

# Monobond<sup>®</sup> Etch & Prime

Self-etching glass-ceramic primer



Scientific  
Documentation



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# 1. Introduction

## 1.1 The success of glass ceramics

Glass ceramics became a successful alternative to amalgam or metal inlays and onlays in the posterior filling therapy since IPS Empress was launched in the 1990s. Long-term clinical trials confirm the success rate [1,2,3] This outcome was not a matter of course. Former glass ceramic inlays, for example Dicor (Dentsply) showed a high number of fractures after cementing with glass ionomer cements [4]. With the implementation of an adhesive luting procedure the survival of IPS Empress and other glass ceramic brands has been dramatically improved [5].



Fig. 1: Treatment of teeth 16 and 17 with amalgam



Fig. 2: Treatment of teeth 16 and 17 with glass ceramic onlays

The adhesive luting procedure is based on a composite material and an adhesive which bonds to dentin and enamel. This can be done in an etch-and-rinse mode including phosphoric acid etching or with self-etching adhesives. The bond to the glass ceramic surface is achieved by etching and silanization. Glass ceramic can be etched by hydrofluoric acid forming a micro-retentive etching pattern. The bulky glass is more susceptible by dissolution by the acid than the crystal parts. A rough ceramic surface is obtained.

In a second step a chemical bond is formed by silanization. In general a functional methacrylate is used with a trimethoxysilane endgroup.

These procedure allows

- a perfect sealing of the dentin and enamel interface
- a strong bond to the restoration
- a high strength of the cement, which minimizes tensile loads within the ceramic structure

Adhesively luted ceramic inlays and onlays in the posterior region provide a number of advantages to other restorative alternatives, i.e. amalgam, glass ionomers or composites.



Ivoclar Vivadent launched Monobond S as silanizing product composed of trimethoxypropyl methacrylate and solvent in 1991. It proved its clinical efficiency in a number of studies [1] and supported the success of glass ceramic restorations in combination with Variolink II or Dual Cement.

In 2009 Monobond Plus was launched by Ivoclar Vivadent. Monobond Plus allows the priming and conditioning of different restorative substrates. It contains the silane plus a phosphoric acid methacrylate and a sulphide in one bottle. Its efficiency could be proved in several studies [6]



### 1.3 Etching with hydrofluoric acid

The combination of silanization and etching of glass ceramic surfaces showed the most effective bonding of luting composites to glass ceramics [7]. The application of a diluted hydrofluoric acid forms a retentive etching pattern by dissolving silicon ions in the glassy state. Silicon has a high chemical affinity to fluoride ions. The formed silicon fluoride derivatives are soluble and can be rapidly washed off with water. Etching of glass ceramic with HF gel is an established method commonly carried out in the technician laboratory. But also dentists know the technique.

Unfortunately hydrofluoric acid is a very strong poison [8] even in the dissolved state. It is a weak acid and can burn the skin. After penetrating it moves quickly into deeper tissue layers and releases the freely dissociable fluoride anion. Fluoride is very toxic due to its high reactivity. It reacts with cellular calcium and magnesium to form insoluble salts. This induces cellular deaths and necrosis. Skin contact with HF (even in dilute solutions) can cause painful burns that heal very slowly. Latent damages can also be observed since the fluoride ions penetrate through all layers of the epidermis, dermis and even the deeper subcutaneous tissues causing severe destruction, necrosis and injuries to the underlying bone due to decalcification.

The high toxic potential is the reason why in some countries the application of ceramic etching gel is forbidden. A safer but also efficient alternative would be a great benefit for the user.

## 1.4 Monobond Etch & Prime



Monobond Etch & Prime is a single bottle ceramic primer which allows etching and silanization of the glass ceramic surface in one step. It contains a trimethoxypropyl methacrylate for silanization and a new polyfluoride for the etching step. The etching creates a roughness pattern which is less pronounced than with HF gel but as efficient for bonding. The following silanization reaction is similar as with Monobond S or Monobond Plus. The efficiency of Monobond Etch & Prime is proved by a number of intra- and extramural bond strength tests (see chapter 3).

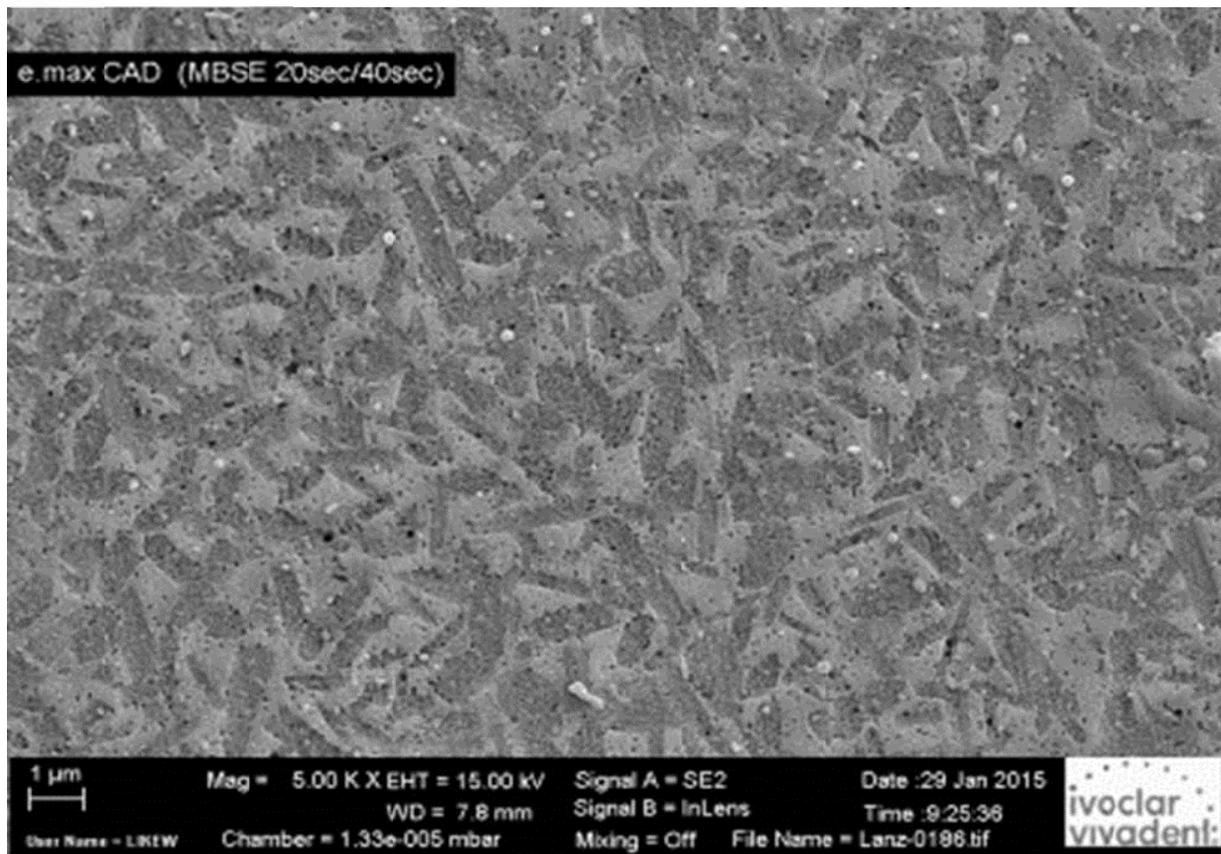


Fig. 4: SEM photo of the etch pattern of IPS e.max Press after application of Monobond Etch & Prime. R&D Ivoclar Vivadent AG, Schaan, FL

With Monobond Etch & Prime the pretreatment of glass ceramic surfaces for the adhesive luting is faster due to less application steps and less harmful due to the avoidance of hydrofluoric acid. Although Monobond Etch & Prime is corrosive its cytotoxicity shown in a XTT assay is with a XTT<sub>50 value</sub> of 1970.1 µg/ml less toxic than many of well-accepted dental products. The health risk for the user is in an accepted level.

Due to its milder reactivity there is no risk of damage to sanitary ceramic. A neutralization step before disposal is not necessary. Monobond Etch & Prime is stable at room temperature.

## 1.5 The mechanism

The application of Monobond Etch & Prime is linked to its reaction mechanism:

Monobond Etch & Prime is applied onto the luting surface with a microbrush and is rubbed for 20 s.

- Monobond Etch & Prime removes saliva and silicon contaminations.

Monobond Etch & Prime remains on the surface for further 40 s for sufficient reaction.

- Ammonium polyfluoride reacts with the clean ceramic surface to achieve a rough etching pattern
- Due to the increased surface area a kind of activation of the ceramic surface is generated

Monobond Etch & Prime is thoroughly washed off with water and then dried with air for another 10 s.

- The polyfluoride and the reaction products with the ceramic are removed
- The reaction between the silane and the active glass ceramic starts
- A chemically bond thin layer of silane remains.

The composition of Monobond Etch & Prime reflects its purpose (table 1).

| Purpose      | Ingredient   |
|--------------|--|
| Etching      | Ammonium polyfluoride                                |
| Silanization | Silane system based on trimethoxypropyl methacrylate |
| Handling     | Solvents: alcohols and water                         |
| Visibility   | Food Colorant: Fast Green                            |

Table 1: Composition of Monobond Etch & Prime

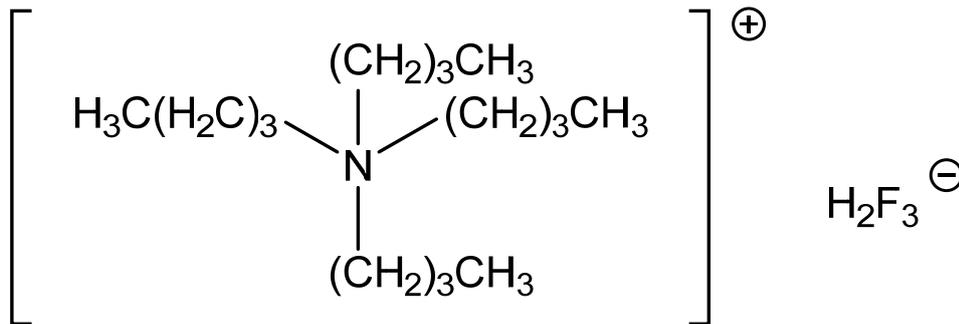


Fig. 5: Structure of Ammonium polyfluoride

Ammonium polyfluoride reacts with the silicon in the glass ceramic without release of HF due to the high chemical affinity between silicon and fluoride. By  $^{19}\text{F}$ -NMR spectroscopy (see fig. 6) the absence of HF can be confirmed.

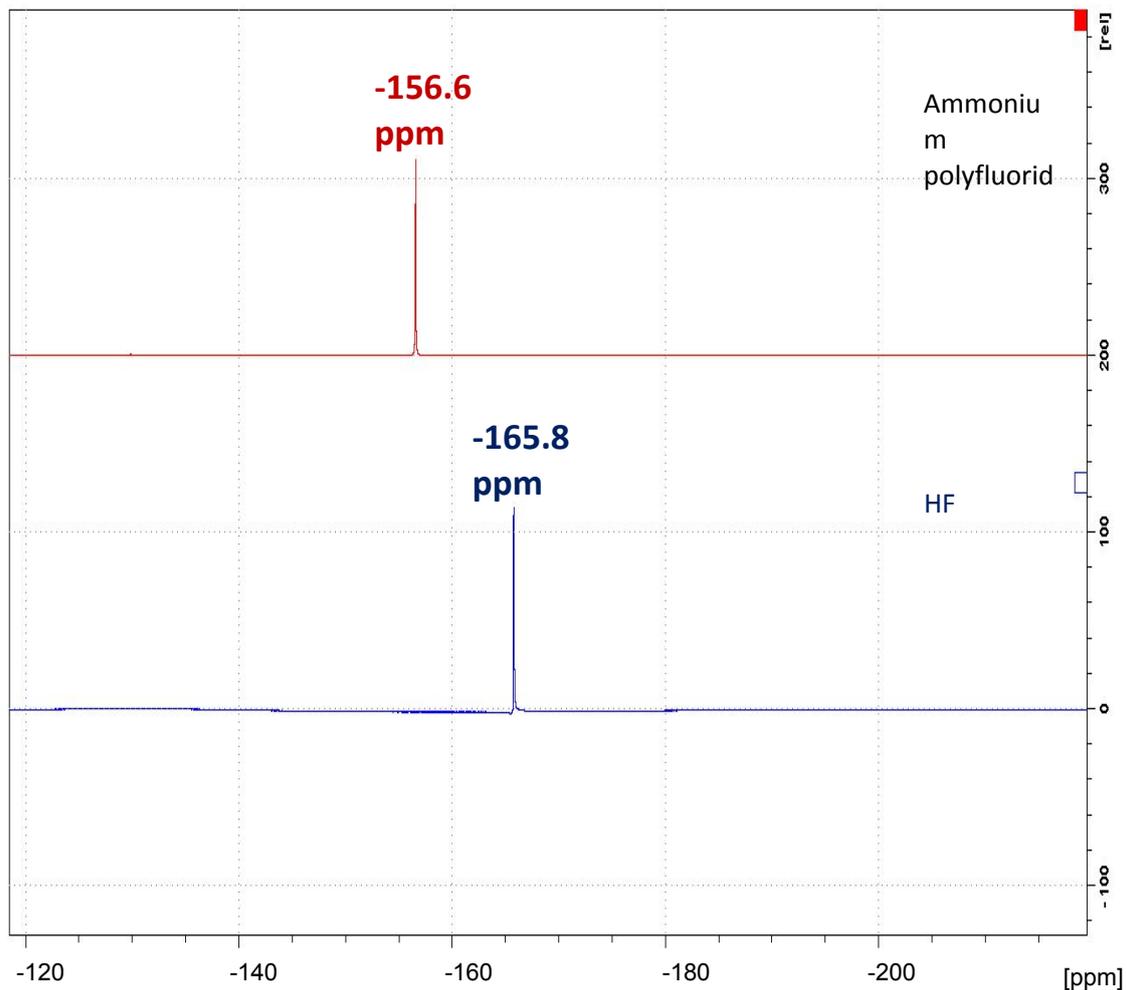


Fig. 6:  $^{19}\text{F}$ -NMR spectrum of ammonium polyfluoride and HF ( $\text{D}_2\text{O}/\text{EtOD}$ ). R&D Ivoclar Vivadent AG, Schaan, FL

After the extraoral application the remaining liquid is thoroughly rinsed off. After drying a thin silane layer in molecular scale remains at the luting surface (see fig. 3), which reacts via the methacrylate group with the luting composite during curing.

## 2. Technical Data for Monobond Etch & Prime

|                                  |                                  |
|----------------------------------|----------------------------------|
| <u>Product</u>                   | <u>Product category</u>          |
| <b>Monobond Etch &amp; Prime</b> | Primer for silica glass ceramics |

| Function | Substance/Component | Weight |
|----------|---------------------|--------|
|----------|---------------------|--------|

|                |                              |         |
|----------------|------------------------------|---------|
| <b>Etchant</b> | <b>Ammonium polyfluoride</b> | 15 - 25 |
| <b>Silane</b>  | <b>Silane methacrylate</b>   |         |
| <b>Solvent</b> | <b>Alcohol and water</b>     | 75 - 85 |
| <b>Pigment</b> | <b>Colourant</b>             | < 1     |

| Characteristics <sup>1</sup>     | Unit | Specification | Example value   |
|----------------------------------|------|---------------|-----------------|
| <b>Bond strength<sup>2</sup></b> | MPa  | ≥ 20          | 49 <sup>3</sup> |

<sup>1</sup> Physical properties,

<sup>2</sup> Tensile bond strength (24h), light-cured, with dual-curing resin-based dental luting material

<sup>3</sup> IPS e.max CAD, Multilink Automix

### 3. Materials science and physical investigations

#### 3.1 Adhesion to restorative materials

Monobond Etch & Prime is a bonding agent and as such must promote a strong and durable bond between the restorative material (ceramic) and luting composite. To confirm that this is the case, the bonding performance of Monobond Etch & Prime has been extensively tested in various material combinations and test conditions.

Bonding strength is determined using various test setups; often the shear bond strength (SBS) and tensile bond strength (TBS) are measured. In shear bond strength measurements, the load is applied parallel to the bonded surface. In tensile bond strength measurements, the load is applied perpendicular to the bonded surface.

Tensile strength measurements should demonstrate less scattering than shear bond strength measurements, as they are less dependent on the surface structure of the material. The bonding material is applied onto a prepared, flat, retention-free substrate block (e.g. restorative material) according to the instructions. Subsequently, another block of a previously defined size is adhesively bonded to the substrate block. The tensile strength is then determined using a suitable universal testing machine.

Since the results are highly dependent on the test setup and the test procedure (e.g. the diameter of the specimens), the results of different test series can only be compared with each other to a limited extent [9, 10].

The illustration below shows a typical test setup for measuring the tensile strength of restorative materials.

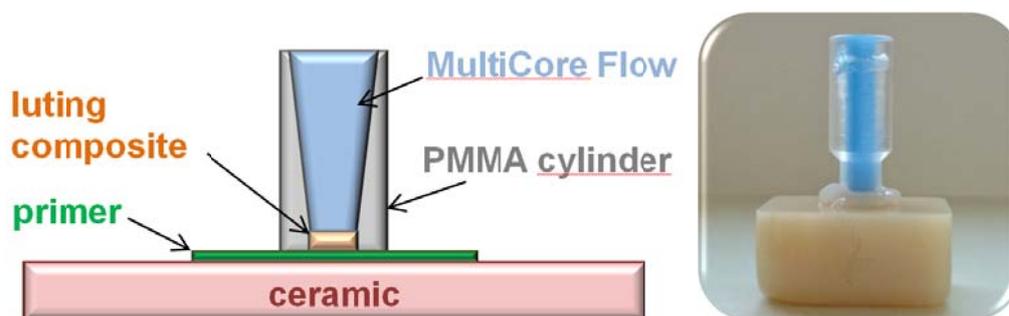


Fig. 7: Test specimen for tensile strength testing

##### 3.1.1 Tensile strength on various substrates

R&D Ivoclar Vivadent AG, Schaan, FL

The bond strength of Monobond Etch & Prime on various ceramic substrates was evaluated. Test specimens etched with hydrofluoric acid and silanized with Monobond Plus were used as reference.

To conduct the measurements, ceramic specimens were fabricated using lithium disilicate (IPS e.max CAD, IVAG), leucite (IPS Empress CAD, IVAG), lithium metasilicate (Celtra,

Dentsply) and feldspar (Mark II, Vita) and conditioned either with 5% hydrofluoric acid gel (IPS Ceramic Etching Gel) and Monobond Plus according to the manufacturer's instructions or with Monobond Etch & Prime. Subsequently, the specimens were bonded to Multicore Flow cylinders using Variolink Esthetic (see Fig. 7: Test specimen for tensile strength testing. Whilst the reaction time required for hydrofluoric acid etching varied from material to material, Monobond Etch & Prime allowed all the ceramic samples to be conditioned using the same contact time (scrubbing for 20s; leaving to react for 40s).

To determine the aging resistance of the adhesive bond, a number of specimens were artificially aged by subjecting them to thermocycling (10,000 cycles between 5 and 55°C). After thermocycling, the tensile bond strength was determined using a universal testing machine (Z010, Zwick-Roell).

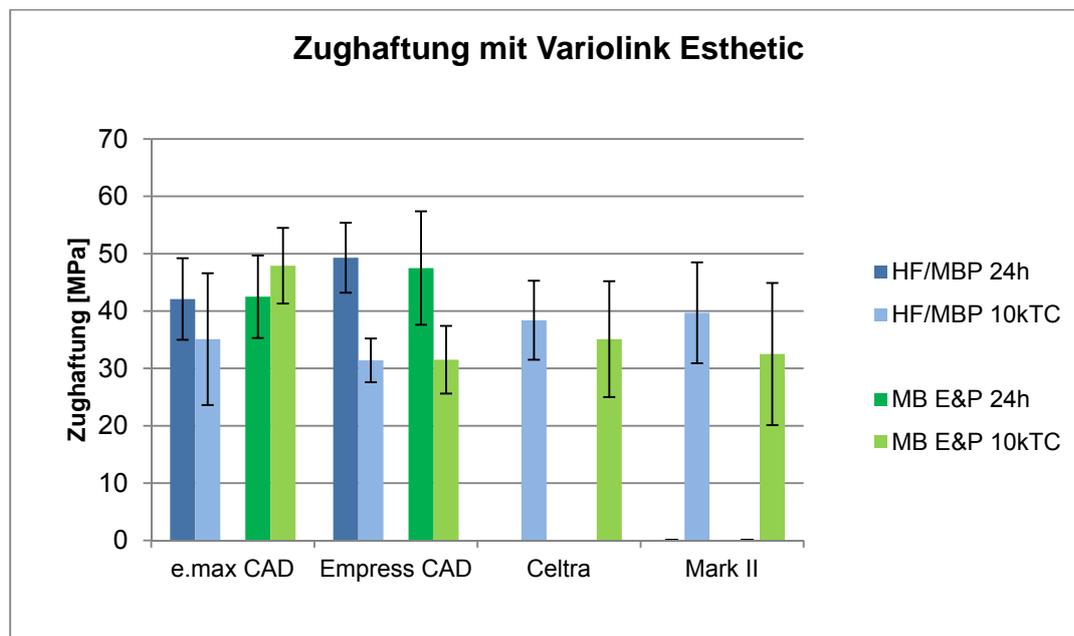


Fig. 8: Tensile bond strength on different ceramic materials: Monobond Etch & Prime (MB E&P) versus Monobond Plus (MBP) with hydrofluoric acid etching (HF), both in combination with Variolink Esthetic as the luting composite. The test specimens were examined after 24-h immersion in water or after 10,000 episodes of thermocycling between 5 and 55°C (10k TC).

Monobond Etch & Prime was also tested in combination with Multilink Automix on IPS e.max CAD and IPS Empress CAD samples. In this combination, Monobond Etch & Prime also showed tensile bond strength values comparable to the conventional combination of hydrofluoric acid etching plus Monobond Plus.

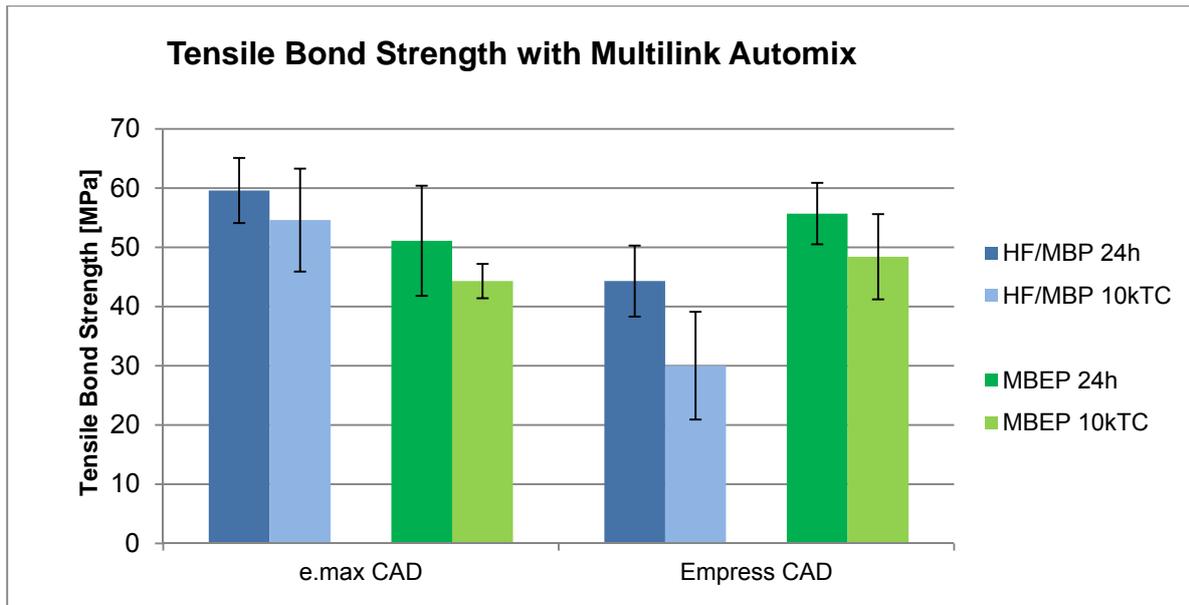


Fig. 9: Tensile bond strength on different ceramic materials: Monobond Etch & Prime (MBEP) compared with Monobond Plus (MBP) and hydrofluoric acid etching (HF), both in combination with Multilink Automix as the luting composite. The test specimens were examined after 24-h immersion in water or after 10,000 thermocycles between 5 and 55°C (10k TC).

**Conclusion:** Monobond Etch & Prime produces a similarly high aging-resistant adhesive bond on various ceramic materials as Monobond Plus after hydrofluoric acid etching.

### 3.1.2 Tensile strength of various adhesives and primers on IPS e.max CAD

R&D Ivoclar Vivadent AG, Schaan, FL

Some manufacturers claim that their universal adhesives can generate a sufficiently strong bond to both the tooth structure and restorative material and are therefore suitable for being used as a bonding agent on ceramic materials after hydrofluoric acid etching. The bonding strength of various product combinations consisting of adhesive / primer and luting composite was examined in relation to the following products:

| Manufacturer     |       | Primer / Adhesive     | Luting composite      |
|------------------|-------|-----------------------|-----------------------|
| 3M ESPE          | HF    | Scotchbond Universal  | RelyX Ultimate        |
| Kerr             | HF    | Optibond XTR          | Nexus NX-3            |
| BISCO            | HF    | Allbond Universal     | Duolink               |
| Ivoclar Vivadent | HF    | Monobond Plus         | Variolink Esthetic DC |
|                  | no HF | Monobond Etch & Prime |                       |

Table 2

The following tensile bond strength results were measured on sandblasted titanium or sandblasted & anodized titanium samples after 24 hours and after 10k TC:

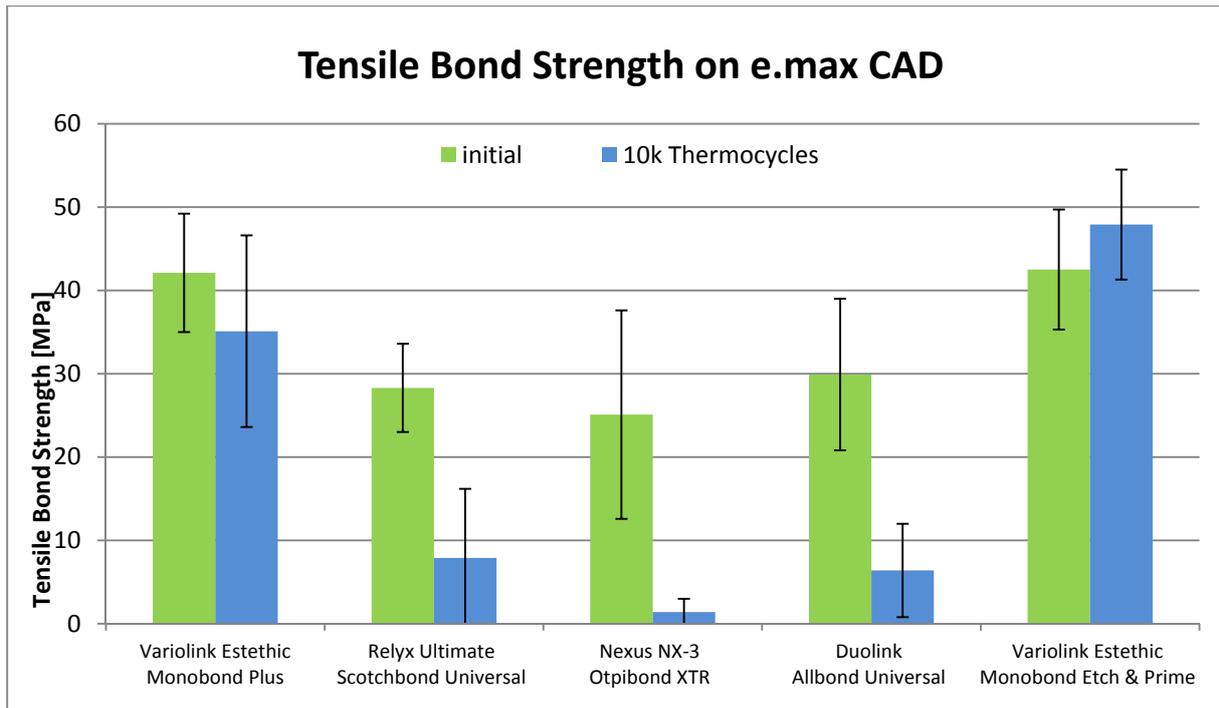


Fig. 10: Tensile bond strength of various adhesives and primers on IPS e.max CAD

\* RU/SBU, DL/ABU: 1 debonding episode each (included as a value of 0 MPa in the mean value calculation)

\*\* NX3/OBX: 2 debonding episodes each (with each episode being given 0 MPa in the mean value calculation)

**Conclusion:** The investigation has shown that Monobond Etch & Prime produces an adhesive bond that is similarly strong and reliable as the bond established with Monobond Plus after hydrofluoric acid etching. By contrast, the universal adhesives resulted in a clearly weaker adhesive bond with spontaneous bond rupturing occurring in some samples in the course of thermocycling.

### 3.1.3 Shear bond strength of various adhesives and primers on IPS e.max CAD

R&D Ivoclar Vivadent AG, Schaan, FL

Similar to the tensile bond strength investigation described in Section 3.1.2, the shear bond strength was also evaluated in a comparison with other systems. The following adhesives / primers and luting composites were tested:

| Manufacturer     |       | Primer / Adhesive     | Luting composite  |
|------------------|-------|-----------------------|-------------------|
| 3M ESPE          | HF    | Scotchbond Universal  | RelyX Ultimate    |
| Kerr             | HF    | Optibond XTR          | Nexus NX-3        |
| BISCO            | HF    | Allbond Universal     | Duolink           |
| Ivoclar Vivadent | HF    | Monobond Plus         | Multilink Automix |
|                  | no HF | Monobond Etch & Prime |                   |

Table 3

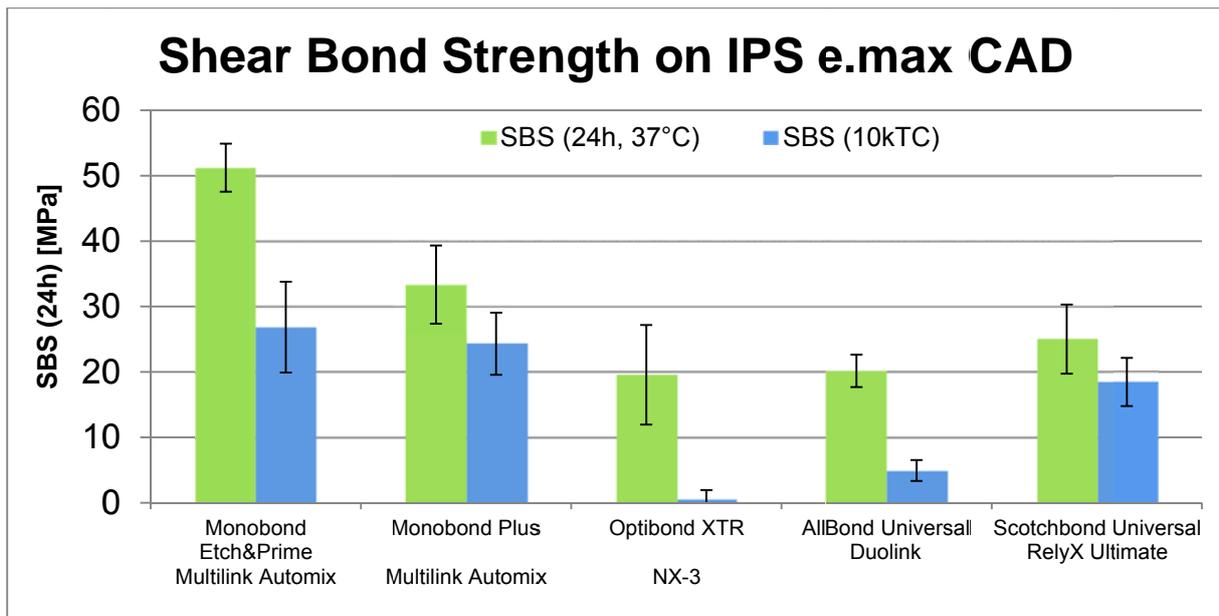


Fig. 11: Shear bond strength on IPS e.max CAD: comparison of Monobond Etch & Prime, Monobond Plus (HF) and various universal adhesives

**Conclusion:** The shear bond strength investigation showed a similar picture as the tensile strength investigation: the highest and most reliable bond strengths were achieved with Monobond Plus and Monobond Etch & Prime. The adhesive bonds of all the universal adhesives - except for Scotchbond Universal – failed to withstand stressing by thermocycling.

### 3.1.4 Shear bond strength on IPS e.max CAD

M. Irie, Okayama University, Japan

The shear bond strength of Monobond Etch & Prime on IPS e.max CAD was also examined by Prof. Irie at Okayama University. The bond strength values were determined on 3.6-mm test specimens according to ISO TR 11405: 2003 [11, 12]. Hence, the results cannot be directly compared with the shear bond strength values obtained in other investigations that use different methods.

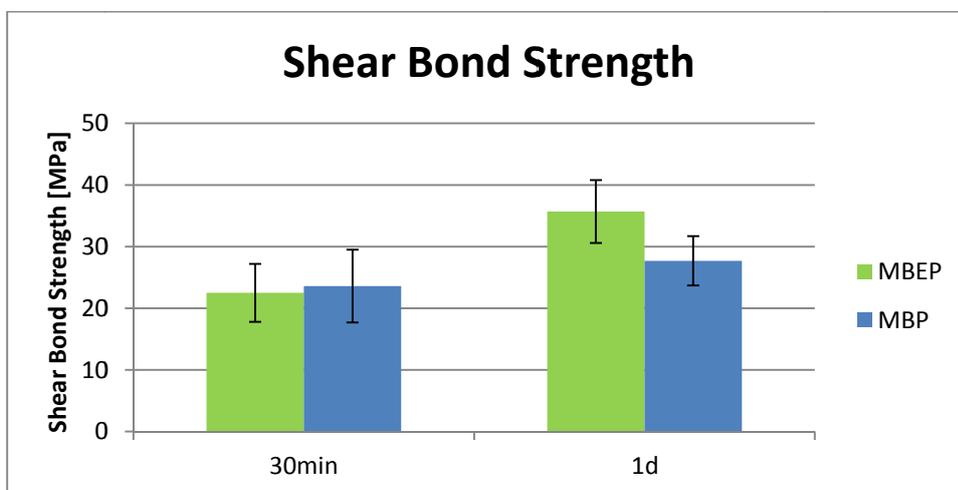


Fig. 12: Shear bond strength value of Monobond Etch & Prime (MBEP) and Monobond Plus (MBP) on IPS e.max CAD.

Also in this study Monobond Etch & Prime and Monobond Plus achieved comparatively high bond strength values on IPS e.max CAD both at the initial measurement after 30 minutes and after 24 hours.

### 3.1.5 Conclusion

Tensile and shear bond strength investigations clearly show that dedicated primers are clearly better suited for providing an aging-resistant adhesive bond to glass-ceramic materials than universal adhesives.

## 3.2 Etching effect of Monobond Etch & Prime versus hydrofluoric acid

Monobond Etch & Prime replaces the conventional two-step ceramic conditioning procedure of etching with diluted hydrofluoric acid (1) and priming with Monobond Plus (2) with a single-step procedure. In the process of ceramic etching, the microretentive surface increases. The reaction time of hydrofluoric acid has to be adapted to each ceramic to achieve a propitious surface structure. By contrast, the application of Monobond Etch & Prime requires the same reaction time for all ceramic materials: scrub for 20s and leave to react for 40s.

### 3.2.1 Scanning electron microscope investigation

R&D Ivoclar Vivadent AG, Schaan, FL

The etching effect of Monobond Etch & Prime and hydrofluoric acid was examined and compared by means of a scanning electron microscope investigation. To conduct the investigation, surface-ground flat ceramic samples made of lithium disilicate (IPS e.max CAD, IVAG), leucite (IPS Empress CAD, IVAG), lithium metasilicate (Celtra, Dentsply), feldspar (Mark II, Vita) were conditioned with IPS Ceramic Etching Gel or Monobond Etch & Prime according to the instructions for use and then rinsed with water. In addition, the samples were rinsed with alcohol and cleaned in an ultrasonic cleaner. Subsequently, the surfaces were analysed in a scanning electron microscope (SEM).

Table 4 lists the ceramic materials and application processes used:

| Ceramic         | IPS Ceramic Etching Gel  | Monobond Etch & Prime   |
|-----------------|--------------------------|---|
| IPS e.max CAD   | 20 s<br>rinse with water | scrub for 20s<br>leave to react for 40s<br>rinse with water<br>blow dry |
| IPS Empress CAD | 60s<br>rinse with water  |   |
| Celtra          | 30s<br>rinse with water  |   |
| Mark II         | 60s<br>rinse with water  |   |

Table 4

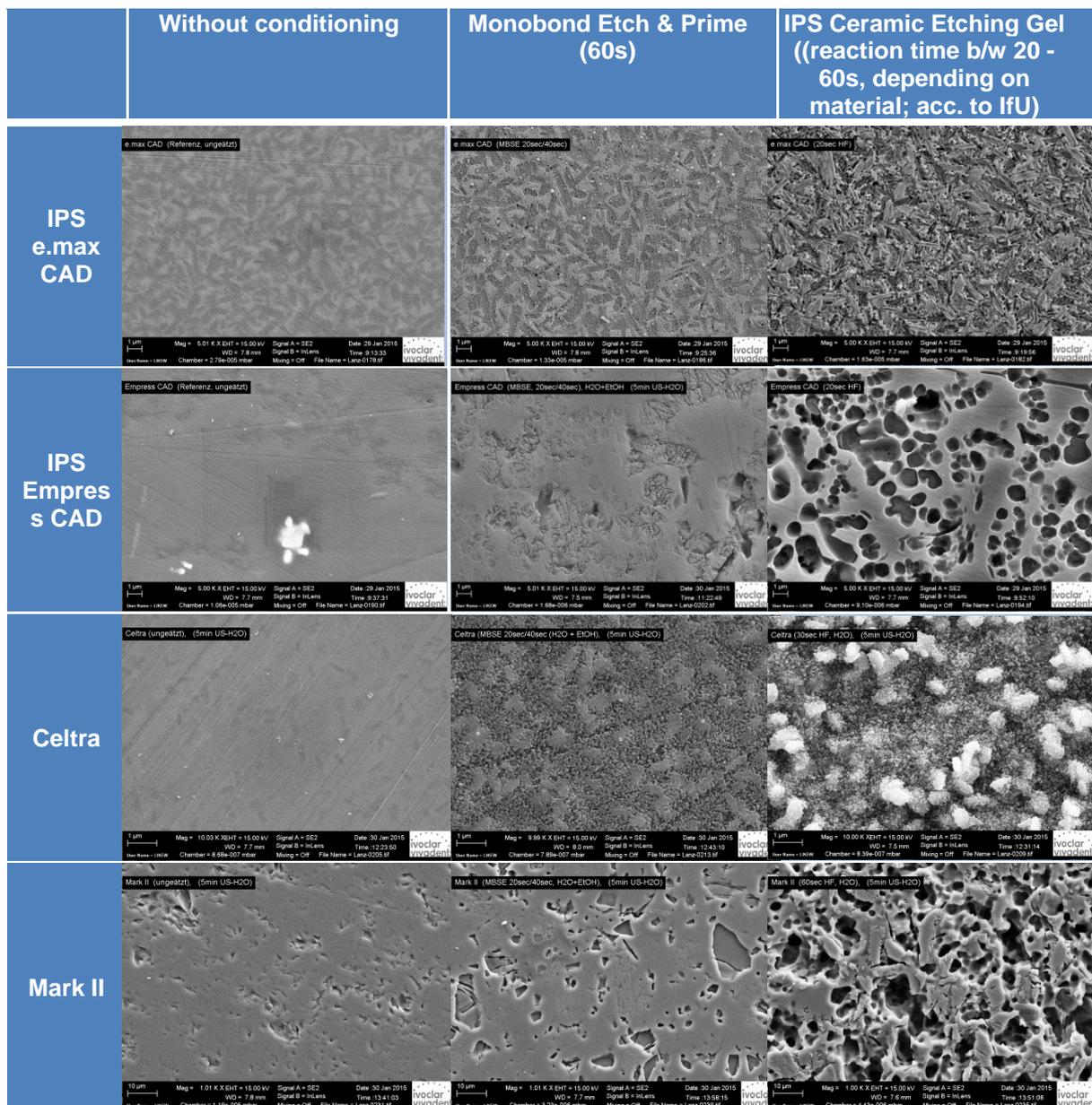


Fig. 13: SEM images of glass-ceramic samples after conditioning with hydrofluoric acid or Monobond Etch & Prime

Monobond Etch & Prime produced a clear etching pattern on all the ceramic materials investigated; the etching effect, however, was less pronounced than the etching effect of hydrofluoric acid. Although the etching effect of Monobond Etch & Prime is weaker than that of hydrofluoric acid, it is still strong enough to produce sufficient microretention for a reliable adhesive bond, as confirmed by the bond strength measurements (see Section 3.1)

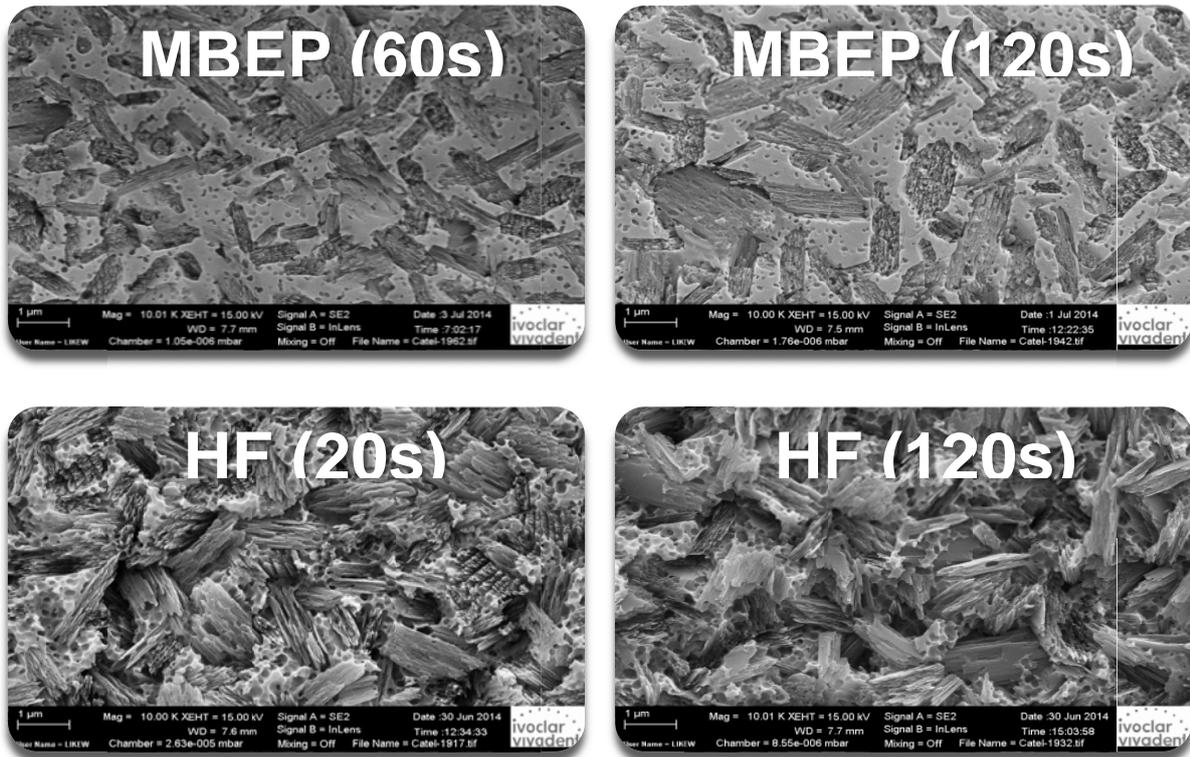


Fig. 14: SEM images of IPS e.max CAD surfaces after varying lengths of contact time with 5% hydrofluoric acid (HF) and Monobond Etch & Prime (MBEP)

The scanning electron microscope investigation clearly shows that ceramic surfaces do not become over-etched even after having been in contact with Monobond Etch & Prime for a prolonged length of time (120s). After a contact time of 120s, 5% hydrofluoric acid results in a substantially stronger etching effect on the ceramic than it does after the recommended reaction time (20s).

### 3.2.2 Mechanical properties (flexural strength)

R&D Ivoclar Vivadent AG, Schaan, FL

Etching may weaken the flexural strength of ceramic materials. For this reason, the effects of Monobond Etch & Prime and hydrofluoric acid etching on the flexural strength of IPS e.max CAD samples were examined.

The ceramic samples were either etched with Ceramic Etching Gel for 20s or conditioned with Monobond Etch & Prime for 60s. Untreated ceramic was used as reference.

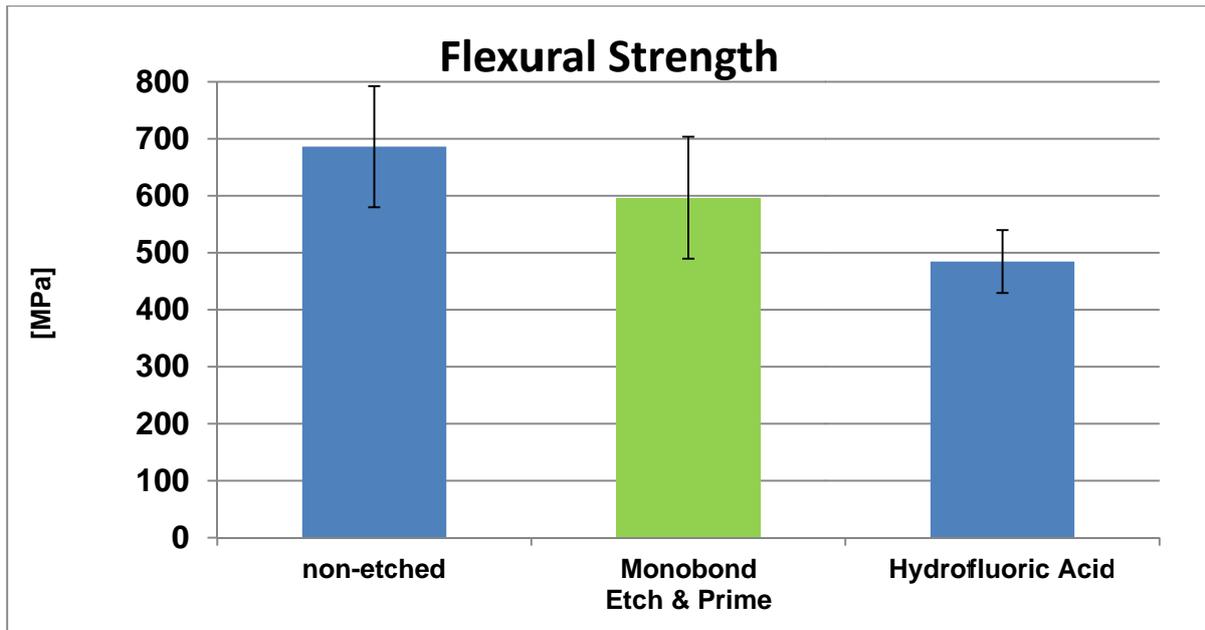


Fig. 15: Flexural strength of untreated IPS e.max CAD and after conditioning with Monobond Etch & Prime, hydrofluoric acid or hydrofluoric acid and Monobond Etch & Prime

The flexural strength of the IPS e.max CAD samples was only minimally affected by the application of Monobond Etch & Prime and does not differ significantly from the reference samples. The practical effect of weakening the ceramic strength by etching is minor; it has been reported that flexural strength reduced by etching was reconstituted when composite was applied [13].

### 3.3 Tolerance to contamination

R&D Ivoclar Vivadent AG, Schaan, FL

Ceramic restorations often become contaminated with saliva during intraoral try-ins and these contaminations are not always completely removed afterwards. In addition, the ceramic surfaces may become contaminated with silicone material during the fit-check. Remaining silicone residue is difficult to remove and may impair the adhesive bond. It is therefore important that Monobond Etch & Prime establishes a reliable adhesive bond even if contamination with saliva or with a silicone-containing material is present.

To examine the tolerance to saliva contamination, IPS e.max CAD test specimens were contaminated with freshly collected human saliva and rinsed with water before Monobond Etch & Prime as applied.

To examine the tolerance to silicone residue, the ceramic samples were brought into contact with Virtual Extra Light Body impression material for 7.5 minutes and then the impression material was removed. No other measures were taken to clean the samples before the application of Monobond Etch & Prime.

Subsequently, the samples were conditioned with Monobond Etch & Prime and bonded with Variolink Esthetic DC.

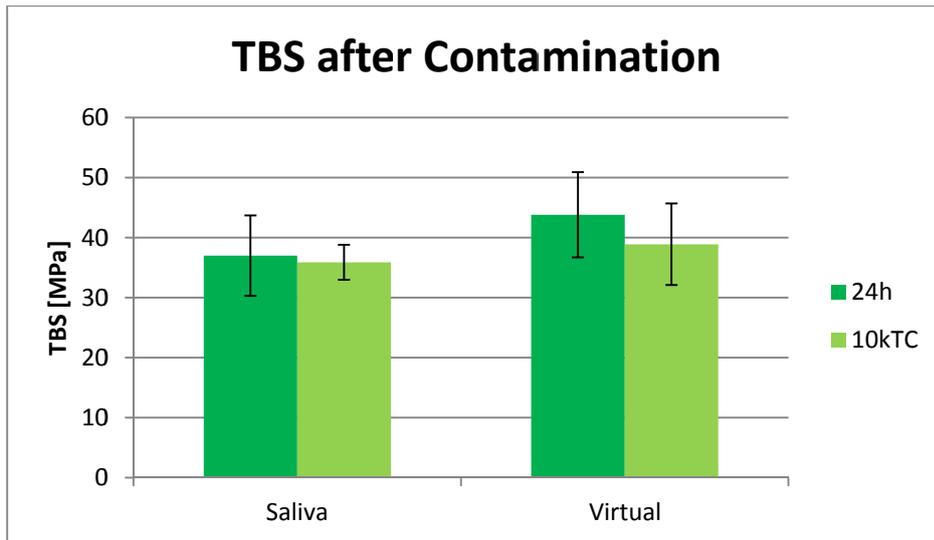


Fig. 16: Tensile bond strength of Monobond Etch & Prime / Variolink Esthetic on IPS e.max CAD samples after contamination with saliva and Virtual Extra Light Body respectively

The results show that Monobond Etch & Prime produces an adhesive bond that is tolerant of the contamination that is likely to occur during clinical procedures in the dental practice.

### 3.4 User tolerance

R&D Ivoclar Vivadent AG, Schaan, FL

To enable a streamlined working procedure during the placement of multiple-unit restorations, exceeding the reaction time of Monobond Etch & Prime should not have an adverse effect on the adhesive bond. Likewise, it should be possible to condition restorations some time in advance before they are inserted. For this reason, the tensile bond strength of ceramic samples conditioned with Monobond Etch & Prime was determined after an extended application time (2 minutes) and after 2 weeks of storage.

| Substrate | Protocol                            | Tensile bond strength value [MPa] |
|-----------|-------------------------------------|-----------------------------------|
| e.max     | 2-minute application time           | 43.0 ± 5.9                        |
|           | 2-week storage of conditioned specs | 46.0 ± 6.3                        |

Table 5: Tensile bond strength values as an indicator of the user tolerance of Monobond Etch & Prime, applied in conjunction with Variolink Esthetic DC

As can be seen in Table 5, reliable tensile bond strength values exceeding the required acceptance criteria of 20 MPa were achieved. Monobond Etch & Prime is therefore considered to be sufficiently tolerant of surfaces conditioned in advance and stored for two weeks and contact times doubled in length.

## **4. Biocompatibility**

### **4.1 Introduction**

Medical devices are subject to very strict requirements, which are designed to protect patients and operators from any potential biological risks. ISO 10993 “Biological evaluation of medical devices” defines how the biological safety of a medical device is to be evaluated. Furthermore, dental medical devices are subject to ISO 7405 “Preclinical evaluation of biocompatibility of medical devices used in dentistry”. The biocompatibility of Monobond Etch & Prime has been examined according to these standards.

### **4.2 Cytotoxicity**

Cytotoxicity refers to the destructive action of a substance or mixture of substances on cells. The XTT assay is used to examine whether or not a substance causes cell death or inhibits cell proliferation in a cell culture. The XTT<sub>50</sub> value refers to the concentration of a substance which reduces the cell number by half. The lower the XTT<sub>50</sub> concentration of a substance, the more cytotoxic it is.

The cytotoxicity of Monobond Etch & Prime was tested in vitro according to ISO 10993-5 (1). Monobond Etch & Prime is water soluble and only showed a cytotoxic effect on the L929 cell line examined when applied in very high concentrations. The calculated XTT<sub>50</sub> value was 1979.1 µg/ml. Given that Monobond Etch & Prime is applied only in small amounts at a time and the application procedure is performed extraorally, the cytotoxic risk of Monobond Etch & Prime is very low for the patient and user.

### **4.3 Genotoxicity**

Genotoxicity refers to the capability of a substance or a mixture of substances to damage genetic material.

Monobond Etch & Prime has been examined regarding its potential gene damaging effect in a number of mutagenicity tests. Neither the Ames assay nor the mouse lymphoma assay (MLA) showed any gene damaging effect for Monobond Etch & Prime (2, 3): On the basis of these results, it can be assumed that Monobond Etch & Prime does not have any mutagenic potential.

### **4.4 Skin irritation and skin damage**

The irritation potential of Monobond Etch & Prime was measured using an EpiDerm skin model (4). To conduct the test, undiluted Monobond Etch & Prime was directly applied to the EpiDerm model for 60 minutes before the irritation effect was assessed. The test showed an irritation potential for Monobond Etch & Prime.

The corrosive effect of Monobond Etch & Prime was examined in another epidermal skin model (5). After a 3-minute application time, the corrosive effect of Monobond Etch & Prime was low; after 60 minutes the corrosive effect had increased.

Monobond Etch & Prime is designed to have an etching effect on ceramic surfaces. It may therefore be expected that it has also an irritating and corrosive effect on the skin. The results showed that a short contact time does not damage the skin.

Once the etching procedure has been completed, Monobond Etch & Prime is rinsed from the restoration. Therefore, patients are not at risk of being affected by the etching effect. Users are made aware of the material's etching effect in the Instructions for Use and notes on the packaging. Furthermore, the etching effect of Monobond Etch & Prime is far less severe than the etching effect of hydrofluoric acid, which is widely used in ceramic etching procedures. Given the widespread dental use of hydrofluoric acid, it is assumed that users have practice in handling corrosive substances.

#### **4.5 Sensitization**

Monobond Etch & Prime contains methacrylate derivatives. Such materials may have an irritating effect and cause sensitization, which can lead to allergic contact dermatitis. Allergic reactions are extremely rare in patients but are increasingly observed in dental personnel, who handle uncured composite material on a daily basis. These reactions can be minimized by clean working conditions and avoiding contact of the unpolymerized material with the skin. Commonly employed gloves, made of latex or vinyl, do not provide effective protection against sensitization to such compounds.

#### **4.6 Conclusions:**

- Monobond Etch & Prime is slightly cytotoxic.
- It is in the nature of Monobond Etch & Prime to have an etching effect because it is designed to etch glass-ceramic materials. The etching compounds are rinsed off after completion of the extraoral application procedure and therefore do not come into contact with the patient.
- Monobond Etch & Prime contains methacrylates, which may cause sensitization; allergic reactions, however, are extremely rare in patients.
- On the basis of the information known to date, Monobond Etch & Prime can be considered non-genotoxic.

The results have shown that Monobond Etch & Prime is safe for use in humans if it is used according to the Instructions for Use. It can be concluded that the benefits provided by the product exceed any potential risk.

#### **4.7 Toxicological data**

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Ivoclar Vivadent AG  
Research & Development  
Scientific Services  
Bendererstrasse 2  
FL - 9494 Schaan  
Liechtenstein

Contents: Dr. Thomas Völkel and Dr. Erik Braziulis  
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