Prime&Bond® XP
Universal Total-Etch Adhesive
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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 nanotechnology 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, Prime&Bond XP stands for eXtra Performance.

Prime&Bond XP is a universal self-priming dental adhesive designed to bond resin based light-cured restorative materials to enamel and dentin.

Prime&Bond XP 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.

Prime&Bond XP offers a new, unique solvent providing easy and comfortable application and thereby a high degree of technique robustness.

2 Product Description – Prime&Bond XP

2.1 Prime&Bond XP: Components and Function

Prime&Bond XP 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.
<table>
<thead>
<tr>
<th>Component</th>
<th>Function</th>
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<tr>
<td>PENTA</td>
<td>Adhesion promoter, wetting aid and crosslinker</td>
</tr>
<tr>
<td>TCB resin</td>
<td>Adhesion promoter, wetting aid and crosslinker</td>
</tr>
<tr>
<td>UDMA</td>
<td>Resin molecule of intermediate elasticity when cured</td>
</tr>
<tr>
<td>TEGDMA</td>
<td>Mobile crosslinking methacrylate resin for good infiltration</td>
</tr>
<tr>
<td>HEMA</td>
<td>Reactive diluent and wetting aid</td>
</tr>
<tr>
<td>Nanofiller</td>
<td>Nanoscale functionalised filler for increasing strength and crosslinking</td>
</tr>
<tr>
<td>Camphorquinone, DMABE</td>
<td>Photoinitiator system</td>
</tr>
<tr>
<td>Butylated benzenediol</td>
<td>Stabilises material during storage</td>
</tr>
<tr>
<td>tert-Butanol</td>
<td>Solvent for the resins and mild stabiliser.</td>
</tr>
</tbody>
</table>

Table 1  Components of Prime&Bond XP and their function

The use of PENTA (Figure 1) and TCB resin (Figure 2) as adhesion promoters in the low viscous adhesive Prime&Bond XP promotes chemical interaction between the monomers and tooth substance and ensures high bond strength to tooth substance.
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 Prime&Bond XP bonding agent formulation improve a number of properties. The most important aspects are

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

Compared to Prime&Bond NT, in the new Prime&Bond XP 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.

![New CliXdish (red cover)](image)

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

A patent for using tert-butanol in adhesives was granted to DENTSPLY.

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 feedback 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 Prime&Bond XP 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 Dentin 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 dentin

(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, Prime&Bond XP 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 Prime&Bond XP with these lamps was tested.

The results in Figure 7 show that Prime&Bond XP 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 to moist, over wet, and over dried dentin

(Mark Latta, Creighton (NE), USA)

Following the protocol previously described, the robustness towards moisture degree of dentin was tested. Dentin was either blot dried to reach an ideal degree of moisture, over wet dentin was reached by spreading 2.5 µl water over a round area with 4.0 mm diameter, and over dried dentin was achieved by a strong air blow onto the flat dentin surface for 10 seconds. Resulting bond strength varied significantly for all adhesives tested. However, Prime&Bond XP showed significantly higher bond strength compared to all other tested adhesives when dentin was over wet or over dried being on a level comparable to most adhesives when applied to dentin with ideal moisture (Figure 8).
3.1.1.3 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 9 SBS to enamel and dentin with either QTH or LED curing unit

Results in Figure 9 show that all tested adhesives provide high levels of bond strength to enamel and dentin regardless of the used light source.
3.1.1.4 Micro Tensile Bond Strength (µTBS) to dentin

(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 dentin 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 10 illustrates how test sticks were prepared before thermo cycling was applied.

![Figure 10](image)

**Figure 10** Preparation of sticks before thermo cycling for µTBS testing

As in the previous investigation either 1800 or 6000 thermo cycles were applied. Prime&Bond XP 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 11  µTBS after 1800 thermo cycles of sticks

Prime&Bond XP 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 11).

Figure 12  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 12).

Since with Prime&Bond XP an active application technique is not needed, a decrease in performance can not be caused by altering the application in such a way,
hence Prime&Bond XP demonstrated a higher technique robustness in this investigation.

3.1.1.5 Micro Shear Fatigue Limit (μSFL) to dentin

(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 Prime&Bond XP and other adhesive systems.

Tooth substance is placed and fixed in a brass mould (left picture of Figure 13). 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 13). 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 13).

![Figure 13 Specimen preparation](image)

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 14).
Figure 14  Number of cycles (bars) and respective load (dots) for each sample.

![Bar Chart](image)

Figure 15  Mean Micro Shear Fatigue Limit to dentin

Prime&Bond XP showed a very high fatigue limit that surpassed most other competitive adhesives including a filled multi bottle system.

3.1.1.6 Shear bond strength to dentin – a practitioner test

(6 private practitioners, Germany)

As improved technique robustness was one aim in the development of Prime&Bond XP, 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 16 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.

3.1.1.7 Summary of bond strength data for direct procedures

It could be proven that Prime&Bond XP 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

Prime&Bond XP 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, Prime&Bond XP 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 dentin 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.

To evaluate the universality of the combination Prime&Bond XP, 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 17](image)

**Figure 17**  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 dentin, Prime&Bond XP showed the highest bond strength.

Even in the pure chemical cure mode, Prime&Bond XP established in combination with SCA and Calibra bond strength to dentin 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 dentin than either of the other systems.

---

1 e.g. DFU Syntac
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 Prime&Bond XP.

![Figure 18](image)

**Figure 18** SBS in indirect procedures where the adhesive layer is light cured

The results shown in Figure 18 support the universal use of Prime&Bond XP in combination with SCA and Calibra.

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

(Marco Ferrari, Livorno, Italy)

Simplified ceramic overlays were luted onto dentin following the different protocols listed in Table 2. Ten teeth per group were used resulting in about 40 beams per group.
Table 2  Techniques and materials used for luting ceramic overlays to dentin

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 19.

![Figure 19](image)

From this data it is obvious that Prime&Bond XP 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 17, Figure 18, Figure 19). Prime&Bond XP 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 Cutting back the composite to allow new layering, the surface is cleaned using phosphoric Etchant (this step is meant for cleaning and would only etch the basic glass filler in materials like Dyract eXtra). After application of the Bonding material the necessary composite is Layered 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.
Prime&Bond XP 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 Prime&Bond XP 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 Prime&Bond XP 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 21 a). Figure 21 b) shows the mould ready for post placement. The luted post is shown in Figure 21 c).
Figure 21  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 22a) is placed in a diamond saw and cut into slices in a first step (Figure 22b) and sticks for micro tensile testing in a second step (Figure 22c).

Figure 22  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)
The results on micro tensile testing shown in Figure 23 clearly demonstrate that the application of Prime&Bond XP 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 dentin

(Marco Ferrari, Livorno, Italy)
Root canals were filled using AH® Plus and Gutta-percha. 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 24 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 25.

Figure 25 Push-out strength of various adhesive cement combinations.
(adhesive: XP = Prime&Bond XP, 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 Prime&Bond XP 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 Prime&Bond XP 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 Prime&Bond XP SCA mix shown in Figure 25 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 Prime&Bond XP 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 dentin. To quantify the quality, either dye penetration or quantitative SEM analysis were applied.

3.2.1.1 Dye penetration and dentin permeability in class V

(Juan Ignacio Rosales, Granada, Spain)

After restoring U-shaped class V cavities with the materials displayed in Figure 27, 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 buccolingual 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 26) between 0 (hermetic seal) and 3 (massive micro leakage).
Additionally, it was documented whether, in the presence of dye along the cavorestorative margin, any dye penetrated into dentin.

Figure 26  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 (dentin) are shown in Figure 27.

Figure 27  Microleakage scores found in slices of class V restorations

Prime&Bond XP 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 dentin, is shown in Figure 28.

<table>
<thead>
<tr>
<th></th>
<th>Occlusal</th>
<th>Gingival</th>
<th>Occlusal</th>
<th>Gingival</th>
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<th>Gingival</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Prime&amp;Bond XP</strong>&lt;br&gt;+ Ceram•X mono</td>
<td>100%</td>
<td>0%</td>
<td>100%</td>
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<tr>
<td><strong>Syntac Classic</strong>&lt;br&gt;+ Tetrac Evo Ceram</td>
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**Figure 28**  Dentin permeability in class V

These results show that Prime&Bond XP totally seals the dentin against dye penetration. This good sealing of dentin was observed in investigations by the same investigator using early versions of Prime&Bond XP, and was finally challenged in an investigation where no phosphoric etchant was used (which is mandatory as pre-treatment for Prime&Bond XP).
Figure 29  Microleakage (upper half) after provoked dye penetration (no etching) and control (etching) and respective dentin permeability (lower half).

Non use of phosphoric acid as pre-treatment of the cavity surfaces results in high micro leakage (upper part of Figure 29). When etching is performed, micro leakage is very low as demonstrated before (Figure 27). Despite the provoked massive penetration of dye along the cavo-restorative interface, no penetration of dye into dentin could be found (lower part of Figure 29), proving the excellent sealing capability of Prime&Bond XP.

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.
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.

Prime&Bond XP 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 32).

![Figure 32](image)

Figure 32  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 dentin 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.
Restorations of Prime&Bond XP 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 33).

Marginal quality provided by Prime&Bond XP in dentin was comparable to that of the control, and better than one of the two tested one bottle adhesives (Figure 34).

3.2.2.2 Summary of data on marginal quality of direct restorations

Prime&Bond XP not only offers a very good seal of the margins in enamel and dentin but provides an exceptional seal of dentin, 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 Prime&Bond XP 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 Prime&Bond XP had any influence (Prime&Bond XP SCA (LC)).

![Figure 35](image)

**Figure 35** Perfect margins of adhesively luted ceramic inlays

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

All three test groups showed comparable performance on a high level.
Therefore, it could be demonstrated that Prime&Bond XP 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 dentin 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 dentin is very sensitive to the degree of moisture. Etched and desiccated dentin is not only difficult to infiltrate and hybridize but it would hinder penetration towards the unaffected dentin leading to lower bond strength.

3.3.1.1 FESEM and TEM investigation of hybrid layer quality

(Jorge Perdigão, Minneapolis (MN), USA)

Dentin 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 dentin. This is not recommended following phosphoric acid etching. Thus the robustness of the adhesive towards surface moisture was investigated.
For both adhesives tested with moist dentin, SEM micrographs of the adhesive dentin interface (Figure 36 and Figure 37) show a distinct adhesive layer, a well and homogenously infiltrated hybrid layer, and well infiltrated peritubular dentin resulting in tags and filled intertubular spaces.
When dentin was air-dried for 10 seconds, detachment of the adhesive from the underlying dentin could be seen for OptiBond Solo Plus in one specimen, as shown in Figure 38.

Figure 38  SEM of Optibond Solo Plus applied on dried dentin.

Using Prime&Bond XP on the same substrate (dentin dried for 10 seconds) resulted in micrographs similar to those from moist dentin (Figure 39 and Figure 40).
Figure 39  Overview SEM of hybrid layer and tags using Prime&Bond XP on dried dentin

Figure 40  SEM of Prime&Bond XP applied on dried dentin.

The investigator stated: “The morphology of the hybrid layer when Prime&Bond XP 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 41).
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, Prime&Bond XP 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 dentin specimens were immersed for 24 hours in 50 wt% ammoniacal AgNO₃ 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 42 shows representative pictures and the mean grade of nanoleakage for the respective adhesive.
Prime&Bond XP showed the lowest degree of nanoleakage proving again its excellent ability to seal dentin.

3.3.3 Summary of micro morphology investigations

Results from SEM, TEM, and light microscopy revealed that Prime&Bond XP is able to infiltrate and penetrate dentin homogenously – even under less ideal conditions when dentin 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 Prime&Bond XP have been initiated. A selection of studies and results are summarized here.

4.1 Class V Studies on Prime&Bond XP

4.1.1 Class V Studies on Prime&Bond XP versus Scotchbond 1XT at the Universities of Berlin, Bologna and Leipzig, short term results (14.1165, 14.1109, 14.1110)

Three identically designed longitudinal, controlled and patient and evaluator blinded clinical class V trials were performed 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 Prime&Bond XP (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:
One test restoration failed for both parameters retention and marginal integrity. Two control restorations failed regarding marginal integrity. Accordingly, the overall success rate amounts to 95 / 96 x 100% = 99.0% for the Prime&Bond XP test group and 93 / 95 x 100% = 97.9% for the Scotchbond 1XT control group. With exception of the restoration failures no other adverse events were observed.

It can be concluded that both adhesives performed well over the first three month. A good short term performance may be an indication for the potential of an adhesive to also provide good longtime results.

### 4.1.2 Class V study on Prime&Bond XP at the University of Bologna, 8 year results (14.1008)

An equivalence randomized controlled trial was performed to evaluate the clinical long term success of Prime&Bond XP used for cervical Ceram•X Duo and Esthet•X restorations.

**Methods:** 50 subjects, 21 males and 29 female aged between 21 and 65 were randomized to receive 150 restorations, 100 with the new restorative material Ceram•X Duo, 50 with the composite Esthet•X as a control, placed in non-caries cervical lesions with the same bonding, Prime&Bond XP. Randomization was number table-generated. Patients, examiner, analysts were blinded to group assignment. Data were analyzed by ANOVA and Cox test (P<.05). The main outcome measure was the cause of failure at 8 years.

---

<table>
<thead>
<tr>
<th>Criteria for evaluated restorations</th>
<th>Prime&amp;Bond XP / Ceram•X Duo [n]</th>
<th>Scotchbond 1XT / Ceram•X Duo [n]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>alpha</td>
</tr>
<tr>
<td>Retention</td>
<td>96</td>
<td>95</td>
</tr>
<tr>
<td>Post-op. sensitivity (Σ)</td>
<td>95</td>
<td>93</td>
</tr>
<tr>
<td>Marginal discolouration</td>
<td>95</td>
<td>94</td>
</tr>
<tr>
<td>Marginal integrity</td>
<td>96</td>
<td>95</td>
</tr>
<tr>
<td>Secondary caries</td>
<td>95</td>
<td>95</td>
</tr>
<tr>
<td>Restoration contour</td>
<td>95</td>
<td>94</td>
</tr>
<tr>
<td>Vitality test</td>
<td>95</td>
<td>95</td>
</tr>
</tbody>
</table>

**Table 3** Pooled 3 month results from class V trials
### Results:

<table>
<thead>
<tr>
<th>Criteria for evaluated restorations</th>
<th>Prime&amp;Bond XP / Ceram•X Duo [n]</th>
<th>Prime&amp;Bond XP / Esthet•X [n]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>alpha</td>
</tr>
<tr>
<td>Retention</td>
<td>80</td>
<td>100%</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>80</td>
<td>75%</td>
</tr>
<tr>
<td>Marginal integrity</td>
<td>80</td>
<td>69%</td>
</tr>
<tr>
<td>Caries</td>
<td>80</td>
<td>100%</td>
</tr>
<tr>
<td>Contour</td>
<td>80</td>
<td>75%</td>
</tr>
</tbody>
</table>

**Table 4** Ryge rating of the 8 year recall of 120 cervical restorations bonded with Prime&Bond XP

After 8 years 44 patients and 128 teeth were included in the analysis of the primary outcome as there were 8 previous failures in the experimental group and 4 previous failures in the control group, observed prior to the 8 year recall. There were two key elements of failure: the presence of sclerotic dentin and the relationship between lesion and gingival margin. The cumulative (total) failure rate at 8 years is 9.1% for both restorative materials (8 retention failures out of 88 ceram.x and 4 retention failures out of 44 Esthet•X restorations) and the annual failure rate (AFR) of both restorative materials is 1.1%.

**Conclusion:** Prime&Bond XP worked excellent with both restoratives, the new Ceram•X Duo and the micro-hybrid composite Esthet•X.

### 4.2 Direct occlusal load bearing Class II restorations: 18 month results

To investigate the long-term behavior of Prime&Bond XP under load bearing conditions, a longitudinal, controlled and patient and evaluator blinded clinical trial of occlusal load bearing composite restorations 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 restorations bonded with Prime&Bond XP (test group) and 40 restorations bonded with Optibond Solo Plus...
(control group) were placed in the same patient wherever possible. All teeth filled in terms of this study were in occlusion. Both adhesives were used in conjunction with Ceram•X Mono Nano-Ceramic Restorative.

Results regarding post-operative hypersensitivity two weeks post placement:

<table>
<thead>
<tr>
<th>Adhesives</th>
<th>Prime&amp;Bond XP</th>
<th>Optibond Solo Plus</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-op. sensitivities</td>
<td>n</td>
<td>no</td>
</tr>
<tr>
<td>spontaneous</td>
<td>32</td>
<td>31</td>
</tr>
<tr>
<td>triggered by chewing</td>
<td>32</td>
<td>30</td>
</tr>
<tr>
<td>triggered by other noxa</td>
<td>32</td>
<td>31</td>
</tr>
<tr>
<td>(Σ)</td>
<td>32</td>
<td>29</td>
</tr>
</tbody>
</table>

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

Based on 32 restorations, the post-operative sensitivity rate amounts to 9.4% for the Prime&Bond XP group and to 12.5% for the Optibond Solo Plus group. Elmar Hellwig states that no adverse effects/ events or other clinical problems occurred. Also considering the rate of post-operative sensitivities that was found for the control group, the value associated with Prime&Bond XP is low and acceptable.

Results of the 18 month recall examination:

<table>
<thead>
<tr>
<th>Criteria for evaluated restorations</th>
<th>Prime&amp;Bond XP / CeramX mono [n]</th>
<th>Optibond Solo Plus / CeramX mono [n]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>alpha</td>
</tr>
<tr>
<td>Retention</td>
<td>23</td>
<td>23</td>
</tr>
<tr>
<td>Marginal discolouration</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td>Marginal integrity</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td>Secondary caries</td>
<td>23</td>
<td>22</td>
</tr>
<tr>
<td>Proximal contact/cont. (d)</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Proximal contact/cont. (m)</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Vitality test</td>
<td>23</td>
<td>27</td>
</tr>
</tbody>
</table>

Table 6  Ryge rating of the 18 month recall of 46 class II Ceram·X Mono restorations

None of the restored teeth exhibited post-operative hypersensitivity at the time of recall neither any adverse events did occure.
Prime&Bond XP as well as the control material performed satisfactory when used to bond occlusal stress bearing posterior restorations. Professor Dr. Elmar Hellwig, Main Investigator at the University of Freiburg, concludes that results indicate no clinical difference between the two adhesive systems. From the observed case of the secondary caries of only one restoration and the small amount of marginal discolorations no further conclusions can be drawn.

4.3 **Indirect ceramic restorations: 5 year results** (14.1111)

A clinical trial on adhesive cementation of indirect ceramic restoration has been conducted at the University of Siena/ Practice Prof. Dr. Marco Ferrari. 53 test restorations (32 full ceramic inlays, 21 full ceramic onlays) were placed in 38 patients. The material combination Prime&Bond XP / SCA / Calibra (base + catalyst) was used in self-cure/ self-cure mode.

**Results:**

All 53 teeth were evaluated at baseline, after 2 weeks, 6 months, 1 and 2 years, 51 restorations after 3 years, 49 after 4 years and 43 restorations after 5 years of clinical service.

At baseline, 3 patients showed preoperative sensitivity at 5 teeth. 10 cases of postoperative sensitivity were observed at the 2 weeks recall and only 3 after 6 months. In one case the postoperative sensitivity raised from 0 to 6 immediately after luting the restoration (after the anesthetic effect vanished) but dropped to grade 3 after 6 months. In 7 cases showing an increase in postoperative sensitivity after 2 weeks, the hypersensitivity disappeared completely after 6 months. In two cases a residual postoperative sensitivity of grade 2 remained after 6 months. After 2 years of clinical service postoperative sensitivity of modest entity residedated only in one patient. All other parameters showed alpha scores. No adverse events/effects occurred.

After 3 years of clinical service postoperative sensitivity was not reported in any of 51 re-evaluated restorations. Five restorations showed bravo and 2 charlie scores for marginal parameters. One restoration showed bravo for pulp vitality. After 3 years of clinical service, all restorations were still clinically acceptable.
During the 4 years recall, postoperative sensitivity was not reported in any of 49 re-evaluated restorations. Three restorations showed bravo and 2 charlie scores for marginal parameters. One restoration showed bravo for pulp vitality and another for interproximal contact. After 4 years of clinical service, all restorations were in a clinical acceptable range.

After 5-year of clinical service the examination showed that post-op sensitivity did not affect any restoration. The ratings of the restorations at the 5 month recall examination are displayed in the below table:

<table>
<thead>
<tr>
<th>Criteria and number of restorations evaluated at 5 year recall</th>
<th>Prime&amp;Bond XP / SCA / Calibra [n]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>alpha</td>
</tr>
<tr>
<td>Marginal discoloration and integrity</td>
<td>43</td>
</tr>
<tr>
<td>Secondary caries</td>
<td>43</td>
</tr>
<tr>
<td>Vitality test</td>
<td>43</td>
</tr>
<tr>
<td>Interproximal contacts</td>
<td>43</td>
</tr>
<tr>
<td>Retention</td>
<td>43</td>
</tr>
<tr>
<td>Fracture</td>
<td>43</td>
</tr>
</tbody>
</table>

**Table 7** Ryge rating of the 5 year recall of 43 ceramic restorations bonded with Prime&Bond XP

Prime&Bond XP with SCA and Calibra used in self-cure mode showed no residual post-op sensitivity in 43 luted porcelain restorations after 5 years of clinical service. After 5 years of clinical service 41 of 43 restorations were still in clinical service, with a survival rate of 95%. 32 of 43 restorations were free from any clinical problem with a success rate of a 75%.

**Conclusion:** The results of this study over a 5 year period prove the suitability of Prime&Bond XP in combination with SCA and Calibra in self-cure mode for cementation of ceramic restorations.
4.4 Summary of clinical trials and conclusion

Clinical data from studies with an observation time of up to eight years are available for Prime&Bond XP. The results of the clinical studies show that restorations bonded with Prime&Bond XP have:

- A high retentive capacity (low incidence of retention failure),
- Good longterm marginal quality, little marginal discoloration and a low incidence of secondary caries,
- A low incidence and degree of post-operative hypersensitivity,
- A high survival and success rate (low total failure rate and AFR).

The indications of Prime&Bond XP given by the Instructions for Use are substantiated by clinical data when taken together with the relevant pre-clinical data. The clinical data show that Prime&Bond XP performances well in comparison to other adhesives.

5 Instructions for Use

The up-to-date version can be found in all European languages on www.dentsply.eu.
6 References


## 7 Glossar and Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DFU</td>
<td>Directions for Use</td>
</tr>
<tr>
<td>E&amp;R</td>
<td>Etch &amp; Rinse</td>
</tr>
<tr>
<td></td>
<td>Etching with phosphoric acid which has to be rinsed off (formerly referred to as Total Etch Technique)</td>
</tr>
<tr>
<td>FESEM</td>
<td>Field Emission Scanning Electron Microscopy</td>
</tr>
<tr>
<td>LED</td>
<td>Light Emitting Diode</td>
</tr>
<tr>
<td>µSFL</td>
<td>Micro Shear Fatigue Limit</td>
</tr>
<tr>
<td>µTBS</td>
<td>Micro Tensile Bond Strength</td>
</tr>
<tr>
<td>ptf</td>
<td>pre-test failure (occurring while preparing sticks for µTBS)</td>
</tr>
<tr>
<td>QTH</td>
<td>Quartz Tungsten Halogen</td>
</tr>
<tr>
<td>SBS</td>
<td>Shear Bond Strength</td>
</tr>
<tr>
<td>SEM</td>
<td>Scanning Electron Microscope</td>
</tr>
<tr>
<td>TC</td>
<td>Thermo Cycles</td>
</tr>
<tr>
<td>TEM</td>
<td>Transmission Electron Microscopy</td>
</tr>
<tr>
<td>TML</td>
<td>Thermo Mechanical Loading</td>
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Brand (abbreviation, Manufacturer):
ExciTE (Ex, Ivoclar Vivadent)
Excite DSC (Ex DSC, Ivoclar Vivadent)
Heliobond (Ivoclar Vivadent)
Multilink (Ivoclar Vivadent)
Monobond S (Ivoclar Vivadent)
Optibond Solo Plus (OBS+, Kerr)
Optibond FL (OFL, Kerr)
Scotchbond XT (SB1XT, SB, 3M ESPE)
Syntac (Syn, Ivoclar Vivadent)
Tetric EvoCeram (Ivoclar Vivadent)
Variolink II (Ivoclar Vivadent)