

# Postoperative Sensitivity: A Comparison of Two Bonding Agents

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## Clinical Relevance

Postoperative sensitivity to cold is a common problem that negatively impacts the patient's dental experience. For this group of participants and over this relatively short period, bonded composite restorations placed in a manner and timeframe consistent with those generally used in private-practice were seen to be less sensitive to cold than they were preoperatively.

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## SUMMARY

**Historically, postoperative pain associated with temperature was considered a thermal conduction problem. More recently, pulpal hydrodynamics has been used to explain this sensitivity. Relative to restorations placed with dentin bonding agents that require a separate etching step, agents that include an acidic primer are believed to result in a better seal of the dentinal tubules. This study compared pain associated with a standardized cold stimulus in two groups of restorations. One group was placed with a self-priming resin that required a separate etch step, the other with a self-etching, self-priming dentin bonding agent.**

**This was a community-based, randomized, double-blind clinical trial. Two hundred and nine restorations were placed for 76 participants. All teeth were asymptomatic at the start of the trial. Immediately following application of a standardized cold stimulus, participants rated the pain for each restored tooth using a Visual Analog Scale (VAS). For each group of restorations, VAS**

scores at 13 weeks were compared to preoperative scores. In addition, the preoperative score was subtracted from the 13-week score, and the two groups of restorations were compared.

For both groups of restorations, the median scores were significantly reduced at 13 weeks. This decrease in the VAS score reflects a reduction in sensitivity below that which existed preoperatively. There was no significant difference between the two groups of restorations in terms of change in sensitivity at 13 weeks.

## INTRODUCTION

According to Brännström,<sup>1</sup> postoperative sensitivity is related to the presence of bacteria and the communication between dental pulp and the oral cavity through microleakage. In theory, removing the bacteria-laden smear layer and sealing the dentinal tubules to prevent the ingress of new bacteria via microleakage should eliminate postoperative sensitivity. Bonded composite restorations have the potential to accomplish both of these goals. However, overcoming the challenges inherent in placing a bonded composite restoration is problematic. Controlling the moisture content of the dentin following acid etching is one of these challenges. Accordingly, the use of a dentin bonding agent that does not require a separate etching step is thought to result in a more uniform penetration of the resin into the etched dentin<sup>2-3</sup> and, thus, a better seal. Opdam and others<sup>4</sup> found that multi-step bonding systems were associated with gaps in the interface between the bonding resin and dentin. These gaps would be more prone to allowing microleakage and postoperative sensitivity. By contrast, self-etching primers were associated with gaps between the bonding resin and composite restorative material, leaving the dentinal tubules sealed.

Self-etching primers have also been associated with less postoperative sensitivity than three-step bonding systems.<sup>5</sup> In that study, participants were recalled after five to seven weeks. At the recall appointment, sensitivity was evaluated in three ways. Participants were asked if they had experienced postoperative sensitivity since placement of the restoration. Participants were next asked about sensitivity following application of force to the occlusal surface, then again following a cold stimulus. Postoperative sensitivity was recorded as being present if there was a positive response in any of these three categories. However, severity of the sensitivity was not assessed. Sensitivity was rated as either present or absent. In this study, a standardized stimulus was delivered and, in order to avoid recall bias, sensitivity was rated immediately afterwards. Rather than simply noting the percentage of participants who experienced postoperative sensitivity, this study recorded the level of sensitivity. The authors believe that this is a more accurate way to evaluate sensitivity.

This project compared sensitivity in two groups of restorations that were provided for a group of 76 people. The treatment group was provided with resin-based composite restorations that were placed with a self-etching, self-priming dentin-bonding agent. The control group restorations were placed using a multi-step system with a self-priming bonding agent. First, within each of the two groups, the preoperative level of sensitivity was compared to the level of sensitivity at 1 and 13 weeks to determine if there was significant postoperative sensitivity. The hypothesis that there was no difference in sensitivity levels was tested against the hypothesis that sensitivity levels were higher or lower postoperatively. Next, the two groups were compared at 13 weeks to determine if one bonding agent provided more protection against postoperative sensitivity. Specifically, the difference between the preoperative and 13-week sensitivity scores were calculated for each tooth, and the two groups of restorations were compared. The hypothesis that there was no difference in sensitivity level between the two groups was tested against the hypothesis that sensitivity was higher or lower for the treatment group.

## METHODS AND MATERIALS

This was a community-based, double-blind, randomized clinical trial. The manner in which studies conducted at academic research centers generally differ significantly from conditions that exist in a primary dental care setting: at academic centers, the focus is on achieving as near perfect a restoration as possible. Primary care providers must be conscious of charges incurred by the patient, while simultaneously maintaining a reasonable profit level. As a result, the time spent and the quality of care provided must be balanced. Accordingly, community-based research is more reflective of the general performance that may be expected from a material. Four general practitioners affiliated with the school as clinical faculty placed the restorations. These faculty members were volunteers who teach one day per month at the school. The operators were required to work at the same pace that they would use in their private practice setting. They were provided with guidelines for patient scheduling prior to the start of the project, and these guidelines were strictly followed. While the restorations were placed at the school, the setting for the operators was a comfortable one. The operators used equipment and worked with dental assistants with whom they were familiar. They used the same preparation and placement techniques that they would use in their own offices. Conversely, full-time academic faculty performed all other aspects of the study. The study design, decisions about eligibility and measurement of sensitivity were all accomplished by academic faculty. This design provided several positive results: first, the skills of both groups were optimized and their weaknesses minimized. The practitioners were not

required to perform tasks for which they have little training, and the restorations were placed by practitioners in the same manner that they would use to provide primary care in their offices each day. Additionally, measurements were made by evaluators who were unaware of which materials had been placed.

The protocol for the project was reviewed and approved by the local institutional review board. Seventy-six people were enrolled, informed about the project and gave their written consent to participate. A total of 209 restorations were placed. To be included in the study, participants were required to be adults in need of at least two and a maximum of four restorations. The included lesions were placed because of caries or defective restorations of amalgam or resin-based composite. Eligibility was confirmed by clinical evaluation and/or radiographic evidence. Only molars or premolars with moderate Class II lesions and moderate Class I restorations on molars were included. To be included, the tooth had to be asymptomatic. A maximum of two restorations were addressed at any one restorative appointment. In order to assure that sensitivity testing was reliable, lesions within the same quadrant were not treated concurrently. Where a second pair of restorations was placed, the second restorative appointment was delayed until after the three-month cold evaluation. The schedule for all subsequent evaluations was based on the date of the restorative appointment and was followed strictly.

Restorations were placed using either a combination of Z250 and Single Bond, the control group, or Z250 and Adper Prompt (3M ESPE Dental Products, St Paul, MN, USA), the treatment group. Single Bond is a self-priming dentin-bonding agent that requires a separate etching step. Adper Prompt is a self-etching, self-priming dentin bonding agent that does not require a separate etching step. Z250 is a highly-filled heavy-body resin-based composite. All materials were handled according to manufacturers' directions. The restorative materials were placed in two-millimeter increments and cured for 20 seconds per increment at 1200 mW/cm<sup>2</sup> (Astralis, Vivadent, Amherst, NY, USA). Times were doubled for darker shades. The protocol specified the use of a calcium hydroxide liner if there was any sign of blushing in the deepest aspect of the preparation; however, no liner was required for any of the restorations.

Each subject received at least one control and one experimental restoration. Subjects received a maximum of two pairs of restorations. For subjects with three acceptable lesions, the unpaired tooth was assigned randomly either to be in the control or experimental group. All group assignments were made randomly. The statistician prepared a pre-arranged randomization schedule for patients with two, three and



Figures 1: Application of cold water stimulus through an occlusal opening in the custom stent.

four restorations. This helped to assure that the number of teeth assigned to the two groups was equivalent. Given the fact that some participants needed three restorations, this was particularly important. The schedule provided a specific order for group assignment. The teeth to be restored were listed by tooth number, from 1 through 32. The first tooth in order was assigned to the group listed first on the schedule, and so on. Since the experimental unit was the person, for those subjects who had more than one treatment or control restoration, the outcome used for statistical analysis was the average of the two sensitivity scores.

At the preoperative 1-week and 13-week evaluations, a standardized cold-water stimulus was applied to the tooth, and the participant recorded his/her VAS score immediately after applying the cold water. A stent was fabricated for each tooth and was used to direct cold water to the tooth of interest. A polyvinyl siloxane impression was made and a stone model poured. For the tooth of interest, a layer of light-cured, flowable resin (LC Blockout, Ultradent, South Jordan, UT, USA) was applied from the buccal-cervical across the occlusal surface to the lingual-cervical. The resin extended from line angle to line angle mesially-distally and was 0.5 mm thick. Next, a layer of pink wax was placed over the quadrant of interest and an autopolymerizing resin was used to make the stent. The pink wax was then removed, the stent lined with a light-bodied polyvinyl impression material and a hole made in the occlusal surface just above the central fossae. The polyvinyl liner provided close adaptation of the stent to the other



teeth in the quadrant, while the block-out resin provided a space or reservoir for cold water to surround the tooth of interest.

Cold water (8°C) was injected through the hole in the occlusal at a rate of 0.5 cc/second. Operators practiced expressing 2 cc of water over a four-second period and were considered calibrated when they could successfully meet the criteria on two separate occasions. A saliva ejector was placed just below and lingual to the opening in the stent to remove excess water. Accordingly, water was injected onto the occlusal of the tooth using the opening in the stent, which accumulated momentarily in the reservoir area, replaced by injection of additional water. The excess water was removed via the saliva ejector (Figure 1).

Participants were advised when the operator started the cold water injection. The participant was instructed to wave a hand when there was a "definite cold sensation coming from the tooth." The phrasing was kept consistent throughout the project. Participants recorded their VAS score immediately after application of the stimulus. When possible, participants were allowed to view their previous scores if they wished. This gave participants, who had a sense of how today's sensitivity level related to previous evaluations, the opportunity to assure greater accuracy in their rating. Each tooth was evaluated using a separate VAS.

When recording their VAS scores, participants were instructed to place a mark at the far left-hand side of a 100 mm line if there was no pain, a line at the far right-hand side of the line if the pain was the most severe that could be imagined or, if the pain was somewhere between these extremes, to mark a line anywhere along the 100 mm line that represented what he/she felt. The VAS score was established by measuring from the left-hand edge of the line to the mark. Scores were recorded to the nearest millimeter.

In addition, at two weeks, participants were asked to rate the average level of sensitivity they experienced in response to everyday stimuli over the previous week. Again, sensitivity was rated for each tooth using a separate VAS, and the results were returned using a self-addressed, stamped envelope. This evaluation provided an opportunity to relate these results to previous work from studies that measured general sensitivity as opposed to using a specific stimulus.

A VAS score higher than the preoperative level correlated with increased postoperative sensitivity. A postoperative VAS score equivalent to the preoperative score or a score that decreased from preoperative levels indicated there was no postoperative sensitivity or reduction from the preoperative endemic level of tooth sensitivity, respectively.

This project featured two major factors: the first was the two groups of restorations. The second was the

Table 1: Number of Restorations by Group

	Single Bond	Adper Prompt
Premolar	49	42
Molar	52	66
Complex Class I	16	18
Class II	85	90

Table 2: Median VAS Scores

Evaluation Period	Single Bond	Adper Prompt
Preoperative n = 76	21.00	22.75
One-week n = 76	18.75	18.00
Two-week n = 76	4.00 <sup>a</sup>	6.75 <sup>a</sup>
Thirteen-week n = 76	13.00 <sup>a</sup>	13.00 <sup>a</sup>

repeated sensitivity measurements of the same teeth over the three evaluation periods. Accordingly, the preferred statistical analysis was a Repeated Measures Analysis of Variance (RMANOVA). Since the data was not normally distributed for each group, a Friedman Repeated Measures Analysis of Variance on Ranks procedure was used to determine whether there was significant association between the VAS score and the evaluation periods, and a Dunnett's multiple comparisons procedure was used to compare all evaluations to the preoperative VAS score. In addition, the difference between the preoperative and 13-week VAS scores was calculated, and a Wilcoxon Signed Rank Test was used to compare the treatment and control groups. Since three statistical tests were required to provide the same analysis that would have been gained from the RMANOVA, in order to maintain an investigation-wide level of 5%, the significance level for each of these three comparisons was set at 1.7%.

## RESULTS

Twenty-one men and 55 women participated in the study. The average age of all patients was 41 years. For men and women, the average age was 38 and 42 years, respectively. The distribution of restorations is noted in Table 1.

The VAS scores for each evaluation period are displayed in Table 2. For both groups, there was a significant association between VAS scores and the three different evaluation periods (Friedman Repeated Measures Analysis of Variance on Ranks;  $p \leq 0.001$ ). Relative to the median preoperative score, the 13-week evaluations were significantly lower (Dunnett's Multiple Comparisons Test;  $p \leq 0.05$ ). The one-week VAS score was not significantly different from the preoperative score for either group.

The median VAS scores for the two-week evaluation were 4.0 and 6.8 for the control and treatment groups, respectively. Again, this evaluation was not in response to a specific stimulus but was the participant's assessment of the level of sensitivity experienced over the previous week in response to day-to-day activities.

The preoperative evaluation VAS score was subtracted from the 13-week score for all participants. The difference in scores for the treatment and control groups was compared and no significant difference was found (Wilcoxon Signed Rank test;  $p=0.711$ ).

## DISCUSSION

The literature generally supports the conclusion that, following an operative procedure, teeth are initially more sensitive and gradually return to preoperative levels. Furthermore, cold is typically the most prominent complaint; while it is reduced from immediate postoperative levels, at one week, pain to cold still remains a source of concern.<sup>6-9</sup> Again, this is thought to be related to pulpal inflammation, which results from the operative procedure and the presence of microleakage. The finding that VAS scores for both groups were virtually unchanged at one week and reduced at 13 weeks relates clinically to participants who, on average, did not experience any increase in sensitivity as a result of having an operative procedure completed. This is a clinically important finding.

In addition, as a group, participants experienced a reduction from their pre-existing levels of cold sensitivity over the 13 weeks of the study. This was true for both dentin-bonding agents. The authors believe that the lack of postoperative sensitivity at one week is attributable to the initial seal attained by the two bonding agents. The fact that sensitivity continued to decrease up to 13 weeks and dropped below preoperative levels is believed to be related to maintenance of the dentinal seal, resolution of any pulpal inflammation resulting from the operative procedure and the resin composite's insulating properties.

Utilizing operators who have a private practice background and placing restorations using the same time constraints and conditions generally experienced in a private practice setting increases the relevance of this study to the care generally provided in the US. Private practitioners must provide care with an eye towards minimizing the length of the appointment. A shorter appointment is more comfortable for, and satisfying to, the patient, plus it constrains cost. By contrast, procedures performed in an academic study are generally focused on placing restorations under optimum conditions and producing restorations that are as near perfect as possible. The academic setting is more appropriate for determining a material's optimal performance,

while a community setting investigates a material's typical performance.

Also, the authors believe that this design improves the quality of the research. People who are more familiar with research protocols than the typical primary care dentist controlled those aspects of the study. Similarly, it is possible to maintain blinding by having evaluators who were not involved in placement of the restorations. It would be difficult or impossible to accomplish this in a typical dental office; it would be unlikely that another trained professional would be available to do the evaluations. Finally, this study design provided for intermediate outcomes, rather than simply following as many restorations as possible until they are replaced or lost to the study. The design is greatly strengthened by assuring that only participants who fit the inclusion/exclusion criteria are included, establishing thorough independent examination that the restorations were all acceptable at baseline and providing intermediate outcomes.

Published studies often report postoperative sensitivity in terms of the percentage of the subject effected.<sup>4-6,10</sup> This first approach gives equal weight to the person who has experienced severe pain and the person who has experienced minimal pain that, under non-study conditions, he/she would not have given it any thought. However, for purposes of research, since there was an increase from normal levels, irrespective of how slight, a positive response was more accurate. Accordingly, studies that rate sensitivity as either present or absent provide rather crude measures.

Other studies report sensitivity levels using an ordinal scale with three or four responses.<sup>7-9</sup> The current approach offers participants a broader range of responses. In addition, use of the VAS, in the authors' opinion, provides more uniform instructions to participants by avoiding descriptors such as mild, moderate and severe, which can be interpreted quite differently from one participant to another.

Similarly, sensitivity has typically been based on the participant's day-to-day experiences to various stimuli<sup>4,6-7,11</sup> rather than a standardized, controlled stimulus. The former requires the participant to recall experiences over a specified timeframe and to calculate a response that best summarizes the whole experience. This approach also fails to account for adaptive and/or protective measures the participant takes in order to minimize discomfort. In this study, the median two-week VAS score for both the treatment and control groups were lower than all other evaluation periods by several fold. Keep in mind that, the two-week assessment differed from the other evaluation periods in that it was not in response to a specific stimulus of cold water. Rather, at this evaluation, participants summarized their day-to-day experience to everyday stimuli

over the second week. The authors believe that these scores were substantially lower, because, in daily function, exposure to direct, prolonged contact with painful stimuli are avoided. The normal position and actions of the tongue and cheeks generally serve as a barrier.

Postoperative sensitivity to cold represents an underlying problem with pulpal inflammation and/or microleakage, and studies similar to this one seek to determine whether one technique and/or material is better suited to resolving these problems. The current data make it clear that a study design that measures response to everyday stimuli rather than to a standardized stimulus severely underestimates the degree to which the restorative materials and techniques being tested may be failing.

### CONCLUSIONS

Within the limitations of this study, it can be concluded that both dentin-bonding agents were associated with a reduction in sensitivity to a cold-water stimulus from the preoperative levels. After 13 weeks, there was no difference between the restorations placed with a self-etching, self-priming dentin bonding agent and those placed with a self-priming dentin bonding agent that required a separate etching step.

### NOTE

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