Retrospective Study of Five-year Clinical Performance of Direct Composite Restorations Using a Self-etching Primer Adhesive System

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This study was conducted to assess the five-year clinical performance of composite restorations using a self-etching primer adhesive system, Clearfil Liner Bond II. Restorations were rated using the following scale: A - Good; B - Clinically acceptable; C - Clinically unacceptable; or D - Already replaced. The ratings were analyzed using Freedman's test (p = 0.01) and Steel-Dwass test (p = 0.05). A total of 83 restorations from 36 patients were identified from treatment records. Twenty-six restorations (31.3%) presented A rating and 36 restorations (43.4%) were clinically acceptable (B rating), while five (6.0%) received C rating and 16 (19.3%) had already been replaced (D rating). The mean survival rate of serviceable restorations (i.e., combined A and B ratings) after five years was 74.7%. It was found that cavity form, including cavity size, and occlusal contact seemed to influence longevity.

Key words: Clinical evaluation, Resin composite, Self-etching primer adhesive system

INTRODUCTION

The concept of minimal cavity preparation has become widely accepted for the placement of direct resin composite restorations11. However, it should be highlighted that the clinical performance of resin composite restorations could be influenced by the use of different types of dentin bonding systems7. Fortuitously, the outcomes of numerous laboratory studies have shown a steady improvement in adhesives. Against this background, it could be reasonably anticipated that the clinical performance of composite restorations using modern adhesive systems will also significantly improve.

Conventional dentin bonding systems of the 1980s were acid-etch-based systems, which comprised phosphoric acid etching and a bonding agent10. The next development of dentin bonding systems in the early 1990s was the three-step system with the use of dentin primers with phosphoric acid etching and a bonding agent15. During the 1990s too, self-etching primer adhesive systems were introduced. These systems were characterized by the combination of etching and priming steps into a self-etching primer followed by the placement of an adhesive resin onto the prepared tooth surface15. Self-etching adhesive systems use weak acidic monomers to condition the enamel/dentin substrate. Dentin bonding performance was greatly improved with self-etching primer adhesive systems7,8. However, the consistency of enamel bonding has been controversial9-11.

Long-term clinical evaluations of resin composite restorations are important to determining reliability. However, few long-term clinical studies have been published12-18. Furthermore, information is scarce concerning the clinical success - or otherwise - of resin composite restorations bonded with a self-etching primer adhesive system14.

The purpose of this study was to retrospectively assess the five-year clinical performance of resin composite restorations using Clearfil Liner Bond II (Kuraray Medical, Tokyo, Japan), which was the first two-step self-etching primer adhesive system introduced in 1993. The null hypothesis of this study was that longevity of resin composite restorations using this self-etching primer adhesive system is independent of the type of cavity form based on Black's classification.

MATERIALS AND METHODS

Cavity preparation was conservative according to the principles established by Fushanaka et al.19. Manufacturer's instructions of Clearfil Liner Bond II, a self-etching primer adhesive system, were followed. Apart from Clearfil Liner Bond II which was generally used for resin composite restorations, several other available resin composite adhesives were also used according to the manufacturers' instructions.

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Clinical evaluation was carried out by nine operators—each of whom had over 10 years of clinical experience following graduation. Further, they had worked in the Operative Dentistry Clinic for at least five years. The restorations placed were evaluated between December, 2002 and January, 2003.

The operators obtained the following information from the treatment records of patients: name of operator, patient ID, date of treatment, age, gender, picture number, tooth vitality, cavity classification, bonding system used, and resin composite used to restore the tooth. Following this, the restoration was analyzed according to the following ratings: A - Good; B - Clinically acceptable; C - Clinically unacceptable; or D - Already replaced. If the operator rated a restoration as B, C, or D, then one main reason must be selected for the decision. Following criteria were used for the clinical decision: marginal discoloration, surface roughness, discoloration of restoration, anatomic form, secondary caries, marginal adaptation, restoration failure, pulpitis, endodontic treatment, restoration fracture, crack within the restoration, tooth extraction. If the restoration had already been replaced, replacement date must be obtained from the treatment record. At the time of clinical evaluation, 1:1 35-mm color photographs were taken of each restoration. After collecting the data, two examiners re-evaluated the rating given and the criteria used to determine the rating for each restoration. When a disagreement between the examiners was observed, the evaluation was repeated until agreement was reached.

The ratings were statistically analyzed using the Friedman’s test \( (p = 0.01) \) and Steel-Dwass test \( (p = 0.05) \).

## RESULTS

Restorations placed in nonvital teeth comprised 15 of a total of 98 restorations evaluated, and were excluded from the analysis. Therefore, a total of 83 restorations from 36 patients (21 male and 15 female) were used based on the treatment records and analyzed. Mean age was 62.5 years, ranging from 13 to 80 years. Distribution of the restorations is listed in Table 2.

Evaluation results of the resin composite restorations are summarized in Table 3. Eighty-three restorations including eight Class I, 13 Class II, 9 Class III, 3 Class IV, and 50 Class V were reviewed. A total of 26 restorations (31.3%) presented an A rating and 36 (43.4%) were clinically acceptable (B rating), while five (6.0%) were given a C rating and 16 (19.3%) had already been replaced (D rating).

Retrospective assessment of restorations (A and B ratings) after five years showed that 74.7% were clinically acceptable. However, the ratings were significantly influenced by restoration type. Distribution of restorations with A and B ratings was 75.0% (Class I), 92.3% (Class II), 77.8% (Class III), 33.3% (Class IV), and 72.0% (Class V). According to Freedman’s test \( (p = 0.01) \), the descending ranking of the longevity of restorations was Class II > Class III > Class I > Class V > Class IV. The Steel-Dwass test \( (p = 0.05) \) revealed that the longevity of Class IV restorations was significantly lower than the other cavity classes.

For rating B, apart from cavosurface marginal discoloration of 59.5% bravo score in 27 restorations, the other reasons given were as follows: colored restoration (4), restoration fracture (3), attrition (2), abrasion (1) and secondary caries (1). Only five of the 83 restorations (6.0%) reviewed were scored as C: two restoration failures, two restoration fractures, and one tooth fracture. For the D rating as described in the treatment records, four were restoration failure, three had irreversible pulpitis, one secondary caries, and one composite fracture, and the remainder did not describe reason for replacement (43.8%).

For restorations rated as D, their replacement dates are summarized in Fig.1. More than half of the replaced restorations were placed within five years after restorative treatment.

The bonding systems used for the restorations were Clearfil Liner Bond II System (46) and other unknown adhesive systems (37). Restorative materials used were Clearfil AP-X (53). Photo Clearfil Anterior (3), and an unknown composite (27).

### Table 1 Manufacturer’s instructions for the adhesive system used in this study

<table>
<thead>
<tr>
<th>Adhesive system</th>
<th>Component</th>
<th>Chemical composition</th>
<th>Directions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clearfil Liner Bond II</td>
<td>LB Primer</td>
<td>Phenyl-P, 5-NMSA, HEMA, water</td>
<td>Apply 30s, dry photoinitiator</td>
</tr>
<tr>
<td></td>
<td>LB Bond</td>
<td>MDP, HEMA, dimethacrylate, photoinitiator, microfiller</td>
<td>Light-cure 20s</td>
</tr>
</tbody>
</table>

Manufacturer: Kuraray Medical, Tokyo, Japan

### Table 2 Distribution of resin composite restorations

<table>
<thead>
<tr>
<th>Location</th>
<th>Anterior</th>
<th>Premolar</th>
<th>Molar</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upper</td>
<td>29</td>
<td>18</td>
<td>1</td>
<td>48</td>
</tr>
<tr>
<td>Lower</td>
<td>9</td>
<td>17</td>
<td>9</td>
<td>35</td>
</tr>
<tr>
<td>Total</td>
<td>38</td>
<td>35</td>
<td>10</td>
<td>83</td>
</tr>
</tbody>
</table>
DISCUSSION

Long-term clinical evaluations of restorations are the best means to provide evidence for the success - or otherwise - of dental materials and clinical techniques. However, data collection is labor-intensive, time-consuming, and costly. In addition, patient recall for long clinical trials can be an uphill task because of the tendency for patients to either move away or otherwise become unavailable for review.

The common method for clinical evaluation is that patients, cases, and materials are selected and treated by a small number of dentists. However, these studies do not always reflect the scenario in general dental practice. The current study was based on patient treatment records from several operators. The protocol used in this study was originally designed to minimize the amount of time required by each operator in the Operative Dentistry Clinic to evaluate the patient. Therefore, this kind of patient selection makes it difficult to fulfill the research protocol as specified by the American Dental Association (ADA).

Nonetheless, a 10-year clinical assessment of resin composite restorations using acid-etch technique was also conducted in the same manner.

Survival rate of restorations (i.e., A and B ratings) after five years was 74.7%. However, restoration longevity was influenced by the type of cavity. The descending ranking of longevity of the restorations was Class II > Class III > Class I > Class V > Class IV. Surprisingly, the survival of Class II restorations was very high (92.3%), while that of Class IV restorations was only 33.3% - which was significantly lower than the other cavity classes. Therefore, the null hypothesis of this study was rejected. However, caution must be exercised when making such a conclusion, since there were few Class IV restorations available for review. Komatsu et al. and Smales and Gerke pointed out that the survival rate of Class V cavities was inferior to that of Class III cavities. The same tendency was observed in this study. Similarly, Kubo et al. reported that the survival rate of Class V restorations decreased more rapidly than that of Class III restorations, although there were no significant differences in the survival rate between Class III and Class V resin composite restorations after 19 years.

Akimoto et al. reported on a seven-year clinical study of composite restorations using the self-etching primer adhesive system, Clearfil Liner Bond II. They demonstrated that the longevity of restorations using Clearfil Liner Bond II was excellent, with no restoration failures after seven years. However, marginal discoloration and imperfect marginal integrity were observed in some cases, but were regarded as being clinically acceptable. The current results also demonstrated that cavosurface marginal discoloration was the main reason for a B rating (59.5%). Although marginal discoloration is caused by numerous factors, development of new adhesive materials and bonding techniques should attempt to improve the quality of the marginal bonding of restorations, as this is frequently a reason for replacement.

Five of the 83 restorations examined (6.0%) received a C rating. The reasons for the C rating were failed restoration, tooth fracture, and restoration fracture, while secondary caries was not given as a reason. On the other hand, Mjör noted that clinically diagnosed secondary caries was the main reason for the replacement of resin composite restorations. In agreement with the results of the present study, a few long-term clinical studies also showed that restored teeth exhibited low susceptibility to secondary caries. In particular, Akimoto et al. reported...
demonstrated that no secondary caries was observed around composite restorations using Clearfil Liner Bond II. Laboratory studies have suggested that self-etching primer adhesive systems may have the potential to inhibit secondary caries around composite restorations.\(^{20,30}\)

A total of 16 restorations (19.3%) had already been replaced before examination (D rating) in which more than half of the restorations were replaced within five years after restorative treatment. Kubo et al.\(^{15}\) reported that the mean period to restoration replacement was 6.5 years. In light of this result, the replacement rate of the restorations in this study may increase after five years. Unfortunately, there are no standardized diagnostic criteria for determining when a restoration should be replaced. It is relatively easy to obtain agreement among operators in the case of pulpitis, restoration failure and fracture. However, it is more difficult to obtain agreement on secondary caries, limited marginal discoloration, mild color mismatching, and wear of composite. Restoration replacements in anterior teeth, especially Class IV restorations, are mostly related to aesthetic issues. Patients might request for replacement of these restorations because of poor esthetics, such as color matching, anatomical form, wear, and surface roughness, which are not always valid replacement reasons if based on functional acceptability.

According to Ainamo and Ainamo\(^{15}\), the dentition is intended to last a lifetime, undergoing natural and individual patterns of occlusal and proximal tooth wear. Thus, biomaterials matching these patterns - and having been clinically and micromorphologically followed up over a long-term period - can fulfill the biological requirements of restored, non-traumatic occlusion.\(^{17}\)

Unfortunately, the brand names in 44.6% of the restorations and 32.5% of the adhesive systems were not clearly specified in the patient treatment records. However, Clearfil Liner Bond II was likely to have been used in most cases in this study, because of the supply control in the Operative Dentistry Clinic of Tokyo Medical and Dental University Hospital. A hybrid composite, Clearfil AP-X, was used in 63.9% of the restorations.

Kubo et al.\(^{15}\) reported that Class V cavities restored with a newly developed adhesive system - which was a total etching system of enamel and dentin with an acid etchant or self-etching primer - showed better survival rates than those restored with previous-generation adhesive systems, which had separate treatment steps for enamel and dentin. These findings strongly suggested that the improved adhesion of recent dentin bonding agents has improved the longevity of restorations. To compare against the results of an acid-etching system that was previously evaluated,\(^{15}\) a 10-year clinical study of composite restorations using the self-etching primer adhesive system will be carried out.

**CONCLUSIONS**

The mean survival rate of restorations using the self-etching primer adhesive system after five years was 74.7%. However, the ratings were significantly influenced by the cavity form of the restorations.

**ACKNOWLEDGEMENTS**

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**REFERENCES**