ORIGINAL ARTICLE

In-vivo prospective comparison of bond failure rates of 2 self-etching primer/adhesive systems

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Introduction: The purpose of this study was to comparatively assess the bond failure rates of orthodontic brackets bonded with 2 self-etching primer (SEP) bonding systems over an 18-month period. **Methods:** Thirty-six consecutively treated orthodontic patients were bonded with Transbond Plus SEP with Transbond XT adhesive (3M Unitek, Monrovia, Calif) and with Ideal 1 SEP with Ideal 1 adhesive (GAC International, Bohemia, NY). In each patient, the teeth were divided into 2 groups based on the universal numbering system (1-32). All even-numbered teeth (340) were bonded with the Transbond system, and all odd-numbered teeth (340) were bonded with the Ideal 1 system. A total of 680 teeth were bonded and followed for a minimum of 18 months. **Results:** The average percentages of bond failures were 12.4% and 4.1% in the teeth treated with Ideal 1 and Transbond Plus, respectively ($P < .001$), for a difference of 8.4 percentage points (95% CI, 4.2 to 12.6 percentage points). **Conclusions:** Because the bond failure rate with the Transbond Plus SEP system was one third that of the Ideal 1 SEP system, Transbond Plus appears to be a better choice for routine orthodontic clinical practices. (Am J Orthod Dentofacial Orthop 2007;132:671-4)

In contemporary orthodontic practice, obtaining a reliable adhesive bond between orthodontic brackets and tooth enamel is essential. Conventional bonding of brackets involves 4 distinct stages. First, the enamel is polished with a slurry of pumice with a slow-speed handpiece. The enamel is then conditioned with phosphoric acid for 15 to 30 seconds, followed by adequate rinsing with water and air drying until the enamel surface has a frosty appearance. The fourth stage involves applying an enamel primer (unfilled resin sealant) to the etched surface. The composite adhesive is added to the base of the bracket and placed on the tooth, followed by light-curing of the adhesive. The need for each of these tedious steps has been questioned in recent studies. Some authors reported that pumicing might be unnecessary because it has no effect on the in-vivo bond failure rate when conventional acid etching is used for bonding.[1,2] Another study also questioned the use of a primer when it was found that a primer had no effect on measured bond strengths.[3] This finding was obtained in a controlled laboratory setting and to date has not been repeated in vivo. Although pumicing and a primer might be unnecessary, the use of an acid conditioning agent is imperative for effective enamel bonding. A minimum etch time of 30 seconds per tooth has been suggested.[2] The etching, rinsing, and drying stage can be tedious and difficult for both patient and operator because of the need for a dry etched enamel surface, free of salivary contamination.

The recent introduction of self-etching primers (SEPs) appears to offer substantial advantages over conventional systems. Combining the etching and priming stages and eliminating the rinsing stage should allow for more efficient bonding procedures and improved patient comfort. If the bond failure rates of SEPs are comparable with conventional 2-step etching and priming, then the reduced chair time should make the self-etching primers more cost-effective. Several articles reported similar bond failure rates between conventionally bonded brackets and those bonded with SEPs.[4-7]

SEPs were recently reported to save 10.2 seconds per tooth, for a total of 204 seconds (3.4 minutes) when bonding 20 teeth.[7] The benefits of fewer bonding steps and less chair time should be weighed against the increased cost of SEPs. Another recently reported advantage of SEPs is a more conservative etch pattern than traditional phosphoric acid etching, thereby reducing enamel loss.[8]

The clinical success of SEPs has prompted many product suppliers to market proprietary systems to

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orthodontists. Currently, most orthodontic supply companies offer these bonding systems, but many of them are being marketed without adequate peer-reviewed published data to support their clinical efficacy. A commonly studied SEP is Transbond Plus (3M Unitek, Monrovia, Calif), which has been shown to provide clinically acceptable bond strengths when used with Transbond XT adhesive. This system uses 2 liquids that must be mixed before use. Transbond Plus SEP contains methacrylated phosphoric acid esters with no volatile organic solvent and a pH of 1.0.[9] The calcium in the enamel is dissolved and removed from hydroxylapatite by the phosphate group of the methacrylated phosphoric acid ester. Instead of rinsing the calcium away, it forms a complex with the phosphate group that is incorporated into the network when the primer polymerizes. Three processes serve to stop the etching process on enamel. First, the acid groups attached to the etching monomer are neutralized by forming a complex with calcium from the hydroxlapatite. Second, the air burst drives the solvent from the primer, increasing the viscosity and slowing the transport of acid groups to the enamel surface. Finally, as the primer is light cured and the monomers are polymerized, the transport of acid groups to the enamel surface is stopped.[10]

Ideal 1 (GAC, Bohemia, NY), a relatively new no-mix SEP/adhesive system, is composed of 2-hydroxyethylmethacrylate and a polymerization accelerator. The recommended composite adhesive to be used with it is Ideal 1 adhesive. One study showed similar shear bond strengths between Ideal 1 and Transbond Plus SEP/adhesive systems, but the results were obtained in a controlled laboratory environment.[11] When we began this study, no published in-vivo studies had evaluated this system or compared it with the Transbond Plus system with regard to bond failure rate. Clinical bond failure studies are the only means of obtaining clinically relevant data for evaluating new products. The purposes of this prospective in-vivo study were to assess each product and to compare the clinical bond failure rates of orthodontic brackets bonded with the 2 SEP /adhesive systems over an 18-month period.

MATERIAL AND METHODS

Approval of clinical protocols by an institutional review board was received before the study. Thirty-six consecutive patients attending the orthodontic department at Albert Einstein Medical Center in Philadelphia took part in this clinical trial. Of the 36 patients receiving treatment, 20 (56%) were female and 16 (44%) were male. The average patient age was 13.5 years (range, 10.6-17.75 years). Both extraction and nonextraction patients participated. Extraction patients were included only if the extraction patterns were symmetrical to balance the number of teeth in each bonding regimen. With the universal numbering system, all even-numbered teeth received Transbond Plus SEP/adhesive system (control group), and all odd-numbered teeth received Ideal 1 SEP/adhesive system (experimental group). As opposed to a split-mouth design, this study design evenly dispersed each product between the right and the left sides in each arch. This helped to reduce any bias because of patient chewing or parafunctional preferences. Also, it allowed the pairing of contralateral teeth for direct comparison according to tooth type. Teeth included in the study were the maxillary and mandibular central incisors, lateral incisors, canines, first premolars, and second premolars. Exclusion criteria were as follows: (1) teeth with porcelain or metal crowns, (2) teeth with composite at the bonding surface, (3) teeth not fully erupted, (4) teeth scheduled for extraction, and (5) teeth requiring repositioning of the brackets early in orthodontic treatment. A total of 680 teeth were bonded in the study.

All appliances were bonded by 1 operator (A.P.). Stainless steel 0.018-in Mini Diamond brackets (Ormco, Orange, Calif) with a standard Roth prescription were used. All teeth were isolated and cleaned with pumice and a rubber cup for 10 seconds and then rinsed with water. The brackets were bonded to the teeth by using 1 of 2 protocols, strictly according to each manufacturer's instructions. For the Transbond Plus group, the SEP components were mixed and rubbed onto the enamel for 5 seconds followed by air drying for 1 to 2 seconds. The brackets were then bonded with Transbond XT adhesive paste and light cured for 40 seconds per tooth (20 seconds on the mesial and 20 seconds on distal aspects) with a halogen curing light (Ortholux; 3M Unitek). For the Ideal 1 group, the SEP has 1 component that does not need to be mixed before use. The primer was rubbed onto the enamel for 5 seconds and left for 30 seconds. This was followed by air drying the surface for 1 to 2 seconds. The bracket was then bonded with Ideal 1 adhesive paste and light cured in the same fashion as the Transbond Plus group.

All teeth receiving both materials were kept isolated for another 3 minutes after curing, and archwires were not placed until at least 10 minutes after bonding. Any brackets that debonded during treatment were recorded and rebonded. Although initial bracket bond failure was counted, rebond failures were excluded from the study. Data on bond failures were collected for the first 18 months of active orthodontic treatment.

Table. Bond failure occurrence

Material	*Teeth (n)*	*Failures (n)*	*Failures (%)*
Ideal 1 SEP	340	42	12.4*
Transbond Plus SEP	340	14	4.1*

*$P < .001$.

Statistical analysis

For each tooth that received Ideal 1 SEP, the contralateral tooth received Transbond Plus SEP. We compared the average bracket failure rates (percentages) of the 2 SEP systems using paired *t* tests (pairing contralateral teeth). In addition, we provided the average of the differences between the percentages of bond failure (for contralateral teeth) and a 95% CI of that average difference. All statistical tests were 2 sided. Statistical analyses were performed with software (version 10; SPSS, Chicago, Ill).

RESULTS

The bond failure rates of the 2 systems are given in the Table. Over the 18 months, the Ideal 1 SEP system had a mean bond failure rate of 12.4% (95% CI, 8.7% to 16.2%), and the Transbond Plus SEP system had a bond failure rate of 4.1% (95%CI, 1.6% to 6.4%). There was an 8.4 percentage point (95% CI, 4.2 to 12.6) advantage for the Transbond Plus SEP system ($P <$ .001). With one-third the bond failure rate, the Transbond system has a clinically important and statistically significant advantage over Ideal 1.

DISCUSSION

The aim of this in-vivo prospective clinical study was to evaluate the bond failure rates of 2 SEP systems to obtain clinically relevant results for the practicing orthodontist. The findings indicate that the Transbond Plus SEP system had statistically significantly fewer bracket bond failures than the Ideal 1 SEP system over an 18-month period (4.1% and 12.4%, respectively). This great advantage for Transbond Plus is clinically significant also; rebonding bracket failures in a private practice is undesirable because it is a costly and time-consuming process. The long-term monitoring of 18 months increases the clinical relevancy of the findings because all patients progressed with treatment to the point that most treatment mechanics were completed, and rectangular stainless steel archwires were in place.

Direct bonding of orthodontic brackets has advanced and streamlined the clinical practice of modern orthodontics. However, there is still a need to improve current bonding procedures. Reducing clinical chair time, without compromising bracket bond strength, would be a desirable improvement to current bonding systems. This reduction of chair time is the suggested advantage of SEPs.[7] Traditionally, the use of an acid etch followed by a primer was an essential step in the bonding process to allow good wetting and penetration of the sealant into the prepared enamel surface.[12] SEPs are believed to simplify the clinical bonding process by combining the etchant and the primer in 1 application, thereby reducing the number of steps in the bonding procedure and the potential for contamination during the bonding procedure.[7] SEPs have also been shown to be less technique sensitive than conventional phosphoric acid etching.[13]

The intent of this study was to compare these 2 proprietary bonding systems as they were designed to be used by each manufacturer and as they would likely be used in clinical practice. We compared 2 complete bonding systems—2 SEPs and 2 adhesives. When a bond failure rate is high, such as in the Ideal 1 SEP system, it is uncertain whether the problem stems from the SEP, the adhesive, or both. Future studies can be designed to evaluate this issue.

Bond failure rates obtained by in-vitro studies might not mirror the real world of clinical practice. Most studies are conducted in vitro and use shear/peel or tensile forces to evaluate bond strength. Sunna and Rock[14] found that in-vitro bond strengths had no correlation with clinical bond failure rates. One explanation might be that brackets bonded to teeth undergoing orthodontic treatment are subjected to many different forces (eg, torque, shear, tensile) and might be subjected to more than 1 type simultaneously. Conversely, in-vitro studies test only pure shear or pure tensile forces independently; this might not accurately represent the intraoral environment. Ultimately, the in-vivo bond failure rate will determine the usefulness of a particular bonding system, and caution should be used when inferences are made from in-vitro bonding studies. To date, published reports on the in-vivo efficacy of SEPs for orthodontic bonding are limited.

CONCLUSIONS

When choosing a SEP bonding system, clinicians should be aware that the bond failure rates are not always equivalent. The results of this prospective in-vivo clinical trial indicate that the Ideal 1 SEP bonding system had 3 times as many bracket failures as the Transbond Plus SEP bonding system. Clinical efficiency is paramount for a successfully managed orthodontic practice, and clinicians should consider the many associated costs of bracket failures (chair time, material costs) when choosing bonding systems.

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