10-year Clinical Evaluation of a Self-etching Adhesive System

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Clinical Relevance

This 10-year clinical evaluation of a self-etching adhesive system showed only slight marginal change of some restorations; however, these changes were not severe. Consequently, these clinical conditions did not require replacement, since no recurrent caries were present. Clinically, these data demonstrate that this self-etching adhesive system is acceptable for placement of a long-term adhesive restoration in human teeth.

SUMMARY

This study evaluated the long-term clinical performance of a self-etching adhesive system, Clearfil Liner Bond 2. Two operators placed a total of 87 restorations among 42 patients. Carious dentin was identified with the help of Caries Detector and was removed using only a low speed round bur. Clearfil Liner Bond 2 was applied following the manufacturer's directions, and the resin composite was then placed. The number of restorations placed by cavity classification were: 8-Class I, 11-Class II, 21-Class III, 2-Class IV and 45-Class V. The restorations were evaluated in 5 categories according to modified

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USPHS criteria: pulpal response, marginal integrity, marginal discoloration, retention and secondary caries. Assessments were done at baseline, immediately after placement and at 6months and 1, 5, 7 and 10 years. Recall rates at each assessment period were 83.9% (6-months), 82.8% (1 year), 59.8% (5 years), 77.0% (7 years) and 50.6% (10 years). In terms of assessment categories, there were no recorded sensitivity, retention loss or secondary caries at any of the five recall periods. At the 10-year assessment, 40 out of 44 restorations (90.9%) were rated Bravo for marginal integrity and 39 restorations (88.6%) were rated Bravo for marginal discoloration (Wilcoxon signed-ranks test p<0.05). This data demonstrates the retention rate and pulpal response of the self-etching adhesive system Clearfil Liner Bond 2 was excellent at 10 years. Most cases showed slight marginal changes during clinical function; however, these changes were not clinically severe by USPHS criteria. These data demonstrate that placement of the Clearfil Liner Bond 2 self-etching adhesive system was demonstrated to be acceptable for the clinical restoration of human teeth following 10 years of clinical function.

INTRODUCTION

In 1993, Kuraray Co (Osaka, Japan) was the first to introduce a self-etching adhesive system, Clearfil Liner Bond 2, to Japanese clinicians and researchers¹⁻⁴ and researchers worldwide;⁵⁻⁹ it was the first self-etching adhesive system for direct composite resin restorations that simultaneously targeted both enamel and dentin substrates. The introduction of this novel self-etching adhesive system offered a major change in the placement of direct resin composite restorations. Since then, other manufacturers have followed suit and developed their own commercial self-etching adhesive systems.

Several short-term *in vitro* studies of self-etching adhesive systems have reported little to no differences in bond strength to enamel and dentin when compared to the earlier generation of traditional total-etch systems;¹⁰⁻¹¹ whereas, various recent studies of self-etching adhesive systems have reported significantly higher bond strengths to dentin.¹²⁻¹⁵ Currently, these self-etching adhesive systems, also seen as one-step or one-bottle self-etch adhesive systems, are clinically acceptable and now widely used throughout the world.

At the time the first self-etching adhesive system became commercially available, some researchers and clinicians expressed concern regarding the physiological capacity of such a system to simultaneously demineralize, penetrate and bond to the enamel interface, thus affecting its long-term clinical permanence. Specifically, it appeared that a prime concern of some individuals, in terms of the chemical capacity of such a system to affect a seal along the restoration-cavosurface interface, was greeted with uncertainty and skepticism. Following the introduction of self-etching adhesive systems to international markets, some publications reported low bond strength to enamel.^{10,16} While several publications reported the self-etching adhesive system is effective on cut or ground enamel, they suggested a reduced etching capacity on uncut intact enamel, 17-23 resulting in lower enamel bond strength when compared to conventional total-etch systems.

Following reports of bond strength differences in these self-etching adhesive systems, many clinicians expressed apprehension about their long-term clinical performance. Various clinical studies report supportive bond strength data when evaluating self-etching adhesive systems in short- and mid-term trials.2,^{2,4,24-34} However, no longitudinal publications have documented the long-term clinical performance of these self-etching adhesive systems beyond 10 years.

Due to the lingering clinical apprehension of certain individuals who only seem to rely on *in vitro* bond-strength testing, this study extended the longitudinal clinical data collection and compared it to previous baseline, short- and mid-term data of the authors' patient source—specifically to evaluate the clinical per-

formance of Clearfil Liner Bond 2 self-etching adhesive system at 10 years in the same patient population.

METHODS AND MATERIALS

Patients were selected from individuals seeking clinical treatment at the Dental Clinic of the Department of Operative Dentistry at Tsurumi University Dental Hospital, Yokohama, Japan. Each patient was given a detailed layperson's explanation regarding the nature of the proposed clinical research study.

A total of 87 restorations were placed in the teeth of 42 patients (14 males and 28 females). All clinical restorations were placed by two of the authors. Following the clinical principal of minimally invasive dentistry, and utilizing the restorative precepts of Professor T Fusayama regarding its use, Caries Detector (Kuraray Medical, Tokyo, Japan) was placed on each defect to visually identify and differentiate the outer insensitive zone of infected carious dentin from the deeper zones of transparent and affected dentin. 35-37 Removal of the outer infected zone was achieved using an ultra low-speed round steel bur without any injection of local anesthesia. Rubber dam retraction isolation was routinely placed. Each cavity was immediately restored using the Clearfil Liner Bond 2 self-etching adhesive system (Table 1). Immediately following clinical preparation, equal amounts of LB Primer A and B were mixed and applied to the enamel and dentin of the entire cavity for 30 seconds, followed by gentle air dispersion with compressed air for 5-10 seconds. The LB Bond adhesive was immediately applied to the entire surface, gently air dispersed and light cured for 20 seconds with Optilux (Demetron, Kerr/Sybron, Orange, CA, USA). This adhesive lined cavity was immediately restored with one of the following four light-cured com-

Table 1: Composition of Clearfil Liner Bond 2 (Kuraray Co, Osaka, Japan) LB Primer A Phenvl-P 5-NMSA Camphorquinone Ethanol LB Primer B HEMA Water Catalyst **LB Bond** MDP **HEMA** Bis-GMA Camphorquinone Microfiller (SiO₂) Phenyl-P: 2-methacryloyloxyethyl phenyl hydrogen phosphate 5-NMSA: N-methacryloyl-5-aminosalicylic acid HEMA: 2-hydroxyethyl methacrylate Bis-GMA: Bisphenol A-diglycidylmethacrylate

MDP: 10-methacryloyloxydecyl dihydrogen phosphate

posites: Clearfil Photo Anterior (Kuraray, Osaka, Japan), Herculite XRV (Kerr/Sybron), Photo Clearfil Bright (Kuraray) and Progress (Kanebo, Tokyo, Japan) and light cured following manufacturers' directions. Each restoration was finished using a super-fine diamond point and polished with Super-snap mini points (Shofu, Kyoto, Japan) or Sof-Lex XT Discs (3M, St Paul, MN, USA).

Clinical evaluations were performed on each restoration at baseline placement. Two of the authors collected longitudinal clinical data on the same restorations at 6 months, 1 year, 5 years, 7 years and 10 years. Intra-oral color slides were taken at baseline and at each recall period. The authors utilized five clinical parameters from published USPHS (United States Public Health

Table 2: Evaluation Criteria

Retention of the Restoration

- A: Retention is present
- B: Retention is missing

Marginal Integrity

- A: The explorer does not catch the steps
- B: The explorer catches the steps
- C: The explorer catches and there is visible evidence of a crevice

Marginal Discoloration

- A: No discoloration
- B: Present but has not penetrated along the margin in a pulpal direction
- C: Discoloration has penetrated along the margin in a pulpal direction

Secondary Caries

- A: There is no caries at margin of the restoration
- B: There is evidence of caries at margin of the restoration

Pulp Response

- A: No post operative sensitivity
- B: Post operative sensitivity present

Table 3: Distribution of Restoration by Cavity Classification Baseline 10 years Class I 8 4 Class II 2 11 Class III 21 17 Class IV 2 2 Class V 45 19

System) criteria and slightly modified (Table 2) the parameters in order to evaluate the adhesive quality of the self-etching adhesive system, recorded as follows: retention of the restoration, marginal integrity, marginal discoloration, secondary caries and patient sensitivity, in order to determine the presence of any possible pulp response (or patient sensitivity). Table 2 shows the evaluation criteria of the five parameters. The Wilcoxon signed-ranks test was used to compare each category at baseline and at each recall period.

RESULTS

Table 3 shows the distribution of each restoration by cavity classification at baseline and again at the 10-year longitudinal recall period. The Class V restorations in this study include non-carious cervical lesions

caused by abfraction, abrasion or erosion. Table 4 shows the results of clinical evaluations at each of the five recall periods. Longitudinal recall rates at each time period were 83.9% at 6 months, 82.8% at 1 year, 59.8% at 5 years, 77.0% at 7 years and 50.6% at 10 years.

Of the 87 original baseline restorations, 43 restorations were unavailable for clinical evaluation at 10 years due to patient unavailability to return to the dental clinic. At each recall period, the operators recorded the sensitivity of each tooth by applying gentle air and water from the chip syringe and tactile evaluation. At all five recall periods, patients reported no post-operative sensitivity in any of the restored teeth. In addition, there was no loss of any resin composite restoration (retention) or clinical evidence of secondary caries at or underneath the margin of any restoration through 10 years of clinical placement.

The operators evaluated marginal integrity using a new, sharp explorer to score tactile measurement. At 10 years, 40 out of 44 restorations (91%) showed a Bravo rating for marginal integrity. Most restorations demonstrated step irregularities when a sharp explorer was drawn across the tooth from the enamel towards the restoration interface. In addition, 39 restorations (89%) showed marginal discoloration at the cavosurface

Table 4: Results of Clinical Evaluations															
	6 Months			1 Year			5 Years			7 Years			10 Years		
	Α	В	С	Α	В	С	Α	В	С	Α	В	С	Α	В	С
Retention	73	0		72	0		51	0		67	0		44	0	
Marginal integrity	73	0	0	72	0	0	16	35	0	14	53	0	4	40	0
Marginal discoloration	73	0	0	72	0	0	23	28	0	22	45	0	5	39	0
Secondary caries	73	0		72	0		51	0		67	0		44	0	
Pulpal response	73	0		72	0		51	0		67	0		44	0	
Recall rates	83.9%			82.8%			59.8%			77.0%			50.6%		
5. 7 and 10 years data of "margin	al integrity" ai	nd "margina	l discolo	ration" sl	nowed stat	istical dit	fferences	(n>0.05)		l			I		

margin at the 10-year recall. These values were different when compared to baseline data (Wilcoxon signed-ranks test p<0.05).

Figures 1 and 2 show a 10-year clinical recall case. Figure 1 shows marginal discoloration and marginal (irregularity) steps around the restorations. The restorations in Figure 2 show slight marginal discoloration and (irregularity) steps.

Figure 3 illustrates the clinical appearance of a Class V restoration from pretreatment to 10 years. Figure 3A and 3B show pretreatment and baseline restoration. The restoration in Figure 3C shows the 5-year recall period; the adjacent canine was extracted for periodontal disease at 3 years, with the clinical crown being adhesively bonded to the adjacent tooth. The first and second premolars showed marginal discoloration of the restoration margins and visible marginal (irregularity) steps on the dentin margin but not on the enamel margin. Marginal discoloration of these restorations was removed at the patient's request by polishing at the 5year recall period (Figure 3D). These restorations were observed throughout the 10-year recall. Although the surfaces of certain restorations were discolored due to smoking and other oral habits, including coffee, tea or wine, there was no marginal discoloration along the



Figure 1: Ten-year clinical recall. Class III restoration of upper lateral incisor shows marginal discoloration and marginal (irregularity) steps around the restorations.



Figure 2: Ten-year clinical recall. Class III restorations of the central incisor shows slight marginal discoloration and steps



Figure 3: Class V restorations of the lower canine and premolars. 3A: Before treatment.



Figure 3B: After restorations (baseline).



Figure 3C: Five-year recall. The adjacent canine was extracted for periodontal disease at 3 years, the clinical crown being adhesively bonded to the adjacent teeth. The first and second premolars show marginal discoloration of the restoration margins and visible marginal (irregularity) steps on the dentin margin but not on the enamel margin.



Figure 3D: Marginal discoloration of these restorations was removed at the patient's request by polishing.



Figure 3E: Ten-year recall. Although the surface of certain restorations were discolored due to smoking and other oral habits, such as coffee, tea or wine, there was no marginal discoloration along the enamel or dentin margins at 10 years.

enamel or dentin margins at 10 years (Figure 3E). In summary, at 10 years, none of the patients reported any tooth hypersensitivity to stimuli of air bursts or cold, suggesting no pulp response or inflammation. In addition, there was no retention loss, no secondary caries and no marginal discrepancy of either enamel or dentin margins.

DISCUSSION

Based on the clinical precepts that Fusayama recommended for the restoration of resin composite restorations, ³⁶⁻³⁷ our profession now readily accepts the niche of minimally invasive dentistry in our daily clinical regimen, displacing the historical use of amalgam, which has been popular since the late 1700s. With such issues as technique sensitivity, when to employ certain cavity configurations, the suitability of dentin and enamel substrate and marginal longevity, the user-friendliness associated with resin composite restorations and the immediate positive aesthetic response by patients, the practice of clinical dentistry has dramatically changed for the better in just a few decades.

The biological issues of pulp vitality associated with certain acidic restorative agents, as reported by Manley³⁸ and Schroff,³⁹ created many clinical obstacles to the biological understanding and development of adhesive dentistry. Others clouded the clinician's view of acids on the tooth and, specifically, on enamel and dentin; in hindsight, they failed to consider that solutions would be rapidly buffered by oral fluids. Championing the new scientific reality, the research of Fusayama,³⁶⁻³⁷ Brännström & Nordenvall and Brännström, Vojinovic & Nordenvall,⁴⁰⁻⁴¹ among others, provided a flourish of new data in a few decades, providing a new scientific understanding—bacterial microleakage is again realized as the real offender, which permits recurrent and secondary caries, ulti-

mately leading to pulp inflammation and eventual irreversible pulp damage.

Another equally important issue for consideration is the use of minimal reduction of insensitive dentin using Caries Detector, which is now worthy of consideration for clinical validation, due to the 10 year success of restoration longevity as demonstrated in this study. Depending on a clinician's geographic location in the world, that clinician may use a local injection of an anesthetic to deaden the nerve of the patient. In many cases, this local nerve injection is equally or even more fear provoking than the actual restorative drilling experience. Clinicians should reflect that, when anesthesia begins to wear off during the restorative period, the instrumentation may actually cause acute patient pain; whereas, removal of infected dentin with the use of a caries detector is painless. This clinical observation supports the clinical-scientific significance of Fusayama's research,35-37 which validated the various zones of sensitive versus insensitive dentin. The data from this study reaffirms the precepts of Fusayama, which states that caries may be removed without anesthesia and tooth substrate can be restored in a painfree manner.

Following the biological acceptance of acid etching prepared dentin and exposed vital pulps, 40-43 routine wet bonding via acid-etching with various inorganic acids, such as phosphoric acid, 44-47 the concept of total-etch for adhesive dentistry is now generally accepted by clinicians worldwide. At the same time, the concept of a selfetching adhesive system has evolved and is now widely applied throughout Japan and many international countries. Clearfil Liner Bond 2, the first self-etching adhesive system that simultaneously targeted both enamel and dentin substrates, reached the market in 1993. Since then, Japanese dental manufacturers began to intensely compete in order to develop their own similar self-etching adhesive systems. More recently, most manufacturers have duplicated similar one-step self-etching adhesive systems or a one bottle self-adhesive that contained all the functions of a onebottle system, often referred to as an "all-in-one adhesive." These materials are now available throughout most international commercial markets.

Recently, many *in vitro* publications have reported on bond strengths or observations of the resin-dentin interface of self-etching adhesive systems. Some clinical research reports of self-etching adhesive systems have been published in recent years. ^{10,26-34} However, many of these reports were only short-term clinical evaluations of self-etching adhesive systems for three years or less. Many of these studies have reported good clinical performance and, as a consequence, many self-etch systems are now readily accepted by worldwide clinicians.

Currently, it is anticipated that continued development of self-etching adhesive systems for resin composites may eventually replace earlier traditional totaletch systems. As mentioned in the authors' literature review, there are no longitudinal reports of long-term clinical evaluation of self-etching adhesive systems beyond 10 years. For clinical comparison and consideration, there are some published reports of long-term (more than 10 years) clinical results of conventional resin composite restorations. All these restorations were performed using the enamel-etch or total-etch technique as adhesive systems. 48-52 Qvist and Strom reported a cumulative 11-year survival rate of 84% of a micro-filled resin composite with the acid etch technique.48 Shimizu and others49 reported that 68 out of 91 posterior restorations, using visible light cured posterior resin composite, showed little wear, good marginal adaptability and no discoloration after 10 years. Thus, long-term clinical evaluation of previous traditional studies and data from this study may be employed to predict the prognosis of restorative treatment.

In the authors' 10-year longitudinal clinical study, 91% of cases showed a Bravo rating for marginal integrity. These restorations demonstrated a slight tactile measurement of step irregularities when a sharp explorer was drawn across the tooth towards the restoration interface. As there was no gap formation between the tooth and resin composites, the authors considered the marginal interfacial irregularity steps were supposedly developed from chip fractures of the resin composite along the cavosurface margin due to overfilling the resin composite onto the uncut enamel or dentin surface.

Marginal discoloration was observed in 39 of 44restorations; however, it did not appear to be associated with notch or gap formation between the tooth substrate and the restoration interface, but appeared to be more likely due to the oral habits of patients, such as smoking or drinking tea, coffee or wine. In addition, no marginal demineralization of the adjacent tooth substrate was associated with the discoloration. Some discoloration was observed on the enamel surface adjacent to the restoration; however, it was considered equal to those same observations seen at previous evaluation periods. These marginal irregularities and discolorations were easily removed with slight surface polishing. As a result, the authors determined these deficiencies did not need to be re-restored or removed, as there was no demineralization or recurrent caries.

Although the failure rate of marginal integrity and discoloration in this study was slightly higher than that reported for total-etch systems, 48-52 the results of retention loss, secondary caries and postoperative sensitivity were excellent. There were no failures after 10 years in categories of longitudinal clinical placement and

functional service when using the Clearfil Liner Bond 2 system. It is remarkable there was no retention loss after 10 years. Since enamel bond strength is higher in total-etch systems than dentin bond strength, it may be considered that the ultimate bond durability of the composite system to the tooth cavity substrate depends more on enamel bond strength than dentin bonding. On the other hand, since the enamel bond strength of the self-etching adhesive system was similar to or less than dentin bond strength, adhesion to the cavity and sealing against bacterial microleakage ultimately depends on dentin bond strength and durability.

Some literature⁵³⁻⁵⁷ has suggested that certain adhesive and resin composite systems are the primary cause of pulp irritation and eventual necrosis. However, other studies⁵⁸⁻⁶¹ continue to demonstrate that pulp inflammation is due primarily to the marginal leakage of bacteria and the invasion of toxic factors, instead of from acid etchants, primers, bonding resins or resin composite systems. In addition, there are few published reports regarding the biocompatibility of self-etching adhesive systems; however, the literature ⁶²⁻⁶⁴ does report that the Clearfil Liner Bond 2 system is biocompatibly acceptable to pulp tissues when placed directly on non-exposed dentin or mechanical pulp exposures. This study shows no pulp response or necrosis in any of the treated teeth during the 10 years of clinical observation.

CONCLUSIONS

These longitudinal clinical data demonstrate that the retention rate and pulpal response of Clearfil Liner Bond 2 self-etching adhesive system is excellent after 10-year placement. Some marginal discoloration was evident; however, these changes were not severe, as clinical conditions requiring replacement from recurrent caries were not present. Clinically, data from this study demonstrate that the Clearfil Liner Bond 2 self-etching adhesive system is acceptable to minimally invasive adhesive restoration in human teeth that presented with initial caries 10 years prior to restoration.

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