2-year Clinical Evaluation of Sodium Hypochlorite Treatment in the Restoration of Non-carious Cervical Lesions: A Pilot Study

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Clinical Relevance
The use of 10% sodium hypochlorite to remove exposed collagen after acid-etching did not affect the clinical performance of composite restorations of non-carious cervical lesions.
The restorations were evaluated for pre- and post-operative sensitivity, retention, marginal staining and secondary caries at baseline, 12 and 24 months after placement, using modified USPHS criteria. Data were analyzed using the Kruskal-Wallis and Wilcoxon statistical tests \((p=0.05)\). At 24 months, the retention rates for Prime & Bond 2.1 with and without NaOCl pretreatment were 80% and 63%, respectively. The corresponding retention rates for Single Bond were 70% and 90%. Marginal staining was minimal. Statistical analyses revealed no significant differences at any time interval between groups for retention or marginal staining. No post-operative sensitivity or secondary caries was detected during the study.

**INTRODUCTION**

The bonding of resin adhesives to dentin has improved substantially in the last few decades, thanks to intense research and development.\(^1\) An effective, long-lasting tooth-restoration bond is desirable, because it would prevent microleakage and, consequently, inhibit the development of secondary caries. This would allow for conservative cavity preparations with less need for mechanical retention.\(^4\)

Dentin bonding can be obtained through etching and hybridization,\(^4\) but in vitro studies show that dentin bond strengths decrease after long-term storage in water,\(^4,7\) and after thermal and mechanical load-cycling.\(^5\) One possible explanation for this phenomenon is that, when dentin is etched with an organic acid (for example, phosphoric acid), the collagen fibrils exposed by acid-etching are not totally infiltrated by the resin adhesive and might undergo hydrolysis,\(^10-11\) which could adversely affect the durability of the adhesive interface.\(^1\) Thus, when the acid-etching technique is used, it is fundamental that the adhesive penetrates fully into the demineralized zone to obtain an effective, stable adhesive interface.\(^4\)

Some studies have demonstrated that dentin collagen does not contribute quantitatively to dentin bond strengths,\(^2,12-13\) while other studies have suggested that removing the etched dentin collagen could prevent or delay degradation of the adhesive interface.\(^4,14\) Resin bond strengths after dentin treatment with sodium hypochlorite (NaOCl), a non-specific proteolytic agent that removes dentin collagen exposed by acid-etching, have been evaluated, but no conclusive evidence regarding the effectiveness of the collagen removal technique is available. Most published data are from in vitro studies that used different methodologies (for example, type of NaOCl, application time and technique, type of adhesive).\(^2,13-14,17\)

The evidence of reflectance FTIR microspectroscopy and tapping mode atomic force microscopy suggest that NaOCl treatment of acid-etched dentin reduces the surface organic matrix but does not affect carbonates and phosphates.\(^18\) NaOCl treatment also increases dentin surface porosity, suggesting that deproteinization provides an alternative method of chemical and morphological modification of the dentin substrate prior to bonding.\(^18\)

Using the collagen removal technique, many in vitro studies have demonstrated an adhesive-specific increase in dentin bond strengths when compared to acid-etch only.\(^14,19-21\) Additionally, Saboia and others found significantly less microleakage around composite restorations placed using an acetone-based adhesive system after a 60-second treatment with 10% NaOCl, when compared with non-deproteinized specimens after 1 year of storage and 5,000 thermal cycles.\(^22\)

Because positive (and sometimes controversial) results have been reported in laboratory studies, despite no clinical data being available, the effectiveness of the collagen removal technique needs to be validated in vivo.

Non-carious cervical lesions (NCCLs) are often used to clinically evaluate the performance of adhesive restorations, because of the large dentin area and ease of visual examination.\(^5,8,23-26\) This study evaluated the effect of removing dentin collagen exposed by acid-etching on the clinical performance of composite restorations placed in NCCLs using 2 different adhesive systems. The null hypothesis tested was that collagen removal would not affect the clinical performance of composite restorations placed in NCCLs, regardless of the adhesive used.

**METHODS AND MATERIALS**

**Experimental Design and Subject Selection**

This study was designed as a pilot to test the null hypothesis and to provide information for planning a more comprehensive clinical trial. The study protocol was reviewed and approved by the University of Campinas Committee for Ethics in Human Subjects Research. To participate in the study, subjects had to be between 18 and 65 years of age, able to provide informed consent, be in good general and oral health, have no periodontal conditions, have normal occlusion, have no known allergies that would compromise the placement of composite restorations, have no contraindications for dental treatment, have at least 4 vital teeth with NCCLs that required restoration due to hypersensitivity or esthetics (minimum depth = 1 mm; minimum mesiodistal width = 2 mm) and be able to return for subsequent follow-up examinations. Fourteen subjects (age range 47 to 56) were enrolled in this pilot study.
Restorative Procedures

Table 1 shows the experimental groups according to the dentin pre-treatment and adhesive used. One calibrated operator placed all the restorations under local anesthesia (Prilocaine HCl, Citanest, AstraZeneca, Wilmington, DE, USA), whenever necessary. After shade selection, the operating site was isolated, using cotton rolls and retraction cord (Ultrapak, Ultradent, South Jordan, UT, USA). A round diamond bur #1014 (KG Sorensen, SP, Brazil) was used at slow-speed for 10 seconds to lightly roughen the NCCL surface, but tooth preparation did not include retentive grooves or enamel bevels. The restorations were placed according to the following protocol (n=14):

Group 1, acid-etch only, acetone-based adhesive: Enamel and dentin were simultaneously etched with 37% phosphoric acid for 15 seconds, rinsed and blot dried with absorbent paper. One coat of Prime & Bond 2.1 (PB, Dentsply Caulk, Milford, DE, USA) was applied and left undisturbed for 30 seconds, lightly dried for 2 seconds and light-cured for 10 seconds. A second coat of PB was applied, lightly dried and light-cured for 10 seconds.

Group 2, collagen removal, acetone-based adhesive: Enamel and dentin were etched, rinsed and blot dried, as in Group 1. A 10% NaOCl aqueous solution was applied to the preparation for 60 seconds, using a microbrush with no rubbing motion. The enamel and dentin were rinsed for 30 seconds and blot dried with absorbent paper. PB was applied and light-cured as in Group 1.

Group 3, acid-etch only, ethanol-based adhesive: Enamel and dentin were etched, rinsed and blot dried, as in the previous groups. Two consecutive coats of Single Bond SB (3M ESPE, St Paul, MN, USA) were applied, lightly dried and light-cured for 10 seconds.

Group 4, collagen removal, ethanol-based adhesive: Enamel and dentin were etched, rinsed and blot dried, as in the other groups. A 10% NaOCl aqueous solution was applied to the preparation for 60 seconds, using a microbrush with no rubbing motion. The enamel and dentin were rinsed for 30 seconds and blot dried with absorbent paper. SB was applied and light-cured, as in Group 3.

Filtek Z-250 (3M ESPE) was used as the restorative material for all specimens. The composite was placed in 2 increments, light-cured individually for 20 seconds using an Ultralux (Dabi-Atlante, Ribeirão Preto, SP, Brazil) light curing unit operating at 550 mW/cm². The restorations were immediately finished with flame-shaped, 12-fluted carbide finishing burs and polished with slow-speed polishing cups and points (Enhance, Dentsply Caulk).

To reduce subject-related effects on the outcome of the study, each subject received 1 restoration from each group, and the restorations were equally distributed between the maxillary and mandibular teeth. A total of 56 restorations were placed, with 14 in each experimental group. All the restorative procedures were randomized in each patient, following the inclusion criteria for this clinical trial, as previously described.

Evaluation Procedures

Pre-operative sensitivity was evaluated prior to placement of the restoration, and post-operative sensitivity, retention, marginal staining and secondary caries were evaluated blindly by an independent evaluator at baseline (1 week after insertion) and at 12 and 24 months after insertion, using modified United States Public Health Service (USPHS) criteria. Pre- and post-operative sensitivity were recorded as absent (alpha, A) or present (charlie, C) after subject inquiry or if the tooth was sensitive to a stream of compressed air at 3 cm from the restoration for 3 seconds. For retention, the restorations were evaluated as retained (A) or missing (C). Marginal staining was recorded as absent (A) or present (C). Whenever present, marginal staining was recorded as enamel or dentin. Secondary caries was also recorded as absent (A) or present (C). The results were tabulated and evaluated for statistical significance using non-parametric tests (Kruskal-Wallis and Wilcoxon’s test) with p=0.05.

RESULTS

Eleven subjects completed all follow-up examinations, for a total of 41 restorations (restoration recall rate of 73%). The 3 subjects who did not complete the study moved from the area and could not participate in the follow-up visits.

Table 2 summarizes the clinical performance findings as frequency of alpha scores. Six teeth presented with pre-operative sensitivity, and no post-operative sensitivity was detected at any evaluation period.

<table>
<thead>
<tr>
<th>Group</th>
<th>Dentin Pretreatment</th>
<th>Adhesive</th>
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<tbody>
<tr>
<td></td>
<td>Acid Etching (37% H₃PO₄)</td>
<td>Collagen Removal (10% NaOCl)</td>
</tr>
<tr>
<td>1</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>2</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>Yes</td>
<td>No</td>
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<td>4</td>
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*N at baseline
Alpha retention rates at 12 months were 81.8% for Group 1 (n=11), 90% for Group 2 (n=10), 90% for Group 3 (n=10) and 90% for Group 4 (n=10). At 24 months, alpha retention rates were 63.3% for Group 1 (n=11), 90% for Group 2 (n=10), 90% for Group 3 (n=10) and 70% for Group 4 (n=10).

At 12 months, 9.1% of the specimens in Group 1 (n=11) had staining at the dentin margin. None of the specimens in Groups 2 and 3 had staining, and 1 restoration in Group 4 had stain at the dentin margin. At 24 months, 2 specimens from Group 1 (18.2%), 1 specimen from Group 2 (10%) and 1 from Group 3 (10%) had staining at the dentin margin. No additional marginal staining was recorded on the Group 4 restorations. Secondary caries was not observed around any restoration at 12 and 24 months.

No significant differences were noted among treatment groups in terms of retention, and marginal staining at baseline (BL) and 12 and 24 months post-insertion (p>0.05). Post-operative sensitivity and secondary caries were not noted at any evaluation time and, therefore, were not subjected to statistical analysis. When the clinical criteria were compared within each group (Wilcoxon’s test), no significant differences were noted for the evaluated times.

**DISCUSSION**

An effective, stable bond between resin and dentin is fundamental for the long-term durability of adhesive restorations, especially when little or no marginal enamel is available for bonding. In vivo studies of NCCCLs restored with composite and without mechanical retentions constitute a good study model for evaluating the clinical performance of adhesive restorations.

This was the first study to evaluate the clinical use of NaOCl, a non-specific proteolytic agent for removing collagen from the etched dentin surface before application of an adhesive. By removing the collagen, there is little or no possibility of hydrolytic degradation of collagen that is not completely infiltrated by the adhesive resin.

The results of this preliminary evaluation are encouraging. Although no statistically significant differences were noted between the 2 techniques (acid etch only vs acid etch and collagen removal), the restorations made with PB (acetone-based) appear to have benefited from the collagen removal technique, while the restorations placed with SB (ethanol- and water-based) had a higher retention rate when no NaOCl was used, suggesting that this adhesive might be negatively affected by the collagen removal technique. A similar trend has also been noted in laboratory studies, although conflicting results have been reported.

Regarding marginal staining, only a few restorations presented localized stains at the gingival margin in dentin, with no statistical or clinical significance or clinical differences noted at 12 and 24 months. Post-operative sensitivity and secondary caries were not observed during any period of evaluation in this study. This suggests that the margins were sealed up to 24 months with both techniques. These results are also supported by in vitro data. Microleakage evaluation has demonstrated that the collagen removal technique can reduce marginal microleakage when compared to the acid-etch only technique. However, other studies suggest that collagen removal after acid etching is not beneficial or can even increase microleakage, depending on the adhesive system used. An explanation of these apparently contradictory results might be that, not only the solvent (acetone or ethanol), but also the type of adhesive monomer, could influence the results.

Micromorphological analyses have shown that the dentin–adhesive interface formed with SB after collagen removal did not contain a hybrid layer and exhibited numerous tags with few and short microtags. Some areas between the tags showed fiber-like projections, which appeared to be mineralized collagen fibrils that were incorporated into the adhesive. However, in this study, after 24 months, no differences in marginal staining and/or retention were noted between Groups 3 and 4, where SB was applied with and without collagen removal, respectively.
Despite collagen fibrils being necessary for the formation of the hybrid layer, it seems that they do not contribute quantitatively to dentin bond strengths or reductions in microleakage. These partially demineralized fibrils might reduce dentin permeability, inhibiting complete monomer diffusion into the interfibrillar spaces, or even preventing resin infiltration into the partially demineralized intertubular dentin. Using the collagen removal technique results in a more permeable substrate, facilitating monomer diffusion and allowing all the demineralized dentin to be completely infiltrated, reducing the chances of creating vulnerable areas at the adhesive interface.

In this pilot study, the authors used a 10% NaOCl solution instead of gel, despite the potential advantages offered by the use of NaOCl in gel form for clinical application. Studies have shown controversial results when using NaOCl gel. Perdigão and others reported higher tensile bond strength values when the collagen removal technique was applied. However, Perdigão and others reported a progressive decrease in shear bond strength after NaOCl gel application. For this investigation, studies done in the laboratory show that, when NaOCl gel is applied, collagen fibrils are not completely removed from the etched dentin surface; however, when a NaOCl solution is used, a surface free of collagen fibrils can be visualized.

The fact that, in this study, only 1 operator placed all restorations and all evaluations were performed by a single examiner, are certainly important limitations. This study was designed as a pilot; however, these design limitations will be addressed in future studies.

The null hypothesis tested was accepted: the collagen removal technique did not affect the clinical performance (post-operative sensitivity, retention rate, marginal staining and secondary caries) of composite restorations placed in NCCLs, regardless of the adhesive used. Further studies with a larger sample size and longer evaluation phase should be conducted to verify these findings.

CONCLUSIONS

Treating dentin with 10% sodium hypochlorite to remove exposed collagen after acid-etching did not affect the clinical performance of NCCL composite restorations placed with either an acetone- or an ethanol-based adhesive.

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References


