Original Article

Self-etching Primers: Is Prophylactic Pumicing Necessary?
A Randomized Clinical Trial

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Abstract: The purpose of this clinical trial was to determine whether pumice prophylaxis is required before the use of a self-etching primer (SEP). A total of 30 patients undergoing treatment with full upper and lower fixed appliances were recruited into this randomized cross-mouth controlled trial. In all cases, stainless steel orthodontic brackets were bonded using Transbond™ XT adhesive after pretreatment of the enamel surface using a new SEP. Diagonally opposite quadrants of the mouth were randomly assigned to have the enamel either pumiced or not pumiced before the use of a SEP. Bond failures, along with the adhesive remnant index (ARI) scores, were recorded at 6 and 12 months into treatment. The data were subsequently analyzed in terms of odds ratio and associated 95% confidence interval. Because of the very high bond failure rates of 55.5% for the no-pumice group and 33.2% for the pumice group, patient recruitment ceased at only 14 patients. Although the bond failure rates were unacceptably high in both groups, pumicing was found to have a clinically and statistically significant effect on reducing clinical bond failure rates. The ARI scores in all cases were 0, indicating that no adhesive remained on the enamel surface at bond failure. The significance of this trial is that pumicing before the use of an SEP is to be recommended, although the SEP used in this study cannot be recommended for clinical use. (*Angle Orthod* 2006;76:114–118.)

Key Words: Clinical trial; Pumice prophylaxis; Self-etching primers

INTRODUCTION

To obtain clinically acceptable bond strengths, it has traditionally been necessary to prepare the enamel surface by first removing the acquired organic pellicle through the use of pumice applied with a rubber cup or brush. The enamel is then etched with an acid (usually 37% *o*-phosphoric acid), rinsed and dried, primed with an unfilled resin, and finally a composite resin is used to bond the bracket to the tooth.

The elimination of one or more of these stages without compromising clinical reliability and minimizing iatrogenic damage to the tooth surface has been the aim of recent research in the field of adhesive dentistry. Indeed, it has been shown that the use of pumice prophylaxis is unnecessary, both when bonding with composite[1] and with a resin-modified glass ionomer cement.[2]

The use of an unfilled resin primer has also been questioned, with studies showing both in vitro bond strengths[3,4] and in vivo bond failure rates[5] to be unaffected by the omission of the resin primer. Despite this fact, it has been suggested (although not demonstrated) that incomplete impregnation of etched enamel leaves it vulnerable to the development of white-spot lesions around the brackets during treatment.[6,7] For this reason, it may still be desirable to use an unfilled resin as part of the bonding process in an effort to minimize iatrogenic damage.

Because of the hydrophobic nature of enamel primers and adhesives, it is important that the etched enamel remains completely dry and free from contamination before its use. Moisture contamination is believed to be the primary cause of bond failure[8,9] and,

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as such, the need to keep etched enamel surfaces free from moisture contamination makes the process highly technique-sensitive.

Dentine bonding agents were developed in the restorative field to address this problem. This is because bonding to dehydrated dentine (unlike dried enamel) is unsuccessful due to collapse of the collagen framework. Such materials have been used with some success in orthodontic bonding[10,11] and were the forerunners of the moisture-insensitive primers (MIPs). MIPs belong to the fifth generation of bonding systems and contain solvents such as ethanol or acetone, which displace water from the etched enamel porosities, permitting access of the unfilled resin and the formation of resin tags.

Although the in vitro performance of MIP was found to be promising when used in moisture-contaminated conditions,[12–15] they were not as reliable as conventional hydrophobic primers when used under optimal conditions. The sole clinical trial of a prototype MIP concluded that because bond failures after its use were twice as likely as those observed with conventional primers, the product could not be recommended for clinical use.[16] These differing results lead to the conclusion that although there may be some use for MIPs, it is not a viable replacement for a more traditional priming system. A second problem is that MIPs, such as conventional primers, still require an initial etching phase using a separate product. The desire to reduce the number of steps required in orthodontic bonding, while minimizing technique sensitivity because of moisture contamination, has led to the development of self-etching primers (SEPs), the so-called sixth generation or type of bonding agents.[17]

The SEP is an etchant and a primer combined into one solution. The proposed advantages of such a system are the reduction in application time, by combining two steps into one; improved patient comfort, because rinsing is unnecessary; and a reduction in the amount of enamel damage.[18] In vitro investigations into the performance of SEPs have produced varying results.

Several authors have reported that SEPs, when used under ''ideal'' conditions, produce a similar force to debond as observed after conventional acid etching,[19–23] whereas others have found that SEPs gave significantly lower force to debond.[24,25] When tested under contaminated conditions, SEPs have also been shown to produce clinically acceptable bond strengths and performed better than the conventional etch and prime technique.[26–28]

To date, only three clinical trials of SEPs have been published,[29–31] and these tested the performance of Transbond™ Plus SEP. These articles gave contrasting results, with one reporting that the SEP produced less bond failures compared with the conventional technique,[29] whereas the reverse was true with the second trial.[30]

When using SEPs, the manufacturers currently recommend the use of pumice prophylaxis. Because this is a stage that can be safely omitted from the conventional acid-etch technique, it would be advantageous both in terms of clinical time and for patient comfort if it could be shown to be unnecessary when using an SEP.

The purpose of this study was to investigate the effect of pumicing or not pumicing on the in vivo bond failure rates of metal orthodontic brackets after using the self-etching primer First Step (Reliance Orthodontic Products Inc, Itasca, Ill).

MATERIALS AND METHODS

A power calculation determined that 30 patients with 20 orthodontic brackets each would be required to give a power of 0.9 at a significance level of 0.05, assuming that a 13% difference in the bond failure rate would be clinically significant. These patients were to be recruited from the patients randomly assigned for treatment to the operator as part of their postgraduate orthodontic training in Bristol Dental Hospital and the Royal United Hospital, Bath.

All eligible patients who met the inclusion criteria were asked to participate. These criteria included the need for maxillary and mandibular fixed appliances, the teeth showed no clinical signs of fluorosis/hypomineralization or abnormal dental morphology, and the patient had good oral hygiene and had not previously worn fixed appliances.

Local research ethics committee approval was granted before the recruitment began, and once entered into the study, subjects were randomly allocated to one of two groups. Randomization was performed by the subject picking a sealed, unmarked envelope that contained the group name ''odd'' or ''even.'' The split-mouth technique was used; in each patient, the teeth in the maxillary left and mandibular right quadrants received one pretreatment and the teeth in the maxillary right and mandibular left quadrants received the alternate pretreatment. The two pretreatments were that the enamel was either pumiced or not pumiced before the use of an SEP.

At the bond-up appointment, the teeth were isolated with a cheek retractor and a saliva ejector. In the control quadrants, the teeth were polished with a slurry of plain pumice and water, using a rubber cup in a slow contraangle handpiece. In the study quadrants, no pumicing was performed. All quadrants were then washed thoroughly with water and each tooth air-dried for 5 seconds. ''First Step'' SEP was then mixed according to the manufacturer's instructions, applied to

TABLE 1. Distribution of Failure as a Function of Pumice and Time

	Six mo				12 mo			
Treatment	No Fail	Fail	Total	% failure	No Fail	Fail	Total	% failure
No pumice	52	65	117	55.6	40	8	48	16.7
Pumice	80	38	118	32.2	65	8	73	11.0
Total	132	103	235	43.8	105	16	121	13.2

TABLE 2. Odds Ratios (OR), Associated Probability and 95% Confidence Intervals (CI) of the OR Along With the Combined Mantel-Haenszel Estimate (M-H) Controlling for Time[a]

Time	OR	χ^2	*P*	95% CI
Six mo	0.38	12.96	.001	0.22 to 0.65
12 mo	0.62	0.82	.366	0.21 to 1.78
M-H combined	0.42	13.22	.001	0.26 to 0.68

[a] Test of Homogeneity (M-H) $\chi^2 = 0.64$, $P = .424$; test that combined OR = 1: M-H $\chi^2 = 13.22$, $P = .001$.

and agitated on each tooth surface for 10 seconds, and then gently air-dried for 5 seconds each, once again according to the manufacturer's instructions. Transbond™ XT adhesive was applied to the bracket base; the brackets were placed on the teeth and firmly seated using a Mitchell's trimmer. Excess adhesive was removed from around the periphery using a probe, and they were light-cured for 10 seconds per interspace (20 seconds per tooth) with an Optilux 501 curing light (Kerr, 21 Commerce Drive, Danbury, Conn).

The brackets used were mesh-based stainless steel orthodontic brackets (Omni 0.022 inch, GAC International Inc, Bohemia, NY). After band cementation, 0.010-inch stainless steel laceback wires were placed in all four quadrants. The archwire sequence was initially 0.012-inch superelastic nickel titanium, followed as required by 0.016 inch and then 0.017 × 0.025–inch nickel titanium archwires.

To maximize moisture control and standardize all patients, the teeth were bonded in a specific order as follows: first, the upper labial segment followed by the lower labial segment, then the right premolars (uppers then lowers), and finally the left premolars (uppers then lowers).

Any brackets that debonded during treatment were rebonded with Transbond™ XT after conventional acid etching with 37% *o*-phosphoric acid. They were subsequently excluded from the trial. Bond failures were recorded prospectively, as was the adhesive remnant index (ARI).[32] Data on bond failure were collected at 6 and 12 months after appliance placement.

RESULTS

Because it became apparent during the trial that bond failures were very frequent, an interim data analysis was performed. The results of this analysis demonstrated an unacceptably high bond failure rate, and therefore, recruitment to the trial was discontinued after only 14 patients had been entered into it.

The data were analyzed using Stata 8.2 (Stata Corp, College Station, Tex). For all the analyses, the significance was predetermined at $\alpha = 0.05$. The distribution of failure as a function of treatment, namely pumice or no pumice, and time is shown in Table 1. If a bond failed in the first 6-month period, it was subsequently excluded from the analysis.

The data were analyzed in terms of the odds ratio (OR) and associated 95% confidence interval (Table 2). From these results, it can be seen that at the six-month time period, the probability of the OR was 0.38 with a 95% confidence interval of 0.22 to 0.65 and an associated probability of 0.001, indicating there is a significant effect of pumice. In other words, if the enamel is not pumiced before the use of an SEP, there will be significantly more bond failures.

For the 12-month time period, the OR was 0.62 with a 95% confidence interval of 0.21 to 1.78 and probability of 0.366, indicating no significant difference between pumice and no pumice. However, the number of bond failures was relatively low in the second 6-month period, and therefore caution must be exercised in interpreting the results of the 12-month time period.

In addition, if most of the bond failures occurred in the first 6 months, as was the case, the effect of pumice is less likely to be significant in the second 6-month period. Certainly, the bond failure rate for the no-pumice group at 6 months was unacceptably high at 55.5%, and even for the pumice group, it was still very high at 33.2%. For the second 6-month period, the failure rates were 16.7% and 11.0%, respectively, which were still very high, and the difference between the no-pumice and the pumice quadrants was still perhaps clinically, if not statistically, significant.

To test whether there was any effect of time, the two ORs were compared using the ''Test of Homogeneity.'' Because the probability was 0.424, it can be concluded there was no difference between the ORs, and therefore, time had no significant effect on bond failure rate. Using the combined ORs for the two time periods, the Mantel-Haenszel estimate (M-H) shows the ratio to be significantly different from 1 ($P = .001$), which again confirms that pumicing has a significant effect. Therefore, more bond failures will occur if the enamel is not pumiced before the use of a SEP.

The ARI score was recorded for each bond failure at both the 6- and 12-month intervals. All the ARI scores were 0, indicating that the locus of bond failure was at the enamel/adhesive interface in every case.

DISCUSSION

The proposed advantages of SEPs over conventional etching are the reduction in application time by combining two steps into one,[32] a reduction of technique sensitivity, and a decreased amount of enamel damage.[18]

In this study, the overall bond failure rates were unacceptably high at 32.2% for the pumiced group and 55.6% for the not-pumiced group, and it is therefore tempting to dismiss SEPs in favor of a more conventional approach. However, it should be noted that these failure rates are significantly higher than those reported in three previous trials,[29,30,32] all of which used Transbond™ Plus SEP (3M Unitek, Monrovia, Calif.), as opposed to the First Step SEP that was used in this trial. It could therefore be suggested that some SEPs are more clinically reliable than others.

It is also possible that the high failure rates reported were because of operator error. Although manufacturer's recommendations were followed, the operator was at the start of specialist training in orthodontics and therefore, relatively inexperienced at orthodontic bonding. Certainly, higher bond failure rates have previously been reported for relatively inexperienced operators.[33] If this is the case however, it raises the question of technique sensitivity. There is a growing school of thought that SEPs may be more technique-sensitive than first hoped. SEPs do not leave a uniform frosty appearance on the enamel, and so it is difficult to determine whether it is adequately etched. It has also been demonstrated in the laboratory that bond strengths achieved by SEPs may be affected by application time[34] and air-dispersion time.[34–36]

Despite the fact that patient recruitment was discontinued after only 14 subjects had entered the trial, this study demonstrated that the omission of pumice prophylaxis resulted in a statistically significant increased incidence of bond failure. This may go some way to explain the contrasting findings of the three previous clinical trials.[29,30,32] Where prophylaxis was performed before bonding, there was no statistically or clinically significant difference between the conventional etching and the use of an SEP,[29,32] whereas in the trial where prophylaxis was omitted,[30] there was a clinically significant difference between the conventional etching and the use of an SEP, the bond failure rate being twice as high in the SEP group.

Combining the two stages of etching and priming, the enamel has been heralded as a means to save chairside time,[32,37] with White[38] claiming that chairside time can be reduced by up to 65% through the use of such a system, a view upheld by Asgari et al.[29] Because pumice prophylaxis can be omitted in conventional bonding using the acid-etch technique, the fact that it is necessary when using an SEP goes some way to negate the proposed advantage of reducing chairside time, a factor that was not considered by Aljubouri et al.[32] It is also no longer thought necessary to use an unfilled resin primer after conventional acid etching of the enamel and before bracket placement to achieve reliable bonding.[5] This, therefore, further reduces the amount of time saved by instead using a combined SEP solution.

Consideration of the ARI scores showed the locus of bond failure to consistently be at the enamel/adhesive interface, such that no adhesive remained on the enamel surface after bond failure. This would suggest the weak link in the bond is therefore at this interface, which may be related to the ability of the SEP to pretreat the enamel surface before bonding. However, if the bond failure rate after the use of an SEP was clinically acceptable, bond failure at this site would save time during debond.

CONCLUSIONS

- This randomized, cross-mouth clinical trial suggests that the omission of pumice prophylaxis before orthodontic bonding with a SEP has a significant effect, leading to an increased bond failure rate.
- However, with the First Step SEP used in this clinical trial, the observed clinical bond failure rates were still unacceptably high at 33.2%, such that this material cannot be recommended for clinical use.

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