Silorane-based composite as repair material: a six-month randomized clinical trial

Resina composta à base de silorano como material de reparo: estudo clínico randomizado de seis meses

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ABSTRACT

Objective
This study investigated the clinical performance of a silorane-based composite resin when used for repairing conventional composite restorations.

Methods
Defective dimethacrylate-based composite resin restorations were randomly assigned to one of two treatment groups: Control group - Adper SE Plus + Filtek P60 (3M/ESPE, St. Paul, EUA) and Test Group - P90 Adhesive System + Filtek P90 (3M/ESPE, St. Paul, EUA). All repaired restorations were evaluated at baseline, and at six-month recall. The parameters examined were marginal adaptation, anatomic form, surface roughness, marginal discoloration, post-operative sensitivity and secondary caries. The restorations were classified according to modified USPHS criteria. Mann-Whitney and Wilcoxon tests were used to compare the groups.

Results
Of the 100 restorations repaired in this study, 93 were reexamined at baseline and 91 at 6-month recall. Drop-out was about 9%. No statistically significant differences were found between the materials for all clinical criteria, at baseline and at 6-month recall ($p > 0.05$). No statistically significant differences were registered ($p > 0.05$) for each material when compared for all clinical criteria, at baseline and at 6-month recall. The hypothesis tested in this randomized controlled clinical trial was accepted.

Conclusion
After the six-month evaluations, silorane-based composite exhibit a similar performance compared to dimethacrylate-based composite when used as repair material.

***Indexing terms**: Composite resins. Corrective maintenance. Dental restoration repair. Silorane resins.*

RESUMO

Objetivo
Investigar o desempenho clínico de uma resina de baixa contração à base de silorano quando utilizada para reparar restaurações convencionais de resina composta.

Métodos
Restaurações defeituosas de resina composta à base de dimetacrilato foram aleatoriamente reparadas por um de dois grupos de tratamento: Grupo Controle - Adper SE Plus + Filtek P60 (3M/ESPE, St. Paul, EUA) e Grupo Teste - Sistema adesivo P90 + Filtek P90 (3M/ESPE, St. Paul, EUA). Todas as restaurações reparadas foram avaliadas em baseline e ao longo de 6 meses. Os parâmetros analisados foram a adaptação marginal, forma anatômica, rugosidade superficial, descoloração marginal, sensibilidade pós-operatória e lesões de cárie. As restaurações foram classificadas de acordo com os critérios do Serviço de Saúde Público dos Estados Unidos modificados. Os testes de Mann-Whitney e Wilcoxon foram utilizados para comparar os grupos.

Resultados
Das 100 restaurações reparadas neste estudo, 93 foram examinadas uma semana após terem sido reparadas - baseline e 91 após 6 meses. A perda foi de aproximadamente 9%. Nenhuma diferença estatisticamente significativa foi encontrada entre os materiais para todos os critérios clínicos, em baseline e ao longo de 6 meses ($p > 0,05$).

Conclusão
A hipótese testada neste ensaio clínico controlado randomizado foi aceita. Após 6 meses de avaliações, resinas compostas à base de silorano apresentaram desempenho clínico semelhante às resinas compostas à base de dimetacrilato quando utilizadas para reparar restaurações de resina composta à base de dimetacrilato.

Termo de indexação: Resinas compostas. Manutenção corretiva. Reparação de restauração dentária. Resinas de silorano.

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INTRODUCTION

Composite resins are today's most widely used direct restorative material. Their main advantages are the adhesive capacity allowing for minimal cavity preparation and superior esthetics[1]. Since the introduction of dental resin-based composites, intense research has attempted to develop materials with acceptable mechanical and physical properties to significantly improve their longevity and aesthetic quality[2].

Recently, in order to minimize the effects of shrinkage, an innovative monomer system was made available for dental restorations - silorane. Obtained from the reaction of oxirane and siloxane molecules, this material contains traditional filler particles, whereas the conventional resin is replaced by silorane monomers. While siloxanes are known for their hydrophobicity, oxiranes are known for their low shrinkage[3-5].

Results from in vitro studies have shown that silorane-based composites demonstrate the lowest polymerization shrinkage as well as more ambient light stability. The new system also has the lowest sorption and water solubility and a lower diffusion coefficient than conventional monomers. Parameters such as tensile modulus, flexural strength and biocompatibility in toxicology tests are comparable to dimethacrylate-based composite[3,6-9].

Despite extensive improvements in the mechanical properties of resin-based tooth-colored restorative materials, volumetric shrinkage and subsequent contraction stress arising during the polymerization reaction are still significant drawbacks[10]. Shrinkage may also cause microleakage, marginal staining, and gap formation, this one an important factor in the development of caries, because it may act as a retention groove[4,11-12].

Reducing shrinkage and the stress generated by polymerization may positively influence marginal integrity. Imperfect margins result in marginal discoloration and secondary caries lesions, the most important cause for the replacement of defective restorations[13].

However, according to the philosophy of 'minimum intervention' operative dentistry, with the exception of conditions in which there is a fracture of the resin restoration, staining of the entire resin/tooth interface and secondary caries, defective restorations should be first evaluated for the possibility of repair, rather than being routinely replaced[14]. This approach allows preservation of sound tooth structure[15-16] being considered a viable long-term clinical procedure for treatment of restorations[17-19].

Clinical studies involving composite resin repairs have shown that, when properly planned, the repairs may increase the clinical longevity of restorations. Thus, once in vitro studies suggest that bonding of silorane-based composites to old dimethacrylate-based composites may be a viable clinical procedure[20-22], it would be desirable to evaluate the clinical performance of this new system for making repairs. The hypothesis tested in this randomized controlled clinical trial was that low-shrinkage silorane-based composites exhibit a similar performance when compared to conventional dimethacrylate-based composites when used to repair composite resin restorations.

METHODS

Study design

This prospective randomized clinical trial had the repaired restorations like observation units. Patients aged 18 to 56 years with 100 defective composite resin restorations participated in this study. They were routinely assigned for treatment at the operative dentistry clinic, School of Dentistry, Federal University of Minas Gerais.

The inclusion criteria were: patients who were older than 18 years of age and signed a consent form approved by the Institutional Ethics Committee; patients with no contraindications for dental treatment; patients who had class I or class II composite resin restorations with occlusal defects and no diagnosis of caries according to clinical and bite-wing radiographic exams; patients who had restorations which scored at least Bravo according to Modified United States Public Health Service (USPHS) clinical criteria (Chart 1). The exclusion criteria were: patients with contraindications for regular dental treatment according to their medical history; patients with xerostomy, including those taking medications that are proven to significantly reduce salivary flow; patients with visible plaque index (VPI) > 30%; patients with defective restorations, unacceptable for repairs, that scored Charlie (Modified USPHS clinical criteria).

This clinical trial was conducted in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects (2000) and approved by the local Institutional Ethics Committee (ETIC 0546.0.203.000-09).

Chart 1. Modified U.S. Public Health Service clinical criteria.

Category	Rating	Criteria descriptions
Marginal adaptation	Alfa (A)	Restoration adapts closely to the tooth structure, there is no visible crevice
	Bravo (B)	There is a visible crevice, the explorer will penetrate, without dentin exposure
	Charlie (C)	The explorer penetrates into crevice in wich dentin or the base is exposed
Anatomic form	Alfa (A)	Anatomic form ideal
	Bravo (B)	Restoration is under-contoured, without dentin or base exposure
	Charlie (C)	Restoration is under-contoured, with dentin or base exposure. Anatomic form is unsatisfactory. Restoration needs replacement
Marginal discoloration	Alfa (A)	No marginal discoloration
	Bravo (B)	Minor marginal discoloration without staining toward pulp, only visible using mirror and operating light
	Charlie (C)	Deep discoloration with staining toward pulp, visible at a speaking distance of 60-100cm
Surface roughness	Alfa (A)	As smooth as the surrounding enamel
	Bravo (B)	Rougher than surrounding enamel. Improvement by finishing is feasible
	Charlie (C)	Very rough, could become anti-aesthetic and / or retain biofilm. Improvement by finishing is not feasible
Post-operative sensitivity	Alfa (A)	No postoperative sensitivity
	Bravo (B)	Short-term and tolerable postoperative sensitivity
	Charlie (C)	Long-term or intolerable postoperative sensitivity. Restoration replacement is necessary
Secondary caries	Alfa (A)	No active caries present
	Charlie (C)	Active caries is present in contact with the restoration

Study methods

The restorations were examined one week after they were repaired for baseline assessment, and at six-month. Two examiners independently evaluated all repaired restorations by direct observation, using a plane buccal mirror and a WHO model explorer. Calibration exercises revealed an inter-examiner agreement ratio ≥ 0.78. Since there was disagreement on the rating, the clinicians reexamined the repaired restoration together and arrived at a joint final decision. The clinical criteria examined were marginal adaptation, anatomic form, surface roughness, marginal discoloration, post-operative sensitivity and secondary caries. The examiners classified all restoration as Alpha, Bravo or Charlie, according to modified USPHS clinical criteria.

Treatment groups

The same operator repaired all defective composite resin restorations in order to minimize preparation variability. Defective surfaces of the restorations were explored using high-speed spherical diamond burs (KG Sorensen, São Paulo, SP, Brazil) compatible with the size of the defect in a hand piece with air-water coolant, beginning with the removal of the restorative material in the area of the defect as well as any stained and soft tooth tissues. The restorations were randomly assigned to one of two treatment groups: Control group (n = 50): Repair with a self-etching primer (Adper SE Plus, 3M /ESPE, St. Paul, MN, USA) and a dimethacrylate-based composite (Filtek P60 Posterior Restorative, 3M/ESPE, St. Paul, MN, USA); Test group (n = 50): Repair with a self-etching primer (P90 System Adhesive Self-Etch Primer and Bond, 3M/ESPE, St. Paul, MN, USA) and a low-shrinking silorane-based composite (Filtek P90 Low Shrink Posterior Restorative, 3M/ESPE, St. Paul, MN, USA) (Chart 2).

Rubber dam isolation was used for the restorative procedures. The surfaces of restorations and enamel margins were etched with 37% phosphoric acid (Magic Acid Gel, VIGODENT/COLTENE, Rio de Janeiro, Brazil) before adhesive procedures, being the materials used according to manufacturer's recommendations (Chart 3).

Chart 2. Materials: chemical composition and manufacturers.

Material	Chemical compostion	Manufactures
Magic acid gel	37% phosphoric acid	Vigodent / Coltene (Rio de Janeiro, Brazil)
Adper™ SE Plus Self-Etch Adhesive - Liquid A	Water, HEMA, Surfactant, Pink colorant	3M / ESPE
Adper™ SE Plus Self-Etch Adhesive - Liquid B	UDMA, TEGMA, TMPTMA, HEMA, MHP, Bonded zircônia nanofiller, Initiator system based ond camphorquinone	3M / ESPE
Filtek P60 Posterior Restorative	Matrix: UDMA (urethane dimethacrylate, TEG-DMA, BIS-EMA; Filler: silica/zirconia; Initiator system: camphorquinone	3M / ESPE
P90 System Adhesive Self-Etch Primer	Phosphorylated methacrylates, Vitrebond™ copolymer, Bis-GMA, HEMA, water and ethanol, silane-treated silica, initiators and stabilizers	3M / ESPE
P90 System Adhesive Bond	3M/ESPE hydrophobic bifunctional monomer, acidic monomers, silane-treated silica, initiators and stabilizers	3M / ESPE
Filtek P90 Low Posterior Restorative	Matrix: silorane; Filler: quartz, yttrium fluoride; Initiator system: camphorquinone, iodonium salts and electron donors; Stabilizers and pigments	3M / ESPE

Chart 3. Clinical sequence of repair procedures.

Repair procedure	Filtek™ P90 / P90 System adhesive	Filtek™ P60 / Adper™ SE Plus
Rubber dam	x	x
Etching of enamel with 37% Phosphoric acid for 15 seconds	x	x
Rinse the acid with water and air dried	x	x
Removal of excess water with absorbent paper	x	x
Application of self-etching primer for 15 seconds	x	
Application of Liquid A (Adper™ SE Plus) for 10 seconds		x
Light cured for 10 seconds	x	
Adhesive application with disposable brush	x	
Aplication of Liquid B (Adper™ SE Plus) for 20 seconds		x
Application of hydrophobic layer		x
Light cured for 10 seconds	x	x
Insertion of 2 mm of maximum thickness horizontal increments and resin sculpture	x	
Insertion of 2 mm of maximum thickness oblique increments and resin sculpture		x
Light curing (600mW/cm²)	40 seconds	20 seconds
Removal of excess restorative material with a scalpel blade #15	x	x
Finishing with #9714FF bur (KG Sorensen, Rio de Janeiro, RJ, Brazil)	x	x
Polishing with Enhance System (Dentsply, Petrópolis, Brazil)	x	x

Outcome measurements and statistical analysis

At baseline and six-month recall, all restorations received a clinical rating like Alpha, Bravo or Charlie. The ordinal dependent variable was the percentage of Alpha, Bravo or Charlie ratings.

Data management and analysis were done using a statistical analysis system (SPSS 15.0.1 for Windows, SPSS, Chicago, IL, USA). Mann-Whitney test was used to assess differences between the materials tested and for all clinical criteria, at baseline and at 6-month recall examination ($p = 0.05$). Wilcoxon test was used to compare each composite resin for all clinical criteria at baseline examinations and at 6-month recall ($p = 0.05$).

RESULTS

Drop-out in this study was about 9%. Of the 100 repaired restorations, 93 (50 for Filtek P60 and 43 for Filtek P90) were examined at baseline and 91 at the 6-month recall (48 for Filtek P60 and 43 for Filtek P90). The main reasons for restorations being repaired were marginal defects (81%) and loss of anatomic form (19%).

Table 1 summarizes the frequency of Alpha and Bravo ratings for restorations in both groups for each clinical criterion at baseline and at 6-month recall examination. No restoration received Charlie ratings. Table 2 shows the comparison between the materials tested for all clinical criteria, at baseline and at six-month recall examination. No statistically significant difference between the materials was found ($p > 0.05$). Table 3 shows the comparison between baseline and six-month recall examination for each material independently, for all clinical criteria. No statistically significant difference was found in any criteria between the examination periods ($p > 0.05$).

Table 1. Frequency of Alpha and Bravo ratings according to the materials tested at baseline and at six-month recall examination.

		P60 (%)		P90 (%)	
		Baseline	6 months	Baseline	6 months
Marginal adaptation	Alfa	94	95.8	100	100
	Bravo	6	4.2	0	0
Anatomic form	Alfa	98	97.9	88.4	88.4
	Bravo	2	2.1	11.6	11.6
Surface roughness	Alfa	80	75	65.1	69.8
	Bravo	20	25	34.9	30.2
Marginal discoloration	Alfa	98	100	100	100
	Bravo	2	0	0	0
Post-operative sensitivity	Alfa	100	100	95.3	100
	Bravo	0	0	4.7	0
Secondary caries	Alfa	100	100	100	100
	Bravo	0	0	0	0

Table 2. Comparison between the materials tested for all clinical criteria at each examination period.

	Restorations rated Alpha (%)					
	Baseline			6 months		
	Filtek P60	Filtek P90	*p-value*	Filtek P60	Filtek P90	*p-value*
Marginal adaptation	94.0	100.0	0.104	95.8	100	0.178
Anatomic form	98.0	88.4	0.061	97.9	88.4	0.069
Surface roughness	80.0	65.1	0.108	75.0	65.1	0.579
Marginal discoloration	98.0	100.0	0.354	100.0	100	1.00
Post-operative sensitivity	100.0	95.3	0.125	100.0	100	1.00
Secondary caries	100.0	100.0	1.00	100.0	100	1.00

Table 3. Comparison between the materials tested for all clinical criteria at each examination period.

		Restorations rated alpha (%)					
		Marginal adaptation	Anatomic form	Surface roughness	Marginal discoloration	Post-operative sensitivity	Secondary caries
Filtek P60	Baseline	94.0	98.0	80.0	98.0	100.0	100.0
	6-month	95.8	97.9	75.0	100.0	100.0	100.0
p-value		0.317	1.00	0.180	0.317	1.00	1.00
Filtek P90	Baseline	100.0	88.4	65.1	100.0	95.3	100.0
	6-month	100.0	88.4	69.8	100.0	100.0	100.0
p-value		1.00	1.00	0.157	1.00	0.157	1.00

DISCUSSION

The low-shrinkage silorane-based composites exhibited a similar clinical performance to dimethacrylate-based composites when used for repairing dimethacrylate-based composite restorations after a six-month observation period, confirming, thus, the null hypothesis tested. Drop-out in this study was about 9%. This response rate is in accordance with other similar clinical studies that had rates of 0% to 15% for the first year recall[4,17,19,23-24].

In general, approximately 50% of resin-based composite restorations are replaced after seven years of service, and the main reasons are secondary caries, marginal defects, discoloration, degradation/wear and loss of anatomic form[17-19]. For many years, despite the subjectivity of restoration removal criteria, total replacement has been the most common treatment in general dental practice[19,25]. Nevertheless, it is known that when a restoration is replaced, there is a loss of healthy dental tissue, including areas away from localized defects[17]. Repairs are alternative treatments that can increase the longevity of restorations,

and several studies have shown a positive impact after first, second and third year observation periods[17-19,26]. Thus, this longitudinal prospective study aimed to discuss the effectiveness of a new low-shrinkage composite - silorane - as a repair material

Silorane is a nonmethacrylate-based resin that has been introduced in order to control polymerization shrinkage. The new monomer is obtained from the reaction of oxirane and siloxane molecules and was developed with the primary purpose of overcoming some drawbacks related to polymerization of dimethacrylate-based composites, such as radical oxygen inhibition, polymerization shrinkage, polymerization stress, water sorption and instability of conventional monomers in aqueous systems. As a result, silorane has the ability to compensate shrinkage by opening the oxirane ring during polymerization, reducing volume shrinkage to 1% from 1.7- 3.5% in dimethacrylate-based materials. Due to the presence of siloxane species, the hydrophobicity is also increased[3-4].

Silorane-based composites have been thoroughly investigated by in vitro tests, and promising results have been obtained regarding biocompatibility and mechanical characteristics, including reduced polymerization shrinkage[3,5]. However, in vitro studies are limited in predicting short- and long-term clinical conditions, and laboratory findings should be substantiated by clinical investigations.

In the present study, the main reasons for repairing restorations were marginal defects and loss of anatomical form. Six modified USPHS criteria - marginal adaptation, anatomic form, surface roughness, marginal discoloration, post-operative sensitivity and secondary caries - were used to verify the clinical performance of repairs performed on failed dimethacrylate-based composite restorations. No statistically significant differences between the groups were found for all clinical parameters tested at each time interval ($p > 0.05$). The frequency of no change in ratings from six-month recall examinations compared to baseline was much higher than the frequency of downgrades from an Alpha to Bravo rating.

It is a consensus that the information provided by USPHS criteria is too broad and may also lead to a misinterpretation as a good clinical performance since any changes over time are not easily detected by the limited sensitivity in short-term clinical investigation[17]. Despite these considerations, it is the most widely used method for clinical evaluations of restorations worldwide, and the main reason for adopting it relies on the fact that it can be compared to previous studies. In addition, this criteria involves visual inspection as well as the use of a dental explorer[17].

Laboratory studies have shown lower values of polymerization shrinkage related to silorane-based composites, but it is difficult to show the effects in clinical studies, mainly because in short-term six-month evaluations, many factors may not still influenced the final result3. In the current study, no statistically significant differences between the materials tested were found for marginal adaptation for the entire six-month follow-up. There are no results from clinical trials that have tested silorane-based composite as repair material available for comparison. However, a recent study investigated marginal adaptation of a low-shrinkage silorane-based composite and compared it with a dimethacrylate-based composite material across one-year interval[4]. Even though such study had outcomes related to total-replaced restorations, their results from one-year investigations are in accordance with the findings from the present study.

No statistically significant differences have been found between the materials tested for secondary caries, which are usually associated with marginal integrity and marginal adaptation is usually associated with reduced polymerization shrinkage. Favourable results were, thus, expected for a low-shrinkage resin-based composite5. Furthermore, within six months, the patients in the study did not develop carious lesions, most likely because patients with inadequate oral hygiene (VPI > 30%) and decreased salivary flow were excluded.

When each composite resin was evaluated independently at baseline and after six months no statistically, no difference was found too. In general, restorations remained stable and unchanged over the six-month observation period. Previous studies that have investigated the longevity of dimethacrylate-based restoration by minimal intervention have found the same good performance when dimethacrylate-based composites were used as repair materials[17-19].

Again, no statistically significant difference between the materials was found for surface roughness at any recall examination. This result is in agreement with studies investigating the longevity of dimethacrylate-based composite restorations by minimal interventions[17-19]. These studies found that surface roughness returned to their original values from the defective restoration values after only a three-year recall examination.

In a recent study related to the repair potential of composite resin materials, the highest bond strength

when a dimethacrylate-based composite was used as substrate was when Filtek P90 was used as the repair material and the P90 System as the adhesive. Although it is customarily assumed that the bond between old and new composite is micromechanical, data from when Filtek P90 was the substrate suggest that there is a possibility of chemical bonding, most likely because products that contain a silane coupling agent have improved wetability of the substrate surface in addition to higher binding of siloxane to inorganic filler particles. In Filtek P90, these are silanated ceramics[22]. It may explain the results from marginal discoloration, when no statistically significant difference between the two materials was found at recall examinations.

At baseline examination, the low incidence of restorations that received Bravo rating for post-operative sensitivity can be explained by the use of a self-etching bonding system in both treatment groups. These systems make the smear layers part of the hybrid layer, providing better penetration of the monomers onto the collagen fibers of the demineralized dentin. At follow-up, the same good performance was observed for all composites, likely because resin-based agents may provide pulp protection as long as the dentin is sealed by hydrophilic resins[23]. Initial post-operative sensitivity has been reported in clinical studies with resin-based composites, but the sensitivity generally decreases during the first weeks after placement of restorations[23].

CONCLUSION

Thus, after six months, this clinical trial shows that low-shrinkage silorane-based composites exhibited a similar performance to the conventional dimethacrylate-based composites when used to repair composite resin restorations. The reduced polymerization shrinkage assigned to silorane-based composites did not establish better clinical performance, indicating that laboratory findings should be substantiated by clinical investigations.

Collaborators

DAV POPOFF, responsible for the literature review, performance of the operative procedures, final writing of the manuscript and data statistical analysis. TTA SANTA ROSA, IP MARQUES and CS MAGALHÃES, responsible for evaluation of the operative procedures and writing of the manuscript. WF OLIVEIRA and AN MOREIRA, responsible for the literature review and partial performance of the operative procedures.

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