Clinical Performance of an Experimental Veneering Composite in FPDs. One-year report.

Jaime Portugal, Mário Filipe Bernardo, Cristiana Pereira,
Pedro Rabaço, Leonel González, Manuel Marques, Tiago Mourão,
António Vasconcelos Tavares, Jorge Leitão

Resumo: Objectivos: *Avaliar o desempenho clínico de pontes fixas com 3 elementos, construídas com um compósito experimental microparticulado, sobre infra-estrutura em compósito com fibra ou em metal.* Materiais e métodos: *Foram fabricadas 60 pontes com uma versão experimental do compósito de revestimento, SR Adoro. Metade das pontes tinha uma infra-estrutura em Vectris, e a outra metade numa liga de ouro. Os parâmetros avaliados foram: "estabilidade cromática", "textura de superfície", "contorno marginal", "fenda marginal", "fractura", "cárie secundária", "retenção" e "sensibilidade dos dentes pilares". As pontes foram classificadas como: R (ideal), S (aceitável) ou T/V (inaceitável). Os resultados obtidos foram analisados estatisticamente com os testes de Mann-Whitney e Wilcoxon.* Resultados: *No grupo Adoro/Ouro, a comparação dos resultados obtidos em Baseline e 1-ano demonstrou não haver alteração na "estabilidade cromática". Foi no entanto encontrada uma degradação estatisticamente significativa em "textura superficial" (p=0.007), "contorno marginal" (p=0.014), "fenda marginal" (p=0.034) e "fractura" (p=0.025). As alterações observadas foram de R para S excepto no critério "fenda marginal" com uma ponte classificada T/V, e "fractura" com 5 classificações T/V. Uma vez que se trataram apenas de pequenas fracturas do SR Adoro, apenas uma ponte foi substituída. No grupo Adoro/Vectris, apenas se observou degradação estatisticamente significativa na "textura de superfície" (p=0.001). A comparação dos resultados obtidos nos dois grupos, em cada período, evidenciou diferenças estatisticamente significativas para "sensibilidade" em Baseline (p<0,001).* Conclusões: *Após 1 ano, embora revelando alguns problemas, a performance global deste novo material pode ser considerada como boa.*

Palavras-Chave: Prostodontia; Ensaio clínico, Compósito de revestimento; Compósitos reforçados com fibras

Abstract: Purpose: *To evaluate the clinical performance of an experimental veneering composite in 3-unit fixed partial dentures and to assess the influence of the framework material on the mentioned performance.* Materials and Methods: *A total of 60 fixed partial dentures were made with the experimental version of SR Adoro veneering composite. Half had a Vectris framework, and the other half gold alloy. Evaluation criteria were: shade match, surface texture, marginal shoulder, marginal gap, fracture, recurrent caries, retention, and abutment tooth hypersensitivity. The fixed partial dentures were rated as: R (ideal), S (acceptable) or T/V (unacceptable). Statistical analysis was performed using Mann-Whitney and Wilcoxon tests.* Results: *Comparison between Baseline and 1-Year in the Adoro/Gold group showed no change in color match. A statistical significant degradation in surface texture (p=0.007), marginal shoulder (p=0.014), marginal gap (p=0.034), and fracture (p=0.025) was found. All changes were minor from R to S except in the criteria marginal gap where 1 bridge was rated T/V, and fracture with 5 T/V ratings. Since fractures consisted in loss of small parts of veneering composite, 4 of these fixed partial dentures remained in service and only 1 was replaced. In Adoro/Vectris group only surface texture degradation was statistically significant (p=0.001). Nevertheless, SR Adoro maintained a clinically acceptable surface texture. Comparing the results for the two groups in each period, the only statistically significant differences found, was on hypersensitivity at Baseline (p<0.001).* Conclusions: *After one year, the overall performance of the experimental veneering composite was acceptable.*

Key-words: Prosthodontics; Clinical trial; Veneering composite; Fixed partial dentures; Glass-fiber reinforced framework

(Portugal J, Bernardo MF, Pereira C, Rabaço P, González L, Marques M, Mourão T, Tavares AV, Leitão J. Clinical Performance of an Experimental Veneering Composite in FPDs. One-year report . Rev Port Estomatol Cir Maxilofac 2007;48:133-139)

Faculdade de Medicina Dentária da Universidade de Lisboa

INTRODUCTION

Missing teeth can be replaced with different types of fixed partial dentures (FPDs). An acceptable long term solution of this problem is usually obtained with metal-ceramic crown and bridge work. However, a metal substructure is often anesthetic, may exhibits corrosion and may elicit allergic reactions in some patients[1].

During the last decade, the demand for aesthetic nonmetallic, highly biocompatible dental restorative materials has increased markedly.

Fiber Reinforced Composites (FRC) were introduced some years ago as an alternative to full ceramic and porcelain fused to metal in the fabrication of single crowns, bridges, inlays, and onlays.

FRC provide good aesthetics due to a translucency similar to natural tooth structure. They also exhibit high flexural strength which renders them less susceptible to fracture. Additionally, their lower hardness prevents the excessive wear of the opposing natural dentition[2]. FRC restorations have been reported to be acceptable but require adequate bonding to the remaining tooth structure[3].

There are several FRC systems with differences in the type of fibers and their layering laboratory preparation.

The Targis/Vectris system (Ivoclar Vivadent) was marketed in 1996[4]. Vectris is a glass-fiber reinforced framework material consisting of several layers of woven glass-fibers and uniaxially oriented fibre bundles embedded in a dimethacrylate matrix. Targis was a highly filled composite resin veneering material for indirect use in dental laboratory technology. This material could be used without any framework material, to fabricate inlays, onlays, veneers, and anterior single crowns. It could also be used as a veneering material for Vectris or metal supported crowns and bridges. In spite of initial promising results[5], long-term clinical studies showed the need for improvement of the veneering composite – Targis – because of susceptibility to wear, discoloration, fracture and fiber exposure[6-8].

Recently, the new microfilled veneering composite SR Adoro was marketed by Ivoclar Vivadent, to replace Targis. SR Adoro consists of a dimethacrylate matrix (19 – 19% wt), prepolymer and silicon dioxide fillers (82 – 83% wt), stabilizers, catalysts and pigments (< 1%). The content of inorganic fillers represents approximately 64 – 65% wt or 46 – 47% vol. The size of the inorganic particles is between 10 – 100 nm.

Preclinical testing of the SR Adoro was performed by comparing it to other materials of well known clinical behavior is[9-10]. In vitro testing included wear testing, surface corrosion through fluoride, resistance against discoloration and biocompatibility. Also, several mechanical properties such as hardness, modulus of elasticity and fracture strength were determined.

The purpose of this study was to evaluate the clinical performance of the experimental version of the SR Adoro veneering composite (TREND) used in 3-unit fixed partial dentures, and the influence of the framework material on that performance.

MATERIALS AND METHODS

In the present longitudinal clinical study the performance of an experimental microfilled veneering composite (TREND) was evaluated. This material has been marketed as "SR Adoro" (Ivoclar Vivadent). Some changes have been made on the marketed material.

The subjects were selected from the regular patients attending the clinics of the School of Dental Medicine, University of Lisbon.

A total of 60 FPDs were placed in 49 subjects and randomly divided in two groups. In one group 30 FPDs were made with SR Adoro over Vectris glass fiber framework (Ivoclar Vivadent). In the other group 30 FPDs were prepared with SR Adoro over a high noble alloy framework (Academy Gold XH, Ivoclar Vivadent).

Clinical Procedures

Clinical procedures started in October 2001 and continued until the last fixed partial denture was cemented in September 2002. Clinical procedures were preformed in strict accordance to manufacturer's instructions by five clinicians experienced in conventional crown and bridge rehabilitation.

Prior to prosthetic procedures, small caries, if present, were restored using a direct composite material, Tetric Ceram (Ivoclar Vivadent). Fixed partial dentures were placed in vital and non-vital teeth. Core build-ups of non-vital teeth were made with Tetric Ceram in the Adoro/Vectris group. Cast metal post and core were made in the Adoro/Gold group. When needed, a glass fiber post – FRC Postec (Ivoclar Vivadent), luted with Variolink II resin cement (Ivoclar Vivadent) was used.

The cervical margin of the preparations consisted on a 1mm chamfer, placed at gingival crest or slightly below,

depending on aesthetic considerations. Tooth reduction on the occlusal surface was 2 mm in the Adoro/Vectris group and 1.8 mm in the Adoro/Gold group. Following preparation, vital teeth were desensitized with Systemp desensitizer (Ivoclar Vivadent) and provisional crowns were placed.

Impressions were made with standard trays using a polyether material – Impregum Penta Soft (3M/ESPE). The fixed partial dentures of both types were fabricated in two commercial dental laboratories, located in Lisbon and Madrid according to the techniques established for Targis and Vectris.

Minor occlusal adjustments were made with FG multiblade carbide burs, silicone rubber points and nylon brushes with Universal Polishing Paste (Ivoclar Vivadent). Adoro/Vectris FPDs were luted with Excite DSC and Variolink II and Adoro/Gold FPDs with zinc phosphate cement – Harvard (Richter & Hoffmann), all in accordance to the manufacturer's instructions.

Clinical Evaluation

The Baseline evaluation took place, one to two weeks after cementation. Follow-up evaluations were made after 6 months and one year. All evaluations were performed independently by the same two calibrated examiners.

The restorations were assessed by direct evaluation, using a system based on the California Dental Association guidelines[11] (Table 1). Parameters such as: 1) *shade match*, 2) *surface texture*, 3) *marginal shoulder*, 4) *marginal gap*, 5) *fracture*, 6) *recurrent caries*, 7) *retention*, and 8) *abutment tooth hypersensitivity* were noted individually by the two examiners. In case of disagreement, a restoration was re-examined jointly by both observers and an agreement was reached in all instances.

The fixed partial dentures were evaluated for each of the individual parameters and rated in one of four possible categories: R, S, T and V. R and S categories are considered respectively ideal and acceptable. Both T and V represent clinically unacceptable situations, requiring repair or substitution.

Baseline shade was established using the Chromascop scale (Ivoclar Vivadent) and *shade match* was evaluated comparing baseline shade with subsequent observations. *Surface texture*, *marginal shoulder*, *marginal gap* and *retention* were assessed by probing. *Fracture* and *recurrent caries* were assessed by probing and clinical observation. *Abutment tooth hypersensitivity* was assessed by questionnaire to determine the presence of hypersensitivity in the period between evaluations. Hypersensitivity was evaluated only in fixed partial dentures with at least one vital abutment tooth.

After each patient evaluation a dental hygiene appointment was scheduled including prophylactic tooth cleaning and oral self-care instruction and motivation.

Statistical analysis were performed to compare the dentures at baseline and at 1-year recall and to check for differences between the two groups. A Wilcoxon Test was used to determine significant differences between baseline and 1-year observations. The existence of significant differences between the two groups, in each evaluation period, was determined by the Mann-Whitney Test. Statistical significance was established at the 5% level.

RESULTS

At baseline all 60 FPDs were evaluated but, at 1-Year recall, only 55 were available because five patients could not be contacted within an acceptable time-frame. This represents a loss to follow-up of 8%.

Results for the Adoro/Gold group are presented in Table 2. Percentage of abutment teeth with hypersensitivity having to provoked stimuli decreased from 23.3% to 3.8%. There were no teeth with spontaneous hypersensitivity in either of the two evaluation periods. One Adoro/Gold FPDs was found to be debonded at the baseline appointment and was immediately recemented. At the 1-Year recall it was still *in situ*.

With the exception of *shade match* and *recurrent caries* there was a degradation from Baseline to 1-Year in all the clinical parameters evaluated. However, comparison between Baseline and 1-Year, showed statistical differences only in *surface texture* ($p=0.007$), *marginal shoulder* ($p=0.014$), *marginal gap* ($p=0.034$) and *fracture* ($p=0.025$).

Table 3 shows the Baseline and 1-Year results for the Adoro/Vectris group. At Baseline a high percentage of abutment teeth were sensitive to provoked stimuli (83.3%). The amount of sensitive teeth dropped significantly to only 4.3% at the 1-Year recall ($p<0.001$). Again, there were no teeth with spontaneous hypersensitivity. As with Adoro/Gold, after one year, there was degradation in all the evaluated variables with the exception of *shade match*, *recurrent caries* and *retention*. However, only *surface texture* degradation was statistically significant ($p=0.001$). Small fractures within the Veneering Composite occurred in three cases. Nevertheless, they did not expose the framework material (Vectris) and had no effect on clinical function and patient comfort.

	R	S	T	V
Shade Match	No mismatch	Slight mismatch	Gross mismatch	Color falls outside the scale
Surface Texture	Smooth surface	Slightly rough or pitted surface (can be polished)	Grossly irregular surface (cannot be polished)	Surface with gross imperfections / porosities
Marginal Shoulder	Absence of under/over contour	Slightly under/over contoured	Grossly under/over contoured without soft or hard tissue lesion	Grossly under/over contoured with soft or hard tissue lesion
Marginal Gap	Absence of marginal crevice or gap	Marginal crevice or gap present, not requiring bridge replacement	Marginal crevice or gap present, requiring bridge replacement	Marginal crevice or gap present, not requiring bridge replacement, with caries
Fracture	Absence of fracture	Veneering fracture, without exposing Vectris / Gold framework	Veneering fracture, exposing Vectris / Gold framework	Fracture involving both Veneering and Vectris / Gold framework
Recurrent Caries	Absence of marginal caries	-----	-----	Presence of marginal caries
Retention	No debonding	Debonding of one or both abutments, may be re-cemented	-----	Debonding of one or both abutments, cannot be re-cemented
Abutment Tooth Hypersensitivity	Absence of hypersensitivity	Hypersensitivity disappearing after removal of the stimulus	-----	Spontaneous pain

Table I - Evaluation criteria based on the California Dental Association guidelines[11]

When comparing the results obtained for the two groups in each period, the only statistically significant difference found between the groups was on *hypersensitivity* at Baseline ($p<0.001$).

At the 1-Year recall 5 FPDs (9.1%) were considered as clinical failures (rated T/V). All these FPDs belonged to the Adoro/Gold group and the reasons for failure were fractures between the metal framework and the veneering composite. Most of these fractured dentures were small and even though they were considered failures, they were kept in function. Only one of the dentures had to be replaced.

The number of failed fixed partial dentures was significantly higher in the Adoro/Gold group ($p=0.014$).

SR ADORO / GOLD	BASELINE			1 YEAR		
	R	S	T/V	R	S	T/V
Shade Match	100% (30)	0% (0)	0% (0)	100% (26)	0% (0)	0% (0)
Surface Texture	96.7% (29)	3.3% (1)	0% (0)	61.5% (16)	38.5% (10)	0% (0)
Marginal Shoulder	33.3% (10)	66.7% (20)	0% (0)	11.5% (3)	88.5% (23)	0% (0)
Marginal Gap	70.0% (21)	30.0% (9)	0% (0)	50.0% (13)	46.2% (12)	3.8% (1)
Fracture	100% (30)	0% (0)	0% (0)	80.8% (21)	0% (0)	19.2% (5)
Secondary Caries	100% (30)	0% (0)	0% (0)	100% (26)	0% (0)	0% (0)
Retention	96.7% (29)	3.3% (1)	0% (0)	100% (26)	0% (0)	0% (0)
Abutment Tooth Sensitivity	76.7% (23)	23.3% (7)	0% (0)	96.2% (25)	3.8% (1)	0% (0)
Failures	100% (30)	0% (0)	0% (0)	80.8% (21)	0% (0)	19.2% (5)

Table 2 - Baseline and 1-Year results for the Adoro/Gold group. (R-Ideal, S-Clinically acceptable, T/V-Clinically unacceptable)

SR ADORO/VECTRIS	BASELINE			1 YEAR		
	R	S	T/V	R	S	T/V
Shade Match	100% (30)	0% (0)	0% (0)	100% (29)	0% (0)	0% (0)
Surface Texture	80.0% (24)	20.0% (6)	0% (0)	37.9% (11)	62.1% (18)	0% (0)
Marginal Shoulder	20.0% (6)	80.0% (24)	0% (0)	13.8% (4)	86.2% (25)	0% (0)
Marginal Gap	53.3% (16)	46.7% (14)	0% (0)	44.8% (13)	55.2% (16)	0% (0)
Fracture	96.7% (29)	3.3% (1)	0% (0)	89.7% (26)	10.3% (3)	0% (0)
Secondary Caries	100% (30)	0% (0)	0% (0)	100% (29)	0% (0)	0% (0)
Retention	100% (30)	0% (0)	0% (0)	100% (29)	0% (0)	0% (0)
Abutment Tooth Sensitivity	16.7% (4)	83.3% (20)	0% (0)	95.7% (22)	4.3% (1)	0% (0)
Failures	100% (30)	0% (0)	0% (0)	100% (29)	0% (0)	0% (0)

Table 3 - Baseline and 1-Year results for the Adoro/Vectris group. (R-Ideal, S-Clinically acceptable, T/V-Clinically unacceptable)

DISCUSSION

In the present study, at the 1-Year evaluation, none of the FPDs showed any changes in *shade match*. However, both groups showed signs of degradation in most of the other clinical parameters. In the Adoro/Gold group this degradation was statistically significant only for *surface*

texture, *marginal shoulder*, *marginal gap* and *fracture*. In the Adoro/Vectris group a statistically significant difference was only observed in the parameter *surface texture*.

Regarding *surface texture*, 3.3% of the FPDs in the Adoro/Gold group and 20% in the Adoro/Vectris group exhibited a slightly rough or pitted surface at baseline and were rated S. At the 1-Year evaluation these values rouse to 38.5% and 62.1%, respectively. Even though the surface texture in several fixed partial dentures changed after one year, this was not clinically significant as it represents a situation recoverable by direct clinical polishing.

In the Adoro/Gold group, the percentage of FPDs with slightly under/over contoured marginal shoulders significantly increased from 66.7% to 88.5%. Marginal crevice or gap presence, not requiring replacement, increased significantly form 30% to 46.2%. In the Adoro/Vectris group there was a small but not significant increase in both parameters.

The significant changes found in the Adoro/Gold group may be explained by two different aspects related to the framework material and laboratory technique used in this group. The Adoro/Gold FPDs were luted with zinc phosphate cement and the Adoro/Vectris's with a luting composite using an adhesive technique. The individual properties of the luting materials may explain the differences in the quality of the marginal adaptation (*marginal shoulder* and *marginal gap*). In fact, the zinc phosphate cement is more prone to degradation when in contact with oral fluids[12].

The fractures in the Adoro/Gold group happened due to delamination of the veneering composite. It appears that the adhesion between the metal framework and the veneering material was not sufficient. Full veneering of occlusal load bearing surfaces, omission of mechanical retentions and too thin layer thickness of the veneering composite may have contributed to increased stress concentration along the interface between the veneering and the framework material. This may have lead to the increased number of fractures in the Adoro/Gold group.

Statistically significant differences regarding abutment tooth hypersensitivity were found between Baseline and 1-Year in the Adoro/Vectris group, and between the two groups at the Baseline evaluation. These differences express the high number of hypersensitivity cases observed in the Adoro/Vectris group at Baseline and its decrease at the 1-Year evaluation. The high prevalence of hypersensitivity in the Adoro/Vectris group is attributed to the nature of the adhesive cementation technique.

Fixed partial dentures scored as T or V in any of the parameters were considered clinical failures. Five FPDs were rated as failures of which one had to be replaced, all belonging to the Adoro/Gold group. The reasons for failure were fracture and association of marginal gap and fracture. None of the Adoro/Vectris restorations were replaced at the time of the 1-year recall.

CONCLUSIONS

After one year the performance of the experimental veneering composite is within acceptable clinical standards.

Problems encountered related to hypersensitivity and marginal adaptation are not associated with the veneering material characteristics but with the luting material and luting techniques.

The framework material affected the fracture resistance of the fixed partial dentures, but again, this situation is not directly associated with the veneering composite characteristics. It resulted from poor bonding between the veneering and the framework materials. This situation has been corrected in the marketed material (SR Adoro) through revised bonding instructions.

ACKNOWLEDGMENTS

This study was supported by Ivoclar/Vivadent and performed at the Instituto de Tecnologia Biomedica – University of Lisbon, Portugal (FCT/MCTES Unit #165).

REFERENCES

1 - Report on base metal alloys for crown and bridge applications: benefits and risks. Council on Dental Materials, Instruments, and Equipment. J Am Dent Assoc 1985;111:479-483.

2 - Freilich MA, Meiers JC, Duncan JP, et al: Fiber-reinforced composites in clinical dentistry. Carol Stream: Quintessence Publishing; 2000.

3 - Behr M, Rosentritt M, Ledwinsky E, et al: Fracture resistance and marginal adaptation of conventionally cemented fiber-reinforced composite three-unit FPDs. Int J Prosthodont 2002;15:467-472.

4 - Krejci I, Boretti R, Giezendanner P, et al: Adhesive crowns and fixed partial dentures fabricated of ceromer/FRC: clinical and laboratory procedures. Pract Periodontics Aesthet Dent 1998;10:487-498; quiz 500.

5 - Gohring TN, Mormann WH, Lutz F: Clinical and scanning electron microscopic evaluation of fiber-reinforced inlay fixed partial dentures: preliminary results after one year. J Prosthet Dent 1999;82:662-668.

6 - Behr M, Rosentritt M, Handel G: Fiber-reinforced composite crowns and FPDs: a clinical report. Int J Prosthodont 2003;16:239-243.

7 - Bohlsen F, Kern M: Clinical outcome of glass-fiber-reinforced crowns and fixed partial dentures: a three-year retrospective study. Quintessence Int 2003;34:493-496.

8 - Monaco C, Ferrari M, Miceli GP, et al: Clinical evaluation of fiber-reinforced composite inlay FPDs. Int J Prosthodont 2003;16:319-325.

9 - Chaabane P, Wigren S, Zappini G: Flexural properties of indirect resin composites after aging. J Dent Res 2004;83(Spec Iss A):#2852.

10 - Wigren S, Chaabane P, Zappini G: Wear and mechanical properties of indirect resin composites. J Dent Res 2004;83(Spec Iss A):# 2853.

11 - Quality evaluation for dental care: guidelines for the assessment of clinical quality and professional performance. Los Angeles: California Dental Association; 1977.

12 - Fraga RC, Luca-Fraga LR, Pimenta LA: Physical properties of resinous cements: an in vitro study. J Oral Rehabil 2000; 27:1064-1067.