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ORIGINAL RESEARCH


# The Short-term Clinical Performance of a Silorane-based Resin Composite in the Proximal Contacts of Class II Restorations

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## ABSTRACT

**Aim:** The aim of this randomized clinical trial was to compare the proximal contact of a silorane-based resin composite with a conventional methacrylate-based resin composite in class II restorations after a 6 months follow-up period.

**Materials and methods:** After obtaining informed consent, 33 patients were randomly allocated into a test group (Filtek P90/Adhesive System-3M ESPE) or control group (Filtek P60/ Adper SE Plus-3M ESPE), and 100 direct resin composite restorations (n = 50) were placed. A single operator performed the cavities and restorations. After rubber dam placement, a metal matrix and wooden wedge were placed. The restorative systems were applied according to the manufacturer's instructions. After 1 week, the restorations were finished and polished. The proximal contacts were assessed blindly and independently by two calibrated examiners (kW = 0.8) at the baseline and after 6 months according to a three-step grading criteria. Data were analyzed with the Mann-Whitney U-test and Wilcoxon signed Rank tests ($\alpha = 0.05$). Results: After 6 months, 96% of the restoration contacts were present for evaluation. The frequencies of restorations classified as Bravo in control and test groups were 6 and 8% at the baseline, and 6.25 and 12.75% after 6 months. No significant difference was found between the restorative materials ($p > 0.05$; Mann-Whitney U-test) neither between baseline and 6 months period ($p > 0.05$; Wilcoxon signed Rank tests).

**Conclusion:** Both materials performed satisfactorily over 6 months follow-up period.

**Clinical significance:** The short-term clinical performance of a silorane-based resin composite in the proximal contacts of class II restorations was similar to the well-known methacrylate-based resin composite.

**Keywords:** Clinical trial, Resin composite, Silorane, Proximal contact.

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## INTRODUCTION

Resin composite is considered to be the most esthetic material for direct restorations due to its similar characteristics to natural teeth, such as color, texture, brightness, translucency and fluorescence. Increased esthetic demand and emphasis on minimally invasive restorative procedures have increased the use of composites for both anterior and posterior restorations. Potential bonding to tooth hard tissues using adhesives is an additional advantage of resin composites that results on the preservation of dental structure and reinforcement of the restored tooth.[1,2]

The application of composite resin to posterior teeth, especially in class II restorations, may be compromised because of the inherent polymerization shrinkage that can cause marginal adhesion breakdown, gap formation, dentinal sensitivity and restoration failure. In addition, the difficulty of adapting the resin to the cervical walls, the proper adjustment of proximal contacts and the cervical fit are other problems associated with composite placement.[3,4] An appropriated proximal contact is important for the prevention of the food impaction, tooth migration, periodontal complications and carious lesions.[5,6] The difficulty in obtaining a tight proximal contact with resin composite has been attributed to the inherent polymerization shrinkage and lack of condensability of resin composite materials, the use of a rubber dam materials and the thickness of the matrix band. To obtain a tight proximal contact with class II composite resin restoration the clinical procedure

has to compensate for the thickness of the matrix as well as the polymerization shrinkage of the composite resin.[7-9]

One of the latest developments in the field is the introduction of a new class of low-shrinkage composites based on silorane technology (Filtek Silorane, 3M ESPE, Seefeld, Germany), which is a combination of siloxane and oxirane. These monomer system have decreased polymerization shrinkage and have resulted in a reduction in shrinkage stress[10-12] as well as better hydrolitic stability.[13,14] *In vitro* studies have shown that this resin have better biocompatibility,[10,13,15,16] marginal adaptation and less microleakage than methacrylate-based systems.[17] However, the laboratory findings should, be substantiated by clinical investigation. The hypothesis (Ho) that was tested in this randomized clinical trial was the following: A composite with low polymerization shrinkage (Filtek P90, 3M ESPE, Seefeld, Germany) presents similar proximal contact to a methacrylate-based resin composite (Filtek P60, 3M ESPE, Seefeld, Germany) in class II restorations, in a 6 months follow-up.

## MATERIALS AND METHODS

This randomized clinical trial was performed between March 2010 and March 2011. The study design was approved by the Ethics Committee of Federal University of Minas Gerais. Most of the patients were recruited from the clinic at School of Dentistry, Federal University of Minas Gerais, Belo Horizonte, Minas Gerais, Brazil. Others patients were students from the university or friends and family members of those participants. After the informed consents were obtained, the patients registered for class II restorations of premolars and molars were included in the study; each patient could contribute more than one tooth. The inclusion criteria were the following: Class II restoration required in at least one tooth, functional occlusion, good oral hygiene status, absence of any active periodontal and pulpal disease, presence of antagonist and adjacent tooth.

Thirty-three patients (10 males, 23 females, aged 21-55 years, mean age of 34.5) participated in this study. One hundred class II composite resin restorations (36 MO/43 DO/21 MOD) were placed in a total of 68 premolars and 32 molars by one operator between March 2010 and June 2010. Bitewing radiographs were taken to assess the extent of the carious lesion, defect or previous restoration. All restoration were placed under rubber dam isolation and according to the following protocol: Local anesthesia (Alphacaine 50, DFL, Rio de Janeiro, Brasil) was administered; a wooden wedge (TDV Dental Ltda, Pomedore, Brazil) was placed interproximally at the surface to be restored to obtain separation of teeth and prevent damage of the papilla during the preparation procedure; the cavity was performed with a high-speed handpiece and a carbide bur FG245 (Jet carbide burs, Beavers Dental, Morrisburg, Canadian); carious tissue was excavated with hand excavators; rounded internal angles and unsupported enamel were instrumented with hand tools without bevelling the margins.

For the restoration, the circumferential steel matrices (Matrix Tofflemire, TDV Dental Ltda, Pomedore, Brazil) with a Tofflemire retainer and wooden wedges were used. In very deep cavities, a closed sandwich technique was used. A calcium hydroxide cement liner (Hydro C, Dentsply, Petrópolis, Brasil) and glass-ionomer cement (Vitrebond, 3M ESPE, St Paul, USA) were applied. The contact area in the matrix band was carefully burnished with a hand instrument to permit no visual space between the matrix and the adjacent tooth; the adaptation of the matrix band at the gingival cavity margin was checked with an explorer. The enamel cavity walls were etched with 37% phosphoric acid (Cond AC 37, FGM Produtos Odontológicos, Joinvile, Brasil) for 15s and washed for 30s; the excess water was removed. The teeth were randomized using simple allocation into two treatment groups (n = 50) as follows: Filtek P60, control group; and Filtek P90, test group. The resin composite and adhesive systems used in this study are listed in Table 1. An adhesive protocol was made according to the recommendations of the manufacturers. The composite material was applied in oblique incremental layers of approximately 2 mm thickness and adapted to the cavity walls with a plugger. Each layer was light cured for 20s (Filtek P60) and 40s (Filtek P90) with a unit of halogen light (Elipar Trilight, 3M ESPE, Seefeld, Germany). The light emission window was placed as close as possible to the cavity margins, and the intensity of the light was checked periodically with a radiometer (Demetron Research Corp, Danburg, USA); it was found to be no lower than 600 mW/cm$^2$. The restorations were additionally light cured for 20s from the buccal, lingual and occlusal aspects after removal of the matrix and wooden wedge. Visible overhangs and defects were removed, and the contacts in centric and eccentric occlusions were adjusted. Finishing and polishing occurred after 1 week using a multilayered carbide burn. 9714FF (KG Sorensen, Cotia, Brasil) and Enhance System (Dentsply, Petrópolis, Brazil).

The proximal contacts of all restoration were assessed blindly and independently by two calibrated examiners (kW = 0.8) at the baseline (1 week after placement) and after 6 months. The proximal contact was measured by passing dental floss (Hilo Indústria e Comércio Ltda, Aperibé, Brazil) interdentally and scored according to a three-step grading criteria (Table 2).[1] When disagreement occurred, a joint examination was conducted and the examiners agreed on a final rating.

The results were tabulated and submitted for statistical analysis using SPSS for Windows XP 15.0 (SPSS Inc, Chicago, USA). The statistical unit was the restoration, and the differences between the groups were evaluated using the Mann-Whitney U-test. Changes in the same group overtime were analyzed by the Wilcoxon signed Rank tests ($\alpha = 0.05$).

## RESULTS

The Table 3 summarizes the type of restored tooth (molar or premolar) in the test and control groups and the type of adjacent contact included in the study. Most of the restorations (76% in the control group and 80% in the test group) had a contact relationship with a restored adjacent surface (resin, amalgam or indirect restoration).

The thirty-three patients allocated for this study received treatment and returned for assessment at the baseline. After 6 months, one patient (two restorations in the test group and two in the control group) did not participate in the evaluation, which represents a recall rate of 96% for both groups. At the baseline, 6 and 8% of the restorations were classified as Bravo in control and test groups, respectively. After 6 months, 6.25 and 12.75% of the restorations were classified as Bravo in control and test groups, respectively. One restoration (2.08%) was classified as Charlie in test group after 6 months.

The statistical test used to compare the same material overtime showed no significant difference ($p > 0.05$; Wilcoxon signed Rank tests) in proximal contacts (Table 4). Between the two composite groups, over the observation period, the restorations revealed no statistically significant differences ($p > 0.05$; Mann-Whitney U-test) in proximal contacts (Table 5).

## DISCUSSION

In the present study, the influence of low-contraction composite resin on proximal contacts was investigated and compared to a methacrylate-based composite resin. The results demonstrated that the null hypothesis (Ho) was accepted. There were not significant changes in proximal contact tightness after 6 months for each material. There are not any results of previous clinical studies comparing the performance of a silorane-based composite to methacrylate-based composite in the proximal contacts of class II restorations. Some clinical studies have compared the effect of different restorative protocols on immediate or delayed tightness of the proximal contacts. One should be careful when evaluating proximal contacts because they may vary overtime due to factors, such as tooth type, tooth location, time of day, postural change, periodontal condition of the tooth, type of adjacent contact and occlusal contact.[18,19] It is unknown when the changes on a proximal contact occur, and a 6 months follow-up study is needed to establish this adaptability. The patients participating this study did not report any discomfort when a tight contact was reconstructed. However, one restoration, involving a

**Table 2:** Three-step grading criteria for proximal contact quality

| *Criteria (code)* | *Description* |
|---|---|
| ALPHA (A) | Normal proximal contact, dental floss can be inserted |
| BRAVO (B) | Moderate proximal contact, without prejudice to tooth, gingiva or periodontal structures, dental floss can pass easily |
| CHARLIE (C) | Absent proximal contact, clear damage to tooth, gingiva or periodontal structures |

Adapted from Hickel et al.[1]

**Table 1:** Materials composition and manufacturer

| *Material* | *Composition* | *Manufacturer* |
|---|---|---|
| Adper SE Plus adhesive Self-etch - Liquid A LOT.8BH | Water; HEMA; pink dye; surfactant | 3M ESPE |
| Adper SE Plus adhesive Self-etch - Liquid B LOT.9BN | UDMA; TEGMA; TMPTMA; HEMA; MHP; camphorquinone; zircônia | 3M ESPE |
| Filtek P60 LOT.N126307 | BIS-GMA; BIS-EMA; urethane dimethacrylate; sílica; zirconia; camphorquinone | 3M ESPE |
| Silorane system adhesive Self-etch primer LOT. N107465 | 15 to 25% 2-hydroxyethyl methacrylate (HEMA); 15 to 25% bisphenol-a-diglycidyl ether dimethacrylate (Bis-GMA), water; 10 to 15% ethanol, 5 to 15% phosphoric acid-methacryloxy-hexylesters; 8 to 12% silane treated silica; 5 to 10% 1,6-hexanediol dimethacrylate; <5% copolymer of acrylic and itaconic acid; <5% ethyl methacrylate, <3% DL-camphorquinone; <3% phosphine oxide | 3M ESPE |
| Silorane system adhesive bond LOT. N098714 | 70 to 80% substituted dimethacrylate; 5 to 10% silane treated silica; 5 to 10% triethylene glycol dimethacrylate (TEGDMA); <5% phosphoric acid methacryloxy hexylesters; <3% DL-camphorquinone; <3% 1.6 hexanediol dimethacrylate | 3M ESPE |
| Filtek P90 LOT.N130928 | 5 to 15% 3, 4 epoxyclohexylethyl-cyclopolymethylsiloxane; 5-15% bis-3, 4-epoxycyclohexylethyl-phenyl-methylsilane; 50 to 70% silanized quartz; 10 to 20%yttrium fluoride; camphorquinone | 3M ESPE |

change in the criteria from Bravo to Charlie overtime, caused discomfort and food impaction. A clinical study indicate that an increased in proximal contact tightness as result of treatment tends to loosen after 6 months period. The 'adaptation mechanism' is based on the orthodontic principle of tooth movement in which tightness applied at the treatment site is spread through the proximal contact; this results in a new balanced situation.[8]

Our results are in accordance with a clinical follow-up study that evaluated the effectiveness of proximal contacts in class II restorations using two types of matrix bands (steel and polyester) and two different restoration techniques (incremental and with prepolymerized particles) with hybrid composite (Prodigy, Kerr). The results revealed a loss of axial contour without statistically significant alterations in proximal contact behavior at the 18 months evaluation. The variation in physical properties of the resin composites may interfere with the effectiveness of the proximal contacts.[20]

Our results are in disagreement with a 6 months follow-up study involving class II restorations with highly filled hybrid composite (Clearfil AP-X, Kuraray, Co) and different matrix systems. They concluded that the changes in proximal contacts after treatment will not always remain stable over-time.[8]

Longer follow-up studies have found an overall reduction in proximal contact quality after 2 and 4 years using Single Bond and P60 (3M ESPE). No differences between a metallic matrix and wooden wedge and a polyester matrix and reflective wedge were found. This clinical finding may be related more to the composite mechanical properties rather than to the difference induced by the matrix systems.[4,21]

It can be assumed that the most relevant changes of contact tightness will occur in the period directly following placement of the restoration.[8] When proximal contact tightness was recorded before and after treatment, clinical studies showed that the proximal contact with better performance was obtained when using a sectional matrix system combined with a separation ring.[6,7,22] In the present study, the restorative protocol designed to achieve tight proximal contacts involved the use of a circumferential matrix system and prewedging. A wooden wedge was pressed firmly into the interdental space before cavity preparation and was kept in place during the preparation.[23,24] This matrix system assists in the production of restorations with proximal contact stable until the end of 6 months period. It is suggested that the differences between our study and the others may be due to the methodologies for clinical evaluation of the proximal contacts.

**Table 3:** Summary of tooth type and adjacent contact included in the study

| *Groups* | *Tooth (n)* | *Adjacent contact* | | | |
|---|---|---|---|---|---|
| | | *Tooth* | *Resin* | *Amalgam* | *Indirect restoration* |
| Control | Molars (18) | 4 (8) | 14 (28) | 0 (0) | 0 (0) |
| | Premolars (32) | 8 (16) | 22 (44) | 2 (4) | 0 (0) |
| Test | Molars (14) | 3 (6) | 10 (20) | 0 (0) | 1 (2) |
| | Premolars (36) | 7 (14) | 28 (56) | 0 (0) | 1 (2) |

Absolut frequency (Relative frequency-%)

**Table 4:** Comparison between the baseline and 6 months follow-up within each group

| *Groups* | *Code* | *Baseline (n = 50)* | *Six-month (n = 48)* | *Wilcoxon signed rank test* |
|---|---|---|---|---|
| Control | A | 47 (94.00) | 45 (93.75) | p = 1.00 |
| | B | 3 (6.00) | 3 (6.25) | 95% CI = 0.67-0.70 |
| | C | 0 (0.00) | 0 (0.00) | |
| Test | A | 46 (92.00) | 41 (85.42) | p = 0.15 |
| | B | 4 (8.00) | 6 (12.50) | 95% CI = 0.13-0.15 |
| | C | 0 (0.00) | 1 (2.08) | |

Absolut frequency (Relative frequency-%)

**Table 5:** Comparison between the test and control groups within each evaluation time

| *Time* | *Code* | *Control* | *Test* | *Mann-Whitney U-test* |
|---|---|---|---|---|
| Baseline | A | 47 (94.00) | 46 (92.00) | p = 0.60 |
| (n = 50) | B | 3 (6.00) | 4 (8.00) | 95% CI = 0.76-0.78 |
| | C | 0 (0.00) | 0 (0.00) | |
| Six-month | A | 45 (93.75) | 41 (85.42) | p = 0.39 |
| (n = 48) | B | 3 (6.25) | 6 (12.50) | 95% CI = 0.38-0.40 |
| | C | 0 (0.00) | 1 (2.08) | |

Absolut frequency (Relative frequency-%)

Most prospective clinical investigions of dental materials and/or techniques have used the USPHS (United States Public Health Service) criteria for quality restoration evaluation. Researchers have adapted the criteria in an effort to make the evaluation more discriminating for modern restorative materials, with the consequence that there are many so, called modified USPHS criteria in use.[1] In clinical studies, the tightness of the proximal contact can be measured by passing dental floss or 25, 50 and 100 µm metal blades interdentally and scoring the strength of the contact point.[1,25] A tooth pressure meter (TPM) was proposed as a more accurate device to measure the proximal contact strength and has been used in clinical trials to record minor changes.[19] This method allows for a thick metal strip that is connected to the device to be inserted interdentally from the occlusal surface. The proximal contact is quantified in several sites as the maximum frictional force when the strip is slowly removed in the occlusal direction.[6-9,22] The criteria used in this study, despite their subjectivity, are recommended worldwide for clinical comparison of materials and techniques. To reduce the variability of the outcome, teeth without existing proximal contacts were excluded in the beginning of the study, and the same type of floss was used for examiners calibration, at baseline and at recall evaluation.[1]

Increased gingival inflammation and attachment loss have also been attributed to plaque accumulation due to lose proximal contacts; however, alveolar bone loss is not directly attributed to open interproximal contacts but is related to the periodontal status of the patient.[26,27] Therefore, it is important to maintain control of the biofilm as well as constantly reinforce proper oral hygiene.

## CONCLUSION

Based on the results of this study, it can be concluded that a silorane-based resin composite shows similar proximal contact to a conventional resin of methacrylate in class II restorations at the baseline and after 6 months. Both composites produced stable proximal contacts immediately and after 6 months.

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