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Glass ceramics are extremely popular as dental materials due to their biological inertness, mechanical strength, esthetic appearance and well-established processing methods. The highly effective adhesive luting technique, comprising hydrofluoric acid followed by a methacrylate-silane primer, contributed to this popularity. Glass ceramic restorations cemented in this way are well-supported by the underlying tooth structure and the range of design possibilities is greatly extended. The adhesive cementation of glass ceramic restorations represents the accepted „state of the art” in indirect restorative therapy.

So, how does one optimize the seemingly optimal? This question arises in almost all research-driven industries. Often, only incremental improvements are possible, because the underlying technology is already at a highly advanced stage. Bond-promoting materials such as glass ceramic primers are particularly challenging, as they contribute decisively to the success of often expensive dental treatment, yet already possess a high degree of technical maturity.

By combining a polyfluoride with a novel silane mixture, the development team at Ivoclar Vivadent AG succeeded in creating the first self-etching glass ceramic primer – Monobond Etch & Prime. Monobond Etch & Prime is designed to meet the needs of modern dentistry i.e. clinical effectiveness, safety of use, efficiency and simple handling.

Its patented technology allows the simultaneous etching and conditioning of chemically resistant glass-ceramics. As conditioning with Monobond Etch & Prime also removes saliva-contamination from the adhesive surface, the procedure also increases treatment-safety. The HF-free formulation leads to good biocompatibility and eliminates toxic hydrofluoric acid from the dental materials kit. Due to its simple, efficient, safe handling, and clinically effective bonding properties, Monobond Etch & Prime has been very well received since its market launch in 2015.

This Scientific Report compiles a selection of in vitro studies with Monobond Etch & Prime. We are extremely pleased to see the excellent results of our developmental tests confirmed by independent working groups worldwide. The success of Monobond Etch & Prime has strengthened our mission to continue to strive for innovative products for our clients – making high-quality dentistry even more efficient, reliable and safe.

Lasting customer satisfaction is our highest priority and we look forward to receiving your feedback and suggestions.

Yours faithfully

Dr Thorsten Bock
Director R&D Organic Chemistry
Introduction

Etch and prime in one easy step

Proper conditioning of the restoration bonding surface is a crucial part of the adhesive luting process. Conventionally, glass-ceramic restorations have been conditioned via etching the contact surfaces with hydrofluoric acid, followed by a silane coupling agent. Hydrofluoric acid creates a micro-retentive etch pattern on the ceramic surface by partially dissolving the glassy phase, it does however carry a strong toxic potential which prohibits intra-oral use. Silanization results in a strong chemical bond between the silicon dioxide surface of glass ceramics and the resin matrix of the luting composite during polymerization (Singhal et al. 2015).

Monobond Etch & Prime is the first single-component ceramic primer in the world. It etches and silanates glass-ceramic surfaces in one easy step, whilst simultaneously cleaning away remaining saliva from ceramic surfaces.

Monobond Etch & Prime can be used with all methacrylate-based luting composites and all silicate-based glass ceramic materials. Etching with hydrofluoric acid is unnecessary. Ammonium polyfluoride is responsible for the etching step and trimethoxysilylpropyl methacrylate for silanization. Although the etching pattern created by Monobond Etch & Prime, is somewhat less pronounced than with hydrofluoric acid – it is similarly efficient in creating a strong and durable bond.

Numerous studies have now evaluated the performance of Monobond Etch & Prime with various materials and as compared to the traditional procedure of hydrofluoric acid plus silane or hydrofluoric acid plus universal adhesive. It is clear that Monobond Etch & Prime is a time-saving, efficacious alternative that produces similar adhesive bond strengths. This Scientific Report summarizes the most pertinent data from these investigations.
Studies
Evaluation of a new self-etching glass ceramic primer

Study location: Prosthodontics department, University of Strasbourg, Strasbourg, France
Study release: 2017
Study author(s): C. Lemoy, L Jacomine, D. Favier, C. Gauthier, O. Etienne

Method:
The study compared the macro shear bond strength (SBS) of a new 1-step versus 2-step etching and silanization method, for bonding dental glass ceramics to dentin. Forty lithium disilicate cylinders (Ø 5 mm) were milled from IPS e.max CAD and divided into two groups. The HF group (n=20) involved hydrofluoric acid etching and silanization with Monobond Plus. The EP group (n=20) involved one-step ceramic conditioning with the self-etching primer Monobond Etch & Prime. Cylinders were bonded to the dentin of freshly extracted, polished wisdom teeth. The universal light-cured adhesive Adhese Universal was used in etch and rinse (E&R) mode along with the dual-cured resin cement Variolink Esthetic. The 20 teeth of each HF and EP group were then randomly divided into 2 sub-groups (n=10) whereby samples were stored in water at 20°C for 7 days or 150 days. All specimens were loaded (0.5mm/min) to failure (Instron-Electropuls E3000) to establish shear bond strength.

Results:

Summary:
There were no significant differences between the EP and HF groups after 7 days or 150 days' of water storage. However, after 150 days, the SBS for each conditioning method (HF or EP) was significantly lower for the HF group and non-significantly lower for the EP group.

Conclusion:
Monobond Etch & Prime showed promising in vitro results. Roughness was decreased in comparison to HF treatment, but mean SBS values were higher than those of the HF group, after both 7 and 150 days’ aging.

Reference: Lemoy et al. (2017)
Influence of silane coupling agents in adhesion to ceramic

Study location: Instituto Superior de Ciências da Saúde Egas Moniz, Lisbon, Portugal
Study release: 2017
Study author(s): J. Germano Alves

Method:
This study evaluated the immediate microtensile bond strength of different ceramic materials to a resin composite, using different silane coupling agents. Four blocks of IPS e.max CAD and four blocks of Lava Ultimate*/3M ESPE were prepared with the following silane coupling agents: Bis-silane/Bisco (BS), Rely Ceramic Primer/3M ESPE (RX), Monobond Plus (MP) and Monobond Etch & Prime (MEP), followed by the adhesive Optibond FL/Kerr. Each block was then bonded to a resin composite Filtek Z100/3M ESPE block of identical dimensions - luted with the same pre-heated resin. The samples were stored in distilled water at 37°C for 24 hours. After this time period, the samples were trimmed into beams and subjected to microtensile testing, at a crosshead speed of 1mm/min.

Results:

Summary:
Monobond Etch & Prime showed significantly higher bond strength values to IPS e.max CAD (40.92 ± 3.27). Monobond Plus showed significantly higher bond strength values to Lava Ultimate (39.17 ± 3.93).

Conclusion:
Microtensile bond strength is significantly influenced by the silane coupling agent used and the type of substrate. Monobond Etch & Prime exhibited the highest microtensile bond strength with IPS e.max CAD.

Reference: Germano Alves (2017)

*Monobond Etch & Prime is indicated for use with silica-based ceramic materials only, not with resin based (composite) materials such as Lava Ultimate.
Durability of resin bonding to lithium disilicate and zirconia ceramic using a self-etching primer

Study location: School of Dentistry, Christian Albrechts University, Kiel, Germany
Study release: 2017
Study author(s): S. Wille, F. Lehmann, M. Kern

Method:
To evaluate the surface conditioning effect and bond durability of Monobond Etch & Prime on both lithium disilicate and zirconia*, specimens of IPS e.max CAD and Zenostar/Wieland Dental were prepared according to the groups below.

<table>
<thead>
<tr>
<th>Group 1</th>
<th>Group 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lithium disilicate (n=16)</td>
<td>Lithium disilicate (n=16)</td>
</tr>
<tr>
<td>Hydrofluoric Acid (HF)</td>
<td>Sandblasting</td>
</tr>
<tr>
<td>Monobond Plus</td>
<td>Monobond Plus</td>
</tr>
<tr>
<td>Water 37°C / 3 days</td>
<td>Water 37°C / 30 days + TC</td>
</tr>
<tr>
<td>(n=8)</td>
<td>(n=8)</td>
</tr>
</tbody>
</table>

Surface conditioning was evaluated with scanning electron microscope. The specimens in both groups were bonded to a composite (Multicore Flow in plexiglass tubes) with a luting resin (Multilink Automix) and divided into 2 subgroups: Storage in water (37°C) for 3 days or 30 days plus thermocycling (7500x at 5°C/55°C). Tensile bond strength tests were carried out in a universal testing machine.

Results:
The etching pattern shown in micrographs of the hydrofluoric acid-treated lithium disilicate was deeper and more pronounced than the Monobond Etch & Prime treated material. Monobond Etch & Prime had little effect on zirconia.*

Summary:
Monobond Etch & Prime only had a significant effect on the surface topography of the lithium disilicate but not zirconia*. After 30 days' water storage and thermocycling, bond strength decreased significantly in all groups.

Conclusion:
Monobond Etch & Prime provided bond strengths to lithium disilicate comparable to those achieved with traditional etching and priming with hydrofluoric acid and silane.

Reference: Wille et al. (2017)

*Monobond Etch & Prime is not indicated for use with zirconia/oxide ceramics
Effect of storage on shear bond strength of self-etch ceramic primer

Study location: Cornell University, Ithaca, NY, USA* / Ivoclar Vivadent, Amherst, NY, USA
Study release: 2016
Study author(s): A. Heleba*, T. Hill, S. Singhal, P McCabe, G. Tysowsky

Method:
Monobond Etch & Prime is a single component ceramic primer combining both the etching and silanization step in one product. In order to establish whether this combination creates long-term stability issues, the storage stability was evaluated as a function of shear bond strength. 50 specimens of lithium disilicate (IPS e.max CAD) were sectioned, crystallized, mounted and then polished with 400-grit SiC paper. Specimens (n=10) were randomly split into five experimental groups. Monobond Etch & Prime was applied to the specimens after having been stored at 50°C for 0, 2, 14, 28 or 56 days. Pre-cured composite rods made of Tetric EvoCeram Bulk Fill (Ø 2.38mm) were sand-blasted with silica particles, steam-cleaned and Adhese Universal was applied. For cementation, Variolink Esthetic DC was then applied to the rods under a constant load and light-cured for 20s each side. Specimens were stored for 24 h (37°C/100% humidity) and shear bond strength was measured using an Instron Universal Testing Machine with a crosshead speed of 1.0mm/min. Fracture surfaces were examined using a light microscope (30x).

Results:

Mean shear bond strengths as a function of (Monobond Etch & Prime) storage time

Summary:
All the mean shear bond strengths were greater than 30 MPa and no statistically significant differences were observed for any time interval. Fracture surfaces were all adhesive failures. No cohesive failures were observed.

Conclusion:
The shear bond strengths achieved using Monobond Etch & Prime remained relatively constant (statistically similar) over the duration of the study. The storage stability of Monobond Etch & Prime could be confirmed.

Reference: Heleba et al. (2016)
Effect of surface treatment of lithium disilicate on shear-bond strength of resin cements

Study location: Ivoclar Vivadent, Amherst, NY, USA* / SUNY at Buffalo, Buffalo, NY, USA
Study release: 2016
Study author(s): S. Singhal*, S. A. Antonson, D. E. Antonson

Method:
In order to measure the effect of different surface treatments (on lithium disilicate) on shear bond strengths with resin cements, various etching/silanization protocols were used. IPS e.max CAD blocks were sectioned, crystallized and mounted. The specimens were randomly distributed to six experimental groups (n = 12) as a function of surface treatment. The exposed surface of each specimen was finished with 400-grit SiC paper except for Group 1 that was polished with 1200-grit SiC paper. Specimens were secured in an Ultradent jig and prepared according to the table below. The resin cements were then applied and light cured. Specimens were stored in an incubator at 37°C/100% humidity for 24h. Shear bond strengths were measured in an Instron Universal Testing Machine with a crosshead speed of 1.0 mm/min.

<table>
<thead>
<tr>
<th>Groups</th>
<th>Surface finish</th>
<th>Surface treatment</th>
<th>Resin cement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>No treatment: Polished</td>
<td></td>
<td>Monobond Plus Multilink Automix (Transparent)</td>
</tr>
<tr>
<td>2</td>
<td>Sandblasted Al₂O₃: (50 µm)/2 bar/Distance-10 mm</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Acid etched 4.5%: HF 4.5%/20 s</td>
<td>Monobond Etch &amp; Prime</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Acid etched 9.5%: HF 9.5% (Non-buffered)/20 s</td>
<td></td>
<td>Scotchbond Universal/ 3M ESPE RelyX Ultimate (Translucent)/ 3M ESPE</td>
</tr>
<tr>
<td>5</td>
<td>Self-Etch Primer: Monobond Etch &amp; Prime</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Acid etched 4.5%: HF 4.5%/20 s</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Results:

Summary:
Within the limitations of the study, the self-etching glass ceramic primer Monobond Etch & Prime exhibited significantly higher bond strengths (Group 5), than the other experimental groups tested. The sandblasted lithium disilicate (Group 2) indicated the lowest bond strengths, similar to no treatment (Group 1).

Conclusion:
Monobond Etch & Prime exhibited significantly higher bond strengths than a sandblasting protocol or various standard hydrofluoric acid plus silanization protocols.

Reference: Singhal et al. (2015)
Effect of self-etching ceramic primer and universal adhesive on bond strength of lithium disilicate ceramic

Study location: College of Dentistry, King Saud University, Riyadh, Saudi Arabia
Study release: 2017
Study author(s): A. Alrahlah, M. M. Awad, F. Vohra, A. Al-Mudahi, Z. A. Al Jeaidi, M. Elsharawy

Method:
In order to evaluate the effect of different surface treatments on resin cement/glass ceramic bond strength, 30 lithium disilicate (IPS e.max Press) specimens (3 mm × 3 mm × 8 mm) were fabricated. Specimens were randomly assigned to three (n = 10) experimental groups according to surface treatment: Group 1: hydrofluoric acid (HF) + silane + universal adhesive, Group 2: HF + universal adhesive, Group 3: Monobond Etch & Prime + universal adhesive. The universal adhesive applied was the silane-containing Scotchbond Universal/3M ESPE. The luting composite was Variolink Esthetic (DC) – which was applied and light-cured. All specimens were stored in distilled water for 24h at 37°C and shear bond strengths were tested at a crosshead speed of 0.5 mm/min (Universal Testing machine-Instron). Failure modes were evaluated using a Hirox digital microscope.

Results:

Summary:
The shear bond strengths exhibited by groups 1 and 3 were comparable and significantly higher than that of group 2. Adhesive, mixed and cohesive failure modes were observed and mixed failure was the most common in all groups.

Conclusion:
Monobond Etch & Prime plus a universal adhesive can be recommended for lithium disilicate, as an alternative to the use of hydrofluoric acid plus silane.

Reference: Alrahlah et al. (2017)
Shear bond strengths with Monobond Etch & Prime compared to Monobond Plus

Method:
The shear bond strengths (SBS) of a 2mm long stainless steel rod (Ø 3.5mm) luted to IPS e.max Press with either the one step Monobond Etch & Prime or the two step hydrofluoric acid (HF) plus Monobond Plus protocol, were compared. The composite luting material Variolink Esthetic DC was used in both groups. The SBS values were evaluated using a universal testing machine: immediately, after 30 minutes and after 24 hours’ water storage.

Results:

Summary:
The shear bond strength values rose over time in both groups. After 24 hours the SBS with Monobond Etch & Prime exceeded that of the conventional hydrofluoric acid plus silane method.

Conclusion:
The Monobond Etch & Prime sample group exhibited a higher SBS value after 24 hours than the Monobond Plus group.

Reference: Irie (2017)
Self-etching glass ceramic primer: Shear bond strength with Monobond Etch & Prime

Study location: Midwestern University, Glendale, Arizona, USA
Study release: 2017
Study author(s): J. C. Mitchell, S. Brownstein, A. Tang, S. Assar, L. Do, M. Pulido

Method:
To compare conventional etching/silanization methods with the self-etching product Monobond Etch & Prime, 30 IPS e.max CAD sections were cut, fired, embedded in acrylic and wet-polished with 600-grit SiC paper. Blocks were randomly assigned to three groups. Groups 1 and 2 were etched with 4.7% hydrofluoric acid (HF) for 20 seconds, followed by rinsing with water and air-drying. Group 3 was not etched. Group 1 received the silane coupling agent Monobond Plus (60s reaction time, excess dispersed with air to ensure solvent removal). Groups 2 and 3 received the single component Monobond Etch & Prime, which was applied and scrubbed into the surface for 20 seconds, allowed to react for 40 seconds, rinsed then air-dried. An Ultradent jig (South Jordan, UT) was used to place two Multilink Automix 2 mm-high posts onto each of the samples of all three groups (n = 20 per group). Posts were light-cured for 20 seconds and stored for 24 hours at 37°C (100% humidity). Shear bond strength was measured with an Electropuls E-3000 (Instron, Norwood, MA) using a crosshead speed of 0.5mm/min.

Results:

Summary:
Samples prepared using Monobond Etch & Prime exhibited significantly stronger shear bond strengths compared to traditional hydrofluoric etching plus silanization treatment.

Conclusion:
The simplified one-step Monobond Etch & Prime treatment may be a superior method for preparing ceramic surfaces prior to bonding.

Reference: Mitchell et al. (2017)
Self-etching ceramic primer versus hydrofluoric acid etching. Etching efficacy and bonding performance

Study location: College of Dental Medicine, University of Sharjah, United Arab Emirates
Study release: 2017
Study author(s): H. M. El-Damanhoury, M. D. Gaintantopoulou

Method:
Differences in the shear bond strengths and surface topography of hybrid and glass ceramics were compared, after various etching pre-treatments. 40 rectangular discs of each of the 3 ceramic materials: IPS e.max CAD, Vita Mark II/VITA and Vita Enamic/VITA were prepared (n = 120). The 40 discs per material were divided equally into one of four surface-pre-treatment methods (n = 10): No treatment (NT) as a negative control, etching with 4.8% hydrofluoric acid followed by Monobond Plus (HFMP), Monobond Etch & Prime (MEP), and Monobond Plus with no etching (MP) as a positive control. The shear bond strength of the resin cement Multilink N to the variously treated ceramic surfaces was tested following a standard protocol involving 24-hour water storage and thermocycling. A stereo microscope was used to determine the mode of failure: adhesive – between the resin cement and the ceramic, cohesive (cement) – within the resin cement itself, cohesive (ceramic) – within the ceramic itself or mixed.

Results:

Summary:
Pre-treatment with HFMP resulted in higher shear bond strength values and increased surface roughness in comparison to MEP and MP. Regardless of the type of surface pre-treatment, the mean shear bond strength value for IPS e.max CAD was significantly higher than that recorded for Vita Mark II or Vita Enamic – except when Vita Enamic was treated with Monobond Etch & Prime, where the difference was statistically insignificant. The failure mode was strongly influenced by the type of surface treatment and type of material. For all tested ceramics, the highest percentage of adhesive failure was associated with the no treatment group, followed by treatment with Monobond Plus only, which can be explained by the absence of porosities caused by etching. Adhesive failure however was never higher than 20% for the HFMP and MEP groups. For IPS e.max CAD most failure (70%) was mixed when HFMP or MEP were used, as opposed to cohesive (ceramic) for the VITA products. This may be attributable to the difference in microstructure and strength of lithium disilicate.

Conclusion:
The authors describe the shear bond strength results obtained with Monobond Etch & Prime as "comparable" with hydrofluoric acid followed by Monobond Plus. Hydrofluoric acid followed by silane treatment remains the gold standard.

Reference: El-Damanhoury et al. (2017)
Stability of silane to lithium disilicate in extreme environmental conditions

Study location: University of Alabama, Birmingham, Alabama, USA
Study release: 2016
Study author(s): B. Chang, N. Lawson, J. Burgess

Method:
The bonding surfaces of finished restorations are often pre-silanized to avoid contamination during shipping from laboratory to dental practice. In order to determine if temperature and light storage conditions (encountered during shipping) affect the bond between pre-silanized lithium disilicate and resin cement, 160 IPS e.max CAD sample discs were polished (320-grit SiC/15 sec/90° rotation/1min), ultrasonicated (distilled water/5min), and silanized. Silanization was carried out using either hydrofluoric acid followed by RelyX Ceramic Primer/3M ESPE or Monobond Etch and Prime. Specimens (n = 10 per group) were either placed in direct light (1hr at 22°C), exposed to cold (48hrs at -21°C), heat (48hrs at 37°C) or bonded immediately (control). Variolink Esthetic DC cement-filled tubes (Ø = 1.5 mm) were then bonded with light polymerization to the IPS e.max CAD. Bonded samples were stored in an incubator (saline/24hrs or 3 months/37°C) and debonded using a universal testing machine (1mm/min).

Results:

Summary:
The 3-month values were lower than after 24 hours for both treatment methods, however the data suggest durable and stable cement-bonding to silane-covered IPS e.max CAD, even after extreme exposure. The control group had significantly lower values than the cold group but statistically similar to the other groups (hot and light). The hydrofluoric acid + RelyX Ceramic Primer group produced significantly higher shear bond strength values than Monobond Etch & Prime.

Conclusion:
Exposure of silane to light, extreme cold, and extreme heat did not adversely affect the stability of silane on IPS e.max lithium disilicate. Both RelyX ceramic primer and Monobond Etch & Prime performed well under 24hr-storage conditions. The authors recommend pre-silanization for shipping.

Reference: Chang et al. (2016)
Influence of new ceramic surface conditioner on bonding performance of resin cements

**Study location:** Dept. of Operative Dentistry, Nihon University School of Dentistry, Tokyo, Japan
**Study release:** 2015
**Study author(s):** M. Takimoto, H. Kurokawa, M. Miyazaki

**Method:**
The influence of various types of ceramic-surface pre-treatments on bond strengths to IPS e.max CAD with various luting cements was investigated. IPS e.max CAD was treated in four different ways: no surface treatment plus silanization as a control, sandblasting plus silanization, hydrofluoric acid (HF) plus silanization or one step ceramic conditioning with Monobond Etch & Prime.

**Results:**
Summary:
The control group exhibited the lowest shear bond strengths for all luting cements and the sandblasted group exhibited the lowest values of the three experimental groups: Sandblasted, Hydrofluoric Acid or Monobond Etch & Prime. The shear bond strengths exhibited by the Monobond Etch & Prime treated samples were similar to those of the Hydrofluoric Acid groups for the various luting cements.

**Conclusion:**
As the trend regarding shear bond strengths showed a similar pattern across the different luting cements, the authors suggested that Monobond Etch & Prime can be used successfully with various adhesive resin cements.

**Reference:** Takimoto et al. (2016)
New self-etching glass-ceramic primer: Innovative alternative for glass-ceramic conditioning

Method:
The tensile bond strengths achieved with various glass ceramics and Monobond Etch & Prime were compared to the gold standard approach of hydrofluoric acid followed by silanization. The following glass ceramic products were tested: IPS e.max CAD (lithium disilicate), IPS Empress CAD (leucite reinforced glass ceramic), Celtra Duo/Dentsply (lithium metasilicate), Vitablocs Mark II/VITA (Feldspar ceramic) and IPS Style Ceram (leucite, fluorapatite and oxyapatite ceramic). Either the single-step (hydrofluororic-acid-free) Monobond Etch & Prime was used or the two-step protocol with hydrofluoric acid (HF) and Monobond Plus. Multicore Flow-filled PMMA cylinders were bonded to the different ceramic specimens with the luting cement Variolink Esthetic in dual cure mode (DC). Tensile bond strengths were calculated for each material and conditioning protocol.

Results:

Summary:
The hydrofluoric-acid-free Monobond Etch & Prime demonstrated comparable bond strength values to the standard protocol with hydrofluoric acid/silanization for each ceramic tested. There was no statistically significant difference between the two protocols.

Conclusion:
Monobond Etch & Prime allows the conditioning of all glass-ceramics with a simple, safe application procedure and represents a more convenient, reliable alternative for cementing glass ceramic restorations.

Reference: Catel et al. (2015)
Performance of a novel self-etching ceramic primer

Study location: Research & Development, Ivoclar Vivadent, Schaan, Liechtenstein
Study release: 2014
Study author(s): T. Bock, D. Catel, S. Koch

Method:
In order to establish the performance of Monobond Etch and Prime compared to hydrofluoric acid (HF) and the universal primer Monobond Plus, the tensile bond strength and etch pattern to/on lithium disilicate (IPS e.max CAD) was investigated. For the tensile bond strength testing, primed ceramic samples were bonded to PMMA cylinders filled with core-build-up composite MultiCore Flow using light-cured Multilink Automix. Samples were then either stored in water at 37°C for 24 hours or thermocycled (10,000 x 5–55°C). A scanning electron microscope was used to establish the etch pattern after ethanol rinsing.

Results:

Summary:
The tensile bond strength measurements were slightly lower with Monobond Etch & Prime (than the hydrofluoric acid protocol) after both 24-hour storage and thermocycling however the difference was not statistically significant. The etch pattern after Monobond Etch & Prime application was slightly less pronounced than after hydrofluoric acid gel.

Conclusion:
Despite a less pronounced etching pattern, the single step procedure with Monobond Etch & Prime produced comparable bond strengths to the established two-step hydrofluoric acid + silane procedure.

Reference: Bock et al. (2014)
Self-etching glass-ceramic primer vs. universal adhesives:
bond strength to lithium disilicate

Study location: Research & Development, Ivoclar Vivadent, Schaan, Liechtenstein
Study release: 2015
Study author(s): S. Koch, D. Catel, T. Bock

Method:
The bond to lithium disilicate (IPS e.max CAD) was tested via shear bond strength (SBS) and tensile bond strength (TBS) tests. The investigation compared Monobond Etch & Prime to hydrofluoric acid (HF) etching followed by either the established primer Monobond Plus or various universal adhesives: Optibond XTR/Kerr, All-Bond Universal/BISCO and Scotchbond Universal/3M ESPE. Thereafter the recommended cement for each material was applied in a single increment using an Ultradent SBS jig for the shear bond strength testing or under composite-filled PMMA cylinders for tensile bond strength testing. Multilink Automix was used with Monobond Etch & Prime and Monobond Plus for the SBS tests and Variolink Esthetic was used for the TBS tests. NX3 Nexus/Kerr, Duo-Link/BISCO and RelyX Ultimate/3M ESPE were used with the corresponding Kerr, Bisco and 3M ESPE adhesives respectively. Samples were light-cured as indicated and stored in water for 24h at 37°C or thermocycled 10,000 times at 5-55°C.

Results:

Summary:
The initial SBS of Monobond Etch & Prime was significantly higher than any other tested group. The SBS values with universal adhesives were lower than with Monobond Etch & Prime or Monobond Plus. After thermocycling all values were lower, however Monobond Etch and Prime still exhibited the highest SBS values.

The TBS values for Monobond Etch & Prime and Monobond Plus were similar after 24 hours and higher than the universal adhesives. After thermocycling the TBS difference between primers and adhesives was significant.

Conclusion:
Monobond Etch & Prime exhibited comparable or better bond strengths than conventional HF + ceramic primer/ universal adhesive.

Reference: Koch et al. (2015)
Bonding to silicate ceramics: Conventional technique compared with a simplified technique

Study location: Department of Dental Medicine, University of Valencia, Spain
Study release: 2017
Study author(s): J-L. Román-Rodriquez, J-A Perez-Barquero, E. Gonzalez-Angulo, A. Fons-Font, J-L Bustos-Salvador

Method:
Shear bond tests were carried out to compare conventional hydrofluoric acid (HF) etching followed by silane compared to the polyfluoride plus silane product Monobond Etch & Prime. Twenty ceramic samples of IPS e.max CAD were divided into 2 groups, with 1 group (G1) receiving the conventional technique and the other (G2) Monobond Etch & Prime. A resin cement cylinder was bonded to each sample using ExciTE F adhesive and Variolink II luting material. Shear bond strength testing was carried out with a universal testing machine.

Results:

Summary:
The shear bond strengths of G1 – the HF group were slightly higher than the Monobond Etch & Prime (G2) group. The difference however was not significant and the values were largely comparable.

Conclusion:
Monobond Etch & Prime appears to provide equivalent bond strength via a simplified application technique.

Reference: Román-Rodriquez et al. (2017)
Efficacy of various surface treatments on saliva-contaminated lithium disilicate ceramics

Study location: Tokyo Medical and Dental University, Tokyo, Japan
Study release: 2017
Study author(s): S. K. Lyann, T. Takagaki, T. Nikaido, T. Wada, M. Uo, M. Ikeda, J. Tagami

Method:
To investigate the efficacy of different ceramic-surface cleaning methods after saliva contamination, bond strength tests to lithium disilicate were carried out. 300 blocks of IPS e.max CAD were polished with 600-grit silicon carbide paper and divided into three groups (n=100) according to the resin cement employed: Variolink Esthetic DC, Multilink Automix or SpeedCEM. The specimens were contaminated with human saliva or remained uncontaminated. Each group was further divided into five subgroups (n = 20) according to the surface treatment performed: No treatment, Monobond Plus, 37% Phosphoric acid + Monobond Plus, 5% Hydrofluoric acid + Monobond Plus, or Monobond Etch & Prime. Chemical analysis of the ceramic surfaces of all groups was carried out via X-ray photoelectron spectroscopy (XPS). 300 treated metal rods were then bonded with the designated luting composites to the IPS e.max CAD specimens. After 24h water storage, tensile bond strength (TBS) was measured in a universal testing machine at a crosshead speed of 2 mm/min. The fractured surfaces were observed via scanning electron microscope (SEM). The results for Variolink Esthetic DC are shown below.

Results:

Summary:
The XPS analysis showed similar elemental distributions both with and without saliva for the phosphoric acid, hydrofluoric acid and Monobond Etch & Prime groups – suggesting the efficacy of the treatments in removing saliva contamination.

Tensile bond strengths were significantly influenced by surface treatment but hydrofluoric acid + Monobond Plus vs. Monobond Etch & Prime did not show any significant differences for any group – with or without saliva contamination. For Variolink Esthetic DC none of the surface treatment options differed in terms of tensile bond strength between the saliva exposed and non-exposed specimens.

Conclusion:
Monobond Etch & Prime was effective in removing saliva contamination. Monobond Etch & Prime would appear to be a possible alternative to hydrofluoric acid etching and silanization after saliva contamination.

Bonding of a universal adhesive to differently pre-treated lithium disilicate

Study location: 3M Oral Care, 3M Deutschland, Seefeld, Bavaria, Germany  
Study release: 2017  
Study author(s): C. Thalacker, G. Raia, K. Claussen, S. Hader, K. Schwarz

Method:
To investigate the shear bond strengths (SBS) achieved with the silane-containing universal adhesive Scotchbond Universal/3M ESPE to lithium disilicate, no etching, prior etching (hydrofluoric acid) or prior etching (Monobond Etch & Prime) were compared and standard primers (Monobond Plus and RelyX Ceramic Primer/3M ESPE) were also compared to the universal adhesive. The table shows the six possible scenarios. To test the shear bond strength, stainless steel rods (4mm diameter) were cemented to the IPS e.max CAD sample discs under standardized pressure (20g/mm²) using RelyX Unicem/3M ESPE. Specimens were stored at 36°C for 24 hours and half were artificially aged via thermocycling (5000x 5°C – 55°C). SBS was measured with a universal testing machine.

<table>
<thead>
<tr>
<th>Method/Scenario</th>
<th>Etchant</th>
<th>Primer</th>
<th>Luting material</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Etch</td>
<td>None</td>
<td>Scotchbond Universal</td>
<td>RelyX Unicem</td>
</tr>
<tr>
<td>2 Step: Universal Adhesive</td>
<td>Hydrofluoric acid</td>
<td>Scotchbond Universal</td>
<td>RelyX Unicem</td>
</tr>
<tr>
<td></td>
<td>Monobond Etch &amp; Prime</td>
<td>Scotchbond Universal</td>
<td>RelyX Unicem</td>
</tr>
<tr>
<td>2 Step: Conventional Primer</td>
<td>Hydrofluoric acid</td>
<td>RelyX Ceramic Primer</td>
<td>RelyX Unicem</td>
</tr>
<tr>
<td></td>
<td>Hydrofluoric acid</td>
<td>Monobond Plus</td>
<td>Multilink Automix</td>
</tr>
<tr>
<td>1 Step: Ceramic etchant/primer</td>
<td>Monobond Etch &amp; Prime</td>
<td>Scotchbond Universal</td>
<td>RelyX Unicem</td>
</tr>
</tbody>
</table>

Results:

<table>
<thead>
<tr>
<th>Etchant/primer scenario</th>
<th>Mean SBS [MPa]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Scotchbond Universal + RelyX Unicem</td>
<td>27.1 ± 2.0</td>
</tr>
<tr>
<td>Scotchbond Universal + RelyX Unicem</td>
<td>42.6 ± 4.2</td>
</tr>
<tr>
<td>Scotchbond Universal + RelyX Unicem</td>
<td>47.3 ± 6.5</td>
</tr>
<tr>
<td>RelyX Ceramic Primer + RelyX Unicem</td>
<td>49.0 ± 7.0</td>
</tr>
<tr>
<td>Monobond Plus + Multilink Automix</td>
<td>42.3 ± 5.6</td>
</tr>
<tr>
<td>Monobond Etch &amp; Prime + RelyX Unicem</td>
<td>47.1 ± 6.5</td>
</tr>
</tbody>
</table>

Shear bond strengths to IPS e.max CAD after thermocycling (aging), for various etch/primer/cement scenarios

Summary:
Etching of some sort is clearly necessary in order to maximize shear bond strength. On etched substrates, the universal adhesive, conventional silane primer scenarios and Monobond Etch & Prime all achieved SBS values of over 40 MPa after aging.

Conclusion:
The 1-step ceramic primer Monobond Etch & Prime (with RelyX Unicem) achieved a statistically comparable SBS to both the 2-step scenarios: Monobond Etch and Prime followed by the universal adhesive and hydrofluoric acid etching followed by RelyX Ceramic Primer and cement.

Reference: Thalacker et al. (2017)
Shear bond strength to two different glass ceramics with different primers and luting composites

**Study location:** University Clinic Jena, Friedrich-Schiller University, Germany

**Study release:** 2017

**Study author(s):** A. Rzanny, R. Göbel

**Method:**
The shear bond strengths of various luting composites (and accompanying primer/universal adhesive) to IPS Empress CAD and IPS e.max CAD were investigated: Monobond Etch & Prime + Variolink Esthetic DC, hydrofluoric acid (HF) + Monobond Plus + Variolink Esthetic DC, HF + Scotchbond Universal + RelyX Ultimate/3M ESPE, HF + Optibond XTR + NX3 Nexus/Kerr. IPS Empress CAD and IPS e.max CAD cylinders were luted to zirconium oxide discs and aged either for 24 hours in water at 37°C or exposed to 25,000 thermocycles (5–55°C). Shear bond testing was carried out with a Universal Zwick machine.

**Results:**

**Summary:**
For IPS Empress CAD the Monobond Plus and Monobond Etch & Prime groups showed the highest SBS values after 24 hours and after thermocycling. All the luting groups exhibited a drop in SBS after thermocycling.

For IPS e.max CAD the Monobond Plus and Monobond Etch & Prime groups also exhibited the highest values after 24 hours but there was a considerable drop for Monobond Etch & Prime after thermocycling.

**Conclusion:**
Monobond Etch & Prime exhibited similarly high values to Monobond Plus after 24 hours’ aging with both IPS Empress CAD and IPS e.max CAD.

**Reference:** Rzanny et al. (2017)
New single-bottle ceramic primer: 6-month case report and laboratory performance

*Study location:* School of Dentistry, Ponta Grossa State University, Paraná, Brazil  
*Study release:* 2016  
*Study author(s):* F. S. F. Siqueira, R. S. Alessi, A. F. M. Cardenas, C. Kose, S.C.S. Pinto, M.C. Bandeca, A. D. Loguercio, J. C. Gomes

**Method:**  
The study combined both an in vitro and short in vivo investigation.

**In vivo:** A 42 year old woman received treatment to improve the esthetic appearance of her upper anterior teeth which had been variously treated – endodontically with metal post (and associated darkening of gingiva), metal-ceramic and composite. The new all-ceramic treatment plan for the upper front six teeth, involved a zirconia crown, an IPS e.max lithium disilicate crown and four lithium disilicate veneers. The zirconia restoration was sandblasted followed by Monobond Plus. The lithium disilicate ceramic restorations were conditioned with Monobond Etch & Prime according to manufacturer instructions. All restorations were cemented using Variolink Veneer resin cement and Excite F DSC.

**In vitro:** IPS e.max CAD specimens were also investigated regarding micro shear bond strength – either with a standard hydrofluoric acid + Monobond Plus protocol or Monobond Etch & Prime.

**Results:**

![Comparison of mean shear bond strengths with different ceramic etching/priming methods](image)

**Summary:**  
**In vivo:** After 6 months, no marginal staining, gaps, chipping or damaged margins were recorded.

**In vitro:** 1-step Monobond Etch & Prime exhibited a slightly higher (statistically non-significant) mean bond strength than the two-step procedure with hydrofluoric acid and silane.

**Conclusion:**  
The self-etching glass-ceramic primer, Monobond Etch & Prime exhibited good in vitro and 6-month clinical results, representing an easy, simple alternative approach to esthetic bonding.

**Reference:** Siqueira et al. (2016)
Biocompatibility
Definition of terms
Literature
Biocompatibility

Biocompatibility can be defined as the ability of a substance/material to be in contact with a living system without producing an adverse effect. Tests can indicate the reactivity or tolerance of cells to soluble compounds of a material. Biocompatibility tests may include in vitro investigations (conducted in artificial environments such as petri dishes) such as cytotoxicity, mutagenicity, irritation and sensitivity tests.

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 was evaluated according to these standards.

Cytotoxicity

Cytotoxicity refers to the capability of a substance to damage cells. The XTT assay is used to determine whether or not the substance being investigated inhibits cell proliferation or even causes cell death. The resulting XTT_{50} value refers to the concentration of a substance sufficient to reduce the cell-viability by half. The lower the XTT_{50} 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 exhibited a cytotoxic effect on the L929 cell line examined when applied in very high concentrations. The calculated XTT_{50} value was 1979.1 µg/ml. Given that Monobond Etch & Prime is only applied in small amounts at a time and this application procedure occurs extra- orally, the cytotoxic risk of Monobond Etch & Prime is very low for both patient and user.

Genotoxicity

Genotoxicity refers to the capability of substances or external influences to damage or alter the genetic material of cells.

Monobond Etch & Prime was examined regarding genotoxicity, 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). It can be assumed that Monobond Etch & Prime has no mutagenic potential.

Skin irritation and skin damage

The irritation potential of Monobond Etch & Prime was measured using an EpiDerm skin model (4). 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. As Monobond Etch & Prime is designed to have an etching effect on ceramic surfaces, it is to be expected that there would be some irritating effect on the skin. The results showed that short contact times did not result in skin damage.

After etching, Monobond Etch & Prime is rinsed from the restoration extra- orally, patients are therefore not at risk from the etching effect. Users are made aware of the material’s etching properties in the Instructions for Use and notes on the packaging.
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.

Conclusions

- Monobond Etch & Prime is slightly cytotoxic.
- It is in the nature of Monobond Etch & Prime to have an etching effect, as it is designed to etch glass-ceramic materials. The etching compounds are rinsed off after the extra-oral application procedure and therefore do not come into contact with the patient.
- Monobond Etch & Prime contains methacrylates, which can cause sensitization and thus allergic reactions. These are however extremely rare in patients.
- Monobond Etch & Prime can be considered non-genotoxic, based on current information.

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

Toxicological data

(2) Sokolowski A. Salmonella typhimurium and Escherichia coli reverse mutation assay Harlan Report No. 1626301. 10 July 2014.
(3) Wollny H-E. Cell mutation assay at the thymidine kinase locus (TK+/-) in mouse lymphoma L5178Y cells Harlan Report No. 1642302. 02 September 2014.
Definition of terms

Studies
Studies are conducted to forecast or examine the behaviour of materials when used for the intended application. Aspects of functionality, reliability, safety, compatibility or user-friendliness are often of most interest.

- **In vitro studies**
  *In vitro* means ‘in glass’. These examinations are conducted in a laboratory outside of their normal biological context. Many materials science or toxicological tests are carried out in vitro, since they cannot be conducted on human beings for practical or ethical reasons. Moreover in vitro studies have the advantage that researchers can work under standardized conditions - plus they are often quicker and less expensive than in vivo studies.

- **In vivo studies**
  *In vivo* means ‘in the living object’. Such studies are carried out within the biological context i.e. in animals/human beings. The advantage is that results are more meaningful as the investigations are conducted under real conditions. They are however complex due to a wealth of possible influencing factors. They require exact planning, systematic methods, ethical permission and statistically correct evaluation. Randomized controlled studies are considered the gold standard.

- **Prospective study**
  A study planned to be conducted in the future in order to test a certain hypothesis, such as material A is as good as material B. After preparation of a test plan, the patients are recruited and the material used. The test subjects are observed over a certain period of time and the results are subsequently evaluated.

- **Retrospective study**
  Analysis of data collected in the past. For example - all cases of bridge fractures that occurred in a dental office are examined to find out if the fractures happen more frequently with one material than with another.

Mechanical properties and *in vitro* tests
In materials science, there are numerous test methods to determine the mechanical properties of materials. The object of mechanical testing in dentistry, is to make estimates about the clinical efficacy of a material. Standard test methods however, frequently test isolated stress conditions, whereas the effects on a material are much more complex in clinical reality. Nevertheless materials science examinations in the laboratory do at least permit the comparison of different materials when tested in exactly the same way.

Bond strength tests
The testing of the bond of indirect restorative materials is usually carried out via shear bond strength or tensile bond strength tests. Bond strength is reported as the nominal stress value (in MPa), that is the failure load (in Newtons) divided by the entire bonded area (in mm$^2$). Bond strength can be tested with tension or shear force and depending on the surface area of the bonded area is referred to as micro (approximately 1 mm$^2$) or macro (4 – 28 mm$^2$) (Sakaguchi 2012). Bond strength values for a specific material can vary greatly amongst studies, due to differences in the bonding substrate, specimen preparation, storage conditions, and loading method.

Shear bond strength
- **Macroshear bond strength**: In a standard macroshear bond strength test, a composite cylinder is built on the bonding substrate and bonded with whatever primer, adhesive and luting cement of interest. After a pre-determined storage time, the specimen is positioned in a universal testing machine where a single-edged chisel, a flat-end rod or a wire loop is attached to the actuator used to dislodge the composite cylinder from the substrate. The cylinder is sheared off parallel to the bonding surface. In shear bond testing, shear refers to the loading mode – the actual stress that causes the debonding is of a tensile nature. Typical dentin bond strength values with these tests are 10–50 MPa. Cohesive and mixed failures may account for up to 55% of specimens (Sakaguchi 2012).
• **Microshear bond strength**: Composite cylinders are built on the substrate using silicone tubes. Typically up to six tube segments are bonded to a surface and filled with composite. The test procedure is similar to the macro procedure. Bond strength values are about 20 MPa typically and the incidence of mixed and cohesive failures is 50% (Sakaguchi 2012).

**Tensile bond strength**

• **Macrotensile bond strength**: For macrotensile bond strength tests, a perpendicular alignment of the bonded interface to the loading axis is important. The load is applied at a right angle to the bonding surface. Stress distribution is more uniform than in shear bond tests (Sakaguchi 2012). Typical dentin bond strength values to dentin are around 10 MPa, with cohesive and mixed failures occurring in approximately 35% of specimens.

• **Microtensile bond strength**: Beam shaped or hourglass shaped specimens with a cross-sectional areas of approximately 1 mm$^2$ are used. There tend to be fewer mixed or cohesive failures than with other methods. Specimen preparation of thin material slices with diamond disks is labour-intensive and pre-test failure is common. Specimens may be glued or actively or passively attached to the testing fixture with grips. Dentin bond strength values vary from 30–50 MPa – higher than the macro tests, as the critical size for flaws is smaller with a microinterface.

**Thermocycling / Chewing simulation / Fatigue / Aging**

During the development of new materials, it is important to determine how susceptible they are to fracture or wear under the expected stress conditions in the oral cavity. In vitro chewing simulation / fatigue tests are often used, as results are available quickly and materials can be tested and compared under standardized conditions. Test specimens are usually adhesively cemented to standardized PMMA dies and subjected to cyclic, eccentric loading with a pointed steel antagonist in a water bath.

**Cementation / Luting**

Dental cements or luting agents are materials used for cementing/luting indirect restorations to the remaining tooth structure. Both adhesive and non-adhesive materials are available.

• **Conventional cementation**
  Zinc phosphate, carboxylate and glass ionomer cements are all conventional materials. Most consist of a powder plus a liquid component, which are manually mixed. Some are available in mixing capsules. The chemical setting process starts immediately after mixing and does not involve additional initiation. No special pre-treatment of the prepared tooth is needed in conjunction with these materials. Usually, the restoration is simply placed as delivered by the dental laboratory. Complete isolation of the prepared tooth is not required. However, a retentive preparation design is necessary which may entail considerable loss of healthy tooth structure. Conventional cements usually have a grey-opaque appearance and, are therefore visible if the cement joint is exposed. Glass-ionomer cements have been further developed to produce a new group of materials known as hybrid cements. In addition to glass-ionomer components, hybrid cements contain monomers, so that both a cement setting reaction and polymerization occurs. These luting materials feature better mechanical properties but also lack an adhesive bond to the tooth structure.

• **Adhesive luting composites**
  Adhesive composite-based luting materials are resins, composed of monomers and inorganic fillers. These materials (in combination with a dentin adhesive) can establish a sound chemical bond with the dental hard tissues and allow minimally invasive techniques. They are classified into self-curing, light-curing and dual-curing materials. By carefully selecting the pigments and colour additives, tooth-coloured luting composites are not visible if the cement joint is exposed. Enamel and dentin are pre-treated as prescribed by the adhesive luting protocol and the glass-ceramic material to be luted is usually etched with hydrofluoric acid and treated with a silane coupling agent.
• **Self-adhesive resin cements**
  These combine the advantages of conventional and adhesive luting materials. Although adhesive luting composites have many advantages, their application involves effort (isolation, application of additional steps with products such as dentin adhesives and primers), whereas conventional cements are simpler to use. Self-adhesive resin cements bond, both to the tooth structure and certain restorative materials, reducing the number of steps involved in their application.
Literature


Thalacker, C., Raia, G., Clausen, K., Hader, S., Schwarz, K. (2017). Bonding of a universal adhesive to differently pretreated lithium disilicate. IADR Abstract #0079, San Francisco

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