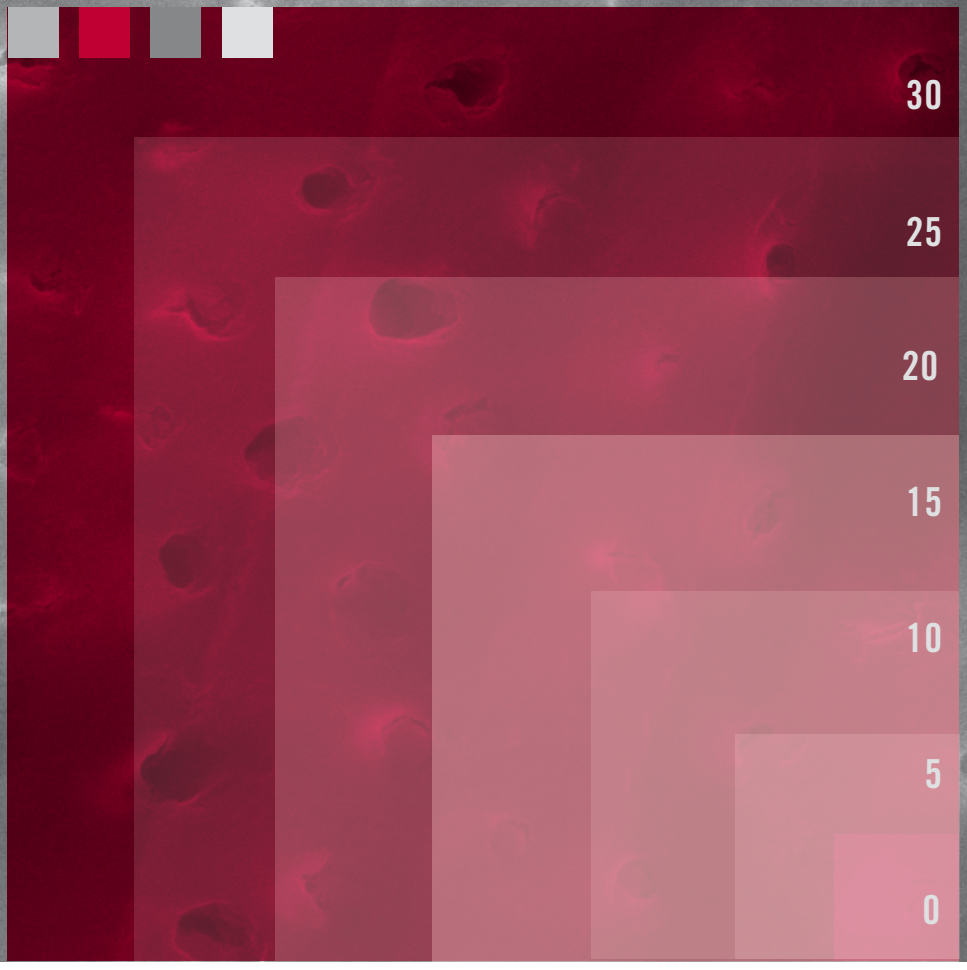
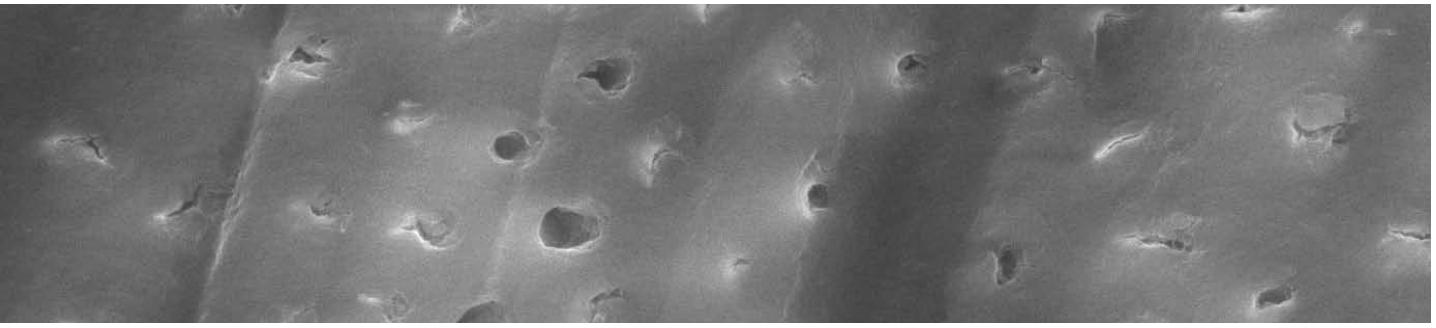
Heraeus

iBOND® Self Etch



Scientific Information

Preface



For more than 25 years, Heraeus Kulzer has been developing and marketing bonding systems: from one of the first enamel adhesive systems, through the 4th, 5th (Etch & Rinse), and finally, 7th generation (Self-Etch) adhesives. iBOND Self Etch was developed based on this bonding expertise and more than four years market experience with self-etching, all-in-one adhesives.

A total of 400 different formulations were compounded and tested to obtain the chemical formulation of iBOND Self Etch. Here, the focus was to simplify application, to improve bonding strength and storage stability compared to iBOND GLUMA inside and other adhesives. These improvements have been and will continue to be tested and verified by external studies and investigations.

An overview of existing studies' results and studies in progress is provided in this brochure (see map and table on pages 5–7).

This pamphlet highlights iBOND Self Etch's stability and impressive bonding properties. We kindly invite you to test iBOND Self Etch yourself its easy single-layer application.

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i|BOND® SELF ETCH

Clinically proven worldwide – Study Overview

External Testing of iBOND Self Etch by 15 Study Groups Worldwide

Dr. Miller,
Reality Research Lab,
USA

Prof. van Meerbeek,
University of Leuven,
Belgium

Prof. Frankenberger,
University of Erlangen,
Germany

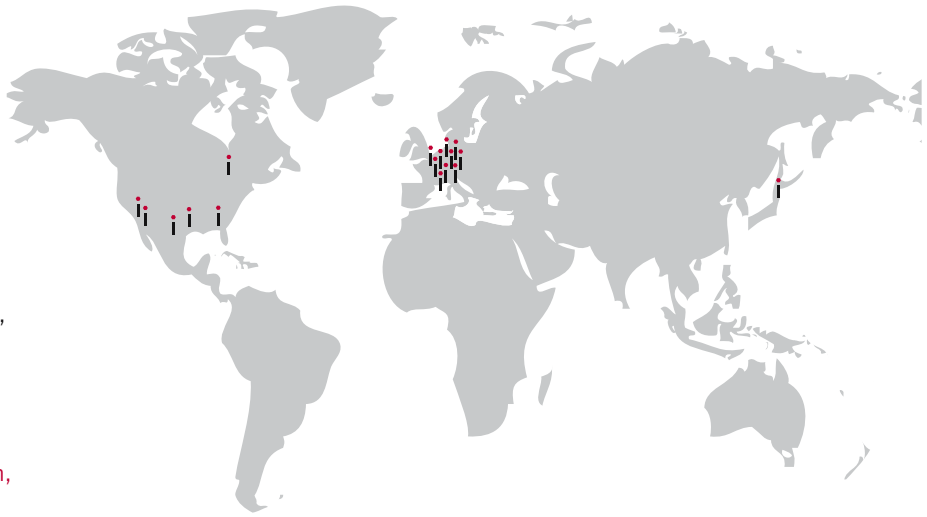
Prof. Finger,
University of Cologne,
Germany

Prof. Lee,
University of
Loma Linda,
USA

Dr. Lu,
University of
Loma Linda,
USA

Prof. Thompson,
University of
San Antonio,
USA

Prof. Soderholm,
University of
Florida,
USA



Prof. Ernst,
University of Mainz,
Germany

Prof. Haller,
University of Ulm,
Germany

Prof. Hannig,
University of Saarland,
Germany

Prof. Uno,
University of Tokyo,
Japan

Prof. Degrange,
University of Paris,
France

Dr. Yapp,
The Dental Advisor,
USA

Dr. Ilie,
University of Munich,
Germany

Prof. Cerutti,
University of Brescia,
Italy

Dr. Rupf,
University of Leipzig,
Germany

i in vivo
in vitro

iBOND® Self Etch – Clinically proven worldwide

Study Group	University	Country	Study Type	Title	Start of the Study	Results
Prof. K.-J. Soderholm	University of Florida, Gainesville	USA	in vivo	Clinical evaluation of a new all-in-one adhesive in class V restorations	Sept. 2006	3-month report partially available, see page 11
Prof. C.-P. Ernst	University of Mainz	Germany	in vivo	Clinical study on the application of a self-conditioning, all-in-one adhesive in class III cavities in secondary teeth	Dec. 2006	3-month report available, see page 12
Prof. J. S. Lee	University of Loma Linda	USA	in vivo	Clinical evaluation of a new dental adhesive in posterior composite restorations	June 2007	Baseline expected for Fall 2007
Prof. A. Cerutti	University of Brescia	Italy	in vivo	Hydrophobic coating on simplified self-etching adhesive: in vivo nano-leakage expression	July 2006	available and published (IADR 2007, # 0374)
Prof. R. Frankenberger	University of Erlangen	Germany	in vitro	µ-TBS trials on dentin	March 2006	available, see page 15
Prof. B. Haller	University of Ulm	Germany	in vitro	In vitro evaluation of the marginal quality of class II composite fillings adjacent to dentin when using a new all-in-one adhesive	January 2007	available, see page 16
Dr. H. Lu	University of Loma Linda	USA	in vitro	SBS comparison of one-step dentin bonding systems on primary tooth dentin	June 2006	available and published (IADR 2007, # 1992), see page 17
Prof. J. Y. Thompson	University of San Antonio	USA	in vitro	In vitro microtensile strength of different bonding systems to human enamel and dentin	Sept. 2006	available, see page 18
Prof. M. Hannig	University of Saarland, Homburg	Germany	in vitro	In vitro investigation on marginal and internal adaptation of different bonding agents and composites in class II cavities	Aug. 2006	available, see page 19
Prof. B. van Meerbeek	University of Leuven	Belgium	in vitro	µ-TBS on enamel and dentin	Sept. 2006	available, see page 20

Study Group	University	Country	Study Type	Title	Start of the Study	Results
Prof. M. Degrange	University of Paris	France	in vitro	In vitro evaluation of the dentin bond strength of the experimental self-etching system iBOND Self Etch	March 2006	available, see page 22
Dr. M. Miller	Reality Research Lab	USA	in vitro	SBS	Dec. 2006	available
Prof. W. Finger	University of Cologne	Germany	in vitro	Shear bond strength and marginal integrity to dentin with iBOND Self Etch	May 2006	available
Dr. S. Rupf	University of Leipzig	Germany	in vitro	Experimental evaluation of the self-etching adhesives iBOND Self Etch and iBOND GLUMA inside in combination with the universal composite Venus for filling class V restorations	April 2007	available
Prof. S. Uno	University of Tokyo	Japan	in vitro	μ-TBS	Aug. 2006	available
Prof. R. Yapp	The Dental Advisor	USA	in vitro	μ-TBS on dentin	March 2007	available
Dr. N. Ilie	University of Munich	Germany	in vitro	Mechanical properties of adhesives	Aug. 2006	available and published (IADR 2007, # 0927)

iBOND® Self Etch

Description

iBOND Self Etch is a light-curing self-etching one-component bonding agent for use in combination with adhesive restorations. Separate conditioning (etching) of the enamel and dentin is not required; however, the use of an additional etching gel on the enamel before application of iBOND Self Etch will not have a negative influence on the bond strength.

iBOND Self Etch was developed for bonding composite resin materials (e.g., composite, compomer and Polyglas®) to the hard tooth structure. iBOND Self Etch etches, primes, bonds, and desensitizes in one step.

Composition
iBOND Self Etch is an acetone/water-based formulation of light-activated methylacrylate resins.

Indications
- Bonding of direct light-cured composite restorations (including Polyglas and compomers).
- Bonding of indirect restorations in combination with a light-curing luting cement: porcelain, Polyglas, and composite restorations (inlays, onlays, veneers, crowns).
- Sealing hypersensitive areas of teeth.

Clinical application

Application of iBOND Self Etch

Shake vigorously

Dispense

Close immediately

Dip brush

Apply 1 x

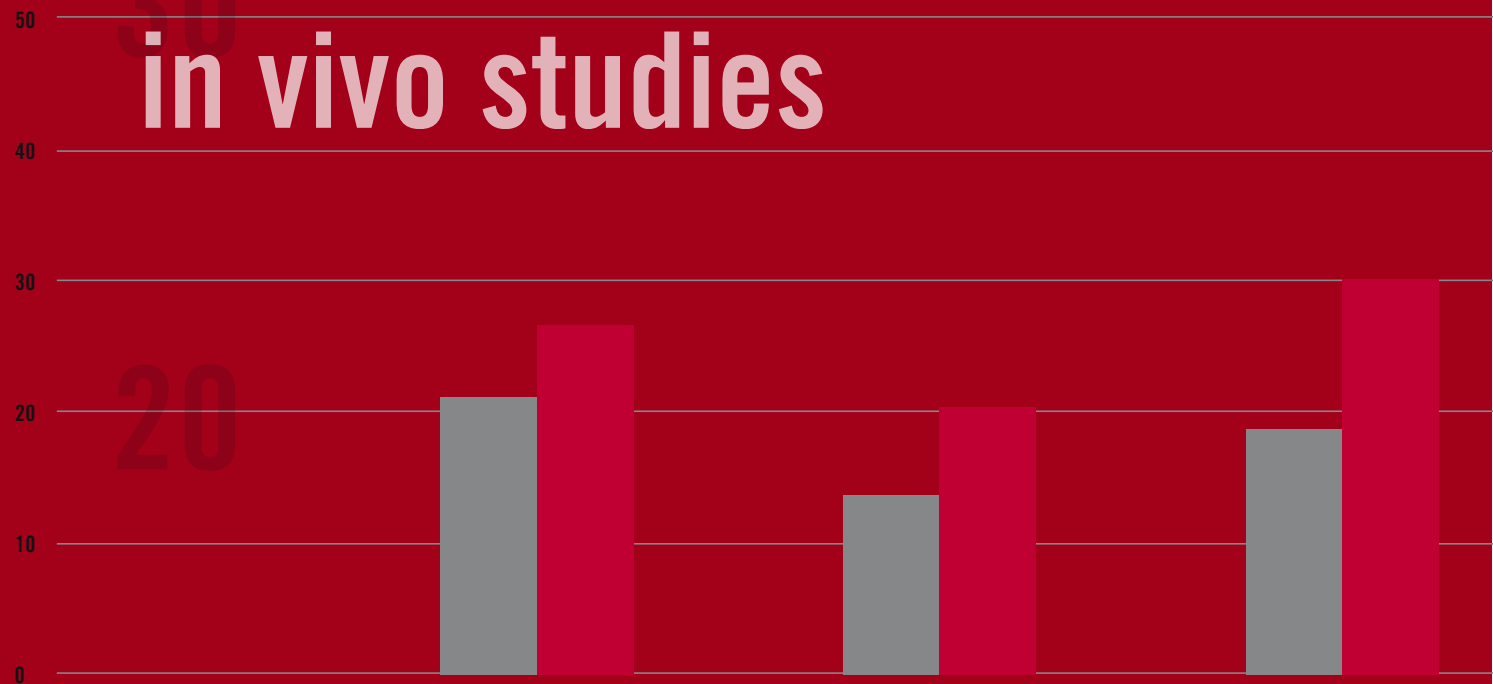
Agitate for
20 seconds

Air dry

Glossy surface
(if not, apply
additional coats)

Light cure for
20 seconds

in vivo studies



First clinical results with iBOND® Self Etch

Clinical evaluation of a new all-in-one adhesive in class V restorations

Source: Karl-Johan M. Soderholm, University of Florida, Gainesville, USA

Data on file

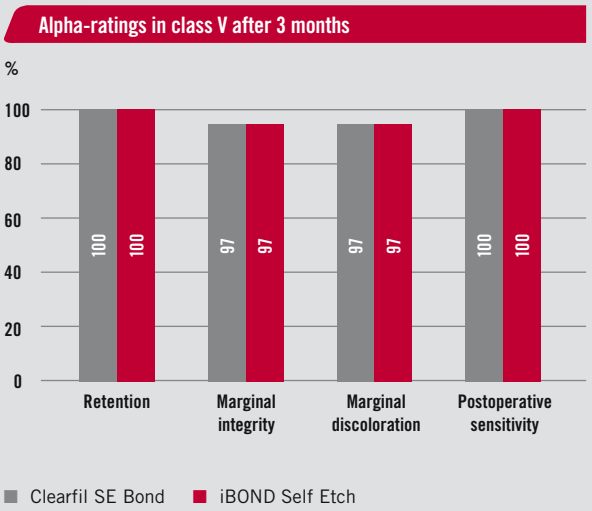
Objective:
The objective of this study was to evaluate the clinical performance of class V restorations bonded with iBOND Self Etch over an observation time up to 48 months.

Materials and Methods:
A total of 84 restorations (42 per adhesive) were placed in a total of 21 patients and are evaluated after 3, 12, 24, and 48 months.
The adhesive to be evaluated was iBOND Self Etch (Heraeus Kulzer) in comparison to Clearfil SE Bond (Kuraray). The restorative material in both cases was Venus (Heraeus Kulzer).

Conclusion:
After 3 months, all the placed restorations are still in use and perform without any signs of postoperative symptoms. Comparing the restorations regarding marginal differences and aesthetic performance does not suggest that there are any differences in performance between these two adhesive materials after 3 months of clinical service. After 3 months, one cannot draw any conclusions about the true clinical performance over time of the two products, but there is no doubt that the results are encouraging.

Results

Until July 2007, 70 (35 per group) of 84 placed restorations have been evaluated after 3 months.



Clinical results with iBOND Self Etch in anterior teeth

Use of a self-etching all-in-one adhesive in class III cavities in the permanent dentition – 3-month report

Source: Claus-Peter Ernst, Anke Schattenberg, University of Mainz, Germany

Data on file

Objective:

The aim of the study was to establish whether iBOND Self Etch self-etching adhesive could guarantee clinical and aesthetic marginal integrity of filled class III cavities over a two-year study period.

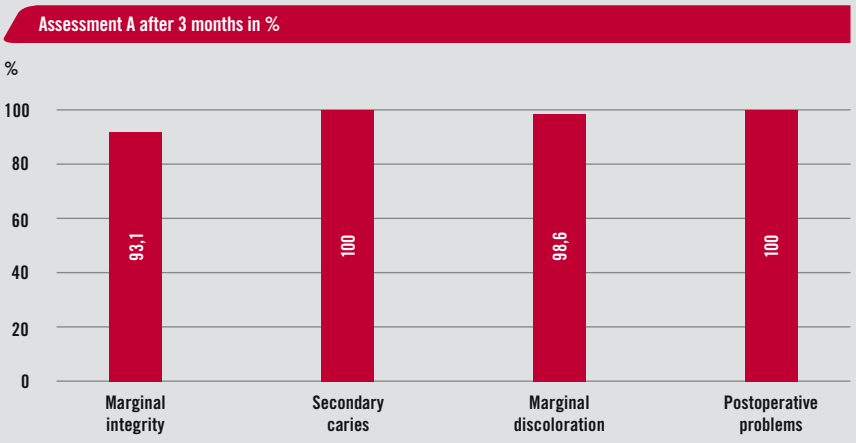
Materials and Methods:

A total of 72 fillings were placed in 38 patients up to March 2007; it was possible to carry out a follow-up examination of all the fillings after three months in July 2007. The class III cavities were preconditioned with iBOND Self Etch self-etching adhesive (Heraeus Kulzer) according to the manufacturer's instructions and filled with Venus microhybrid composite (Heraeus Kulzer), after determining the correct tooth shade for each patient. The fillings were assessed according to Ryge and CDA criteria by two examiners.

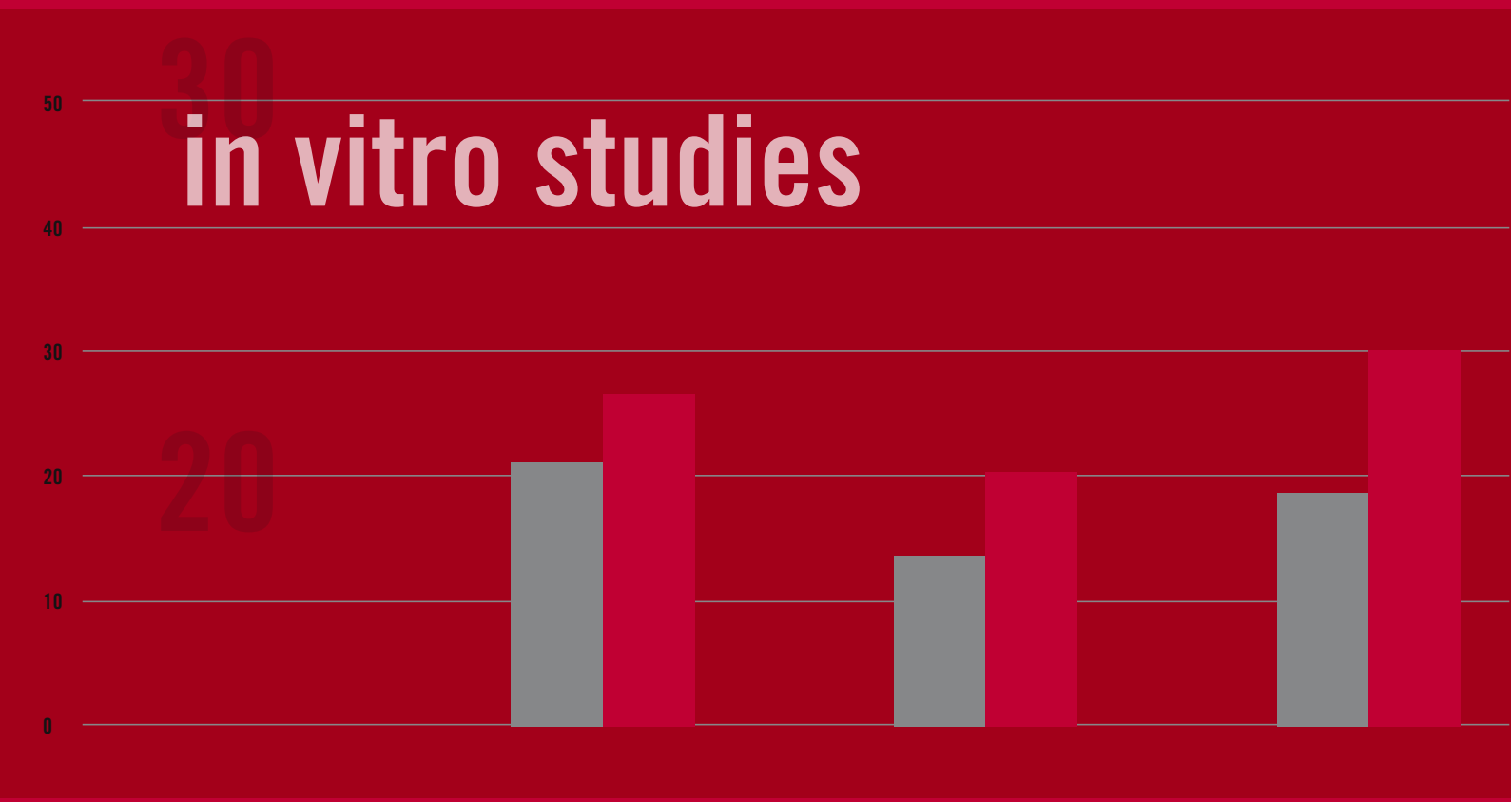
Conclusion:

Based on the very limited assessment period of 3 months, the initial conclusion is that there does not seem to be any problem with marginal discoloration when using iBOND Self Etch. The assessment criterion of marginal gap was always within the anticipated parameters of an effective adhesive system with assessments A and B. In the case of postoperative sensitivity assessment A also indicates excellent sealing of the dentin surface and a reduction in technique sensitivity.

Results



in vitro studies



Microtensile bond strength to dentin

µ-TBS trials on dentin
Source: Roland Frankenberger, Sergej A. Nikolaenko,
University of Erlangen, Germany
Data on file

Objective:
The objective of this in vitro study was to measure the microtensile bonding strength of five different adhesives.

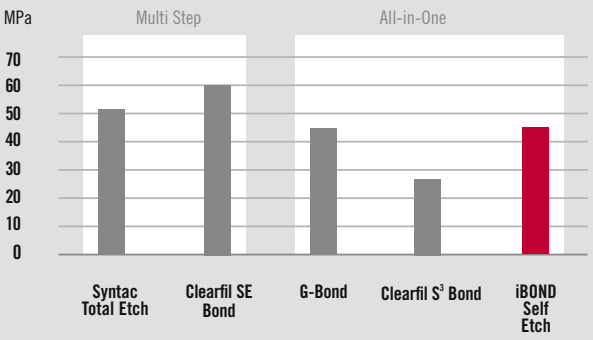
Materials and Methods
The bonding strength of the composite Filtek Z250 (3M ESPE) when bonded to dentin using different adhesives was measured. The following adhesives were used: iBOND Self Etch (Heraeus Kulzer), G-Bond (GC), Clearfil SE Bond (Kuraray), Clearfil S³ Bond (Kuraray), and Syntac Total Etch (Ivoclar Vivadent). Adhesive and composite were applied to a class I cavity, and then adhesion to the cavity floor was determined. The tests were carried out after storage in water for 24 hours at 37 °C using a microtensile machine at a displacement speed of 1 mm/min. The mean bond strengths were analyzed using the Kolmogorov-Smirnov test and the Wilcoxon test (p= 0.05). Samples that fractured before the test were included in the measurement using 0 MPa.

Conclusion:
In this study, iBOND Self Etch shows equivalent or substantially better bond strength than Syntac Total Etch and G-Bond or Clearfil S³ Bond and demonstrates the best results in the all-in-one group of adhesives.

Results

The mean microtensile bond strengths in MPa with standard deviation on dentine were:
iBOND Self Etch, 45.2±8.2
G-Bond, 44.4±7.4
Clearfil SE Bond, 59.4±6.3
Clearfil S³ Bond, 27.2±2.9
Syntac Total Etch, 50.4±8.4
The differences between iBOND Self Etch and Syntac Total Etch, as well as between iBOND Self Etch and G-Bond, were not significant.

Microtensile bond strengths on dentin in MPa



Marginal integrity at the enamel and dentin

Marginal integrity of class II composite fillings with iBOND Self Etch
Source: Bernd Haller, University Hospital Ulm, Germany
Data on file

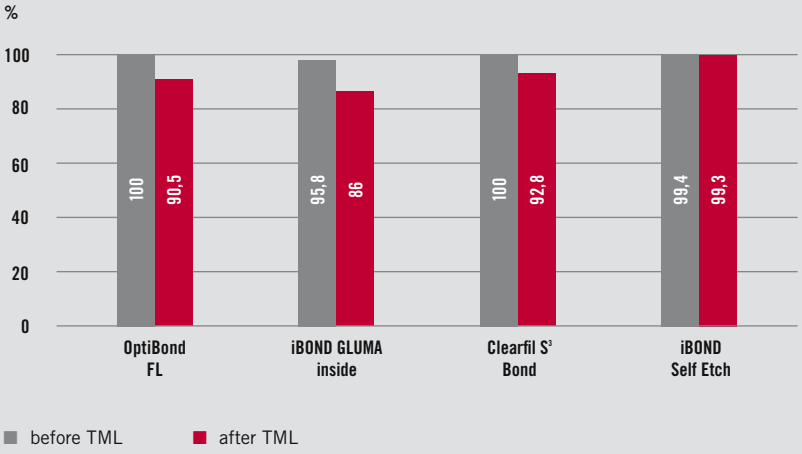
Objective:
The aim of this in vitro study was to investigate, with the aid of quantitative SEM marginal analysis, the extent to which iBOND Self Etch could prevent the formation of marginal gaps at the proximal enamel margins and cervical dentin margins in class II composite fillings with a dentin interface.

Materials and Methods:
Two two-surface class II cavities were prepared in 20 caries-free extracted third molars and each cavity was filled with composite (Venus, Heraeus Kulzer). One of the following bonding systems was used for 10 of the test cavities: Clearfil S^3 Bond (Kuraray), iBOND GLUMA inside (Heraeus Kulzer), iBOND Self Etch (Heraeus Kulzer) and OptiBond FL (Kerr). After the fillings were finished and polished, the teeth were stored in water for 24 h at 37 °C. An impression was then taken of the restored proximal surfaces using a low viscosity A-silicone (Flexitime, Heraeus Kulzer). The test teeth were then subjected to thermocycling (1500x, 55/5 °C, 25 s) and mechanical loading (TML) in a masticatory load simulator (50,000x, 50 N) and a new impression was then taken. The silicone impressions were used for fabricating plastic resin replicas, which were sputtered with gold. The replicas were assessed in the SEM at 300–500 x magnification based on the marginal criteria of seamless transition, marginal gap, tooth margin fracture and composite margin fracture. Furthermore, a dye penetration test was performed on the test teeth using 0.5 % basic fuchsin solution (24 h, 37 °C). The Kruskal-Wallis H test and the Wilcoxon test were used for statistical analysis.

Conclusion:
The marginal adaptation of iBOND Self Etch at the dentin margins was not only very good initially but also stable after loading. The dentin marginal integrity in the SEM after thermomechanical loading was comparable to that of Clearfil S^3 Bond and it was significantly superior not only to that of its forerunner iBOND GLUMA inside but also to that of the OptiBond FL multi-step, etch-and-rinse system. Phosphoric acid etching (OptiBond FL) at the enamel margins produced optimal marginal integrity without any marginal gaps, though there was no significant difference in enamel marginal integrity between iBOND Self Etch and Clearfil S^3 Bond.

Results

Perfect integrity at cervical dentin margins before and after TML in %



IN VITRO STUDIES

Shear bond strength of iBOND® Self Etch on primary tooth dentin

SBS comparison of one-step dentin bonding systems on primary tooth dentin

Source: B. Nelson, R. Grabowsky, H. Lu, W. Okumura, J. Peterson, Loma Linda University, Loma Linda, USA

IADR 2007 New Orleans, Poster 1992

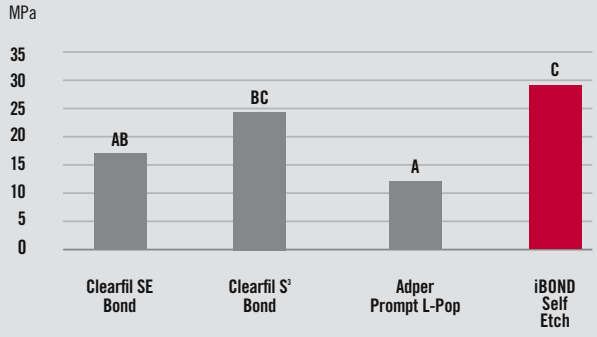
Objective:
To compare shear bond strengths (SBS) of composite materials to primary dentin when used with various one-step dentin bonding agents.

Materials and Methods:
Extracted primary teeth were divided into 4 groups of 15 specimens each. The teeth were mounted in phenolic rings with acrylic resin and wet-ground to expose an experimental dentin testing surface of at least 2.5 mm in diameter. The following bonding agents were used in each group: group I (control) – Clearfil SE Bond (Kuraray), group II – Adper Prompt L-Pop (3M ESPE), group III – iBOND Self Etch (Heraeus Kulzer), and group IV – Clearfil S³ Bond (Kuraray). A 2.38 mm projection of Herculite XRV Unidose composite (Kerr) was bonded to the dentin surface. After 1000 cycles of 5 – 55 °C thermocycling, the specimens were tested in MTS machine with shear force until failure occurred. Load at failure was recorded in Newton, and bond strength was calculated into Mega-Pascal. The debonded surfaces were evaluated for cohesive or adhesive failures.

Conclusions:
Different dentin bonding agents created different shear bond strengths between the composite and the primary dentin. iBOND Self Etch appears to have the highest bonding strength on primary tooth dentin, when taking cohesive failure into account.

Results

Shear bond strength of the tested adhesives



Shear bond strength (standard deviation) in MPa

Clearfil S³ Bond	Clearfil SE Bond	Adper Prompt L-Pop	iBOND Self Etch
24 (6)[bc]	17 (10)[ab]	12 (6)[a]	29 (6)[c]

6 specimens in iBOND Self Etch group had cohesive failures in dentin, while all the other specimens broke in the bonding interface. Means of SBS (MPa) are listed in the following table with standard deviation in parentheses. A 1-way ANOVA test showed that the bonding agent had a statistically significant influence on SBS.

Means with the same superscripted letter are not statistically different from each other at $p < 0.05$.

IN VITRO STUDIES

Microtensile bond strength of iBOND® Self Etch

In vitro microtensile strength of different bonding systems to human enamel and dentin

Source: Jeffrey Y. Thompson, University of Texas, San Antonio, USA, Erica Teixeira, University of North Carolina, Chapel Hill, USA
Data on file

Objective:
The objective of this in vitro study was to examine microtensile bond strengths to human dentin and enamel of different adhesives.

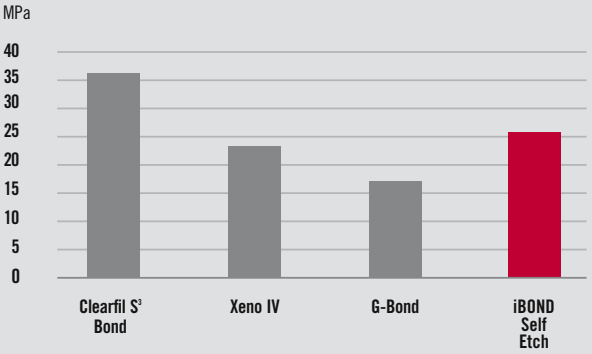
Materials and Methods:
Human teeth were cleaned of debris. In half of the teeth, the occlusal surface was ground flat until exposure of the dentin, and the other half, until exposure of enamel. The bonding procedures followed the manufacturers' recommendations. The adhesive systems evaluated in this study were: GLUMA Comfort Bond (Heraeus Kulzer), Prime&Bond NT (Dentsply), Xeno IV (Dentsply), G-Bond (GC), Clearfil SE Bond (Kuraray), Clearfil S^3 Bond (Kuraray), and iBOND Self Etch (Heraeus Kulzer). Six to seven teeth (min. three for enamel and three for dentin groups) were prepared for each material. A crown was built up incrementally over the adhesive resin using a resin composite (Venus, Heraeus Kulzer) for all groups. The roots were then removed, and the pulp chambers were sealed with composite resin. The bonded assemblies (n=20 per group) were stored in water for one day at 37 °C and then sectioned perpendicular to the bonded interface into approximately 1 mm thick beams with a diamond saw. Microtensile bond tests were performed for all specimens using a table-top material tester (EZ test, Shimadzu Co., Kyoto, Japan) at a crosshead speed of 1 mm/min. Bond strength data was subjected to one-way ANOVA followed by Tukey test at 95 % level of confidence.

Conclusion:
iBOND Self Etch was equivalent to the other self-etching bonding agents in regard to microtensile bond strength to enamel, except for Clearfil SE Bond, which had a statistically higher mean strength. For microtensile bond strength to dentin, iBOND Self Etch was statistically the same as the other self-etching bonding agents, except for Clearfil SE Bond and Clearfil S^3 Bond.

Results

The mean results with standard deviation for microtensile bond strength to enamel/dentin were:
GLUMA Comfort Bond, 28.4±9.6/46.3±10.2
Prime&Bond NT, 28.7±12.3/42.1±9.8
Clearfil SE Bond, 28.8±9.8/54.7±16.4
Clearfil S^3 Bond, 19.5±9.9/36.2±12.5
Xeno IV, 18.0±7.2/23.2±12.6
G-Bond, 17.8±7.3/17.1±7.6
iBOND Self Etch, 17.4±7.0/25.7±9.6

Microtensile bond strength to dentin of tested all-in-one adhesives



Marginal integrity of iBOND® Self Etch

In vitro investigation on the marginal and internal adaptation of different bonding agents and composites in class II cavities
Source: Matthias Hannig, University of Saarland, Homburg, Germany
Data on file

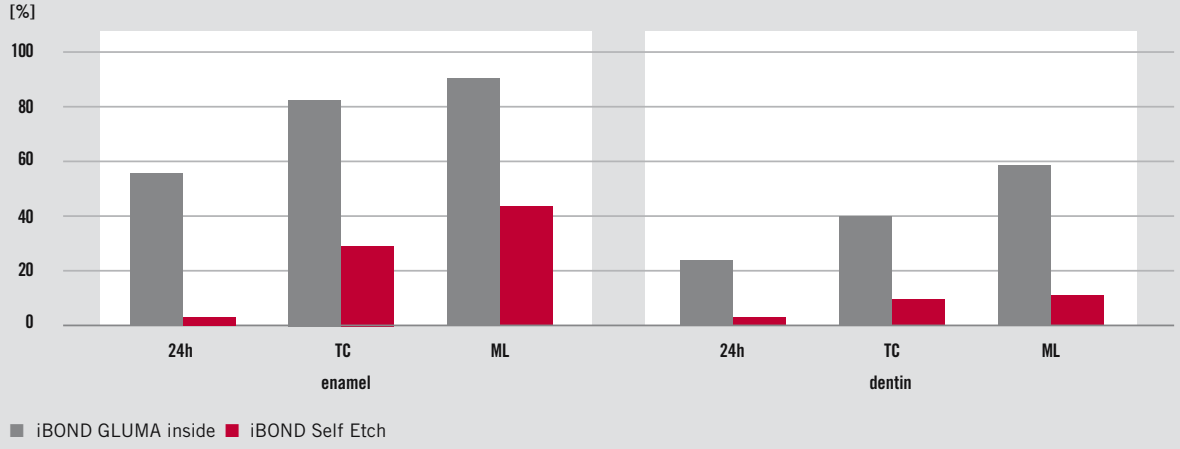
Objective:
The purpose of this in vitro study was to investigate the marginal and internal adaptation of different bonding agents and composites.

Materials and Methods:
Class II cavities with small occlusal cavity, cervical margin in cementum, and chamfered proximal enamel margins were prepared using caries-free, extracted human teeth. The two adhesives were applied according to the manufacturer's instructions, and the composite restoration was prepared using the incremental technique. Inspection then took place using the incident light microscope. The analysis of marginal adaptation was performed by SEM marginal gap analysis by means of the replica method after storage for 24 hours in water (24h), thermocycling (TC) (1500 x, 2/60 °C, 45/7/45 s), and chewing simulation (ML) (200,000 x). Analysis of internal adaptation was done using the dye penetration test after chewing simulation. Here, discontinuity was defined as follows: an interruption in the transition from composite to dental substance (e.g., marginal gaps, hairline cracks, crevices). The following adhesives were examined: iBOND GLUMA inside (Heraeus Kulzer) and iBOND Self Etch (Heraeus Kulzer). Venus A3 (Heraeus Kulzer) was used as the composite material.

Conclusion:
In strain tests, iBOND Self Etch demonstrates more than 50 % fewer marginal gaps compared to iBOND GLUMA inside. With iBOND Self Etch, after storage in water for 24 hours, no marginal gaps were found on enamel or dentin.

Results

Percentage of discontinuity in enamel and dentin



IN VITRO STUDIES

Microtensile bond strength on enamel and dentin

µ-TBS on enamel and dentin

Source: Bart van Meerbeek, University of Leuven, Belgium

Data on file

Objective:

The objective of this in vitro study was to investigate the bonding effectiveness and interaction with enamel and dentin of iBOND Self Etch compared to iBOND GLUMA inside.

Materials and Methods:

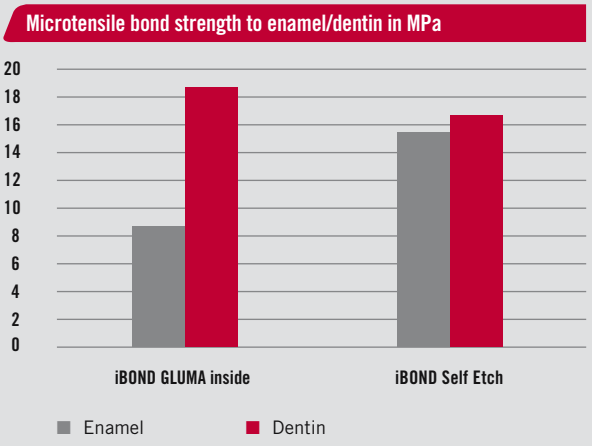
The adhesives iBOND Self Etch (Heraeus Kulzer) and iBOND GLUMA inside (Heraeus Kulzer) were examined. The enamel samples were produced by grinding the lingual and buccal enamel from extracted human third molars. The occlusal third of the teeth was removed to produce the dentin samples. A thin layer was removed at the surface using a high speed medium-grit (100 µm) diamond grinder in order to obtain a standardized application layer. The adhesives were applied according to the manufacturer's instructions, and the composite Z100 (3M ESPE) was built up to a height of 5–6 mm. The samples were then stored in water for 24 hours at 37 °C. The teeth were cut perpendicular to the bonding surface into rectangular samples. The 48 samples obtained were shear-loaded to failure using an LRX test machine at a displacement speed of 1 mm/min.

Conclusion:

Compared with iBOND GLUMA inside, iBOND Self Etch demonstrates better bond strength to enamel, whereby a clinical improvement of the marginal integrity is to be expected.

Results

The microtensile bond strengths in MPa with standard deviation for enamel/dentin were 15.6±11.8/16.2±4.3 for iBOND Self Etch and 8.3±15.2/18.7±10.0 for iBOND GLUMA inside.



Shear bond strength and marginal adaptation to dentin

Test on the shear bond strength and marginal adaptation at the dentin of AdheSE One, Xeno V and iBOND Self Etch

Source: Research & Development, Heraeus Kulzer Wehrheim, Germany
Data on file

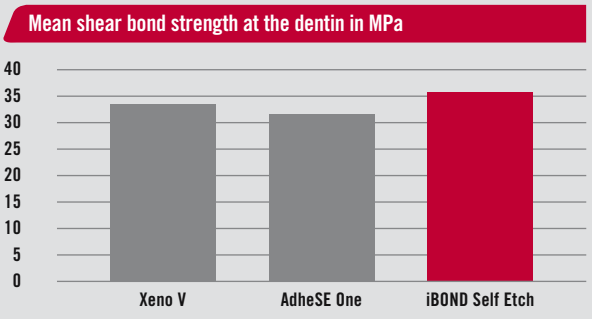
Objective:
The aim of this in vitro study was to test the shear bond strength and marginal adaptation at the dentin of three new self-etching all-in-one adhesives.

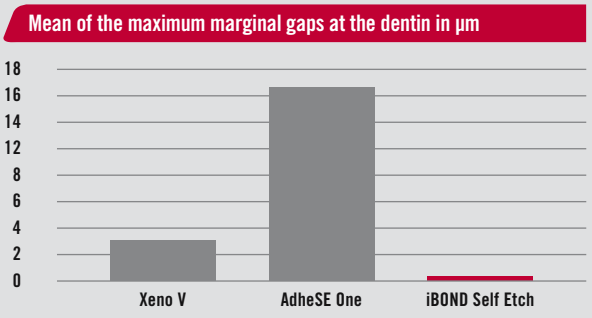
Materials and Methods:
The self-etching all-in-one adhesives tested were AdheSE One (Ivoclar Vivadent), Xeno V (Dentsply) and iBOND Self Etch (Heraeus Kulzer). The adhesives were used according to the manufacturer's instructions in both tests.
The shear bond strength was determined using the Ultradent technique (template with a 2.38 mm diameter) on extracted human molars with an exposed dentin surface (n=8). The composite used for the tests was Venus (Heraeus Kulzer). Following preparation, the test teeth were stored in water for 24 h at 37 °C. The shear strength was determined in a universal testing machine (Zwick Z010) with a thrust speed of 1 mm/min. In order to test the marginal gap, extracted human molars (n=8) were cut down to the dentin; class I cavities were prepared in the dentin and filled with Venus composite (Heraeus Kulzer) after application of the adhesive. The test teeth were then stored for 10 minutes in water. The marginal gap was determined by surface analysis of the digitized images using the Analysis Soft Imaging programme (Olympus) with measurement of the largest marginal gap respectively.

Conclusion:
iBOND Self Etch exhibited the best results at the dentin with regard to shear bond strength and marginal adaptation.

Results

The shear bond strength at the dentin was 31.2 ± 10.7 MPa for AdheSE One, 34.1 ± 8.6 MPa for Xeno V, and 35.7 ± 2.1 MPa for iBOND Self Etch. With regard to gap-free marginal adaptation at the dentin of the teeth tested, AdheSE One attained 0 %, Xeno V 50 % and iBOND Self Etch 100 %.





IN VITRO STUDIES

“Battle of the Bond” – Shear bond strength of iBOND® Self Etch

In vitro evaluation of the dentin bond strength of the experimental self-etching system iBOND Self Etch

Source: Michel Degrange, Biomaterials Lab, University of Paris, France
Data on file

Objective:
The objective of this in vitro study was to assess the dentin bond strength of iBOND Self Etch.

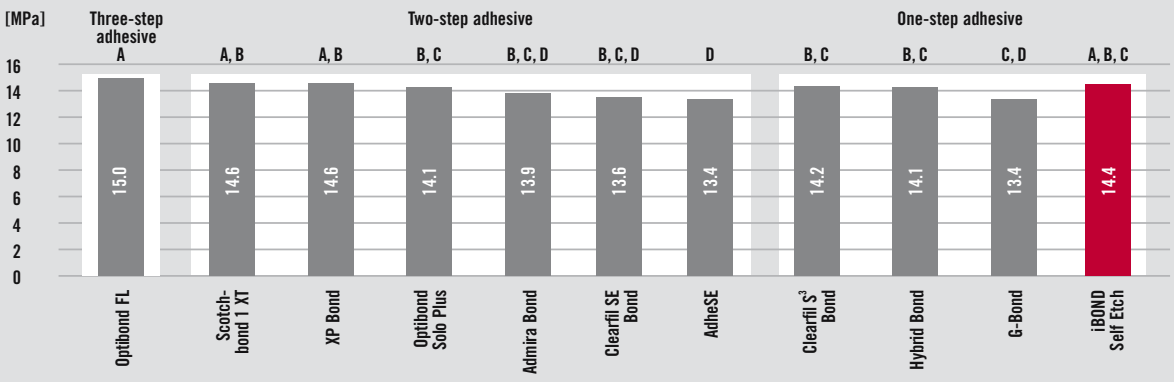
Materials and Methods:
iBOND Self Etch was tested in four practical courses of the “Battle of the Bond”. The trials took place in meeting rooms especially equipped for this experiment. Sufficient specimens (extracted human molars) were prepared in advance for each series of tests according to the numbers of participants. The teeth were embedded in acrylic resin, and flat dentin surfaces were produced by wet grinding on SiC paper # 800. To achieve the specimens, the practitioners used Teflon split molds. After the application of the adhesive, the molds were filled in 2 increments (light-cured for 20 seconds each) with a composite resin. Only one composite material was used for all the trials (Z 100, 3M ESPE). The light intensity emitted by the available units was checked before using (a threshold of 600 mW/cm^2 was required). The bonded samples were stored in water and tested approximately 10 minutes after bonding. Shear bond strength was measured using a guillotine-type device on the tensile machine at a cross-head speed of 5 mm/min until fracture occurred. The shear bond strength values were recorded in an EXCEL table as the tests were conducted. Shear bond data were statistically analyzed with a Student’s test at the level of p=0.05.

Conclusion:
The main advantage of the “Battle of the Bond” was to record a large database extracted from tests made by general practitioners. In this study, more than one hundred tests were performed with iBOND Self Etch. Recently, a publication grouping together all the clinical trials of dentin bonding systems has shown a positive correlation between this data and the clinical behavior of the same dentin bonding systems (Peumans et al., 2005).

Results

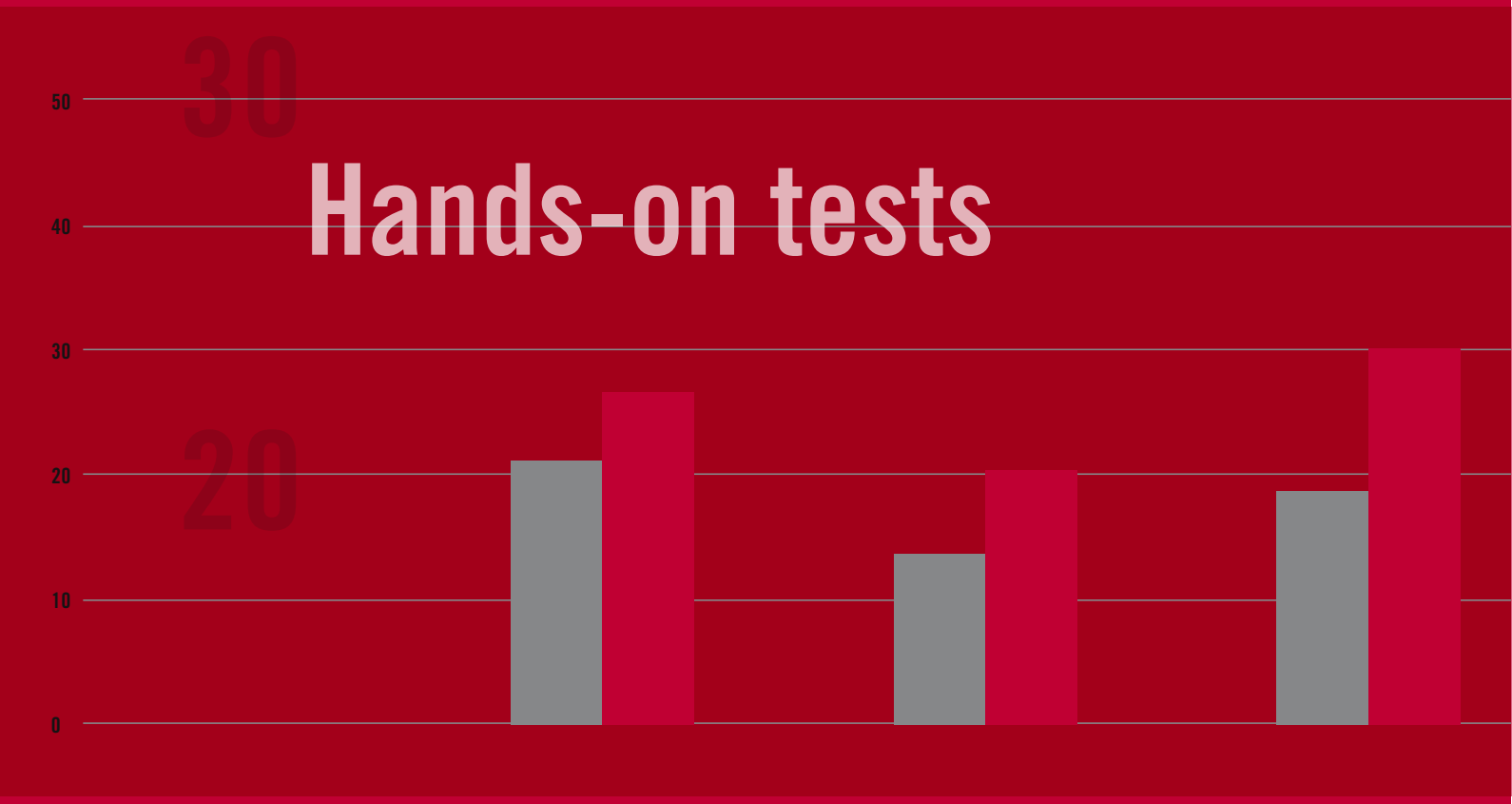
In total, 106 specimens of iBOND Self Etch were tested. The shear bond strength of iBOND Self Etch was 14.39 ± 4.5 MPa.

Initial shear bond strength to dentin in MPa in comparison to other tested adhesives*



*Results with the same superscripted letter are not statistically different from each other ($p < 0.05$).
The other adhesives were tested at least 100 times with the same method in at least five courses of the “Battle of the Bond”.

Hands-on tests



Hands-on observation

Evaluation of iBOND® Self Etch under everyday clinical conditions

iBOND Self Etch evaluation under everyday conditions
Source: internal data
Data on file

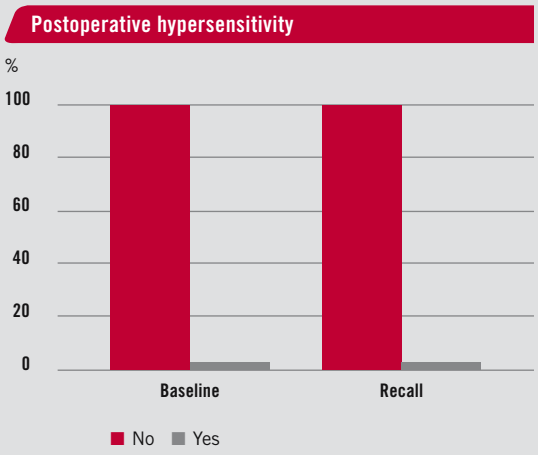
Objective:
The objective of this hands-on test was to evaluate the clinical performance (marginal quality and postoperative hypersensitivity) of iBOND Self Etch (Heraeus Kulzer) under everyday clinical conditions.

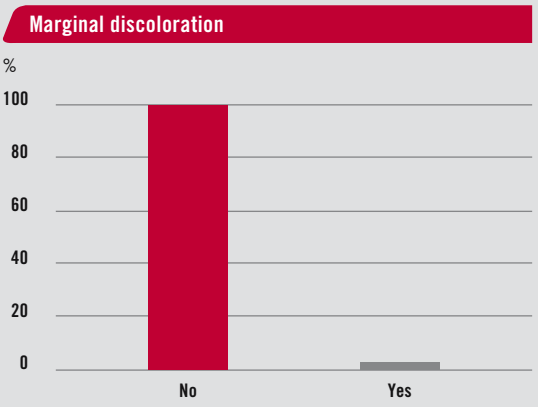
Materials and Methods:
After product registration (CE mark), iBOND Self Etch was given to 6 dental practitioners (DP). Altogether, 66 restorations in classes I through V were placed with iBOND Self Etch as the adhesive and the DP's preferred composite. iBOND Self Etch was used according to the manufacturer's instruction: apply one coat, agitate for 20 seconds, air blast, and then light cure for 20 seconds. The restorations were evaluated for marginal discoloration and postoperative sensitivity by the DP directly after placement and then again after 2 to 8 weeks. Evaluation criteria were only the answers "yes" or "no" to facilitate integration into the routine of the dental office.

Conclusion:
Practice-based research can be an adequate tool to evaluate clinical performance of new products under everyday conditions. The results of this test show excellent marginal quality and prevention of postoperative hypersensitivity under clinical conditions. However, evaluation of a larger amount of restorations, and over a longer period of time, is needed.

Results

56 of the 66 restorations were evaluated after 2 to 8 weeks (median: 3.5 weeks). Class distribution was: 3 class I, 13 class II, 3 class III, 5 class IV and 29 class V. None of the restorations showed postoperative hypersensitivity or any marginal discoloration directly after placement (baseline) or at recall.





Europe-wide user test of iBOND® Self Etch

iBOND Self Etch hands-on observation
Source: Internal data
Data on file

Objective:
The objective of this test was to evaluate the new iBOND Self Etch adhesive under practical conditions before introduction to the market.

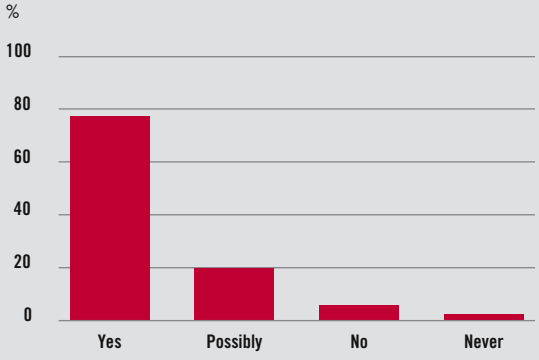
Materials and Methods:
After product registration, iBOND Self Etch (Heraeus Kulzer) was provided to 350 practitioners in Germany, France, Italy, and Great Britain, together with a questionnaire for testing.

Conclusion:
In almost 6,000 fillings tested under everyday conditions, dentists were overwhelmingly satisfied with the easy handling and fast application of iBOND Self Etch.

Results:

Altogether, 310 completed questionnaires were returned, and a total of 5,950 fillings were prepared using iBOND Self Etch during this user test. Results showed that 75 % of the dentists found iBOND Self Etch to be better than the bonding agent(s) they had previously used, and 93 % of the participants would recommend it to their colleagues. After the test, 75.6 % of the dentists surveyed indicated they would continue to use iBOND Self Etch as the main bonding agent in their practices.

Are you going to use predominantly iBOND Self Etch in your dental office in the future?



Responses in %

Notes:
All graphs and page titles were provided by Heraeus Kulzer.
The studies on pages 12, 15, 16, 19 and 21 were translated into English.
The studies are presented in an abridged version.
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In compliance with the European guideline 93/42/EWG our medical devices are CE-marked according to the classifications.

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