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# Repair of Dimethacrylate-Based Composite Restorations by a Silorane-Based Composite: A One-Year Randomized Clinical Trial

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### Clinical Relevance

A one-year clinical trial showed that a low-shrinkage silorane-based composite exhibited a similar performance to conventional dimethacrylate-based composites when used to repair composite resin restorations. This corroborates *in vitro* studies suggesting that bonding of silorane-based composites to old dimethacrylate-based composites can be a viable clinical procedure.

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## SUMMARY

**Purpose**: **To investigate clinical performance of a low-shrinkage silorane-based composite resin when used for repairing conventional dimethacrylate-based composite restorations.**

**Background**: **Despite the continued development of resin-based materials, polymerization shrinkage and shrinkage stress still require improvement. A silorane-based monomer system was recently made available for dental restorations. This report refers to the use of this material for making repairs and evaluates the clinical performance of this alternative treatment.**

**Materials and Methods**: **One operator repaired the defective dimethacrylate-based composite resin restorations that were randomly assigned to one of two treatment groups: control (n=50) repair with Adper SE Plus (3M/ESPE) and Filtek P60 Posterior Restorative (3M/**

**ESPE), and test (n=50) repair with P90 System Adhesive Self-Etch Primer and Bond (3M/ESPE) and Filtek P90 Low Shrink Posterior Restorative (3M/ESPE). After one week, restorations were finished and polished. Two calibrated examiners (Kw≥0.78) evaluated all repaired restorations, blindly and independently, at baseline and one year. The parameters examined were marginal adaptation, anatomic form, surface roughness, marginal discoloration, postoperative sensitivity, and secondary caries. The restorations were classified as Alpha, Bravo, or Charlie, according to modified US Public Health Service 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. Dropout from baseline to one-year recall was 11%. No statistically significant differences were found between the materials for all clinical criteria, at baseline or at one-year 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 one-year recall.**

**Conclusions**:**The hypothesis tested in this randomized controlled clinical trial was accepted. After the one-year evaluations, the silorane-based composite exhibited a similar performance compared with dimethacrylate-based composite when used to make repairs.**

## INTRODUCTION

The demand for esthetic restorations, the development of new adhesives and curing systems, and improvement of material properties have made dental composites the most widely used direct restorative material today.[1–3] Despite such developments, two features still require improvement: polymerization shrinkage and the development of polymerization shrinkage stress.[4]

The intrinsic contraction of the composite remains a challenge, and changes in the monomer composition seem to be the most promising way to minimize the effects of shrinkage.[5–8] Clinically, the incremental insertion and control of polymerization rate are the main strategies used to control polymerization shrinkage.

Recently, an innovative monomer system was made available for dental restorations: silorane, obtained from the reaction of oxirane and siloxane molecules; oxiranes are known for their low shrinkage, while siloxanes are known for their hydrophobicity.[5,9] *In vitro* studies have compared the new system to dimethacrylate-based composites. The results show that silorane-based composites demonstrate the lowest polymerization shrinkage as well as more ambient light stability, contributing to the convenience of handling the composite material. The new system also has the lowest sorption and water solubility and a lower diffusion coefficient than conventional monomers. Other parameters such as tensile modulus, flexural strength, and biocompatibility in toxicology tests are comparable to dimethacrylate-based composite.[5,8,10–12]

Imperfect margins result in marginal discoloration and secondary caries lesions, the most important cause for the replacement of restorations.[4] Reducing shrinkage and the stress generated by polymerization may positively influence marginal integrity. Total replacement is the most common treatment adopted for restorations that are clinically diagnosed as defective. However, the assessment of the quality of restorations is made subjectively, and often minimum deviations from ideal determine the systematic replacement of restorations.[13,14]

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, total removal is considered undesirable and inappropriate.[3,15] Thus, keeping in mind the current trends toward minimally interventional procedures, several studies have suggested partial removal of the restoration.[14,16–21] This approach allows preservation of sound tooth structure.[22,23]

Clinical studies involving composite resin repairs have shown that when properly planned, the repairs may increase the clinical longevity of restorations, representing a conservative choice for treatment of restorations.[13,14,24]

Thus, once *in vitro* studies suggest that bonding of silorane-based composites to old dimethacrylate-based composites may be a viable clinical procedure,[25–27] 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 with that of conventional dimethacrylate-based composites when repairing composite resin restorations.

## MATERIALS AND METHODS

### Study Design

This was a prospective randomized clinical trial. The observation unit was the restoration, and the dependent variable was qualitative categorical ordinal. 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, Belo Horizonte, Minas Gerais, Brazil.

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 bitewing radiographic exams, and patients who had restorations that scored at least Bravo according to Modified United States Public Health Service (USPHS) clinical criteria (Table 1). The exclusion criteria were patients with contraindications for regular dental treatment according to their medical history; patients with xerostomia, including those taking medications that are proven to significantly reduce salivary flow; patients with visible plaque index (VPI) >30%; and patients with defective restorations, unacceptable for repairs, that scored Charlie (modified USPHS clinical criteria).

This study was approved by the Institutional Ethics Committee (ETIC 0546.0.203.000–09). A written informed consent was obtained from all patients.

### Study Methods

The restorations were examined one week after they were repaired for baseline assessment and at one year. Two examiners independently evaluated all repaired restorations by direct observation, using a plane buccal mirror and a WHO model explorer. A calibration exercise revealed an interexaminer agreement ratio $\geq$0.78. If there was disagreement on the rating, the clinicians reexamined the repaired restoration together and arrived at a joint final decision. The parameters examined were marginal adaptation, anatomic form, surface roughness, marginal discoloration, postoperative sensitivity, and secondary caries. The examiners classified all restoration as Alpha, Bravo, or Charlie, according to modified USPHS clinical criteria.

### Treatment Groups

To minimize preparation variability, the same operator repaired all defective composite resin restorations. The 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 operator randomly assigned the restorations to one of two treatment groups: control group (n=50), repair with a self-etching primer (Adper SE Plus, 3M/ESPE, St Paul, MN) and a dimethcrylate-based composite (Filtek P60 Posterior Restorative, 3M/ESPE), and test group (n=50), repair with a self-etching primer (P90 System Adhesive Self-Etch Primer and Bond, 3M/ESPE) and a low-shrinking silorane-based composite (Filtek P90 Low Shrink Posterior Restorative, 3M/ESPE; Table 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. Materials were used according to the manufacturer's recommendations (Table 3).

### Outcome Measurements and Statistical Analysis

At baseline and 12-month recall, all restorations received a clinical rating of 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). Mann-Whitney test was used to assess differences between the materials tested and for all clinical criteria, at baseline and one-year recall examination ($\alpha$=0.05). Wilcoxon test was used to compare each composite resin for all clinical criteria at baseline examinations and one-year recall ($\alpha$=0.05).

## RESULTS

In the present study, the main reasons for restorations being repaired were marginal defects (81%) and loss of anatomic form (19%). Of the 100 repaired restorations, 93 (50 for Filtek P60 and 43 for Filtek P90) were examined at baseline. From those, 83 were reexamined at the one-year recall (42 for Filtek P60 and 41 for Filtek P90). The flow of participants and

Table 1: *Modified US Public Health Service Clinical Criteria*

| Category | Rating | Criteria Description |
|---|---|---|
| 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 which dentin or the base is exposed |
| Anatomic form | Alfa (A) | Anatomic form ideal |
| | Bravo (B) | Restoration is undercontoured, without dentin or base exposure; |
| | Charlie (C) | Restoration is undercontoured, 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 to 100 cm |
| 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 antiesthetic and/or retain biofilm; improvement by finishing is not feasible |
| Postoperative 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 |

the number of restorations through each examination period of the study are shown in Figure 1. Dropout in this study was about 11% from baseline to one-year recall.

Table 4 summarizes the comparison between the materials tested for all clinical criteria at one-year recall examination and baseline. Bravo ratings can be derived by subtraction, and no restoration received Charlie ratings. No statistically significant difference between the materials was found ($p>0.05$).

Table 5 shows the comparison between baseline and one-year recall examination for each material independently, for all clinical parameters. No statistically significant difference was found in any criteria between the examination periods ($p>0.05$).

## DISCUSSION

Silorane is a nonmethacrylate-based resin that has been introduced to control polymerization shrinkage. The new monomer is obtained from the reaction of

Table 2: *Materials: Chemical Composition and Manufacturers*

| Material | Chemical Composition | Manufacturer |
|---|---|---|
| Magic Acid Gel | 37% Phosphoric acid | Vigodent/Coltene |
| 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 zirconia 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 sílica, initiators and stabilizers | 3M/ESPE |
| Filtek P90 Low Shrink Posterior Restorative | Matrix: silorane; Filler: quartz, yttrium fluoride; Initiator system: camphorquinone, iodonium salts and electron donors; stabilizers and pigments | 3M/ESPE |

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% to 3.5% in dimethacrylate-based materials. Because of the presence of siloxane species, the hydrophobicity is also increased.[5,28–30]

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.[5,9,31] However, *in vitro* studies are limited in predicting short- and long-term clinical conditions, and laboratory findings should be substantiated by clinical investigations.

Dropout in this study was about 11% after one year. This response rate is in accordance with other similar clinical studies that had rates of 0% to 15% for the first year recall.[13,24,28,32,33] The dropout rates highlight part of the problems associated with long-term clinical studies and having multiple restorations in one patient.[28]

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, postoperative 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 one-year recall examinations compared with baseline was much higher than the frequency of downgrades from an Alpha to Bravo rating.

It is generally agreed that USPHS criteria may have a limited application since the information provided is too broad; the criteria 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.[13,34] However, 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 with previous

Table 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 | |
| Application 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 (600 mW/cm$^2$) | 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, RJ, Brazil) | x | x |

studies. In addition, this criterion involves visual inspection as well as the use of a dental explorer.[13]

### Marginal Adaptation and Secondary Caries

In the current study, no statistically significant differences between the materials tested were found for marginal adaptation for the entire one-year follow-up. There are no results from clinical trials that have tested silorane-based composite as repair material available for comparison. However, a recent clinical trial investigated marginal adaptation of a low-shrinkage silorane-based composite and compared it with a dimethacrylate-based composite material across the same time interval.[28] Even though this study had outcomes related to total-replaced restorations, they disagree with the findings from the present study, since a better performance was found for the dimethacrylate-based composite material. 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, where so many factors influence the final result.[5,35,36]

In this study, no statistically significant differences have been found between the materials tested for secondary caries. Because secondary caries are

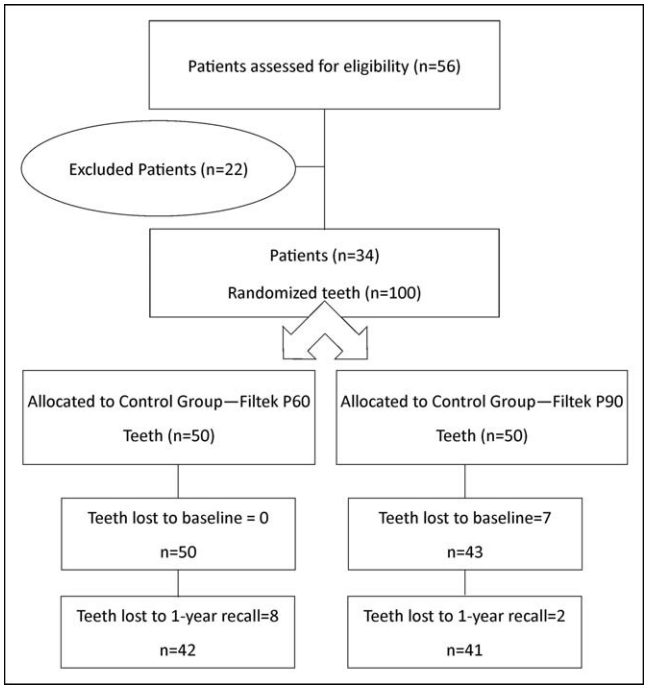


Figure 1. *Flowchart of patients and number of restorations through each stage of the study.*

usually associated with marginal integrity and marginal adaptation is usually associated with reduced polymerization shrinkage, we expected favorable results for a low-shrinkage resin-based composite.[5] On the other hand, the observation time reported in this study may not be considered long enough for the development of secondary caries. Furthermore, patients in the study did not develop carious lesions, most likely because those with inadequate oral hygiene (VPI>30%) and decreased salivary flow were excluded.

### Anatomic Form

No statistically significant difference was found when each composite resin was evaluated independently at baseline and after one year. Regarding the difference of 10% in the baseline results between the two materials, this did not remain in the one-year results since some restorations scored better at follow-up than at baseline. It may reflect the difficulty of assessing some criteria clinically, even with an interexaminer agreement ratio $\geq$0.78. Moreover, if a study requires recording of minute detail, calibration becomes difficult with the concomitant risk of recording differences in clinical judgment between evaluators rather than between experimental and control groups.[35]

In addition, general practitioners in five European countries were asked to rate several handling criteria of the Filtek P90 on a five-point scale, in which rating 1 was assigned for an excellent performance and rating 5 for a poor performance. Regarding the criteria sculptability, the best score assigned for Filtek P90 was 3 (3M ESPE, Filtek P90 Technical Profile). This was also observed in the present study and could explain the percentage of Bravo ratings registered for anatomic form in the test group.

In general, restorations remained stable and unchanged over the first-year observation period. Previous studies that have investigated the longev-

Table 4: *Comparison Between the Materials Tested for All Clinical Criteria at Each Examination Period*

| **Frequency Number of Restorations Rated Alpha and Percentage (%)** | | | | | | |
|---|---|---|---|---|---|---|
| | **Baseline** | | | **One Year** | | |
| | **Filtek P60** | **Filtek P90** | ***p* Value** | **Filtek P60** | **Filtek P90** | ***p* Value** |
| Marginal adaptation | 47 (94.0) | 43 (100.0) | 0.104 | 40 (95.2) | 40 (97.6) | 0.573 |
| Anatomic form | 49 (98.0) | 38 (88.4) | 0.061 | 40 (95.2) | 36 (87.8) | 0.226 |
| Surface roughness | 40 (80.0) | 28 (65.1) | 0.108 | 30 (71.4) | 26 (63.4) | 0.439 |
| Marginal discoloration | 49 (98.0) | 43 (100.0) | 0.354 | 42 (100.0) | 38 (92.7) | 0.076 |
| Postoperative sensitivity | 50 (100.0) | 41 (95.3) | 0.125 | 42 (100.0) | 41 (100.0) | 1.00 |
| Secondary caries | 50 (100.0) | 43 (100.0) | 1.00 | 42 (100.0) | 41 (100.0) | 1.00 |

Table 5: *Comparison Between Each Material Independently for All Clinical Parameters, at Baseline and at One-Year Recall Examination*

| Frequency Number of Restorations Rated Alpha and Percentage (%) | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | **Marginal Adaptation** | **Anatomic Form** | **Surface Roughness** | **Marginal Discoloration** | **Postoperative Sensitivity** | **Secondary Caries** |
| Filtek P60 | Baseline | 47 (94.0) | 49 (98.0) | 40 (80.0) | 49 (98.0) | 50 (100.0) | 50 (100.0) |
| | 12-month | 40 (95.2) | 40 (95.2) | 30 (71.4) | 42 (100.0) | 42 (100.0) | 42 (100.0) |
| *p* value | | 0.317 | 0.317 | 0.180 | 0.317 | 1.00 | 1.00 |
| Filtek P90 | Baseline | 43 (100.0) | 38 (88.4) | 28 (65.1) | 43 (100.0) | 41 (95.3) | 43 (100.0) |
| | 12-month | 40 (97.6) | 36 (87.8) | 26 (63.4) | 38 (92.7) | 41 (100.0) | 41 (100.0) |
| *p* value | | 0.317 | 1.00 | 0.317 | 0.083 | 0.317 | 1.00 |

ity of dimethacrylate-based restoration by minimal intervention have found the same good performance when dimethacrylate-based composites were used as repair materials.[13,14,24]

### Surface Roughness

The surface roughness property of any material is the result of the interaction of multiple factors. Some of them are related to the material itself, such as the filler (type, shape, size, and distribution of the particles), the type of resinous matrix as well as the ultimate degree of cure reached, and the bond efficiency at the filler-matrix interface.[37,38] In this context, a direct correlation was found between the hardness and surface roughness, indicating that a composite with a higher hardness value is usually associated with a higher surface roughness.[38,39]

In the current study, no statistically significant difference between the materials was found for surface roughness at any recall examination. However, there is a trend that indicates a problem, since there is a 15% difference in roughness between the materials at baseline and an 8% difference at follow-up, indicating a better performance to the methacrylate-based composite resin. A previous study has shown a higher Knoop hardness for Filtek P90 than for dimethacrylate-based composites due to its organic matrix composed mainly by silorane resin and inorganic particles as quartz and yttrium fluoride (76% by weight),[40] explaining the current findings for surface roughness.

Furthermore, the percentages of Bravo ratings found for both materials could be explained by the fact that assessment "alpha" is given to a surface as smooth as the surrounding enamel, and maybe the evaluators were very critical in their evaluation, since it is known that there is no material to replace all the qualities of the enamel, and this especially applies for its smooth, polished surface.[41]

### Marginal Discoloration

For marginal discoloration, no statistically significant difference between the two materials was found at recall examinations. 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 the wettability of the substrate surface and the ability to effect a chemical (siloxane) bind to inorganic filler particles; in Filtek P90, these are silanated ceramics.[27]

### Postoperative Sensitivity

Initial postoperative sensitivity has been reported in clinical studies with resin-based composites, but the sensitivity generally decreases during the first

weeks after placement of restorations.[28,42] At baseline examination, the low incidence of restorations that received a Bravo rating 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.[28,42]

Thereby, the null hypothesis tested in this study was confirmed since the low-shrinkage silorane-based composites exhibited a similar clinical performance to the dimethacrylate-based composites when repairing dimethacrylate-based composite restorations after a one-year observation period. Nevertheless, it is appropriate to highlight that short-term results can provide only an early prediction of the material clinical performance and that no evidence of early failure or sudden change in the clinical characteristics occurred. Longer observation periods are thus necessary to confirm these findings.

## CONCLUSIONS

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.

Repairs with a different resin chemistry were successful as long as the bonding agent was of the new chemistry being used for the repair.

After one year, 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, and a long-term answer to the question should be determined after a longer recall period.

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### Conflict of Interest

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

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