Comparison of 2 Bonding Systems and Survival of Fiber-Reinforced Composite Inlay Fixed Partial Dentures

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> Purpose: This pilot clinical trial evaluated the clinical behavior of 3-unit inlay fixed partial dentures (IFPDs) made of the glass-fiber composite system SR Adoro/Vectris and luted with 2 different bonding systems over an observation period of 2 years. Materials and Methods: Thirty-nine glass-fiber-reinforced composite IFPDs were made to replace 1 missing maxillary or mandibular tooth. Nineteen IFPDs were randomly assigned to group A and luted with a 2-step bonding system (Excite DSC), while the other 20 IFPDs of group B were cemented with a 3-step adhesive (Syntac). Events such as partial or total debonding of the IFPDs, fracture of the framework, or veneer and fiber exposures were considered failures. Color match, marginal discoloration, secondary caries, marginal adaptation, postoperative sensitivity, and surface texture were evaluated according to the United States Public Health Service modified criteria. *Results:* Two debondings and 2 fiber exposures occurred during the observation period. All failures occurred in group A. Some fatigue microcracks in the pontic area of the 2 detached IFPDs were observed under scanning electron microscopy. The postoperative sensitivity of group A was much higher than that of group B, and the abutments luted with Excite DCS showed postoperative sensitivity during the first month in 42.2% of cases. The sensitivity disappeared completely after 6 months. Statistical analysis indicated significant differences in postoperative sensitivity (P < .05) between the 2 groups. Conclusion: The IFPDs bonded with a 3step adhesive demonstrated good clinical service in the short observation period. The microfractures of the layering material observed on the debonded IFPDs may suggest excessive flexibility of the fiber structures, which occurs if the framework is fabricated without observing the recommended dimensions. Int J Prosthodont 2006;19:577-585.

For several years, the metal-ceramic fixed partial denture (FPD) has been regarded as the standard restoration for single-tooth replacement. Furthermore, the porcelain-fused-to-metal (PFM) technique has

demonstrated an excellent service record in spite of its several drawbacks,¹ particularly the significant amount of sound tooth structure that must be removed for its use. Other disadvantages are gingival discoloration and visible metal margins or "shine through" effects of the metal frameworks.² Moreover, the use of substitute base metal alloys may result in corrosion and/or elicit an allergic reaction from a portion of the patient population.³

Current research suggests that implant-supported single restorations may provide a better alternative to conventional FPDs. However, such treatments may not be possible in every case. Patients may reject surgical treatment, the cost of implant therapy may be prohibitive, the potential host bone site may be compromised and grafting may be necessary, or patient-related behavior (eg, smoking,⁴ poor oral hygiene habits⁵) may preclude treatment.

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In these situations, an inlay FPD (IFPD) offers a more conservative method of tooth replacement compared to a crown-retained conventional FPD, because abutment preparations are minimized.⁶ However, these preparations are more technique sensitive and require a careful adhesive luting procedure.⁷ Since the bonding procedures strengthen the cusps and provide additional support for dentition, minimally invasive preparation is indeed feasible.⁸

The alternatives to conventional PFM prostheses include all-ceramic, all-particulate composite, and fiberreinforced composite (FRC) systems. The all-ceramic and all-particulate composite systems have been described for FPDs⁹ and IFPDs,¹⁰ but, in general, exhibit low resilience and toughness and are subject to fracture.^{11,12}

FRC is composed of 2 types of composite materials: fiber composites to build the substructure and a hybrid or microfilled composite to veneer the external surfaces. Initial in vitro investigations of FRC restorations demonstrated promising results. After simulation of oral stresses, the fracture resistance and marginal adaptation of adhesively fixed molar crowns, IFPDs, and 3-unit complete-coverage FPDs were better than for all-ceramic restorations.13 The fracture resistance of IFPDs showed a mean of about 700 N, a value that led to the expectation that these restorations would be successful under clinical conditions.¹⁴ Marginal adaptation of adhesively cemented FRC restorations was shown to remain statistically unchanged after simulation of 5 years of oral stress. It can be concluded from the in vitro wear investigations that the veneering composite will have a wear rate comparable to that of enamel during a period of 5 years, and that it can bear the load in occlusal contact areas.^{15,16}

After 2 years of observation, a previous study of 40 IFPDs reported 89.6% of continuous margin at the tooth-luting composite interface, but 4 IFPDs failed from debonding or delamination of veneering material.¹⁷ Similar results regarding the survival rate were obtained in 2 different studies after a 3-year observation period using 2 different FRC systems. Behr et al¹⁸ achieved a 72% survival rate using the Targis/Vectris (Ivoclar-Vivadent) system, and Freilich et al¹⁹ reported a 75% survival rate for FiberKor/Sculpture (Pentron Laboratory Technologies). FRC used in IFPDs is a promising material, but little clinical information is available in comparison to traditional prosthodontic materials.

The purpose of this pilot clinical trial was to collect survival data on posterior IFPDs using a new microfilled composite in combination with a fiber framework system (SR Adoro/Vectris, Ivoclar-Vivadent) placed under controlled clinical conditions, and to identify the clinical behavior of 2 different bonding systems used to lute the IFPDs (Excite DSC versus Syntac, Ivoclar-Vivadent). The null hypothesis was that there is no difference in postoperative sensitivity and clinical behavior between the 2-step dual-cured adhesive versus the 3-step adhesive bonding system for IFPDs.

Materials and Methods

Thirty-nine patients accepted for the study received an indirect restoration. Patient selection followed 2 criteria: their refusal to be treated with dental implants and informed written consent. The study was approved by the Ethics Committee of the University of Bologna, and selection of both male and female subjects was restricted to those aged 18 to 60 years and in good general and periodontal health. Patients with the following factors were excluded from the clinical trial: pregnancy or breast feeding, use of drugs that modify pain perception, eating disorders, periodontal surgery, known allergies to chemical compounds used in this study, and an absence of dentin hypersensitivity in teeth to be used as abutments. The inclusion criteria were: a missing tooth, absence of any active periodontal or pulpal disease, potential for abutment proximal margin to be located above the cementoenamel junction, potential for placement of rubber dam, and the greatest distance between the abutments less than or equal to 12 mm. The patients were randomly assigned to 2 groups. In group A (n = 19), the Excite DSC adhesive system was used; in group B (n = 19), the cementation was carried out with Syntac. The randomization of the patients was performed with a coin toss.

From June 2002 to July 2004, 39 IFPDs were delivered. Twenty-two restorations were placed in mandibular teeth and 17 in maxillary teeth, and were evaluated using the United States Public Health Service (USPHS) criteria. Three IFPDs were luted to replace the first premolar, 15 the second premolar, and 21 the first molar (Fig 1). Twenty-four restorations were between 2 and 3 years old, 11 were between 1 and 2 years, and only 4 restorations were less than 1 year (but more than 6 months). Average service time of the IFPDs was 23.4 months.

Clinical Preparation

At baseline, all patients were tested for dentin sensitivity. In the rank order data, a score of zero was defined as no pain (Alfa) and 1 to 4 as mild sensitivity (Bravo), both of which were provoked by the clinicians' air blast. A score of 5 to 10 was defined as strong sensitivity (Charlie), and was spontaneously reported by the patient during drinking or eating. The same measurement was performed again at each recall. The status of the gingival tissues adjacent to the test sites was observed at baseline and each recall.



Fig 1a Preoperative radiograph.



Fig 1c The cavity preparation.



Fig 1b Right second premolar and second molar prior to treatment.



Fig 1d An IFPD made with FRC.



Fig 1e The IFPD after cementation under rubber damn.

Before cavity preparation, rubber dam was placed and all cavities were prepared according to modified principles for adhesive inlay retainers to obtain adequately strong dental restorations. No additional bonding FRC wings were made to obtain more adhesional surface. The cavities were prepared with 80-µm diamond burs (no. 8113R, no. 8113NR, Intensiv SA) and finished with 25-µm diamond burs (no. 3113R, no.



Fig 1f Follow-up image after 2 years.

3117, Intensiv) in a medium-speed handpiece with water irrigation. The design of the cavity preparations followed the philosophy of maximal preservation of sound tooth.²⁰ Pre-existing restorations were removed, and their cavities were used as abutments after appropriate preparation. In situations of primary caries lesions, defect-oriented tooth cavities were prepared following a concept of minimal, but adequately sized,

Table I Type and Distribution of Preparatic
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Туре	No.
Slot	9
Mesio-occlusal	21
Disto-occlusal	23
Mesio-disto-occlusal	14
Onlay	5
Overlay	4
Crown	2
Total	78

inlay abutments. The cavity had to allow space for the fiber framework to completely support the pontic element. The form of the cavity was at least 2 surfaces with the following extension: depth of occlusal cavity ≥ 2.5 mm, occlusocervical height ≥ 4 mm, axial depth ≥ 1.2 mm, and buccolingual width ≥ 3.5 mm. The measurements of the cavities were verified with a periodontal probe after the finishing of the cavity margins. Nevertheless, if allowed by the extension of the defect, an attempt was made to create a larger axial depth. A taper of ≤ 4 degrees (or larger if provided by the pre-existing restoration) was chosen to simplify insertion. Because of pre-existing restorations, most proximal boxes were larger. The distribution of the cavity preparations is described in Table 1.

All dentin surfaces of the cavity preparations were etched for 15 seconds with 35% phosphoric acid and sealed with 1 of 2 bonding systems: Excite DSC or Syntac. The same adhesive system used for the dentin hybridization was employed for the luting procedure. Undercuts and deep parts of the cavities were covered in increments with a highly viscous composite (Tetric Ceram, Ivoclar-Vivadent) polymerized for 40 seconds. The excess bonding material on the enamel surfaces was removed with 25-µm diamond burs in a mediumspeed handpiece with water irrigation. All cavity margins were in enamel and extrasulcus. The distance to the marginal gingiva was at least 1 mm. Complete mandibular and maxillary arch impressions were taken with a polyether material (Permadyne, 3M ESPE). A light-cured resin (Fermit-N, Ivoclar-Vivadent) was used as a temporary restoration.

Laboratory Technique

According to the manufacturer's instructions, the Vectris frameworks in the IFPDs were made with preimpregnated pontic and frame fibers, and all restorations had an oval-shaped framework to hold the layering material in a continuous manner and to reach a high volume of the substructure. The final design of the framework was similar to a metal framework, with extensions in the vestibular and buccal side to completely support the veneer composite.

The design of the fiberglass framework was first premodeled with a photo-curing resin (Spectra Tray, lvoclar-Vivadent) to obtain the oval shape, and its thickness was checked against the molding model. This model was embedded in a transparent silicone impression paste to form a mold. The resin was removed and the fibers were applied into the silicone mold (Transil, Ivoclar-Vivadent). The pre-impregnated pontic fibers were condensed into the desired shape by a vacuum-forming process and then light cured in a VS1 unit (lvoclar-Vivadent) for 10 minutes. According to the manufacturer's recommendations, the FRC was treated with silane (wetting agent, lvoclar-Vivadent). A sheet of wave fibers was placed on the pontic structure, and the VS1 cycle was repeated. The dimension of the connection between the pontic and the abutments was 3 \times 3 mm. The SR Adoro material was built incrementally using a Quick light-curing unit (lvoclar-Vivadent) and the thickness of the layering material was at least 1.5 mm. Finally, the IFPD was placed into a Lumamat-100 unit (lvoclar-Vivadent) for the final application of light and heat (104°C) to complete polymerization and maximize the strength and other physical characteristics.

Adhesive Procedure

The IFPDs restorations were placed within 2 weeks after the impression was made. The operating field was isolated with rubber dam, provisional restorations were removed with a sharp probe, and the prepared teeth were cleaned with nylon-bristle brushes and water spray. The inner surfaces of the inlay retainers were sandblasted with CoJet system (3M ESPE) with a small grain size of 30 µm at 2 bars of pressure for 10 seconds. These treated inner surfaces were then silanated using Monobond-S (lvoclar-Vivadent). Just before the final cementations, the bonding agent (Heliobond or Excite DSC) was brushed on the surfaces and air thinned. To prevent early polymerization of this layer, especially for the Heliobond, the IFPD was shielded against light until insertion. All enamel finish lines were conditioned with 35% phosphoric acid gel (lvoclar-Vivadent) for 30 seconds, whereas the dentin surfaces were etched with the same acid for 15 seconds. Group A was treated with Excite DSC and Group B with Syntac, according to the manufacturer's instructions. Neither bonding system was polymerized before placement of the luting composite. The bonding agent was blown to a thin layer and the dual-cured resin composite cement Variolink II (Ivoclar-Vivadent) was used to lute the restorations. The luting composite was light activated (Optilux 500, Kerr) for 60 seconds each at the cervical, buccal, lingual, and occlusal surfaces. Occlusion and articulation were carefully checked after cementation.

		Alpha				Bravo					Charlie				
	1 wk		Last recall			1 wk		Last recall			1 wk		Last recall		
Group	А	В	А	В		А	В	А	В		А	В	А	В	
Abutments (n = 78)															
Marginal discoloration	38	40	37	40		-	-	-	-		-	-	1	-	
Secondary caries	38	40	38	40		-	-	-	-		-	-	-	-	
Marginal adaptation	38	40	34	40		-	-	4	-		-	-	-	-	
Postoperative sensitivity	23	38	36	40		5	2	-	-		10	-	2	-	
Debonding	38	40	35	40		-	-	-	-		-	-	3	-	
IFPDs $(n = 39)$															
Fracture (including chipping)	19	20	17	18		-	-	-	-		-	-	2*	2	
Surface texture	18	20	18	20		1	-	1	-		-	-	-	-	
Color match	17	17	17	16		2	3	2	4		-	-	-	-	
Fiber exposure	19	20	19	18		-	-	-	-		-	-	-	2	

Table 2 Clinical Results Based on USPHS Criteria After 2 Years

*The microfractures were visible only under SEM examination after detachment of the IFPDs.

The restorations were then finished with 15-µm diamond burs (Composhape, Intensiv) and polished with a finishing and polishing kit (Hawe Neos Dental) and silicone-carbide-impregnated bristle brushes (Astrobrush, Ivoclar-Vivadent) in a slow-speed handpiece. Approximal finishing was performed with flexible disks and abrasive strips (Soflex pop-on, 3M ESPE).

Evaluation

Two independent examiners evaluated all restorations under magnification (Zeiss 3.6×35 mm) directly after final polishing, after 1 week, and after 6, 12, 24, and 36 months. At baseline and at 1- and 2-year examinations, radiographs were taken to check the luting material, marginal gaps, and secondary caries. During the recalls, patients answered questions about postoperative sensitivity. Partial or total debonding of IFPDs, framework or resin composite fractures, and fiber exposures were considered failures. The restorations were evaluated using the USPHS²¹ modified parameters to check their stability and longevity in regard to the following characteristics: color match, marginal discoloration, secondary caries, surface texture, marginal adaptation, fracture, and postoperative sensitivity. A score of Alfa meant the restorations showed perfect condition, Bravo meant clinically acceptable, and Charlie indicated a need for immediate replacement. In cases with only 2 decision possibilities, eg, debonding or no debonding, the rating comprised only Alfa or Charlie. Plaque growth and gingival health at the gingival pontic surfaces, abutment inlays, and contralateral control teeth were also measured using the Plaque Index (PI) and Gingival Index (GI).

Statistical Analysis

Statistical analysis was applied to compare the restorations at baseline and after the last recall and to check for differences between groups A and B. The Wilcoxon matched-pairs signed ranks test measured the restorations' success at the appropriate time intervals and was used to rate all parameters. The Mann-Whitney test was used to compare the data between the 2 groups. The null hypothesis was rejected at the 5% significance level. The Kaplan-Meier survival estimation method was performed using statistical software (JMP 5.1, SAS).

Results

The results are summarized in Table 2. During the observation period, 2 debondings after 2 and 8 months were detected for IFPDs luted with the Excite DSC bonding system. The debonded IFPDs were immediately replaced with IFPDs luted with Syntac. Some microcracks in the pontic area of the 2 detached IFPDs were observed under a scanning electronic microscope (SEM) (Figs 2a and 2b). Two fiber exposures were noted after 8 months on the occlusal surface of 1 IFPD. The framework was visible under low magnification (Zeiss 3.6 \times 35 mm) for self-evident color change.

This kind of failure was likely the result of previous occlusal adjustments made after cementation, which had left a thin layer of resin composite on the fiber framework. The IFPD was not replaced and is still under observation. Some hairline fractures of the veneering materials near the connection between the pontic and the abutment were detected in 2 cases (Figs 3 and 4).



Figs 2a and 2b (a) Gingival side of a detached IFPD. Some fractured glass fibers are visible (magnification \times 1,000). (b) The pontic fibers are clearly visible under magnification (\times 1,000) after fracture of the veneering composite.



Figs 3a and 3b (a) The presence of old restorations on the abutments near the edentulous space is the typical situation for IFPDs. (b) The height of the coronal tooth structure does not permit fabrication of a fiber framework with ideal dimensions, which can cause flexibility of the FPD.



Figs 4a and 4b The IFPD after 8 months (a) and 2 years (b). The *arrow* indicates the hairline fracture of the veneering material in the pontic element near the connection with the inlay.



Figs 5a and 5b (a) Impression of the dentin surface after hybridization with Excite DSC (magnification \times 100). Some areas show the presence of hallows because of the intrapulpal pressure, which could cause the hypersensitivity during chewing. (b) At \times 1,000, the ditching created by the dentinal fluid is clearly visible.

No statistical differences regarding detachment were found between baseline and last recall between groups A and B (P > .05).

There were no fractures of the pontics, inlay retainers, or inlay margins. The IFPDs were all rated Alfa with respect to secondary caries and surface texture. At the last recall, the 2 debonded FPDs were rated Charlie regarding the marginal adaptation on 6 abutments and marginal discoloration on 1 abutment. Moderate to severe postoperative sensitivity was found during the first 6 months of the observation period. All hypersensitive teeth belonged to group A. Higher sensitivity values during the temporary restoration period were reported for group A. These patients primarily reported strong pain during mastication and less temperature sensitivity (Figs 5a and 5b). Dentinal sensitivity diminished after approximately 12 weeks and completely disappeared after 6 months in all cases, except 1 abutment that was endodontically treated in the retainer area without removal of the IFPD. Statistical analysis showed significant differences (P < .05) between the sensitivity levels of groups A and group B at baseline and within group A during the observation period. Group A showed 42.2% dentinal sensitivity after 1 month, whereas group B showed 0%. The percentage of restorations rated Bravo for color match was stable at 86.8% during the observation period and did not change at any time. Plaque growth was moderate, but no statistical differences occurred in PI and GI between the abutments, pontics, and contralateral teeth. The Kaplan-Meier survival estimation was 89.4% for group A and 100% for group B after 24 months (Fig 6).

Discussion

The results of this study show that IFPDs made with a light- and heat-polymerized microfilled resin composite bonded with FRC exhibited a high percentage of



Fig 6 Kaplan-Meier estimated cumulative survival rates for IFPDs of groups A and B.

clinical survival throughout the short observation period. This was particularly true when a 3-step adhesive bonding system was used. It appears that 2 important elements must be controlled to achieve success: design of the fiber framework and the cavity preparation. The design of the FRC framework and the positions of the fibers can play important roles in supporting the layering material in a continuous manner and strengthening the fiber substructure. Ellakwa et al²² showed that different techniques of laboratory construction of fiber frameworks in the pontic area significantly affected the fracture resistance of fiber-reinforced FPDs. Maximizing fiber volume fraction by increasing the proportion of fiber to composite should significantly improve strength.²³ The position of the FRC layer can have an effect on the flexural strength. Continuous unidirectional fibers gave the highest strength and stiffness only in the direction of the fiber, while woven fibers were able to reinforce the denturebase polymers in 2 directions.²⁴

The laboratory technique used in this study allows extensions in the vestibular and buccal sides to support the layering material, similar to a metal framework, and hold it in all loading directions. The framework in the FRC was made in an anatomic shape in the pontic element with parallel and woven fiberglasses. Vestibular and buccal FRC extensions in the pontic element can increase the bonding area between the framework and resin composite, as well as hold the veneer material better during occlusal loading. This suggests that the modified framework design could increase the bond strength of resin composite to the fiber framework when chewing.²⁵ A similar approach was used by Freilich et al,²⁶ who hypothesized that the increased rigidity and broader base of support provided by the FRC substructure were needed to support the resin composite veneer. Thus, they added a substantial amount of FRC bulk to the pontic component of the substructure (low-volume design), resulting in the creation of a high-volume substructure design, and then examined the clinical performance. They observed a 95% survival rate for the high-volume prostheses, in contrast to a 62% survival rate for low-volume prostheses, over a 3-year observation period. Similar clinical results were shown in a previous study²⁷ of the relationship between composition and substructure design and clinical performance of the Targis/Vectris system after a 4-year follow-up period. The authors achieved a 97.5% survival rate for the framework built with parallel and woven fibers modifying the design of the pontic element in an anatomic shape, versus an 84% survival rate for the restorations with simplified frameworks made only with parallel fibers. Göhring and Roos²⁸ observed 36 posterior FRC IFPDs and reported a 71% survival rate after 5 years. Most failures were related to delaminations of the veneering material, which is in agreement that a modified framework design significantly reduces the delamination rate.²⁹ However, long-term clinical studies are needed to confirm this hypothesis.

Detachments occurred in 2 clinical borderline cases. The first occurred after 2 months in a patient with parafunctional habits, whereas the second occurred after 8 months in a case with long-span replacement (11 mm). Examination of the failed IFPDs under SEM disclosed microcracks in the gingival areas between the pontic element and the inlay, probably because of fatigue phenomena of the veneering material. Lassila and Vallittu³⁰ achieved the highest flexural strength when the FRC layer was located at the tension side of the test specimens. The particulate filler composite is the weaker phase of the system. They demonstrated that when it is located on the tension side, fracture could easily result. The FRC structure benefits most when the tensile stresses can be transferred to the reinforcing fibers. The veneering particulate filler composite is strong in

compression stress and thus the FRC structure requires fewer reinforcement fibers on the compression side. This area represents a tensile zone, and the SEM images showed the inner glass fiber of the substructures.

Key elements of concern include a tooth preparation design that allows an adequate amount of FRC, accurate interocclusal registration, and proper insertion technique. Inadequate interocclusal registration could result in a need for considerable occlusal adjustment, with the potential for inadvertent occlusal exposure of the FRC substructure or an extremely thin layer of the veneer in functional areas.

Color match of the veneering composite (SR Adoro) was extremely stable, unlike that of the predecessor material (Targis), which in a previous study³¹ was rated as Bravo for color match in 29% of cases at the last recall, and showed significant deterioration compared to the initial status. In this study, clinical evaluation of the FRC IFPDs showed that the microfilled composite veneer material exhibited good color stability and resistance to wear. The surface texture exhibited no change, except for 1 case with a small chipped area, which was likely the result of a fabrication error.

Group A showed a dentinal sensitivity slightly below 50% after 1 month, whereas group B did not record any postoperative sensitivity. Excite DSC is an ethanolbased, 2-step, dual-curable, single-bottle adhesive. Total-etch or simplified adhesives are more sensitive to the technique, because optimal hybridization and sealing of dentinal tubules with the wet-bonding technique may differ with each bonding system.³¹ Ferrari and Tay³² confirmed the sensitivity of the technique with this adhesive system in vivo, by showing no hybrid layer and extensive nanoleakage after excessive drying and water-tree formation along resin-dentin interfaces during excessive wetting. Since the volatile adhesive solvent evaporates quickly, the continuous transudation of dentinal fluid through open dentinal tubules before polymerization of the adhesive may result in the entrapment of water-filled blisters along the adhesive interface.^{33,34} As the patient masticates, these blisters may create a pumping effect that causes rapid movement of fluid through the tubules, which in turn may trigger the A-delta nerve fibers in the pulp-dentin complex.35 Although most bonded restorations are retained because there is sufficient well-bonded surface area, a common clinical manifestation of inconsistent bonding within a restoration is postoperative sensitivity.³⁶ Clinically, no postoperative sensitivity was reported by the patients of group B. This favorable outcome may be related to the 3-step adhesive bonding system along with the method used in the study to seal the dentin before taking the impression. Accurate control times of the primer and bonding agent (> 20 seconds) can ensure prevention of postoperative sensitivity.

Conclusions

Within the limits of this study's short-term observation period, the FRC showed good clinical service. However, these results suggest the need for a longer observation time to more definitively asses this technique. Very specific indications, contraindications, and instructions must be followed to achieve a satisfactory clinical result. If a conservative IFPD is clinically indicated, the patient must be informed that loss of sound hard tissue is minimal, but that the durability of a conventional ceramic-fusedto-metal full-coverage FPD or implant treatment is currently supported by more rigorous clinical research.

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