Published in final edited form as:

Compend Contin Educ Dent. 2013 March ; 34(3): e44–e52.

Postoperative Hypersensitivity and Its Relationship to Preparation Variables in Class I Resin-Based Composite Restorations: Findings from the Practitioners Engaged in Applied Research and Learning (PEARL) Network. Part 1

Gary S. Berkowitz, DDS [PEARL Network Practitioner-Investigator; Private Practice Dentist; Clinical Associate Professor],

Department of Cariology and Comprehensive Care, New York University College of Dentistry, New York, New York

Howard Spielman, DDS [PEARL Network Practitioner-Investigator],

Private Practice Dentist, Plainsboro, NJ

Abigail G. Matthews, PhD [Biostatistician],

The EMMES Corp., Rockville, Maryland

Donald Vena, BS [Statistician],

The EMMES Corp., Rockville, Maryland

Ronald G. Craig, DMD, PhD [PEARL Network Director of Information Dissemination; Associate Professor],

Basic Sciences and Craniofacial Biology, Department of Periodontology and Implant Dentistry, New York University College of Dentistry, New York, New York

Frederick A. Curro, DMD, PhD [PEARL Network Director of Recruitment, Retention and Operations], and

Clinical Professor Oral & Maxillofacial Pathology, Radiology and Medicine, New York University College of Dentistry, New York, New York

Van P. Thompson, DDS, PhD [PEARL Network Director of Protocol Development and Training; Professor, Chairperson]

Biomaterials and Biomimetics, New York University College of Dentistry, New York, New York

Abstract

Background—This study investigated postoperative hypersensitivity at 1, 4, and 13 weeks following resin-based composite (RBC) restorations of occlusal caries and its relationship with preparation (baseline) sensitivity and preparation-related variables, including dentin caries activity, cavity dimension and volume, and lesion radiographic visibility.

Disclosure

This study was supported by grant U01-DE016755 awarded to New York University College of Dentistry by the National Institute of Dental and Craniofacial Research.

Methods—Investigators in a practice-based research network enrolled patients with occlusal caries deemed to require operative treatment. The 45 dental practitioners then placed restorations using their preferred techniques. Complete baseline data on 665 restorations from 602 patients included patient-reported sensitivity (pre-preparation); dentists' ranking of dentin caries on opening the enamel; measurements of preparation depth, width, and length; and patient demographics. At 1, 4, and 13 weeks post-treatment, patients anonymously reported any sensitivity to hot and cold stimuli, sweets, clenching, and chewing, as well as quality-of-life indicators related to the restorations.

Results—At baseline, 30% of teeth had reported sensitivities of 3 on an anchored scale from 0 to 10 points and were designated as appreciable hypersensitivity (AH). Appreciable hypersensitivity at baseline was related to lesion radiographic visibility and patient age but not to dentin caries activity ranking, type of posterior tooth, gender, or race/ethnicity. Patients reported on 491 restorations at 4 weeks post-treatment—18% had AH. Of those who had AH, 39% (34 of 87) had no baseline AH. With restoration, 63% of teeth with baseline AH no longer had AH. Changes in AH were not associated with preparation depth, length, width, or volume.

Conclusion—Patient-reported occlusal caries tooth sensitivity was high at baseline and eliminated by RBC restoration in 63% of cases; however, new sensitivity after restoration was reported in 10% of lesions that had none at pretreatment. Sensitivity was not related to preparation dimensions, volume, tooth type, or patient demographics (other than age) in these early lesions.

The New York University Practitioners Engaged in Applied Research and Learning (PEARL) Network and The EMMES Corporation, the network's data coordinating center, comprise a National Institute of Dental and Craniofacial Research-supported practice-based research network (PBRN). The PEARL Network recently completed a study on postoperative hypersensitivity in resin-based composite (RBC) occlusal restorations, which included patient-reported baseline findings and 1-week, 4-week, and 13-week outcomes. Interim results of this study have been published.^{1,2} In the present report, the authors address the sensitivity findings related to preparation variables associated with restoration and patient demographics. (To read Part 2, Restoration Variables and Postoperative Hypersensitivity in Class I Restorations: PEARL Network Findings, [click here](#).)

Background

Based on a survey of PEARL Network practitioner-investigators (PIs), the PEARL Executive Committee acknowledged that postoperative hypersensitivity (POH) is a major concern among network members and instituted the study described below. A review of the literature found that the number of studies directly investigating POH is small. In the current body of research, the variables of interest typically are not replicated in other studies, and when they are, measurement approaches are dissimilar. These inconsistencies and singularly examined factors in POH studies prove to hinder the understanding of the overall problem, as well as in determination of which influences and elements are clear risk factors.

Definition of Postoperative Hypersensitivity

Postoperative hypersensitivity can be defined as pain in a tooth associated with mastication or with sensitivity to hot, cold, and sweet stimuli that occurs 1 week or more after

restoration. Pain during clenching only usually indicates a restoration in hyperocclusion; however, pain during chewing is considered a form of POH related to polymerization shrinkage gaps between the restoration and dentin that fill with fluid, and during mastication the restoration and tooth deform causing the accumulated fluid to flow down the dentin tubules causing hypersensitivity.^{3,4}

Reports of POH following posterior RBC restorations vary widely, although most studies mention a level of transient responses among some patients. The majority of these studies are small and associated with evaluations of particular bonding agents or RBC formulations. Relevant studies, summarized below, indicate the range of POH and the lack of standardization in measurement and reporting.

Postoperative Hypersensitivity in Clinical Studies

RBC Formulation Studies

Opdam et al⁴ included postoperative hypersensitivity as a secondary outcome of interest when they examined premolar restorations that were scheduled for extraction using two bonding agents and two composite placement techniques. During the first recall ranging from 5 to 7 weeks, 14% of restorations exhibited hypersensitivity, while 56% of restorations exhibited occlusal loading (mastication) hypersensitivity. A clinical evaluation of a new RBC formulation (Ormocer®s, Fraunhofer ISC, www.ormocer.de) employed 5 clinics with 356 restorations in 117 patients comprising a mix of Class I to Class V restorations.⁵ A total of 2% of the restorations were replaced because of strong sensitivity, with an additional 5% having sensitivity at 1 week. In another study comparing RBC formulations, 7% (4 of 57) of patients reported POH; however, the study provided no details as to the extent of the condition.⁶ In contrast, no POH was reported in a 2-year clinical study of RBC restorations with or without a flowable liner.⁷ In a study examining Class I and Class II restorations while using the same dentin bonding agent (DBA), Yip et al⁸ found at 1 week a cold sensitivity in 7% of restorations for 1 RBC formulation as compared with 3% for another.

More recently, 3% (1 each) among 35 Class I restorations of microhybrid, packable, or nanofilled composite restorations were replaced by 6 months as a result of POH (evaluated at baseline, 2 weeks, and 6 months postoperatively).⁹ In another study including random use of a CaOH liner in 123 patients with 1 restoration each, logistic regression showed the 3 variables used in the study—cavity depth, calcium hydroxide liner, and restorative material—had no statistically significant influence on the occurrence of pain or hypersensitivity.¹⁰

Bonding Agent Studies

In a study that evaluated a self-etching dentin bonding agent, the transient nature of POH was demonstrated. Placement of 48 restorations comprising 28 Class I and 18 Class II in 25 patients resulted in 4% (2 of 48) reporting POH at 7 days (15% [7 of 48] at 2 days), whereas no reports of POH were recorded at 30 days.¹¹ In a 4-year clinical study of a total-etch DBA (Scotchbond™ Multi-Purpose, 3M ESPE, www.3MESPE.com) and RBC restorations, POH was present in 24% of the teeth.¹² The majority of POH (86%) cases had replacement restorations as opposed to newly carious teeth, suggesting that deeper restorations may have more POH. Akpata and Behbehani¹³ in bilateral Class I restorations compared a total-etch

DBA (One-Step Plus®, BISCO, Inc., www.bisco.com) with a self-etch DBA (Clearfil™ SE Bond, Kuraray America, Inc., www.kuraraydental.com) in 28 patients. Cold response decreased with time, but no difference was observed at any period between treatments. Swift et al¹⁴ in a 60-restoration Class I study comparing 2 bonding agents and associated RBC materials found 1-week POH of 23%, which was reduced with time. Using a 3-step DBA, Briso et al¹⁵ found patient-reported POH in 6% of mesio-occlusal-distal (MOD) restorations, 15% of mesial-occlusal/distal-occlusal (MO/DO) restorations, and 5% of Class I restorations at 1 week. Sensitivity in all decreased with time by 90 days.¹⁵ Comparing total-etch systems with self-etch systems in shallow, medium, and deep RBC restorations,¹⁶ researchers found 1-week POH incidences were similar, with an increasing incidence of POH for both types of systems with preparation depth.

In a study of cold sensitivity following composite restorations, Kaurani and Bhagwat¹⁷ reported that use of a 2-step self-etch adhesive significantly reduced sensitivity compared with a 3-step DBA. These findings contrast with a study by Browning et al¹⁸ in which a 2-step self-etch DBA was compared with a total-etch DBA. They used a cold stimulus postoperatively at 13 weeks and compared those results with the preoperative baseline. No difference was found between the DBAs regarding reduction of cold sensitivity with time.

Perdigão et al¹⁹ reported sensitivity to air after 2 years with 1 adhesive system (One-Step Plus) in use with 4 brands of RBCs in Class I and Class II restorations. At baseline, the preoperative air-blast hypersensitivity percentage for the approximately 30 teeth in each of the 4 groups ranged from 23% to 37%.²⁰

Liner Studies

Many dentists employ resin-modified glass ionomers (RMGIs) as liners to reduce the possibility of POH, as this was recommended by American Dental Association consultant Gordon Christensen.²¹ Utilizing an RMGI liner as compared with direct application of a DBA, Akpata and Sadiq²² found less self-reported POH at 7 days postoperatively with the RMGI (22%) as compared with that of the bonding agent-alone method (47%). This was reduced to 10% and 26%, respectively, at 30 days. These results contrast with a combined Class I and Class II study of packable composite resin (Solitaire®, Heraeus Kulzer, www.heraeus-dental-us.com),²³ in which 4.8% (12 of 250) of restorations had been replaced within 3 years (10 within the first 6 months) as a result of POH on mastication. Also, 5% of Class I restorations failed from this form of POH, and the majority of all failed restorations were those lined with glass ionomers. Türkün et al,²⁴ in a study examining the use of a CaOH liner in deep areas of the preparation, found no instances of patient-reported hypersensitivity at 6 months, 1 year, or 3 years postoperatively in 16 Class I restorations (39 Class II also included). In a dental school setting, Auschill et al²⁵ investigated how a large number of variables affected POH in 600 teeth distributed throughout a range of restoration classes (Class I to Class V). Any sensitivity was considered a failure, with 6% of teeth so classified. Only cavity depth into the inner third of dentin was related to POH. It has been suggested that POH may be present regardless of the use of a dentinal desensitizer or a cavity disinfectant in bonded RBC restorations.²⁶

As shown, POH is documented in various studies; however, a clear picture of the problem and factors contributing to its development does not exist. Because POH is often a secondary focus of studies primarily examining restorative material and placement techniques, measurement approaches have not been uniform. Due to the complexity of studying the underlying triggers of POH and predicting the occurrence, sophistication and standardization of measurement have not evolved. The following PEARL protocol was used to investigate a number of clinical variables associated with POH that have not previously been combined into a single study. This was to elucidate the relationships and examine how POH affects quality of daily life.

Methods

Study Design

The New York University School of Medicine Institutional Review Board approved the study protocol. Following training and calibration (which includes review of the protocol and after study of manuals and videos passing related online quizzes on techniques and ranking and patient enrollment criteria), staff members in 45 dental offices overseen by PEARL member dentists (practitioner-investigators [PIs]) enrolled eligible participants. Enrollment concluded when the study had recruited 613 patients identified as having Class I carious lesions that were judged by the PIs as requiring operative intervention and being suitable for treatment with RBC restorations. PIs recorded specific treatment data, including patient-reported presence of preoperative hypersensitivity, using an 11-point numeric pain assessment scale (NPAS) questionnaire for sensitivity to cold and hot stimuli, sweets, clenching, or chewing; ranking of dentin caries activity after removal of enamel; and preparation depth, width, and length measured to the nearest 1 mm with a marked periodontal probe. In addition, data were collected by classes and brand names for cavity disinfectants and liners if used, bonding agents, and manner of placement of the RBCs (layer or bulk fill). Patients were surveyed using questionnaires comprising three distinct parts: the NPAS questionnaire to determine sensitivity; an assessment for analgesic use; and an Oral Health Impact Profile-14 (OHIP-14) survey to measure oral health-related quality of life. 27-30 Survey data were collected from patients in person preoperatively, and either via mail or electronically at 1 week, 4 weeks, and 13 weeks post-treatment, with the post-treatment results anonymous to the dentist and staff.

Patient Inclusion and Exclusion Criteria

Included were patients who had fully erupted second molars and were not older than 60 years. The tooth to be restored had to be in occlusion, with no existing restorations. Details of the inclusion and exclusion criteria have previously been provided.³¹

Radiograph Evaluation

Practitioner-investigators evaluated preoperative radiographs and categorized the visibility of the caries in dentin as distinct and visible, equivocal, or not visible.

Dentin Caries Activity

Practitioner–investigators ranked dentin caries activity using tactile evaluation and appearance methods we described previously.³¹ The dentin caries was ranked on a scale of 1 to 5 (Table 1) based on descriptions of dentin caries.^{32,33} These rankings can be classified as rapidly progressing or slowly progressing dentin caries.³¹

Preparation Measurements

Following cavity preparation, PIs measured lesion depth, width, and length according to a standardized methodology utilized in a previous study.⁸ A periodontal probe with 1-mm markings was used, and the cavity depth from the enamel cavosurface margin to the deepest point in the preparation (at the enamel location providing the most axial orientation of the probe) was determined to the nearest millimeter. The greatest and narrowest dimensions (designated as length and width) of the preparation at the enamel cavosurface margins were also recorded. Written instructions, with pictures showing measurements being taken on prepared teeth, were provided to the PIs as chairside references.

Patient-Reported Baseline Hypersensitivity

Via questionnaires, patients reported any hypersensitivity of the tooth to be prepared with regard to the following stimuli: cold, heat, sweets, clenching, and chewing. A scoring of 3 on the NPAS (scale of 0 to 10) for any stimulus was considered AH. Values for pain scores of 3 on the NPAS are deemed bothersome to patients and of clinical significance.³⁴ AH at baseline and at 4 weeks for each stimulus was examined for a relationship of the prepared dentin ranking and to lesion radiographic visibility, as well as to cavity depth and volume.

Statistical Analysis

Descriptive statistics (PROC FREQ, PROC UNIVARIATE, and PROC MEANS in SAS® version 9.2, SAS Institute Inc., www.sas.com) were used to evaluate the distribution of categorical and continuous study variables. These summary statistics consider only study teeth/patients with an observed baseline value for appreciable hypersensitivity. Medians and interquartile ranges (IQRs) were used to summarize the 4 continuous measures; counts and percentages summarize the 6 categorical variables. Logistic regression with generalized estimating equations (GEEs)³⁵ to adjust for patients contributing multiple teeth was used to assess relationships among patient demographics, baseline characteristics and preparation dimensions, and baseline AH. The primary outcome of this study is the change in AH between baseline and 4 weeks post-treatment. The change in sensitivity at 4 weeks was categorized as follows: did not develop AH, did develop AH, AH resolved, or AH still present. Due to the ordered nature of this outcome variable, we used polychotomous logistic regression for all analyses. All odds ratios (ORs) presented are relative to the category of change in AH being “did not develop AH” because this was the most common category.

Results

A total of 613 patients were enrolled, with 605 having baseline data on AH. Of these, 540 patients contributed 1 study tooth and 65 contributed 2 study teeth for a total of 670 eligible teeth. Complete data, excluding radiographic visibility, were available on 665 study teeth;

only 646 of these had complete data, including radiographic visibility. Most study teeth were molars (88%), with the remainder being premolars (12%), and were fairly equally distributed in the posterior quadrants. The female-to-male ratio was 1.47, and these patients were distributed throughout age groups, with 34% between 20 and 30 years.

Of the 670 teeth with baseline sensitivity reported, follow-up sensitivity questionnaires were completed for 513 teeth at 1 week, 491 teeth at 4 weeks (27% loss to recall for primary outcome), and 382 teeth at 13 weeks. The percentages of teeth with AH for each stimulus at baseline and at weeks 1, 4, and 13 are shown in Figure 1. Note that most AH was associated with cold stimulus at all periods. Presented herein are the baseline findings and 4-week outcomes.

Baseline AH did not differ according to gender, race/ethnicity, or tooth type (Table 2). Appreciable hypersensitivity at baseline was found to be significantly lower ($P = .017$) for increasing age.

Dentin caries activity ranking was not related to AH (Table 2). (Dentin caries activity findings and their implications have been previously reported.³¹) Radiographic assessments of the lesions indicated that almost half (45%) were deemed not visible by PIs. Lesions were visible in 41% of study teeth and equivocal in the remaining 14%. Analysis indicated that baseline AH was associated with lesion visibility on radiographs ($P = .004$); the effective sample size for this analysis was 647 teeth due to incomplete radiographic data. Although being related to radiographic visibility, baseline AH was not related to the dimensions or volume of the cavity.

Among the 491 teeth for which questionnaires were submitted at 4 weeks, 87 teeth had AH and 404 teeth had no AH (Figure 2). At baseline, of these same teeth, 143 teeth had AH and 348 teeth had no AH. Note that 90% of teeth with no AH at baseline continued without AH, but the remaining 10% of these teeth developed AH after restoration. Restoration led to AH resolution in 63% of those with baseline AH; however, 37% of teeth with baseline AH did not have AH resolved by restoration. This led to the question of whether the development or resolution of AH might be related to the preparation depth or volume. Table 3 presents the results, expressed as odds ratios, for development of AH, resolution of AH, or no change in AH with preparation variables. The reference group comprises teeth that did not have AH either at baseline or at 4 weeks. The odds ratios for the development, resolution, or continuation of AH were not changed by preparation variables.

Among 65 patients with 2 teeth in different quadrants restored, AH was found to be consistent in most instances (95%). The prevalence of baseline AH was similar in these 130 teeth as for participants contributing only 1 tooth (32% and 30%, respectively). The same is also true at week 4, at which 16% of those responding with 2 study teeth had AH, compared with 18% of the single-tooth participants.

Discussion

This PBRN study depends on both PI training and patient reports, the latter independent of the dentists at 1, 4, and 13 weeks. Patients at baseline, in the presence of their dentists or

office staff members, completed their baseline questionnaires to assess sensitivity, pain medication, and indicators for oral health-related quality of life. This step was intended to train the patients for their subsequent reports. Practitioner–investigator training was with Web-based and CD-supplied videos or narrated Microsoft® PowerPoint® presentations. In addition, laminated chairside guides were provided. For PBRN research, this approach is necessary, as one-on-one or classroom training and calibration sessions are not feasible given the wide geographic distribution of participating clinicians.

One such training for PIs was for ranking of dentin caries (Table 1) upon unroofing the lesion. As described in our earlier publication, baseline AH was not found to be related to whether the caries was ranked as rapidly progressing or slowly progressing.³¹ Approximately 38% of lesions were deemed as rapidly progressing caries—a level different from that found in a Thailand dental clinic study on POH with and without use of an RMGI liner, in which >90% of Class I preparations were ranked as having slowly progressing caries. That study had determined no difference in the low rates of POH found with or without the liner.³⁶

In our study, the baseline level of sensitivity found (results not shown) was unanticipated, with 54% of patients reporting sensitivity related to the treated tooth. This resulted in our decision to consider sensitivity scores of <3 on the NPAS as of minor importance. We considered only sensitivity reported as scores of 3 (AH) as the basis of our analysis because these scores have been determined to be the points at which patients in other tooth pain studies deemed bothersome.³⁴ AH was noted for a variety of stimuli, with cold sensitivity being the most commonly reported (Figure 1), followed by sweet and hot stimuli. Chewing and clenching sensitivity were included to attempt to distinguish the sensitivity of a restoration in hyperocclusion (clenching sensitivity) from restoration sensitivity related to internal debonding, sometimes referred to as occlusal loading sensitivity. Almost 8% of patients reported chewing or clenching sensitivity before restoration was performed. Chewing AH increased at 1 week to almost 10% restoration while clenching remained the same. At 4 weeks chewing sensitivity was at approximately 7% while clenching was reduced to about 5%. Whether this difference is related to occlusal loading sensitivity has not been determined. The baseline sensitivity found in this study might be related to other or adjacent teeth in the quadrant, or to cervical exposed dentin on the tooth to be treated. This was not addressed in the current study design. However, of those teeth with AH at baseline, 63% had AH eliminated by restoration (Figure 2), indicating that the AH was related to the presence of caries. Also, in the group of patients who reported no AH for the tooth to be restored, placement of a restoration resulted in development of AH in 10% of these teeth (Figure 2). Together, these indicate that AH is not related to adjacent teeth in these patients.

The only patient-level variable found to be related to baseline AH was patient age: patients older than 30 years reported significantly less AH initially (Table 2). This was not unexpected with the known increase in dentin depth with age.

Given the strong association of baseline AH with radiographic visibility (Table 2), we anticipated baseline AH to be related to the preparation variables: width, length, depth, or volume.¹⁶ However, this was not the case, perhaps because many lesions were moderately

extensive but not visible on radiographs. Further, we had anticipated that cavity volume would be related to POH. These occlusal restorations are of high C factor (ratio of bonded to unbounded area ≈ 5),^{37,38} and polymerization stress is expected to be high. These high stresses could potentially lead to debonding at the pulpal floor or cavity walls, leading to gaps³⁹ and the potential for pulpal stimulation through fluid flow-down tubules during mastication, as well as from margin microleakage.⁴⁰ The larger and deeper the preparation, the more likely is postrestoration AH. By comparing the odds for developing AH with those for not developing AH at week 4, it can be discerned that the transition from no AH to postoperative AH was not related to any preparation variable.

This study may be biased by the 27% loss to follow-up by week 4, as we believe patients without AH might be less likely to file or report outcomes compared with patients experiencing AH. This possibility must be taken into consideration when reviewing our results.

A limitation is that the study did not collect information on caries stages. The International Caries Diagnosis and Assessment System II (ICDAS II) has become a standard tool in caries research. Now mandated in European Union-supported studies, this system is being incorporated into the European Union dental curriculum.⁴¹ We depended on clinical judgment regarding the need for restoration. This lack of standardization of caries staging is being addressed in a continuation study (PEARL PRL1013), in which network clinicians are assessing POH following RBC restorations randomized with and without the use of RMGI liners. Practitioner–investigators in this effectiveness study are ranking both caries stages and dentin caries activity, as well as measuring preparation variables.

Another possible limitation in our study is that the results apply only to early lesions because a limited number (41%) of lesions were radiographically visible. The inclusion of early lesions was to avoid pulpal involvement that might at baseline contribute to sensitivity, as well as to limit extensive/deep preparations that may compromise the pulp. Lesions in this study were of moderate depth, not exceeding one-half the dentin depth as seen on radiographs. However, median restoration depth is 3 mm with an IQR of 1 (Table 2), so some preparations could be considered moderate or deep. We had not expected AH to be present at baseline. If a lesion was present, we had anticipated it to be related to visibility on radiographs. This was found to be the case; more than 38% of lesions visible on radiographs had baseline AH.

Note that in our study when 2 teeth were restored in the same patient, both teeth were treated at the same appointment (“slice of time”). In 95% of these instances, the same sensitivity rankings were found for both teeth, and 83% of these paired lesions were within 1 mm of each other in depth (58% for length, 69% for width). These lesions were shallow with many not visible on radiograph. This lack of initial depth in the dentin may limit baseline and subsequent sensitivity. Given that in these patients, the same materials and techniques generally were applied in the 2 restorations and the AH was almost always the same, we may in these and other instances be treating cases in which dentin will be sensitive given any preparation intervention.

Another limitation in our study is characteristics of the patient base. Most PEARL PIs who enrolled patients in this study have well-established suburban-based practices, and their patients are generally perceived as having low or moderate risks for caries. Whether the findings from the present study regarding baseline hypersensitivity in early lesions, lesion visibility on radiograph, and lack of a relationship to preparation variables will be comparable with those from community clinics remains unseen.

The relationship between restoration techniques/materials and AH at 1 and 4 weeks will be presented in a separate study to be published in *Compendium of Continuing Education in Dentistry*.

References

1. Berkowitz GS, Horowitz AJ, Curro FA, et al. Postoperative hypersensitivity in class I resin-based composite restorations in general practice: interim results. *Compend Contin Educ Dent*. 2009; 30(6):356–363. [PubMed: 19715013]
2. Curro FA, Craig RG, Vena D, Thompson VP. The role of interim analysis as a quality assurance function in practice-based research network clinical studies. *Compend Contin Educ Dent*. 2009; 30(6):352–354. [PubMed: 19715012]
3. Hirata K, Nakashima M, Sekine I, Mukouyama Y, Kimura K. Dentinal fluid movement associated with loading of restorations. *J Dent Res*. 1991; 70(6):975–978. [PubMed: 2045578]
4. Opdam NJ, Feilzer AJ, Roeters JJ, Smale I. Class I occlusal composite resin restorations: in vivo post-operative sensitivity, wall adaptation, and microleakage. *Am J Dent*. 1998; 11(5):229–234. [PubMed: 10388382]
5. Rosin M, Steffen H, Kenschake C, et al. One-year evaluation of anOrmocer restorative-a multipractice clinical trial. *Clin Oral Investig*. 2003; 7(1):20–26.
6. van Dijken JW, Sunnegårdh-Grönberg K. A two-year clinical evaluation of a new calcium aluminate cement in Class II cavities. *Acta Odontol Scand*. 2003; 61(4):235–240. [PubMed: 14582592]
7. Efes BG, Dörter C, Gömec Y, Koray F. Two-year clinical evaluation of ormocer and nanofill composite with and without a flowable liner. *J Adhes Dent*. 2006; 8(2):119–126. [PubMed: 16708724]
8. Yip KH, Poon BK, Chu FC, Poon EC, Kong FY, Smales RJ. Clinical evaluation of packable and conventional hybrid resin-based composites for posterior restorations in permanent teeth: results at 12 months. *J Am Dent Assoc*. 2003; 134(12):1581–1589. [PubMed: 14719754]
9. Sadeghi M, Lynch CD, Shahamat N. Eighteen-month clinical evaluation of microhybrid, packable and nanofilled resin composites in Class I restorations. *J Oral Rehabil*. 2010; 37(7):532–537. 25. [PubMed: 20202097]
10. Wegehaupt F, Betke H, Solloch N, Musch U, Wiegand A, Attin T. Influence of cavity lining and remaining dentin thickness on the occurrence of postoperative hypersensitivity of composite restorations. *J Adhes Dent*. 2009; 11(2):137–141. [PubMed: 19492715]
11. Gordan VV, Mjör IA. Short- and long-term clinical evaluation of post-operative sensitivity of a new resin-based restorative material and self-etching primer. *Oper Dent*. 2002; 27(6):543–548. [PubMed: 12413217]
12. Baratieri LN, Ritter AV. Four-year clinical evaluation of posterior resin-based composite restorations placed using the total-etch technique. *J Esthet Restor Dent*. 2001; 13(1):50–57. [PubMed: 11831309]
13. Akpata ES, Behbehani J. Effect of bonding systems on post-operative sensitivity from posterior composites. *Am J Dent*. 2006; 19(3):151–154. [PubMed: 16838478]
14. Swift EJ Jr, Ritter AV, Heymann HO, Sturdevant JR, Wilder AD Jr. 36-month clinical evaluation of two adhesives and microhybrid resin composites in Class I restorations. *Am J Dent*. 2008; 21(3):148–152. [PubMed: 18686764]

15. Briso AL, Mestreneur SR, Delício G, et al. Clinical assessment of postoperative sensitivity in posterior composite restorations. *Oper Dent*. 2007; 32(5):421–426. [PubMed: 17910217]
16. Unemori M, Matsuya Y, Akashi A, Goto Y, Akamine A. Self-etching adhesives and postoperative sensitivity. *Am J Dent*. 2004; 17(3):191–195. [PubMed: 15301216]
17. Kaurani M, Bhagwat SV. Clinical evaluation of postoperative sensitivity in composite resin restorations using various liners. *N Y State Dent J*. 2007; 73(2):23–29. [PubMed: 17472181]
18. Browning WD, Blalock JS, Callan RS, et al. Postoperative sensitivity: a comparison of two bonding agents. *Oper Dent*. 2007; 32(2):112–117. [PubMed: 17427818]
19. Perdigão J, Dutra-Corrêa M, Anauate-Netto C, et al. Two-year clinical evaluation of self-etching adhesives in posterior restorations. *J Adhes Dent*. 2009; 11(2):149–159. [PubMed: 19492717]
20. Perdigão J, Dutra-Corrêa M, Castilhos N, et al. One-year clinical performance of self-etch adhesives in posterior restorations. *Am J Dent*. 2007; 20(2):125–133. [PubMed: 17542208]
21. Christensen GJ. Preventing postoperative tooth sensitivity in Class I, II and V restorations. *J Am Dent Assoc*. 2002; 133(2):229–231. [PubMed: 11868844]
22. Akpata ES, Sadiq W. Post-operative sensitivity in glass-ionomer versus adhesive resin-lined posterior composites. *Am J Dent*. 2001; 14(1):34–38. [PubMed: 11806478]
23. Ernst CP, Martin M, Stuff S, Willershausen B. Clinical performance of a packable resin composite for posterior teeth after 3 years. *Clin Oral Investig*. 2001; 5(3):148–155.
24. Türkün LS, Türkün M, Ozata F. Clinical performance of a packable resin composite for a period of 3 years. *Quintessence Int*. 2005; 36(5):365–372. [PubMed: 15892534]
25. Auschill TM, Koch CA, Wolkewitz M, Hellwig E, Arweiler NB. Occurrence and causing stimuli of postoperative sensitivity in composite restorations. *Oper Dent*. 2009; 34(1):3–10. [PubMed: 19192831]
26. Sobral MA, Garone-Netto N, Luz MA, Santos AP. Prevention of postoperative tooth sensitivity: a preliminary clinical trial. *J Oral Rehabil*. 2005; 32(9):661–668. [PubMed: 16102079]
27. Bernabé E, Marcenes W. Periodontal disease and quality of life in British adults. *J Clin Periodontol*. 2010; 37(11):968–972. [PubMed: 20880054]
28. McGrath C, Hegarty AM, Hodgson TA, Porter SR. Patient-centred outcome measures for oral mucosal disease are sensitive to treatment. *Int J Oral Maxillofac Surg*. 2003; 32(3):334–336. [PubMed: 12767883]
29. Slade GD, Spencer AJ. Development and evaluation of the Oral Health Impact Profile. *Community Dent Health*. 1994; 11(1):3–11. [PubMed: 8193981]
30. Soe KK, Gelbier S, Robinson PG. Reliability and validity of two oral health related quality of life measures in Myanmar adolescents. *Community Dent Health*. 2004; 21(4):306–311. [PubMed: 15617416]
31. Lehmann M, Veitz-Keenan A, Matthews AG, et al. Dentin caries activity of early occlusal lesions selected to receive operative treatment: findings from the Practitioners Engaged in Applied Research Learning (PEARL) Network. *J Am Dent Assoc*. 2012; 143(4):377–385. [PubMed: 22467698]
32. Kidd EA, Banerjee A, Ferrier S, Longbottom C, Nugent Z. Relationships between a clinical-visual scoring system and two histological techniques: a laboratory study on occlusal and approximal carious lesions. *Caries Res*. 2003; 37(2):125–129. [PubMed: 12652050]
33. Zheng L, Hilton JF, Habelitz S, Marshall SJ, Marshall GW. Dentin caries activity status related to hardness and elasticity. *Eur J Oral Sci*. 2003; 111(3):243–252. [PubMed: 12786956]
34. Curro, FA.; Friedman, M.; Leight, RS. Design and conduct of clinical trails on dentin hypersensitivity. In: Addy, M.; Embery, G.; Edgar, MW.; Orchardson, R., editors. *Tooth Wear and Sensitivity*. Martin Dunitz Ltd.; London, UK: 2000.
35. Liang KY, Zeger SL. Longitudinal data analysis using generalized linear models. *Biometrika*. 1986; 73(1):13–22.
36. Burrow MF, Banomyong D, Harnirattisai C, Messer HH. Effect of glass-ionomer cement lining on postoperative sensitivity in occlusal cavities restored with resin composite—a randomized clinical trial. *Oper Dent*. 2009; 34(6):648–655. [PubMed: 19953773]

37. Watts DC, Satterthwaite JD. Axial shrinkage-stress depends upon both C-factor and composite mass. *Dent Mater.* 2008; 24(1):1–8. [PubMed: 17920115]
38. Carvalho RM, Pereira JC, Yoshiyama M, Pashley DH. A review of polymerization contraction: the influence of stress development versus stress relief. *Oper Dent.* 1996; 21(1):17–24. [PubMed: 8957911]
39. Cho BH, Dickens SH, Bae JH, Chang CG, Son HH, Um CM. Effect of interfacial bond quality on the direction of polymerization shrinkage flow in resin composite restorations. *Oper Dent.* 2002; 27(3):297–304. [PubMed: 12022463]
40. Sun J, Eidelman N, Lin-Gibson S. 3D mapping of polymerization shrinkage using X-ray micro-computed tomography to predict microleakage. *Dent Mater.* 2009; 25(3):314–320. [PubMed: 18762335]
41. Pitts N, Melo P, Martignon S, Ekstrand K, Ismail A. Caries risk assessment, diagnosis and synthesis in the context of a European Core Curriculum in Cariology. *Eur J Dent Educ.* 2011; 15(Suppl 1):23–31. [PubMed: 22023543]

Figure 1.

Figure 2.

TABLE 1
Visual and Tactile Dentin Caries Evaluated by Explorer or Spoon Excavator

1 = Soft and serous	Rapidly progressing
2 = Soft and dry	Rapidly progressing ^b
3 = Soft, dry, and granular ^a	Slowly progressing ^b
4 = Leathery	Slowly progressing ^b
5 = Firm but discolored	Slowly progressing ^b

^a New description added for this study.

^b May be inactive/arrested.

TABLE 2
Demographics, Baseline Characteristics, Preparation Dimensions, and Baseline AH

Characteristic	No. Teeth	Overall	No AH at Baseline (n = 468)	AH at Baseline (n = 202)	P value
Frequency (% ^a)					
Radiographic Visibility	647				.004
Lesion visible and 0.5 dentin depth		267 (41%)	166 (37%)	101 (52%)	
Equivocal		89 (14%)	67 (15%)	22 (11%)	
Lesion not visible		291 (45%)	220 (49%)	71 (37%)	
Age (yrs)	670				.017
<20		231 (34%)	151 (32%)	80 (40%)	
20-30		226 (34%)	152 (32%)	74 (37%)	
>30		213 (32%)	165 (35%)	48 (24%)	
Dentin Caries Activity Ranking	666				.434
1 = Soft and serous		90 (14%)	59 (13%)	31 (16%)	
2 = Soft and dry		166 (25%)	112 (24%)	54 (27%)	
3 = Soft, dry, and granular		125 (19%)	85 (18%)	40 (20%)	
4 = Leathery		122 (18%)	87 (19%)	35 (18%)	
5 = Firm but discolored		163 (24%)	123 (26%)	40 (20%)	
Dentin Caries Activity Designation	666				.188
Slowly Progressing		410 (62%)	295 (63%)	115 (58%)	
Rapidly Progressing		256 (38%)	171 (37%)	85 (43%)	
Tooth Type	670				.523
Molar		592 (88%)	411 (88%)	181 (90%)	
Premolar		78 (12%)	57 (12%)	21 (10%)	
Race/Ethnicity	670				.593
Non-Hispanic White		475 (71%)	335 (72%)	140 (69%)	
Other		195 (29%)	133 (28%)	62 (31%)	
Gender	670				.886
Male		275 (41%)	193 (41%)	82 (41%)	
Female		395 (59%)	275 (59%)	120 (59%)	
Median (IQR) ^b					
Depth (mm)	668	3 (1)	3 (0)	3 (1)	.305

Characteristic	No. Teeth	Overall	No AH at Baseline (<i>n</i> = 468)	AH at Baseline (<i>n</i> = 202)	<i>P</i> value
Length (mm)	667	5 (3)	5 (3)	5 (4)	.352
Width (mm)	668	3 (3)	3 (3)	3 (2)	.453
Volume (mm³)	666	31 (49)	31 (46)	31 (55)	.563

Abbreviations: AH = appreciable hypersensitivity, IQR = interquartile range.

^a Rounding may result in some percentages not totaling 100%.

^b IQR = difference between the values of the upper and lower quartiles.

TABLE 3
Preparation Variables Odds Ratios for Change in AH at Week 4

Change in AH at Week 4	Volume (mm ³) ^a	Width (mm) ^b	Length (mm) ^c	Depth (mm) ^c
Did not develop AH^e				
Median (IQR)	31 (45)	3 (3)	5 (3)	3 (1)
Developed AH				
Median (IQR)	36 (35)	3 (2)	5 (3)	4 (2)
OR (95% CI)	1.00 (0.99-1.01)	1.04 (0.80-1.35)	1.20 (0.99-1.44)	1.14 (0.85-1.52)
P value	.584	.760	.060	.380
AH resolved				
Median (IQR)	28 (57)	3 (2)	5 (3)	3 (1)
OR (95% CI)	1.00 (1.00-1.01)	0.88 (0.73-1.06)	1.03 (0.91-1.17)	1.01 (0.83-1.23)
P value	0.724	0.172	0.620	0.903
AH unresolved				
Median (IQR)	33 (60)	3 (2)	5 (3)	4 (1)
OR (95% CI)	1.00 (0.99-1.01)	0.87 (0.70-1.10)	1.02 (0.88-1.20)	1.08 (0.85-1.37)
P value	0.936	0.239	0.767	0.548

Abbreviations: AH = appreciable hypersensitivity, CI = confidence interval, IQR = interquartile range, OR = odds ratio.

^a *Global P* = .939

^b *Global P* = .370

^c *Global P* = .310

^c *Global P* = .795

^e *Reference group.*