Monolithic Polymer-Infiltrated Ceramic Network CAD/CAM Single Crowns: Three-Year Mid-Term Results of a Prospective Clinical Study

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Purpose: To evaluate the clinical outcomes of monolithic CAD/CAM–fabricated polymer-infiltrated ceramic network (PICN) single crowns (SC) after 3 years. Materials and Methods: A total of 34 patients who received 76 single crowns were included in this cohort study. Full-coverage crown preparation with reduced thickness (1.0 to 1.5 mm) was applied. All monolithic PICN SCs (VITA Enamic) were manufactured using a CAD/CAM system and adhesively seated. Clinical follow-up evaluations were performed at 6, 12, 24, and 36 months after insertion using modified United States Public Health Service (USPHS) criteria. Kaplan-Meier survival and success methods were applied to calculate absolute and relative failures. To determine effects of time and restoration, a mixed logit model was adjusted for the modified USPHS criteria (P < .05). Results: PICN SCs revealed an estimated Kaplan-Meier survival rate of 93.9% after 3 years. Four clinically unacceptable fractures occurred, which resulted in replacement of the affected SCs. Neither secondary caries nor debonding were recorded. The 3-year Kaplan-Meier success rate was 92.7%. Significant increases in marginal discoloration (P = .0002) and surface roughness (P < .0001) were noted over time. Color match, anatomical form, and marginal adaptation remained favorable over the given observation period. Conclusion: PICN CAD/CAM crowns with reduced thickness showed acceptable survival and success rates over a service time of 36 months. However, extended clinical follow-up periods are needed to evaluate the long-term performance.


Today, all-ceramic computer-aided design/computer-assisted manufacture (CAD/CAM) restorations are mainly produced out of translucent lithium disilicate glass-ceramics or high-strength zirconia. Both materials are well known to be reliable and fracture resistant, but require milling in a presintered stage and need additional firing and sintering steps after CAD/CAM processing. Novel speed and super-speed sintering protocols have emerged for zirconia materials to accelerate this time-consuming procedure. Nevertheless, ceramics are brittle and susceptible to fractures, especially when used in bilayer configuration.

To overcome some of the shortcomings of porcelain restorations, more flexible resin matrix ceramic (RMC) materials, which can be applied without any additional treatment steps (e.g., firing, sintering, or glazing), were recently introduced to the dental market. RMC CAD/CAM materials can be grouped by specific microstructure and manufacturing process into two classes: ceramic particle-filled composites with dispersed fillers, and polymer-infiltrated ceramic networks (PICNs). RMCs were designed to fuse the advantageous mechanical properties of ceramics and resins into one single
material.6,7 Flexural strengths of 150 to 240 MPa and a modulus of elasticity between 10 and 30 GPa, which are close to natural tooth tissues, have been described by in vitro studies.8–10 RMC materials are reported to have a high damage tolerance and appear to be less susceptible to bur adjustments.11,12 These flexible materials enable minimally invasive treatment concepts due to optimized and thinner restoration margins with high edge stability compared to conventional ceramics.13

The PICN material Enamic (VITA Zahnfabrik) reveals a dual-network structure and mainly consists of a porous ceramic scaffold structure, which is infused by a polymer mixture of triethylene glycol dimethacrylate (TEGDMA) and urethane dimethacrylate (UDMA).5,7,14 The fact that all RMC materials need no additional sintering procedure enables a time and cost-effective fabrication of CAD/CAM single-tooth restorations.

A recent review, however, found that the clinical short- and long-term evidence on this new material group is still scarce.1 Based on this lack of currently available literature, the aim of this controlled in vivo trial was to assess the clinical performance of PICN single crowns (SCs). The present study describes the mid-term behavior of PICN SCs up to 36 months after crown installation.

MATERIALS AND METHODS

Study Group

Adult patients in need of full-coverage crowns were recruited for this cohort trial. A total of 34 subjects, recruited from the daily patient allocation of the Department of Prosthodontics of the University Hospital Freiburg, Breisgau, Germany, were restored with 76 single crowns. Treatments were performed by dentists experienced with all-ceramic CAD/CAM restorations. According to the study protocol, patients had to comply with the following inclusion criteria: older than 18 years of age; good oral hygiene and periodontal conditions (probing depth < 4 mm, tooth mobility and furcation involvement < degree II); and one or more vital abutment teeth or a sufficient endodontic treatment. Temporomandibular disorders or any kind of bruxism (parafunctional grinding or clenching), alcohol or drug abuse, or life-threatening diseases (American Society of Anesthesiologist classification)15 in medical/dental ailments led to exclusion from the study.

The study protocol was performed according to the Declaration of Helsinki for clinical trials and was inspected and approved by the local ethics committee of the Medical Center, University of Freiburg (Registration Number 241/101 10628). Informed consent was obtained from each participant. Furthermore, each patient received an oral and written explanation of the study protocol from the dentist.

Prosthodontic Treatment Sequence

Prior to treatment, all abutment teeth were checked for tooth vitality with a carbon dioxide sensitivity test (Frisco Spray, ad-Arztbedarf). First, if necessary, the selected abutment teeth were endodontically treated and received an adhesive core buildup (Clearfil Core New Bond, Kuraray) to block out defect-related undercuts to maintain a standardized preparation protocol. A rubber dam was applied for all these procedures. Subsequently, all abutment teeth received full-coverage crown preparation with a reduced occlusal reduction of 1 to 1.5 mm followed by a circular epigingival chamfer preparation (0.8 mm). Manufacturers’ recommendations for minimum material thickness were strictly maintained during preparation.

Temporary crown restorations were produced with a silicone key and a self-curing temporary composite material (Luxatemp Automix Plus, DMG America) and cemented with a eugenol-free temporary cement (TempBond NE, Kerr). Shade selection was performed using the VITA Toothguide 3D-Master (VITA Zahnfabrik). Gingival tissues were retracted using the double-cord technique (Ultrapak, Ultradent) to expose preparation margins and to control bleeding. Full-arch impressions were carried out with a vinylsiloxanether impression material (Identium, Kettenbach).

After digitalization (inEos Blue, Dentsply Sirona) of the stone master models (Fujirock EP Type IV, GC Europe), the PICN SCs were CAD/CAM designed, milled (inLab SW 4.0/CEREC inLab MC XL milling unit, Dentsply Sirona), and polished.

Abutment teeth were pretreated with 37% phosphoric acid (enamel etched for 40 seconds and dentin etched for 15 seconds with Total Etch [Ivoclar Vivadent]), rinsed, dried, and subsequently bonded with two primers (Syntac Primer and Syntac Adhesive, Ivoclar Vivadent) and a light-curing bonding agent (Heliobond, Ivoclar Vivadent). Monolithic PICN SCs were adhesively cemented with a dual-curing composite (Variolink II, Ivoclar Vivadent) after surface treatment with 4.9% hydrofluoric acid (IPS Ceramic Etching Gel, Ivoclar Vivadent) for 60 seconds and subsequent silanization (Monobond-S, Ivoclar Vivadent). All treatment steps followed the manufacturers’ recommendations. Finally, the occlusion was checked, and, if necessary, the occlusal surfaces were polished (VITA Enamic Polishing Set, VITA Zahnfabrik).

Clinical Evaluation

Follow-up examinations were performed at baseline and 6, 12, 24, and 36 months after insertion of the PICN crown restorations (Fig 1). Modified United States Public Health Service (USPHS) criteria (Table 1) were used to evaluate the restorations.16 The modification of the USPHS criteria included evaluation of the following...
Fig 1  PICN single crowns on the maxillary right second premolar and first molar at the (a) baseline and (b) 6-, (c) 12-, (d) 24-, and (e) 36-month evaluations.
Statistical calculations, including Kaplan-Meier analysis and Cox proportional hazard model, were performed with SAS 9.2 (SAS Institute) and STATA 13 (StataCorp). The probability level for statistical significance was set to a $P$ value < .05. Kaplan-Meier survival and success rates were calculated based on absolute and relative failures.

Replacement of SCs due to clinically unacceptable fracture, secondary caries, debonding, or Charlie classifications of clinically unacceptable marginal discoloration or marginal adaptation were defined as absolute failures (survival rate). Clinically acceptable deteriorations at follow-ups, such as minimal cohesive fractures, minor cracks, minor marginal stains, or deviation in marginal fit (Bravo rating), were recorded as relative failures (success rate).  

To investigate time and restoration effects of the modified USPHS criteria, a mixed logit regression model with a random intercept using the SAS 9.2 PROC GLIMMIX procedure was adapted.

## RESULTS

A total of 34 subjects—20 (58.8%) female and 14 (41.2%) male patients with 48 maxillary and 28 mandibular teeth (28 molars, 41 premolars, 7 incisors) and an age mean of 52.6 ± 10.5 years—were included in this prospective clinical investigation.

Four SCs (6.5%) were categorized as absolute failures due to catastrophic fracture (Table 2). The failures occurred 15.9 (maxillary right first molar), 23.6 (maxillary left second molar), 34.2 (mandibular right second molar), and 35.9 (maxillary right second molar) months after insertion (Fig 2) and were limited to the crown restoration (the underlying tooth structure was not affected). Two abutment teeth were nonvital and endodontically treated. This resulted in a fracture rate of 6.5% after 3 years (Table 2). All four SC restorations had to be replaced and were no longer listed in the subsequent recalls.
Surface roughness (\(P < .0001\)) and marginal discoloration (\(P = .0002\)) were identified. While surface roughness was recorded as 82.9% Alpha at baseline, a 100% Bravo rating was observed at the 3-year recall (Table 3). Surface roughness was predominantly noted in fissures, as well as in occlusal contact points and masticatory cusps. The calculated Kaplan-Meier success rate was 92.7% (Table 4 and Fig 3b).

After 3 years, neither patient gender nor age had a statistically significant effect on the survival (\(P = .831\)) or success rate (\(P = .852\)). At baseline, 27 abutment teeth showed a negative sensitivity (Table 2) and revealed neither secondary caries (Table 3) nor debonding (Table 2) were observed. The Kaplan-Meier estimation for survival was 93.9% after 3 years (Table 4 and Fig 3a). The criterion marginal adaptation stayed favorable over the whole observation period with a 93.4% Alpha rating (Table 3). Likewise, no change in anatomical form could be observed at baseline (98.7% Alpha) or after 36 months (98.4% Alpha). Increases in Bravo ratings for marginal discoloration and surface roughness were observed as the most frequent events after 36 months (Table 3) and contributed to a decrease in success rate. Significant drops in Alpha rankings for surface roughness (\(P < .0001\)) and marginal discoloration (\(P = .0002\)) were identified. While surface roughness was recorded as 82.9% Alpha at baseline, a 100% Bravo rating was observed at the 3-year recall (Table 3). Surface roughness was predominantly noted in fissures, as well as in occlusal contact points and masticatory cusps. The calculated Kaplan-Meier success rate was 92.7% (Table 4 and Fig 3b).

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sufficient endodontic treatment. During the follow-up examinations, 3 additional abutment teeth showed endodontic complications and needed a root canal treatment. The access cavity was sealed with composite, and the restorations could be left in situ (Table 2). No changes or fractures of these endodontically treated teeth occurred.

Fig 2  Occlusal view of PICN single crown on the mandibular right second molar at (a) baseline and (b) 24 months, with visible surface wear at the buccal masticatory cusp and (c) a clinically unacceptable fracture after 34.2 months of service. (d) CAD file (cross section) of the single crown with adequate thickness as recommended by the manufacturer (light blue shading displays minimal thickness, 1.0 mm on the occlusal aspect and 0.8 mm on the axial aspect).
A total of 34 patients participated at the baseline investigation, and 27 patients with 61 SCs could be examined at the final follow-up (Tables 2 and 3). Seven patients (20.6%) with 15 SCs (19.7%) were lost to follow-up (Table 2). Two patients (1 patient with 3 SCs and 1 patient with 1 SC) revealed absolute failures and were therefore excluded from the study. Two patients (1 with 3 SCs and 1 with 2 SCs) had moved to other cities during the follow-up examinations, and 1 patient (3 SCs) was no longer reachable by phone or email. Two patients (1 with 2 SCs and 1 with 1 SC) did not want to take part in the study anymore due to personal reasons.

**DISCUSSION**

There is still a lack of in vivo studies on PICN SCs or RMC SCs.1 This prospective trial reported for the first time on the mid-term clinical performance of PICN SCs (VITA Enamic) and revealed reasonable 3-year estimated Kaplan-Meier survival and success rates of 93.9% and 92.7%, respectively. The major goal of this prospective study was to investigate the clinical mid-term performance of these innovative PICN restorations from a material behavior perspective rather than to address the digital workflow, as it is well known in the dental literature that the chairside fabrication is clinically successful.1,18

So far, only one other study has retrospectively evaluated chairside-fabricated PICN SCs after 2 years in a private practice.19 In total, 45 restorations were observed, 31 cemented with a self-adhesive (SA) cement and 14 with a resin-modified glass-ionomer (RMGI) cement. High survival rates of 92.9% for RMGI- and 96.8% for SA-inserted PICN restorations were reported, although the applied bonding protocol with airborne-particle abrasion pretreatment did not fulfill the manufacturer’s requirements. Several in vitro studies validated the bonding protocols provided by the manufacturer and recommend hydrofluoric acid etching as a surface treatment prior to adhesive cementation.20,21 The reliable adhesive bond was confirmed by the results of the present clinical study, in which no clinical debonding of an SC could be observed.

Clinical studies on IPS e.max CAD (Ivoclar Vivadent) crowns revealed comparable short-term survival rates of 100% after 2 years.22,23 However, whether the reported long-term data for PICN SCs can be comparable to those for CAD/CAM–processed feldspathic and lithium disilicate single restorations—with survival rates of 90.7% after 12 years24 and 83.5% after 10 years25—remains to be seen.

A systematic review and meta-analysis of all-ceramic tooth-supported SCs reported framework fracture rates for early feldspathic and silico–based restorations of 6.7% and for leucite and lithium disilicate glass-ceramics of 2.3% after 5 years of clinical service.26 These reported fracture rates are comparable to the present results of 6.5% after 3 years.

All of the observed fractures in this cohort study occurred on molars, two of which were endodontically treated. It is well described in the dental literature that endodontically treated abutment teeth are prone to surface wear,19,30–31 which led to a reduction in restoration thickness (Fig 2b), ultimately resulting in bulk fracture.

Recent in vitro studies32,33 tested the fracture load and fatigue behavior of PICN single crowns with occlusal thicknesses of 1.0 and 1.5 mm. SCs were subjected to single-load fracture testing before and after fatigue application in a chewing simulator. All crown restorations with the tested occlusal thicknesses survived the simulated 5-year aging in the artificial mouth and revealed failure loads well above 2,000 N. For full-coverage crown restorations,
recently published study37 reinforced these findings and the two-body wear of different monolithic ceramics, reported that RMCs led to less abrasiveness and wear than zirconia, lithium disilicate, and zirconia-reinforced lithium silicate CAD/CAM materials.35 It seems there is a strong correlation between the hardness of the restoration material and wear behavior.32,35

Moreover, the impact of surface finishing techniques and recommendations of the manufacturer on VITA Enamic were tested.36 Specimens were both polished and finished with the manufacturer’s clinical kit (silicone burs), technical kit (silicone burs), or special glaze kit (light-curing glaze). The smoothest surfaces could be achieved with the clinical and technical kits, whereas the technical kit recorded the best surface roughness values. The authors concluded that the clinical kit should only be used for minor corrections after preadjustment.36 A recently published study37 reinforced these findings and recommended polishing systems instead of the application of light-curing glazing material. Further, differences in surface roughness were measured after simulation of mechanical tooth brushing for four RMCs (Enamic, Lava Infiltration [3M ESPE], Cerasmart [GC America], and Block HC [Shofu]) compared to a lithium disilicate glass-ceramic (IPS e.max CAD) before and after abrasion.38 The outcomes of the study38 indicated smoother surfaces for Enamic and e.max CAD after the abrasion simulation compared to the other tested materials.

Recently, multicolored and highly translucent PICN blocks were launched by the manufacturer to further enable the indication for esthetic monolithic anterior restorations in highly demanding patients.39 Furthermore, PICN has been suggested as a veneering material for zirconia copings with rapid layer technology, as no fractures were recorded after sliding contact fatigue.40 Some limitations of this clinical cohort study include the study design with no control group or randomized clinical study set-up and the fact that multiple restorations were inserted per patient and accounted for in the data analysis. This further leads to a relatively high dropout rate at the patient level (7 patients) after 56 months of observation. However, these dropout rates are similar to data reported in the literature26 and should lead to future clinical investigations with randomized controlled study designs. Based on the present mid-term data of the investigated polymer-infiltrated ceramic, this CAD/CAM material reveals to be a potential time- and cost-effective treatment approach in daily clinical practice. Future studies with longer observation periods, larger patient cohorts, and a fully digital chairside workflow are desirable to explore the possible capabilities of this group of RMCs.

CONCLUSIONS

Within the limitations of the present clinical investigation, CAD/CAM-fabricated PICN SCs with reduced thickness showed acceptable survival and success rates after 56 months. However, the increased surface roughness highlights the need for regular recall check-ups, and further studies should address the development of fatigue-resistant surface topographies of PICN materials. The long-term success of PICNs, with focus on the time and cost efficiency of digital workflows, should be investigated in future clinical research.

ACKNOWLEDGMENTS

All procedures performed in this study were in accordance with the ethical standards of the ethics committee of the Albert-Ludwigs-University Freiburg (Registration Number 241/101 10628) and with the 1964 Helsinki Declaration and its later amendments. Informed consent was obtained from all of the participants included in the study. This study was supported by VITA Zahnfabrik.

REFERENCES

Can You Be Too Old for Oral Implants? An Update on Ageing and Plasticity in the Oro-Facial Sensorimotor System

This review focuses on the capacity of the brain for plasticity and on the utility and efficacy of oral implants in helping to restore orofacial sensorimotor functions, especially in elderly patients. The review first outlines the components of the orofacial sensorimotor system, which encompasses both orofacial tissues and a number of brain regions. One such region is the sensorimotor cortex, which controls the activity of the numerous orofacial skeletal muscles. These muscles are involved in a number of functions, including reflexes and the more complex sensorimotor functions of mastication, swallowing, and speech. This review outlines the brain’s use of sensory inputs from orofacial receptors in order to provide for exquisite sensorimotor control of the activity of the orofacial muscles and highlights the role in more complex sensorimotor functions of mastication, swallowing, and speech. This review outlines the brain’s capacity for plasticity. This review also notes the evidence that rehabilitation that incorporates adjunctive approaches—such as sensorimotor training paradigms—in addition to oral prostheses such as implants may enhance these processes and help maintain or facilitate recovery of sensorimotor functioning in the elderly.

Sessle BJ. J Oral Rehabil 2019;46:936–951. References: 135. Reprints: Barry J. Sessle, barry.sessle@utoronto.ca — Carlo Mariniello, Switzerland