©Operative Dentistry, 2009, **34-6,** 648-655

Effect of Glass-ionomer Cement Lining on Postoperative Sensitivity in Occlusal Cavities Restored with Resin Composite— A Randomized Clinical Trial

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Clinical Relevance

Glass-ionomer lining showed no benefit in reducing postoperative sensitivity associated with occlusal resin composite restorations. The use of self-etching adhesive demonstrated postoperative sensitivity similar to that of total-etching adhesive.

SUMMARY

This study investigated the ability of a glass-ionomer cement (GIC) lining to reduce postoperative sensitivity in occlusal cavities restored with resin composite. In addition, the effects of a total-etch and self-etch adhesive on postoperative sensitivity were also compared. Patients who had moderate to deep occlusal caries of at least one molar were recruited. Overall, 103 restorations were placed in 70 participants, with an average age of 22.8 ± 3.8 years. Preoperatively, each tooth was evaluated for cold-stimulated tooth sensitivity using a visual analog scale. If present, tooth sensitivity induced by cold/hot drinks or occlusal function was also noted. Caries was stained with a caries detector dye, then removed using slow-speed burs and hand excavators. The cavity was restored with one of four randomly allocated restorative procedures: 1) bonded with a two-step, total-etch adhesive (Single Bond 2); 2) lined with a resin-modified GIC liner (Fuji Lining LC), then bonded with total-etch adhesive; 3) bonded with a two-step, self-etch adhesive (Clearfil SE Bond) and 4) lined

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DOI: 10.2341/08-098-C

with the GIC liner, then bonded with self-etch adhesive. The cavities were incrementally filled with a nanofilled hybrid resin composite. At recall, postoperative sensitivity was evaluated at one week and one month. Overall, postoperative sensitivity in daily function was rare. No significant difference in postoperative sensitivity, either in daily function or in response to a cold stimulus, was observed between the restorative procedures with or without the GIC liner, regardless of the adhesive used ($p>0.05$). In addition, no difference in postoperative sensitivity was noted between use of the self-etch and total-etch adhesive.

INTRODUCTION

When light-cured resin composite was first introduced, its use was limited to the direct restoration of anterior teeth. Since then, resin composite has been continuously developed and can be used in both anterior and posterior restorations. The cavity preparation required for resin composite restorations should conserve tooth structure, and the restorations can bond to tooth substrate when used with a dental adhesive. However, resin composite still has limitations and disadvantages, especially when restoring posterior teeth.[1] In particular, shrinkage stress created during polymerization is a major concern. Polymerization shrinkage stresses negatively affect the bond between the restoration and the cavity walls. Consequently, gap formation, leakage and cuspal deflection may occur.[1-2] Clinical studies have reported that postoperative sensitivity is occasionally observed after resin composite restoration and is more frequently detected in restorations in deep cavities.[3-4]

Several approaches have been proposed to eliminate or reduce postoperative sensitivity. In a cavity with a remaining dentin thickness of less than approximately 1.5 mm, a liner/base should be applied to protect the pulp.[5] It has been suggested that postoperative sensitivity may be reduced by application of a lining material, such as glass-ionomer cement (GIC), or using a self-etching primer adhesive as an alternative to a total-etch adhesive.[6] Conversely, some clinicians believe that use of a lining application is not an important factor in reducing postoperative sensitivity, even when the remaining dentin thickness is minimal.[3] The remaining 0.5-1.0 mm-thick dentin might be enough to protect the pulp from toxic irritants.[7] Furthermore, it is believed that a hybrid layer, which is a resin-impregnated collagen fiber network, is an effective protective barrier, although the thickness of this layer is only a few micrometers.[8]

Unemori and others[3] studied postoperative sensitivity after resin composite restorations were placed by undergraduate students. They concluded that liner protection with GIC did not reduce postoperative sensitivity. However, the operators were inexperienced and not calibrated in this retrospective study, and data were pooled from both anterior and posterior restorations. In contrast, a decrease in the prevalence of postoperative sensitivity when a GIC lining was applied has been reported in a clinical trial of posterior resin composite restorations.[9] Thus, the ability of GIC lining to reduce postoperative sensitivity associated with resin composite restorations is unclear.

This randomized controlled clinical trial investigated the ability of a GIC lining to reduce postoperative sensitivity after occlusal resin composite restoration placement. In addition, the effects of a total-etch and a self-etch adhesive on postoperative sensitivity were also compared. The null hypothesis was that there is no significant difference in postoperative sensitivity between teeth restored with and without GIC lining, regardless of the type of adhesive used.

METHODS AND MATERIALS

This randomized controlled clinical trial was conducted following the Consolidated Standards of Reporting Trials (CONSORT) Statement[10-11] and the Recommendations for Conducting Controlled Clinical Studies of Dental Restorative Materials[12] in the Postgraduate Clinic of the Faculty of Dentistry, Mahidol University, Thailand. The project was approved by the Ethics in Human Research Committee of the University of Melbourne, Australia (ethics ID: 0607777) and the Committee of Mahidol University, Thailand (ethics ID: MU 2007-109).

Recruitment of Participants

Patients between 18 and 40 years of age with at least one moderate to deep occlusal caries lesion in a first or second maxillary/mandibular molar were recruited. Each participant was informed of the nature of the study and consent was obtained. The sample size was calculated using Minitab14 statistical software (Minitab Inc, State College, PA, USA). The calculated minimum sample size of each group was 13 restorations, following these input conditions: power 0.9; level of significance 0.05; estimated standard deviation is 13 on a visual analog scale and the difference in clinical significance[13] is 20 on a visual analog scale. To compensate for the dropout of participants during follow-up, the sample size was increased to 25 restorations per group.

Inclusion and exclusion criteria are listed in Table 1. Participants were not enrolled if any medical problems were present or if they were unable to return for follow-up appointments. The criteria for the investigated teeth are also described in the table. Additionally, teeth were excluded if either the cavity depth after caries removal was less than 2 mm or a pulp exposure or near pulp

Table 1: *Inclusion and Exclusion Criteria Used for the Recruitment of Participants in the Clinical Trial*
Inclusion Criteria
Dental—an investigated tooth:
1) clinically diagnosed as moderate to deep occlusal caries; no caries detected on other surfaces
2) did not have any signs or symptoms of pulpal and periapical disease
3) may exhibit preoperative sensitivity, but relieved immediately after stimulus removal
4) had at least one antagonist tooth with occlusal contact more than 50% of the occlusal surface
5) had healthy or mildly inflamed gingival tissues, without gingival recession/alveolar bone loss
Exclusion Criteria
Patients with one of the following medical conditions:
1) psychological disorders
2) neurological diseases
3) temporo-mandibular disorders
4) pregnancy or breast feeding
5) taking any analgesic or anti-inflammatory drugs regularly
6) allergy to materials used in this trial
Dental—an investigated tooth:
1) with previous restoration(s), tooth surface loss (attrition, erosion, abrasion or abfraction)
2) diagnosed as "cracked tooth syndrome"
3) received orthodontic treatment within the previous three months

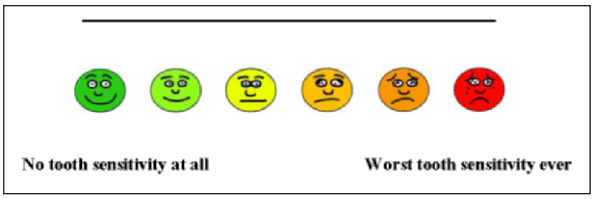

Figure 1: *Modified visual analog scale. Illustration of facial expressions with color codes added below a 10-centimeter line in an attempt to make the scale easier to understand. Each participant was requested to mark the level of tooth sensitivity on a daily basis and respond to cold stimulation. The marked point was then measured in millimetres that ranged from 0 to 100.*

exposure, in which a calcium hydroxide agent was placed.

Preoperative Records

The patients general information, including name, gender and age, was recorded. To maintain privacy and confidentiality, a serial number was used to replace each patient's name. Medical and dental histories were taken. The investigated tooth, supporting periodontal tissues and the existence of an opposing tooth or teeth were thoroughly examined. A preoperative radiographic examination using bitewing radiographs was routinely taken to rule out proximal caries.

Under isolation from the adjacent teeth with gauze, the investigated tooth was tested with a 5-mm diameter ice stick applied to the buccal surface for 20 seconds or until the patient sensed the stimulus. Preoperative sensitivity to cold stimulation was recorded on a modified visual analog scale[14] (Figure 1) and the response time in seconds was also recorded. If there was any tooth sensitivity on a daily basis to any stimuli (occlusal function, cold/hot water or sweet), the tooth sensitivity was recorded using the same scale.

Caries Removal and Cavity Preparation

If requested, a local anesthetic, Mepivacaine hydrochloride 2% with epinephrine 1:100,000 (Scandonest 2% special, Septodent, Saint-Maur-des-Fosses Cedex, France), was administered to control tooth pain/sensitivity during caries removal. The field of operation was isolated with the application of a rubber dam, if moisture control was difficult to achieve. Otherwise, gauze/cotton rolls and use of a saliva ejector with high powered evacuation were employed for moisture control.

Caries was removed using a minimal intervention technique. To gain visible access, entrance to the lesion was initially gained using a round or fissure high-speed diamond bur (Intensiv SA, Grancia, Switzerland) under air-water coolant. Dentin caries at the pulpal floor and surrounding walls was then stained with a caries detector dye (Caries Detector, Kuraray Medical Inc, Okayama, Japan) for 10 seconds, rinsed off, then removed using slow-speed round steel burs (similar in size to the caries lesions) (Emil Lange, Engelskirchen, Germany) and spoon excavators (Sci-Dent Inc, Algonquin, IL, USA). The procedure was repeated two to three times until the dentin surface was stained pale pink and was relatively hard.

Cavity size in the mesio-distal and bucco-lingual directions at the greatest distances and cavity depth at the deepest point were measured (in mm) using a periodontal probe (PCP-UNC 15, Hu-Friedy, Chicago, IL, USA). Overall caries activity was defined as a slowly progressing or rapid progressing lesion.[15] A slow progressing lesion was discolored (dark brown or black) and had slightly softened tooth tissue, while a rapidly progressing lesion was slightly discolored (yellow) and had markedly softened tooth tissue.

Table 2: *Materials, Components, Batch Numbers and Manufacturers*

Materials	Components	Batch #	Manufacturers
Fuji Lining LC Paste Pak (FLC)	Paste A—Alumino silicate glass 70-80%, HEMA 10-15%, Urethane dimethacrylate 5-10%;	0611082,	GC Corp, Tokyo, Japan
	Paste B—HEMA 30-40%, Polyacrylic acid 25-35%, Proprietary Ingredient 5-10%, Silica powder 1-5%	0605093	
Single Bond 2 (SB2)	Etchant—35% phosphoric acid	7KH, 7JB	3M ESPE, St Paul, MN, USA
	Bonding- Bisphenol-A diglycidyl ether dimethacrylate, HEMA, dimethacrylate, colloidal nanofiller 10%, solvent, water	7KC, 6JR	
Clearfil SE Bond (SE)	SE Primer- 10-MDP, HEMA, hydrophilic dimethacrylate, dl-camphoquinone, N,N-diethanol-p-toluidine, water	00683A, 00664A	Kuraray Medical Inc, Okayama, Japan
	SE Bond- 10-MDP, Bis-GMA, HEMA, hydrophobic dimethacrylate, dl-camphoquinone, N,N-diethanol-p-tolluidine, silanated colloidal silica	00976A, 00946A	
Filtek Supreme XT Shade A2B	BIS-GMA, UDMA, TEGDMA, Bis-EMA, inorganic fillers 59.5% (by volume)	6GY	3M ESPE, St Paul, MN, USA

HEMA: 2-hydroxyethyl methacrylate; 10-MDP: 10-methacryloyloxydecyl dihydrogen phosphate; BIS-GMA: Bisphenol A diglycidyl methacrylate; UDMA: urethane dimethacrylate; TEGDMA: triethylene glycol dimethacrylate; Bis-EMA: Bisphenol A polyethylene glycol dimethacrylate

Random Allocation of Investigated Restorations

One to four restorations were randomly allocated in each patient by a single operator (DB) according to a blocking randomization list. In cases where multiple restorations were allocated, the restorations were placed separately in different quadrants at different appointments. Each participant was unaware of the restoration type placed; however, blinding the operator to which intervention was used was not possible.

The prepared cavity was restored using one of the following restorative procedures: 1) SB2—bonded with a two-step total-etch adhesive (Single Bond 2) without lining; 2) SB2/FLC—lined with a resin-modified GIC liner (Fuji Lining LC), then bonded with total-etch adhesive; 3) SE—bonded with a two-step self-etch adhesive (Clearfil SE Bond) without lining and 4) SE/FLC—lined with GIC liner, then bonded with self-etch adhesive. Each allocation of the restoration procedure was kept in an envelope labeled with a restoration number, which was then unsealed and revealed to the operator when the next available participant was recruited. Manufacturers, compositions and batch numbers of the materials are listed in Table 2, and all materials were used according to the manufacturers' instructions.

In the groups in which lining with GIC was indicated, the lining was applied 0.5 mm- to 1 mm-thick over the entire dentin surface. Each lined and/or bonded cavity was incrementally filled with a nanofilled hybrid resin composite (Filtek Supreme XT, shade A2B). Each increment did not exceed 2 mm in thickness and was light cured for 40 seconds using an LED light-curing unit (Bluephase, Ivoclar Vivadent AG, Schaan, Liechtenstein) in high-power mode. Next, occlusal interferences were checked and corrected using high-speed and subsequent slow-speed finishing diamond burs (Intensiv SA) under air-water coolant. The restoration was finished, then polished with a series of abrasive-impregnated silicone polishing points (Astropol, Ivoclar Vivadent AG) under copious water.

The participants were instructed to avoid taking any analgesic or anti-inflammatory drugs and report any postoperative sensitivity during the trial period. Each patient was recalled at approximately one week (one to two weeks) and one month (four to six weeks) after restoration.

Postoperative Sensitivity Assessment

At recall, the evaluator (DB) was blinded to the restoration that was being evaluated. Each restoration was examined, and postoperative sensitivity during daily function due to any stimulus was evaluated; in addition, cold stimulation was evaluated in exactly the same manner as the preoperative evaluation.

In this time-series study, the marked scale of preoperative or previous measurement was shown to the participant before making a new mark for the following measurement. It is likely to reduce the patient's perception error by reminding the patient where the point was previously marked as the level of previous tooth sensitivity.[14]

Statistical Analysis

Data were blindly analyzed using Minitab14 statistical software. General linear model analysis of variance (ANOVA) was used to compare treatments, then multiple comparisons with the Tukey's test were performed with the level of significance set at 0.05.

Table 3: *General Information and Cavity Depth According to Each Treatment Group*

Group	Number of Restorations	Patients' Age (years)	Cavity Depth (mm)
(1) SB2	26	22.7 (3.7)	3.0 (0.5)
(2) SB2/FLC	24	21.4 (3.4)	2.8 (0.6)
(3) SE	26	22.5 (2.6)	2.8 (0.5)
(4) SE/FLC	27	22.7 (4.5)	2.8 (0.8)

Patients' ages and cavity depths are presented as means and SD in parenthesis

RESULTS

From December 2007 to September 2008, 106 restorations were placed in 72 participants, 54 females and 18 males. Patients' ages ranged from 18 to 37 years (mean 22.8 ± 3.8 years). Two patients (three restorations) were lost during recall and were excluded before data analysis (from telephone interviewing, these patients reported no postoperative tooth sensitivity in daily function). Of the remaining participants, another five patients (five restorations) missed the one-week recall; however, these patients were still included in the data analysis. All patients attended the one-month recall. For the 103 restorations that were evaluated, 54 restorations were placed in maxillary molars and 49 restorations were placed in mandibular molars. Overall, the average depth of the prepared cavities was approximately 3 mm and ranged from 2.0 to 4.5 mm. Cavity width and length averaged approximately 3 mm and 4 mm, respectively. In the majority of lesions, the caries activity of 93 lesions was rated as progressing slowly. For the remaining lesions, 11 were rapidly progressing and two lesions were a combination of both. The number of restorations and the patients' age and cavity depth for each treatment group are shown in Table 3.

The overall prevalence of preoperative sensitivity in daily function was low (four restorations, 4%). One restoration was in the SB2 group, while the other three restorations were in the SE group. Most restorations had low to moderate sensitivity in response to cold water or occlusal function and were absent after restoration. The mean VAS score in each group was

Table 4: *Prevalence (percentage) and Means (in VAS score) of Tooth Sensitivity on a Daily Basis at the Three Time-points Shown According to the Four Restorative Procedures*

Group	Tooth Sensitivity on a Daily Basis					
	Preoperative Baseline		One Week Recall		One Month Recall	
	Prevalence (%)	Mean (SD)	Prevalence (%)	Mean (SD)	Prevalence (%)	Mean (SD)
1) SB2	4.0	0.7 (3.5)	4.3	1.7 (8.4)	0.0	0.0 (0.0)
2) SB2/FLC	0.0	0.0 (0.0)	0.0	0.0 (0.0)	0.0	0.0 (0.0)
3) SE	13.0	3.2) (12.0)	0.0	0.0 (0.0)	0.0	0.0 (0.0)
4) SE/FLC	0.0	0.0 (0.0)	0.0	0.0 (0.0)	0.0	0.0 (0.0)

No significant difference in means of the tooth sensitivity was found among the four groups, regardless of the time-point (P>0.05). In addition, there was no significant difference between the tooth sensitivity at the preoperative baseline and at the recalls within each restorative procedure (P>0.05).

Table 5: *Prevalence (percentage) and Means (in VAS score) of Tooth Sensitivity in Response to Cold Stimulation at the Three Time Points Shown According to the Four Restorative Procedures*

Group	Tooth Sensitivity in Response to Cold Stimulation					
	Preoperative Baseline		One Week Recall		One Month Recall	
	Prevalence (%)	Mean (SD)	Prevalence (%)	Mean (SD)	Prevalence (%)	Mean (SD)
1) SB2	18.2	5.7 (14.0)	14.3	3.3 (9.8)	13.0	2.9 (10.1)
2) SB2/FLC	33.3	3.4 (8.9)	15.0	3.3 (9.6)	14.3	2.2 (6.3)
3) SE	23.8	5.8 (14.4)	8.7	0.9 (4.2)	8.3	1.8 (6.3)
4) SE/FLC	35.0	6.1 (14.1)	12.5	0.4 (1.3)	3.8	0.2 (1.0)

No significant difference in means of cold-stimulated tooth sensitivity was found among the four restorative procedures regardless of time (p>0.05). Moreover, there was no significant difference between cold-stimulated tooth sensitivity at preoperative (baseline) and at recall within each restorative group (p>0.05).

very low (<5) or zero at the preoperative stage and at the one-week and one-month measurements (Table 4), with the median of all the groups being zero at all time periods. Thus, no significant difference in means of tooth sensitivity on a daily basis was found among the restorative procedures with or without a GIC lining, regardless of the adhesive used at preoperative baseline and at recall ($p>0.05$). In addition, there was no significant difference in tooth sensitivity between the two adhesives at baseline or at recalls ($p>0.05$).

Preoperative sensitivity to cold stimulation was present in 21.4% of lesions (22 cases). The levels of preoperative sensitivity were low (VAS score 3 to 26 in 15 cases) to moderate (VAS score 34 to 60 in seven cases). After restoration, the overall prevalence of postoperative sensitivity was 10.7% at one week (11 cases) and 8.7% at one month (nine cases). The intensity of postoperative sensitivity at recall was usually low (VAS score 2 to 25), while a few cases reported postoperative sensitivity in the moderate range (VAS score = 40). The prevalence and mean of tooth sensitivity to cold stimulation according to restoration type are shown in Table 5. Regardless of the presence of a GIC lining, prevalence in the groups bonded with self-etching adhesive tended to decrease gradually over the period, while prevalence in groups using total-etch adhesive decreased at one week and only changed slightly thereafter. In all groups, the means of tooth sensitivity were very low at both the preoperative and postoperative records, and the medians of tooth sensitivity in all groups at all times were zero. No significant differences ($p>0.05$) were found among treatment groups at baseline or at either recall, and within each group, no differences were found between baseline and either recall. However, a significant difference was found among the three time points when data were pooled from all groups; tooth sensitivity to cold stimulation at one week and one month was lower than at preoperative baseline ($p=0.02$ and $p=0.01$, respectively) but was not significantly different from each other ($p>0.05$).

DISCUSSION

In the current study, the effect of GIC lining on postoperative tooth sensitivity was examined in occlusal cavities. It is believed that less postoperative sensitivity might be anticipated if a restoration provides a superior seal of the dentin.[16] In occluso-proximal cavities (Class II), cuspal deflection may also play an important role in postoperative sensitivity.[2] In order to exclude the effect of cuspal deflection, the authors of the current study limited the investigation to occlusal cavities. Also, teeth with existing restorations were excluded, because the pulpal status of previously restored teeth might be altered due to the pulpal insult from previous procedures.[17] Furthermore, shallow cavities were not included, since postoperative sensitivity is usually low or infrequently detected, as reported in other clinical studies.[3-4] In the current study, operative procedures were carefully performed to minimize the effects of operative trauma.[18]

Caries detector dye was used in an attempt to distinguish between outer/infected dentin, which is stained and must be removed, and inner/affected dentin, which is unstained and should be preserved.[19-20] However, the caries detecting dye must be used with caution, as it can also stain less-mineralized dentin close to the pulp or at the dentino-enamel junction.[21] Even though caries detector dye was used with caution and caries removal was carefully performed, carious dentin was occasionally over-prepared because of the difficulties in selective removal of a caries lesion.[22]

In the current study, the majority of caries lesions progressed slowly; wherein dentinal sclerosis and tubular occlusions are frequently detected and dentin permeability is reduced.[15] Preoperative tooth sensitivity is unlikely to occur in a tooth with a slow-progressing lesion. In this clinical study, preoperative tooth sensitivity due to regular function was rarely observed. The participants were recalled at one week and one month after restoration.

It has been reported that most postoperative sensitivity usually disappears within 30 days after restoration placement.[17,23] None of the participants in the current study reported postoperative sensitivity during regular function at the one-month recall. The infrequency of postoperative sensitivity in teeth with occlusal restorations was similar to another study.[24] However, other clinical trials have reported a higher prevalence of sensitivity, about 10% to 20% at one week and one month recalls.[9,25] Since the prevalence of sensitivity was minimal in the current study, no significant difference in postoperative sensitivity due to regular function was detected among the restorations with or without a lining, regardless of the adhesive used. The lack of difference between the two adhesive systems has also been reported in other clinical studies.[4,24-26] In contrast, a lower prevalence of postoperative sensitivity was reported in one clinical trial when the restorations were lined with a resin-modified GIC (Vitrebond, 3M ESPE) and a two-step, total-etch adhesive was used.[9]

The insignificant difference in postoperative sensitivity induced by cold stimulation between total-etch adhesive and self-etch adhesive was similarly reported in another clinical trial[4] in which the results were obtained mostly from restorations in shallow or moderate occlusal cavities. Despite the fact that the cavities in the current study were moderate to deep, the results still showed the same trend. In the prevailing study, the lack of difference in postoperative sensitivity to cold between teeth restored with or without a GIC

liner was dissimilar to the results previously reported, which showed reduced postoperative sensitivity of teeth in which the cavities were lined with GIC.[9] Postoperative sensitivity to cold commonly decreased over time, while the response time usually increased. This is similar to observations reported in other clinical studies for restorations using total-etch adhesives without a lining.[9,24-25] These changes might be explained by the healing of pulp after mild injury and trauma resulting from the procedure and, as a result, the pain/sensitivity threshold was restored to the normal level.

In the current study, all the restorations were placed by an experienced operative dentist in an academic environment. In addition, adhesive and restorative materials were used according to the manufacturers' instructions. Hence, the results of this clinical trial may not be totally applicable to a general practice situation. Some factors, which might explain the differences between academic and general practice, are the operator's experience/skill, operation time and familiarity with use of the materials.[24] A clinical trial with the same protocol in a general practice should be further investigated.

CONCLUSIONS

In conclusion, the null hypotheses were accepted. No significant difference in patient-reported tooth sensitivity or in response to cold stimulation was found among the restorations with and without a resin-modified GIC lining regardless of the adhesive used (total-etch or self-etch). Postoperative sensitivity was not a major problem following the restoration of moderate to deep occlusal cavities if the restorative procedures were carefully performed. Further investigations should be conducted in a general practice setting, as well as in other types of cavities, such as occluso-proximal restorations, to support these findings.

(Received 21 November 2008)

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