Dental Materials Journal 26(1): 14−20, 2007

One-year Clinical Evaluation of Five Single-step Self-etch Adhesive Systems in Non-carious Cervical Lesions

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Received July 30, 2006 /Accepted September 25, 2006

This study evaluated the clinical performance of five single-step self-etch adhesive systems over a one-year follow-up period in 98 restorations. Independent evaluations were performed at baseline (one week), after three months, six months, and one year, by two trained examiners using the modified US Public Health Service rating criteria. Color match, marginal integrity, anatomical form, surface roughness, marginal or interfacial staining, postoperative sensitivity, and secondary caries were evaluated. Results were analyzed using the Kruskal-Wallis test at a significance level of $p<0.05$. After one year, the restorations were re-evaluated and 100% retention rate was recorded. No caries were detected in association with any of the restorations. Marginal adaptation was the only measure that showed a slight deterioration over time, and there were no significant differences in this factor among the adhesive systems tested ($p=0.464$).

Keywords: Clinical study, Single-step system, Cervical lesion

INTRODUCTION

Tooth-colored restorative materials, including resin composites, continue to undergo development and improvements. Resin composites are popular due to their superior aesthetics, ease of handling, "tooth-friendly" conservative restorative procedures, and broad applicability in a wide range of uses[1]. The most remarkable feature of resin restorations is the strength of their bonding to tooth substrates. Moreover, recently developed adhesive systems have enabled higher bond strengths to be realized with less clinical steps and shorter treatment time[2-4].

In terms of restorative treatment outcome, margins of restorations are not always entirely within the tooth enamel. As a result, erosion lesions often develop at the gingival margin in dentin[5]. Previously, erosion lesions in the cervical area were mainly prevalent among the elderly people due to the many years of service and wear. However, owing to dietary changes and inadequate oral hygiene, these disorders are also becoming more prevalent among the young people. Cervical erosion lesions are largely due to physical and chemical factors at work in the area of tooth neck, resulting in enamel loss, dentin exposure, and dentin erosion[6].

In terms of restoration repair or replacement, secondary caries and fractures are the most frequently cited causes[7]. In this connection, so-called permanent restorations are by no means permanent in the true sense of the word: the median period of time before resin restorations require replacement is in fact six years[8]. However, marked improvements in longevity have been achieved during the past few decades due to development of reliable adhesive systems. Nonetheless, apart from the properties of restorative materials, other factors also significantly influence the clinical performance of cervical restorations. Indeed, cervical restoration failures may be associated with dentin sclerosis, location, size, and shape of lesion, operator variability, and even occlusal factors[9].

For many years, the dental profession has strongly advocated for strong adhesion of resin composites to the tooth substrate, with the aim of reducing microleakage and thus providing a strong and stable bond in the oral environment. However, bonding is traditionally achieved through a multi-step clinical procedure, such that the success of adhesive systems is heavily influenced by several technique-sensitive and material-related factors[10]. Fortuitously, following vast improvements in adhesive dentistry, the clinical procedure to bond restorative materials to enamel and dentin has been drastically simplified[11], and that tooth and aesthetic defects can now be restored successfully by directly applying resin composites.

Recently, single-step self-etch adhesive systems, which combine the functions of a self-etching primer and a bonding agent, have been developed[12]. The single-step self-etch adhesive is applied to the tooth surface prior to resin composite placement to ensure

Table 1 Materials tested.

Adhesive (Manufacturer)	Main components	Lot No.	Restorative
Adper Prompt L-Pop (3M ESPE)	Methacrylated phosphoric esters, Bis-GMA, CQ, initiator, stabilizer, HEMA, polyalkenoic acid, water	127613	Filtek Supreme
AQ Bond Plus (Sun Medical)	4-META, UDMA, MMA, water, acetone, initiator *p*-toluenesulfonate, reductant	B: GV1 S: GL-2	Metafil C
Fluoro Bond Shake One (Shofu Inc.)	PRG, fluoroaluminosilicate glass 4-AET, 4-AETA, bis-GMA, HEMA, initiator, water, solvent	A: 551F-2 B: 551F-2	Beautifil
G-Bond (GC Corp.)	4-MET, UDMA, acetone, water silanated colloidal silica, initiator	031015	Gradia Direct
One-Up Bond F Plus Σ (Tokuyama Dental)	MAC-10, HEMA, MMA multifunctional methacrylic monomer, fluoroaluminosilicate glass, water, photoinitiator, aryl borate catalyst	A: MS-13 B: MS-13	Palfiqu Estelite

maximum adhesion with the following mechanisms: improve monomer penetration into the tooth substrate as well as wettability of the tooth surface *via* the resin components. While self-etch adhesives certainly simplify the clinical procedure — since no separate acid etching step is required, careful management of the products is still required to achieve optimal clinical[3,4,13]. In addition to the benefit of ease of use in clinics, another benefit is that removal of the smear layer and smear plug is not required. In this manner, the potential for postoperative sensitivity is reduced, and likewise the problems associated with transudation of dentinal fluid through patent dentinal tubules.

However, single-step self-etch adhesives are moderately acidic with pH values between 1.5 and 2.8[10]. This weak acidity thus poses the question of whether the adhesives are able to penetrate the dentin surface to yield optimum bonding with the restored teeth. Moreover, the effectiveness of this newly developed adhesive system remains to be tested in the oral environment. Against this backdrop of reasons, the purpose of the current study was to investigate *in vivo* the clinical effectiveness of single-step self-etch adhesive systems in the oral environment.

MATERIALS AND METHODS

Materials

Table 1 lists the single-step self-etch adhesive systems that were used in this study in combination with their respective manufacturers' restorative resins: Adper Prompt L-Pop/Filtek Supreme (3M ESPE, St. Paul, MN); AQ Bond Plus/Metafil C (Sun Medical, Shiga, Japan); Fluoro Bond Shake One/Beautifil (Shofu Inc., Kyoto, Japan); G-Bond/Gradia Direct (GC Corp., Tokyo, Japan); and One-Up Bond F Plus/Palfique Estelite (Tokuyama Dental, Tokyo, Japan). Application protocols suggested by each manufacturer are summarized in Table 2.

For light curing, an Optilux 501 visible light activating unit (SDS Kerr, Danbury, CT) was employed. Power density (800 mW/cm^2) of the curing light was checked with a Model 100 dental radiometer (SDS Kerr) before the clinical procedures were performed.

Experimental protocol

In total, 98 teeth with cervical lesions were restored in 46 patients (20 male and 26 female; mean age = 46 years; age range = 31-82 years). The criteria used to select patients included the presence of non-carious cervical lesions and the absence of severe medical complications, xerostomia, and chronic periodontitis. Written informed consent was obtained from all patients at the beginning of the clinical study. Protocol adopted in this study was also approved by the Ethical Research Committee of Nihon University School of Dentistry, Japan.

The cavity wall of each cervical lesion was gently and superficially roughened with a diamond bur without local anesthesia. The cavities were prepared without the need for additional extensions,

Table 2 Application protocols for single-application adhesive systems.

Adhesive system	Application protocol
Adper Prompt L-Pop (blister-packed)	Activate blister pack by emptying liquid from red blister into yellow blister. Apply activated solution to tooth for 15 s with moderate finger pressure. Use gentle stream of air to dry. Apply second coat of adhesive. Use gentle stream of air to dry. Light-irradiate for 10 s.
AQ Bond Plus (two components)	Dispense one drop of liquid into well. Mix with sponge. Apply to tooth for 20 s. Use relatively strong stream of air to dry. Light-irradiate for 10 s.
Fluoro Bond Shake One (two bottles)	Mix equal amounts of bond agents A and B. Apply to tooth for 20 s. Briefly air-dry. Light-irradiate for 10 s.
G-Bond (single bottle)	Apply sufficient amount of adhesive to tooth for 10 seconds. Use strong air flow to dry. Light-irradiate for 10 s.
One-Up Bond F Plus (two bottles)	Mix equal amounts of bond agents A and B until pink homogenous liquid mixture is obtained. Apply to tooth for 10 s with agitation. Light-irradiate for 10 s.

undercuts, or rounding of the walls. As the cervical lesions had suitable enamel walls and margins, beveled cavities were not employed. To avoid contaminating the cavities, adjacent gingiva were retracted using cords and the operating fields isolated with rolls of cotton wool. All the adhesive systems were applied strictly according to the instructions provided by the respective manufacturers (Table 2). Shade selection was performed under natural light conditions following the guidelines of each manufacturer.

A thin-bladed instrument with a slight curve (Duralite, Nordent Manufacturing Inc., Elk Grove Village, IL) was used to manipulate the resin composite into the appropriate cavity. Each increment was polymerized in a curing unit for 30 seconds. Diamond finishing burs (BluWhite Composite Finishing Diamonds, SDS Kerr) were used at high speed with a water spray to remove any excess product. Final finishing was achieved with Super-Snap disks (Shofu Inc.) at a slow speed without a water spray.

Clinical evaluation

A modified version of the US Public Health Service (USPHS) criteria[14] was used to evaluate the color match, marginal adaptation, anatomical form, surface roughness, marginal staining, postoperative sensitivity, and secondary caries (Table 3). Restorations were assessed at baseline, and after three months, six months, and one year. Baseline was defined as one week after the polishing procedures were performed. Each clinical evaluation was carried out independently by two clinicians who were not involved in the original placement of the restorations. In cases of disagreement, consensus was reached by discussion and re-examination. Photographs were taken, with standardized magnification (1×1), using a Medical Nikkor 120 mm F/4.0 IF lens (Nikon Corp., Tokyo, Japan) mounted on a Nikon F60 camera (Nikon Corp.) with Fujichrome Sensia II film for slides (Fuji Photo Film Co., Tokyo, Japan) at each follow-up time interval. Impressions of the restorations were made at the time of each evaluation and were cast in an epoxy resin (Epon 812, Nisshin EM Co., Tokyo, Japan). For typical cases, epoxy resin replicas were coated in a vacuum evaporator (Quick Coater Type SC 701, Sanyu Denshi Inc., Tokyo, Japan) with a thin film of gold. Specimens were then observed under an ERA-8800FE field emission scanning electron microscope (Elionix Ltd., Tokyo, Japan).

Statistical analysis

Changes in the evaluated parameters during the one-year period were analyzed using the Kruskal-Wallis test by Sigma Stat® Ver. 3.1 software (SPSS Inc., Chicago, IL). Statistical significance level was set at $p<0.05$.

RESULTS

During the one-year follow-up period, all the restorations were evaluated at the stipulated time intervals described above (Table 4). Figure 1 shows a

Table 3 Modified USPHS criteria used in this study.

Color match	Alpha	Restoration matches the adjacent tooth structure in color and translucency
	Bravo	Mismatch in color and translucency is within the acceptable range
	Charlie	Mismatch in color and translucency is outside the acceptable range
Marginal adaptation	Alpha	Explorer does not catch or has a one-way catch when drawn across the restoration/tooth interface
	Bravo	Explorer falls into a crevice when drawn across the restoration/tooth interface
Anatomical form	Alpha	General contour of restoration follows the overall contour of the tooth
	Bravo	General contour of restoration does not follow the overall contour of the tooth
Surface roughness	Alpha	Surface of restoration does not have any defects
	Bravo	Surface of restoration has minimal defects
	Charlie	Surface of restoration has severe defects
Marginal staining	Alpha	No discoloration between restoration and tooth
	Bravo	Discoloration on less than half of the circumferential margin
	Charlie	Discoloration on more than half of the circumferential margin
Postoperative sensitivity	Alpha	No sensitivity when air syringe is activated for 2 s at a distance of 0.5 inches from the restoration/unrestored lesion with the facial surface of the proximal tooth covered with gauze
	Bravo	Sensitivity is present when the air syringe is activated for 2 s at a distance of 0.5 inches from the restoration/unrestored lesion with the facial surface of the proximal tooth covered with gauze, and ceases when the stimulus is removed
	Charlie	Sensitivity is present when the air syringe is activated for 2 s at a distance of 0.5 inches from the restoration/unrestored lesion with the facial surface of the proximal tooth covered with gauze, and does not cease when the stimulus is removed
Secondary caries	Alpha	No clinical diagnosis of caries
	Bravo	Clinical diagnosis of caries

representative photograph of a restoration scored as Bravo for marginal adaptation after one year.

No secondary caries were found in any of the groups, and none of the patients reported postoperative sensitivity during follow-up. Color match, anatomical form, and surface roughness were classified as excellent for all the restorations. Statistical analysis revealed no significant differences among the adhesive systems employed for any category at any examination period.

With regard to marginal adaptation, 42.9-66.7% of the restorations showed evidence of slight crevices along the marginal interface of the incisal wall, although there were no significant differences in this factor among the adhesive systems employed (Chi-square = 3.593, $p = 0.464$). Compared with the baseline observation, a significant increase was observed in the "Bravo" rating for marginal adaptation for all materials.

DISCUSSION

The performance of five adhesive systems used for the restoration of teeth with cervical erosion lesions was evaluated in this study. These model lesions are ideal test cavities, because they are located mainly within the dentin and present no macromechanical undercuts. A chief purpose of this study, therefore, was to determine whether the evaluated materials could be used in complex clinical situations where

Table 4 Clinical evaluation of single-step self-etch adhesive systems.

Factor	Material	Baseline			3 months			6 months			1 year		
		A	B	C	A	B	C	A	B	C	A	B	C
Color match	Adper Prompt L-Pop	21	0	0	21	0	0	21	0	0	21	0	0
	AQ Bond Plus	21	0	0	21	0	0	21	0	0	21	0	0
	FB Shake One	24	0	0	24	0	0	24	0	0	24	0	0
	G-Bond	14	0	0	14	0	0	14	0	0	14	0	0
	One-Up Bond F+	18	0	0	18	0	0	18	0	0	18	0	0
Marginal adaptation	Adper Prompt L-Pop	21	0	-	18	3	-	15	6	-	11	10	-
	AQ Bond Plus	21	0	-	16	5	-	13	8	-	7	14	-
	FB Shake One	24	0	-	19	5	-	15	9	-	8	16	-
	G-Bond	14	0	-	9	5	-	8	6	-	8	6	-
	One-Up Bond F+	18	0	-	15	3	-	11	7	-	8	10	-
Anatomical form	Adper Prompt L-Pop	21	0	-	21	0	-	21	0	-	21	0	-
	AQ Bond Plus	21	0	-	21	0	-	21	0	-	21	0	-
	FB Shake One	24	0	-	24	0	-	24	0	-	24	0	-
	G-Bond	14	0	-	14	0	-	14	0	-	14	0	-
	One-Up Bond F+	18	0	-	18	0	-	18	0	-	18	0	-
Surface roughness	Adper Prompt L-Pop	21	0	0	21	0	0	21	0	0	21	0	0
	AQ Bond Plus	21	0	0	21	0	0	21	0	0	21	0	0
	FB Shake One	24	0	0	24	0	0	24	0	0	24	0	0
	G-Bond	14	0	0	14	0	0	14	0	0	14	0	0
	One-Up Bond F+	18	0	0	18	0	0	18	0	0	18	0	0
Marginal staining	Adper Prompt L-Pop	21	0	0	21	0	0	21	0	0	21	0	0
	AQ Bond Plus	21	0	0	21	0	0	21	0	0	21	0	0
	FB Shake One	24	0	0	24	0	0	24	0	0	24	0	0
	G-Bond	14	0	0	14	0	0	14	0	0	14	0	0
	One-Up Bond F+	18	0	0	18	0	0	18	0	0	18	0	0
Postoperative sensitivity	Adper Prompt L-Pop	21	0	0	21	0	0	21	0	0	21	0	0
	AQ Bond Plus	21	0	0	21	0	0	21	0	0	21	0	0
	FB Shake One	24	0	0	24	0	0	24	0	0	24	0	0
	G-Bond	14	0	0	14	0	0	14	0	0	14	0	0
	One-Up Bond F+	18	0	0	18	0	0	18	0	0	18	0	0
Secondary caries	Adper Prompt L-Pop	21	0	-	21	0	-	21	0	-	21	0	-
	AQ Bond Plus	21	0	-	21	0	-	21	0	-	21	0	-
	FB Shake One	24	0	-	24	0	-	24	0	-	24	0	-
	G-Bond	14	0	-	14	0	-	14	0	-	14	0	-
	One-Up Bond F+	18	0	-	18	0	-	18	0	-	18	0	-

aesthetics are also of paramount importance.

In the current study, all the restorations remained intact irrespective of the adhesive system used. Postoperative sensitivity and secondary caries were not reported after one year. On the overall, there were no statistically significant differences between the baseline values and those measured after one year for any of the criteria evaluated, except for marginal adaptation. Although minor marginal defects were observed on scanning electron microscope images after one year, marginal discoloration and secondary caries were not detected.

In a previous five-year clinical evaluation of adhesive systems in non-carious cervical lesions, progression of marginal defects was revealed[15]. Marginal adaptation is a less common reason for replacing cervical restorations as compared to marginal discoloration or secondary caries. Pertaining to marginal adaptation, its failure is usually caused by breakdown or loss of restorative material[8]. Marginal gaps can occur over time due to exposure of the restorations to the oral environment, and therefore being subjected to thermal and mechanical stresses[16]. It has been suggested that the clinical retention of an adhesive restoration depends not only on the retention capacity of the adhesive system, but also on the viscoelastic properties of the restorative material[17]. Several factors can bring about dimensional changes to these materials, including thermal changes and water absorption[18]. Restoratives might be subjected to mechanical stresses generated by differences in thermal conductivity and thermal expansion coefficient between different tooth substrates. It has also been suggested that the cervical area of a tooth is subjected to unique stress caused by occlusal function[19]. With due consideration to the different kinds of stress restorations are subjected to *in vivo*, the elastic modulus of restorative materials should also

be carefully taken into account. In the current clinical study, bevels were not used in the cavities; therefore it might be necessary to modify the preparation procedure to improve marginal integrity.

For bond strength observed under laboratory conditions, many factors play a contributory role. In general, single-step self-etch adhesive systems exhibit slightly lower bond strengths than two-step systems[20]. In terms of bonding performance to enamel and dentin, our previous report showed that single-step self-etch adhesive systems yielded similar results[21]. This is advantageous because polymerized composites are then less likely to be pulled toward the more strongly bonded site. In the current clinical study, the bond strength to enamel appeared satisfactory. If the bond strength had been insufficient, more restorations would be expected to show staining along the margin. However, this did not occur, and thus did not pose a clinical problem.

The cured layer of single-step self-etch adhesives might act as a permeable membrane, which allows water diffusion from the dentin to the intermixed zone between the adhesive and the composite[22,23]. Water diffusion into the bonding interface formed between an adhesive and a tooth substrate can cause the resinous components to swell and become plasticized[24]. In the oral environment, water might accelerate the hydrolysis of resins and cause poorly polymerized resin oligomers to leach[25]. The weakened mechanical properties of the composite resin might then lead to a decrease in bond strength, thereby causing restoration failure. Therefore, it must be highlighted that although the application methods for the newly developed bonding systems are relatively simple and the manufacturers' instructions easy to follow—thereby improving the chances of achieving optimal clinical performance, careful management of the products is nonetheless required.

Scientific advances in restorative materials and their application methods, as well as better understanding in the pathology and prevention of caries, have led to more efficient oral health management[26]. According to the principles of minimal intervention, non-invasive strategies are preferred for the treatment of decayed lesions[27]. As prevention is better than cure, efforts have focused on reducing the risk of caries in patients and on promoting a closer relationship between dentists and dental manufacturers to ensure satisfactory aesthetic results from the adhesive systems. Results of the current study indicated that majority of the adhesive systems evaluated showed excellent performance throughout the one

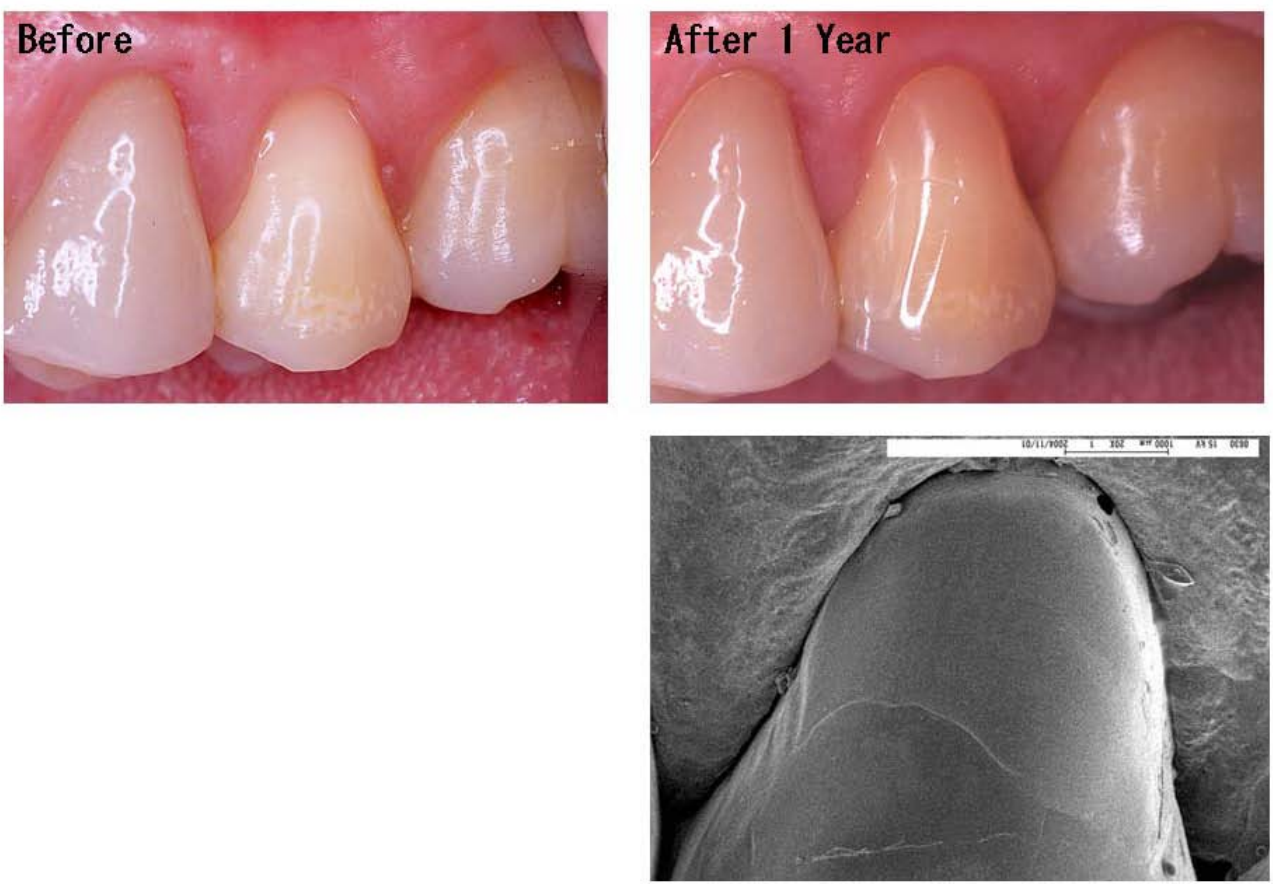

Fig. 1 Restoration (Adper Prompt L-Pop) scored as "Bravo" for marginal adaptation after one year.

year of clinical service, whereby ratings for all evaluated criteria were within the acceptable range.

ACKNOWLEDGEMENTS

This work was supported in part by Grants-in-aid for Scientific Research (C) (No. 17592004) and Young Scientists (B) (Nos. 16791164 and 18791411) from the Japan Society for the Promotion of Science. It was also supported by the Sato Fund from the Nihon University School of Dentistry, and by a grant from the Dental Research Center, Nihon University School of Dentistry.

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