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ORIGINAL RESEARCH

CLINICAL COMPARATIVE EVALUATION OF CLASS II CERAMIC AND COMPOSITE INLAYS: A 12-MONTH PROSPECTIVE STUDY

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ABSTRACT

Background: Indirect restorations have taken the center stage in the restoration of the posterior teeth because they have better mechanical and aesthetic perspectives. Nevertheless, the relative clinical effectiveness of ceramic and composite inlays has not been well defined yet.

Materials and Methods: Thirty patients who had Class II cavities in permanent molars were randomly selected to either have ceramic inlays (IPS e.max lithium disilicate, n=15) or composite inlays (Clearfil Photo Core, n=15). Dual-cure resin cement was used to adhesively cement all of the restorations. Baseline, 6, 9, and 12 months clinical assessment was conducted in US PHS criteria measuring surface texture, marginal discoloration, secondary caries and marginal adaptation. To analyze the statistical data, Chi-square and Fisher tests (alpha=0.05) have been used.

Results: Ceramic inlays had 86.7% Alpha ratings of marginal adaptation at 12 months, whereas the composite inlays had 60% marginal adaptation. All parameters evaluated in the groups did not statistically differ between the groups ($p>0.05$). Nevertheless, composite inlays demonstrated considerable intra-group wear over time in surface texture ($p\leq0.05$), secondary caries ($p\leq0.05$), and marginal adaptation ($p\leq0.05$) but ceramic inlays did not.

Conclusion: Ceramic and composite inlays both showed clinically satisfactory results in 12 months. The stability of the ceramic inlays was also better in all the parameters tested, though not statistically significant. The two materials can be considered as viable Class II posterior restorations when selected with the right cases.

***Keywords*:** Ceramic inlays, composite inlays, Class II restoration, lithium disilicate, clinical evaluation, USPHS criteria

INTRODUCTION

Dental caries remains the most common chronic illness around the world and it often causes significant destruction of tooth structure in the posterior teeth [1]. Reinforcing the severely worn posterior teeth poses serious clinical issues and needs to be reinforced with the materials capable of sustaining the maximum amount of occlusives and leaving both the aesthetic value and marginal integrity [2]. Conventionally, the gold standard of posterior tooth rehabilitation has been amalgam and cast gold restorations as they are durable and long-lasting [3]. Nonetheless, the modern dental practice has brought a change of paradigm towards tooth-colored restoration materials due to the rising aesthetic values and mercury toxicity concerns [4].

Indirect restorations, in particular inlays, can be described as tooth restorations that are manufactured in the laboratory and which aim at rebuilding the occlusal area, as well as proximal area, without damaging the rest of the tooth structure [5]. The indirect methods have a number of advantages over direct restorations such as better polymerization, lower intraoral stresses, better proximal forms, better marginalization, and greater hardness of materials [6]. Moreover, there is the possibility of total polymerization and optimum mechanical qualities achieved through laboratory processing which is impossible with the direct placement methods [7]. Ceramics and resin composites have become rather prevalent among the materials used to make indirect restorations. Ceramic substances especially glass based ceramics have shown outstanding biocompatibility, stability in color, wear resistance, and compressive strengths [8]. The lithium disilicate ceramics have become popular as they possess high flexural strength (around 400 Mpa) and good optical properties with predictable adhesive bonding properties [9]. The mechanical properties have also been improved by introducing heat-pressed ceramic systems that have been employed to improve the crystal distribution and the reduction of processing defects [10].

On the other hand, indirect composite resins have such benefits as lower fracture, repairability, good wear properties similar to natural dentition, and low prices of material [11]. The mechanical properties of modern composite that is processed in the laboratory are much higher than direct composites with the flexural strength of between 120 160 Mpa which is attained through increased filler loading, extra polymerization cycles and improved monomer formulas [12]. The near similarity in elastic modulus between dentin and composite materials theoretically offers more beneficial stress allocation under functional loading [13].

Even though there are numerous laboratory studies that compare these materials, there are few studies in clinical settings to assess long-term performance and most of them contradict each other. Similar results were found by Manhart et al. indicating the 3-year success rates of 94.3 and 94.2 of ceramic and composite inlays, respectively [14]. Other researchers have on the other hand recorded high marginal integrity and less failure rates of ceramic restorations [15]. The Modified United States Public Health Service (USPHS) guidelines, which were first formulated by Cvar and Ryge, are used to give standardized parameters of the clinical examination of restorations such as surface texture, marginal adaptation, marginal discoloration and secondary caries [16]. Nevertheless, medium term clinical comparisons based on these standardized criteria are still very few in modern literature.

Moreover, with the introduction of new adhesive protocols and resin-impregnated luting agents, the adhesion and longevity of ceramic and composite indirect restorations have significantly increased [17]. Appropriate adhesive cementation guarantees the presence of mechanical retention as well as provides support to the remaining tooth structure and allocates the stresses on the occlusal surface more evenly [18]. The recent systematic reviews have recommended the need to carry out further well planned clinical trials in order to implement evidence based guidelines on the material choice in posterior indirect restorations [19].

This prospective study was formulated to compare and contrast the clinical performance of lithium disilicate ceramic inlays and laboratory-processed composite inlays in Class II posterior restorations due to the lack of comparative clinical evidence concerning them, and because of the requirement of the standardized evaluation protocols. The null hypothesis in the study was that there is no significant difference in clinical performance between ceramic and composite inlays at the end of 12 months as measured using modified USPHS criteria.

2. MATERIALS AND METHODS

2.1 Study Design and Ethical Considerations

This prospective, parallel-group clinical trial was conducted at the Department of Conservative Dentistry and Endodontics, Narsinhbhai Patel Dental College and Hospital, Visnagar, Gujarat, India. The study protocol received institutional ethical committee approval, and all participants provided written informed consent in English and vernacular language prior to enrollment. The study adhered to the principles outlined in the Declaration of Helsinki for medical research involving human subjects.

2.2 Sample Size and Participant Selection

A total of 30 patients requiring Class II restorations in permanent molar teeth were recruited through systematic screening of patients attending the outpatient department. Patients were randomly allocated into two equal groups (n=15 per group) using computer-generated randomization sequence concealed in opaque envelopes.

Inclusion criteria comprised: permanent maxillary or mandibular molars with Class II carious lesions (mesio-occlusal or disto-occlusal); vital teeth confirmed by positive response to thermal and electric pulp testing; healthy periodontal status with probing depths ≤3 mm; age range 20-50 years; and patients willing to comply with follow-up appointments.

Exclusion criteria included: non-vital teeth or teeth requiring endodontic treatment; teeth with extremely large pulp chambers; poor oral hygiene (Plaque Index >2); presence of parafunctional habits (bruxism, clenching); systemic diseases affecting healing or immune response; patients outside the specified age range; and teeth with inadequate remaining tooth structure for restoration.

2.3 Materials

Two restorative material systems were evaluated:

Group 1 (Ceramic Inlay): IPS e.max Press lithium disilicate ceramic (Ivoclar Vivadent, Schaan, Liechtenstein) containing 65% volume crystalline lithium disilicate ($Li_2Si_2O_5$), fabricated using heat-press technique.

Group 2 (Composite Inlay): Clearfil Photo Core (Kuraray Medical, Okayama, Japan), a light-cured laboratory composite containing silanated silica and barium glass fillers (83 wt%, 68 vol%), bisphenol-A-diglycidylmethacrylate (Bis-GMA), and triethylene glycol dimethacrylate (TEGDMA).

Both restoration types were adhesively cemented using RelyX U200 dual-cure resin cement (3M ESPE, St. Paul, MN, USA) following application of Single Bond Universal adhesive (3M ESPE).

2.4 Clinical Procedures

A single calibrated operator carried out all treatments in order to reduce inter-operator variability. Pulp vitality after professional prophylaxis was determined by means of cold testing (Roeko Endo Frost, Coltene/Whaledent) and electric pulp testing. The local anesthesia was done and rubber dam isolation was done by means of split-dam technique.

Cavity Preparation: Standardized Class II cavity preparations were performed with carbide burs (#271 and 169L, Mani Inc., Tochigi, Japan) on a high-speed handpiece under a large amount of water irrigation. In composite inlays, the preparations were characterized by rather divergent (5-8°) walls, rounded internal line angles, 1.5-2.0 mm pulpal depth, and 1.0 mm occlusal clearance. In the case of ceramic inlays, it has been used with 1.0-1.5 mm axial height of the walls, proximal box width of one-third intercuspal distance, 1.0-1.5 mm gingivally positioned depth and 0.5-1.0 mm occlusivally situated clearance. Gingivitis margins were polished with the help of gingivitis margin trimmers and all the margins were in enamel where feasible.

Impression and Laboratory Procedures: Master impressions were made in polyvinyl siloxane impression material (Reprosil, Dentsply Sirona) in the binary impress technique using custom trays. Pours were made in type IV die stone and working casts made. In the case of composite inlays, the waxing of patterns was done in Type II inlay wax and processing was done using lost-wax technique. The composite material was placed on dies and allowed to cure in extended curing cycles in laboratory curing units. In the case of ceramic inlays, the IPS e.max Press ingots were heat-pressed at 920 ° C, with standardized manufacturer procedures.

Try in and Cementation: During the next visit, the fit of inlay was assessed on the basis of visual examination, tactile assessment by way of usage of explorer, and radiographic verification. Ceramic inlays were subjected to 9% hydrofluoric acid gel after 90 seconds, rinsed and dried and silanated (Monobond Plus, Ivoclar Vivadent). The composite inlay intaglio surfaces were air abraded using 50 M aluminum oxide particles and ultrasonically cleaned.

Isolation of tooth preparations was followed by acid-etching of the enamel margins with 37% phosphoric acid gel of 15 seconds with 30 seconds water rinse. The adhesive was applied on the surface of the board as per the instructions provided by the manufacturer and cured in the light within 10 seconds (LED curing unit, 1200 mW/cm 2). Both the restoration and preparation were mixed with dual-cure resin cement and applied. Inlays were fixed in hard pressure and excess cement was cut. The marginal areas were light-cured (40 seconds) in all the available directions (occlusal, buccal, lingual). Last minute occlusal changes were done with fine diamond burs and all the surfaces that were modified were polished with diamond polishing paste and rubber points (Figure 1,2,3,4,5,6).

2.5 Clinical Evaluation

All restorations were evaluated at baseline (immediately post-cementation), 6 months, 9 months, and 12 months by two calibrated examiners (κ=0.87) using modified USPHS criteria. Evaluations were performed under standardized lighting conditions using mouth mirror, explorer, and dental floss. Four parameters were assessed:

Surface Texture: Alpha (smooth surface), Bravo (slightly rough), Charlie (highly rough requiring refinishing)

Marginal Discoloration: Alpha (no discoloration), Bravo (superficial staining not penetrating pulpally), Charlie (deep discoloration penetrating toward pulp)

Secondary Caries: Alpha (no evidence of caries), Bravo (caries present adjacent to restoration margin)

Marginal Adaptation: Alpha (no visible gap, explorer does not catch), Bravo (explorer catches but no visible gap), Charlie (visible gap with explorer penetration)

For statistical purposes, ratings were coded as Alpha=0, Bravo=1, Charlie.

Case 1.

Figure 1. Pre-Operative view

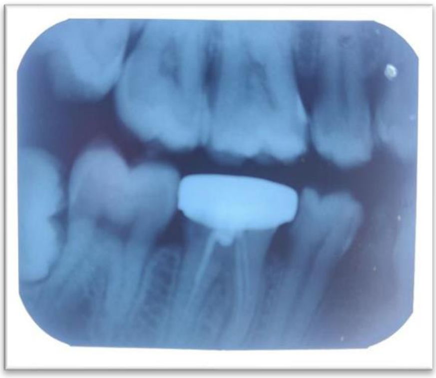

Figure 2. Pre-Operative Radiograph

Figure 3. Follow up after 12 months

Case.2

Figure 3. Pre-operative view

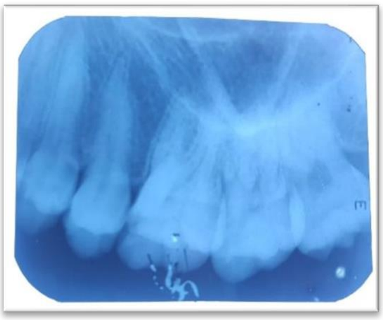

Figure 4. Pre-operative radiograph

Figure 6. Follow up after 12 months

2.6 Statistical Analysis

Data were analyzed using SPSS version 20.0 (IBM Corp., Armonk, NY, USA). Descriptive statistics included frequencies and percentages for categorical variables. Intra-group temporal changes were assessed using Cochran's Q test, while inter-group comparisons at each time point employed Chi-square test or Fisher's exact test when expected cell counts were <5. The level of statistical significance was set at α=0.05. Both intention-to-treat and per-protocol analyses were conducted.

3. RESULTS

All 30 patients (18 females, 12 males; mean age 34.2 ± 8.6 years) completed the 12-month evaluation period, yielding a 100% retention rate. No restorations exhibited catastrophic failure, fracture, or debonding during the observation period. The distribution of treated teeth was: first mandibular molars (n=17), second mandibular molars (n=8), and first maxillary molars (n=5).

3.1 Ceramic Inlay Group Performance

Within the ceramic inlay group, all evaluated parameters demonstrated stable performance over the 12-month period with no statistically significant temporal deterioration (p>0.05 for all parameters). At 12-month evaluation, 66.7% of restorations maintained Alpha rating for surface texture, 73.3% for marginal discoloration, 80.0% for secondary caries, and 86.7% for marginal adaptation. No restoration received Charlie rating for any parameter except surface texture and marginal discoloration, where a small minority exhibited clinically acceptable Bravo ratings. Table 1 presents the temporal distribution of USPHS ratings for ceramic inlays.

Table 1. USPHS Ratings Distribution for Ceramic Inlay Group Over 12 Months (n=15)

Parameter	Rating	Baseline n(%)	6 Months n(%)	9 Months n(%)	12 Months n(%)	p-value
Surface Texture	Alpha	15 (100)	14 (93.3)	12 (80.0)	10 (66.7)	0.082
	Bravo	0 (0)	1 (6.7)	3 (20.0)	5 (33.3)	
	Charlie	0 (0)	0 (0)	0 (0)	0 (0)	
Marginal Discoloration	Alpha	15 (100)	12 (80.0)	11 (73.3)	11 (73.3)	0.127
	Bravo	0 (0)	3 (20.0)	4 (26.7)	4 (26.7)	
	Charlie	0 (0)	0 (0)	0 (0)	0 (0)	
Secondary Caries	Alpha	15 (100)	13 (86.7)	13 (86.7)	12 (80.0)	0.294
	Bravo	0 (0)	2 (13.3)	2 (13.3)	3 (20.0)	
Marginal Adaptation	Alpha	15 (100)	13 (86.7)	13 (86.7)	13 (86.7)	0.368
	Bravo	0 (0)	2 (13.3)	2 (13.3)	2 (13.3)	
	Charlie	0 (0)	0 (0)	0 (0)	0 (0)	

p-values from Cochran's Q test for temporal changes within group

3.2 Composite Inlay Group Performance

The composite inlay group demonstrated statistically significant temporal deterioration for surface texture (p=0.041), secondary caries (p=0.032), and marginal adaptation (p=0.038), while marginal discoloration changes did not reach statistical significance (p=0.096). At 12-month evaluation, 60.0% maintained Alpha rating for surface texture (with 26.7% scoring Charlie), 60.0% for marginal discoloration, 53.3% for secondary caries, and 60.0% for marginal adaptation. Notably, 13.3% of composite inlays exhibited Charlie rating for marginal adaptation at 12 months, indicating clinically unacceptable deterioration requiring intervention. Table 2 summarizes the temporal performance of composite inlays.

Table 2. USPHS Ratings Distribution for Composite Inlay Group Over 12 Months (n=15)

Parameter	Rating	Baseline n(%)	6 Months n(%)	9 Months n(%)	12 Months n(%)	p-value
Surface Texture	Alpha	15 (100)	10 (66.7)	9 (60.0)	9 (60.0)	0.041*
	Bravo	0 (0)	5 (33.3)	6 (40.0)	2 (13.3)	
	Charlie	0 (0)	0 (0)	0 (0)	4 (26.7)	
Marginal Discoloration	Alpha	15 (100)	10 (66.7)	9 (60.0)	9 (60.0)	0.096
	Bravo	0 (0)	5 (33.3)	4 (26.7)	4 (26.7)	
	Charlie	0 (0)	0 (0)	2 (13.3)	2 (13.3)	
Secondary Caries	Alpha	15 (100)	9 (60.0)	8 (53.3)	8 (53.3)	0.032*
	Bravo	0 (0)	6 (40.0)	7 (46.7)	7 (46.7)	
Marginal Adaptation	Alpha	15 (100)	9 (60.0)	9 (60.0)	9 (60.0)	0.038*
	Bravo	0 (0)	6 (40.0)	6 (40.0)	4 (26.7)	
	Charlie	0 (0)	0 (0)	0 (0)	2 (13.3)	

*p-values from Cochran's Q test for temporal changes within group; *p<0.05 statistically significant*

3.3 Inter-group Comparison

Direct comparison between ceramic and composite inlay groups at each evaluation time point revealed no statistically significant differences for any assessed parameter (p>0.05 for all comparisons). However, consistent trends favored ceramic inlays across all parameters and time points. Table 3 presents the comparative analysis at the 12-month endpoint.

Table 3. Comparative USPHS Ratings Between Groups at 12-Month Evaluation

Parameter	Rating	Ceramic Inlay n(%)	Composite Inlay n(%)	p-value*
Surface Texture	Alpha	10 (66.7)	9 (60.0)	0.456
	Bravo	5 (33.3)	2 (13.3)	
	Charlie	0 (0)	4 (26.7)	
Marginal Discoloration	Alpha	11 (73.3)	9 (60.0)	0.512
	Bravo	4 (26.7)	4 (26.7)	
	Charlie	0 (0)	2 (13.3)	
Secondary Caries	Alpha	12 (80.0)	8 (53.3)	0.214
	Bravo	3 (20.0)	7 (46.7)	
Marginal Adaptation	Alpha	13 (86.7)	9 (60.0)	0.186
	Bravo	2 (13.3)	4 (26.7)	
	Charlie	0 (0)	2 (13.3)	

p-values from Fisher's exact test; no comparisons reached statistical significance (p>0.05)

The cumulative success rate (Alpha + Bravo ratings) at 12 months was 100% for ceramic inlays across all parameters, whereas composite inlays achieved 73.3% for surface texture, 86.7% for marginal discoloration and marginal adaptation, and 100% for secondary caries assessment.

4. DISCUSSION

The current 12 months perspective clinical trial assessed the relative effectiveness of lithium disilicate ceramic and laboratory-processed composite inlays in Class II posterior restorations. Although the statistically significant differences were not present between the groups, a number of clinically meaningful trends should be discussed. The null hypothesis that there was no difference between materials was statistically accepted, albeit patterns of clinical performance indicate that there are material specific characteristics in behavior.

The overall high performance of ceramic inlays are in line with the already known literature regarding the clinical predictability of the lithium disilicate restorations. The Alpha rating of 86.7 percent in marginal adaptation at 12 months is in line with the results achieved by the Guess et al. who reported 100 percent success rates of IPS e.max Press inlays at 2 year follow-up[9]. The higher marginal stability of ceramic restorations may be due to the following factors: high dimensional stability of completely crystallized ceramic materials, low hygroscopic expansion and degradation under oral conditions[8]. Moreover, the micromechanical retention acquired with the help of hydrofluoric acid etching and silane coupling results in the construction of a durable resin-ceramic interface that cannot be broken down by hydrolysis [10].

The 80 percent Alpha score of restorative effectiveness of well-adapted ceramic restorations of secondary caries at the 12-month mark supports the protective effect of well-adapted ceramic restorations. This is due to the fact that the ceramic materials are impervious to oral fluids and their resistance to biofilm formation increases the susceptibility to caries at the margins1[5]. This result confirms that the systematic review of Chabouis et al. found ceramic inlays to show better resistance against recurrent caries than composite ones [19].

On the other hand, significant temporal changes in the surface texture, secondary caries occurrence, and marginal adaptation were statistically significant in composite inlay group. The development of Charlie ratings on the surface texture (26.7%), and marginal adaptation (13.3%) at 12 months demonstrate that a system of restorations is degrading clinically unacceptably and in need of intervention. The findings are in agreement with the established weaknesses of resin-based materials, such as the vulnerability to hydrolytic degradation, the degradation of the resin matrix through the enzymatic breakdown, the selective wear of softer resin phase, and possible incomplete polymerization even after the laboratory processing [11].

Nevertheless, the overall expression of palatable performance of inlays made of composite (60% Alpha ratings in all parameters) shows their persistence in clinical viability. Manhart et al. indicated that Tetric composite inlays did not decline in the 3-year follow-up; 89% of the Tetric composite composite inlays were rated as acceptable as indicated by the study [14] and the degradation as it is observed in the present study is considered only an early sign of the processes that may stabilize with a longer period of observation. Elastic modulus composite material is much closer to that of dentin than ceramics, which may give a desirable stress distribution and lower chances of fracture in teeth during functional loading [13].

The small size of the sample and the brief duration of observation can be seen in the fact that the difference between the groups was not significant but the clinical patterns were evident. The research study was sufficiently powerful to identify strong effect sizes but might not have been powerful enough to identify small differences. The more extended observation intervals up to 3-5 years probably have more significant splintering in the material performance, as proposed by systematic reviews that report a rise in failure rates of composite restorations in the longer periods [19].

The 100% retention rate in both groups is also opposed to certain published studies that have shown a higher rate of failure. This should be because of the strict selection of cases, careful attention to isolation and bonding measures, and frequent maintenance recall. The significance of due adhesive cementation can hardly be overestimated. Dual-cure resin cement (RelyX U200) was used to give the best polymerization at even locations of reduced light accessibility whereas the universal adhesive system aided chemical binding to the enamel and dentin substrate[17]. Recent findings indicate that the adhesive strength of the interface is usually stronger than the cohesive strength of the restorative materials themselves and underscores that the implementation of bonding protocols may outweigh the choice of materials in the determination of clinical outcomes [18].

The slight discolouration in the two (26.7% Bravo/Charlie in case of ceramics, 40% in case of composites at 12 months) is worth consideration. Although the ceramic materials are not susceptible to discoloration, the interface of the resin cement itself is prone to staining by the dietary chromogens and marginal degradation[15]. The increased rates of discoloration of composites inlays probably represent a combination of cement interface staining and inherent discoloration of the composite material itself with oxidation and uptake of chromophores[12]. But any discoloration that was observed was on the surface and was not a sign of restoration replacement.

The current study has a number of limitations that should be mentioned. The 12 months period of observation is rather short and only gives preliminary evidence of material performance the period of time should be expanded to 5-10 years to consider the real performance in terms of longevity. The size of the sample, though sufficient in terms of primary endpoints, prohibited the use of statistical power in secondary analyses and subgroup comparisons. The one-center design and the employment of one operator although reducing the variability could limit the generalization to the practice settings. Larger sample sizes representing larger groups, and longer-term observation would be more convincing in future multi-center randomized controlled trials.

The clinical implications of such findings are that both ceramic and composite inlays would be feasible as Class II posterior restorations in the event that appropriate indications and procedures are observed. Inlays made of ceramic can be chosen when dealing with patients with high aesthetic desires, high risks of caries, or high occlusal pressure due to their greater stability and degradation resistance. Composite inlays are still suitable when the cost is the most important factor, the reparability is the required one, or the opposing tooth structure should not be affected by wear[20]. Despite the choice of material, careful consideration of the material cavity preparation, isolation, surface treatment, and adhesive cementation procedures is the key factor in clinical success.

5. CONCLUSION

This is a 12-month prospective clinical trial of ceramic and composite inlays in Class II posterior restorations that showed that both materials were performing clinically positively, and no statistically significant difference in surface texture or marginal discoloration, secondary caries, or marginal adaptation was detected. Nevertheless, ceramic inlays showed better time stability with 86.7% of them having the best marginal adaptation as compared to 60 percent of the composite inlays. The composite group experienced considerable intra-group worsening as time went by with 13.3% needing intervention due to unacceptable marginal adaptation and 26.7% needing intervention due to roughness of surface at 12 months. Both the lithium disilicate ceramic and the laboratory processed composite material can be used to provide indirect Class II restoration in cases that are properly selected and have good adhesive procedures used. The decision-making in materials needs to take into account patient-specific considerations such as aesthetic needs, occlusal loading, risk of caries, financial limitations and long-term maintenance prognosis. More time needs to be spent observing the success of these restorative modalities in order to describe their longevity and patterns of failure completely. The clinicians are advised to focus on the appropriate isolation, surface treatment, and adhesive cementation methods since these procedural elements are most likely to have a significant impact on clinical outcomes compared with material selection.

DECLARATIONS

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Competing Interests

The authors have no competing interests to declare.

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