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Evaluation of an antimicrobial and fluoride-releasing self-etching primer on the shear bond strength of orthodontic brackets

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SUMMARY The enhanced risk of dental caries is one negative side-effect of fixed appliances. A new antimicrobial and fluoride-releasing self-etching bonding system (Clearfil Protect Bond™) has been introduced in restorative dentistry and clinical studies have already shown the potential for this primer to be used clinically with effective antiplaque properties. Therefore, this *in vitro* study was conducted in order to evaluate the new primer in comparison with a conventional bonding preparation.

One hundred and twenty extracted human teeth were randomly divided into three groups of 40 specimens each (20 incisors, 20 premolars). In group 1 a conventional bonding procedure was used (etching, Transbond XT), in group 2 the new primer was used according to the manufacturer's recommendations when bonding to intact enamel, while in group 3 the new primer was used without prior etching. Shear bond strength (SBS) was measured with a universal testing machine and the adhesive remaining after debonding was determined using an optical microscope at ×10 magnification. The adhesive remnant index was used in order to assess the mode of failure.

No enamel fractures were detected in any of the specimens. In all groups acceptable bond strengths were observed. The only statistically significant difference ($P = 0.004$) was found for the incisors in group 2, which showed the highest mean SBS (17.46 MPa).

Considering the acceptable bond strength and the mode of failure, use of the new primer without prior etching is recommended in patients with fixed appliances. Further *in vivo* studies will be carried out in order to evaluate clinical performance.

Introduction

Fixed orthodontic appliances are routinely used in daily orthodontics. One negative side-effect of the placement of fixed appliances is the enhanced risk of dental caries, which is caused by the increase of *Streptococcus mutans* due to a low resting pH value in the plaque, and impeded oral hygiene with increased retentive sites and retention of food particles (Balenseifen and Madonia, 1970; Mattingly *et al.*, 1983; Scheie *et al.*, 1984; Øgaard *et al.*, 2001).

Therefore, new bonding techniques and materials constantly focus on caries protective features. In order to decrease the decalcification rate during orthodontic treatment, various preventive measures have been discussed in the literature and these may be divided into four groups: fluoride, chlorhexidine, sealants, and bonding materials. According to two systematic reviews (Benson *et al.*, 2004; Derks *et al.*, 2004) and an overview (Mitchell, 1992), the scientific evidence of these attempts to prevent enamel demineralization is weak.

A new antimicrobial and fluoride-releasing bonding system has been introduced in restorative dentistry: Clearfil Protect Bond™ (Kuraray Medical Inc., Okayama, Japan) is an advanced type of Clearfil SE Bond™ (Kuraray Medical Inc.) and consists of a self-etching primer and a bonding agent. The self-etching primer comprises adhesive phosphate monomer [10-methacryloyloxdecyl dihydrogen phosphate (MDP)], which is responsible for the etching mechanism, 2-hydroxyethylmethacrylate (HEMA) water, initiators, and monomer 12-methacryloyloxydodecyl pyridinium bromide (MDPB). The manufacturer introduced MDP as an acidic monomer, which retains its hydrolytic stability in conjunction with highly acidic pH values. The bonding agent comprises MDP, HEMA and co-monomers, initiators, and functionalized sodium fluoride. As previous studies in the field of restorative dentistry have already shown, MDPB demonstrates significant bacteriostatic effects without releasing antibacterial components and is useful for incorporation into dental resin-based materials (Ebi *et al.*, 2001; Nakatsuka *et al.*, 2001; Imazato *et al.*, 2002, 2003; Kawashima *et al.*, 2002; Peters *et al.*, 2004). The biocompatible MDPB has the potential to be used clinically with an effective antiplaque property (Imazato *et al.*, 1999).

Therefore, the aim of the present study was to analyse the influence of the new primer on shear bond strength (SBS). In the case of acceptable bond strength, clinical studies can then be undertaken to assess the effectiveness of the new primer in preventing demineralization associated with fixed appliances.

Materials and method

Specimens

One hundred and twenty caries-free human incisors and premolars, stored for a maximum of 3 months in an aqueous 1 per cent chloramines-T solution, were used in this investigation. After detachment of two-thirds of the root and elimination of all soft-tissue structures, the teeth were embedded in chemically cured resin (Palavit G®, Heraeus Kulzer, Wehrheim, Germany) with their labial surfaces upward and parallel to the surface of the plastic tube. Finally, the teeth were pumiced with a non-fluoride containing polishing paste.

Bonding procedures

The teeth were randomly divided into three groups of 40 teeth each (20 incisors, 20 premolars).

Group 1 (control) utilized the conventional acid-etch technique. The enamel surfaces were etched for 20 seconds with 35 per cent phosphoric acid (Gel Etch®, 3M Unitek, Monrovia, California, USA), then rinsed with water for 10 seconds, and air-dried. Sealant (Transbond XT®, 3M Unitek) was applied to the etched surface.

In group 2, the self-etching primer was used according to the manufacturer's recommendations when using the product on uncut enamel, as in restorative dentistry. After etching for 10 seconds with 35 per cent phosphoric acid (Gel Etch®, 3M Unitek), the teeth were washed with water spray for 10 seconds. The primer (Clearfil Protect Bond™, Kuraray Medical Inc.) was applied to the etched enamel and left for 20 seconds, then sprayed with an air stream to evaporate the solvent. The bonding agent was applied and light cured for 10 seconds.

In group 3 the same bonding procedure was performed as in group 2 but without etching prior to using the primer.

All teeth were bonded with Mini Diamond® brackets (Ormco, Orange, Cailfornia, USA). Upper lateral incisor brackets (order no. 351-0271) were used for the incisors and premolar brackets (order no. 350-0514) for the premolars. The average surface of the bracket base was 8.75 mm^2 for the upper lateral incisor brackets and 11.25 mm^2 for the upper premolar brackets.

The bracket base was initially cleaned with alcohol and all brackets were then coated with Transbond XT®. After placing the brackets on each tooth at room temperature, a 250 g force was applied for 5 seconds to ensure a uniform adhesive thickness. Excess adhesive was removed prior to 20 seconds light polymerization with a halogen light (Ortholux™ XT, 3M Unitek). Prior to bond strength testing, the prepared specimens were stored in distilled water at 37°C for 48 hours. The bonding procedure was conducted by one orthodontist (LH).

Debonding procedures

Shear peel testing was performed on the prepared specimens with a Zwicki Z2.5 testing machine (Zwick, Ulm, Germany). A force was applied close to the bracket base at the wings in an occluso-gingival direction with a crosshead speed of 1 mm/minute for measurement of the SBS. The force resulting in bond failure was measured in newtons (N).

Residual adhesive

The mode of failure was assessed using the adhesive remnant index (ARI) developed by Årtun and Bergland (1984). With this index, the amount of residual adhesive adhering to the enamel surface is scored by visual inspection and is allocated to the following groups:

0, no adhesive remains on the tooth;
1, less than 50 per cent of the adhesive remains on the tooth;
2, more than 50 per cent of the adhesive remains on the tooth;
3, all adhesive remains on the tooth.

For each specimen, the substrate surface was examined with an optical stereomicroscope (magnification ×10) and ARI scores were assessed by the same operator.

Statistical analysis

To calculate the SBS, the debonding forces (N) were converted into stress values (MPa) by taking into account the surface area of the bracket base.

Bond strength data were analysed by Kaplan–Meier survival analysis using log rank statistics. Follow-up analyses (Kruskal–Wallis and Mann–Whitney tests) were adjusted for the number of comparisons made using the Bonferroni correction.

To determine if there were any significant differences in the ordinal ARI values, Kruskal–Wallis and Mann–Whitney non-parametric tests were used ($P < 0.05$).

Results

Figure 1 and Table 1 show the results of the Kaplan–Meier survival analysis. The log rank test revealed statistically significant differences ($P = 0.0001$) in SBS. When the Mann–Whitney test was applied, those differences were found between the group 2 incisors when compared with the group 1 incisors ($P = 0.004$). No further statistically significant differences were found.

No enamel fractures were observed in any of the specimens. The medians and distribution of the ARI results are shown in Table 2. The Kruskal–Wallis test indicated that there were no differences among the groups for premolars ($\chi^2 = 4.309$; $P = 0.116$), whereas significant differences were detected for the incisors ($\chi^2 = 9.988$; $P = 0.007$). The Mann–Whitney test showed that the ARI score for the incisors in group 2 was significantly higher than for groups 1 and 3. The ARI scores for the incisors of groups 1 and 3 were not significantly different. For the premolars, the

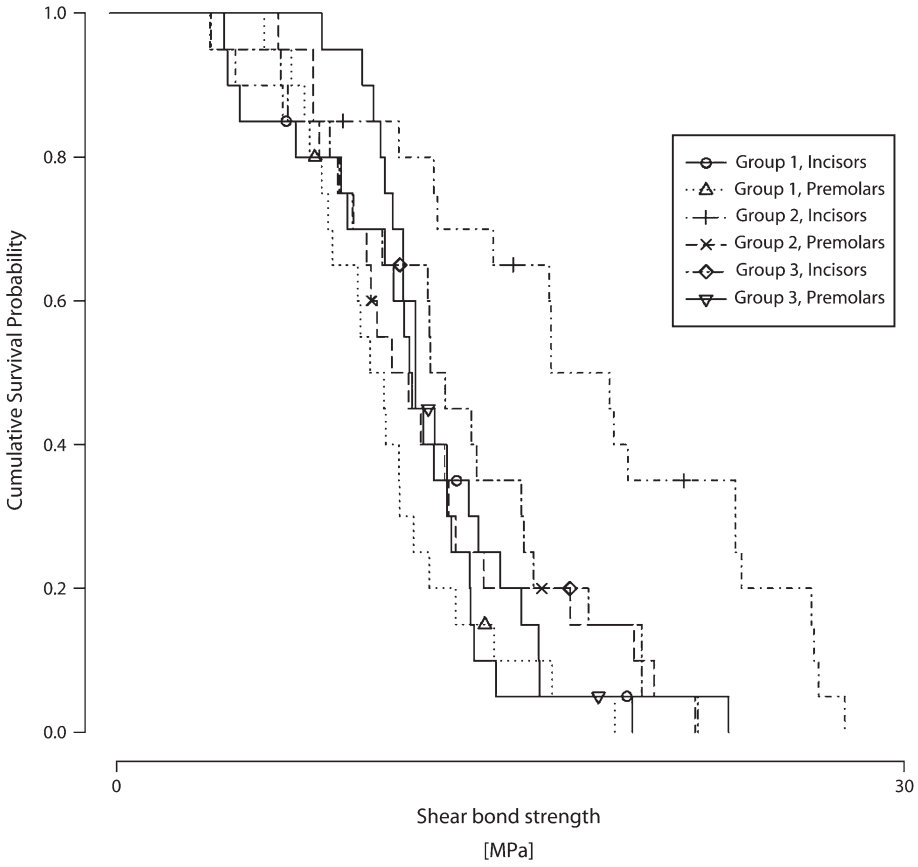

Figure 1 Kaplan–Meier survival analysis for incisors and premolars separately. Group 1: acid etch + Transbond XT primer; group 2: Clearfil Protect Bond on uncut enamel; group 3: Clearfil Protect Bond without additional etching.

Table 1 Shear bond strength (MPa; means, standard deviations, medians, standard errors, 95% confidence intervals).

Teeth	Bonding	Mean	SD	Median	Standard error	95% CI		Group differences*
Incisors	Group 1	11.40	4.65	11.15	0.35	10.47	11.83	A
	Group 2	17.46	7.52	16.57	2.49	11.68	21.46	B
	Group 3	12.74	5.00	11.95	0.69	10.59	13.31	A
Premolars	Group 1	10.36	3.36	9.67	1.01	7.70	11.64	A
	Group 2	12.04	4.57	10.50	1.34	7.87	13.13	A
	Group 3	11.93	2.46	11.38	0.34	10.71	12.05	A

Group 1, acid etch + Transbond XT primer; group 2, Clearfil Protect Bond on uncut enamel; group 3, Clearfil Protect Bond without additional etching.
*Groups with the same letters are not significantly different from each other (adjusted P value using Bonferroni correction $P < 0.008$).

Mann–Whitney test showed that the ARI scores were not significantly different between the groups.

Discussion

The results of this *in vitro* study showed that the new primer applied with and without prior etching did not affect the SBS, which in group 3 were comparable with those of the control and were within the range of 5.9–7.8 MPa recommended for composite and etched enamel (Reynolds, 1975). Significantly higher bond strengths were only observed for the group 2 incisors bonded with the new primer and prior acid etching.

Contrary to the manufacturer's recommendations, group 3 (bonding without prior acid etching) was established in the study design. The fact that the SBS values within this group were acceptable is perhaps not surprising given that the new primer is an advanced type of the already tested self-etching primer, Clearfil SE Bond™. Different results on the effects of Clearfil SE Bond™ on bond strengths have been reported. Some studies recommend the use of this self-etching primer since similar bond strengths were obtained and the sensitivity

Table 2 Frequency distribution of adhesive remnant index (ARI) scores.

Bonding	Teeth	ARI scores				
		0	1	2	3	Median
Group 1	Incisors	2	2	9	7	2
	Premolars	3	5	3	9	2
Group 2	Incisors	1	0	3	16	3
	Premolars	2	1	4	13	3
Group 3	Incisors	0	7	6	7	2
	Premolars	1	5	9	5	2

Group 1, acid etch + Transbond XT primer; group 2, Clearfil Protect Bond + acid etch; group 3, Clearfil Protect Bond without prior etching.

of the technique is reduced by eliminating the steps of washing and drying the tooth surfaces (Buyukyilmaz *et al.*, 2003; Lopes *et al.*, 2004; Naughton and Latta, 2005), while other researchers observed significantly lower bond strengths compared with those of conventional acid-etching and bonding systems (Bishara *et al.*, 1998, 1999; Park and Lee, 2004; Cehreli *et al.*, 2005). The thin and less uniform resin tags noted on the scanning electron micrographs of acidic primer-treated enamel were taken as an explanation for the poor adhesion (Bishara *et al.*, 1998). Based on the significantly lower bond strengths after thermal cycling, Cehreli *et al.* (2005) questioned the clinical use of self-etching primers for orthodontic bonding.

Application of antimicrobial agents may result in differences in the site of failure (Karaman and Uysal, 2004). Therefore, the additional features in the advanced primer such as antibacterial and fluoride-releasing characteristics might have a negative effect on bond strength. However, the results of this laboratory study show that even the etching step before using the new primer may not be necessary clinically because the SBS values compared favourably with recommended bond strength values in the literature (Reynolds, 1975).

The prevalence of new enamel lesions among patients with fixed appliances, who brush their teeth with a fluoride toothpaste is reported to range between 13 and 75 per cent (Wenderoth *et al.*, 1999; Fornell *et al.*, 2002). Therefore, the potential risk of developing caries in patients treated with fixed appliances has to be taken seriously.

According to systematic reviews (Benson *et al.*, 2004; Derks *et al.*, 2004) on caries-inhibiting effects of preventive measures in patients with fixed appliances, only the use of toothpaste and gel with a high fluoride concentration (1500–5000 ppm) or of 0.05 per cent daily fluoride rinse showed a demineralization-inhibiting tendency, while the use of polymeric tooth coating on the surface around the brackets or a fluoride-releasing bonding material showed almost no demineralization-inhibiting effect. The risk of caries development is still determined by the patient's oral hygiene status and diet during orthodontic treatment (Zimmer and Rottwinkel, 2004).

Previous studies have shown that the new primer exhibits caries-preventing characteristics (Nakatsuka *et al.*, 2001; Imazato *et al.*, 2002; Kawashima *et al.*, 2002): MDPB showed significant inhibitory effects against *S. mutans* growth even after treatment with saliva (Imazato *et al.*, 2003; Peters *et al.*, 2004). The bacterial numbers were reduced to a quarter of those in the starting solution after 18 hours of incubation (Imazato *et al.*, 1999). The plaque inhibitory effect of MDPB was found to depend on the potential to omit the attachment, glucan synthesis, and growth of bacteria on its surface (Ebi *et al.*, 2001). Therefore, the potential of minimizing the risk of caries development with the use of the new primer is less dependent on patient compliance.

In all groups the ARI scores varied considerably. There were no statistical differences for the premolars in any group. The ARI scores for the incisors in group 2 were significantly higher than those in groups 1 and 3. The ARI scores in group 3 showed less composite remaining on the tooth after debonding compared with group 2.

As in previous studies, the achieved SBS values were acceptable and failure primarily occurred within the adhesive, indicating that the new primer can be extended in its use to orthodontic patients with fixed appliances.

Since *in vitro* evaluations of SBS do not consider environmental factors such as saliva, wear, and masticatory forces (Pickett *et al.*, 2001), mean SBS measurements might be of limited value for interpreting *in vitro* bond strength. In order to come close to clinical settings, the testing procedure was based on recommendations in the literature (Fox *et al.*, 1994; Eliades and Brantley, 2000; Klocke and Kahl-Nieke, 2005). A prospective randomized *in vivo* study has now been initiated in order to test clinical performance and to provide evidence-based advice to orthodontists on the optimal strategy for preventing white spot lesion formation during orthodontic treatment with fixed appliances.

Conclusion

Within the limitations of this *in vitro* study, the use of the new primer without prior etching provides acceptable bond strength and leaves less composite on the tooth surface when compared with the results after use of the primer according to the manufacturer's recommendations on uncut enamel.

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