Secondary caries	Alpha	100% (47)	100% (37)	100% (84)	100% (45)	100% (35)	100% (79)
	Bravo	–	–	–	–	–	–
Marginal adaption	Alpha	87.2% (41)	86.5% (32)	86.9% (73)	86.4% (38)	88.6% (31)	87.3% (69)
	Bravo	12.8% (6)	13.5% (5)	13.1% (11)	13.6% (6)	11.4% (4)	12.7% (10)
	Charlie	–	–	–	–	–	–
Marginal discoloration	Alpha	91.5% (43)	89.2% (33)	90.5% (76)	86.4% (38)	91.4% (32)	88.6% (70)
	Bravo	8.5% (4)	10.8% (4)	9.5% (8)	13.6% (6)	8.6% (3)	11.4% (9)
	Charlie	–	–	–	–	–	–
Surface roughness	Alpha	2.1% (1)	5.4% (2)	3.6% (3)	2.3% (1)	2.9% (1)	2.5% (2)
	Bravo	97.9% (46)	94.6% (35)	96.4% (81)	97.7% (43)	97.1% (34)	97.5% (77)
	Charlie	–	–	–	–	–	–
Color match	Alpha	93.6% (44)	97.3% (36)	95.2% (80)	97.7% (43)	97.1% (34)	97.5% (77)
	Bravo	6.4% (3)	2.7% (1)	3.8% (4)	2.3% (1)	2.9% (1)	3.8% (2)
	Charlie	–	–	–	–	–	–
Anatomical form	Alpha	100% (47)	100% (37)	100% (84)	100% (44)	100% (35)	100% (79)
	Bravo	–	–	–	–	–	–
	Charlie	–	–	–	–	–	–

restorations [25, 27] and 5% for CAD/CAM composite restorations after 3 years [24].

However, it has to be awaited if these promising preliminary short-term results are comparable to CAD/CAM glass-ceramic inlays and onlays with long-term survival rates of 91% after 10 years [16] and up to 88.7% after 17 years [29].

In the current clinical trial, four PCRs (5%) showed minimal cohesive fractures within the PICN material (chipping) that could remain in situ. These repaired restorations were therefore rated as relative failures [30].

The evaluation of the modified USPHS criteria revealed a significant change in surface roughness, marginal adaptation,

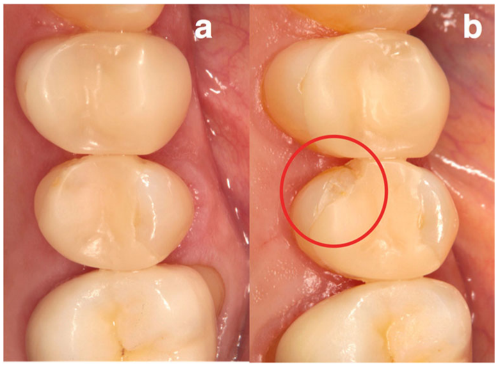

Fig. 4 Kaplan-Meier-survival rate of Enamic inlays and PCRs after 36 months according to time interval of duty

and marginal discoloration over the mean service time of 36 months. Thus, the overall estimated success rate of PICN restorations was 83.6% (84.8% for inlays and 82.4% for PCRs) after 36 months.

The degradation processes of the adhesive interface were mostly attributed to the decrease of the criterions marginal adaptation and marginal discoloration [15]. Marginal deterioration, especially for inlay restorations, has also been addressed in other clinical and in vitro studies [26, 31, 32]. However, the susceptibility of the cement joint towards aging did not affect the clinical performance and did not result in replacement of any restorations. Secondary caries did not occur at either inlay or partial coverage restorations. This is in line with the review of Morimoto et al. [16], where secondary caries was only accountable for 1% of failures. Biological failures in terms of endodontic problems occurred at only one restoration (1.2%). Yet, the review by Morimoto et al. reports of much higher complication rates (3%) due to endodontic failures [16]. To reduce the risk of catastrophic tooth fractures, all ETT were restored with PCRs [21, 33, 34].

At baseline, the criteria surface roughness was rated with Alpha for 70% of the restorations. After 3 years, the surface roughness of almost all restorations (97.5%) was evaluated with Bravo. The increase of surface roughness was mainly recorded in functionally stressed areas. Other clinical studies for Lava Ultimate partial crowns [19] and for Vita Enamic

Table 5 Kaplan-Meier-success rate and confidence interval (95% CI)

Service time in years	Number of followed restorations (patients)			Success probability (95% CI)		
	PCRs	Inlays	Total	PCRs	Inlays	Total
0.50	55 (31)	42 (24)	97 (44)	100% (−)	97.6% (84.3–99.7%)	98.9% (92.9–99.9%)
1.00	50 (30)	40 (23)	90 (43)	96.1% (85.2–99%)	90.1% (75.8–96.1%)	93.5% (86–97%)
2.00	47 (28)	37 (20)	84 (39)	89.5% (76.5–95.5%)	87.5% (72.4–94.6%)	88.6% (79.9–93.7%)
3.00	44 (26)	35 (19)	79 (37)	82.4% (67.7–90.8%)	84.8% (69.2–92.8%)	83.6% (73.9–90%)

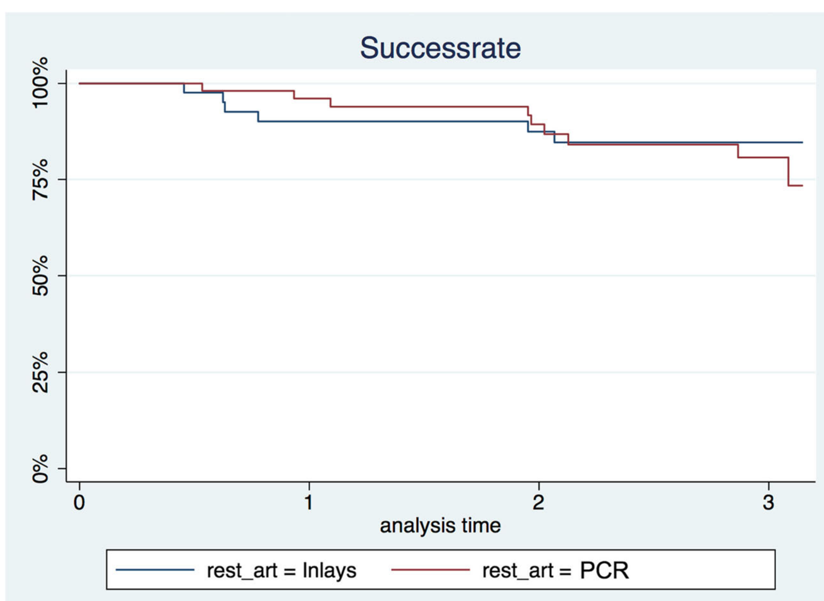

Fig. 5 Kaplan-Meier-success probability of Enamic Inlays and PCRs after a mean observation time of 3 years

Table 6 Pulp sensitivity, debonding, and fracture rate of Enamic inlays and PCRs divided by type of restoration and follow-up time in % (number of patients)

		Baseline (0 months)			1. Recall (6 months)			2. Recall (12 months)			3. Recall (24 months)			4. Recall (36 months)		
		PCR ($n = 58$)	Inlays ($n = 45$)	Total ($n = 103$)	PCR ($n = 55$)	Inlays ($n = 42$)	Total ($n = 97$)	PCR ($n = 50$)	Inlays ($n = 40$)	Total ($n = 90$)	PCR ($n = 47$)	Inlays ($n = 37$)	Total ($n = 84$)	PCR ($n = 44$)	Inlays ($n = 35$)	Total ($n = 79$)
Pulp sensitivity	Positive	91.4% (53)	100% (45)	95.1% (98)	94.5% (52)	100% (42)	96.9% (94)	94% (47)	100% (40)	96.7% (87)	93.6% (44)	100% (37)	96.4% (81)	93.2% (41)	100% (35)	96.2% (76)
	Negative	8.6% (5)	–	4.9% (5)	5.5% (3)	–	3.1% (3)	6% (3)	–	3.3% (3)	6.4% (3)	–	3.6% (3)	6.8% (3)	–	3.4% (3)
	Root canal treatment	8.6% (5)	–	4.9% (5)	5.5% (3)	–	3.1% (3)	6% (3)	–	3.3% (3)	6.4% (3)	–	3.6% (3)	6.8% (3)	–	3.4% (3)
	Root canal treatment necessary	–	–	–	1.8% (1)	–	1.0% (1)	–	–	–	–	–	–	–	–	–
Fractures	Clinically acceptable	–	–	–	–	–	–	2% (1)	–	1.1% (1)	4.2% (2)	–	2.4% (2)	9.0% (4)	–	5.0% (4)
	Clinically inacceptable	–	–	–	–	–	–	–	–	–	2.1% (1)	2.6% (1)	2.4% (2)	4.5% (2)	2.8% (1)	3.8% (3)
Debonding	Recemented	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
	Loss	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–

crowns [35] reported also significant differences for the surface gloss criterion after observation periods of 24 months.

A laboratory study investigating the surface behavior of CAD/CAM materials, also showed that resin-matrix materials exhibited a higher gloss reduction and a higher surface roughness than all-ceramic materials after simulated wear [36]. However, the measured data did not differ significantly from the behavior of human enamel [36].

Controversial results were reported in another in vitro study, where even smoother surfaces for resin-matrix ceramics could be obtained after polishing than for leucite-reinforced ceramics [37]. A further laboratory study examined the effects of artificial toothbrushing and water storage on new CAD/CAM materials. Both VITA Mark II and VITA Enamic were not prone to simulated toothbrushing and surface roughness remained unchanged before and after aging [38].

The color match of polymer-infiltrated ceramic inlays and overlays was favorable at baseline and at the 36 months recall (97.5% alpha ratings). A good color match was also described for VITA Enamic crowns [35] and a susceptibility towards discoloration as observed in a recent in vitro study [39] could not be confirmed in the present clinical study.

The harmonic integration of the restorations to the anatomical shape of the residual dentition remained stable over the whole observation time (100% Alpha rating). Due to the advances and developments in the field of CAD/CAM dentistry, it is nowadays possible to design and mill detailed and natural anatomical morphologies, which are even superior to conventional wax-up structures created by dental technicians [40].

Long-term success of all-ceramic and resin-ceramic restorations is essentially influenced by the quality of their adhesive cementation joint [41, 42]. Comparable clinical studies observed failures of one Empress CAD restoration (1.8%) [28], two lost Empress II restorations [43] (3.2%), and three lost VITA Mark II partial ceramic crowns [26] (4.4%) due to debondings after 2–5 years. In the current study, none of the Enamic restorations detached over a follow-up period of 3 years. All PICN restorations were adhesively bonded according to manufacturer's instructions. An adequate bonding protocol and surface treatment via hydrofluoric acid etching and silanization is strongly recommended for polymer-infiltrated ceramics in the literature [42, 44]. A clinical study [35] showed that if manufacturer's instructions are not strictly followed, PICN materials can be susceptible towards cementation failures. The observed debonding rate was comparatively high (7.1% after 24 months), as air abrasion and resin modified glass ionomer cement were used for adhesive cementation [35]. In 2015, 3M ESPE has withdrawn the crown indication for Lava Ultimate due to a high reported debonding rate [4, 45]. Inadequate surface treatment and the low flexural modulus of 12 GPa and a consequent bending under load might be a possible explanation [45, 46]. This is in conclusion with the clinical findings by Zimmermann et al. [19]. In their trial, three Lava Ultimate PCRs (7.1%) detached, although all restorations were first air-particle abraded and afterwards adhesively bonded. In all three debonding failures, the luting composite remained at the tooth surface [19].

With respect to biological interactions, CAD/CAM PICN blocks are considered to be superior when compared to traditional composites. The high temperature-high pressure polymerization mode used for the manufacturing process of these CAD/CAM blocks resulted in a significant increase of conversion. Due to different monomer composition these CAD/CAM blocks seem more advantageous in terms of toxicity and monomer release.

The investigated PICN material and the CAD/CAM workflow used within this study appears to be a good treatment approach for minimal invasive defects. As there is no additional firing or sintering process necessary, this material represents a reasonable time- and cost-efficient benefit for patient and clinician, enabling natural-looking defect-oriented restorations. As the present study is to our knowledge the first prospective clinical study on the polymer-infiltrated ceramic Enamic, the implementation of the chairside approach was not the major focus of this study. Future clinical trials could address the fully digital workflow in combination with the PICN material. One further limitation of this prospective study is the loss to follow-up of patients; however, similar clinical investigations reported similar numbers [26, 27, 47].

Conclusions

In this prospective clinical study, CAD/CAM-fabricated minimal invasive PICN inlays and partial coverage restorations showed favorable results after an observation period of 3 years. However, further prospective clinical investigations, which evaluate the long-term behavior of polymer-infiltrated ceramics, are necessary. Future research should focus on modification of gloss and glazing surface modalities as well as on development of fatigue-resistant adhesive cementation protocols.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in this study were in accordance with the ethical standards of the ethics committee of the Alberts-Ludwigs-University Freiburg (Registration Number 241/101 10628) and with the 1964 Helsinki Declaration and its later amendments.

Informed consent Informed consent was obtained from all of the participants included in the study.

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