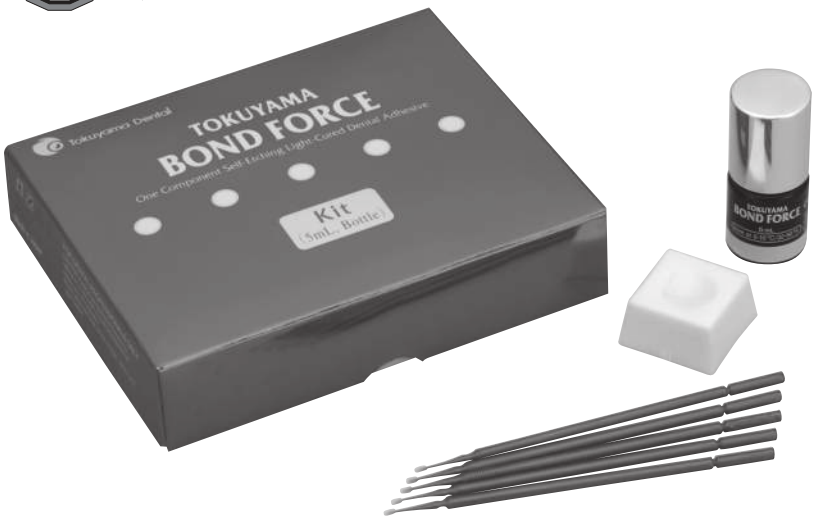
Scientific Research Result

TOKUYAMA
BOND FORCE

Tokuyama Dental



Introduction

Recently an additional breakthrough adhesive has been introduced to the market. As compared to other systems, Tokuyama Bond Force is a 7th generation single component, self-etching, fluoride releasing bonding agent. With the Self-Reinforced monomer, the revolutionary technology in this Bond Force creates a 3-D link to the tooth generating an extremely strong bond to enamel and dentin. It is truly a chemical bonding. It is designed to be used on both cut/uncut enamel and dentin. Bond Force, this 7th generation used adove and must be consistent and reduce the potential for being technique sensitivity.

As part of our continuing improvement efforts in research and development, we make every attempt to work closely with our colleagues at universities and private facilities from around the world. As a result of this global effort, this booklet consists of a collection of analysis on Tokuyama Bond Force. Based on the results and the diverse range of protocols published herein, the proven performance of Tokuyama Bond Force is clearly evident. Once the numerous test results and data have been reviewed, we are positive it will become apparent that Bond Force is truly an innovative 7th generation bonding agent.

I N D E X

1. Evaluation of the adaptation to cavity of Tokuyama Bond Force

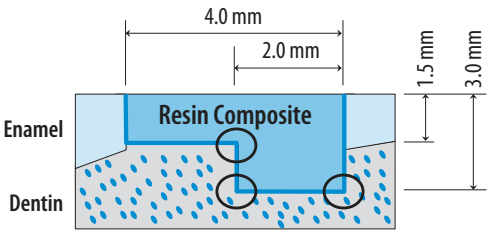
Authors: M. KIMURA, Q. CUI, A. DODOMI, K. MATSUSHIGE, and H. KAZAMA,
Tokuyama Dental Corporation, Tsukuba, Japan

Objectives: To evaluate the adaptation to step-form cavity of three adhesives including Tokuyama Bond Force.

Methods: The step-form cavity (4-mm diameter/3-mm depth + 2-mm diameter/1.5-mm depth) was prepared with fresh bovine teeth by using a diamond bur. Tokuyama Bond Force (BF/Tokuyama Dental), S^3 Bond (S3/Kuraray), and SE Bond (SE/Kuraray) were used. The adhesives were applied to the cavity walls following the manufacturer's instructions. Subsequently, resin composite (Estelite Flow Quick/Tokuyama Dental) was filled in the cavity and polymerized by light irradiation followed by Estelite Sigma (Tokuyama Dental). The specimens were kept in water at 37 °C for 24 hours. The specimens were cut along the symmetrical axis to expose the cross-section of teeth/adhesive. The cross-section was polished to a high gloss with diamond pastes (grit 6, 3, 1, 1/4 um) and observed by using laser microscope (VK9700/KEYENCE).

Results: In Bond Force, a uniform thin bonding layer was formed even around the corner and the edge part. The bonding layer is combined with resin composite and the cavity wall remarkably. In SE, the bonding layer is combined with resin composite and the cavity wall tightly. However, the bonding layer is thick especially around the corners. In S3, the bonding layer is thick especially around the corners. The slight abrasion in the bonding layer after being polished was observed.

Adhesive	Bonding layer thickness	
	around the corner / μm	at cavity floor / μm
BF	**11.6 -13.3**	**10.7 -12.3**
S3	35.0 -107.1	21.5 -24.2
SE	326.0 -600.6	58.9 -163.3



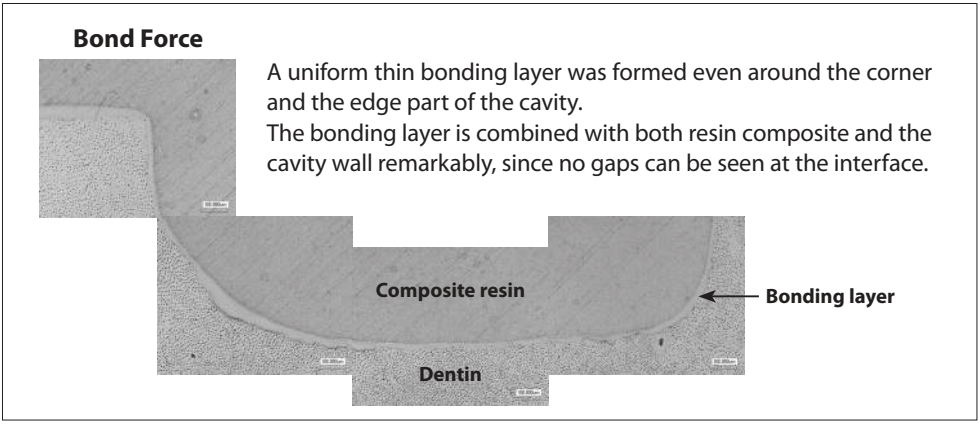


Fig. 1 Adaptation to cavity of Tokuyama Bond Force

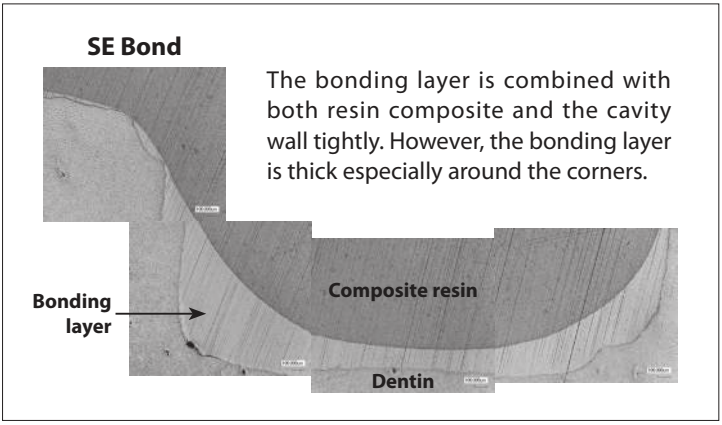


Fig. 2
Adaptation to cavity of SE Bond

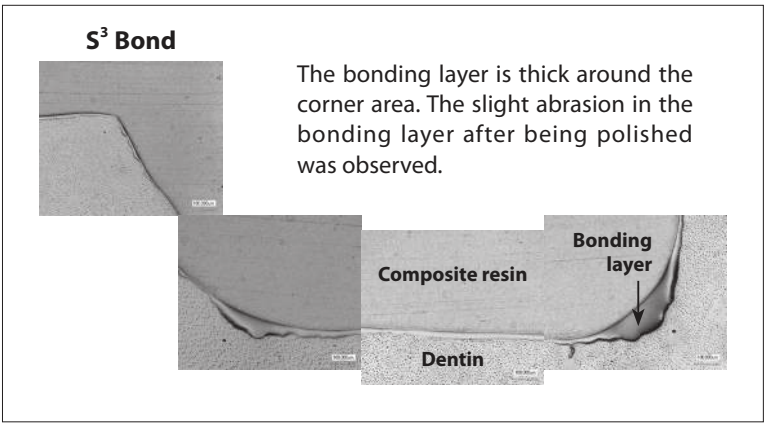


Fig. 3
Adaptation to cavity of S^3 Bond

Conclusion: Tokuyama Bond Force showed excellent adaptability to the step-form cavity.
(Published in 2008 IADR General session)

2. One-year bond strengths of "all-in-one" adhesives to dentin

Authors: R. Walter, University of North Carolina, Chapel Hill, NC
E.J. Swift, Jr., University North of Carolina, Chapel Hill, NC

Objectives: The purpose of this study was to test the long-term in vitro performance of "all-in-one" adhesives for bonding to dentin.

Methods: Six "all-in-one" adhesives were tested: Adper Prompt Self-Etch (3M ESPE), Bond Force (Tokuyama), Brush & Bond (Parkell), iBond (Heraeus Kulzer), OptiBond All-In-One (Kerr), and Xeno IV (Dentsply Caulk). The self-etching primer system Clearfil SE Bond (Kuraray) served as positive control. Twenty-one extracted human teeth were assigned to groups. Dentin was ground to 600-grit. Adhesives were applied according to manufacturer's instructions, and resin composite (Filtek Z250, 3M ESPE) build-ups were placed. Teeth were sectioned into beams after 24 h of storage in water. Following storage of the beams in water, micro tensile bond strength (MTBS) was determined using an EZ-Test device (Shimadzu). Beams from each tooth were assigned to be tested either at baseline or at one year. The data were analyzed using two-way ANOVA with adhesive and time as the variables. One-way ANOVA and Fisher's PLSD test were used where appropriate. Statistical analyses were done at a significance level of 0.05.

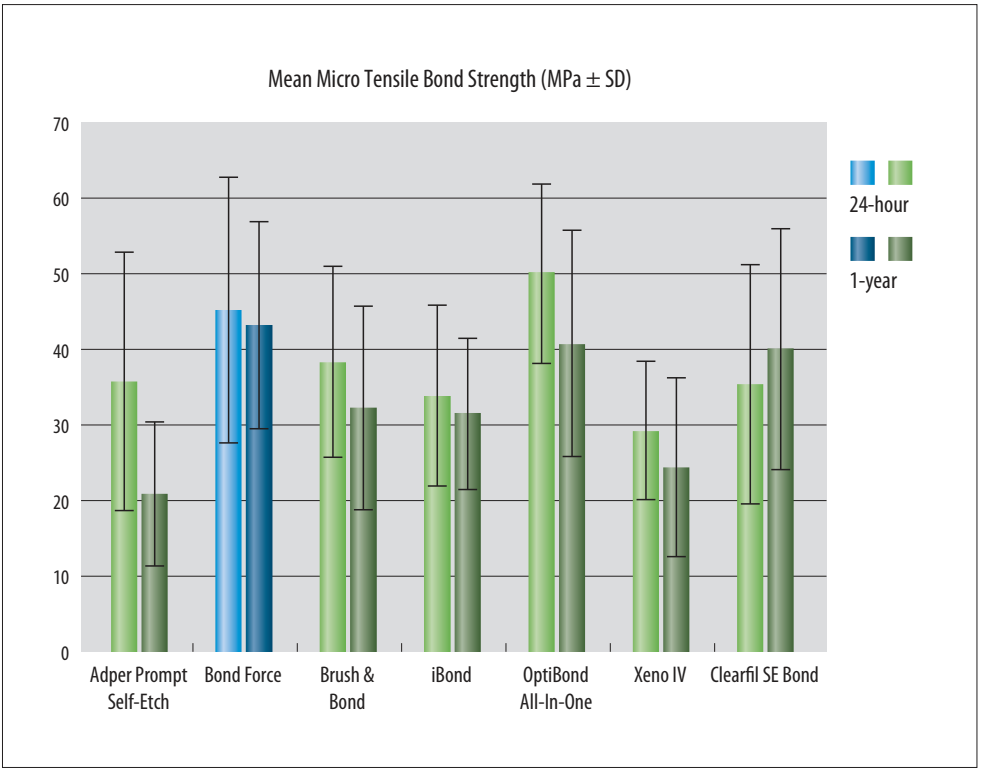
Results: Mean Micro Tensile Bond Strength (MPa ± SD) are summarized in the table:

Adhesive	24-hour	n	1-year	n
Adper Prompt Self-Etch	35.7 (17.1)c	15	20.9 (9.7)b	11
Bond Force	**45.2 (17.7)ac**	**12**	**43.2 (13.8)a**	**12**
Brush & Bond	38.3 (12.7)c	16	32.3 (13.5)c	15
iBond	33.8 (12.0)b	13	31.6 (9.9)bcd	12
OptiBond All-In-One	50.2 (11.8)a	15	40.7 (15.0)ac	15
Xeno IV	29.2 (9.2)b	14	24.4 (11.9)bd	11
Clearfil SE Bond	35.4 (15.8)c	15	40.1 (15.8)acd	16

Different superscript letters within a column denote means that are significantly different.

Conclusions: Some "all-in-one" adhesives, i.e., Bond Force and OptiBond All-In-One, have in vitro bond strengths to dentin that are comparable to those of Clearfil SE Bond after one year of aging.

(Published in 2009 IADR General session)


Mean Micro Tensile Bond Strength (MPa ± SD)
70
60
50
40
30
20
10
0
24-hour
1-year
Adper Prompt Self-Etch
Bond Force
Brush & Bond
iBond
OptiBond All-In-One
Xeno IV
Clearfil SE Bond

3. Shear Bond Strength of All-In-One-Bonding Agent to Enamel and Dentin

Authors: M. HARSONO, C. DEFURIA, R. PERRY, G. KUGEL, J. TOWERS, P.C. STARK,
Tufts University, Boston

Objective: To measure the shear bond strength of all-in-one-bonding agent on enamel and dentin.

Methods: 140 extracted caries-free human teeth were obtained and stored in water solution with sodium azide disinfectant prior to specimen preparation. Each tooth was embedded in acrylic resin. A flat enamel or dentin surface on a tooth was obtained by grinding the tooth surface with a 320-grit silicon carbide paper (Ecomet 3, Buehler). Seven adhesives were used Clearfil SE Bond (Kuraray Medical)- a two steps bonding system was used as a control, Bond Force (Tokuyama Dental), Xeno IV (Dentsply), Brush and Bond (Parkell), AdheSE One (Ivoclar Vivadent), Tri-S Bond (Kuraray Medical) and G-Bond (GC). All adhesive were placed to enamel or dentin according to the manufacturer's instruction. The resin composite (Filtek Z250, 3M) was placed on the prepared enamel or dentin tooth surface using a bonding jig (Ultradent products Inc) and light-cured for 20's. After 24 hour immersion in water at 37°C, the shear bond test was carried out using a universal testing machine (Instron 4202, Canton, MA) with a cross head speed 5mm/min.

Results: One-way ANOVA with Scheffe analysis for pairwise comparison was done to determine if there is a significant difference among groups. Significance for statistical tests was predetermined at $p<.05$.

Shear Bond Strength (MPa)

Adhesives	Enamel	Dentin	Enamel	Dentin
Clearfil SE	37.18	19.03	(9.6)a	(4.8)bc
Bond Force	**26.01**	**17.32**	**(7.4)ab**	**(4.3)bc**
Xeno IV	18.2	21.7	(7.8)bc	(11.4)b
Brush&Bond	6.5	19.88	(3.4)d	(6.3)b
AdheSE	8.86	10.05	(3.15)cd	(3.38)bc
Tri-S Bond	14.42	14.25	(3.12)bc	(4.71)bc
Gbond	13.95	14.95	(5.8)bc	(4.4)bc

Conclusion: There was no statistically significant difference in the shear bond strength among all dentin groups in this study. On the cut enamel groups, Clearfil SE and Bond Force groups showed significantly higher shear bond strength. This study was supported by Tokuyama Dental.

(Published in 2009 IADR General session)

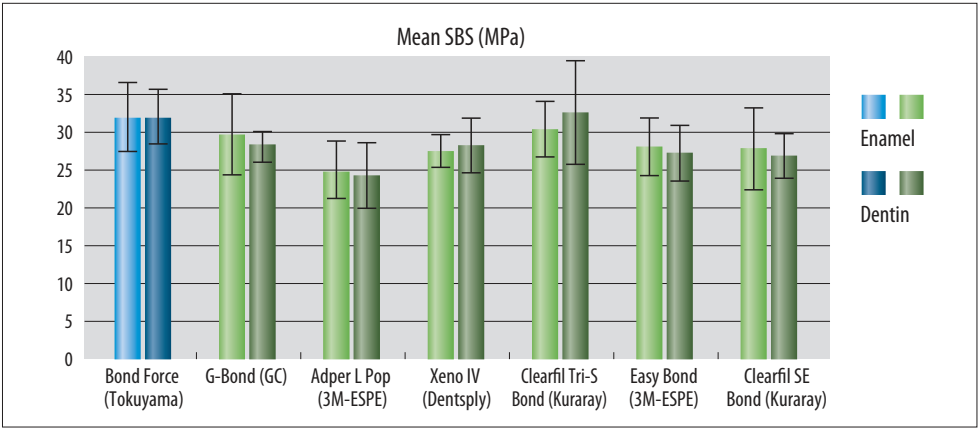
4. Shear Bond Evaluation of Current Self-Etching Adhesive Systems

Authors: M. FALEMBAN, and D. NATHANSON, Boston University

Introduction New generation all-in-one self-etching (SE) adhesives are promoted for dentin and enamel bonding, but reports about their performance vary.
Objectives: This study evaluates the shear bond strength (SBS) of several current SE adhesive systems.
Methods: Seven SE adhesive systems were tested in this in-vitro study: A. **Bond Force (Tokuyama)**; B. G-Bond (GC); C. Adper L Pop (3M-ESPE); D. Xeno IV (Dentsply); E. Clearfil Tri-S Bond (Kuraray); F. Easy Bond (3M-ESPE) and G. Clearfil SE Bond (Kuraray) as control. Human extracted permanent teeth were mounted into acrylic resin cylinders and sectioned to reveal either dentin or enamel. Each group was treated according to the manufacturers' instructions. Composite (Z-250, 3M-ESPE) was used in conjunction with all adhesives. The composite was placed over the tooth surface using special molds and holding clamps (Ultradent). All specimens were photopolymerized with the same light curing unit (Astralis 10 – Ivoclar). All specimens were tested in shear mode after 24 hours in water. Data was analyzed for significant differences using two ways ANOVA.

Results: Mean Shear Bond Strength (MPa) and SD are shown in the table below:

Material	Bond Force (Tokuyama)	G-Bond (GC)	Adper L Pop (3M-ESPE)	Xeno IV (Dentsply)	Clearfil Tri-S Bond (Kuraray)	Easy Bond (3M-ESPE)	Clearfil SE Bond (Kuraray)
Enamel	**31.9(4.6)**	29.7(5.4)	24.8(3.5)	27.5(2.3)	30.4(3.7)	28.1(3.9)	27.9(5.4)
Dentin	**32.0(3.7)**	28.4(2.4)	24.3(4.4)	28.3(3.6)	32.6(6.8)	27.3(3.7)	26.9(2.8)



Conclusion: ANOVA revealed a significant difference in SBS to enamel and dentin between all materials. Post-Hoc multiple comparison test concluded that Bond Force and Clearfil Tri-S Bond generated significantly higher shear bond strength than other groups tested, but not significantly different from each other. This study demonstrates the capability of new generation SE adhesives to yield mean shear bond strength and variance comparable to conventional adhesives. *(Published in 2008 IADR General session)*

5. Micro Tensile Bond Strengths of All-in-one Adhesives to Dentin and Enamel

Authors: F. PELOGIA , Sao Paulo State University, São José dos Campos, Brazil
M.R.D.P. MACEDO , Universidade de Sao Paulo, Sao Paulo - Cidade Universitaria, Brazil
A. DELLA-BONA , University of Passo Fundo, Passo Fundo, RS, Brazil
T.J. HILTON , Oregon Health & Science University, Portland, OR
J.L. FERRACANE , Oregon Health & Science University, School of Dentistry, Portland, OR

Purpose: The aim of this study was to compare the microtensile bond strength (MTBS) to human dentin and cut and uncut enamel for 6 self-etch adhesive systems (Bond Force, Tokuyama; AdheSE One, Ivoclar Vivadent; Brush & Bond, Parkell; G-Bond, GC America; Tri-S Bond, Kuraray; and Clearfil SE Bond, Kuraray).

Methods: Buccal and lingual surfaces of third molars were ground for "cut" enamel testing. For dentin, the occlusal enamel was ground flat just below the occlusal DEJ. Unprepared buccal and lingual enamel surfaces were used for "uncut" enamel. Each tooth was mounted in stone. "Cut" enamel and dentin surfaces were reground on 600 grit SiC paper before bonding. Surfaces were then treated with each adhesive according to the manufacturer's instructions and irradiated for 10 s (700 mW/cm2; Ultralume 5 LED, Ultradent). Composite (Filtek Z250, 3M ESPE) was added in two increments and irradiated for 30s. After 24h of storage (100% humidity, 37°C), the samples were cut (low-speed diamond saw, Buehler) into sticks (~1mm2 cross-section). Six sticks from each tooth were randomly chosen, bonded with ZapIt adhesive to the Bisco micro tensile bond strengrh jig and submitted to micro tensile bond strengrh testing (1 mm/min) and. The results of the six sticks per tooth were averaged, and the averages of 4-5 teeth/group were evaluated with two-way ANOVA/Tukey's ($a<0.05$).

Micro Tensile Bond Strengrh (MPa)

Adhesive	Dentin	Uncut Enamel	Cut Enamel
Bond Force	**61.06±8.02a**	**24.3±1.02bcd**	**21.84±3.24cde**
AdheSE One	22.35±2.56bcde	11.02±1.58e	14.63±1.97de
Brush & Bond	51.22±3.73a	17.34±3.69cde	18.85±3.24cde
Clearfil SE Bond	56.03±1.60a	34.18±6.49b	24.47±3.62bcd
G-bond	11.56±1.24e	20.28±3.61cde	18.4±5.38cde
Tri-S Bond	50.59±1.60a	28.97±6.31bc	18.73±2.76cde

Conclusion: Bonds to dentin exceeded those to cut and uncut enamel for Bond Force, Brush&Bond, Clearfil SE Bond and Tri-S Bond, but all self-etch adhesives provided equivalent bonds to unground vs. ground enamel. Supported by Tokuyama Dental.
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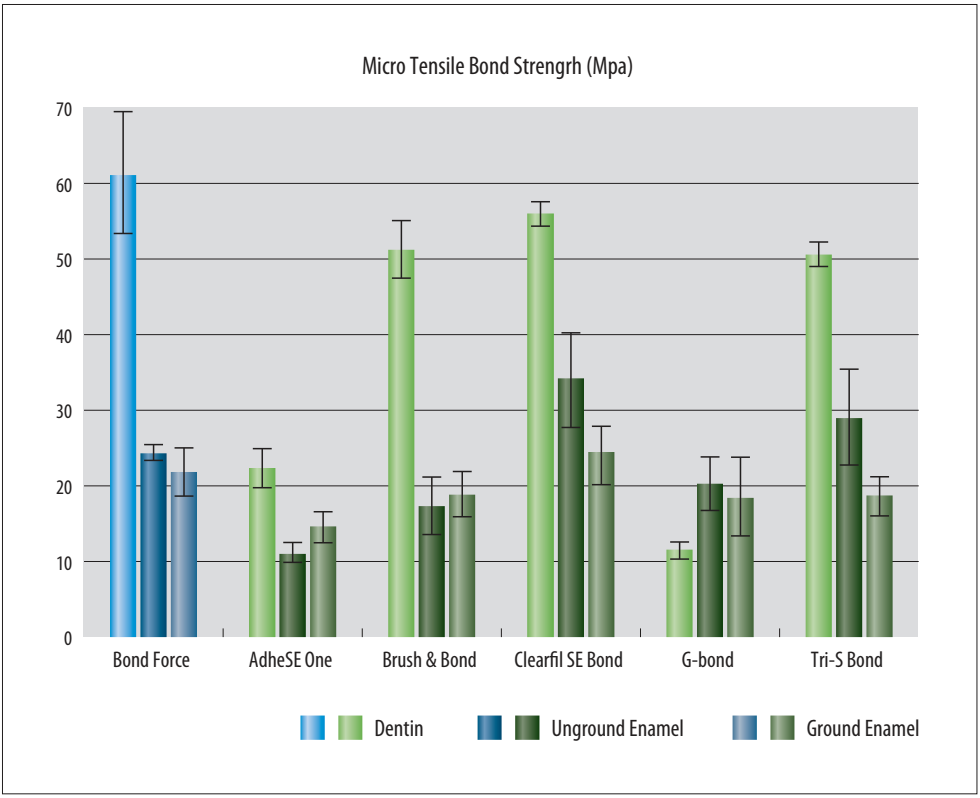

Micro Tensile Bond Strengrh (Mpa)
70
60
50
40
30
20
10
0
Bond Force
AdheSE One
Brush & Bond
Clearfil SE Bond
G-bond
Tri-S Bond
Dentin
Unground Enamel
Ground Enamel

6. Micro tensile bond strength to coronal dentin

Authors: Marco Ferrari, MD, DDS, PhD, University of Siena

Objectives: To evaluate the bonding effectiveness of self-etching adhesive systems to coronal dentin.

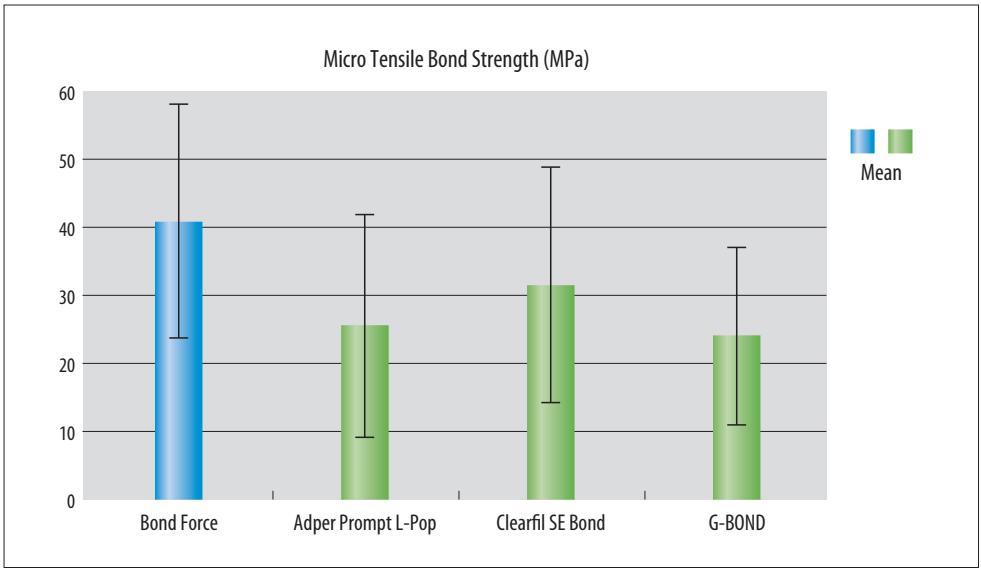
Materials and Methods: Four self-etching adhesive systems (Bond Force-Tokuyama, Adper Prompt L-Pop, G-Bond, Clearfil SE Bond) were applied to coronal dentin. A resin cylinder was built-up using proprietary materials Estelite Sigma, Filtek Supreme XT, Gradia direct and Majesty respectively). After storage for 1 day (37°C, 100% relative humidity), the specimens were sectioned into micro tensile sticks 81mm29 and stresscd failure with the micro tensile bond strength test TBS, cross-head speed 0.5 mm/min). Data were statistically analysed with Kruskal-Wallis on ranks ($P<0.05$) and Mann-Whitney tests ($P<0.01$) including premature failures. The fracture pattern was evaluated under SEM.

Results: Bond Force-Tokuyama performed significantly better than the other three adhesives. No significant differences for Adper Prompt L-Pop, Clearfil SE Bond and G-Bond bonded specimens were recorded.

Conclusions: The use of Bond Force-Tokuyama showed a superior bond strength to coronal dentin than others competitors when tested in vitro.

Micro Tensile Bond Strength (MPa)

Adhesive	Mean(SD)
Bond Force	**40.8(17.4)A**
Adper Prompt L-Pop	25.6(16.5)B
Clearfil SE Bond	31.5(17.3)B
G-BOND	24.1(13.1)B



7. Micro tensile bond strength of several simplified bonding systems to unground enamel

Authors: Marco Ferrari, MD, DDS, PhD, University of Siena

Objectives: To evaluate the bonding effectiveness of self-etching adhesive systems to unground enamel.

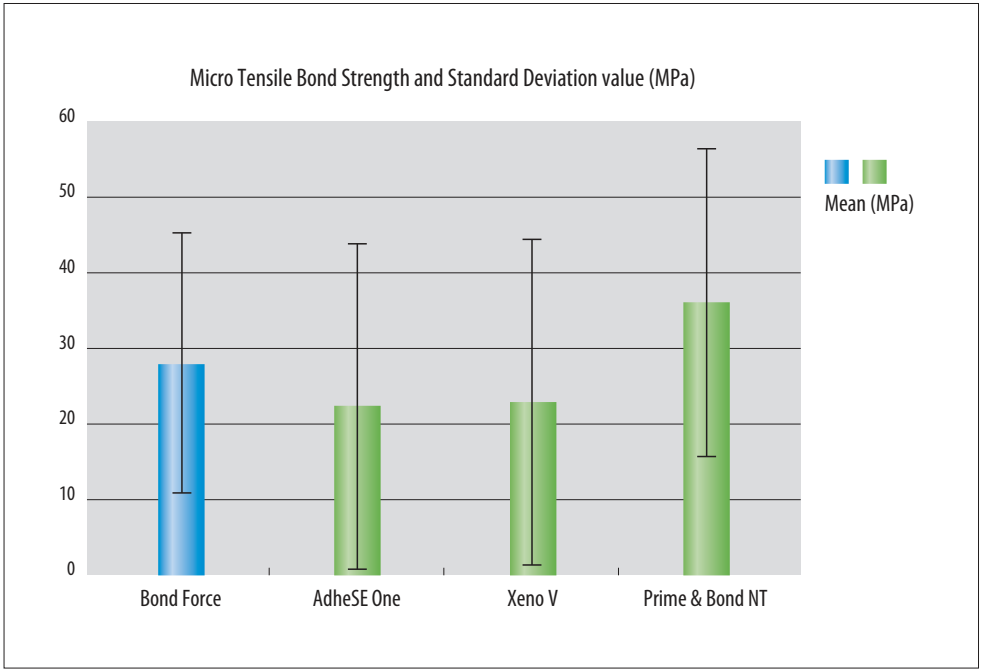
Materials and Methods: Four self-etching adhesive systems (Tokuyama Bond Force, AdheSE One, Xeno V, Prime & Bond NT) were applied to unground enamel. A resin cylinder was built-up using proprietary materials (Estelite P Quick, Tetric Evo Ceram and Esthet-X respectively). After storage for 1 day (37°C, 100% relative humidity), the speciments were sectioned into microtensile sticks (1mm2) and stressed to failure with the microtensile bond test (TBS, cross-head speed 0.5 mm/min). Data were statiscally analysed with Kruskal-Wallis on ranks ($P<0.05$) and Mann-Wintnery tests ($P<0.001$) including premature failures. The fracture pattern was evaluated under SEM.

Results: Premature failures were included in the statistical calculations as zero values. As the data distribution was not normal according to the Klomogorov-Sminmov test, the Kruskall-Wallis Analysis of Variance on Ranks was applied, followed by the Dunn's Multiple Range test for multiple comparisons.

Condusion: Bond Force Showed the best microtensile bond strength result when compared to other all-in-one competitors. Prime & Bond NT (control group) showed the highest bond strength value. The table reports descriptive statistics and significance of between group comparisons. Mixed type of failure was the most commonly found.

Micro Tensile Bond Strength (MPa)

Adhesive	N	Pretest failures %	Mean (MPa)	Median (MPa)	Std. Deviation (MPa)	Significance (p<0.05)	Type of Failure C/A/M
Bond Force	**56**	**12.5**	**27.9**	**28.5**	**17.37**	**AB**	**5/8/43**
AdheSE One	51	37.2	22.4	20.3	21.5	B	3/19/29
Xeno V	59	38.9	22.9	24	21.5	B	2/23/33
Prime & Bond NT	58	15.5	36.1	38.7	20.5	AB	10/8/40



Type of failure C: cohesive (within the cement, dentin or composite), A: adhesive (between the composite and the cement or at the cement / dentin level) or M: mixed (adhesive and cohesive fractures occurred simultaneously)

8. Short-term Clinical Investigation of All-in-one Adhesive and Restorative System

Authors: M. KONDO, M. MORIGAMI, J. SUGIZAKI, S. UNO, and T. YAMADA,
Toranomon Hospital, Tokyo, Japan

Objective: Current trend of resin bonding is a one-bottle/one-step self-etching adhesive. A one-bottle/one-step resin bonding "Bond Force" was newly designed with fluoride-releasing property by Tokuyama Dental Corp. The purpose of this study was to examine a clinical performance of EstediteΣ (Tokuyama Dental) composite restorations in combination with Bond Force up to 12 months after placement.

Methods: Minimally-invasive Class V and V-shape cervical cavities in permanent teeth were restored by 3 dentists from January 15 to February 28 in 2007. The prepared tooth were treated with Bond Force and filled with EstediteΣ according to the manufacturer's instructions. The items of the evaluation were retention, marginal discoloration, marginal adaptation, surface texture, abrasion, marginal fracture, body fracture, secondary caries, spontaneous pain, cold water pain, hot water pain, occlusal pain, gingival irritation, and soft tissue irritation according to the Ryge's criteria. All the restorations were examined immediately after placement, at 6 and 12 months recalls.

Results: A total of 39 restorations were placed in 39 patients (average age: 54.6, SD: 15.0). All the teeth restored were reported to be dentin cavities (shallow: 27, medium: 12) and vital at the time of placement of the restorations. Cold water pain in 3 cases, hot water pain in 2 cases, occlusal pain in 1 case were observed before preparation. Sensation during cutting were none in 36 cases and slight in 3 cases. All the restorations seemed to be clinically satisfactory in all aspects examined up to 12 months after placement.

Conclusions: According to this clinical study, **it has been demonstrated that Bond Force and EstediteΣ was a satisfactory restorative system for the minimally-invasive ClassV and V-shape cervical cavities over a period of 12 months, and Kaplan-Meier statistics was 1.00.**
(Published in 2008 IADR General session)

9. Bond Strength of Self – Etching Adhesives to Caries Affected Dentin

Authors: E. MOBARAK , University of Cairo, Cairo, Egypt
W. EL-BADRAWY , University of Toronto, Toronto, ON, Canada
H. JAMJOOM , University of King Abdulaziz, Jeddah, Saudi Arabia

Objectives: The aim of this study was to compare μSBS of normal dentin to different adhesives with that of caries affected dentin.

Methods: 50 freshly extracted carious human molars were flattened to expose sound and caries affected dentin. Teeth divided into five groups according to adhesive tested, Clearfil SE Bond (SE), Clearfil DC Bond (DC) (Kuraray- Japan), **Bond Force (BF) (Tokuyama Dental- Japan)**, AdheseOne (AH) (Ivoclar-Vivadent, USA), Adper Prompt-L-pop (PR)(3M/ESPE- USA). Each group was further divided to 2 subgroup; normal dentin (ND) and caries affected dentin (AD). Dye permeability using 2%methylene blue was done to qualitatively and objectively distinguish between both dentin substrates. Adhesives were applied and composite cylinders (0.9mm diameter x 0.7mm length) were formed using Z250 (A3). Specimens were tested following 24 hours storage in distilled water at 37°C using crosshead speed of 0.5mm/min. Mode of failure was determined using stereomicroscope at 40× magnification. Data analysis was done using kruskal-Wallis and Mann-Whitney tests. Results: Mean μSBS and standard deviation values in MPa were: SE-ND= 22.34 (6.4), SE-AD= 18.70 (4.0), BF-ND = 24.52 (4.9), FB-AD = 18.31 (4.9), DC-ND = 24.49 (8.0), DC-AD= 18.97 (9.4), AH-ND= 17.21 (6.8), AH-AD = 17.03 (10.3), PR-ND = 13.67 (4.4), PR-AD = 7.31 (2.4). Statistical significant difference was found among the adhesive systems to both normal ($P < 0.01$) and caries affected dentin ($P < 0.001$). However, μSBS means of some adhesive systems (SE, DC and AH) to normal dentin were not significantly different from that of affected dentin ($P > 0.05$). Different failure modes were recorded for each adhesive system to different dentin substrate.

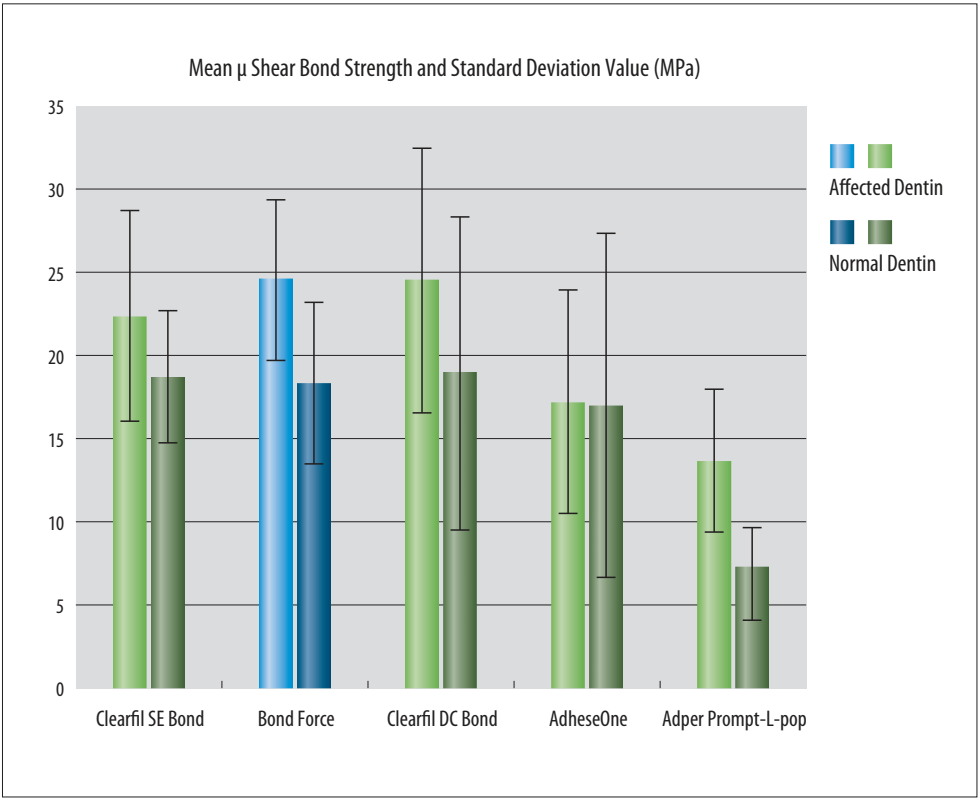
Conclusion: Under the conditions of this study, it can be concluded that few adhesive systems are less sensitive in their bond to the structural differences between normal and caries-affected dentin. **Bond Force showed the highest bond to normal dentin.**

Acknowledgment: Tokuyama, Kuraray.

(Published in 2009 IADR General session)

Shear Bond Strength (MPa)

Adhesive	Affected Dentin	Normal Dentin
Clearfil SE Bond	22.34(6.4)	18.7(4.0)
Bond Force	**24.52(4.9)**	**18.31(4.9)**
Clearfil DC Bond	24.49(8.0)	18.97(9.4)
AdheseOne	17.21(6.8)	17.03(10.3)
Adper Prompt-L-pop	13.67(4.4)	7.31(2.4)


Mean µ Shear Bond Strength and Standard Deviation Value (MPa)
35
30
25
20
15
10
5
0
Affected Dentin
Normal Dentin
Clearfil SE Bond
Bond Force
Clearfil DC Bond
AdheseOne
Adper Prompt-L-pop

10. Marginal behavior of composite resin restorations placed with Bond Force applied with and without agitation in combination with Estelite Sigma in vitro after thermocycling.

Authors: Uwe Blunck, Charité-Universitätsmedizin Berlin
Campus Virchow-Klinikum Dental School
Dept. of Operative Dentistry, Preventive Dentistry and Endodontics

1. Purpose

Adhesive systems are used to improve the marginal seal of composite resin restorations at the dentin/composite and enamel/composite interface. Since all composite resin materials show a certain amount of polymerization shrinkage an adhesive system must be able to resist the forces that are created during setting of composite materials. Therefore, we are testing dentin adhesives by examining the marginal integrity of composite resin restorations in Class V cavities with margins in dentin and in enamel, filled with an incremental technique. This means to proof the effectiveness of an adhesive system under simulation of a clinical situation.
The stability of the adhesive/dentin and enamel/adhesive interface can be tested by thermocycling procedures because of the differences in the coefficients of thermal expansion of the tooth and the restoration. Therefore, we examine the marginal integrity before and after thermocycling.

2. Materials and Methods

2.1. Class-V-cavities

Class V cavities were prepared with a diamond bur at high speed using water as a coolant in eight extracted teeth per group, stored in a 0.1 % thymol solution. The oval preparation was approximately 1.5 mm deep, 3 mm wide, and 4 mm high (2 mm were apical to the cemento-enamel junction). The enamel portions were bevelled with a finishing diamond bur and the cavosurface margins in dentin finished to a 90 degree angle with a finishing diamond.
The adhesive system Bond Force was applied on beveled enamel and prepared dentin for 20 s in two different ways:
• group A: with agitation,
• group B: without agitation.
In both groups the surface was then dried with a gentle air stream until a glossy surface was seen, then the surface was dried for at least another 5 s with a moderate pressure of an air stream and the layer was light-cured for 10 s.
The cavities were then filled with the composite resin ***Estelite Sigma*** in two incremental insertions
starting at the cervical margin and each increment was light-cured for 40 s.

2.2. Additional treatment

After polishing, the teeth were stored for 21 days in water and then thermocycled for 2000 cycles between +5°C and +55°C. Before and after the thermocycling procedure, impressions were taken with a polyvinylsiloxan impression material and replicas were produced by casting the impressions with an epoxy resin and by coating with gold in a sputter device.
The margins of the restorations at the dentin/composite and enamel/composite interface were

examined and quantified with a scanning electron microscope (SEM) at a magnification of 200X using defined criteria (Tab. 2) to assess the margin qualities. The amount of length for the different defined criteria were summarized in percent of the total margin length in dentin and enamel respectively for each cavity.
The statistical evaluation was performed with the SPSS statistical software using non parametric tests.

Table 2 Criteria for the marginal examination in the SEM at a magnification of 200 X

Margin-quality	Definition
1	Margin not or hardly visible No or slight marginal irregularities; No gap
2	No gap but severe marginal irregularities
3	Gap visible (hairline crack up to 2 µm) No marginal irregularities
4	Severe gap (more than 2 µm) slight and severe marginal irregularities
	the term "marginal irregularities" means porosities, marginal restoration fracture, bulge in the restoration

3. Results

The results for the tested material with two different application procedures are summarized as graphs in figure 5 and 6 for enamel and dentin respectively.

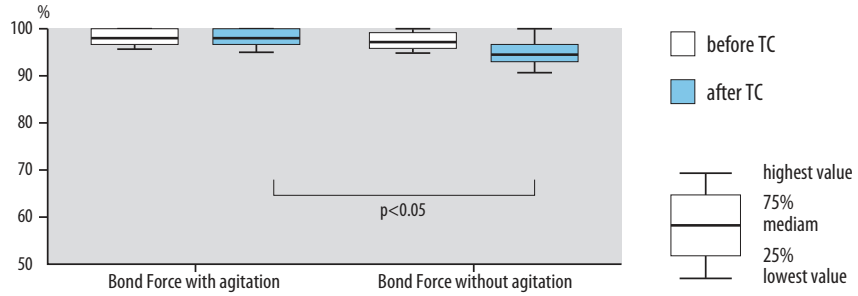


Fig. 5 Amount of margin quality 1 in % of the entire margin length in **enamel** at Class V cavities for ***Bond Force*** with and agitation before TC(TM 1) and after TC (TM 2)

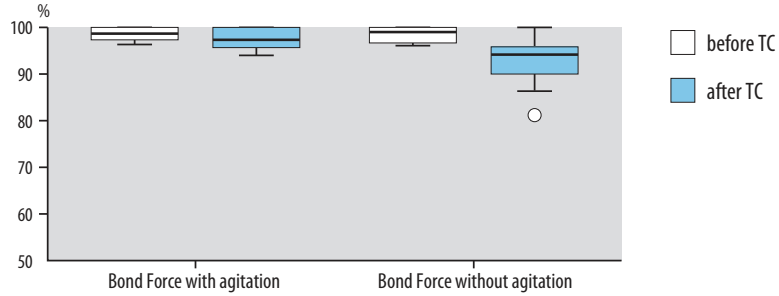


Fig. 6 Amount of margin quality 1 in % of the entire margin length in **dentin** at Class V cavities for ***Bond Force*** with and agitation before TC(TM 1) and after TC (TM 2)

The evaluation of the marginal adaptation in the SEM showed very high amounts of margin quality “continuous margin” in enamel and also in dentin after thermocycling with median values between 95,2 % and 99,5 % at margins in enamel and in dentin for the tested adhesive system Bond Force independent of the application technique (with or without agitation). The statistical evaluation showed only for the results in enamel significant differences in the amount of margin quality “continuous margin”. However, the two evaluated median values are 95,2 % when the adhesive is applied without agitation and 99 % for the active application.

Discussion

Effectiveness of adhesive systems can be generally judged by the marginal adaptation of composite resin restorations at the interface with the tooth substrate. Marginal adaptation is affected by many different parameters. These might be greatly influenced by the inherent properties of the restorative material such as shrinkage and shrinkage stress, the chemistry of the adhesive system used the size of the cavity, the c-factor, the insertion technique and the polymerization protocol. In this study a high resolution quantitative marginal analysis method was used to evaluate the marginal adaptation of composite resin restorations over a long period of water storage followed by TC. This quantification method relies on imaging of precision replicas of restored teeth with a scanning electron microscope (SEM) followed by quantitative quality analysis of the entire margin length. The replica technique is non-destructive to the natural-tooth samples and thus the margins can be assessed and marginal defects detected and compared at different times and after applying different stresses to the tooth specimens. The high sensitivity of this method, due to the SEM's excellent detail reproduction, is a great advantage for the evaluation of such bonding of adhesive systems. The evaluation for the tested material showed rather high amounts of excellent margins at Class V cavities in dentin and enamel after thermocycling for both application techniques. It has been shown that especially for short application times the active application (agitation of the applied adhesive) improves the bond strength of some adhesive systems. The high effectiveness of the system tested in this study can be recognized in the fact that even without agitation the evaluation revealed median values of margin quality “continuous margin” of 95 % and higher. The statistical calculation found significantly better results after thermocycling at the enamel margins when the adhesive is applied with agitation. However, the improvement from 95 % to 99 % seems not to be clinically relevant. Nevertheless it shows that active application enhances the effectiveness of the tested adhesive system. From the results of this in vitro investigation it can be concluded that the tested self etching adhesive Bond Force is very effective in the marginal adaptation in dentin and enamel.

11. Effectiveness of new one-step self-etch adhesive in the restoration of non carious cervical lesions: a paired-tooth design study

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This report provides preliminary scientific results on the Bond Force study (result at 12 months).

Objective: The aim of this study was to evaluate the clinical performance of a new one-step self-etch system (Bond Force/Tokuyama) in the restoration of non-carious cervical lesions, with and without selective phosphoric-acid etching of enamel. The null hypothesis is that there is no significant difference regarding to the marginal adaptation, between the two procedures, after a two-year follow-up period.

Material and methods: The clinical effectiveness of Tokuyama Bond Force was evaluated when applied strictly following a self-etch approach according to manufacture's instructions, and compared to the application of the same application protocol, but after the enamel cavity margins were selectively acid-etched with 40% phosphoric acid. This clinical controlled, single blind, multi-centric (5 dentists involved) trial follows a paired-tooth design, with a consecutive inclusion of subject. The total follow-up period for each subject is 24 months, beginning 4th September 2007.

Inclusion, non-inclusion and exclusion criteria: The inclusion criteria are as follows: subjects have to be affiliated to a social welfare organization, aged> 18 years, presenting at least 2 cervical erosions to be restored on 2 different teeth (non-carious lesions, >1 mm depth, interesting both enamel and dentin of a vital incisors, canine or premolar without mobility), with acceptable level of personal oral hygiene level. Prior to participating in the study all patients signed a written consent. Non-inclusion criteria are: compromised medical history, periodontal disease, bruxism and/or traumatic occlusion and carious lesions.
Finally, exclusion criteria are defined as modification of the restorations by other dentist during the follow-up period and loss or fracture of a tooth supporting a restoration, for independent reasons.

Restorative procedure: A preliminary cleaning of the tooth surface aimed to remove salivary pellicle and remaining dental plaque. Then sclerotic dentin and/or discolored tooth tissue was removed, and a short enamel bevel (1-2 mm) was prepared. Lesions were restored according to the manufacture's instructions, except for the control group, when the enamel margins were beforehand selectively etched with 40% phosphoric acid. After moderate rinsing and air-drying, the self-etch adhesive was applied for 20 seconds, then indirectly air-dried for 5 seconds and finally directly air-dried for 5 seconds.
Polymerization was performed during 10 seconds with a light output not less than 550mW/cm^2. Estelite Flow Quick-Tokuyama, first, and Estelite Sigma-Tokuyama, second, were used as restorative composite for all the restorations. After a final 10 seconds polymerization, restorations were finished and polished using pinetree-shaped contouring diamonds, rubber points and flexible discs.

Evaluation criteria and procedure: Restorations were examined at baseline, 6 months, 12 and 24 months, Relevant outcomes were marginal integrity deviates from the ideal, but could be upgraded to ideal by polishing, or several small marginal fractures that are unlikely to cause

long-term effects, and 1: localized or generalized gap resulting in exposure of dentine or base. Repair is necessary).
Other outcomes taken into consideration are retention of the restoration, post-operative sensitivity, marginal staining at the enamel, marginal staining at the cement, and restoration staining. All parameters were recorded using a simplified scoring system initially introduced by Hickel et al (2007). All dentists received a standardized notebook for data management.

Statistical analysis: Statistical analysis compare on a pair-wise basis the ratings of marginal adaptation, retention, post-operative sensitivity and staining between the two procedures, using the Chi-2 McNemar test at a significance level of 5%.
All statistical analysis will be performed using Stata software (version 9.1).

Results:

∗ Baseline – Visit 1

Subject characteristics at baseline are summarized in Table 1.

Number of subjects	28
Mean Age	53.2±13.7
Gender	11M; 17F
Mean number of teeth	27.8±2.9

Table 1 Subject characteristic at baseline

Each included for restoration of a cervical lesion was randomly assigned into a procedure protocol (with or without preliminary phosphoric-acid etching). Table 2 shows this assignation by type of tooth.

	Procedure with phosphoric-acid etching	Procedure without phosphoric-acid etching
Incisors (n)	2	2
Canines (n)	3	4
Premolars (n)	23	22

Table 2 Restorative procedure by type of tooth.

∗ Visit 3 (12months)

The recall rate at visit 2 was 78% (22/28 subjects), with a mean delay of 185.4±31days since Visit 2. None of the restorations was lost during the period (between 6 months and 12 months) resulting in an **excellent 100% retention rate.**

Table 3 shows the clinical results of the different parameters evaluated at visit 3 **(in percentage).**

	Procedure with phosphoric-acid etching n=22	Procedure without phosphoric-acid etching n=22	p-value
Retention rate	100	100	NS
Marginal adaptation	100	90	0.48
Absence of post-operative sensitivity	100	100	NS
Absence of marginal staining (enamel)	95	80	0.34
Absence of marginal staining (cement)	100	100	NS
Absence of restoration staining	100	95	1.00
Total (absence of major defects)	95	75	0.18
Absence of minor defects	100	77	0.048

Table 3 Clinical results at visit 3.

If one looks carefully at the evolution of the restorations:

In the group with phosphoric acid

- 1 major defect appeared
- 1 minor defect is lost

In the group without phosphoric acid

- 2 major defects appeared
- 1 minor defect appeared
- 4 minor defects (at 6 month recall) kept minor
- 3 minor defects (at 6 month recall) became major defect
- 1 minor defect is lost

Discussion: In vivo, the skill and experience of the operator is a source of variability in the results. In this clinical trial, operative procedures were performed in their dental office by 5 specially instructed and experienced dentists. Isolation of the tooth was done using aspiration and cotton rolls, with the help of a dental assistant. Isolation was not done with rubber dam, near seldom used by general practitioners. So the results of this study were expected to be less good than those published in the literature where rubber dam was always used. Despite this point, one can see that **this pair tooth design study revealed that up to 12 months of clinical service Bond Force adhesive performed excellent.**

At 12 months recall, The only parameter that appeared significantly different between both group is the higher prevalence of minor defects recording when Bond Force was applied following a solely self etch approach (p=0.048). But it should be emphasized that these defects are small. They did not require any repair nor replacement of the whole restoration and therefore should be regarded as being of clinically negligible relevance. These results confirm several studies (Van Meerbeek et al, 2005; Van Dijken and Pallesen, 2008).

Comparing the results at 6 and 12 months recall, one can notice the very good score of post-operative sensitivity and marginal staining at the dentin level. Patients that received Bond Force restorations reported hardly and post-operative sensitivity. This indicates that dentin tubules must have been adequately sealed by the self etching adhesive. Thus it explains also the absence of marginal staining at the dentin level in the two groups.

Besides, results at 12 months shows that minor defects at 6 months are likely to become major defects at 12 months (3/7), and the new minor defects continue to appear at 12 months in the group without phosphoric acid.

Last but not least, the almost absence of restoration staining indicates **that the composite used in this study (Estelite Sigma) works very nicely at 12 months clinical service.**

Conclusion: This preliminary report **(12 months recall)** shows that the clinical effectiveness of Bond Force adhesive was excellent after one year. Although no significant differences was found between the group tested, a trend for the procedure without phosphoric acid etching to be at higher risk for loss of retention and for minor margin defects is noticed. It will be interesting to follow these restorations on a longer period to confirm or not this trend.

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