Moritz Zimmermann

Indirect zirconia-reinforced lithium silicate ceramic CAD/CAM restorations: Preliminary clinical results after 12 months

Moritz Zimmermann, Dr med dent[1]/Christina Koller, Dr med dent[2]/Albert Mehl, Dr med dent, Dr rer nat, Professor[3]/Reinhard Hickel, Dr med dent, Professor[4]

Objective: No clinical data are available for the new computer-aided design/computer-assisted manufacture (CAD/CAM) material zirconia-reinforced lithium silicate (ZLS) ceramic. This study describes preliminary clinical results for indirect ZLS CAD/CAM restorations after 12 months. **Method and Materials:** Indirect restorations were fabricated, using the CEREC method and intraoral scanning (CEREC Omnicam, CEREC MCXL). Sixty-seven restorations were seated adhesively (baseline). Sixty restorations were evaluated after 12 months (follow-up), using modified FDI criteria. Two groups were established, according to ZLS restorations' post-processing procedure prior to adhesive seating: group I (three-step polishing, n = 32) and group II (fire glazing, n = 28). Statistical analysis was performed with Mann-Whitney U test and Wilcoxon test ($P < .05$). **Results:** The success rate of indirect ZLS CAD/CAM restorations after 12 months was 96.7%. Two restorations clinically failed as a result of bulk fracture (failure rate 3.3%). No statistically significant differences were found for baseline and follow-up criteria (Wilcoxon test, $P > .05$). Statistically significant differences were found for criteria surface gloss for group I and group II (Mann-Whitney U test, $P < .05$). **Conclusion:** This study demonstrates ZLS CAD/CAM restorations have a high clinical success rate after 12 months. A longer clinical evaluation period is necessary to draw further conclusions. *(Quintessence Int 2017;48:19–25; doi: 10.3290/j.qi.a37017)*

Key words: CAD/CAM, CEREC, clinical study, zirconia-reinforced lithium silicate ceramic

Dental ceramics are widely used for restoration fabrication.[1] According to chemical composition, silicate-, lithium disilicate-, and oxide ceramics can be distinguished.[2] Four ceramic production procedures have been described in the literature, including firing, pouring, pressing, and computer-aided design/computer-assisted manufacture (CAD/CAM) fabrication.[3,4] The CAD/CAM fabrication procedure is promising, as there are several advantages. First, due to the use of homogenous industrial blanks and blocks, fewer material failures are likely to occur while milling. Second, pre-fired oversized ceramics, such as zirconia, can be milled while taking the respective firing shrinkage into account before milling. If overload or inappropriate load is performed, ceramics are more brittle and more susceptible to fracture than composite materials.[5]

[1] Assistant Professor, Department of Computerized Restorative Dentistry, Center of Dental Medicine, University of Zurich, Switzerland; and Department of Restorative Dentistry and Periodontology, Ludwig-Maximilians-University Munich, Germany.

[2] Assistant Professor, Department of Restorative Dentistry and Periodontology, Ludwig-Maximilians-University Munich, Germany.

[3] Professor, Head of Department, Department of Computerized Restorative Dentistry, Center of Dental Medicine, University of Zurich, Switzerland.

[4] Professor, Head of Department, Department of Restorative Dentistry and Periodontology, Ludwig-Maximilians-University Munich, Germany.

Correspondence: Dr med dent Moritz Zimmermann, Department of Computerized Restorative Dentistry, Center of Dental Medicine, University of Zurich, Plattenstrasse 11, 8032 Zurich, Switzerland. Email: moritz.zimmermann@zzm.uzh.ch

Table 1 Inclusion and exclusion criteria; in total 41 patients participated (24 male, 17 female patients, average age 45 years ± 12 years)

Inclusion criteria	Exclusion criteria
Oro-vestibular defect size: > 50% of tooth cusp distance	Oro-vestibular defect size: < 50% of tooth cusp distance
Complete or partial reconstruction of tooth cusp	Need of direct/indirect capping prior to reconstruction
Molars or premolars with antagonist	Patient suffering from bruxism/temporomandibular disorder

Defined material thicknesses are necessary for a restoration's fabrication, and the adhesive seating of a restoration is mandatory for ceramics of a fracture strength below 200 MPa.[6,7] Recent material research aims to improve the characteristics for dental ceramics. Several improvements, regarding shear and fracture strength by structure strengthening and defect minimizing production procedures, have been recently described.[8] Additionally, new ceramic materials have been developed, such as zirconia-reinforced lithium silicate (ZLS) ceramics. ZLS ceramics contain 10% by weight of dispersed zirconia particles embedded in a fine-grained glass matrix of 500 to 800 nm.[9] In contrast to lithium disilicate ceramics, such as e.max CAD, ZLS ceramics can be milled in a finally crystallized state. No clinical data are available for ZLS ceramic CAD/CAM restorations. This study aims to evaluate the clinical outcome of indirect ZLS ceramic restorations after 12 months.

METHOD AND MATERIALS

Ethical approval and recruitment criteria

All procedures in this study involving human participants were conducted in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its amendments or comparable ethical standards. The study was performed as part of protocol number 490-13, accepted by the ethical committee of the Ludwig-Maximilians-University Munich. The patients were recruited from the daily patient collective of the Department of Restorative Dentistry and Periodontology at the Ludwig-Maximilians-University Munich. All patients gave written consent for participation in the study. There were 41 patients requiring at least one posterior tooth for an inlay or a partial crown in the study. The distribution of gender was 24 male patients and 17 female patients. The patients' average age was 45 years (± 12 years standard deviation [SD]). The patients' good general health status (ASA-criteria 1) was mandatory. Sixty-seven indirect restorations were fabricated. There were 38 maxillary teeth and 29 mandibular teeth treated (42 molars and 25 premolars). Inclusion and exclusion criteria are shown in Table 1. Baseline evaluation was performed 1 day after restoration seating (baseline). Recall evaluation was performed after 12 months (follow-up). The evaluation criteria were modified FDI criteria.[10-13]

Clinical protocol

Local anesthesia (Ultracain D-S 2%; Sanofi Aventis) was administered prior to tooth preparation. The teeth were prepared, according to guidelines.[6] Dropping below the minimum thickness of 1.5 mm meant a shortening of the cusps in partial crown preparation. The preparation margins ended within the enamel or dentin. Quadrant scans of the maxillary and mandibular arch were made with the CEREC Omnicam (Dentsply Sirona), according to the respective scanning strategy.[14] An astringent paste (Astringent Retraction Paste; 3M Espe) was used for hemorrhage control. Provisional restorations were provided for the prepared teeth (Luxatemp; DMG) and seated using RelyX Temp NE (3M Espe). The CAD design of final restorations was performed with special CAD software (CEREC software v4.2). ZLS ceramic blocks were selected as restorative material (Celtra Duo; Dentsply DeTrey) and milled with the CEREC MCXL milling unit (cylinder pointed bur 12

and step bur 12s). The milling mode was set to "standard". Thirty-three partial crowns and 27 inlays were fabricated. Two groups were established, according to the post-processing procedure of the ZLS restorations. The post-processing method was randomly selected by coin toss, prior to restoration seating:

- Group I (three-step ceramic polishing set 4313B [Brasseler]). Protocol: 5,000 to 6,000 rpm; time per instrument, 30 seconds; water cooling, 50 mL/minute; light contact pressure; n = 32
- Group II (fire glazing). Protocol: T = 500°C; 55°C/minute; H = 820°C; t = 90 seconds; no vacuum; n = 28.

The CAD/CAM restorations were seated adhesively. The luting surfaces of the restorations were etched for 30 seconds with 5% hydrofluoric acid, then rinsed off with water spray for 30 seconds. The restorations were cleaned with alcohol and air dried with oil- and water-free air. Before luting, silane (Monobond S; Ivoclar Vivadent) was applied to the luting surface of the restorations for at least 60 seconds. The prepared teeth were isolated with rubber dam and etched with 37% phosphoric acid (30 seconds enamel, 15 seconds dentin). Syntac was used as an adhesive bonding agent (15 seconds primer, 10 seconds adhesive; Heliobond) with a dual-polymerizing composite resin system. After removing the excess, an oxygen layer inhibitor material was applied to the area of the cementation interface (Airblock; Dentsply DeTrey). Luting composite resin was polymerized with a polymerization lamp (Satelec MiniLED; KaVo), using 16 J/cm^2 from the occlusal, mesial, distal, buccal, and lingual aspects for 60 seconds each. The restoration margins were finished, and the occlusal contacts were adjusted, using fine diamond rotary instruments, coupled with constant water-cooling.

Evaluation criteria and statistical analysis

Evaluation was performed 1 day after adhesive seating of the restoration (baseline) and at 12 month's recall (follow-up). The evaluation criteria were modified FDI criteria.[10-13] There were three evaluation categories (esthetics, function, and biology), each with five subcategories. From best to worst, the subcategories were:

1. clinically excellent
2. clinically good
3. clinically sufficient
4. clinically not sufficient but repairable
5. clinically inacceptable.

In the present study, evaluation with categories 4 and 5 was rated as clinical failure. A blinded and calibrated experienced dentist performed follow-up evaluation. Statistical analysis for baseline and follow-up criteria was performed with Wilcoxon test ($P < .05$) (SPSS; IBM). Statistical analysis for each criterion within the two post-processing groups at follow-up evaluation was performed using Mann-Whitney U test ($P < .05$) (SPSS; IBM).

RESULTS

Thirty-seven of 41 patients appeared for follow-up evaluation after 12 months. Sixty restorations of 67 restorations could be evaluated at follow-up evaluation (dropout rate 10.45%; follow-up rate 89.55%). Due to drop out, five partial crowns and two inlays could not be evaluated. These restorations have been eliminated from baseline evaluation results in order to ensure comparability between baseline and follow-up results.

Altogether, 33 partial crowns and 27 inlays were evaluated at follow-up. Thirty-four maxillary teeth and 26 mandibular teeth (38 molars and 22 premolars) were evaluated at follow-up. The distribution of gender at follow-up evaluation was 20 male patients and 17 female patients. Two of the 60 restorations were rated as clinical failure as a result of bulk fracture. Both restorations required refabrication (failure rate 3.3%). The success rate of indirect ZLS CAD/CAM restorations after 12 months was 96.7%. The results for baseline and follow-up evaluation are summarized in Table 2.

Esthetic characteristics

There was no change for surface gloss criteria at follow-up evaluation, compared to baseline evaluation. Four restorations had a decrease for criteria surface/marginal staining from clinically excellent (category 1) to clinically good (category 2) at follow-up evaluation.

Table 2 Clinical evaluation of indirect zirconia-reinforced lithium silicate ceramic (ZLS) CAD/CAM restorations after 12 months; time of evaluation at baseline (0) and follow-up (12); evaluation criteria, modified FDI criteria

Category		Time of evaluation (mo)	Criteria 1	2	3	4	5	Restorations evaluated (Σ)†
Esthetic	Surface gloss*	0	47	13	0	0	0	60
		12	47	13	0	0	0	60
	Surface/marginal staining	0	60	0	0	0	0	60
		12	56	4	0	0	0	60
	Color match	0	48	12	0	0	0	60
		12	48	12	0	0	0	60
	Anatomic form	0	54	5	1	0	0	60
		12	52	7	1	0	0	60
Functional	Fractures and retention	0	60	0	0	0	0	60
		12	58	0	0	2	0	60
	Marginal adaption	0	47	13	0	0	0	60
		12	42	18	0	0	0	60
	Wear	0	NA	NA	NA	NA	NA	‡
		12	51	8	1	0	0	60
	Contact point	0	41	4	1	0	3‖	60
		12	49	7	1	0	3‖	60
Biology	Patient satisfaction	0	NA	NA	NA	NA	NA	‡
		12	59	1	0	0	0	60
	Postoperative hypersensitivity	0	NA	NA	NA	NA	‡	‡
		12	47	0	0	0	0	47§
	Caries/erosion/abfraction	0	NA	NA	NA	NA	NA	‡
		12	60	0	0	0	0	60
	Tooth integrity	0	60	0	0	0	0	60
		12	58	2	0	0	0	60
	Periodontal response	0	NA	NA	NA	NA	NA	‡
		12	48	10	2	0	0	60

*Statistically significant difference for group I and II for baseline and follow-up (Mann-Whitney-U test, $P < .05$).
†67 restorations seated at baseline, due to drop out rate only 60 restorations were evaluated at follow-up.
‡Not relevant at baseline.
§47 vital teeth were treated.
‖5 restorations with no neighboring tooth.
NA, not applicable

There was no change for color match criteria at follow-up evaluation. Two restorations had a decrease for anatomic form criteria from clinically excellent (category 1) to clinically good (category 2).

Functional characteristics

At follow-up evaluation, two restorations showed a bulk fracture (category 4), whereas 58 restorations showed no restrictions (category 1). Five restorations had a decrease for marginal adaptation criteria from clinically excellent (category 1) to clinically good (category 2). At follow-up evaluation, 85% of the restorations showed no difference in the wear rate, compared to enamel wear (category 1); 13.3% showed a wear rate between 50% and 150% of the reference enamel (category 2); one restoration showed a wear

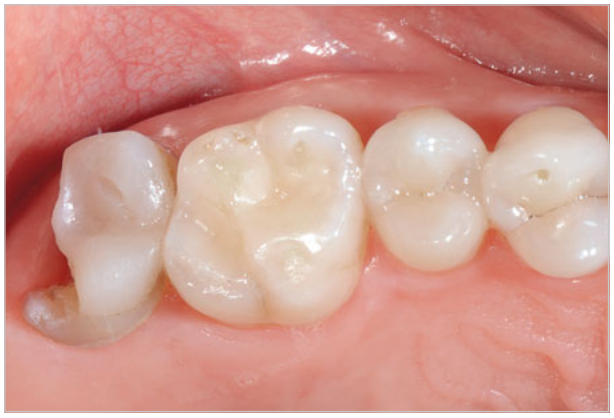

Fig 1 Clinical failure after 8 months; partial crown maxillary right second molar; endodontically treated tooth; bulk fracture; fire-glazing (group II).

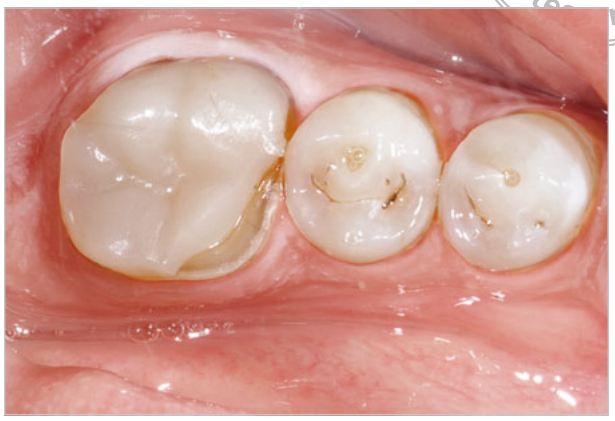

Fig 2 Clinical failure after 12 months; partial crown mandibular right first molar; vital tooth; bulk fracture; three-step polishing (group I).

rate between 150% and 300% of the reference enamel (category 3). Three restorations showed a decrease for the criteria contact point from category 1 to category 2.

Biological characteristics

At follow-up evaluation, 98.3% of the patients were satisfied with their restorations (category 1). One test person mentioned criticism concerning minor esthetic shortcomings (category 2). None of the 47 restorations fabricated on vital teeth showed postoperative hypersensitivity at follow-up evaluation (category 1). There was no recurrence of initial pathology, like caries, erosion, or abrasion, at follow-up evaluation (category 1). Compared to the baseline evaluation, two restorations showed small cracks in the enamel (category 2). Forty-eight restorations showed no sign of gingival inflammation (category 1), 10 restorations were associated with minimal plaque present (category 2), and two restorations were associated with one reduced Papillary Bleeding Index grade compared to baseline evaluation (category 3).

Restoration failures

After 12 months, two restorations had to be declared as clinical failure as a result of bulk fracture. Both restorations required refabrication.

Restoration failure 1 was a bulk fracture of a partial crown after 8 months (maxillary right second molar). Prior to treatment, the tooth had been restored with a large composite resin filling. The post-processing protocol for the restoration was fire-glazing (group II). The patient attended the dental clinic spontaneously, and the situation was photographed (Fig 1). Neither a fracture of tooth substance, nor any other clinical abnormality could be detected. Percussion test of the endodontically treated tooth was negative. The fracture line reached from the buccal to the oral aspect and to the middle of the occlusal contact area. The remaining restoration, including the luting composite resin, was carefully removed, and a new partial crown was fabricated, using Celtra Duo and the CEREC method.

Restoration failure 2 was a bulk fracture of a partial crown after 12 months (mandibular right first molar). Prior to treatment, the tooth had been restored with a large composite resin filling. The post-processing protocol for the restoration was three-step polishing (group I). Restoration failure was detected at follow-up evaluation, and the situation was photographed (Fig 2). There were no cracks within the tooth substance, the percussion test of the tooth was negative, and the vitality test was positive. There were no clinical abnormalities. The fracture line covered the whole mesiolingual cusp. The remaining filling was carefully removed, and a new Celtra Duo partial crown was fabricated, using the CEREC method.

Statistical analysis

The success rate of indirect ZLS CAD/CAM restorations after 12 months was 96.7%. Two restorations clinically failed as a result of bulk fracture (failure rate 3.3%). The statistical analysis between baseline and follow-up criteria, using the Wilcoxon test ($P < .05$), revealed no statistically significant differences for baseline and follow-up criteria. Mann-Whitney U test ($P < .05$) was performed for each evaluation criteria for group I and group II. There were significant differences for criteria surface gloss for group I and II ($P = .048$). There were no significant differences in other criteria for group I and II.

DISCUSSION

This study is the first clinical study evaluating the clinical behavior of a ZLS ceramic CAD/CAM material after 12 months. Two restorations were declared as clinical failure as a result of bulk fracture. The clinical success rate of ZLS CAD/CAM restorations after 12 months was 96.7%. The success rate of ZLS CEREC restorations is in good accordance with the success rate of indirect CEREC restorations fabricated with other ceramic materials.[15] A longer clinical evaluation period is necessary to draw further conclusions. Several aspects need to be discussed.

The material composition of ZLS ceramics might provide several advantages. Due to fine-grained glass matrix microstructure of 500 to 800 nm and the small diameter of zirconia crystallites, polishing procedures might be performed effectively.[9] However, in the present study there were statistically significant differences for surface gloss criteria for group I and group II. Significantly better results had been seen if restorations had been fire-glazed prior to adhesive luting. Even if ZLS material characteristics might be advantageous, polishing procedures might not be performed as sufficiently as glazing procedures. There were 23 restorations for category 1 and nine restorations for category 2 in group I. There were 24 restorations for category 1 and four restorations for category 2 in group II. However, both glazed and polished restorations showed no changes at follow-up evaluation, compared to baseline evaluation. The polishing technique applied in this study provided stable surface gloss after 12 months. A longer clinical evaluation period is necessary to draw further conclusions.

According to the manufacturer's information, the flexural strength of ZLS ceramics increases from 200 MPa to 370 MPa by performing a fire-glazing post-processing protocol.[9] Fire-glazed ZLS restorations have a flexural strength, comparable to lithium disilicate ceramic materials, such as e.max CAD. According to the manufacturer's information, polished ZLS restorations have a flexural strength of 210 MPa, comparable to leucite-reinforced silicate ceramics, such as Empress CAD.[9] In the present study, one fire-glazed restoration and one polished restoration showed a bulk fracture. There was no statistically significant difference in performance of fire-glazed restorations compared to polished restorations, regarding clinical failure. Scientific data (not yet published), referring to the flexural strength of several ceramic restorative materials, including different types of ZLS ceramics, show the so-called strengthening effect by fire-glazing might not be as effective as claimed by the manufacturer. The clinical survival rates found for both post-processing types of ZLS are in good accordance with literature published for ceramic CAD/CAM materials.[16,17] A longer clinical evaluation period is necessary to draw further conclusions.

This study is a prospective observation study, without a typical control group with a different CAD/CAM material. Due to the fact that there are two different post-processing procedures available for ZLS ceramics, the authors purposely did not draw direct conclusions to a specific control group. From a material point of view, there might have been two possible control groups, one for each post-processing procedure: for group fire-glazing, e.max CAD would have been suitable; for group polishing, Empress CAD would have been suitable.

The ZLS ceramic CAD/CAM restorative material is a new class of ceramic material with the post-processing method claimed to alter the material's clinical behavior. In the present study, instead of adding more control

groups, the influence of the post-processing protocol for the clinical behavior of the new ZLS ceramic material was the main focus of interest. However, the results were in good accordance with survival rates for other CAD/CAM materials, such as e.max CAD.[18,19]

It would be interesting to compare future study results with specific control groups for each ZLS post-processing procedure to the results found in the present study. The aim of this study was to compare the clinical behavior of zirconia-reinforced lithium silicate ceramic as a function of different post-processing protocols. This study shows there is no statistically significant difference, regarding the post-processing protocols, of fire-glazing and three-step polishing at 12 months' follow-up. A longer clinical observation period is required to draw further conclusions.

CONCLUSION

This study demonstrates that zirconia-reinforced lithium silicate ceramic CAD/CAM restorations have a high clinical success rate after 12 months. A longer clinical evaluation period is necessary in order to draw further conclusions.

REFERENCES

1. Brown, D. The status of indirect restorative dental materials. Dent Update 1998;25:23–34.
2. Kappert HF, Eichner K (ed). Fullceramic systems, dental materials and their processing, Volume 2. Clinical aspects of dental materials [in German]. Stuttgart: Georg Thieme Verlag, 2008:269.
3. Kappert HF, Eichner K (ed). Fullceramic systems, dental materials and their processing, Volume 1 Basics and processing [in German]. Stuttgart: Georg Thieme Verlag, 2008:326.
4. Kappert HF. The dental material ceramic. In: Strub JR, Türp JC, Witkowski S, Hürzeler MB, Kern M (eds). Dental materials curriculum prosthodontics, 2005. Berlin: Quintessence, 2005:607–641.
5. Mormann WH, Stawarczyk B, Ender A, Sener B, Attin T, Mehl A. Wear characteristics of current aesthetic dental restorative CAD/CAM materials: two-body wear, gloss retention, roughness and Martens hardness. J Mech Behav Biomed Mater 2013;20:113–125.
6. Ahlers MO, Mörig G, Blunck U, Hajtó J, Pröbster L, Frankenberger R. Guidelines for the preparation of CAD/CAM ceramic inlays and partial crowns. Int J Comput Dent 2009;12:309–325.
7. Pröbster L. Is there a scientific evidence for full ceramic crowns and bridges? [in German] Scientific Recommendation DGZMK 2003.
8. Pospiech, P. All-ceramic crowns: bonding or cementing? Clin Oral Investig 2002;6:189–197.
9. Zimmermann M, Mehl A, Reich S. New CAD/CAM materials and blocks for chairside procedures. Int J Comput Dent 2013;16:173–181.
10. Hickel R, Roulet JF, Bayne S, et al. Recommendations for conducting controlled clinical studies of dental restorative materials. Science Committee Project 2/98--FDI World Dental Federation study design (Part I) and criteria for evaluation (Part II) of direct and indirect restorations including onlays and partial crowns. J Adhes Dent 2007;9(Suppl 1):121–147.
11. Hickel R, Roulet JF, Bayne S, et al. Recommendations for conducting controlled clinical studies of dental restorative materials. Clin Oral Investig 2007;11:5–33.
12. Hickel R, Peschke A, Tyas M, et al. FDI World Dental Federation: clinical criteria for the evaluation of direct and indirect restorations-update and clinical examples. Clin Oral Investig 2010;14:349–366.
13. Hickel R, Peschke A, Tyas M, et al. FDI World Dental Federation: clinical criteria for the evaluation of direct and indirect restorations. Update and clinical examples. J Adhes Dent 2010;12:259–272.
14. Ender A, Mehl A. Full arch scans: conventional versus digital impressions: an in-vitro study. Int J Comput Dent 2011;14:11–21.
15. Posselt A, Kerschbaum T. Longevity of 2328 chairside Cerec inlays and onlays. Int J Comput Dent 2003;6:231–248.
16. Fasbinder D, Dennison JB, Heys D, Neiva G. A clinical evaluation of chairside lithium disilicate CAD/CAM crowns: a two-year report. J Am Dent Assoc 2010;141(Suppl 2):10–14.
17. Wittneben JG, Wright RF, Weber HP, Gallucci GO. A systematic review of the clinical performance of CAD/CAM single-tooth restorations. Int J Prosthodont 2009;22:466–471.
18. Toman M, Toksavul S. Clinical evaluation of 121 lithium disilicate all-ceramic crowns up to 9 years. Quintessence Int 2015;46:189–197.
19. Sulaiman TA, Delgado AJ, Donovan TE. Survival rate of lithium disilicate restorations at 4 years: a retrospective study. J Prosthet Dent 2015;114:364–366.