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SCIENTIFIC SECTION

A randomized control clinical trial investigating orthodontic bond failure rates when using Orthosolo universal bond enhancer compared to a conventional bonding primer

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Objective: This study assessed the *in vivo* bond failure rates of orthodontic brackets bonded using Orthosolo universal bond enhancer and compared it with the conventional bonding primer, Transbond XT.

Design: This was a single centre randomized controlled clinical study.

Setting: Department of Child Dental Health, Bristol Dental Hospital, Bristol, UK.

Materials and methods: Thirty-three consecutive patients undergoing fixed orthodontic appliance therapy were included in this study. Using a split-mouth design, diagonally opposite quadrants were randomly allocated a primer, either Orthosolo universal bond enhancer (Ormco, Orange, CA, USA) or Transbond XT primer (3M Unitek, Monrovia, CA, USA). A total of 555 teeth were bonded using a conventional acid-etch technique. 277 received Orthosolo as their primer and 278 received the Transbond XT primer. Bond failures and their positions were recorded at six months.

Results: There was an overall bond failure rate of 1.26%. Four brackets failed in the Orthosolo group (0.72%) and three failed in the Transbond XT group (0.54%).

Conclusion: There was no clinical or statistically significant difference in the *in vivo* bond failure rates between orthodontic brackets bonded using either Orthosolo universal bond enhancer or the conventional Transbond XT primer.

Key words: Bond enhancer, bonding primer, orthodontic bonding, randomized controlled trial

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Introduction

The acid etch technique provides the background for the bonding of orthodontic brackets to enamel,[1] allowing the penetration of low viscosity bonding resins up to a depth of 50 μm, dependent on factors such as acid concentration and etching time.[2] Once polymerized a micro-mechanical bond is established between the bonding resin and enamel. However, for such bonding to take place the enamel must first be etched for 15–30 seconds with 37% orthophosphoric acid, then rinsed with copious water to remove the etchant and finally air dried until a frosted appearance is achieved.[3] A low viscosity resin is then frequently painted onto the etched surface before a more heavily filled resin is used to bond the brackets to the teeth. The low viscosity resin is usually the unfilled bonding agent and its primary purpose is enamel surface penetration to improve the effectiveness of the final bond. Transbond XT primer (3M Unitek, Monrovia, CA, USA) is one such conventional primer and is an unfilled compatible resin containing triethylene glycol dimethacrylate (TEGDMA) and bisphenol A diglycidyl ether methacrylate (BIS-GMA). However, the benefits of conventional priming

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with regard to improved bond strength have been called into question. A retrospective study comparing the retention of fixed appliances bonded with or without a conventional primer showed no significant difference in bond failure rate between the two groups.[4]

More recently, 'adhesion promoters' have been developed which aim to reduce bond failure by the incorporation of hydrophilic monomers and other bond enhancers into a primer. Orthosolo universal bond enhancer (Ormco, Orange, CA, USA) is one such adhesion promoter that can replace the unfilled resin used in light-cured composite adhesive systems. It is a sixth generation bonding resin based on the hydrophilic acrylic HEMA (hydroxyethyl methacrylate) and has been developed from Solo, a product which has applications in restorative dentistry for bonding to both dentine and enamel. Solo differs from Orthosolo chiefly in having a higher ethanol content, and therefore requires assisted evaporation of the ethanol before placement of the filled resin. The primary constituent of Orthosolo is BIS-GMA, the high-molecular-weight resin that is the basis for most composite resin systems, but it also contains a methacrylated phosphoric acid ester. In addition there is a small amount of submicron silica filler which, it is stated, improves both strength and viscosity.[5]

Orthodontic bonding is technique sensitive and moisture contamination, cited as one of the most common reasons for clinical bond failure,[6,7] must be minimized. A recent *in vitro* bond strength study investigating the effect of moisture contamination has shown Orthosolo to be more effective than a conventional primer under such conditions.[5]

It is well known that moisture control in the clinical situation is sometimes less than perfect and this may be related to both operator and patient factors. Any bonding material that is therefore less moisture sensitive under clinical conditions may help reduce in service bond failure rates. This in turn will reduce chairside time, the overall length of treatment, and have an economic impact on clinical practice.[8]

Previous studies have determined the overall failure rate of orthodontic brackets using conventional Transbond XT primer and composite to be between 6 and 7%.[9,10]

The aim of this study was to investigate the *in vivo* bond failure rates of the orthodontic bonding primer resin, Orthosolo universal bond enhancer, and to compare it with the conventional bonding primer Transbond XT.

The following hypothesis was tested:

there is no statistically significant difference in the *in vivo* bond failure rate between Orthosolo orthodontic universal bond enhancer and Transbond XT conventional primer when used to bond brackets to teeth.

Material and methods

Thirty-three consecutive patients attending the Orthodontic Department at Bristol Dental Hospital were enrolled in the study, 14 male and 19 female. Their ages ranged from 13 to 45 years of age. All patients were treated with GAC Omni brackets with 0.022×0.028-inch slot dimensions in an MBT prescription.

A power calculation had determined that to have adequate power (80%), to show a statistically significant difference ($P<0.05$) in proportions with at least one failed bracket after six months, the study required 33 patients in each group using a log rank test ignoring the matching. This assumes a difference of 35 percentage points (45% versus 80% with a hazard ratio of 3.6). As an approximate allowance for the effect of matching, an estimated 33 patients in total were required.[10] No adjustment was made for clustering of teeth within patients. A split mouth study design was used. Analysis of failure was to be carried out at 'bracket level' (based on individual brackets rather than patients).

Inclusion criteria

- All patients were eligible if they were to receive upper and lower fixed appliances as part of their treatment.
- Orthognathic cases were included in the trial.
- Consented to take part in the trial.

Exclusion criteria

- Any patient who had more than one tooth missing in each quadrant.
- Any patient who had received functional appliance treatment before the commencement of fixed orthodontic treatment.
- Any patient who had impacted teeth, or unerupted teeth at the start of treatment.

Local research ethics committee approval was obtained before the recruitment of participants (Central and South Bristol Local Research Ethics Committee, Study No. DE/2004/1778). All subjects eligible for inclusion were provided with information leaflets describing the purpose of the trial and given the opportunity to ask the researcher questions. Those patients willing to participate gave their written consent. Treatment commenced within six weeks of recruitment. The recruitment period was between January and July 2006.

One clinician (NW) treated all 33 patients. The bonding protocol for each patient followed a contralateral

pattern to eliminate operator bias (Table 1). One quadrant was selected randomly to receive the Orthosolo universal bonding primer together with the contralateral quadrant in the opposing arch. The teeth in the other two quadrants were selected to receive the conventional Transbond XT primer.

Subjects were unaware of the primer used for each quadrant of the mouth, although the operator was able to distinguish between the primers due to the difference in their appearance and consistency. Patients were randomly allocated using random number tables with permuted blocks to ensure parity between the numbers in each group.

All teeth were pumiced for five seconds per tooth irrespective of the primer to be used. This was performed using a slurry of pumice in water and a slow speed hand piece with a rubber polishing cup. Following pumicing the teeth were washed, dried and isolated using retractors. Thirty-seven per cent orthophosphoric was applied to each tooth for 15 seconds, followed by rinsing with copious amounts of water and then dried until the enamel was frosted white in appearance. Both primers were then applied to the etched enamel according to the manufacturer's instructions.

The light-cured filled composite Transbond XT was then applied to the bracket base of each bracket irrespective of the primer used. The brackets (Omni 0.022×0.028-inch GAC International Inc., Bohemia, NY, USA; MBT bracket prescription) were placed firmly onto the teeth, and the excess composite removed using a Mitchell's trimmer. The composite was then light cured for 20 seconds per tooth using a halogen curing lamp (Ortholux, 3M Unitek, Monrovia, CA, USA). The light was tested using the unit's in-built radiometer before each bond-up appointment in order to ensure a consistent light intensity.

The failure rate of molar bonds or bands was not included in the study. The archwire sequence was individual to the needs for each patient. Any brackets that failed were rebonded following conventional acid etching of the enamel and Transbond XT primer and subsequently excluded from the trial. Data on bond failure rate were collected for the six months following bracket placement. However, no attempt was made to assess the Adhesive Remnant Index (ARI) as multiple operators were likely to see patients as casuals when a bracket debonded, leading to problems of standardization.

All the patients received the standard intervention as allocated and were followed up initially for six months. A CONSORT diagram showing the flow of patients through each stage of the trial is shown in Figure 1.

Results

Thirty-three patients fulfilled the inclusion criteria and were initially entered into the study. However, one patient subsequently withdrew due to relocation overseas, and so a total of 32 patients completed the trial.

The primers were randomly allocated to all 32 patients according to the split-mouth design. In total 555 brackets were bonded, 277 in the Orthosolo group and 278 in the Transbond XT group. The distribution of bond failures for each primer and the time and location of bond failures are illustrated in Tables 1 and 2. It can be seen that four brackets failed in the Orthosolo group and three in the Transbond XT group during the six month study period. It had been intended to perform a Kaplan–Meier survival analysis but the low bond failure rate deemed this inappropriate. Statistical advice was sought and it was decided that although it would be possible to perform a McNemar's test, the difference between the two primers would clearly not be significant. This very low bond failure rate, therefore, precluded formal statistical analysis.

There was no readily identifiable pattern in the distribution of bond failures within the mouth. Six failures occurred in male patients and only one in the female group.

Discussion

From the results of this randomized controlled clinical trial it is evident that there was no clinical or statistically significance differences observed in the bond failure rate when comparing Orthosolo and Transbond XT primer in the bonding of orthodontic brackets. The bond failure rates of both Orthosolo and Transbond XT (0.72

Table 1 Distribution of bond failures during the 6-month study period.

	No. of patients with at least one failure	Percentage patients with at least one failure	Total no. of bonds	No. of bonds failed	Overall percentage failure rate of all bonds
Orthosolo	4	12.5%	277	4	0.72%
Transbond XT	3	9.36%	278	3	0.54%

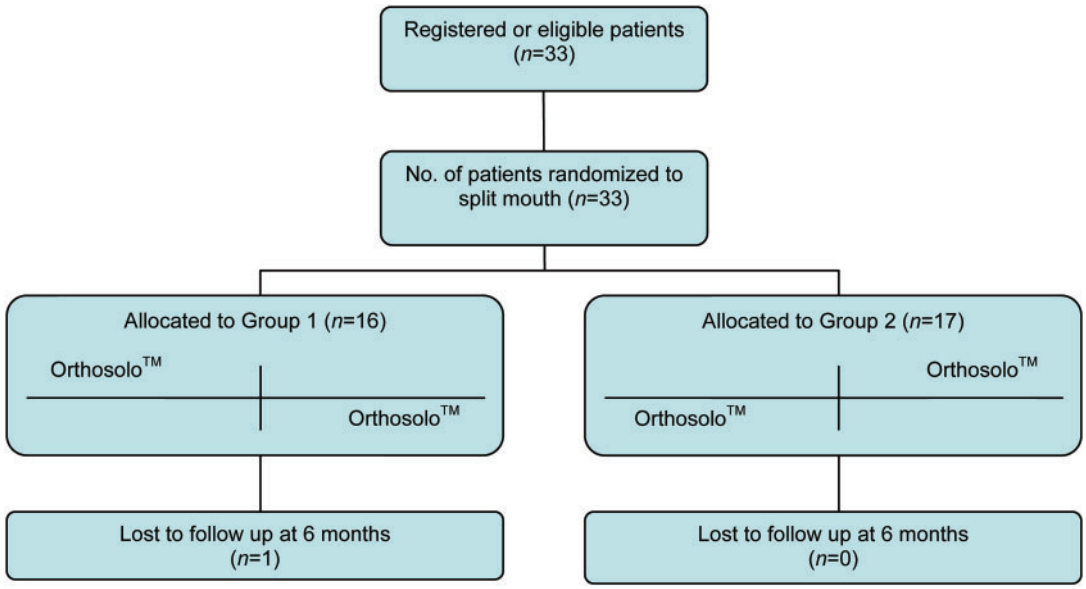

Figure 1 Profile of randomized control trial

and 0.54% respectively) were very low during the six-month study period.

Strengths of the study

The design of the trial was established to eliminate as many factors as possible that could introduce bias. The use of only one operator reduced the chance of experimental bias, although it was not possible to blind the operator as to the primer being used due to differences in colour and consistency. However, it is unlikely this would have any effect in the longer term. The use of a split mouth study design allows the patient to act as a self control. By the very nature of *in vivo* fixed appliance therapy, teeth are connected together by the archwire and as such each bond cannot be viewed as being truly independent.[11] The bracket failure on one tooth may affect the integrity of the bond of adjacent teeth. Nevertheless each patient acted as a self control and the same conditions applied to both experimental groups. From the results in Table 2, it can be seen that no two adjacent brackets failed within the study period and this lack of true independence is perhaps more hypothetical than practical in nature. Confirmation of this will be evident at the completion of treatment.

Table 2 Time and location of bond failure for the 7 brackets that failed during the 6-month study period.

Primer	Time to failure, days	Tooth (FDI notation)
Orthosolo	10	12
Orthosolo	28	22
Orthosolo	38	25
Orthosolo	42	43
Transbond XT	46	43
Transbond XT	84	41
Transbond XT	85	41

Weaknesses of the study

The observation period of this study was set at six months, which was chosen as a result of the findings of a number of previous *in vivo* bonding studies. O'Brien *et al.* found that 82% of bond failures occurred within the first six months of their study,[12] while Aljubouri *et al.* found that both the overall and mean bond failure rates per patient were not statistically or clinically significant between 6 months and 12 months of active treatment.[13] Indeed Choo *et al.* concluded that there was no effect of time in bond failure rate with there being no clinically or statistically significant differences in the bond failure rates at 6 months and 12 months.[14] Manning *et al.* did, however, find an increase in bond failure from the 6 month stage and the completion of treatment but it was still low at 7.4 and 7.0% respectively in their comparison groups.[15] It should be noted that recent recommendations have been made that bonding studies should be followed up until the end of fixed appliance therapy in an effort to add strength to future research in this field.[16,17]

Context and implications for clinical practice

It has previously been reported that a mean bond strength of 6–8 MPa is necessary for the effective clinical bonding of orthodontic brackets.[18] A recent *in vitro* study demonstrated that with Transbond XT filled composite bonding material a mean shear bond strength of 12.27 MPa was obtained when used with Transbond XT primer and compared to a mean bond strength of 14.52 MPa when used with Orthosolo universal bond enhancer.[19] Although both materials tested showed clinically adequate bond strengths, the *in vitro* increased mean bond strength seen when using Orthosolo has been suggested as a way of reducing *in vivo* bond failure rates during clinical practice. In addition a further *in vitro* study found that even with total saliva contamination, Orthosolo performed at least as well as conventional primers used in a dry state.[5] Therefore, Orthosolo may have advantages in areas of moisture contamination during *in vivo* bonding. Although the results of this present *in vivo* study would suggest this is not the case, the use of Orthosolo may be more important in the case of partially erupted teeth, e.g. second molars and where moisture control might be more difficult.[5]

Previous *in vivo* studies have determined the overall bond failure rate of orthodontic brackets bonded using conventional Transbond XT primer and composite to be between 6 and 7%.[10,11] The observed failure in this study of only 1.26% at six months, irrespective of the primer used in the bonding process was probably due to the operator rather than just due to the materials used.

Conclusions

- The results of this randomized control clinical trial showed there to be no clinically or statistically significant differences in the *in vivo* bond failure rates of orthodontic brackets bonded using either Orthosolo universal bond enhancer, or the conventional Transbond XT primer.
- The low bond failure rates observed would suggest both primers may be used with confidence in the clinical setting.

Contributors

Nick Wenger was responsible for patient recruitment, carried out the clinical study, and collated the results. Scott Deacon obtained ethical approval. Nigel Harradine was lead investigator and guarantor for the paper and research. Statistical advice was provided by Paul Ewings.

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References

1. Buonocore MG. A simple method of increasing the adhesion of acrylic filling materials to enamel surfaces. *J Dent Res* 1955; **34:** 849–53.
2. Bishara SE, Vonwald L, Laffon JF, Jacobsen JR. Effect of altering the type of enamel conditioner on the shear bond strength of a resin-reinforced glass ionomer adhesive. *Am J Orthod Dentofacial Orthop* 2000; **118:** 288–94.
3. Gange P. Paul Gange on the present state of bonding. Interview by Homer W. Phillips. *J Clin Orthod* 1995; **29:** 429–36.
4. Tang AT, Björkman L, Lindbäck KF, Andlin-Sobocki A, Ekstrand J. Retrospective study of orthodontic bonding without liquid resin. *Am J Orthod Dentofacial Orthop* 2000; **118:** 300–6.
5. Swartz M. Bond strength of a universal orthodontic bonding agent. *Ormco Clinical Impressions* 2005; **14:** 14–16.
6. Kinch AP, Taylor H, Warltier R, Oliver R, Newcombe RG. A Clinical trial comparing the failure rates of directly bonded brackets using etch times of 15 or 60 seconds. *Am J Orthod Dentofacial Orthop* 1988; **94:** 476–83.
7. Wang WN, Lu TC. Bond strengths with various etching times on young permanent teeth. *Am J Orthod Dentofacial Orthop* 1991; **100:** 72–79.
8. Northrup RG, Berzins DW, Bradley TG, Schuckit W. Shear bond strength comparison between two orthodontic adhesive and self-ligating and conventional brackets. *Angle Orthod* 2007; **77:** 701–6.
9. Millett DT, Hallgren A, Cattanach D, McFadzean R, Pattison J, Robertson M, Love J. A 5-year clinical review of bond failure with a light-cured resin adhesive. *Angle Orthod* 1998; **68:** 351–56.
10. Littlewood SJ, Mitchell L, Greenwood DC. A randomized controlled trial to investigate bracket bonded with a hydrophilic primer. *J Orthod*; 2001; **28:** 301–5.
11. House K, Ireland AJ, Sherriff M. An investigation into the use of a single component self-etching primer adhesive system for orthodontic bonding: a randomized controlled clinical trial. *J Orthod* 2006; **33:** 38–44.
12. O'Brien KD, Read MJ, Sandison RJ, Roberts CT. A visible light-activated direct-bonding material: an in-vivo comparative study. *Am J Orthod Dentofacial Orthop* 1989; **95:** 348–51.
13. Aljubouri YD, Millett DT, Gilmour WH. Six and 12 months' evaluation of a self-etching primer versus two-stage etch and prime for orthodontic bonding: a randomized clinical trial. *Eur J Orthod* 2004; **26:** 565–71.

14. Choo SC, Ireland AJ, Sherriff M. An *in vivo* investigation into the use of resin-modified glass poly(alkenoate) cements as orthodontic bonding agents. *Eur J Orthod* 2001; **23:** 403–9.
15. Manning N. Chadwick SM, Plunkett D, Macfarlane TV. A randomized clinical trial comparing 'one-step' and 'two-step' orthodontic bonding systems. *J Orthod* 2006; **33:** 276–83.
16. Mandall NA, Millet DT, Mattick CR, Hickman J, Worthington HV, Macfarlane TV. Orthodontic adhesives: a systematic review. *J Orthod* 2002; **29:** 205–10.
17. Mandall NA, Millet DT, Mattick CR, Hickman J, Macfarlane TV, Worthington HV. Adhesives for fixed orthodontic brackets. *Cochrane Database Syst Rev* 2003; **(2):** CD002282.
18. Reynolds IR. A review of orthodontic bonding. *Br J Orthod* 1975; **2:** 171–78.
19. Vicente A, Bravo LA, Romero M, Ortiz AJ, Canteras M. Effects of 3 adhesion promoters on the shear bond strength of orthodontic brackets: an in-vitro study. *Am J Orthod Dentofacial Orthop* 2006; **129:** 390–95.