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In-Vitro Comparison of Two Self Etching Primers as part of an Indirect Bonding Method

(Spine Title: Self Etching Primers as part of an Indirect Bonding Method) (Thesis Format: Monograph)

by

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Submitted in partial fulfillment of the requirements for the degree of Master of Clinical Dentistry

School of Graduate and Postdoctoral Studies The University of Western Ontario London, Ontario February 2011

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In-Vitro Comparison of Two Self Etching Primers as part of an Indirect Bonding Method

> is accepted in partial fulfillment of the requirements for the degree of Master of Clinical Dentistry

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ABSTRACT

The purpose of this in-vitro study was to investigate the shear peel bond strength (SPBS), incidence of immediate bond failure, enamel fracture and adhesive remnant index (ARI) for two different self-etching primer systems^{3,4} compared to both a directly bonded separate etch and prime control as well as an indirectly bonded separate etch and prime control ^{1,2}.

One hundred ninety-two human bicuspid teeth were arranged to duplicate human archforms, with four arches of twelve teeth per group. The teeth were etched, bonded and stored for 100 days at 37°C, thermocycled and subsequently debonded with an Instron universal testing machine.

All adhesive groups demonstrated sufficient mean *in-vitro* bond strength values of 13.3 MPa¹, 11.2 MPa³, 10.5 MPa² and 10.0 MPa⁴. ANOVA showed a statistically significant difference (p<0.05) among the four adhesive groups. The Tukey-Kramer test found that the directly bonded separate etch and primer group had a significantly higher bond strength compared to the other three groups. Three bond failures were noted upon transfer tray removal, all in the indirectly bonded Reliance self-etching primer group. ARI scores revealed that for two thirds of all the teeth some amount of composite remained on the tooth. The highest incidence of enamel fracture occurred in the directly bonded separate etch and prime group.

¹ Direct (37% phosphoric acid, MIP, APC adhesive)

²Indirect (37% phosphoric acid, MIP, APC adhesive)

³ Indirect (Transbond Plus Self-Etching primer, APC adhesive)

⁴ Indirect (Reliance Self-Etching Primer, APC adhesive)

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INTRODUCTION

Successful orthodontic treatment includes successful bonding¹. Self-etching primers and indirect bonding have been individually shown to optimize patient and doctor time, improve patient comfort, and result in clinically acceptable bond strength ¹⁻¹⁴. Combined together, self-etching primer (SEP) and indirect bonding may provide the clinician with a method to further increase bonding effectiveness and efficiency^{2,6,15,16}. To date, no study has assessed self-etching primers as part of an indirect bonding technique.

Newman introduced Buonocore's acid etch (AE) technique to orthodontics in $1965^{17,18}$, using three components to bond brackets: an enamel conditioner, a primer solution and an adhesive resin⁵⁻⁷. SEP's, combining the first two components, were initially developed for dentin bonding in restorative dentistry, and then brought to orthodontics when the bond to enamel was found to also be effective^{2,6,17,18}. In the AE technique, water lavage arrests the etching process, while with SEP, etching is thought to be self limiting for three reasons: 1) the acidic primer forms a neutralizing complex with Ca²⁺, 2) when air is used to blow off the solvent, viscosity increases and slows diffusion of any remaining active acidic groups towards the enamel, and 3) when the primer is polymerized by light, any remaining acid is trapped^{6,19-21}.

Advantages to SEP's include a reduction in the number of steps and chair time, and a simplification of the process, thus reducing technical errors^{2,6,7-9}. Bonding with SEP is significantly faster than with AE, and using SEP reduces risk of contamination since there is no rinse and dry step²²⁻²⁷. The shallower etch pattern produced by SEP's may lead to less enamel damage during bracket debonding²⁵. Disadvantages to SEP's are cost, greater difficulty removing excess composite, and residual acid seeping into the oral cavity²¹.

Loss of enamel can occur when debonding leading to at minimum, a rougher enamel surface to which plaque can adhere, and at maximum, a clinically significant loss of enamel^{2,28, 29, 62}. Increased enamel fracture and cracking may occur with the AE technique^{8,9,30-32}. The Adhesive Remnant Index (ARI) classifies the location of bond failure, and is also used to assess risk of enamel damage^{7,33}. A bond failure at the bracket-adhesive interface or within the adhesive is safer, while failure at the enameladhesive interface may carry a greater risk of enamel fracture ^{2,7,34}. A "clean separation" would be ideal – occurring at the enamel adhesive interface, leaving no adhesive to clean and no enamel damage³⁵. Any failure at the enamel-adhesive interface however, results in some enamel loss due to the micro mechanical bond present^{29,34}.

Despite its advantages, SEP must have sufficient bond strength to last the duration of treatment. Compared to an AE technique, results indicate certain restorative SEP's to have statistically significant lower, but clinically acceptable bond strengths, while other restorative SEP's result in significantly lower, clinically unacceptable bond strengths^{8,9}. Korbmacher *et al* found one restorative SEP to have significantly higher, clinically acceptable bond strength compared to an AE technique³⁶. Various *orthodontic* SEP's have been found to have higher^{24,37-39}, lower^{40,41} and equivalent^{22,23, 30,42} *in vivo* bond failure rates compared to an AE technique. *In vitro* studies have shown bond strengths for orthodontic SEP's to be clinically acceptable^{2,8,43}, higher³², or lower⁹ than bond strength values achieved with an AE technique.

In indirect bonding, brackets are positioned on stone casts with composite to form a customized base^{4,45-47}. A transfer tray is then fabricated to transport the brackets from

the cast to the mouth, and another adhesive is used to bond the brackets to the teeth^{4,47}. The amount of adhesive needed during bonding is small due to the custom base⁴⁴, and this thin layer maximizes bond strength¹¹. Advantages include decreased chair time during bonding, less patient discomfort (shorter appointment), improved vision and access to bond posterior teeth, accurate bracket positioning, healthier ergonomics, and ability to delegate initial bracket set up ^{4,5,10-14, 47,48}. Improved accuracy may only be in the vertical dimension⁴⁹. Disadvantages to indirect bonding include increased lab time, technique sensitivity and increased lab material costs^{4,10,16,48}.

Multiple variations of 1) custom base material, 2) tray material, and 3) adhesive systems have been attempted in order to reduce bond failure rate^{4, 11-14,46-49,51-55}. Materials to hold brackets to models (thermal cure resin, light cure resin), tray materials (vacuform acrylic shells, poly vinyl siloxanes, double trays), and adhesive bonding materials (cement, chemical cure resin, light cure resin) have all been used^{4,6,10-14}. Most methods of indirect bonding produce clinically acceptable bond strength *in vitro*, and clinically acceptable bond failure rates *in vivo*^{10-14, 48, 50}.

Although, Silverman *et al* described using a light cured material in the original technique, using light cured (LC) adhesives did not become popular until the 1990's. Advantages of an LC adhesive include longer working time during bracket placement, less curing time during bonding^{4,51}, and a reduction in voids while maintaining the viscosity required to stay on the bracket before the tray is seated^{4,51}. A disadvantage of a LC adhesive is that it is cured by ambient light, and the thermal cure custom base method was designed to correct this problem^{4,47,52}. Several clinical reports describe a protocol using a LC custom base with LC adhesive^{51,53}, but little bond strength data can be found in the literature for this method. One group has shown no difference in bond strength

between a directly bonded LC adhesive group and an indirect LC custom base/adhesive group^{13,14}. *In vivo*, Read *et al* reported bond failure for this method to be acceptable and similar to a directly bonded control⁵⁰.

Study Objectives

The purpose of this *in vitro* study was to evaluate the shear peel bond strength (SPBS), incidence of immediate bond failure, adhesive remnant index, and incidence of enamel fracture for four different bonding adhesive systems: acid etch + primer directly bonded (AED), acid etch + primer indirectly bonded (AEI), Transbond Plus Self Etching Primer^a indirectly bonded (TSEPI), and Reliance Self Etching Primer^b (RSEPI) indirectly bonded.

Null hypotheses:

1. There is no difference in shear peel bond strength between brackets bonded indirectly using the conventional acid etch technique and brackets bonded indirectly using a selfetching primer technique (TPSEP or RSEP).

2. There is no difference in shear peel bond strength of brackets bonded using a direct or indirect bonding method.

^{° 3}M Unitek, Monrovia Ca

^b Reliance Orthodontic Products, Itasca II

MATERIALS AND METHODS

Sample

One hundred and ninety-two extracted human bicuspid teeth without restorations, caries or visible enamel defects were collected and stored in de-ionized water with thymol crystals (1%) to inhibit bacterial growth. The teeth were numbered from 1 to 192 on the lingual surface with an indelible marker. Based on mean bond strengths and standard deviations from a previous *in-vitro* indirect bonding study⁵⁷, a sample size of at least 38 teeth per group was required in order to detect at least a 20% difference in bond strength with 80% power (α = 0.05). Each tooth was then randomly assigned to one of sixteen arch forms.

The teeth were arranged in simulated uniform human arch forms of 12 teeth per arch using orthodontic acrylic^a. Only the roots of the teeth were submerged in acrylic, leaving the entire crown surface exposed for subsequent bonding. The arch forms were then randomly assigned to one of four bonding groups (AED - acid etch directly bonded^b, AEI - acid etch indirectly bonded^c, TSEPI - self etching primer (Transbond Plus) indirectly bonded^d and RSEPI - self etching primer (Reliance) indirectly bonded^e).

Indirect Bonding Groups

Impressions^f were taken of the arch forms in the AEI, TSEPI and RSEPI groups and models were poured five minutes afterwards with Type IV dental stone^g. Two coats

^a Forestadent Acrylic, Forestadent, Pforzheim, Germany

^b Direct AE (35% phosphoric acid, MIP primer, APC adhesive), 3M Unitek, Monrovia CA

^c Indirect AE (35% phosphoric acid, MIP primer, APC adhesive), 3M Unitek, Monrovia CA

^d Indirect SEP (Transbond Plus Self Etching Primer, APC adhesive), 3M Unitek, Monrovia CA

[•] Indirect SEP (Reliance Self Etching Primer), Reliance Orthodontic Products, Itasca IL with APC adhesive 3M Unitek Monrovia CA

Ar C dunesive SM Uniter Monitovia CA

^t Kromopan 100 alginate, Cerum Dental Supplies, Calgary, AB

Silky Rock Dental Stone, Whip Mix Corporation, Louisville KY

of liquid separator^h diluted 1:1 with water were applied to the stone models and air-dried overnight. Bracketsⁱ were set up on casts and trays were fabricated using a soft inner/hard outer dual tray method as described by Sondhi⁵². The models were soaked in water for one hour to allow the separating medium to dissolve. The transfer trays were removed from the casts and placed in a light curing chamber for one minute to ensure total polymerization of the custom base resin. The soft inner tray was sectioned at the midline to facilitate removal following bonding. The trays were then cleaned in an ultrasonic cleaner with a dishwashing detergent and distilled water for 10 minutes and then in distilled water for an additional five minutes. The trays were air dried overnight. The resin bases were micro-etched with aluminum oxide particles^k to remove any aluminum oxide particles.

Simulated clinical bonding

The buccal surfaces of all 192 teeth were cleaned with a rubber prophylactic cup in a slow speed handpiece with oil free non-fluoridated pumice¹ for 5 seconds and then thoroughly rinsed with water. Any excess water was then removed.

Acid etch directly bonded group (AED)

The teeth were acid-etched for 30 seconds with 35% phosphoric acid^m, and rinsed copiously with water for 30 seconds. The teeth were dried with air, and a frosted

^h Great Lakes Separator, Great Lakes Orthodontics, Tonawanda NY

¹ Victory Series 022 Universal upper bicuspid miniature mesh twin bracket, 3M Unitek Monrovia CA

k 50 micron aluminum oxide, Danville Engineering, San Ramon, CA

¹ First and Final, Reliance Orthodontic Products, Itasca IL

^m Transbond XT etching gel, 3M Unitek, Monrovia, CA

appearance to the enamel of each tooth was visually confirmed. A liberal coat of MIPⁿ was applied to the buccal surface of each tooth, and lightly dried with air for 2 seconds. An APC pre-pasted bracket^o was positioned on the buccal tooth surface with bracket placement tweezers. Any flash was removed, and each bracket was light-cured with an LED light-curing unit^p for 20 seconds (10 seconds from the mesial and distal aspects respectively). The intensity of the light-curing unit was regularly tested during the bonding procedure to ensure that it always stayed above 1000mW/cm².

Acid etch indirectly bonded group (AEI)

The teeth were acid etched for 30 seconds with 35% phosphoric acid, and rinsed copiously with water for 30 seconds. The teeth were dried with air, and a frosted appearance to the enamel on each tooth was visually confirmed. A small amount of flowable composite resin^q was placed on the custom base of each bracket. A syringe tip was used to distribute the resin so that it covered the entire base. The tray was then placed into a black box⁵² to prevent ambient light from curing the composite. A liberal coat of MIP was applied to the buccal surface of each tooth, and lightly dried with air for two seconds. The tray was seated onto the arch form and the brackets were cured for 20 seconds from the occlusal aspect through the transparent trays. The hard outer tray was removed and the brackets were then cured for an additional five seconds from both the mesial and distal aspects. The soft inner tray was then removed.

n Moisture Insensitive Primer, 3M Unitek, Monrovia CA

[°] Adhesive Pre-Coated adhesive coated brackets, 3M Unitek, Monrovia CA

P Ortholux LED curing light, 3M Unitek, Monrovia CA

Filtek Supreme Plus, 3M ESPE, St Paul MN

<u>Transbond Plus self-etching primer indirectly bonded group (TSEPI)</u>

A small amount of flowable composite resin was placed on the custom base of each bracket. A syringe tip was used to distribute the resin so that it covered the entire base. The tray was then placed into a black box to prevent ambient light from curing the composite. The separate components of the TPSEP were mixed using a roller from the manufacturer^r followed by five seconds of mixing with a micro-brush. The micro-brush tip was verified to be yellow in colour and then rubbed onto the buccal tooth surface while applying some pressure for five seconds. The micro-brush was re-dipped into the reservoir to re-saturate it between each tooth. Using an oil and moisture free air source a gentle air burst from mesial to distal for two seconds was delivered to each tooth. The tray was then seated onto the arch, and the brackets were cured for 20 seconds through the transparent trays. The hard outer tray was removed and the brackets were cured for an additional five seconds from both the mesial and distal aspects. The soft inner tray was removed.

<u>Reliance self-etching primer indirectly bonded group (RSEPI)</u>

A small amount of flowable composite resin was placed on the custom base of each bracket. A syringe tip was used to distribute the resin so that it covered the entire base. The tray was then placed into a black box, to prevent ambient light from curing the composite. A new cartridge of Reliance SEP was loaded into the manufacturers dispenser and used to dispense the separate liquids into one mixing well. The dispensed liquids were then thoroughly mixed. A micro-brush was saturated and used to scrub the enamel surface for 5 seconds. This was repeated for all the teeth in the arch, re-saturating the micro-brush between each tooth. The mixing well shield was closed over the RSEP

r Transbond Easy Roller, 3M Unitek, Monrovia CA

solution to shield from ambient light between each tooth/etch procedure. The enamel surfaces were then dried with two prolonged bursts of oil and moisture free air. The tray was then seated onto the arch form and the brackets were cured for 20 seconds each through the transparent trays. The hard outer tray was removed and the brackets were then cured for an additional five seconds from both the mesial and distal aspects. The soft inner tray was then removed. Upon tray removal, any immediate bond failures were recorded for all indirect groups.

Storage and Thermocycling

The bracketed teeth in the arch forms were then stored at 37 $^{\circ}$ C in de-ionized water with thymol crystals (1%) for 30 days. The samples were thermo cycled for 1000 cycles (30 seconds alternating in 10 $^{\circ}$ C and 50 $^{\circ}$ C water baths).

Debonding

Following thermocycling, a short segment of 0.021 x 0.025 stainless steel wire was ligated in each bracket slot to minimize any potential for bracket deformation during debonding. Brackets were debonded using an Instron universal testing machine^s using a 5kN load cell with a crosshead speed of 0.5 mm per minute. Teeth were oriented using an adjustable vice capable of articulation in all three planes of space, such that the shear peel load was applied in a gingival direction parallel to each bracket base. The load applied at the time of bond failure was recorded in Newtons (N), and the SPBS was calculated and recorded in megapascals (MPa). Bond strength in MPa was calculated by dividing the debonding force (N) by the bracket base surface area (9.61mm²). Following debonding, the ARI score was recorded using 16X stereomicroscopy³³. The ARI index was modified to include enamel fractures (Table II)⁶⁶.

^s Instron model 3345, Instron, Norwood MA

Statistical analysis

Descriptive and inferential statistics were generated using JMP v8.0 statistical analysis software^t. The distributions of the variables were examined for recording errors and the assumptions associated with parametric statistical tests were validated. One-way analysis of variance (ANOVA) was used to determine whether there was a statistically significant difference in the mean SPBS among the four treatment groups. The Tukey-Kramer test was used to determine statistically significant pair-wise group differences. A p-value of 0.05 or less was considered to be statistically significant. An effect size of 20% or greater difference between treatment group means was deemed to be clinically significant. Associations between the ARI scores and treatment group were analyzed using the chi-square statistical test.

[†] JMP version 8, SAS, Cary NC

RESULTS

A total of ten teeth were excluded from the analysis. The resultant samples sizes were 46, 46, 46 and 44 for the acid etch directly bonded group (AED), acid etch indirectly bonded group (AEI), Transbond Plus self-etching primer indirectly bonded group (TSEPI), and Reliance self-etching primer indirectly bonded group (RSEPI) respectively. Of these ten teeth, three experienced a bond failure upon tray removal; all were in the RSEPI group, resulting in a 6.5% bond failure rate, compared to a 0% bond failure rate for the other three groups. In four cases a fracture occurred at the enamel-dentin interface and the bracket remained bonded to the enamel. This occurred once in each of the four treatment groups. One bracket was debonded accidentally and two brackets were not debonded because the width of the shearing blade was wider than the inter-bracket distance available.

Shear Peel Bond Strength

The mean shear peel bond strength (SPBS), standard deviations, and ranges for the four treatment groups are shown in Table I and Fig 1. The assumptions for ANOVA were satisfied. The mean SPBS (MPa) for the AED, AEI, TSEPI and RSEPI groups were 13.3 ± 3.5 , 10.5 ± 3.5 , 11.2 ± 3.8 and 10.0 ± 4.1 respectively. The highest single SPBS value was recorded in the TSEPI group (24.5 MPa) and the lowest SPBS was found in the RSEPI group (1.7 MPa). Two extreme SPBS values of 24.5 and 20.8 MPa (outliers) were observed in the TSEPI treatment group.

Analysis of variance was used to determine whether there was any difference in SPBS among the treatment groups. A statistically significant difference was observed in SPBS values among the four treatment groups (p=0.0002). Post hoc, pairwise comparisons with the Tukey Kramer test revealed that the three indirect groups (AEI,

TSEPI, RSEPI) all had statistically significant lower mean SPBS values compared to the AED group. When the two aforementioned extreme SPBS values were excluded from the ANOVA, the mean SPBS of the TSEPI group was reduced to 10.7 MPa. Exclusion of these extreme SPBS values did not affect the statistical significance of the results, thus they were retained in the data set.

Adhesive Remnant Index and Enamel Fracture

The frequencies of adhesive remnant index (ARI) scores, including incidence of enamel fracture were evaluated (Table II, Fig 2). A chi-square test indicated that the distribution of ARI scores was not significantly different among the four treatment groups (p=0.24). In all four treatment groups, approximately one third of the teeth had bond failure at the bracket adhesive interface and approximately two thirds of the teeth had some amount of composite remaining on the tooth after debonding. Both of the SEP groups showed a higher number of failures at the enamel-adhesive interface, compared to the AED and AEI groups. The RSEPI group, showed the most bond failures at this location. Enamel fracture occurred in twelve teeth (6.6%). Five enamel fractures occurred in the AED group, giving this group the highest proportion of enamel fractures (Table III).

DISCUSSION

Shear bond strength

In 1975, Reynolds proposed that minimum acceptable bond strength for orthodontic treatment was in the range of 6-8 MPa⁵⁹. Although this value has never been tested in-vivo, most in-vitro studies use it as the benchmark value^{58,60}. All four treatment groups displayed acceptable mean shear peel bond strengths (SPBS). The range of individual bond strengths was 2-25 MPa. All groups displayed SPBS values that were lower than 8MPa: 4%, 28%, 22% and 30% of the acid etch directly bonded (AED), acid etch indirectly bonded (AEI), Transbond Plus self-etching primer indirectly bonded (TSEPI), and Reliance self-etching primer indirectly bonded (RSEPI) groups respectively. In the routine bonding of 28 teeth, the difference between 4% and 30% equates to a respective difference of 1 and 8 brackets that may debond during treatment.

One indication of inadequate bond strength (in indirect bonding) was debonding of brackets upon tray removal. Three of these occurred, all in the RSEPI group. In the routine bonding of 28 teeth this is equivalent to 1.7 teeth debonding immediately, which was deemed clinically important. Interestingly, the lowest mean SPBS and lowest individual SPBS value were both recorded in the RSEPI group.

Enamel Preparation – Acid Etch + Primer versus Self Etching Primer

The AED group, using MIP as the primer and APC as the adhesive resin, yielded a mean SPBS of 13.3 MPa, which is comparable to values found by Miller *et al*⁵⁷, Meehan *et al*⁶³, Lowder⁶⁴ *et al*, and Strasdin⁶⁵ *et al* who established mean SPBS of 14.74 MPa, 14.82 MPa, 13.92 MPa, and 13.31 MPa respectively for direct bonding with MIP and Transbond XT adhesive. Using APC instead of Transbond XT as the adhesive resin did not appear to affect SPBS, which has also been shown in other studies^{67,68}. The mode of enamel preparation (AE vs. SEP) had no effect on mean SPBS when indirect bonding was used, which was in agreement with other reports comparing TPSEP to AE in a direct bonding setup^{2,8,9,19,69}. The mean SPBS for TSEPI and RSEPI was higher than the Reynolds range, which was in agreement with other direct bonding studies that have assessed TPSEP ^{2,8,9,19,32,69} and RSEP⁴³. Directly comparing the SEP products, Wong *et al* reported no difference in SPBS, however both values were below the clinically acceptable range⁴⁴. Conversely, Trites *et al* reported the SPBS of RSEP to be significantly lower than TPSEP, but within a clinically acceptable range⁴³. The results presented here were not in complete agreement with either study, since TSEPI and RSEPI were found to have similar *and* clinically acceptable SBPS values. Differences in methodology could account for these differences (materials, storage time, storage medium, thermocycling temperature and length, sample size, direct bonding).

Bonding technique – Direct vs. Indirect

In the present study, the bonding method used had a significant influence on SPBS. The mean SPBS of the AED group was significantly higher than the AEI, TSEPI and RSEPI groups. This is not in agreement with reports that have shown no difference in SPBS^{10-14,48}, but in agreement with others^{11,48,57,72} that compared direct to indirect bonding (of various techniques). The indirect technique used could account for this dissimilarity. Firstly, since the inner tray was soft, it was possible to over seat the tray if excess pressure is applied⁷⁰. This would result in the custom base no longer being customized, and thus the flowable composite layer would not be evenly thin¹² which could have lead to a decreased bond strength^{11,48}. Secondly, the buccal pressure placed on the brackets by the tray could also influence film thickness⁷¹. Decreased compressive force from the bonding tray leading to a thicker flowable composite layer could have

resulted in the lower SPBS values⁷¹. The various tray materials in different indirect techniques may play a role here. A compressive force of 250-300g has been used to place brackets directly in previous studies^{7,36}. Finally, the bond interface could also explain the difference between the direct and indirect groups. In the technique used, a third interface was introduced: enamel-flowable composite-cured custom base, which has been proposed to be a "weak link"⁶⁹. To improve bond strength some incorporate as air abrasion or primer application to the custom base⁶⁹.

Adhesive Remnant Index

Mode of enamel preparation was not related to ARI. Less composite remaining on the tooth post debonding has been observed ^{9,25,32,36} and proposed to be due to the shallower etch pattern seen with SEP's ^{8,20}. Other studies have not seen this pattern with statistical significance^{2,19}. These discrepancies may be explained by differences in magnification. It was recently determined that at least 20x magnification is required before significant differences in ARI can be determined compared to the naked eye⁷⁹. The studies that reported less residual composite remaining on the tooth when using SEP used 10x magnification^{9,25,32,36}. 16x magnification was used here in order to be able to compare to previous studies that used similar methodology^{57,63-66}. ARI can also be influenced by the application of adhesive to bracket mesh; the use of APC brackets standardized adhesive application in the present study^{61,71}.

Bonding technique was not related to ARI. This was in agreement with some studies comparing direct to indirect bonding^{11-14,48,57}, but in disagreement with others^{10,13,72}. When comparing direct to indirect bonding, studies that report an association between ARI and bonding method used different indirect bonding methods than that used in this study^{10,72}. Of the studies reporting no significant differences in ARI

between direct and indirect bonding, a similar technique to this study was used^{13,14}, thus agreeing with the present study. Using the same indirect bonding technique (with acid etch and light cured adhesive system), Miller *et al*, reported no significant differences in ARI between direct and indirect bonded adhesive groups⁵⁷.

Adhesive Remnant Index Relevance

Whether SEP or indirect bonding affect residual composite after debonding may not have clinical relevance. ARI is influenced by the debonding method^{10,61,71} : *in vitro*, a shear force is applied to debond the bracket and shearing forces may result in more adhesive failures⁷¹ while *in vivo*, brackets are not debonded in a shear manner (except perhaps during mastication). Debonding by squeezing the bracket wings, as may be done clinically, results in more adhesive remaining on the tooth⁶¹. We cannot assume *in vivo* bond failure to be the same as *in vitro* bond failure¹⁰.

<u>Enamel Fracture</u>

A fracture between the enamel and dentin (bracket remained bonded) occurred in two percent of the entire sample and was equally distributed among the four groups. This was likely a reflection of the nature of the sample, not the adhesive system or bonding technique used. The premolars collected were extracted under force that could predispose to this phenomenon. Six per cent of the entire sample experienced fracture *within* the enamel, which was similar to a comparable study⁵⁷.

Study Limitations

Methodology among *in-vitro* bonding studies is variable, thus making inter study comparisons difficult^{58,60,76}. Three variables in particular affect comparisons of SPBS: 1) Water storage decreases SPBS by 10.7 MPa compared to storage in artificial saliva, 2) each additional second of polymerization time increases bond strength by 0.077 MPa, and

3) an increase of 1mm/minute in crosshead speed increases bond strength by 1.3MPa⁶⁰. Eliades noted that while cross-head speed is often set at 0.5mm/min, clinically a higher velocity is actually used⁷¹. This means that the visco elastic behavior of the adhesive will play a role in *in vitro* studies that it does not have clinically⁷¹. Thermocycling also affects bond strength⁶⁷. It is used to simulate the oral environment and account for the differences in co-efficient of expansion between the adhesive, metal bracket, and enamel when exposed to different temperatures as this can cause weakened areas to propagate, and lower the bond strength ^{14,68}. In order to standardize *in vitro* bonding studies the International Organization for Standardization recommends 500 thermocycles, between 5 and 55 degrees, stored in water at 37° C⁷³. Since significant decreases in bond strength after more than 500 cycles however, have been demonstrated^{14,25,44,67}, 1000 cycles was used. Finally, this study used 16x magnification to assess ARI in order to compare to similar studies, but future studies should use 20x magnification⁷⁹.

Conclusions from *in- vivo* studies are also difficult to make⁷⁴. Methodology between studies is variable, double blinding is difficult and patient related factors are complicated to control (extreme pH and temperature variations, eating habits, oral micro flora)^{71,74,75}. *In-vitro* studies are more amenable to standardization and for this reason *in-vitro* studies are still relevant to orthodontic research^{60,75}.

Clinical Effectiveness and Efficiency

The present data show that combining SEP with indirect bonding resulted in clinically acceptable bond strength. Other factors may be used to decide between the two SEP products: due to packaging, RSEP is more amenable to single bracket bonding compared to the TSEP package which bonds twelve teeth per package^{77,84}. It may be possible to store and reuse TSEP after activation⁷⁸. Also, RSEP may be able to be

combined with any type of light cure adhesive and result in acceptable SPBS⁷⁷, allowing increased freedom in adhesive choices.

When SEP and indirect bonding are combined, there is a significant time delay to bonding the first tooth compared to the last tooth that is etch/primed⁸². For TPSEP, up to two minutes can elapse before the first tooth requires another coat of SEP⁸⁴, highlighting the importance of having the brackets covered with flowable prior to etching in order to accomplish tray seating/curing of the first tooth in time. For RSEP, up to five minutes can elapse before a new coat of SEP is required⁸⁰.

The popularity of indirect bonding and self etching primers have steadily increased^{81,83}. In combination with previous studies, the present data shows that effectiveness and efficiency in bonding has the potential to improve when a self-etching primer is combined with indirect bonding.

CONCLUSIONS

- The method of enamel preparation (acid etch versus self-etching primer) did not effect mean shear peel bond strength in indirect bonding. There was no statistically significant difference in mean SPBS between the acid etch and the self-etching primer treatment groups, using an indirect bonding method.
- 2. Brackets bonded in a direct fashion resulted in a statistically significant higher mean SPBS than brackets bonded in an indirect fashion.
- 3. There was no statistically significant difference in mean SPBS between the indirectly bonded TSEPI and RSEPI treatment groups.
- 4. All treatment groups had clinically acceptable bond strength for orthodontic treatment.
- 5. There was no statistically significant difference in the distribution of ARI scores among the four treatment groups

TABLES

	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				
Group	Mean	SD	Minimum	Maximum	n
AED	13.3 A	3.5	6.9	21	46
AEI	10.5 B	3.5	3.8	19.4	46
TSEPI	11.2 B	3.8	4.6	24.5	46
RSEPI	10.0 B	4.1	1.7	18.9	44

 Table I. Mean SPBS (MPa), standard deviations, minimum and maximum SPBS, and sample size by group

Means with same letters are not significantly different at the α = 0.05 level, using the Tukey Kramer test

Table II. Frequency (%) of ARI and EF by group

Group	ARI 0	ARI 1	ARI 2	ARI 3	EF	n
AED	4.35	23.91	28.26	32.61	10.87	46
AEI	0	19.57	41.3	34.78	4.35	46
TSEPI	8.7	19.57	32.61	32.61	6.52	46
RSEPI	15.91	25	22.73	31.82	4.55	44

0 = No adhesive remaining on the tooth 1 = < 50% adhesive remaining on the tooth 2 = > 50% adhesive remaining on the tooth 3 = All adhesive remaining on the tooth

EF = Enamel fracture

Table III. SPBS of the teeth that had EF (n=12)

Group	SPBS
AED	16.5
AED	17.4
AED	17.9
AED	14.1
AED	11.2
AEI	10.6
AEI	11.3
TSEPI	13.1
TSEPI	20.8
TSEPI	12.1
RSEPI	15.4
RSEPI	16.4

FIGURES

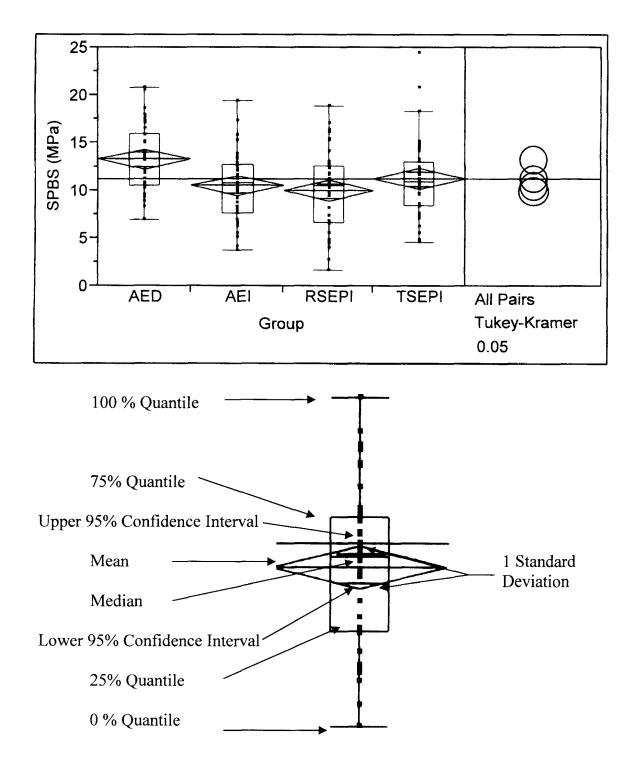


Figure 1. One – way ANOVA and Tukey-Kramer pairwise comparison of SPBS

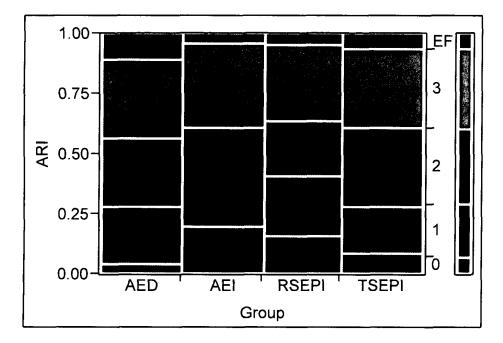


Figure 2. Mosaic plot of ARI and Incidence of Enamel Fracture by Adhesive Group

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APPENDIX

	Group						
Tooth ID #	#	Group	SPBS	SPBS	ARI	EF	Reason for no data
			(N)	(MPa)			
5	1	AED	132.5	13.79	3		
11	1	AED	89	9.26	3		
32	1	AED	66.1	6.88	3		
55	1	AED	170.6	17.75	3		
61	1	AED	92.6	9.63	0		
76	1	AED	171.7	17.87	3		
89	1	AED	130.3	13.56	1		
115	1	AED	100.9	10.5	2		
166	1	AED	107.5	11.19	EF	yes	
178	1	AED	126.2	13.13	1		
189	1	AED	85.6	8.91	3		
192	1	AED	67	6.97	2		
23	2	AED	113.5	11.8	2		
26	2	AED	113.4	11.8	2		
45	2	AED	158.3	16.47	EF	yes	
48	2	AED	79.51	8.27	3		
66	2	AED	116.8	12.15	1		
83	2	AED	98.58	10.26	1		
88	2	AED	100.8	10.5	1		
107	2	AED	200.8	20.9	2		
110	2	AED	127.1	13.2	3		
120	2	AED	98.6	8.31	0		
159	2	AED	101.4	10.56	3		
165	2	AED	126.6	13.2	3		
35	3	AED	164.2	17.1	1		
43	3	AED	104.4	10.87	2		
51	3	AED	133.9	13.9	1		
58	3	AED	197.9	20.6	2		
73	3	AED	145.9	15.2	3		
78	3	AED	128.6	13.4	3		
93	3	AED	132.5	13.8	2		
128	3	AED	169.5	17.6	3		
137	3	AED	104.2	10.8	3		
144	3	AED	135.8	14.1	EF	yes	
164	3	AED				-	position
174	3	AED	134.6	14	3		
22	4	AED					Gross EF
25	4	AED	79.5	8.3	1		
40	4	AED	131.9	13.72	2		
46	4	AED	167.3	17.4	EF	yes	
54	4	AED	178.4	18.6	2	• -	
84	4	AED	152.2	15.8	2		
- •	-						

Appendix 1. Complete data for all groups

Gross EF	Accident	
, Yes		yes yes
る F 1 2 1 2 2 2 2 2 3 2 2 3 2	889999999999999999999999999999999999999	エット3ー22 Η 213211122
14.1 17.9 15.3 15.3 15.3 17.8 17.8 17.8 17.8 17.8 13.8 6.7 13.8 13.4	7.6 6.4 7.9 7.9 7.9 7.5 7.5 7.5 7.5 7.5 7.5 7.5 7.5 7.5 7.5	10.6 12.1 11.3 12.6 8.3 13.3 8.3 12.6 12.6 12.6 12.6 12.6 12.6 12.7 12.6 12.7 12.6 12.7 12.6 12.7 12.7 12.7 12.7 12.7 12.7 12.7 12.7
135.9 172 172 146.7 146.7 146.7 146.7 146.7 146.7 119.3 96.9 96.9 93 93 128.6	72.7 116 61.1 33.1 33.1 33.1 33.1 56.8 56.8 56.8 103.6 59.5 59.5 59.5 59.5 59.5 59.5 59.7 112.5 53.8	102.2 116.7 73.7 73.7 87.4 152.3 152.3 121.8 80.1 94 109.1 19.3 119.3 186
AEEEEEEEEEEEEE AEEEEEEEEEEEEEE AEEEEEEEE		
4 4 4 4 4 0 0 0 0 0 0 0 0 0 0 0 0	<u>,</u>	~~~~~~~~~
97 176 176 170 170 123 123 123 123 123 123 123 123 123 123	2,42 1,53 1,53 1,53 1,53 1,53 1,55 1,55 1,55	64 96 75 75 75 75 75 75 75 75 75 75 75 75 75

155	8	AEI	78.8	8.2	2		
172	8	AEI	129.3	13.5	2		
176	8	AEI	85.1	8.7	2		
179	8	AEI	36.5	3.8	3		
47	9	TSEPI	126	13.1	EF	yes	
60	9	TSEPI	200.2	20.8	EF	yes	
69	9	TSEPI	102.5	11	2	,	
72	9	TSEPI	176	18.3	1		
98	9	TSEPI	141.4	14.7	1		
105	9	TSEPI	47.4	4.9	1		
132	9	TSEPI	82.1	8.6	3		
134	9	TSEPI		•			Gross EF
152	9	TSEPI	43.7	4.6	3		
154	9	TSEPI	145	15.1	3		
173	9	TSEPI	98.1	10.2	0		
183	9	TSEPI					Position
4	10	TSEPI	135.7	14.1	3		
20	10	TSEPI	106.5	11.1	2		
28	10	TSEPI	120.5	12.5	2		
33	10	TSEPI	111	11.6	0		
39	10	TSEPI	235.5	24.5	2		
56	10	TSEPI	72.6	7.6	1		
70	10	TSEPI	91.8	9.6	1		
77	10	TSEPI	99.1	10.3	2		
130	10	TSEPI	137.8	14.3	2		
139	10	TSEPI	118	12.4	2		
158	10	TSEPI	128.2	13.3	1		
184	10	TSEPI	73.1	7.6	0		
10	11	TSEPI	74	7.7	0		
19	11	TSEPI	102.8	10.7	3		
75	11	TSEPI	102.2	10.6	2		
101	11	TSEPI	142.7	14.9	1		
109	11	TSEPI	97.9	10.2	3		
114	11	TSEPI	125.8	13.1	3		
116	11	TSEPI	97.9	10.2	3		
119	11	TSEPI	71.1	7.4	3		
124	11	TSEPI	139.2	14.5	3		
171	11	TSEPI	68	7.1	2		
177	11	TSEPI	116.6	12.1	EF	yes	
185	11	TSEPI	92.7	9.7	2		
27	12	TSEPI	114.3	11.9	2		
29	12	TSEPI	107.9	11.23	3		
30	12	TSEPI	56.2	5.6	3		
38	12	TSEPI	71.3	7.4	1		
81	12	TSEPI	105	10.9	2		
87	12	TSEPI	59.1	6.2	3		
90	12	TSEPI	116.9	12.2	3		
99	12	TSEPI	118.5	12.3	2		
113	12	TSEPI	82.3	8.6	1		
125	12	TSEPI	127.1	13.2	3		

141	12	TSEPI	104	10.8	2		
191	12	TSEPI	80.1	8.3	2		
57	13	RSEPI					DB tray removal
118	13	RSEPI	52.6	5.5	1		-
127	13	RSEPI	100.1	10.4	2		
135	13	RSEPI	38	4	3		
142	13	RSEPI	113.7	11.8	2		
151	13	RSEPI	123.2	12.8	2		
160	13	RSEPI			-		DB tray removal
161	13	RSEPI	107	11.1	3		22 a a j 1 a a a a
169	13	RSEPI	65.8	6.85	3		
180	13	RSEPI	208.9	12.7	0		
181	13	RSEPI	62.2	6.5	1		
188	13	RSEPI	103.4	10.8	2		
18	14	RSEPI	16	1.7	0		
31	14	RSEPI	148	15.4	ĒF	yes	
37	14	RSEPI	123.7	12.9	3	yes	
52	14	RSEPI	120.7	12.0	5		DB tray removal
52 71	14	RSEPI	122.1	12.7	2		DD lidy femoval
86	14		98.9	10.3	3		
111	14	RSEPI	90.9 90.8	9.5	2		
		RSEPI			2 1		
117	14	RSEPI	70.8	7.4			
121	14	RSEPI	155.2	16.1	3		
136	14	RSEPI	91.4	9.5	2		
168	14	RSEPI	42.3	4.4	1		
186	14	RSEPI	94.4	9.8	3		
2	15	RSEPI	42.7	4.4	0		
8	15	RSEPI	65	6.8	0		
16	15	RSEPI	46.5	4.8	0		
34	15	RSEPI	64.8	6.7	1		
59	15	RSEPI	63.6	6.6	3		
62	15	RSEPI	70	7.3	0		
91	15	RSEPI	108.8	11.3	1		
95	15	RSEPI	105.5	11	1		
103	15	RSEPI	105	10.9	3		
112	15	RSEPI	111.3	11.6	3		
149	15	RSEPI	181.2	18.9	3		
190	15	RSEPI	136.7	14.2	3		
9	16	RSEPI	92.2	9.6	1		
14	16	RSEPI	125.7	13.1	2		
15	16	RSEPI	106.6	11.1	2		
42	16	RSEPI	157.2	16.4	EF	yes	
53	16	RSEPI	105.8	11	3		
67	16	RSEPI	26.6	2.8	1		
92	16	RSEPI					Gross EF
129	16	RSEPI	45.4	4.7	0		
145	16	RSEPI	147.4	15.3	1		
162	16	RSEPI	78.4	8.2	1		
163	16	RSEPI	164.1	17.1	3		
167	16	RSEPI	119.1	12.4	2		