DENTSPLY
DETREY

XP BOND™
... for eXtra Performance

Universal Total-Etch Adhesive

(For Individual Attention Only) 2006-08-14

With the compliments of

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SCIENTIFIC COMPENDIUM

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1 Introduction

With the introduction of **Prime&Bond® - the first one-bottle-bond** for the Etch&Rinse (Total-Etch) technique in dentistry - DENTSPLY set a milestone in the development of dental adhesives. Over the last decade this approach was further exploited resulting in the state-of-the-art adhesive Prime&Bond NT introducing nano-technology to dental adhesives. The main objective for such development is to create a high and reliable adhesion – when used by dentists in their daily practice.

Based on the knowledge DENTSPLY gained in 13 years of developing one-bottle-bonds, the emphasis was directed to optimize performance of the adhesive when used by practitioners, rather than under ideal laboratory conditions and to ensure a broad field of indications including indirect luting procedures.

Therefore, XP *BOND*™ stands for e**X**tra **P**erformance.

XP *BOND* is a universal self-priming dental adhesive for the Etch&Rinse technique designed to bond resin based light-cured restorative materials to enamel and dentine.

XP *BOND* is indicated for bonding all types of indirect restorations when mixed with Self Cure Activator (SCA) and combined with a dual-cure or self-cure resin cement such as Calibra® Esthetic Resin Cement.

XP *BOND* offers a new, unique solvent providing easy and comfortable application and thereby a high degree of technique robustness.

2 Product Description – XP *BOND*

2.1 XP *BOND*: Components and Function

XP *BOND* is a universal self-priming dental adhesive designed to bond light-cured restorative materials to the tooth substrate. The components and their specific functions are given in Table 1 below.

Component	**Function**
PENTA	Adhesion promoter, wetting aid and crosslinker
TCB resin	Adhesion promoter, wetting aid and crosslinker
UDMA	Resin molecule of intermediate elasticity when cured
TEGDMA	Mobile crosslinking methacrylate resin for good infiltration
HEMA	Reactive diluent and wetting aid
Nanofiller	Nanoscale functionalised filler for increasing strength and crosslinking
Camphorquinone, DMABE	Photoinitiator system
Butylated benzenediol	Stabilises material during storage
tert-Butanol	Solvent for the resins and mild stabiliser.

Table 1 Components of XP *BOND* and their function

The use of PENTA (Figure 1) and TCB resin (Figure 2) as adhesion promoters in the low viscous adhesive XP *BOND* promotes chemical interaction between the monomers and tooth substance and ensures high bond strength to tooth substance.

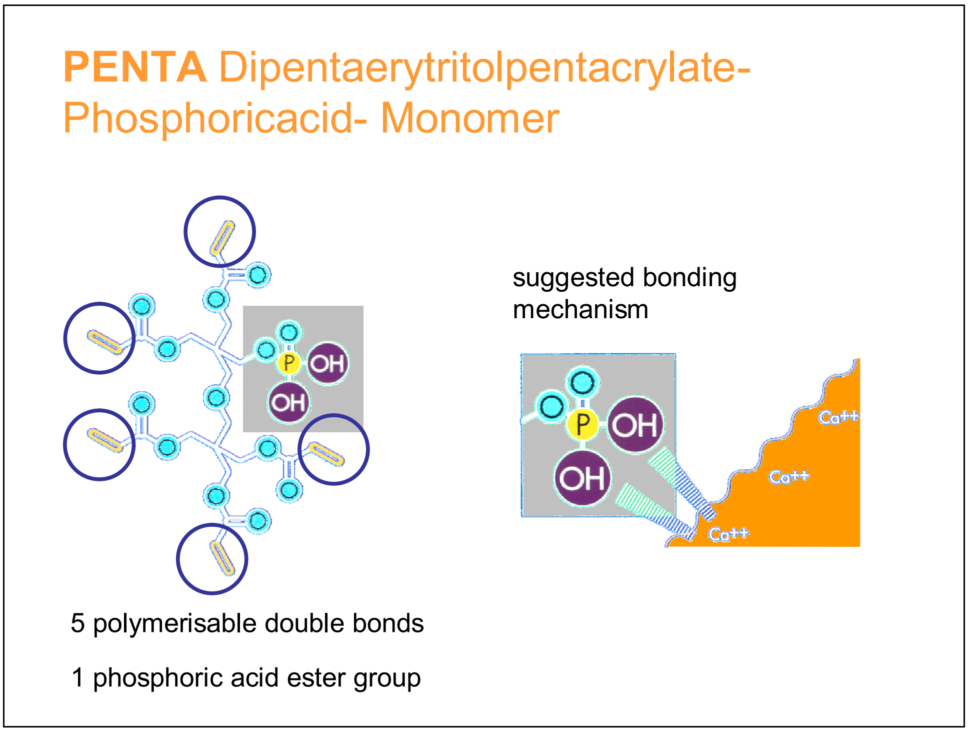


Figure 1 Chemical structure of PENTA and schematic interaction with tooth substance

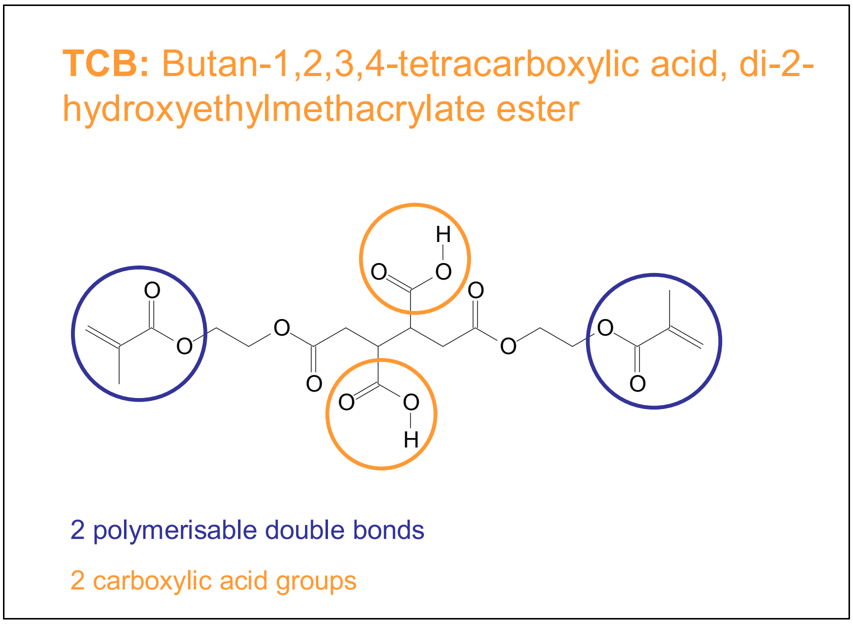


Figure 2 Chemical structure of TCB resin

A crosslinking agent, UDMA resin, has been added to the formulation leading to a denser network of the resin matrix and resulting in higher toughness of the adhesive layer, respectively.

HEMA was added to allow further increase of resin content while reducing volatile constituents. Additionally, HEMA is known to increase penetration into moist collagen meshes typically after etching and rinsing.

The nanofiller in the XP *BOND* bonding agent formulation improve a number of properties. The most important aspects are

- Increased adhesion strength to both enamel and dentine
- Increased marginal integrity
- Sufficient film thickness for one-coat, one-cure technique.

Compared to Prime&Bond NT, in the new XP *BOND* acetone is replaced by tert-butanol. This solvent has a higher boiling point than acetone. Hence, tert-butanol is advantageous in daily practice by allowing the use of a dappen dish (e.g. CliXdish in Figure 3) and the increase of the resin content. Both lead to increased adhesive layers thickness.

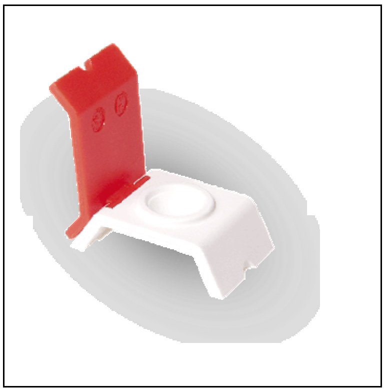


Figure 3 New CliXdish (red cover)

Because of the tertiary group, the shape of the t-butanol molecule is approximately spherical rather than long and thin (see Figure 4).

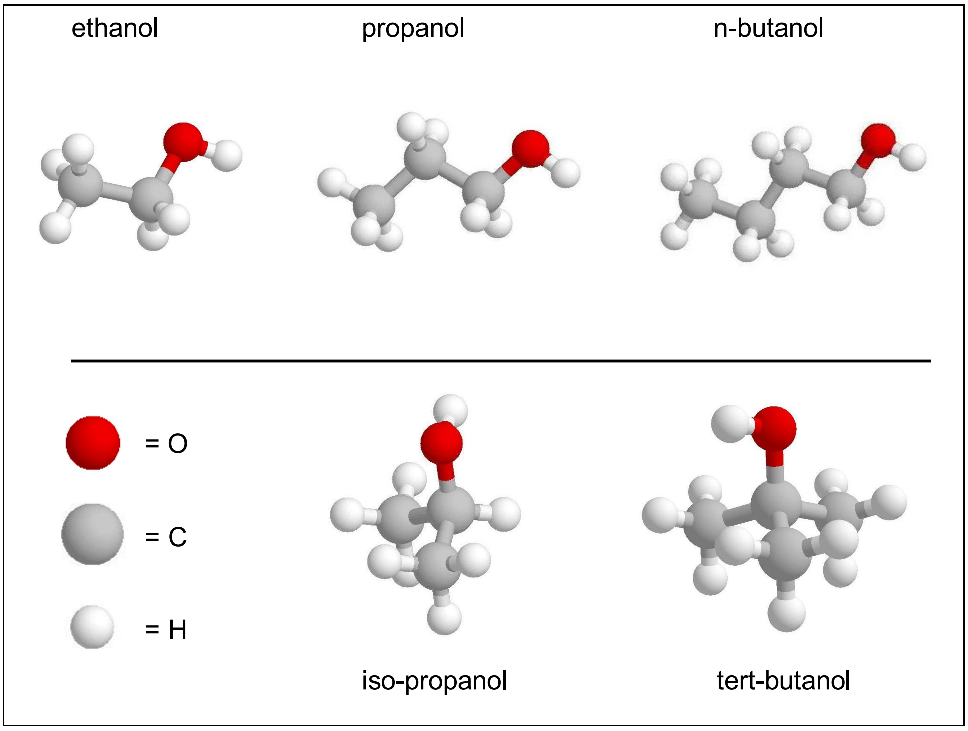


Figure 4 Chemical structure of alcohols

The alcohol group in t-butanol is therefore shielded by the surrounding methyl groups (see Figure 5) and this has additional important consequences:

- T-butanol is totally miscible with both water and with the polymerisable resins. It therefore helps the resin containing adhesive to wet a moist tooth surface.
- Because the alcohol group is shielded, attraction between the alcohol groups on individual t-butanol molecules is much less than in ethanol or isopropanol. Although the molecular weight of t-butanol is higher than that of either ethanol or isopropanol the rate of evaporation of t-butanol is therefore approximately the same as for ethanol. As there is less hydrogen bonding between molecules the latent heat of

vaporisation of t-butanol and ethanol are approximately the same, (41kJ/mol and 42kJ/mol respectively compared to 47.5 kJ/mol for isopropanol and 51kJ/mol for n-butanol.

- The alcohol group in t-butanol makes the molecule polar enough that it does not pass easily through polyethylene packaging. The rate of loss of solvent during storage is therefore very low.
- Because of the tertiary group, t-butanol is not able to chemically react with the resins in the same way that ethanol and isopropanol do. For this reason formulations containing t-butanol are chemically more stable than those containing ethanol or isopropanol.

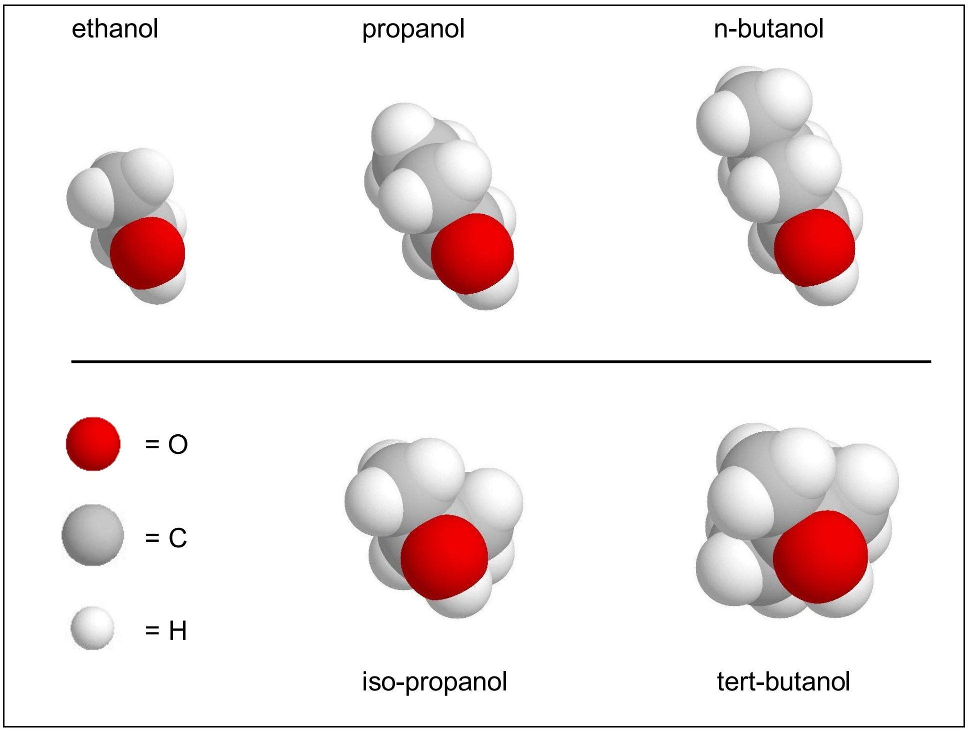


Figure 5 Chemical structure illustrating the electron space of each atom

DENTSPLY has applied a patent for using tert-butanol in adhesives because of the aboved mentioned features this solvent offers.

3 In vitro Investigations

Before the final proof in the clinical situation (see chapter 4) it is needed to conduct in vitro investigations not only to verify the performance under standard situations but also to challenge the adhesive in different ways in order to get feed back for additional

improvements. These investigations involve different aspects of variability including methods, operators, procedures and others.
In the following investigations of bond strength, marginal quality, and micro morphology are described.

3.1 Adhesion

Although the development of XP *BOND* was focused on the improvement of handling properties and practicality in use, in-vitro investigations of adhesion have been performed at a number of sites to evaluate the performance in comparison to other adhesives. The results are described in the following sections.

3.1.1 Bond Strength to Dentine and Enamel

Bond strength was tested at different sites by external experts and by DENTSPLY researchers under well established and standardized conditions.
Additionally, practitioners were involved to prepare samples to investigate the technique robustness.

3.1.1.1 *Shear bond strength on enamel and dentine*

(Mark Latta, Creighton (NE), USA)
One experienced operator performed all samples for testing. Shear bond strength (SBS) after 1800 thermo cycles was compared to SBS measured after 6000 thermo cycles.

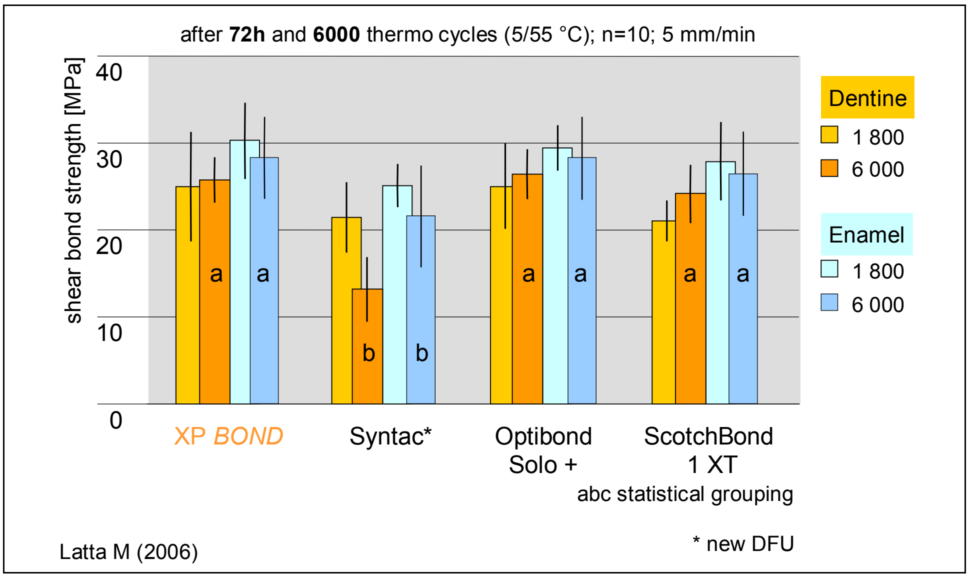


Figure 6 Shear bond strength after 1800 and after 6000 thermo cycles

The multi bottle system included as control was adversely affected by higher numbers of thermo cycles (see Figure 6).
However, XP *BOND* and the other one bottle Etch&Rinse adhesives were not affected by higher numbers of thermo cycles and performed on a significantly higher level.

Since LED light curing units are becoming more and more popular the compatibility of XP *BOND* with these lamps was tested.

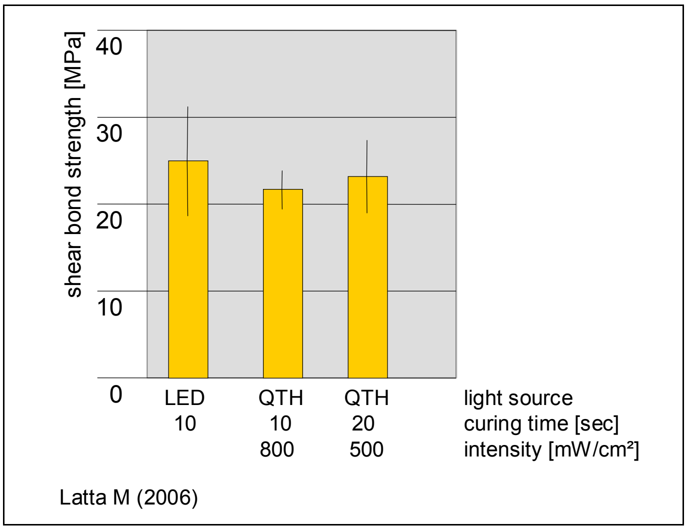


Figure 7 SBS of XP *BOND* using different light sources

The results in Figure 7 show that XP *BOND* performs on the same high level using either Quartz Tungsten Halogen (QTH) or LED curing lights. It could also be demonstrated that prolonging the curing time from 10 to 20 seconds allows the use of lamps with lower power output (500 mW/cm² or higher).

3.1.1.2 *Shear bond strength by three operators*

(DENTSPLY DeTrey, Konstanz, Germany)
Three well trained operators performed bond strength testing using either a QTH curing unit (Spectrum® 800) or a LED curing unit (SmartLite™PS).

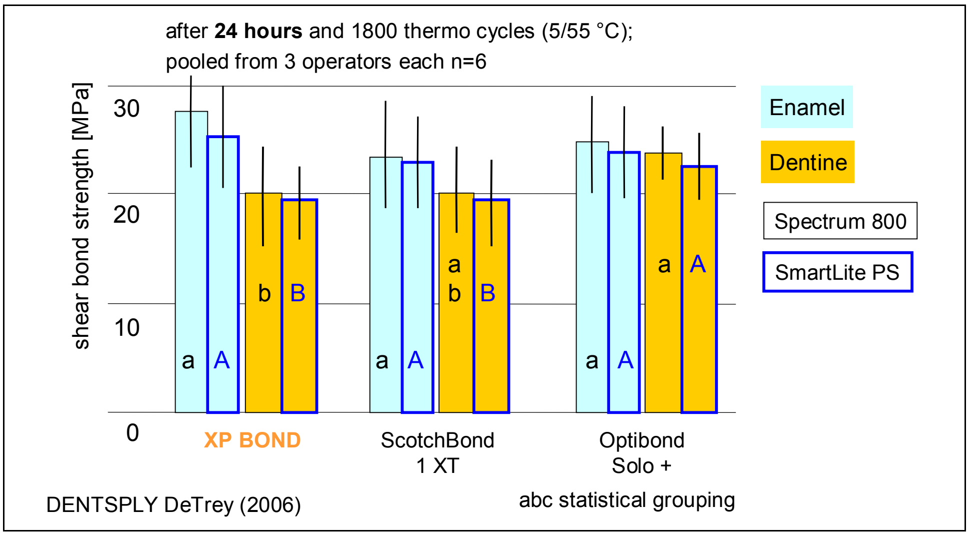


Figure 8 SBS to enamel and dentine with either QTH or LED curing unit

Results in Figure 8 show that all tested adhesives provide high levels of bond strength to enamel and dentine regardless of the used light source.

3.1.1.3 *Micro Tensile Bond Strength (µTBS) to dentine*

(Jan De Munck, Bart Van Meerbeek, Leuven, Belgium)

An alternative method to test bond strength is to pull the bonded materials apart instead of shearing one material from the other. In particular, composite is bonded to flat dentine surface and this assembly is cut into small sticks which then can be thermo cycled and tested for micro tensile bond strength (Shirai et al., 2005).

Figure 9 illustrates how test sticks were prepared before thermo cycling was applied.

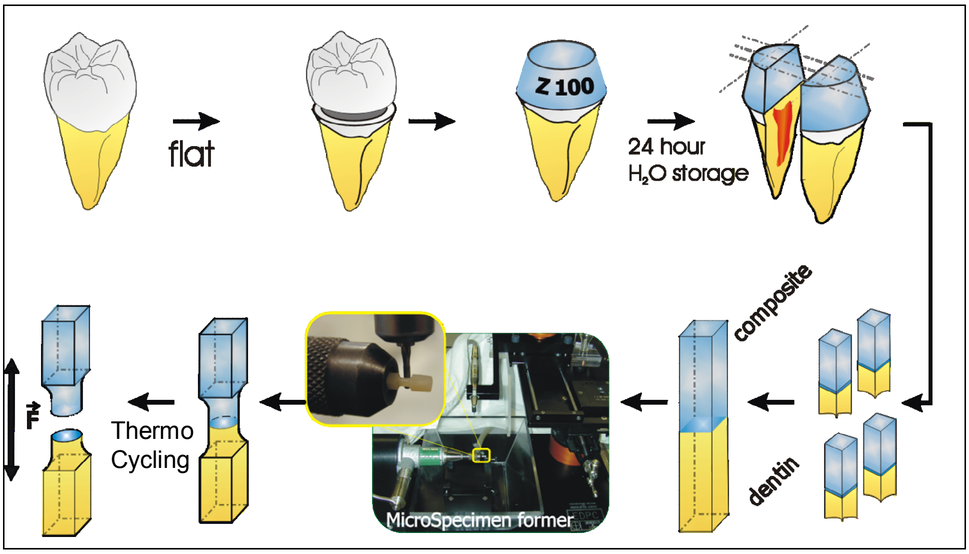


Figure 9 Preparation of sticks before thermo cycling for µTBS testing

As in the previous investigation either 1800 or 6000 thermo cycles were applied.

XP *BOND* was designed to allow an easy application procedure. The adhesive is applied onto the cavity surfaces and left undisturbed for 20 seconds. However, active rubbing or scrubbing is recommended by other manufacturers for their respective one bottle adhesive. By comparing passive versus active application for these adhesives the significance of this application procedure could be clarified.

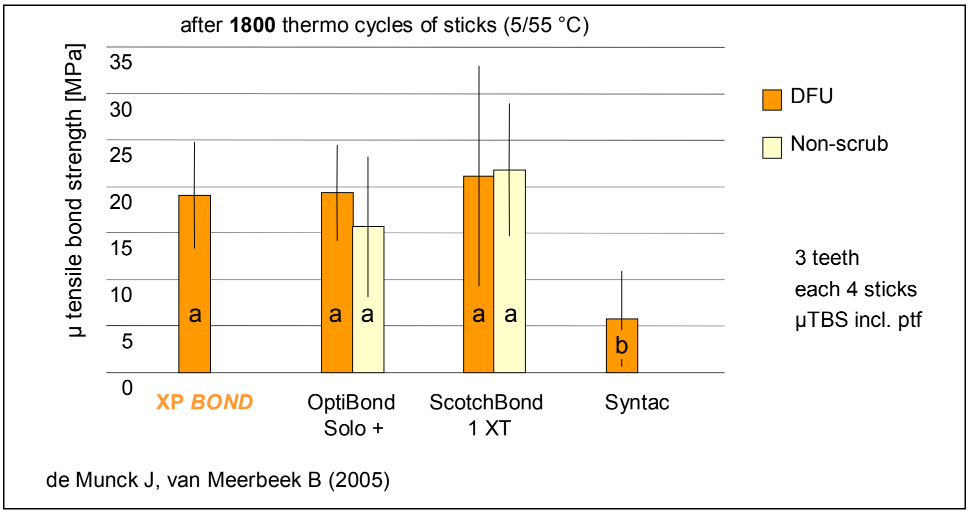


Figure 10 µTBS after 1800 thermo cycles of sticks

XP *BOND* and two other one bottle adhesives showed significantly higher bond strength values compared to the control – a multi bottle adhesive.

Results after 1800 thermo cycles of the adhesion test sticks showed no influence of the application technique for those one bottle adhesives that need active application (rubbing or scrubbing) according to the respective DFU (Figure 10).

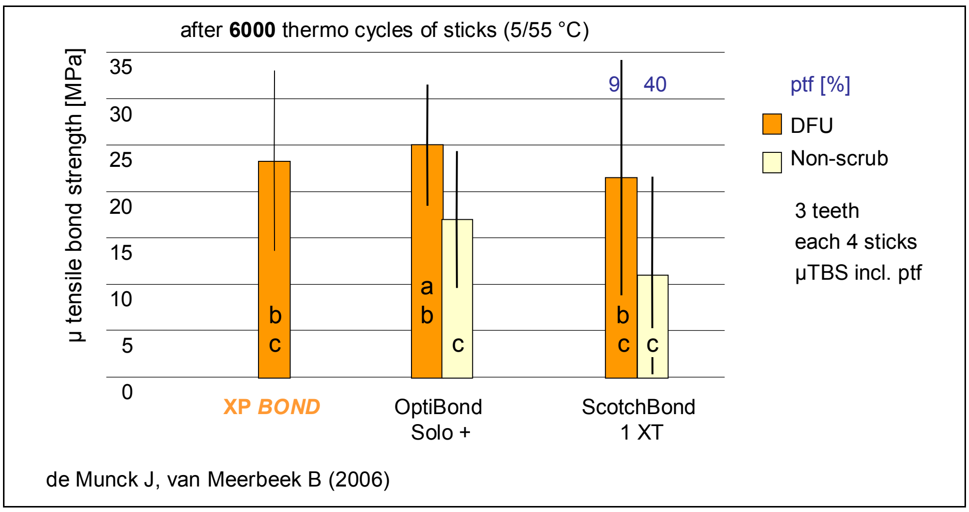


Figure 11 µTBS after 6000 thermo cycles of sticks

After 6000 thermo cycles there was however a significant decrease in bond strength for one of the adhesives when the recommended scrubbing application technique was not performed (Figure 11).
Since with XP *BOND* an active application technique is not needed, a decrease in performance can not be caused by altering the application in such a way, hence XP *BOND* demonstrated a higher technique robustness in this investigation.

3.1.1.4 *Micro Shear Fatigue Limit (µSFL) to dentine*

(Marc Braem, Antwerp, Belgium)
Achieving a long lasting bond between the restoration and the tooth substance is the ultimate goal of adhesive dentistry. Besides chemical degradation, it might be expected that the adhesive degrades mechanically through fatigue.
Therefore, a recently developed method was used to investigate the fatigue behaviour of XP *BOND* and other adhesive systems.

Tooth substance is placed and fixed in a brass mould (left picture of Figure 12). After the adhesive is applied and light cured a Mylar strip with a hole 1 mm in diameter is centrically placed over this bonded surface (middle picture of Figure 12). Finally another brass mould is fixed onto the first brass mould and composite is placed on top to bond through the 1 mm hole to the tooth surface (right picture of Figure 12).

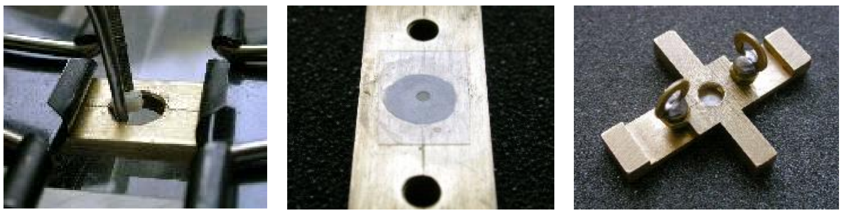


Figure 12 Specimen preparation

The assembled brass moulds are place into a test chamber where one brass mould is fixed and the other mould is loaded for 10 000 cycles to a specified limit with a frequency of 2 Hz.
The load is increased by 8% each time a specimen survives these 10 000 cycles, or decreased by 8% if the specimen fails prematurely. This staircase approach results in a set of data of which the mean fatigue limit can be calculated (see Figure 13).

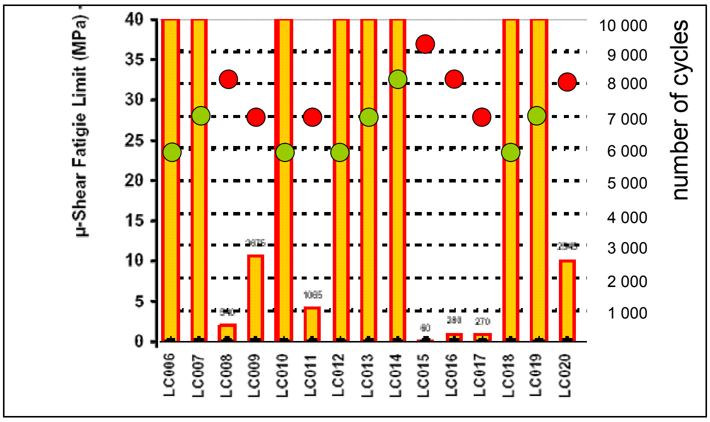


Figure 13 Number of cycles (bars) and respective load (dots) for each sample.

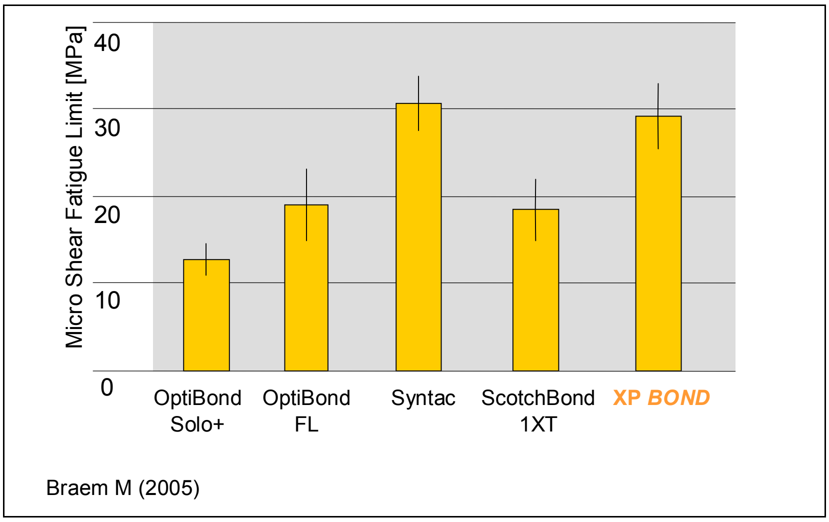


Figure 14 Mean Micro Shear Fatigue Limit to dentine

XP *BOND* showed a very high fatigue limit that surpassed most other competitive adhesives including a filled multi bottle system.

3.1.1.5 *Shear bond strength to dentine – a practitioner test*

(6 private practitioners, Germany)

As improved technique robustness was one aim in the development of XP *BOND*, six practitioners were asked to prepare samples for bond strength testing.

The practitioners were visited in their dental practice and asked to use four different adhesives. After they had read the DFU and the illustrated DFU, the practitioners were asked to use the adhesive as if treating patients.

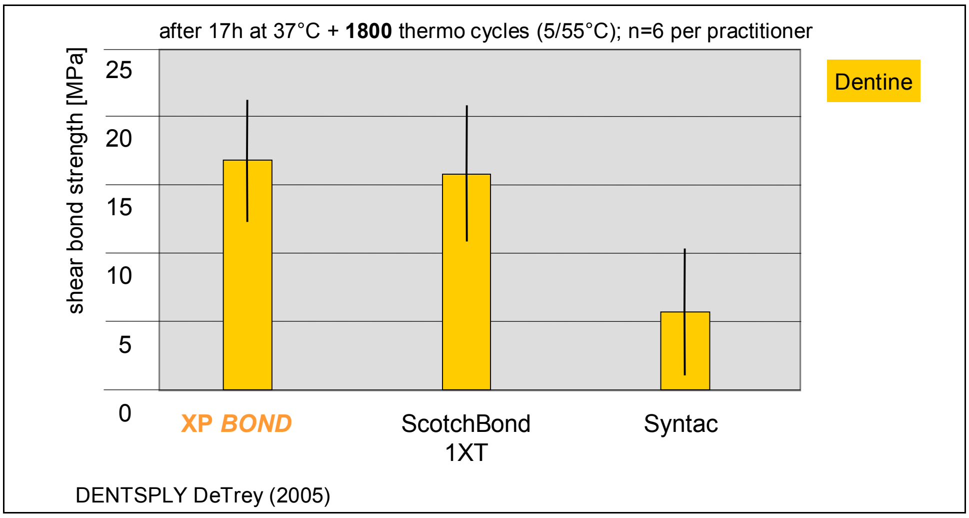


Figure 15 Mean shear bond strength after 1800 thermo cycles between 5 and 55 °C – pooled data from 6 practitioners

Figure 15 shows the mean shear bond strength from the pooled data of all six practitioners. It is obvious that in the hands of these practitioners the tested one bottle adhesives performed much better than the control – a multi bottle system.

3.1.1.6 *Summary of bond strength data for direct procedures*

It could be proven that XP *BOND* shows bond strength data that

- could not be surpassed by any other adhesive tested
- reaches this high level of performance with a simple application technique in which active rubbing or scrubbing is not needed
- is compatible with either LED or QTH curing lights
- shows very high shear fatigue limit
- works very well in the hands of practitioners

3.1.2 Adhesion for indirect procedures

XP *BOND* on its own can be used for luting indirect restorations if purely light curing materials are used. In the case where the clinician wishes to use dual or chemical curing resin cements, XP *BOND* is mixed with SCA – this mixture is compatible to the chemistry used for such cements. If Calibra® resin luting cement (DENTSPLY) is used light curing of the adhesive layer before seating the restoration could be omitted or it is ensured that parts of the luting interface not being exposed sufficiently to light are well bonded, respectively.

3.1.2.1 *Shear Bond Strength to enamel and dentine for indirect procedures*

(DENTSPLY DeTrey, Konstanz, Germany)

Practitioners are often concerned that light curing the adhesive before seating an indirect restoration may interfere with the proper fit. For this reason, manufacturers of systems having rather thick consistency bondings explicitly instruct not to cure the adhesive layer in these situations[1].

To evaluate the universality of the combination XP *BOND*, SCA, and Calibra, shear bond strength testing was performed after storage of samples in water for 24 hours and the values compared to a variety of competitive systems which were therefore used beyond the indications given in their respective DFU's.

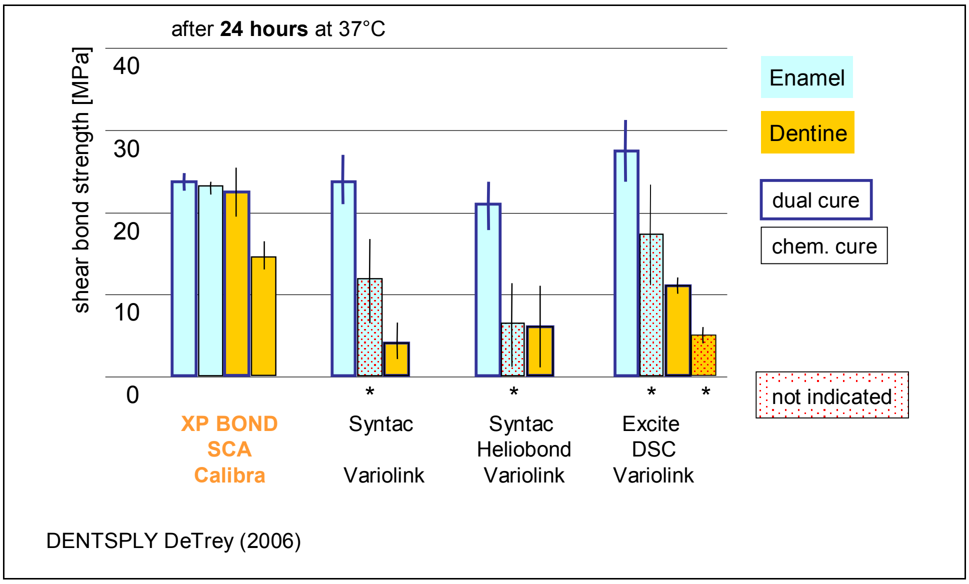


Figure 16 SBS for indirect procedures when adhesive is not light cured

In the cases where light was applied after seating of the restoration (dual cure), enamel bond strength was comparable among the tested systems. On dentine, XP *BOND* showed the highest bond strength.

Even in the pure chemical cure mode, XP *BOND* established in combination with SCA and Calibra a bond strength to dentine that is higher than that achievable by dual curing a well established system.

The multi bottle system used as control provided, in the dual cure mode, worse adhesion to dentine than either of the other systems.

In situations where the adhesive could be light cured but the seated restoration might not allow penetration of any light, it is of interest to know whether the dual cured (DC) adhesive layer builds up bond strength to the chemical curing (CC) cement and how this compares to a dual cured cement.

Again, the control material had to be used beyond its indications in order to be compared to XP *BOND*.

[1] e.g. DFU Syntac

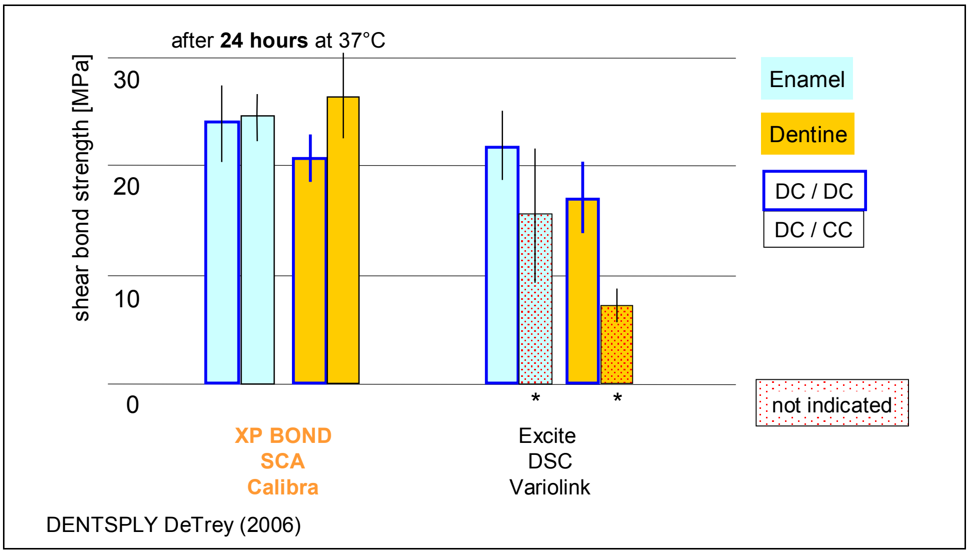


Figure 17 SBS in indirect procedures where the adhesive layer is light cured

The results shown in Figure 17 support the universal use of XP *BOND* in combination with SCA and Calibra.

3.1.2.2 *Micro Tensile Bond Strength to dentine for indirect procedures*

(Marco Ferrari, Livorno, Italy)

Simplified ceramic overlays were luted onto dentine following the different protocols listed in Table 2. Ten teeth per group were used resulting in about 40 beams per group.

Adhesive	**SCA**	**cement**	**curing adhesive**	**curing cement**	**ceramic overlay**
OptiBond Solo +	no	Calibra	LC	DC	3 mm
XP *BOND*	no	Calibra	LC	DC	3 mm
XP *BOND*	yes	Calibra	NC	DC	2 mm
XP *BOND*	yes	Calibra	NC	DC	3 mm
XP *BOND*	yes	Calibra	NC	DC	4 mm
XP *BOND*	yes	Calibra	NC	**SC**	2 mm
Syntac	no	Calibra	NC	**SC**	2 mm

NOTE DFU Syntac: when combined with self-curing composite Heliobond is mandatory and must be light cured

Ferrari M (2005)

Table 2 Techniques and materials used for luting ceramic overlays to dentine

A multi bottle adhesive was included and used beyond indications given in the respective DFU.

Mean μTBS calculated after eliminating any pre-test failures are shown in Figure 18.

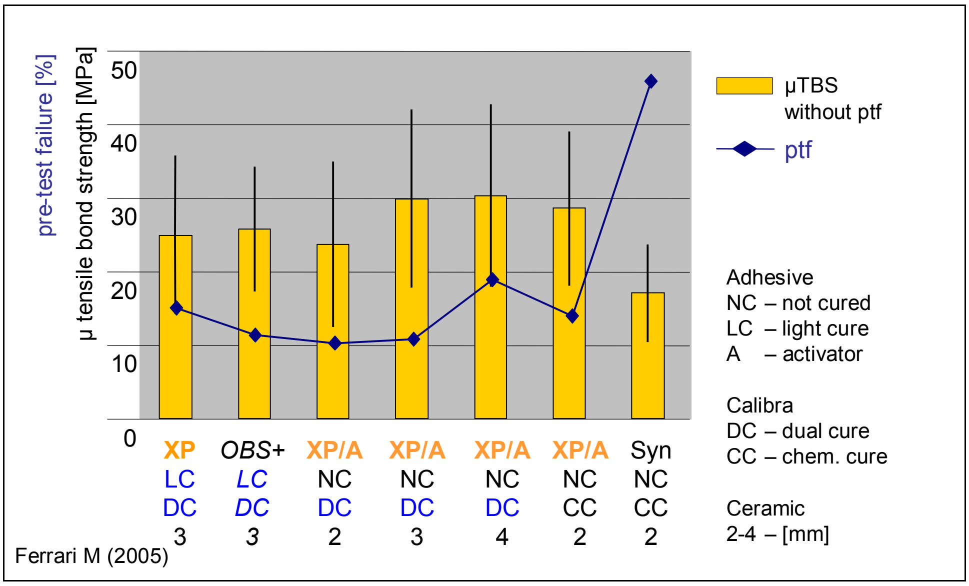


Figure 18 Mean µTBS without pre-test failure (ptf) and percentage of ptf

From this data it is obvious that XP *BOND* combined with SCA can be universally used when luting indirect restorations with Calibra.

As curing of the adhesive layer is induced by the chemically curing cement, it is important to note that proper curing in those situations when no light is applied at all is only ensured by use of Calibra.

3.1.2.3 *Summary of bond strength data for indirect restorations*

Luting indirect restorations is, within restorative dentistry, the most demanding situation for a lot of practitioners. Failure, either while luting or during the lifetime of the indirect restoration, is regarded as a high financial risk since costly lab-made restorations are involved.

It is highly recommended to strictly follow the DFU for each system, as use beyond indications may lead to failures (Figure 16, Figure 17, Figure 18).

XP *BOND* in combination with SCA and Calibra is therefore the ideal system, since all possible situations regarding what should be light cured when can be covered.

3.1.3 Adhesion to composite

More and more practitioners understand that composite restorations with modern systems provide an aesthetic alternative to indirect fabricated and luted veneers and crowns. Systems like Ceram•X™ duo allow the restoration of teeth in a natural layering concept (Dietschi et al., 2006) using two different translucencies.

It was the purpose of the following trial to investigate whether a procedure called the CEBL-technique (Blank et al., 2005) would allow immediate corrections when layering direct restorations with composite.

After **C**utting back the composite to allow new layering, the surface is cleaned using phosphoric **E**tchant (this step is meant for cleaning and would only etch the basic glass filler in materials like Dyract eXtra). After application of the **B**onding material the necessary composite is **L**ayered again.

This technique was applied to simulate repair of an old composite filling by bonding to a specimen made of Spectrum TPH which had been boiled for 1 hour and then stored for an additional 23 hours in water. Composite layered onto freshly polymerized composite, simulating incremental filling, was used as control.

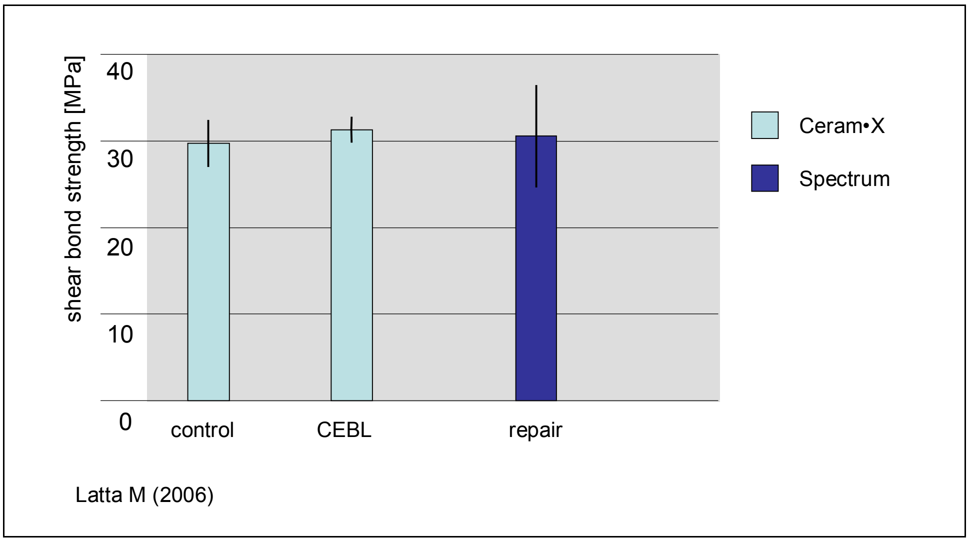


Figure 19 SBS composite to composite after re-layering (CEBL) or repair

XP *BOND* not only provides bond strength as high as the control when re-layering a composite filling during initial restoration, but also offers very high bond strength when old composite is repaired.

3.1.4 Adhesion for post cementation

Adhesion has gained high importance over the recent years in the field of endodontology. The mechanical properties of fibre reinforced posts better fit tooth substances. In addition such posts are available in light transmitting versions and allow decent adhesion cement to post.

Therefore, the purpose of two investigations was to investigate the performance of XP *BOND* for this indication in order to support the claim being a true universal adhesive.

3.1.4.1 *Bond strength cement to fibre reinforced post*

(Marco Ferrari, Livorno, Italy)

It was evaluated whether XP *BOND* SCA mix would increase bond strength at the cement post interface.

Moulds were made of luting cement using the post and a thin insulation layer to simulate cement layer thickness in the root canal (Figure 20 a). Figure 20 b) shows the mould ready for post placement. The luted post is shown in Figure 20 c).

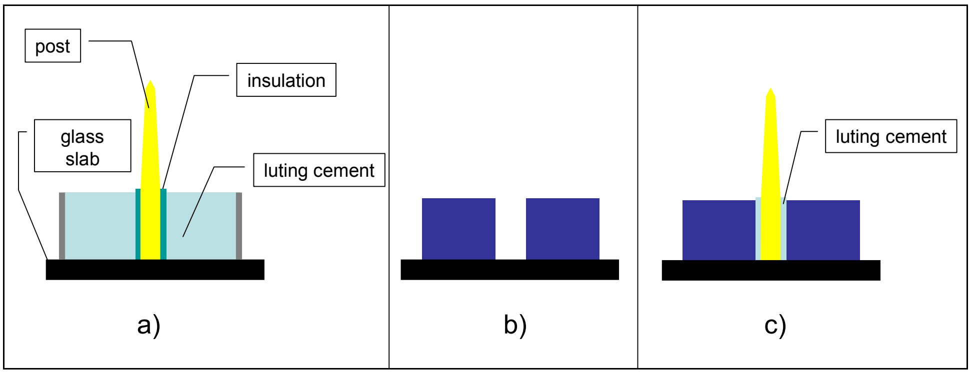


Figure 20 Mould fabrication
a) mould out of luting cement is created b) mould ready for post placement c) post luted into mould

The block made of post, luting cement, and mould (Figure 21a) is placed in a diamond saw and cut into slices in a first step (Figure 21b) and sticks for micro tensile testing in a second step (Figure 21c).

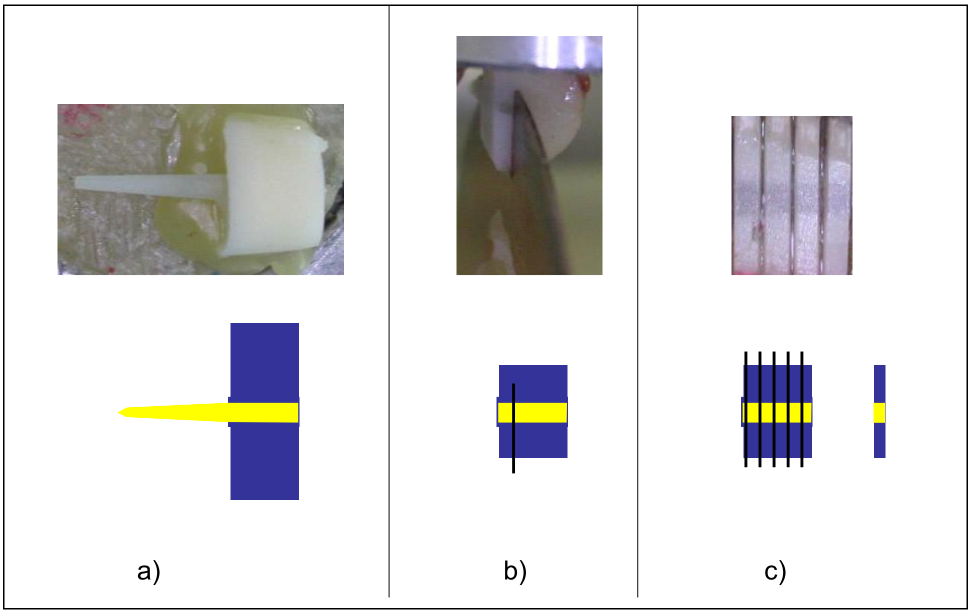


Figure 21 Cutting of post-cement unit
a) luted post in cement block b) block cut in one direction c) sticks of luting cement and post (middle part)

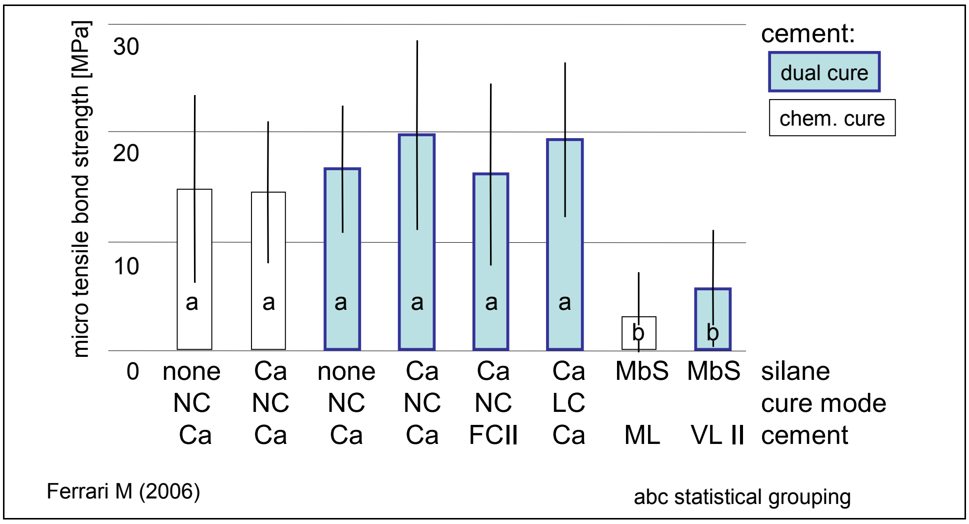


Figure 22 µTBS cement to post
(silane: Ca = Calibra Silane, MbS = Monobond S
cure mode: NC = adhesive not cured, LC = adhesive was light cured
cement: Ca = Calibra, FC II = Fluorocore II, ML = Multilink, VL II = Variolink II)

The results on micro tensile testing shown in Figure 22 clearly demonstrate that the application of XP *BOND* SCA mix improves the bond strength cement to post to a significant higher level compared to competitive systems (for which application of silane is recommended) when this mix was not light cured and Calibra as luting cement was chemically curing. Neither application of silane, nor curing the adhesive mix, nor application of light on Calibra (dual curing mode) did significantly increase the bond strength further.

3.1.4.2 *Push-out strength cement to root dentine*

(Marco Ferrari, Livorno, Italy)

Root canals were filled using AH®Plus and Guttapercha. Fibre reinforced light transmitting posts were cemented following conventional technique.

After cutting the root into thin slices the center part being the cemented post was pushed out.

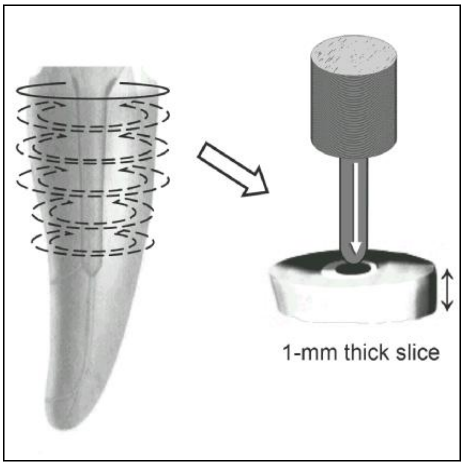


Figure 23 Push-out test
schematic drawing of the cutting levels for thin root slices and the set up for the push-out test. (Illustration Ferrari M)

The push-out strength calculated via the circumferential surface (using the post to determine the radius) is shown in Figure 24.

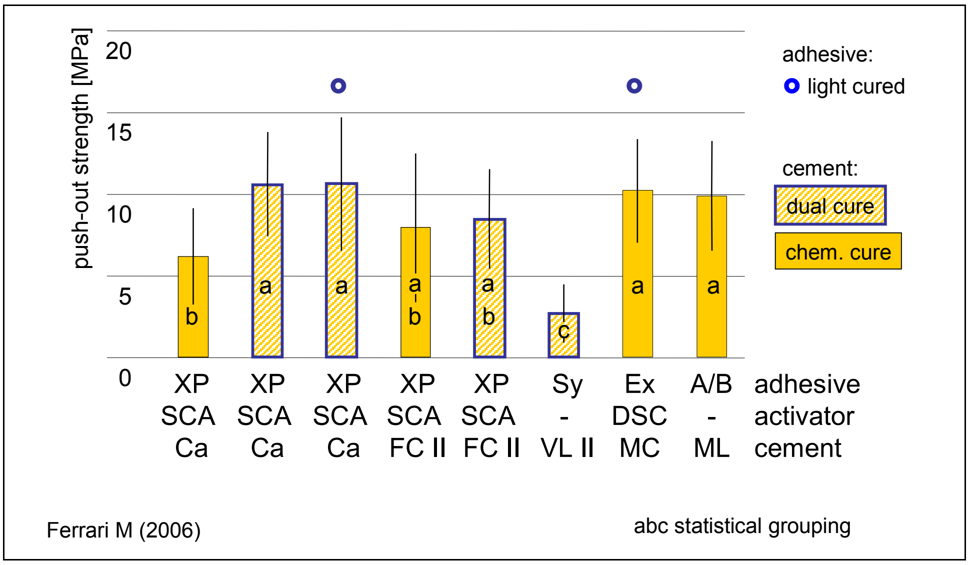


Figure 24 Push-out strength of various adhesive cement combinations.
(adhesive: XP = XP *BOND*, Sy = Syntac, Ex = Excite DSC, A/B = Primer A and B (Multilink)
activator: SCA, DSC = Excite DSC
cement: Ca = Calibra, FC II = Fluorocore II, VL II = Variolink II,
MC = MultiCore flow, ML = Multilink)

Using XP *BOND* SCA mix and Calibra the push-out strength could be significantly increased, when light is applied onto the post after seating. However, without application of any light XP *BOND* SCA mix showed significantly higher push-out strength compared to Syntac combined with Variolink II being dual cured.

Any other application mode or material combination for XP *BOND* SCA mix shown in Figure 24 was equal to either light cured Excite DSC before seating the post (which potentially could interfere with the fit of the post) or using the multi bottle Multilink adhesive with the chemically curing Multilink cement.

3.1.4.3 *Summary of data on endodontic luting*

In addition to data on luting indirect restorations XP *BOND* combined with SCA and Calibra again demonstrated its true universality as it ensures high level of adhesion to root canal dentin and at the same time increases bond strength cement to post. It is not needed any longer to use specialised systems for such indications.

3.2 Marginal Integrity

Bond strength is only the first step to evaluate the potential of a newly developed adhesive. To simulate the more complex configuration and stresses found in a restoration, marginal integrity was tested in different cavity classes using different methods in order to evaluate the quality of the margin before and after stress was applied.

3.2.1 Marginal Integrity of class V cavities

Class V restorations allow easy access and simultaneous evaluation of marginal quality in enamel and dentine. To quantify the quality, either dye penetration or quantitative SEM analysis were applied.

3.2.1.1 *Dye penetration and dentine permeability in class V*

(Juan Ignacio Rosales, Granada, Spain)
After restoring U-shaped class V cavities with the materials displayed in Figure 26, teeth were thermo cycled between 5 and 55 °C and immersed in a 0.5 % water solution of basic fuchsine for 24 hours, embedded in acrylic resin and cut into bucco-lingual slices. The in-vitro micro leakage of the occlusal and gingival cavity walls was evaluated using an optical microscope. The extent of the dye penetration along the restoration was ranked (Figure 25) between 0 (hermetic seal) and 3 (massive micro leakage).
Additionally, it was documented whether, in the presence of dye along the cavo-restorative margin, any dye penetrated into dentine.

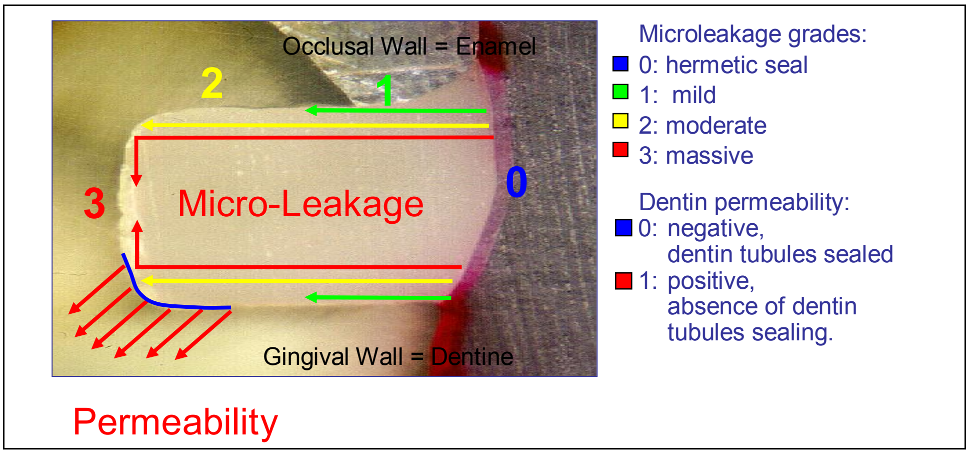


Figure 25 Scoring of micro leakage in class V restorations

The teeth were either stored for 24 hours in water, or thermo cycled (TC) 4001 times before being immersed in dye. Results for the occlusal margin (enamel) and gingival margin (dentine) are shown in Figure 26.

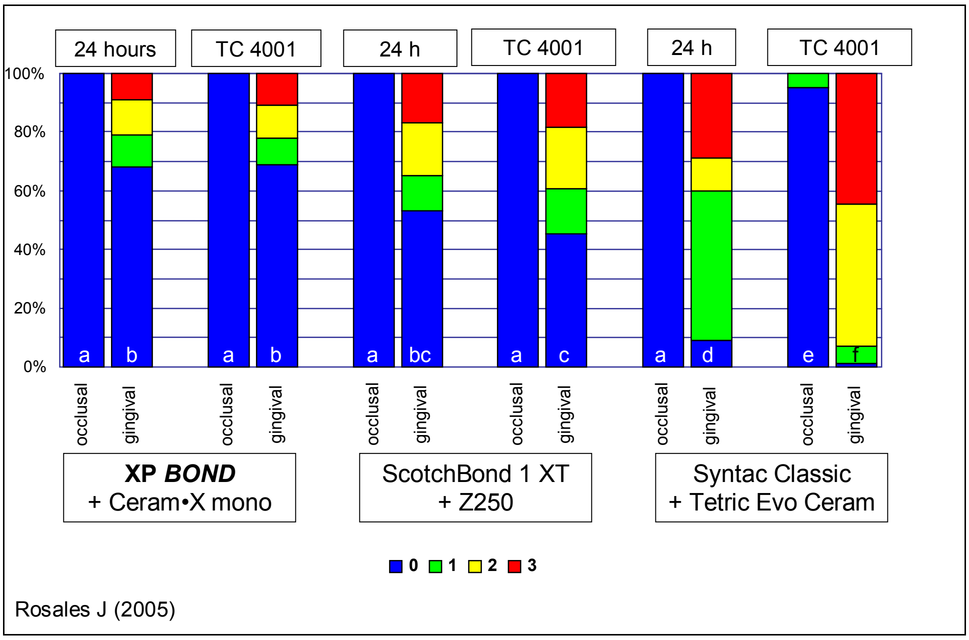


Figure 26 Microleakage scores found in slices of class V restorations

XP *BOND* showed the lowest microleakage scores, being comparable to another one bottle adhesive. Both performed significantly better than a multi bottle system.

Whether the dye could penetrate not only between the restoration and the cavity walls but also into the dentine, is shown in Figure 27.

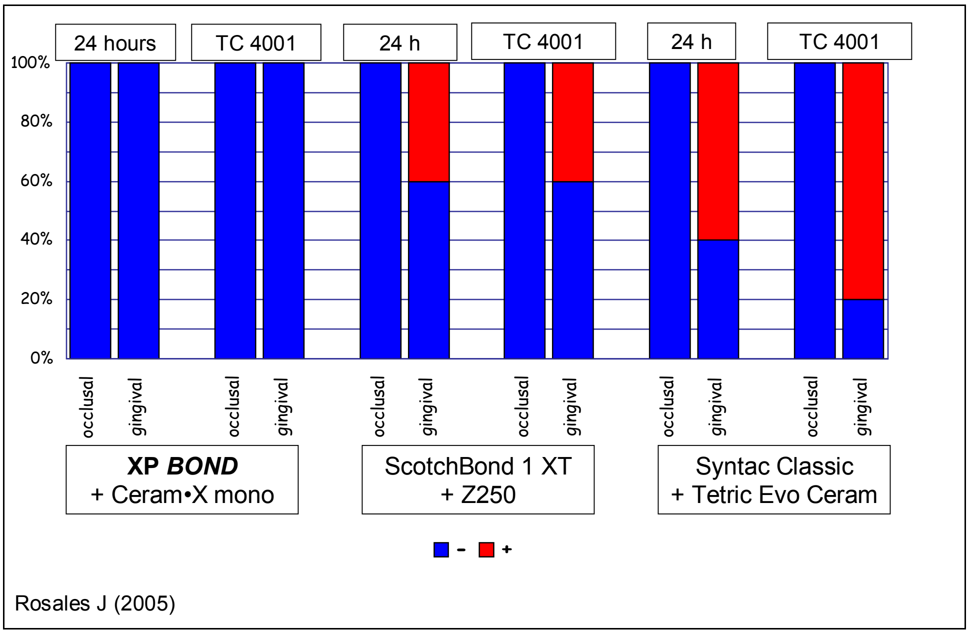
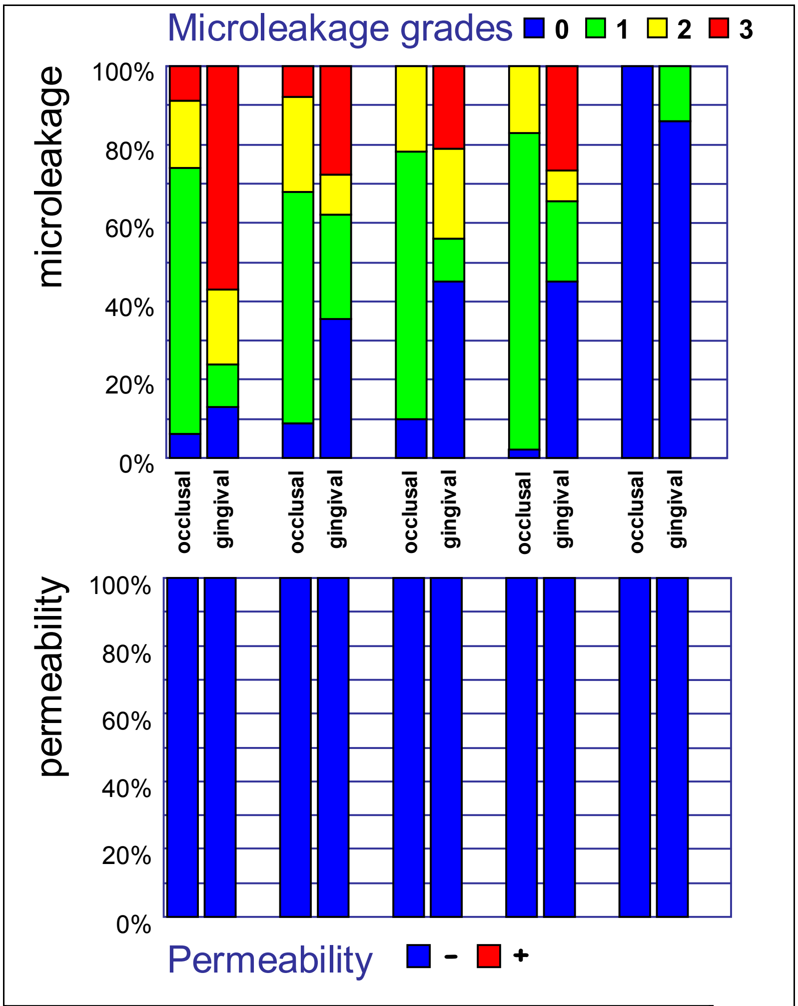


Figure 27 Dentine permeability in class V

These results show that XP *BOND* totally seals the dentine against dye penetration. This good sealing of dentine was observed in investigations by the same investigator using early versions of XP *BOND,* and was finally challenged in an investigation where no phosphoric etchant was used (which is mandatory as pre-treatment for XP *BOND*).



Etching	No	No	No	No	Yes
Aging	1 day	30 days	90 days	TC 4001	TC 4001

Figure 28 Microleakage (upper half) after provoked dye penetration (no etching) and control (etching) and respective dentine permeability (lower half).

Non use of phosphoric acid as pre-treatment of the cavity surfaces results in high micro leakage (upper part of Figure 28). When etching is performed, micro leakage is very low as demonstrated before (Figure 26).

Despite the provoked massive penetration of dye along the cavo-restorative interface, no penetration of dye into dentine could be found (lower part of Figure 28), proving the excellent sealing capability of XP *BOND*.

3.2.1.2 *Marginal Quality of class V under SEM*

(Uwe Blunck, Berlin, Germany)

Marginal quality of class V restorations using SEM was quantified in teeth after storage for 3 weeks in water and 2000 thermo cycles.

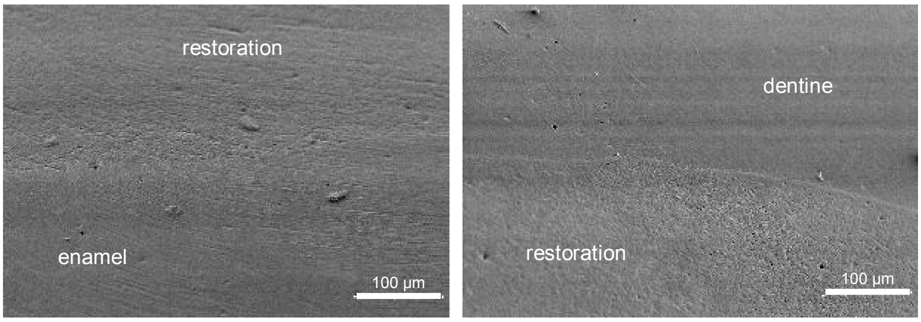


Figure 29 SEM micrograph of perfect margins in enamel and dentine using XP *BOND*

Again, variables in the application technique were tested in this investigation. The widespread use of an air-syringe to remove excess water after rinsing off the phosphoric acid was tested and compared to the additional use of an applicator tip to homogenously re-distribute left moisture in the cavity.

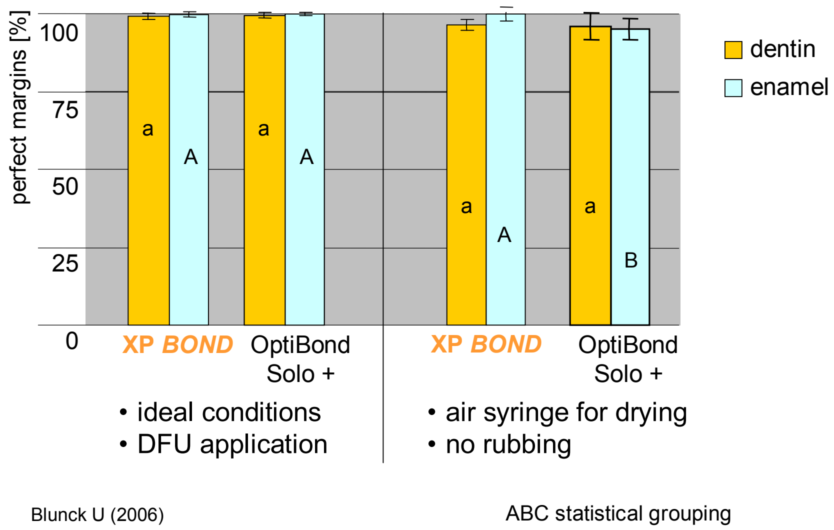


Figure 30 Percentage of perfect margins under different application scenarios

XP *BOND* was found to perform on an extremely high level. Statistical differences on this high level were rated as “not clinically relevant” by the investigator, meaning that both adhesives tested provide high marginal quality after either application technique.

3.2.2 Marginal Integrity of class II cavities

Marginal quality in class II restorations was investigated in order to fully understand the behaviour of an adhesive, to see whether it can withstand stresses that are built up during restoring posterior teeth, and to understand how these adhesive restorations withstand forces from chewing and temperature changes.

3.2.2.1 *Dye penetration in class II*

(Jürgen Manhart, Munich, Germany)

There are numerous protocols to restore class II cavities concerning how and where to place increments and light source. As most practitioners tend to use simplified techniques, such a layering concept was applied for this investigation (Figure 31).

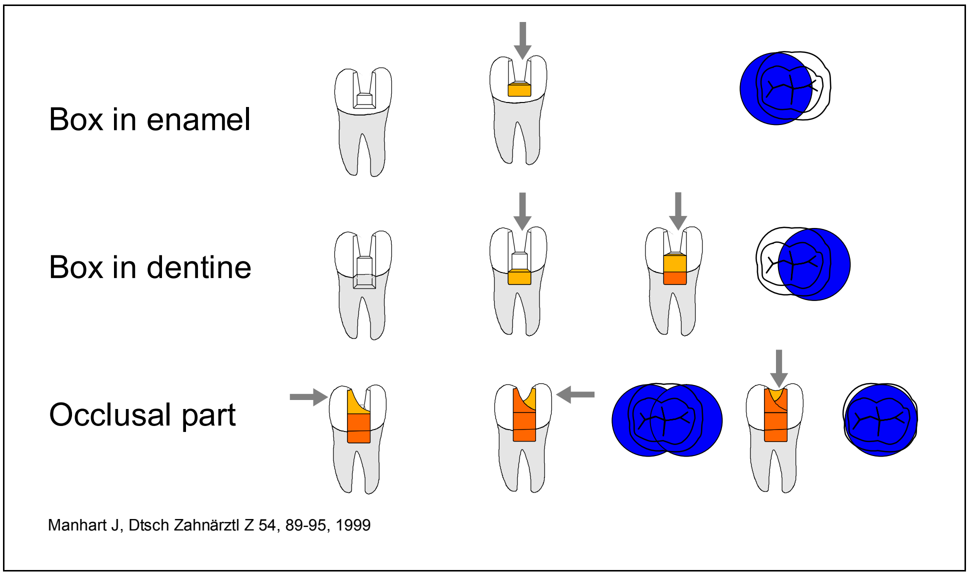


Figure 31 Layering concept for class II cavities and directions of light source

After restoring, the teeth were stressed in a chewing simulator by 2000 thermo cycles between 5 and 55°C, and 50,000 chewing cycles using an artificial antagonist loaded with 50N (Manhart J et al. 1999).

Dye penetration was evaluated separately for enamel margins in the approximal box limited to enamel and dentine margins in the deeper approximal box.

It is always discussed whether in such investigations the same restorative should be used to rule out influencing factors as shrinkage force and E-Modulus, or whether each competitive adhesive should be used with a composite from the same manufacturer.

For this investigation both variations were realized.

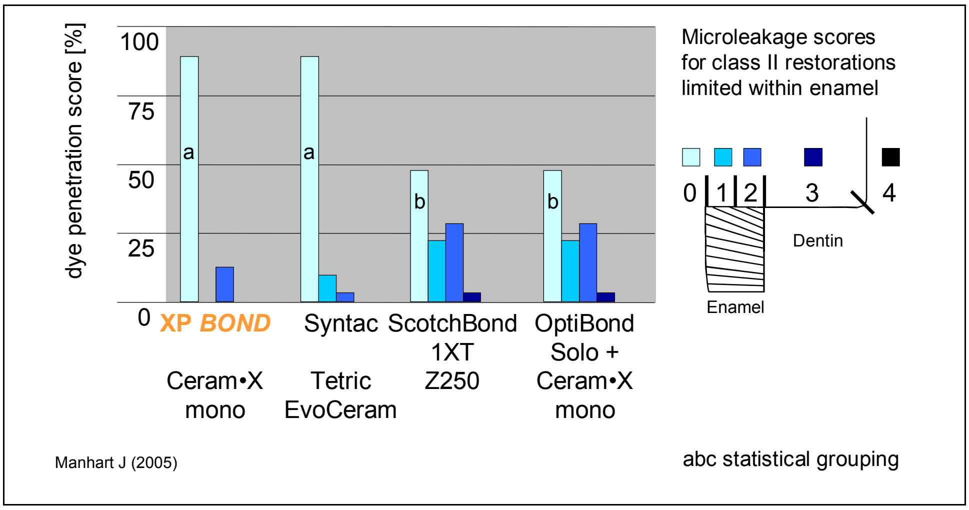


Figure 32 Micro leakage scores for enamel margins in class II.

Restorations of XP *BOND* and Ceram•X Mono showed enamel margins of the same quality as a multi bottle system that served as control and both were statistically better than two other one bottle systems (Figure 32).

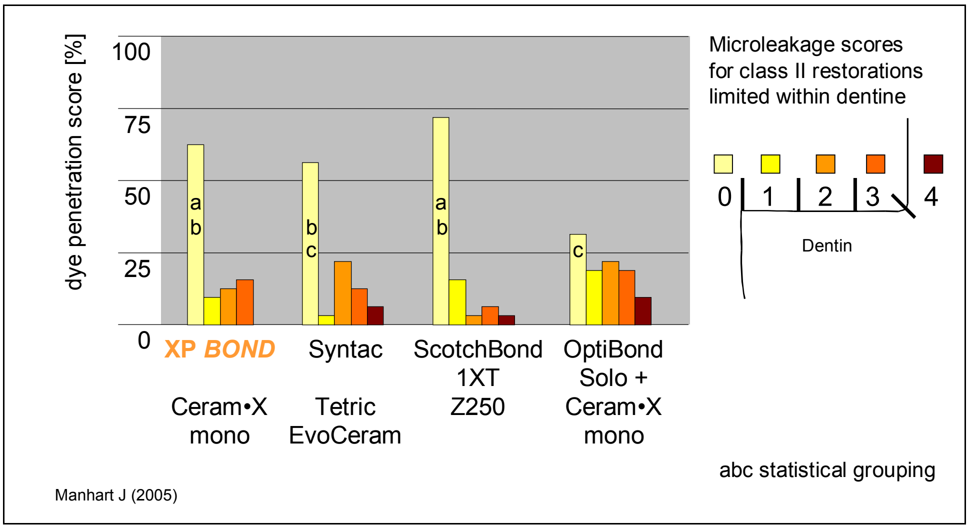


Figure 33 Micro leakage scores for dentine margins in class II.

Marginal quality provided by XP *BOND* in dentine was comparable to that of the control, and better than one of the two tested one bottle adhesives (Figure 33).

3.2.2.2 *Summary of data on marginal quality of direct restorations*

XP *BOND* not only offers a very good seal of the margins in enamel and dentine but provides an exceptional seal of dentine, too.

3.2.3 Marginal integrity of luted ceramic inlays

3.2.3.1 *Marginal integrity with and without curing the adhesive layer*

(Roland Frankenberger, Erlangen, Germany)

Practitioners very often hesitate to light cure the adhesive when luting indirect restorations because of possible interference of pooled and cured adhesive with the fit while seating the restoration for luting.

For systems including high viscous bonding materials (e.g. Heliobond) the respective manufacturer recommends not to light cure the adhesive because of this reason.

Therefore, it was the aim to compare the performance of XP *BOND* in combination with SCA and Calibra when the adhesive is not light cured to Syntac, Heliobond, and Variolink. In addition it was evaluated whether light curing the adhesive layer in the case of XP *BOND* had any influence (XP *BOND* SCA (LC)).

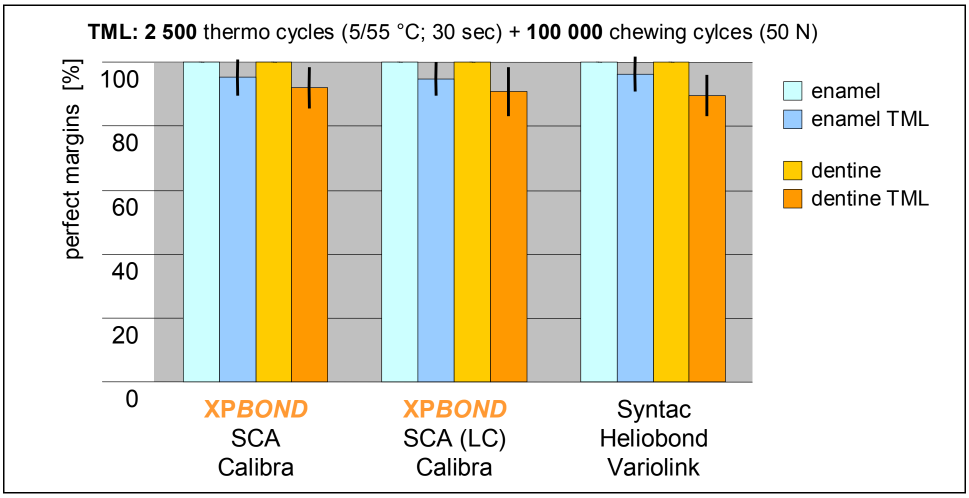


Figure 34 Perfect margins of adhesively luted ceramic inlays

Initially all three groups showed 100% perfect margins in enamel and dentine. After thermo-mechanical loading (TML) 94.8% (XP-LC) to 96.3% (Syntac) of enamel margins and 89.7% (Syntac) to 92% (XP) of dentine margins were still rated as perfect.

All three test groups showed comparable performance on a high level.

Therefore, it could be demonstrated that XP *BOND* and SCA when using Calibra as cement performs equally well with and without being light cured before seating the restoration.

3.3 Micro-Morphology

In order to illustrate and understand the interaction between adhesive and tooth substance specimens were investigated using FESEM, TEM and light microscopy.

3.3.1 FESEM and TEM investigation

Since etching of dentine with phosphoric acid was introduced one focus of research has been the question whether the demineralised collagen network can be infiltrated by the resin of the adhesive to form a homogenous hybrid layer. In addition it became obvious that etched dentine is very sensitive to the degree of moisture. Etched and desiccated dentine is not only difficult to infiltrate and hybridize but it would hinder penetration towards the unaffected dentine leading to lower bond strength.

3.3.1.1 *FESEM and TEM investigation of hybrid layer quality*

(Jorge Perdigão, Minneapolis (MN), USA)
Dentine was prepared either so as to establish a moist surface before application of the adhesive according to the DFU, or was air-dried with an air-syringe for 10 seconds to simulate overdrying of dentine. This is not recommended following phosphoric acid etching. Thus the robustness of the adhesive towards surface moisture was investigated.

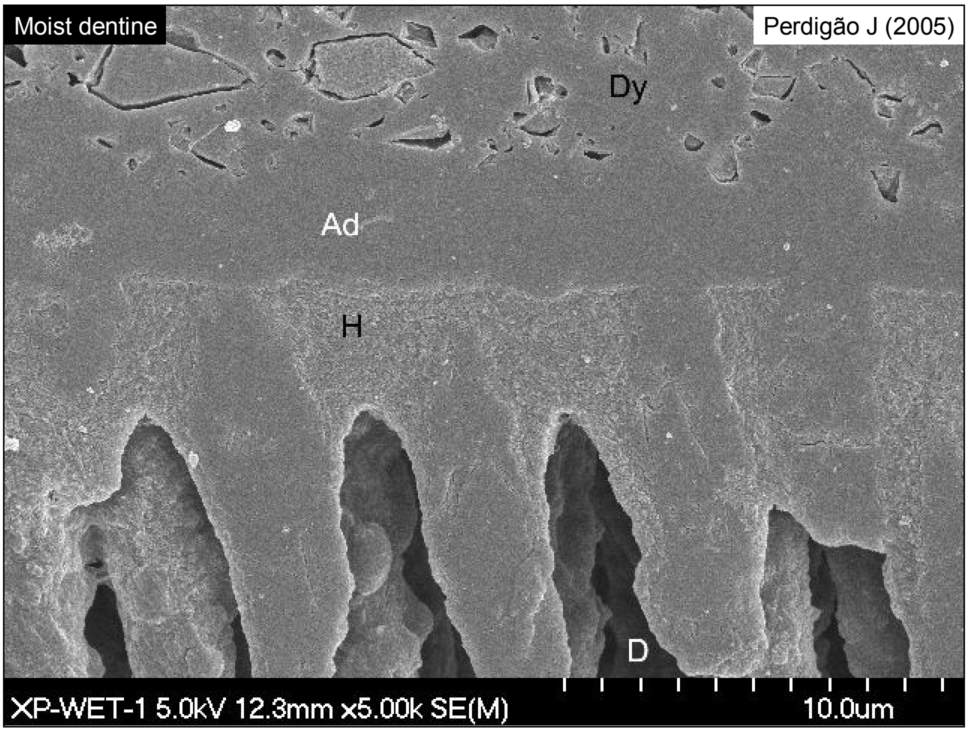


Figure 35 SEM on moist dentine using XP *BOND* (Ad = Adhesive layer; H = Hybrid layer; D = Dentine (was etched away leaving resin infiltrated tags)

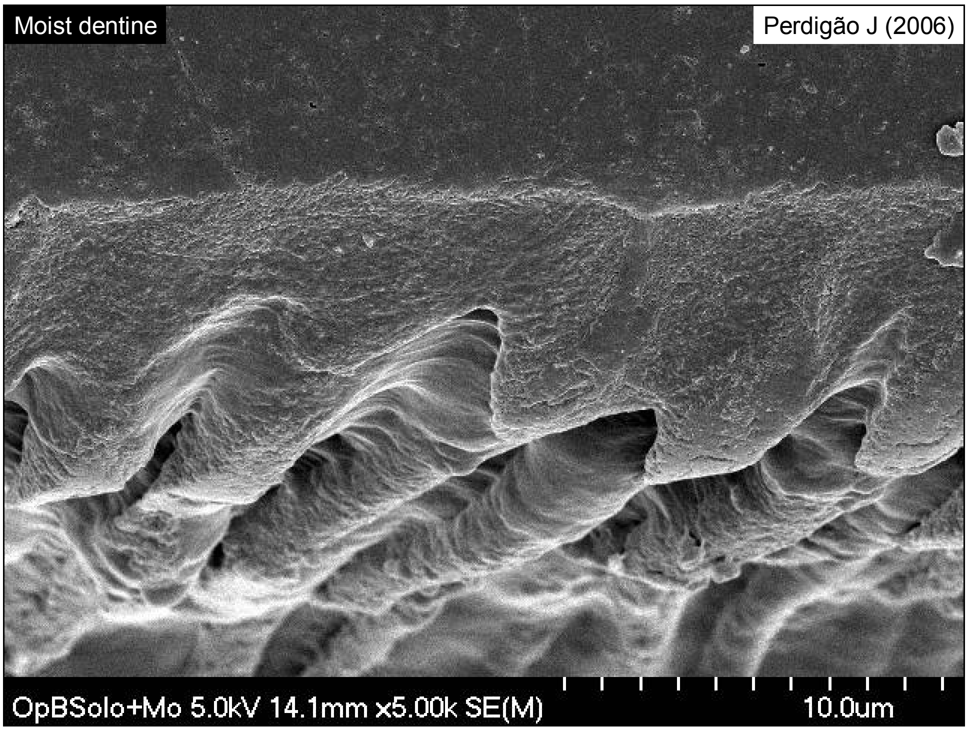


Figure 36 SEM on moist dentine using Optibond Solo Plus.

For both adhesives tested with moist dentine, SEM micrographs of the adhesive dentine interface (Figure 35 and Figure 36) show a distinct adhesive layer, a well and homogenously infiltrated hybrid layer, and well infiltrated peritubular dentine resulting in tags and filled intertubular spaces.

When dentine was air-dried for 10 seconds, detachment of the adhesive from the underlying dentine could be seen for OptiBond Solo Plus in one specimen, as shown in Figure 37.

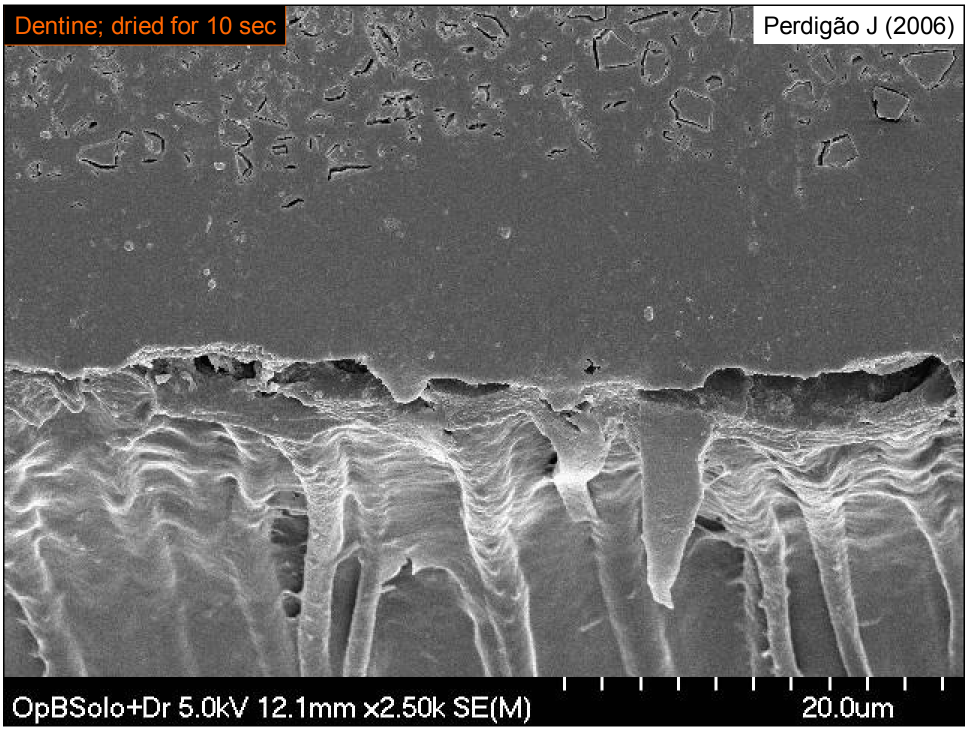


Figure 37 SEM of Optibond Solo Plus applied on dried dentine.

Using XP *BOND* on the same substrate (dentine dried for 10 seconds) resulted in micrographs similar to those from moist dentine (Figure 38 and Figure 39).

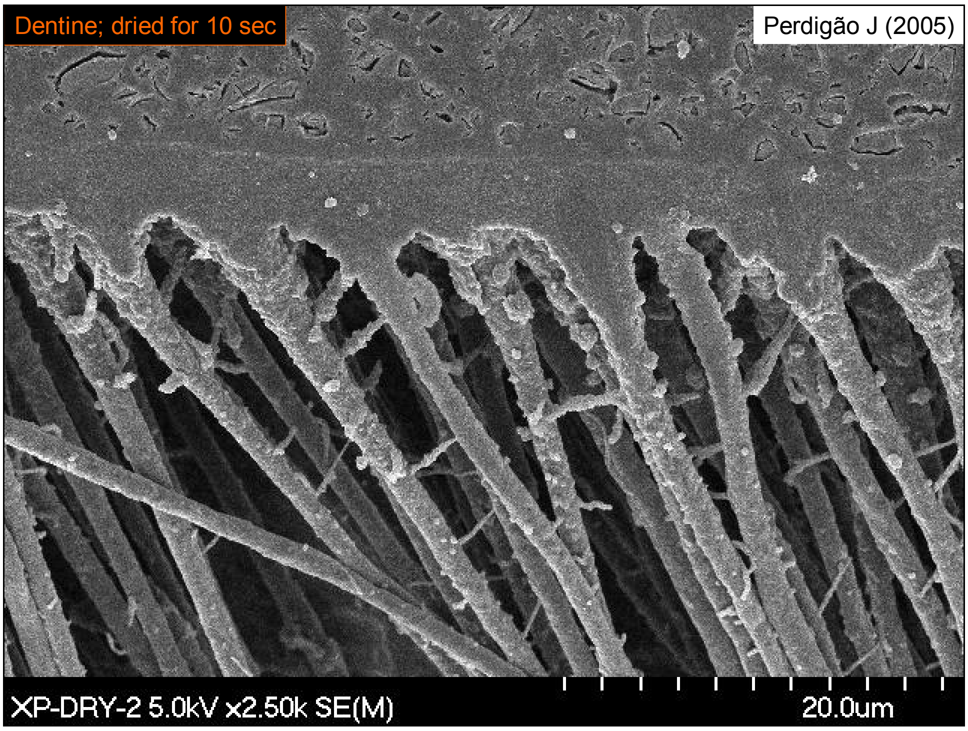


Figure 38 Overview SEM of hybrid layer and tags using XP *BOND* on dried dentine

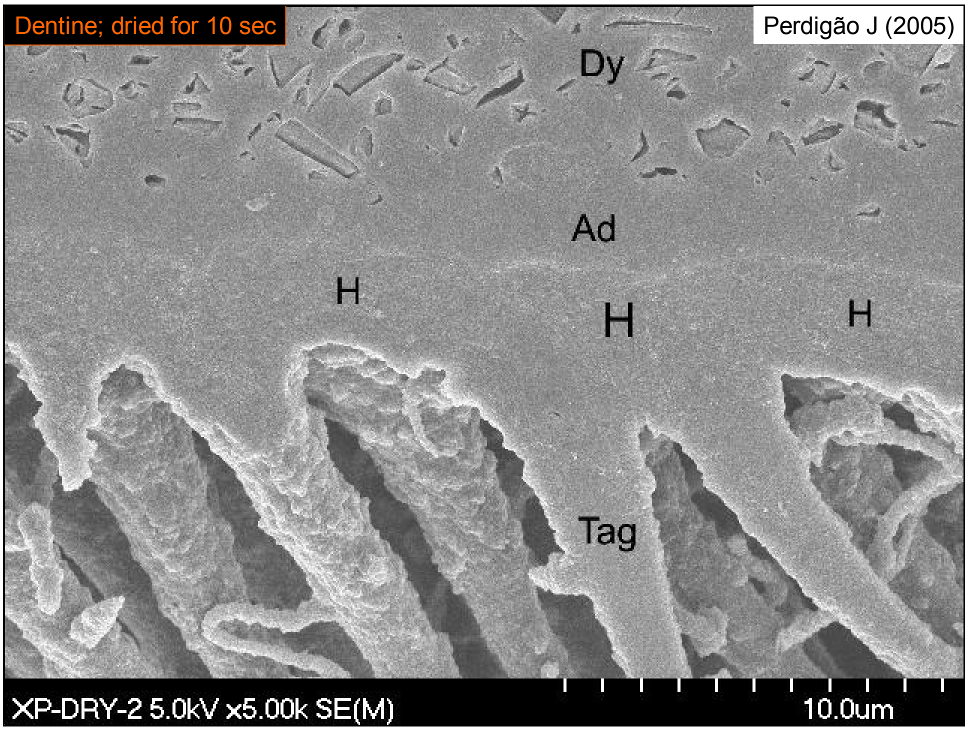


Figure 39 SEM of XP *BOND* applied on dried dentine.

The investigator stated: "The morphology of the hybrid layer when XP *BOND* was applied on dried dentin was not very distinct from the morphology corresponding to the application of the same adhesive on moist dentin."

The hybrid layer was investigated further using transmission electron microscopy (TEM) (Figure 40).

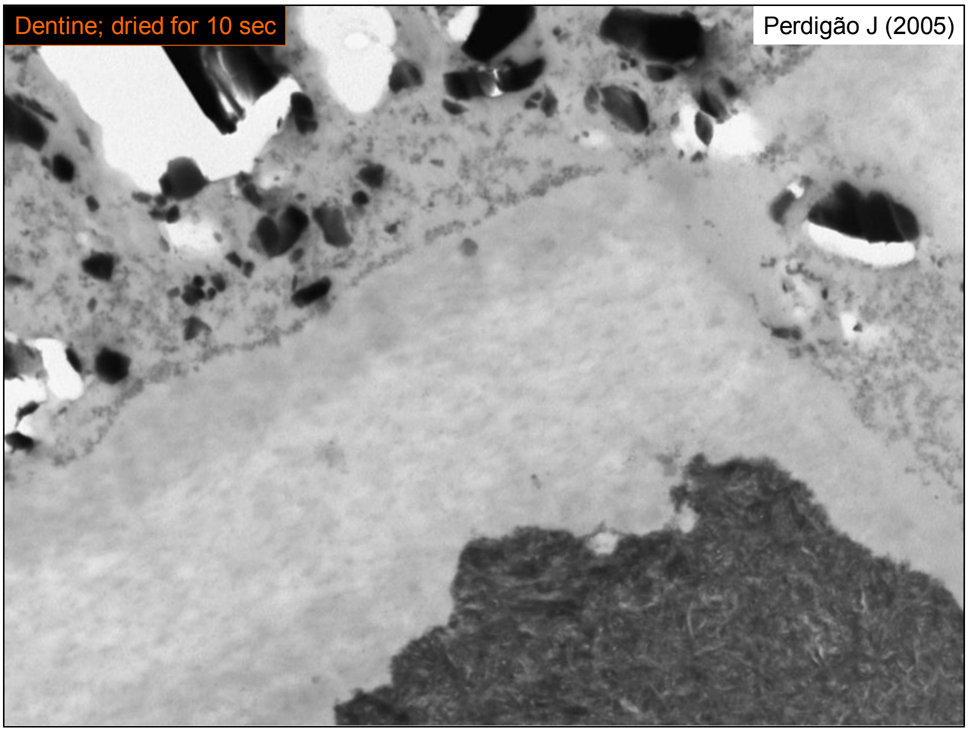


Figure 40 TEM of hybrid layer when XP *BOND* was applied on dried dentine

This time the report stated: “Under the TEM the hybrid layer displayed a top 1 µm thick band more electron-dense than the hybrid layer underneath. This layer may be a result of the collagen collapse. In spite of being applied on dried dentin, XP *BOND* infiltrated the demineralized collagen layer very well, forming a sealed hybrid layer.”

3.3.2 Investigation using light microscopy

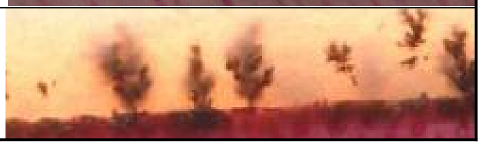
In addition to the usually applied technique of TEM to investigate nanoleakage, this phenomenon can also be nicely visualized by light microscopy.

3.3.2.1 *Nanoleakage investigation using light microscopy*

(Lorenzo Breschi, Trieste, Italy)

Small sticks prepared from bonded dentine specimens were immersed for 24 hours in 50 wt% ammoniacal $AgNO_3$ solution. Thin undemineralized sections were gained using an ultra microtome. These sections were investigated under a light microscope and categorized according to the grade of nanoleakage.

Figure 41 shows representative pictures and the mean grade of nanoleakage for the respective adhesive.

Adhesive	Nanoleakage Grade **1**: < 25%; **2**: 25-50% ; **3**: 50 - 75% ; **4**: > 75%	
XP *BOND*	grade 2	
Optibond Solo +	grade 3	
Scotchbond 1 XT	grade 4	

Breschi L (2005)

Figure 41 Nanoleakage: mean grade (percentage of bonded interfaces) and pictures from light microscopy

XP *BOND* showed the lowest degree of nanoleakage proving again its excellent ability to seal dentine.

3.3.3 Summary of micro morphology investigations

Results from SEM, TEM, and light microscopy revealed that XP *BOND* is able to infiltrate and penetrate dentine homogenously – even under less ideal conditions when dentine is not moist.
This might explain and further illustrate the very low permeability found in the class V dye penetration study (3.2.1.1).

4 Clinical Studies

Despite of the significance of in-vitro investigations, only clinical trials provide final certainty upon the efficiency of new adhesive technologies. Therefore, several clinical studies on XP *BOND* have been initiated from which first results have recently become available.

4.1 Class V Restorations

Three identically designed longitudinal, controlled and patient and evaluator blinded clinical class V trials are running at The Universities of Berlin, Bologna and Leipzig under scientific headship of Uwe Blunck, Giovanni Dondi dall'Orologio and Knut Merte.

All three trials were designed with reference to the Guidelines for Acceptance of Enamel and Dentin Adhesive Materials, issued by the American Dental Association (ADA 2001a). 40 XP *BOND* (test group) and 40 Adper Scotchbond 1XT restorations (control group) have been placed at each site. Wherever possible, one test and one control group restoration was placed in one patient. All teeth filled in terms of this study are in occlusion. Both adhesives were used in conjunction with Ceram•X Duo NanoCeramic Restorative.

96 test and 95 control group restorations were recalled after three months. Pooled results are displayed in the below table:

Criteria for evaluated restorations	XP BOND / Ceram•X Duo [n]					Scotchbond 1XT / Ceram•X Duo [n]				
	n	alpha	bravo	charl.	delta	n	alpha	bravo	charl.	delta
Retention	96	95	0	0	1	95	93	0	0	2
Post-op. sensitivity (∑)	95	93	2	0	0	93	85	8	0	0
Marginal discolouration	95	94	1	0	0	93	90	3	0	0
Marginal integrity	96	95	0	0	1	95	89	4	0	2
Secondary caries	95	95	0	0	0	93	93	0	0	0
Restoration contour	95	94	1	0	0	93	91	2	0	0
Vitality test	95	95	0	0	0	93	93	0	0	0

Table 3 Pooled 3 month results from class V trials

One and two failures in terms of marginal integrity were recorded for the test and the control group, respectively. Accordingly, the overall success rate amounts to 95 / 96 x 100% = 99.0% for the XP *BOND* test group and 93 / 95 x 100% = 97.9% for the Adper Scotchbond 1XT control group. The investigators state that no adverse events/ effects were observed.

It can be concluded that safety and efficiency were demonstrated for XP *BOND*, and that the material is suitable for clinical use.

4.2 Class I and II Restorations

To investigate the long-term behavior of XP *BOND* under load bearing conditions, a longitudinal, controlled and patient and evaluator blinded clinical class I and II trial has been initiated at The University of Freiburg under scientific headship of Elmar Hellwig.
The trial was designed with reference to the Guidelines for Acceptance of Resin Based Composites for Posterior Restorations, issued by the American Dental Association (ADA 2001b). In this study, pairs of 40 XP *BOND* (test group) and 40 Optibond Solo Plus restorations (control group) are placed in the same patient wherever possible. All teeth filled in terms of this study will be in occlusion. Both adhesives are used in conjunction with Ceram•X Mono Nano-Ceramic Restorative. The baseline results are displayed in the below table:

Criteria for evaluated restorations	XP *BOND* / Ceram•X Mono [n]					Optibond SP / Ceram•X Mono [n]				
	n	alpha	bravo	charl.	delta	n	alpha	bravo	charl.	delta
Retention	32	32	0	0	0	32	32	0	0	0
Marginal discolouration	32	32	0	0	0	32	32	0	0	0
Marginal integrity	32	32	0	0	0	32	32	0	0	0
Secondary caries	32	32	0	0	0	32	32	0	0	0
Restoration contour	32	32	0	0	0	32	32	0	0	0
Vitality test	32	32	0	0	0	32	32	0	0	0

Table 4 Baseline results from class I and II trial

The trial is in an early stage. However, data concerning post-operative sensitivity has already become available:

Post-op. sensitivities	n	no	yes	mean	SD	n	no	yes	mean	SD
spontaneous	32	31	1	3	0	32	31	1	3	0
triggered by chewing	32	30	2	3.5	1.5	32	29	3	4.3	2.9
triggered by other noxa	32	31	1	5	0	32	31	1	5	0
(Σ)	32	29	3			32	28	4		

Table 5 Sensitivities recorded 2 weeks post-placement, preliminary results. Mean value and standard deviation: 1 = lowest sensitivity, 10 = highest sensitivity

Based on 32 restorations, the post-operative sensitivity rate amounts to 3 / 32 x 100% = 9.4% for the XP *BOND* group and to 4 / 32 x 100% = 12.5% for the Optibond Solo Plus group.

Elmar Hellwig states that no adverse effects/ events or other clinical problems occured. Also considering the rate of post-operative sensitivities that was found for the control group, the value associated with XP *BOND* is low and acceptable.

4.3 Indirect Ceramic Restorations

A longitudinal, patient and evaluator blinded clinical trial on adhesively cemented indirect ceramic inlays and onlays is currently running at the University of Siena/ Practice Marco Ferrari.

The trial was designed with reference to the Guidelines for Acceptance of Resin Based Composites for Posterior Restorations, issued by the American Dental Association (ADA 2001b). In this study, 53 restorations (32 full ceramic inlays and 21 full ceramic onlays) were placed in 38 patients. The material combination XP *BOND* + SCA (Self Cure Activator) / Calibra Esthetic Resin Cement was used in self-cure/ self-cure mode. The restorations were made from Empress II pressed ceramic. All teeth restored in terms of this study are in occlusion. Baseline results are displayed in the below table:

Criteria and **number** of restorations evaluated at baseline		XP *BOND* / SCA / Calibra [n]			
		alpha	bravo	charlie	delta
Marginal discoloration and integrity	53	53	0	0	0
Secondary caries	53	53	0	0	0
Vitality test	53	53	0	0	0
Interproximal contacts	53	53	0	0	0
Retention	53	53	0	0	0
Fracture	53	53	0	0	0
		No	Yes	Mean	SD
Post-operative sensitivities	53	43	10	1.9	2.1

Table 6 Trial on indirect ceramic restorations, overview on baseline results. For the post-operative sensitivities, mean value and standard deviation is provided (1 = lowest sensitivity, 10 = highest sensitivity)

XP *BOND* + SCA / Calibra Base&Catalyst [n]			
teeth affected	pre-operative sensitivity		post-operative sensitivity
1	0	→	6
2	0 / 0	→	3 / 3
5	0 / 0 / 0 / 0 / 0	→	1 / 1 / 1 / 1 / 1
1	3	→	1
1	4	→	1
∑ = 10			

Table 7 Number of teeth affected, intensity and changes in pre- and post-operative sensitivities. 1 = lowest sensitivity, 10 = highest sensitivity.

The overall post-operative sensitivity rate amounts to 10 / 43 x 100% = 23.3%. It should be noted that 7 out of these 10 post-operative sensitivities are of slightest intensity (= grade 1 on a scale of up to 10). No adverse events/ effects were observed. The investigator concludes that XP *BOND* is clinically suitable.

4.4 Summary of Clinical Trials and Conclusion

99.0% of the XP *BOND* class V restorations were rated acceptable after 3 months of clinical service (control group: 97.9%). For the class I and II trial, the number of post-operative sensitivities observed for XP *BOND* (9.4%) is slightly lower than the one recorded for the control group (12.5%). The post-operative sensitivity rate observed for the trial on indirect restorations (23.3%) is acceptable. This takes into account that the majority of sensitivities is of slightest intensity, and that the restorations placed are indirect ceramic inlays or onlays with possibly not yet perfectly adjusted occlusion. No adverse events/ effects were observed in any of the trials.

It can be concluded that XP *BOND* is suitable for clinical use.

5 Directions for Use

XP *BOND*™

Universal Total-Etch Adhesive

XP *BOND*™ is a universal self-priming dental adhesive designed to bond resin based light-cured restorative materials to enamel and dentine. **XP *BOND*** stands for eXtra Performance due to high bond strength on enamel and dentine, easy and comfortable application and a high degree of technique robustness.

By mixing **XP *BOND*** with **Self-Cure Activator** (SCA), a dual-cure or self-cure dental adhesive system is obtained. The system is indicated for bonding all types of indirect restorations in conjunction with a dual-cure or self-cure resin cement such as **Calibra**® Esthetic Resin Cement.

XP *BOND* is to be used in conjunction with **DeTrey**® **Conditioner 36**.

COMPOSITION

carboxylic acid modified dimethacrylate (TCB resin)

phosphoric acid modified acrylate resin (PENTA)

urethane dimethacrylate (UDMA)

triethyleneglycol dimethacrylate (TEGDMA)

2-hydroxyethylmethacrylate (HEMA)

Butylated benzenediol (stabilizer)

ethyl-4-dimethylaminobenzoate

camphorquinone

functionalised amorphous silica

t-butanol

INDICATIONS

1. **XP *BOND*** is a self-priming bonding agent for use in combination with light cured direct restoratives or light cured resin cements.
2. In conjunction with **Self-Cure Activator** (SCA), **XP *BOND*** is indicated for adhesive cementation of indirect restorations in conjunction with **Calibra®** dual-cure or self-cure resin cement. For details, please refer to the Directions for Use of SCA.

CONTRAINDICATIONS

XP *BOND* is contraindicated for

1. Direct or indirect pulp-capping.
2. Use in patients with a known allergy to methacrylate resins or any other of the components.

WARNINGS

1. **XP *BOND*** contains methacrylates which may be irritating to skin and eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. After contact with skin, wash immediately with plenty of soap and water. Do not take internally.

2. **XP *BOND*** contains t-butanol. t-butanol is flammable and harmful. Keep away from sources of ignition - no smoking. Do not breathe in vapour. Take precautionary measures against static discharges. Avoid contact with soft tissues, mucous membranes or eyes.
3. **XP *BOND*** contains polymerizable monomers which may cause skin sensitisation (allergic contact dermatitis) by contact with skin or mucous membranes in susceptible persons. Wash thoroughly with soap and water after contact. If skin sensitisation occurs, or if a known allergy to methacrylate resin exists, discontinue use.

PRECAUTIONS

1. Avoid **XP *BOND*** saturating the gingival retraction cord. If **XP *BOND*** soaks into the cord, it may set hard and bond the cord to the underlying tooth surface making removal difficult.

INTERACTIONS WITH DENTAL MATERIALS

XP *BOND*

1. If H_2O_2 has been used to clean the cavity, proper rinsing is essential. Higher concentration H_2O_2 may interfere with the setting of polymerizable material and should not be used prior to the application of **XP *BOND*** .
2. Eugenol containing dental materials should not be used in conjunction with **XP *BOND*** because they may prevent setting and cause softening of the polymeric components of the adhesive.

ADVERSE REACTIONS

The following adverse reactions have been associated with the use of methacrylate monomers:

1. Skin sensitisation (allergic contact dermatitis).
2. Reversible inflammatory changes of the oral mucosa after accidental contact.

STEP-BY-STEP INSTRUCTIONS

1. Cleaning

Cavity cleanliness is paramount for the development of adhesion. Clean freshly instrumented enamel and dentin with water spray, then air dry. In cases where no cavity preparation or instrumentation has been made, clean uninstrumented enamel and dentin with a rubber cup and pumice or a non-fluoride cleaning paste such as Nupro® prophylaxis paste. For class V cavities, refresh surface of lesion with a rotating instrument. Bevel enamel margins if desired to improve the esthetic outcome of restoration. Wash thoroughly with water spray and air dry. Do not desiccate.

2. Pulp Protection

In deep cavities cover the dentine close to the pulp (less than 1 mm) with a hard-setting calcium hydroxide liner (Dycal®) leaving the rest of the cavity surface free for bonding with **XP *BOND*** .

3. Acid Conditioning (Total-Etch Procedure)

Attach disposable needle to the end of DeTrey Conditioner 36 gel syringe. Needle tip may be bent for easy access. Gently extrude gel to the cavity surfaces starting at the enamel margins and extending it to dentine surface. For best results, condition enamel for at least 15 seconds and dentine for 15 seconds or less. Remove gel with aspirator tube and/or vigorous water spray and rinse conditioned areas thoroughly for at least 15 seconds. Remove rinsing water completely by blowing gently with an air syringe or by blot-drying with a (cotton) pellet. Do not desiccate.

Once the surfaces have been properly treated, they must be kept uncontaminated. If salivary contamination occurs, thoroughly clean with vigorous water-spray, dry, and repeat conditioning procedure of enamel for 5 seconds only. Rinse and dry as described above.

4. Application of XP ***BOND***

DIRECT RESTORATIONS

4.1 Application of XP ***BOND***

STEP 1: Dispense **XP *BOND*** into a DENTSPLY CliXdish or standard dappen dish. Alternatively, dispense **XP *BOND*** directly onto a fresh Applicator Tip or onto a disposable brush.

STEP 2: Wet all cavity surfaces uniformly with **XP *BOND***. Avoid pooling.

STEP 3: Leave the surface undisturbed for 20 seconds.

STEP 4: Evaporate solvent by thoroughly blowing with air from an air syringe for at least 5 seconds. The cavity surface should have a uniform, glossy appearance. Otherwise repeat steps 2 and 4.

STEP 5: Light-cure for a minimum of 10 seconds[2]. Ensure uniform exposure of all cavity surfaces.

STEP 6: Immediately place the restorative material over cured **XP *BOND***.

4.2 Composite/ Compomer Repairs

STEP 1: Roughen and clean fractured restoration surface with a fine diamond bur and create mechanical retention, if possible.

STEP 2: Etch exposed cavity and fractured restoration surface with 36 % phosphoric acid (DeTrey Conditioner 36). Start with enamel margins and restoration surface, then extending the acid gel to dentin. Etch enamel and restoration surface for at least 15 seconds and dentine for up to 15 seconds.

STEP 3: Rinse with water for at least 15 seconds, and air-dry. Remove rinsing water completely by blowing gently with an air syringe or by blot-drying with a (cotton) pellet. Do not desiccate.

STEP 4: Apply **XP *BOND*** according to chapter 4.1 ("Direct Restorative Procedures"). Apply adhesive also to fractured restoration surface.

INDIRECT RESTORATIONS

XP *BOND* can be used for the adhesive cementation of indirect restorations in conjunction with light-cure, dual-cure or self-cure resin cements such as **Calibra**® Esthetic Resin Cement.

4.3 Light-Cure Resin Cements

If the application of light-cure resin cement (e.g. for bonding of indirect composite/ porcelain inlays) is intended, the application procedure described for direct restorations (chapter 4.1) is to be followed.

4.4 Dual-Cure or Self-Cure Resin Cements

If the application of dual-cure (e.g. for bonding of translucent fiber posts) or self-cure (e.g. for bonding of PFM-crowns or metal posts) resin cement is intended, **XP *BOND*** must be used in conjunction with **Self-Cure Activator** (SCA). The application procedure is described in the Directions for use of Self-Cure Activator.

For further information on how to use Calibra® resin cement or other resin based luting cements, please refer to the Directions for Use of the respective product.

STORAGE

All products: Keep out of sunlight. To be stored at temperatures between 10 and 28 °C. Inadequate storage conditions will shorten the shelf life and may lead to malfunctions of the products. All products should be used at room temperature.

DeTrey Conditioner 36: Replace cap immediately after use.

[2] Check your curing light for a minimum output level of 800 mW/cm². Light cure adhesive for at least 20 seconds if the light intensity is between 500 and 800 mW/cm².

XP *BOND*	The **XP *BOND*** bottle should be tightly closed immediately after use. Keep in a well ventilated place. Protect from direct sunlight.

BATCH NUMBER(LOT) AND EXPIRY DATE ( )

Do not use after expiry date.

The batch number should be quoted in all correspondence which requires identification of the product.

If you have any questions, please contact:

DENTSPLY DeTrey GmbH (Manufacturer), De-Trey-Straße 1, 78467 Konstanz, Germany

Phone +49 (0) 7531- 583- 0

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7 Glossar and Abreviations

DFU	Directions for Use
E&R	Etch&Rinse Etching with phosphoric acid which has to be rinsed off (formerly referred to as Total Etch Technique)
FESEM	Field Emission Scanning Electron Microscopy
LED	Light Emitting Diode
µSFL	Micro Shear Fatigue Limit
µTBS	Micro Tensile Bond Strength
ptf	pre-test failure (occurring while preparing sticks for µTBS)
QTH	Quartz Tungsten Halogen
SBS	Shear Bond Strength
SEM	Scanning Electron Microscope
TC	Thermo Cycles
TEM	Transmission Electron Microscopy
TML	Thermo Mechanical Loading

8 List of Figures

The following materials are not trademarks of DENTSPLY International but of the respective manufacturer.

Abreviation	Brand (Manufacturer)
Empress II	Empress® II (Ivoclar Vivadent)
Excite DSC	Excite® DSC (Ivoclar Vivadent)
Heliobond	Heliobond® (Ivoclar Vivadent)
MbS	Monobond-S (Ivoclar Vivadent)
ML	Multilink® (Ivoclar Vivadent)
MC	MultiCore®flow (Ivoclar Vivadent)
OB FL	OptiBond™ FL (Kerr)
OBS+	OptiBond Solo™ Plus (Kerr)
SB1XT	Adper™ Scotchbond™ 1 XT (3M Espe)
Syn	Syntac® (Ivoclar Vivadent)
TEC	Tetric EvoCeram® (Ivoclar Vivadent)
Variolink	Variolink® II (Ivoclar Vivadent)
Z250	Filtek™ Z250 (3M Espe)