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Clinical Research

Clinical Evaluation of Ceramic Inlays and Onlays Fabricated With Two Systems: Five-Year Follow-Up

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Clinical Relevance

The adhesively bonded ceramic restorations presented satisfactory results after five years of clinical service. There was no significant difference between ceramic systems regarding survival.

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SUMMARY

This study evaluated the five-year clinical performance of ceramic inlays and onlays made with two systems: sintered Duceram (Dentsply-Degussa) and pressable IPS Empress (Ivoclar Vivadent). Eighty-six restorations were placed by a single operator in 35 patients with a median age of 33 years. The restorations were cemented with dual-cured resin cement (Variolink II, Ivoclar Vivadent) and Syntac Classic adhesive under rubber dam. The evaluations were conducted by two independent investigators at baseline, and at one, two, three, and five years using the modified United States Public Health Service (USPHS) criteria. At the five-year recall, 26 patients were evaluated (74.28%), totalling 62 (72.09%) restorations. Four IPS restorations were fractured, two restorations presented secondary caries (one from IPS and one from Duceram), and two restorations showed unacceptable defects at the restoration margin and needed replacement (one restoration from each ceramic system). A general success rate

of 87% was recorded. The Fisher exact test revealed no significant difference between Duceram and IPS Empress ceramic systems for all aspects evaluated at different recall appointments ($p>0.05$). The McNemar chi-square test showed significant differences in relation to marginal discoloration, marginal integrity, and surface texture between the baseline and five-year recall for both systems ($p<0.001$), with an increased percentage of Bravo scores. However, few Charlie or Delta scores were attributed to these restorations. In conclusion, these two types of ceramic materials demonstrated acceptable clinical performance after five years.

INTRODUCTION

Ceramic restorations are considered an excellent option to restore posterior teeth when esthetics is required and the size of the cavity preparation has exceeded the conventional indication for direct resin composites. Ceramic systems can combine esthetics with wear resistance, being considered a reliable treatment choice. Peutzfeldt[1] investigated the failure rate of different restorative materials used in posterior teeth and reported that gold inlays did not present a much lower failure rate than ceramic or composite inlays. Consequently, the author suggested that other aspects besides longevity, such as esthetics, price, and number and duration of dental appointments should also be considered when comparing treatment options. Different ceramic systems for fabricating inlay and onlay restorations are available on the market. Some of these ceramic restorations are made using feldspathic ceramic (from the conventional application of a slurry powder onto a refractory die); the CEREC computer-aided design/computer-aided manufacturing, CAD/CAM system, (Sirona Dental Systems GmbH, Bensheim, Germany); or the hot-pressed leucite-reinforced ceramic fabricated by the conventional lost-wax technique (IPS Empress, Ivoclar Vivadent, Schaan, Liechtenstein). Other systems that employ alumina or zirconia are available, but they are generally indicated for single- and multiple-unit crowns.[2,3]

Clinical studies have shown that higher success rates can be achieved when ceramic systems are used in conjunction with an adhesive cementation technique.[4,5] In order to accomplish the bonding requirements, the ceramic should permit selective dissolution via etching to create micromechanical adherence to the resin-based cements.[6] When etchable ceramics are treated with a hydrofluoric acid (HF), a volatile silicon tetrafluoride complex is first formed, and then a second reaction takes place to form a soluble complex ion, hexafluorosilicate, which will further react with the protons to form tetrafluorosilicic acid, which can be rinsed off with water.[2] This reaction enables the etched ceramic surface to be bonded to resin-based cements through the silane. The silane coupling agent is used to promote the chemical adhesion, functioning as a mediator between inorganic and organic substrates through dual reactivity to achieve adhesion.

Although short- and long-term clinical studies have shown low failure rates of adhesively bonded ceramic inlay and onlay restorations, some drawbacks have been reported, bulk fracture and marginal discoloration being the most commonly cited problems.[7–13] Deterioration of marginal quality has been addressed with regard to cement wear, which may be accelerated due to high differences in modulus of elasticity between ceramic and resin cement materials,[8,14] while bulk fracture has been associated with crack propagation through the ceramic, due to the brittle characteristic of the ceramic material.[1] Also, some other factors have been reported as coadjutants on the ceramic crack propagation, such as the microstructure of the ceramic material, the fabrication technique, the surface finishing, and the luting protocol.[15] It has been suggested that an observation period of at least five years should be employed to evaluate the performance of all-ceramic restorations in the posterior region.[16,17]

In that context, the aim of the present prospective study was to evaluate the clinical performance of adhesively bonded all-ceramic inlay and onlay restorations made with two different systems (IPS Empress and Duceram), according to United States Public Health Service (USPHS) criteria over five years. The null hypothesis tested was that there would be no difference in clinical performance between the two systems: IPS Empress and Duceram.

MATERIALS AND METHODS

This study involved 86 Class II inlay and onlay restorations fabricated with two different ceramic systems: 42 sintered ceramics (Duceram Plus and Duceram LFC, Dentsply Degussa Dental, Hanau, Germany) and 44 pressable ceramics (IPS Empress, Ivoclar Vivadent). A total of 33 onlays and 53 inlays were made in 27 premolars and 59 molars by one operator to create a standardized cavity preparation. In patients who had more than one restoration

placed, the two systems were used in an attempt to achieve the same number of each ceramic system in all patients.

Thirty-five patients, including 17 women and 18 men, with a median age of 33 years (ranging from 25 to 44 years) who required inlay and onlay restorations were selected for this study. The involved teeth were in occlusal contact. The volunteers underwent a careful case history review, and bitewing and periapical radiographs were taken. Vitality of the teeth was tested with carbon dioxide snow of −26.2°C.

The following items were considered as exclusion criteria: high caries risk (presence of incipient lesions, plaque, and xerostomia), periodontal disease, the presence of a removable or fixed orthodontic appliance, signs of bruxism or clenching, the absence of more than one unit in the posterior region, and poor oral hygiene or pregnancy. All patients were treated at the Bauru Dental School, University of São Paulo, SP, Brazil. They were informed about the research methodology, risks and benefits, and their right to withdraw participation in this research at any time. A written informed consent was signed. The study was carried out according to research norms and guidelines for human beings deriving from Resolution 196 approved in October 1996 by the National Health Council and Ethics Research Committee from the Bauru Dental School, University of São Paulo, SP, Brazil.

Tooth Preparation

All cavities were prepared according to the general principles for adhesive inlays and onlays.[18–19] The isthmus width was established between 1.5 and 2.0 mm, the pulpal floor depth was between 1.5 and 2.0 mm, the axial wall depth was 1.5 mm, the internal line angles were rounded, and the divergence angle of the cavity was approximately 10° to 15°, with no bevel. For onlays, the cusp reduction was established at 2.0 mm for centric cusps, and 1.5 mm for noncentric cusps. The undercuts were covered with resin-modified glass ionomer (Vitremer, 3M ESPE Dental Products Div, St Paul, MN, USA) to achieve the cavity form by removing the build-up material in order to preserve sound tooth structure. The tooth was prepared by means of a tapered, rounded diamond tips #4137 (ISO #025) and #4138 (ISO #018) (KG Sorensen Ind Com Ltda, São Paulo, SP, Brazil) in a high speed handpiece with water spray. The enamel margins were subsequently finished using hand instruments (Zerfing chisel, Duflex, S.S. White, Rio de Janeiro, RJ, Brazil).

Impression and Provisional Restoration Procedures

Full-arch impressions were made with a polyvinylsiloxane material (Express, 3M ESPE) for the prepared arches and with irreversible hydrocolloid (Jeltrate, Dentsply International Inc, York, PA, USA) for the antagonist arches. Both casts were poured with dental stone type IV (Durone, Dentsply). The bite-registration records were made by a polyvinylsiloxane material (Bite Registration, 3M Dental). Two dental ceramists were selected to produce the inlays and onlays, whose shades were selected from the Classical Vita shade guide (VITA Zahnfabrik, Bad Säckingen, Germany).

Provisional restorations were directly fabricated with the use of self-curing acrylic resin (DuraLay, Reliance Dental Mfg Co, Worth, IL, USA) and fixed with eugenol-free cement (TempBond NE, Kerr, Orange, CA, USA).

Luting Procedures

The intraoral fit was evaluated under rubber dam, and the internal adjustments were performed using diamond burs (KG Sorensen) with low speed. When the fit was not considered satisfactory, the restoration was rejected. Only two restorations were repeated.

Following adjustments, the internal surfaces were sandblasted with 50-μm aluminum oxide particles at a pressure of 87 psi (Opiblast, Buffalo Dental Mfg Inc, New York, NY, USA). These surfaces were then etched with 10% hydrofluoric acid (Dentsply) for 60 seconds and washed, and the silane agent (Monobond-S, Ivoclar Vivadent) was applied for 60 seconds and dried. The cavity was cleaned with pumice slurry and etched with 35% phosphoric acid gel for 15 seconds, rinsed with water, and gently air dried, taking care to avoid desiccation of the tooth substrate. The dentinal surface was treated with a dentin-bonding agent (Syntac primer and adhesive, Ivoclar Vivadent). Subsequently, the cavity preparation and intaglio surface of the ceramic inlays were covered with a layer of bonding agent (Heliobond, Ivoclar Vivadent) that was air-thinned but not light-cured. The dual-cured resin cement Variolink II (Ivoclar Vivadent) was used for the cementation of all inlays and onlays according to the manufacturer's instructions. The same color luting cement was used for all restorations. Polymerization of the luting

agent was performed by light curing the restoration from different positions—occlusal, buccal, lingual, and proximal surfaces for 60 seconds in each direction (XL2500, 570 mW/cm^2; 3M Dental).

Finishing Procedures

Excess luting composite was removed and the occlusal contacts adjusted with diamond finishing burs #1190 FF (ISO #010) and #3203 FF (ISO #012) (KG Sorensen) under water cooling. The surfaces were carefully polished with rubber tips (Cerapol Plus, Edenta AG Dental Rotary Instruments, Au, Switzerland) and the final polishing was conducted using felt discs with diamond polishing gel (KG Sorensen).

Evaluation Procedures

One week following placement, the restorations were assessed according to the modified USPHS criteria[20] (Table 1) by two independent investigators calibrated in the use of the system using only mirrors and probes. The investigators did not participate in the clinical procedures and did not know which system was used on the teeth they were evaluating. The same procedures performed at the baseline were performed at one, two, three, and five years. Statistical analyses were carried out with Fisher and McNemar tests at a 0.05 level of significance.

RESULTS

Table 2 summarizes the results of Alpha ratings obtained for both ceramic materials at baseline and at one-, two-, three-, and five-year recalls, according to the USPHS criteria.

Recall Rate

At five-year recall, 26 patients (including 62 restorations) were evaluated. Thirty-two IPS Empress restorations (72.72%) and 30 Duceram restorations (71.42%) were assessed by two independent evaluators. The recall rate at five-year examination was 74.28%.

Marginal Discoloration/Marginal Integrity

Marginal discoloration increased drastically after the five-year recall. A small number of restorations from both groups were rated as Alpha (Duceram=23.3%; IPS=21.9%). Nevertheless, marginal discoloration was considered clinically acceptable (Bravo), and no Charlie score was rated for any of the ceramic restorative materials. Concerning marginal integrity, only 33.3% of Duceram ceramic restorations and 31.3% of IPS Empress ceramic restorations exhibited perfect marginal adaptation and were rated as Alpha. However, for most of the ceramic restorations from the Duceram and IPS Empress systems, the decrease in marginal integrity was rated as clinically acceptable (Bravo). Just one restoration from each group was rated as Charlie and needed replacement.

Surface Texture

Upon assessment of the surface texture, there was no significant difference between the two ceramic systems ($p>0.05$). The number of restorations presenting ideal surface texture decreased noticeably after five years (Duceram=10%; IPS=25%).

Postoperative Sensitivity/Secondary Caries

After the five-year follow-up, none of the teeth restored with Duceram presented postoperative sensitivity (100%), and just two patients reported sensitivity for the IPS system (93.8%). In relation to secondary caries, one onlay ceramic restoration from the Duceram system and one onlay ceramic restoration from the IPS Empress presented recurrent caries and were classified as failures.

Fracture

Four restorations from the IPS Empress ceramic system exhibited fractures, lowering the Alpha rate to 87.5%. The fractured restorations consisted of two inlays and two onlays located on the molar region. No fractures were recorded for the restorations fabricated with the Duceram ceramic system (100%).

Color Match

In assessing the color match between the restoration and the tooth, 56.7% of the Duceram ceramic restorations were rated Alpha, while 37.5% of IPS Empress restorations were categorized as Alpha. One restoration of the Duceram system was rated Charlie, while four restorations from the IPS Empress system were classified as Charlie. Although the Duceram system showed slightly better results, this difference was not statistically significant ($p>0.05$).

Clinical Success Rate

At the five-year recall, four IPS Empress ceramic restorations were fractured, two restorations presented secondary caries (one from the IPS Empress system and one from Duceram system) and two

Table 1: *Modified United States Public Health Service Criteria for the Clinical Evaluation of Ceramic Inlays and Onlays Used in This Study*

Characteristic	Rating	Criteria
Postoperative sensitivity	Alpha	No postoperative sensitivity
	Bravo	Postoperative sensitivity
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 discoloration	Alpha	No discoloration on the margin between the restoration and the tooth structure
	Bravo	Discoloration on the margin between the restoration and the tooth structure
	Charlie	Discoloration has penetrated along the margin of the restorative material in a pulpal direction
Surface texture	Alpha	Smooth surface
	Bravo	Slightly rough or pitted, can be refinished
	Charlie	Rough, cannot be refinished
Marginal integrity	Alpha	No visible evidence of ditching along the margin
	Bravo	Visible evidence of ditching along the margin not extending to the dentinoenamel junction
	Charlie	Dentin or base is exposed along the margin
	Delta	Restoration is mobile, fractured, or missing
Color match	Alpha	No mismatch in color, shade, and translucency between restoration and adjacent tooth structure
	Bravo	Mismatch between restoration and tooth structure within the normal range of color, shade, and translucency
	Charlie	Mismatch between restoration and tooth structure outside the normal range of color, shade, and translucency
Fracture	Alpha	No evidence of fracture
	Bravo	Evidence of fracture

restorations showed unacceptable defect at the restoration margin, needing replacement (one restoration from each ceramic system). A general success rate of 87% was recorded for IPS Empress and 93.3% for Duceram. The Fisher exact test revealed no significant difference between Duceram and IPS Empress ceramic systems for all aspects evaluated at different recall appointments ($p>0.05$). Regarding the influence of the covariables (inlay × onlay; premolar × molar) on the clinical behavior of ceramic restorations, the Fisher exact test showed no statistical difference ($p>0.05$).

Table 2: *Alpha Results of IPS Empress (IPS) and Duceram (D) Ceramics According to Modified United States Public Health Service Criteria at Baseline, and at One, Two, Three, and Five Years (n = number of restorations evaluated)*

Recall	Baseline (n=86) 100%		1 Year (n=86) 100%		2 Years (n=86) 100%		3 Years (n=79) 92%		5 Years (n=62) 72%	
	IPS	D	IPS	D	IPS	D	IPS	D	IPS	D
Criterion										
Postoperative sensitivity	97.6	92.1	100	100	100	100	100	100	93.8	100
Secondary caries	100	100	100	100	100	100	97.5	97.4	96.9	96.7
Fracture	100	100	100	100	100	100	100	100	87.5	100
Color match	97.7	90.5	95.5	90.5	95.4	90.5	95.0	89.7	37.5	56.7
Marginal discoloration	100	100	75.0	88.1	68.2	76.2	62.5	64.1	21.9	23.3
Marginal integrity	100	100	88.6	90.5	81.8	88.1	77.5	84.6	31.3	33.3
Surface texture	97.7	88.1	97.7	88.1	97.7	85.7	82.5	56.4	25.0	10.0

The McNemar chi-square test was used to draw a comparison between baseline and five-year recall data for each ceramic system. Significant differences in relation to marginal discoloration, marginal integrity, surface texture, and color match were detected between the baseline and five-year recall ($p<0.001$) for the IPS Empress ceramic. For the Duceram ceramic, a significant difference was found in relation to marginal discoloration, marginal integrity, and surface texture ($p<0.001$).

DISCUSSION

The null hypothesis that there would be no difference in clinical performance between the two ceramic systems was supported. At five-year evaluation of adhesively luted ceramic inlay and onlay restorations, no significant difference between Duceram and IPS Empress ceramic systems was found for any aspect evaluated at different recall appointments ($p>0.05$). This result is in accordance with a previous study that reported no significant difference between the conventional porcelain (Vitadur Alpha) and the leucite-reinforced porcelain (IPS Empress) at five-year evaluation.[21] Regarding the conventional ceramic systems, it has been reported that the main disadvantage of fired ceramic restorations is the degree of microporosities and inhomogeneities between the ceramic particles due to the fabrication technique used to process these restorations.[22] On the other hand, the IPS Empress system has been considered a more homogeneous ceramic through the use of precerammed ingots and has also shown superior flexure strength in laboratory tests when compared to less reinforced ceramics.[23] However, the clinical relevance of such a difference between the two systems could not be upheld in this study at five-year evaluation. Both systems presented satisfactory results with a success rate of 87% for IPS Empress and 93.3% for Duceram.

Other studies with a similar time frame of evaluation have reported overall success rates of between 90% and 95% of ceramic restorations investigated.[7,9,21,24,25] In these previous studies, the main cause of failure was associated with bulk fracture of the ceramic restoration and secondary caries.

In the present study, 67 restorations were evaluated at five years. The sample size may not be large, but it is comparable to previous studies[7,9,11,13,25] in which one operator carried out all of the restorative treatments, rather than multiple operators carrying out treatments at multiple centers. The dropout rate with regard to the number of restorations was 22% (19 restorations), and 26% with respect to the number of patients (nine patients). Of the nine patients who could not participate in the five-year recall, four had moved to another city, three could not be reached by telephone nor e-mail, and two did

not want to participate. At five-year recall, eight restorations needed to be replaced (11.9%). Four IPS Empress restorations suffered cohesive bulk fractures (6%), two restorations presented secondary caries (one from IPS and one from Duceram) and two restorations showed unacceptable defects at the restoration margin needing replacement (one restoration from each ceramic system). Bulk fracture is still considered one common problem reported in clinical trials.[26] The failure rate associated with bulk fracture in the present study is in accordance with other studies that performed their evaluations in the same time frame (Arnelund and others,[21] 8% after five years; Naeselius and others,[27] 7.3% after four years; Krämer and others,[9] 5.5% after four years). Molin and Karlsson[7] investigated the five-year performance of three inlay ceramic systems (CAD-CAM, Vita Cerec-Siemens; a conventional porcelain buildup sintering technique, Mirage, Myron; and a glass ceramic casting high-pressure technique, IPS Empress, Ivoclar Vivadent) and reported that among the 60 ceramic inlays placed, five inlays (8%) fractured within the five-year follow-up period, four being from the IPS Empress system and one from the Cerec system.

Unlike metals, resin composites, and dental tissues, ceramic materials are unable to endure elastic deformation to the same level. Ceramic materials possess a high modulus of elasticity and low flexural strength, which is a limiting property of brittle materials.[28]

Fischer and others[29] evaluated the long-term failure probability of different ceramic materials using a computational method and reported a high tendency for failure of the IPS Empress system (2.6% after one year, 4.6% after five years, and 6.0% after 10 years, respectively). Previous clinical studies that have investigated the IPS Empress system have reported different failure rates due to fracture in different periods of evaluation (Studer and others,[26] 2.3% after three years; Galiatsatos and Bergou,[11] 3.1% after six years; Frankenberger and others,[10] 16% after 12 years). However, it is relevant to take in account that factors other than the ceramic material may have an influence on the restoration survival. According to Martin and Jedynakiewicz,[30] the most common reasons for all-ceramic restoration failures are fracture of the ceramic, fracture of the supporting tooth, postoperative hypersensitivity, and wear of the resin luting agent. In their study, the main reason for fracture was usually related to either excessive occlusal loads or insufficient ceramic thickness. The recommended minimum thickness of 1.5 mm should always be observed in order to improve strength. According to van Dijken and others[31] a cuspal overlay should permit a material thickness of ideally 2 mm. Also, the presence of cracks on the ceramic restoration can lead to fracture of the ceramic material by crack propagation under excessive tensile stresses. These cracks can be produced by finishing and polishing procedures, by processing, or by intrinsic defects in the structure of the material.[32] So, a careful finishing procedure should be employed when adjusting the occlusal surface of the restoration, since it has been reported that cracks as small as 25 μm can lead to fracture of the ceramic restoration under function.[28]

Drawing a comparison between the data collected at the five-year recall appointments, no fracture was observed until five-year evaluation. Secondary caries were observed in one restoration from each system at three-year recall, and one more for each system at five-year recall. It is interesting to notice that the number of Alpha scores for marginal discoloration, marginal integrity, and surface texture has declined significantly for both systems ($p<0.001$), from the baseline to all other subsequent follow-ups. Color match showed a significantly reduced performance for the IPS Empress system ($p<0.001$) after five-year evaluation. The explanation may be related to the fading of the extrinsic painting used on the external surface of these IPS ceramic restorations to enhance the esthetic result. In this system, a precerammed monochromatic ingot is selected, heated, and pressed to process the ceramic restoration using the traditional lost-wax technique, while for the conventional porcelain buildup sintering technique, layers with different degrees of translucencies and opacities can be employed.

Because of esthetic reasons, there is a tendency nowadays to select ceramic materials, rather than gold, when dealing with partial restorations. Wagner and others[33] evaluated the performance of gold and ceramic onlays for about seven years and found no statistical difference between the two restorative groups. Federlin and others[34] have reported similar survival rates for both gold and ceramic onlays at five and a half years of evaluation; however, they verified a statistically significant decrease of Alfa ratings for anatomic form and marginal discoloration criteria on the ceramic restorations.

In relation to marginal discoloration and marginal integrity, significant differences were detected between the baseline and the five-year recall data. After five years, significant reduction on Alpha scores was observed for marginal discoloration,

marginal integrity, color match, and surface texture (McNemar chi-square test, $p<0.001$). Several studies have reported a significant increase of marginal discoloration and decrease of marginal integrity over time.[7–13] Frankenberger and others[35] verified that 94% of the surviving restorations exhibited marginal deficiencies after six years. Deterioration and wear of the resin luting agent has been considered a contributory factor in the marginal deterioration of the ceramic restorations.[7,8,11,13,35] This fact was associated with a very high modulus of elasticity of the ceramic material, which during masticatory forces transmits stress to the cement, whose modulus of elasticity is lower.[8,14] Although marginal discoloration has been regarded as a common phenomenon addressed in clinical trials, it has not been considered critical for the clinical performance of the ceramic restorations.[8,11–13]

Some studies[35,36] have considered postoperative sensitivity as another clinical complication; however, it was not an issue in the present study. In this study, all deep areas and undercuts were covered with a resin-modified glass ionomer (Vitremer, 3M ESPE) before final preparation to protect the exposed deep dentin and to help standardize the depth of the pulpal floor (from 1.5 to 2.0 mm). All restorations were adhesively cemented with the three-step etch and rinse Syntac adhesive and Variolink II resin cement. Krämer and others[9] used the same cementation protocol employed in the present study and reported low sensitivity with the use of Syntac adhesive and Variolink resin cement.

The occurrence of dropped participants is inevitable in clinical trials. In the present study 35 patients, representing 86 restorations (100%) were evaluated at the two-year recall. At the five-year examination, 62 restorations in 26 patients were evaluated (74.28%), totalling 32 IPS Empress restorations (72.72%) and 30 Duceram restorations (71.42%).

Comparing inlay vs onlay restoration types and in relation to premolar and molar regions, no statistically significant differences were observed. These results are in accordance with Arnelund and others,[21] whose clinical evaluations revealed no significant difference between ceramic inlays and onlays after five-year evaluation. Manhart and others,[37] however, observed significantly higher failure rates for inlays placed in molars compared with premolars. In the present study, the fractures occurred in the molar region for both inlay and onlay restorations; however, this result was not statistically significant. In addition, despite the fact that molars are usually subjected to more intense chewing forces, this negative effect did not result in significant influence at the five-year recall evaluation.

CONCLUSIONS

It can be concluded that the adhesively bonded ceramic restorations presented satisfactory results at five-year evaluation. The null hypothesis was not rejected, since no significant differences were noticed between the two ceramic systems. The advantages of these partial all-ceramic inlay and onlay restorations include less tooth destruction; avoidance of subgingival restoration margins, usually required by crowns; and good esthetic results.

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Conflict of Interest

The authors of this manuscript certify that they have no proprietary, financial or other personal interest of any nature or kind in any product, service and/or company that is presented in this article.

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