

# Adhese® Universal

The universal adhesive



## Scientific Report

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English



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# Foreword



Over the last 25 years, dentistry has experienced significant generational changes as well as new materials categories, chemistries, and clinical protocols with dental adhesives – much of it driven by an effort to simplify and shorten the bonding procedure.

The evolution of esthetic, tooth-coloured composite filling materials and the adhesive luting technique could not have taken place without the development of suitable adhesive systems. Since these products generate a strong and reliable bond between the dentition and restorative composite material, adhesive systems are essential for the long-term success of direct and indirect restorations.

For decades, bonding agents have been categorized as either total- or self-etch systems with different methods of dispensing and application. A new category of so-called "Universal Adhesives" has quickly evolved which combines different adhesive types together – making them compatible with any technique and all restorative materials for both direct and indirect bonding procedures. With its all-encompassing definition and wide-spread use, it is easy to see how this new adhesive category has become so appealing to clinicians, but yet somewhat confusing due to the ambiguity when making comparisons.

Developing our own universal adhesive was not defined by new technology alone, but rather by the market demand for efficiency, simplicity and reliability. In order to meet these requirements, the following criteria needed to be met: single-component delivery in the bottle and VivaPen® delivery systems, compatibility with direct and indirect bonding procedures using any etching technique, high technique tolerance on wet or dry surfaces, ideal film thickness for cementation of indirect restorations, fast and easy application, consistently high bond strength with good marginal integrity on enamel, storage at room temperature and a very low risk of post-operative sensitivity.

The final result is an optimized balance between hydrophilic and hydrophobic adhesive monomers with a mild-etching formulation that is suitable for direct and indirect bonding procedures and all etching protocols. Additionally, it is the only universal bonding agent available in the conventional bottle as well as the unique VivaPen for efficient and convenient direct intraoral application.

Adhese® Universal was approved for clinical use in March 2014. Since then its market acceptance is growing very fast. The following scientific and clinical data collected is very promising and continually expanding. We are very excited about this new product and are confident that you, your staff and your patients will enjoy it.

This Scientific Report highlights just some of the key findings. Since your continued satisfaction is important to us, we would welcome your feedback and suggestions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Thomas Hirt', written over a light blue horizontal line.

Dr Thomas Hirt  
Chief Technology Officer

# Introduction

**Adhese® Universal** from Ivoclar Vivadent is a single-component, light-curing universal adhesive for bonding direct and indirect restorations. It is the only universal bonding agent available in the conventional bottle as well as the unique VivaPen® for fast and convenient direct intraoral application.



Adhese Universal balances an optimized mix of hydrophilic and hydrophobic monomers with a low acidic concentration and mild etching effect into one formulation, making it suitable for direct and indirect bonding procedures and all etching protocols. It also demonstrates a high tolerance on different degrees of dentin moisture to ensure for consistent and reliable bond strengths using any etching protocol.

The solvent used in Adhese Universal facilitates rewetting of the collapsed collagen fibers so that the adhesive can effectively infiltrate into the dentinal tubules for high bond strength. The micro-fillers and water solvent enhance penetration into the dentin tubules, stabilizing and supporting the collagen network. This combination helps form a homogenous layer and achieves high bond strengths to enamel and dentin using only one coat of adhesive, resulting in optimum sealing of the dentinal tubules to help prevent movement of dental fluid, thus minimizing the risk of post-operative sensitivity.

Simple “Click” activation with the unique VivaPen delivery system dispenses the exact amount of material needed for each procedure. Dispensing of adhesive material into a mixing well is no longer required, which results in a significant reduction in material waste. In comparison to conventional bottle delivery forms, the VivaPen provides enough material for approximately 190 single-tooth applications which is almost 3 times more applications per millilitre.

## Key features:

- Efficient Click & Bond® dispensing with the VivaPen
- Suitable for direct and indirect bonding procedures and all etching protocols
- Wet & Dry Bonding – high technique tolerance on wet and dry dentin
- Integrated desensitizing effect – low risk of post-operative sensitivity
- Consistently high shear bond strength

# Integrated Desensitization

Dentin hypersensitivity is a common condition, notably after dental restorative work. The development of post-operative dentin hypersensitivity can occur if the dentin tubules and collagen network become exposed due to insufficient coverage by adhesive layer (e.g. too thin, degradation). In such cases, fluids will penetrate into the dentin tubules causing hypersensitivity. This phenomenon is referred to as microleakage.<sup>1</sup>



## Hydrodynamic theory of pain

Several theories have been proposed to explain the mechanism of dentin sensitivity and therefore of dentin hypersensitivity. Of these, the most widely accepted is the hydrodynamic theory of sensitivity from Dr Brännström et al. in 1967. Brännström suggests that sensation of pain (hypersensitivity) can occur from the movement of fluid within the dentin tubules. That is, when dentin tubules are exposed to external stimuli, such as cold, warmth or osmotically active substances, the dentinal fluid will flow. This flow results in the stimulation of the odontoblasts and nerve fibers leading to the pulp, which patients perceive as pain<sup>2</sup> (Fig. 1).

## How does Adhese® Universal work?

Adhese® Universal is scrubbed onto the tooth surface for at least 20 seconds to maximize contact of the enamel and dentin with the acidic monomers.

During this step:

- The hydrophilic solvents (water and ethanol) and hydroxyethyl methacrylate (HEMA) optimize wetting, priming and infiltration of the hydrophilic resin monomers into dry or moist dentin tubules and collagen network to ensure the formation of a reliable dentin seal via a homogenous adhesive layer with defined resin tags.
- The acidic monomers (MDP, MCAP) precipitate as insoluble calcium salts in the dentin, facilitating mechanical blockage and sealing in the dentin tubules. This helps prevent the movement of fluid in the dentin as well as post-operative sensitivity associated with that movement.
- The formation of a stable, thin homogenous layer with a low film thickness is ensured by the optimized thickening agents - fumed silica and methacrylated carboxylic acid polymer.

This integrated “Desensitizing Effect” prevents movement of dentinal fluid within the tubules minimizing the risk of microleakage and post-operative sensitivity (Fig. 2).

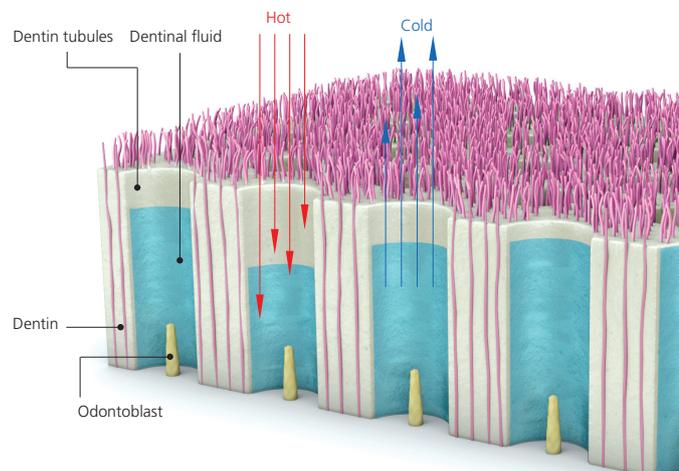


Fig 1: Diverse stimuli (heat, cold, desiccation etc.) trigger fluid flow within the dentin tubules. The subsequent activation of pulpal nerves leads to the perception of pain.

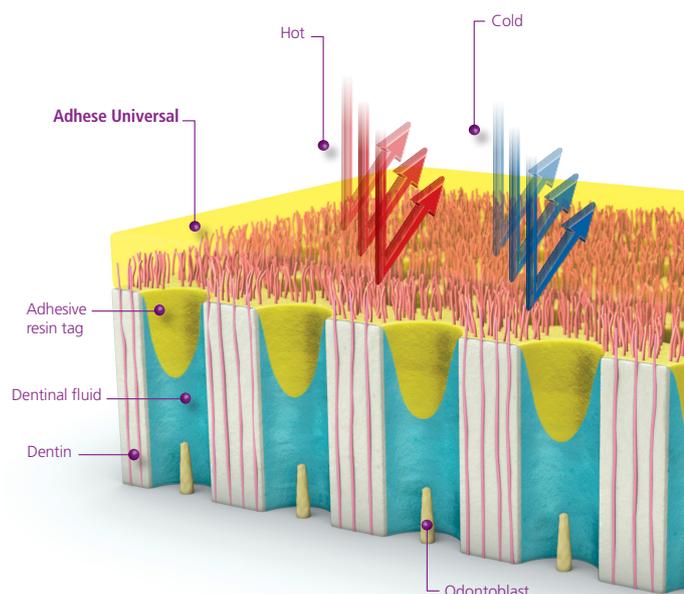


Fig 2: Application of Adhese Universal to exposed dentinal surfaces blocks dentin tubules and hence reduces fluid flow and tooth hypersensitivity



# ***In vitro studies***

# An ultra-morphological characterization of dentin using Adhese® Universal

*Study location:* University of Lisbon – Lisbon, Portugal  
*Study period:* 2013  
*Study author(s):* Lopes M.

## Objective:

To examine the ultra-morphological characterization of wet and dry dentin using Adhese® Universal with the self-etch and total-etch technique.

## Method:

56 extracted human molars (refrigerated in a solution of 0.5% chloramine for up to one month post-extraction) were used in this study. Teeth were left in distilled water at 37°C for 24 hours. The occlusal enamel was then removed with an Isomet 1000 diamond saw (Buehler GmbH) and 56 dentin discs with a thickness of  $800 \pm 200 \mu\text{m}$  were obtained from middle dentin by slow speed sectioning. A standard smear layer was created on the occlusal surface by wet sanding with 600-grit SiC sandpaper for 60 seconds. In the total-etch group, the surfaces were etched for 15 seconds with phosphoric acid. Adhese Universal was applied to the dentin surfaces and specimens were randomly divided into 4 equal ( $n=14$ ) groups. After the application of Adhese Universal, a 1 mm thick layer of Tetric EvoFlow was applied to the treated dentin and light-cured for 40 seconds. The samples then underwent ultra-morphological examination via scanning electron microscopy.

## Results:

Both self-etch groups (wet and dry) exhibited a sealed acid-resistant resin-dentin inter-diffusion zone. Adhese Universal penetrated profusely into the dentin tubules up to  $100 \mu\text{m}$  in all specimens analysed (Fig. 1). The hybrid layer was  $0.6\text{--}0.8 \mu\text{m}$  thick. In both total-etch groups (wet and dry), the hybrid layer was thicker at  $3.5\text{--}5.0 \mu\text{m}$ , and densely infiltrated (Fig. 2). Resin tags were funnel shaped with peri-tubular triangular hybridization, which is characteristic of most total-etch systems.

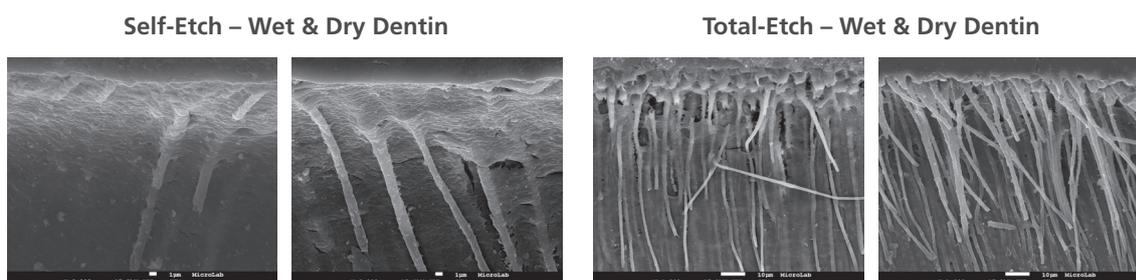


Fig 1: SEM (x 3000) of dentin tubules after application of Adhese Universal using the self-etch technique under wet (left) and dry (right) conditions. M. Lopes, University of Lisbon, August 2013.

Fig 2: SEM (x 1000) of dentin tubules after application of Adhese Universal using the total-etch technique under wet (left) and dry (right) conditions. M. Lopes, University of Lisbon, August 2013.

## Conclusion:

The SEM photos show relatively uniform sealing and mechanical blockage of the dentin tubules under all conditions – which support the ability of Adhese Universal to form a strong bond to dentin while providing protection against hypersensitivity. More sealed tubules are visible in Fig. 1 than Fig. 2 (irrespective of the magnification) due to the total-etch technique having removed the smear layer. The similarity between dry and moist substrates supports the lack of technique sensitivity with Adhese Universal.

# Characterization of dentin infiltration using Adhese® Universal in the etch & rinse approach

*Study location:* R&D Ivoclar Vivadent AG – Schaan, Liechtenstein

*Study period:* 2016

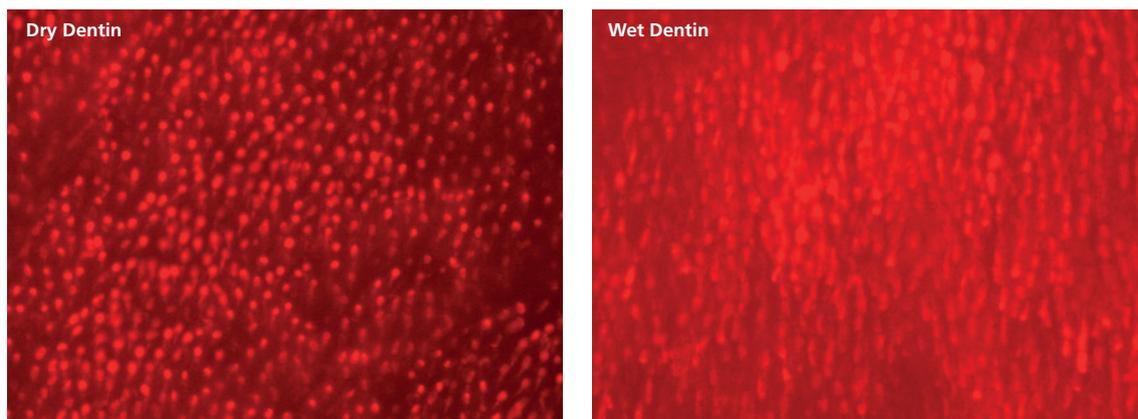
## Objective:

To determine the degree and depth of dentin infiltration for Adhese® Universal using fluorescent dye following the total-etch protocol.

## Method:

Perylene-type fluorescent red dye was dissolved in the Adhese Universal to make the adhesive detectable by fluorescence microscopy. The dentin surface of bovine teeth was prepared according to ISO 29022. The to-be-treated parts of the dentin surface were etched using 37% phosphoric acid gel Total Etch (Ivoclar Vivadent) for 15s, rinsed and dried. One group of specimens was dried vigorously using strong stream of air to obtain dry dentin, while the other group was blot-dried to give a shiny surface with a visible, thin moisture film. Fluorescent Adhese Universal was then applied to previously etched wet and dry dentin. The surface of the adhesive layer was scraped off the dentin using a scalpel and the exposed dentin gently ground to remove residual adhesive. The teeth were rinsed with water, etched again with phosphoric acid gel for 15s to remove residual fluorescent smear layer. The height of the embedding cylinder was determined using a digital caliper in 4 places on the circumference of the cylinder. The average of the 4 measurements was calculated to obtain the initial height of the cylinder. Specimens were inspected with a fluorescent microscope at 50x magnification. Adhesive resin tags infiltrated into the dentin tubules were clearly differentiated from the non-infiltrated dentin. The teeth were then gently ground once more and re-etched with phosphoric acid gel. After gentle grinding, an even layer of 20–30 µm thickness could be removed from the embedded teeth, providing a view of the adhesive at various depths within the dentin tissue. The procedure was repeated until no further adhesive was visible with the dentin tubules.

## Results:



Fluorescent microscopy photos: Bright red spots represent adhesive in dentin tubules on both dry (left) and wet (right) dentin after application of Adhese Universal with the total-etch technique (50x magnification, depth in dentin specimens is approx. 20 µm)

## Conclusion:

The fluorescence microscopy photos demonstrated Adhese Universal to give uniform sealing and mechanical blockage of the dentin tubules on both dry and wet dentin. This can be derived from the uniform pattern of tubule infiltration by this adhesive, regardless of degree of dentin surface moisture. This observation supports the ability of Adhese Universal to provide additional protection against hypersensitivity - even after removal of the smear layer using the total-etch technique.

## Formation of precipitates within the dentinal tubules after application of the acidic components in Adhese® Universal

Study location: R&D Ivoclar Vivadent AG – Schaan, Liechtenstein

Study period: 2016

### Objective:

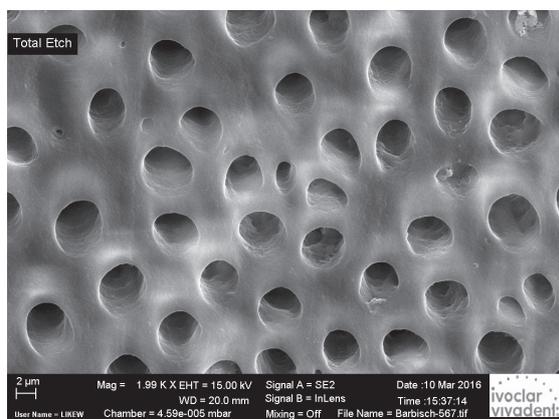
Electron microscopy was used to investigate the formation of precipitates on dentin after application of a solution containing the acidic components in Adhese® Universal.

### Method:

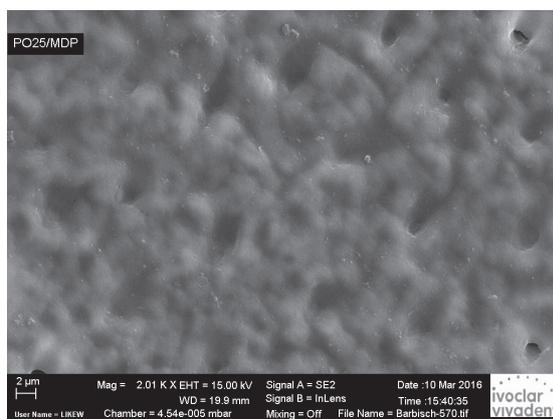
The dentin surface of bovine teeth was prepared according to ISO 29022 and etched using 37% phosphoric acid gel Total Etch (Ivoclar Vivadent) for 15 s, rinsed and dried. A solution containing phosphoric acid monomer (MDP) and methacrylated carboxylic acid polymer (MCAP), in concentrations present in Adhese Universal, was agitated onto the etched dentin surface for 20 s. Residual liquid was then removed immediately by vigorous rinsing with water spray. Specimens were inspected with electron microscopy at 1000x magnification.

### Results:

The SEM micrographs demonstrate that treatment of etched dentin with a solution of MDP and MCAP resulted in a dense, strongly adhering precipitate layer. After the treatment, no open tubules were visible in the micrographs shown below.



SEM photos (x1000) of etched dentin using the total-etch technique



SEM photos (x1000) demonstrate effective mechanical blockage and sealing of the exposed dentin tubules after application of MDP and MCAP.

### Conclusion:

Electron microscopy demonstrated effective mechanical blockage and sealing of exposed dentin tubules after application of the phosphate acid monomer MDP and the methacrylated carboxylic acid polymer MCAP. This illustrates the synergistic effect between the phosphate acid monomer MDP and methacrylated carboxylic acid polymer MCAP in Adhese Universal. These compounds precipitated as insoluble layer on the dentin, supporting the ability of Adhese Universal to provide protection against hypersensitivity.

# Effect of shear bond strength on moist, dry and desiccated dentin surfaces using different universal adhesives

*Study location:* University at Buffalo – Buffalo, New York USA  
*Study period:* 2014  
*Study author(s):* Singhal S., Antonson S., Antonson D., Bush P.

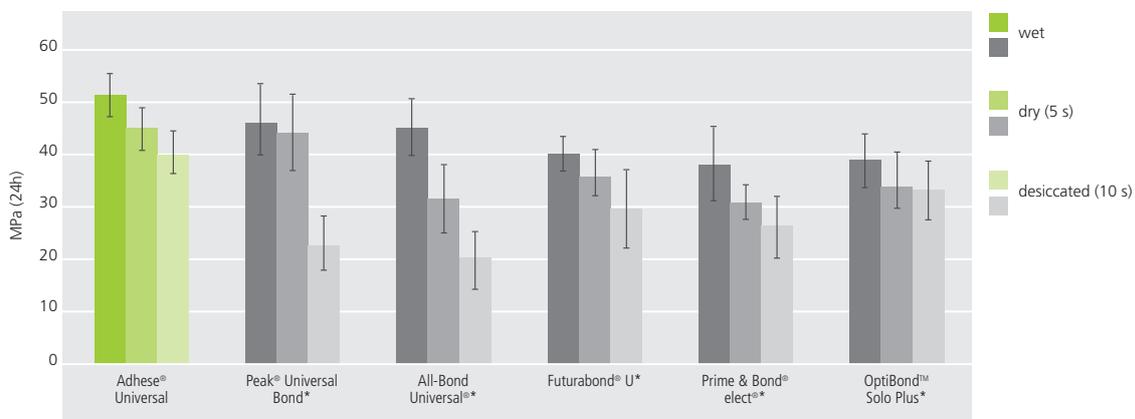
## Objective:

To evaluate the effect of moist, dry and desiccated dentin surfaces on the shear bond strength of different universal adhesives.

## Method:

Extracted human molars were sectioned, mounted and ground to a flat dentin surface using 600-grit SiC sand paper; and then etched using phosphoric acid. Specimens were randomly distributed in 18 groups (n=10) based on dentin surface preparation after acid etching: moist (blot dry), dry (5 sec. air dry) and desiccated (10 sec. air dry). The adhesives were then applied and light cured according to the manufacturer’s instructions for use. The specimens were secured in the Ultradent jig. The resin composite (Tetric EvoCeram® Bulk Fill) was condensed and light cured (10 seconds/Bluephase® G2) after storing the specimens for 24 hours (100% humidity/37°C. The shear bond strength was measured using an Instron Universal Testing Machine (1kN load cell/crosshead speed of 1.0 mm/min).

## Results:



Shear bond strength on dentin after different surface treatments (moist, dry and desiccated)  
 \* Not registered trademarks of Ivoclar Vivadent AG

## Conclusion:

Different surface treatments affected the shear bond strength of all tested adhesives. Adhese® Universal achieved consistently high shear bond strength on dentin after different surface treatments in comparison to the other universal bonding agents tested.

**Reference:** Singhal et al. Academy of Dental Materials 2014<sup>3</sup>

## Shear bond strength on dentin and enamel before and after simulated aging using different universal adhesives with composite for direct-placed restorations

Study location: R & D Ivoclar Vivadent AG – Schaan, Liechtenstein

Study period: 2014

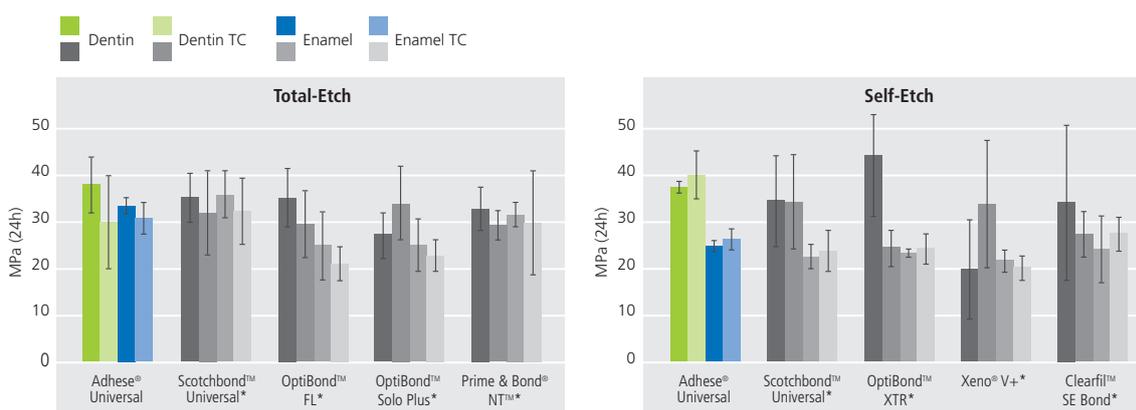
### Objective:

To evaluate the shear bond strength on dentin and enamel before and after simulated aging for 5 different universal adhesives used in combination with Tetric EvoCeram® Bulk Fill for direct-placed restorations.

### Method:

Each adhesive was applied to the bovine tooth substrate using the total-etch and self-etch technique. All materials were applied according to the manufacturer's instructions for use. Sample preparation and measurements were conducted according to ISO 29022. The shear bond strength was tested before and after 10,000 thermal cycles (TC) between 5°C and 55°C. The test samples were thermal cycled to simulate aging and thermal stress on the adhesive bond induced by eating, drinking and breathing.

### Results:



Shear bond strength on enamel and dentin before and after 10,000 thermal cycles (TC) using different etching protocols

\* Not registered trademarks of Ivoclar Vivadent AG

### Conclusion:

Using both etching protocols, Adhese Universal demonstrated consistently high shear bond strength before and after simulated aging.

# Shear bond strength on dentin and enamel after simulated aging using different combinations of universal adhesives and luting composites for indirect restorations

*Study location:* R & D Ivoclar Vivadent AG – Schaan, Liechtenstein  
*Study period:* 2015

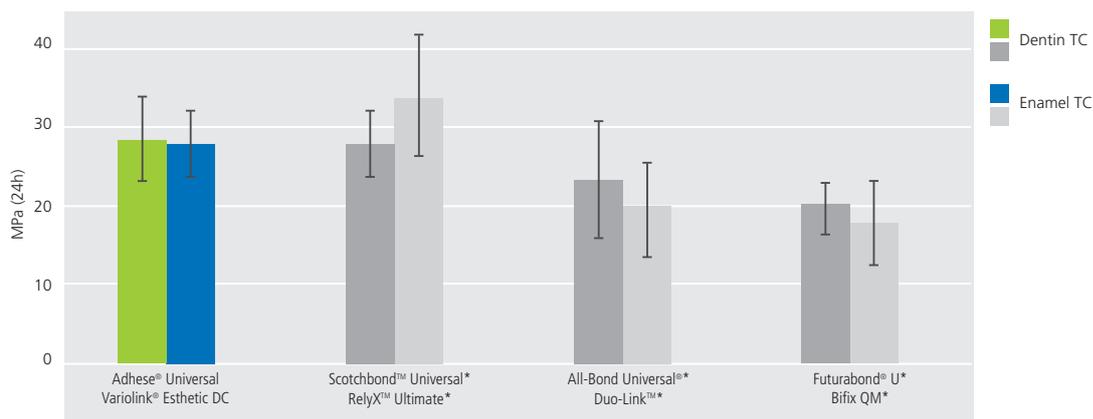
## Objective:

To evaluate the shear bond strength on dentin and enamel after simulated aging for 4 different combinations of universal adhesives and luting composites for indirect restorations.

## Method:

Each adhesive was applied to the bovine tooth substrate using the selective-enamel-etch technique. All materials were applied according to the manufacturer's instructions for use. Sample preparation and measurements were conducted according to ISO 29022. The shear bond strength was measured before and after 10,000 thermal cycles (TC) between 5°C and 55°C. The test samples were thermal cycled to simulate aging and thermal stress on the adhesive bond induced by eating, drinking and breathing.

## Results:



Shear bond strength of different adhesive/luting composites after dual-curing and 10,000 thermal cycles (TC) using the selective-enamel-etch technique

\* Not registered trademarks of Ivoclar Vivadent AG

## Conclusion:

The combination of Adhese® Universal with Variolink® Esthetic DC in the dual-curing mode demonstrated consistently high shear bond strength on dentin and enamel after simulated aging.

## Marginal quality on dentin and enamel before and after simulated aging using adhesive systems for class V restorations

Study location: Charité – Universitätsmedizin Berlin – Berlin, Germany  
Study period: 2014  
Study author(s): Blunck U.

### Objective:

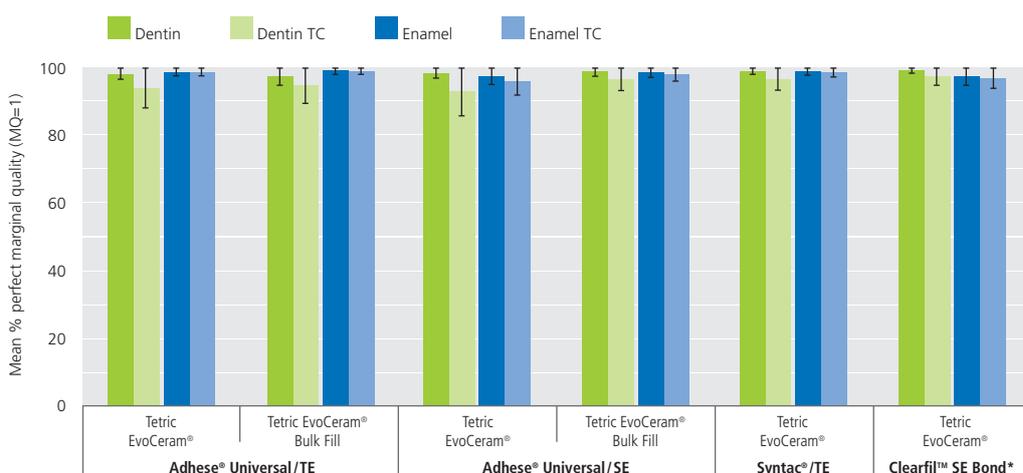
To evaluate the marginal quality on dentin and enamel before and after simulated aging using different adhesive systems with different etching protocols for class V restorations. The test samples were thermal cycled (TC) to simulate aging and thermal stress on the adhesive bond induced by eating, drinking and breathing.

### Method:

8 oval-shaped cavities approximately 4 mm (incisal-apically), 3 mm (mesio-distally) and 1.5 mm deep were prepared in extracted, caries-free human teeth. Adhese® Universal with the self-etch (SE) and total-etch (TE) technique and either Tetric EvoCeram® (2-layers) or Tetric EvoCeram Bulk Fill (1-layer) were applied into the cavities. Syntac® (Ivoclar Vivadent) with the total-etch technique and Clearfil™ SE Bond (Kuraray) with the self-etch technique were used as controls in combination with Tetric EvoCeram – establishing a total of 6 different adhesive/composite groups. Silicone impressions were taken before and after thermal cycling (2,000 cycles between 5°C and 55°C), to evaluate the surface quality. Margins were examined using a scanning electron microscope (200x). Marginal quality (MQ) was evaluated according to the scale MQ 1–4: 1 represents perfect continuous margins with no marginal gaps observable, and 4 represents large marginal gaps of >2 µm. The mean values for MQ1 are shown in the table below.

### Results:

There was no statistically significant difference in the marginal quality in dentin or enamel either before or after thermal cycling. There was no statistically significant difference between Adhese Universal and Syntac (in combination with Tetric EvoCeram) when used with the total-etch technique. There was also no statistically significant difference between Adhese Universal and Clearfil SE Bond (in combination with Tetric EvoCeram) when used with the self-etch technique.



Mean percentage of perfect marginal quality on dentin/enamel before/after 2,000 thermal cycles (TC) using different adhesives and etching protocols

\* Not registered trademarks of Ivoclar Vivadent AG

### Conclusion:

In comparison to proven adhesive systems, Adhese Universal was highly effective on dentin and enamel in Class V cavities after simulated aging using different restorative composite materials with the total-etch or self-etch protocol.

## Marginal quality on dentin and enamel after simulated aging using universal adhesives for MOD restorations

*Study location:* Philipps-Universität Marburg und Universitätsklinikum Giessen und Marburg – Marburg, Germany  
*Study period:* 2014  
*Study author(s):* Frankenberger R.

### Objective:

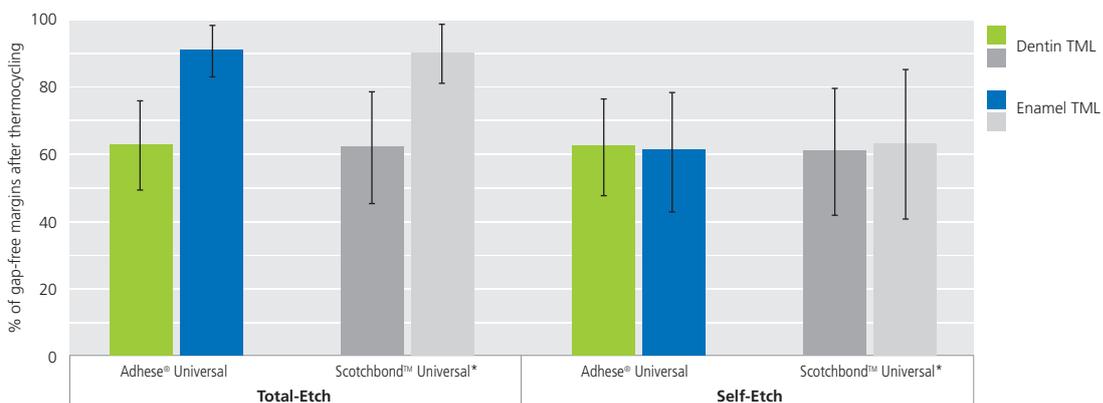
To evaluate the marginal quality on dentin and enamel after simulated aging for direct-placed composite restorations in MOD-cavities using different universal adhesives with different etching protocols.

### Method:

32 MOD cavities with one proximal box beneath the cemento-enamel junction were prepared in extracted human molars. Restorations were placed with Tetric EvoCeram® Bulk Fill and either Adhese® Universal or Scotchbond™ Universal (3M ESPE) using both self-etch and total-etch technique. Marginal gaps in the enamel were analyzed via SEM of epoxy-resin replicas, before and after thermal cycling (100,000 x 50N, 2,500 cycles between 5°C and 55°C). After thermal-mechanical loading (TML), specimens were cut longitudinally to investigate the internal dentin adaptation under SEM (200x magnification). Results were analyzed with Kruskal-Wallis and Mann-Whitney U-tests ( $p < 0.05$ ).

### Results:

Prior to thermal cycling, the percentages of margin with perfect integrity were high in both enamel and dentin for both adhesives and techniques. After thermal cycling, there was no significant difference between the etching techniques or adhesives in dentin. In enamel, the percentage of gap-free margins was higher in the total-etch group than the self-etch group, but the differences were not significant.



Percentage of gap-free margins on dentin and enamel after thermal-mechanical loading (TML) for different universal adhesive systems using different etching protocols

\* Not registered trademarks of Ivoclar Vivadent AG

### Conclusion:

When compared to adhesives and filling composites tested previously under equal conditions, Adhese Universal performed very well on dentin and enamel after aging using the total-etch and self-etch technique.

## Tensile bond strength to etched lithium disilicate ceramic after simulated aging using universal adhesive systems

Study location: Christian-Albrechts University – Kiel, Germany  
 Study period: 2015  
 Study author(s): Younes F., Kern M.

### Objective:

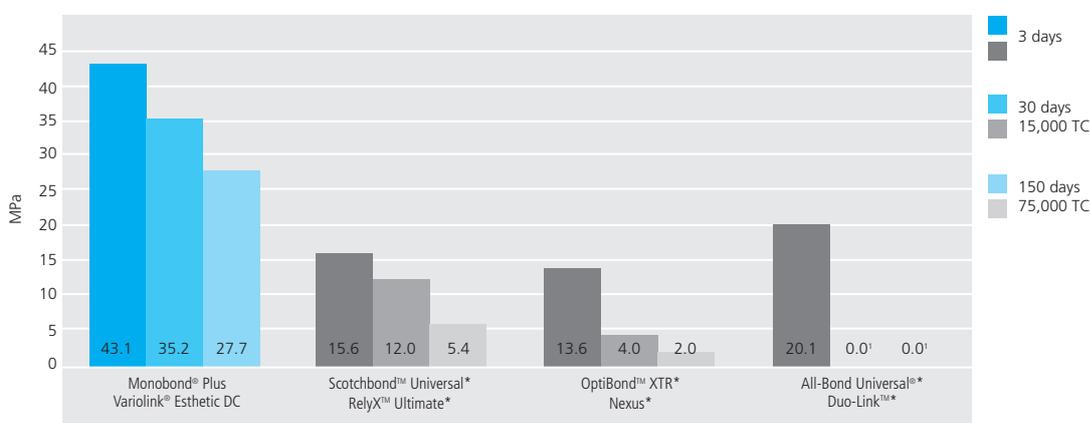
To evaluate the tensile bond strength of different universal adhesive systems to etched lithium disilicate ceramic after simulated aging.

### Method:

120 disc-like lithium disilicate ceramic specimens IPS e.max® CAD (Ivoclar Vivadent) were etched and bonded with 4 different adhesive bonding systems to Plexiglas tubes filled with a composite resin. The specimens were stored in water at 37°C for 3 days without thermal cycling or for 30 or 150 days with 7,500 or 37,500 thermal cycles (TC) between 5°C and 55°C, respectively. Then, all specimens underwent tensile bond strength testing. Statistical analysis was performed by using Kruskal-Wallis and Wilcoxon tests with a Bonferroni-Holm correction for multiple testing.

### Results:

Initially, all adhesive systems exhibited considerable tensile bond strength, but some showed a significant reduction after 30 days of storage. After 3, 30 and 150 days, Monobond® Plus (Ivoclar Vivadent) silane-containing ceramic priming bonding system demonstrated significantly higher bond strengths to lithium disilicate ceramic compared to other universal adhesive systems, some of which did not contain silane.



Durability of the adhesive bond with lithium disilicate ceramic using different primers/luting systems  
 \* Not registered trademarks of Ivoclar Vivadent AG

### Conclusion:

Tensile bond strength to lithium disilicate ceramic is influenced significantly by the ceramic priming bonding system. Universal adhesive systems (some which did not contain silane) demonstrated inferior tensile bond strength and durability on lithium disilicate ceramics compared to separate silane-containing ceramic priming bonding systems. The combination of Monobond Plus with Variolink® Esthetic DC in the dual-curing mode demonstrated consistently high shear bond strength and stability after simulated aging.

# Efficiency, residual waste and cost-effectiveness of the VivaPen® compared to conventional bottle delivery forms

Study location: Berndt + Partner Crealty GmbH – Berlin, Germany

Study period: 2013

## Objective:

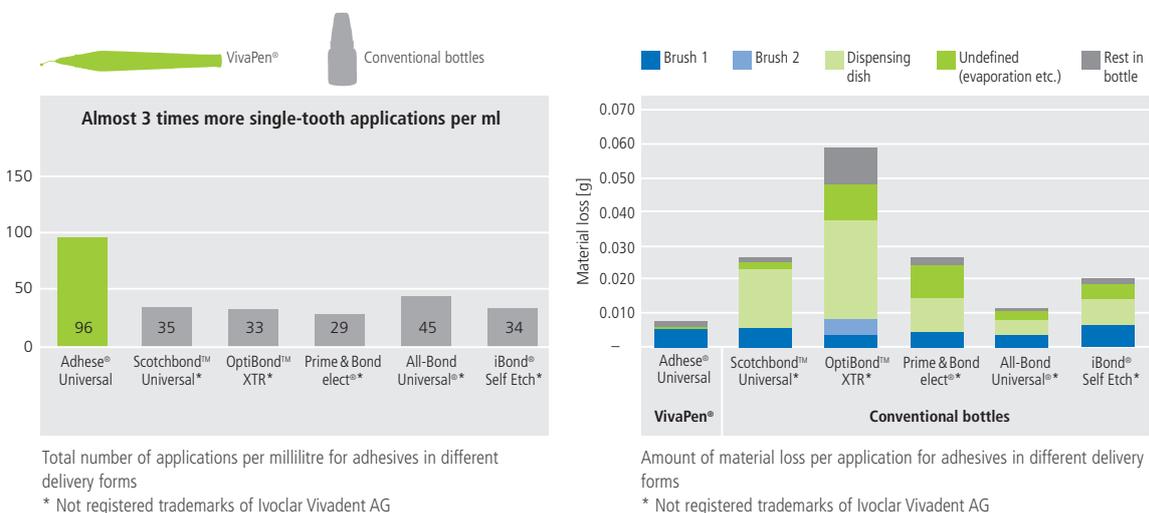
An independent evaluation by Berndt+Partner analysed the efficiency, residual waste and cost-effectiveness of the VivaPen compared to conventional bottle delivery forms using weight analysis during simulated daily clinical use.

## Method:

Each adhesive was used 5 times a day to simulate daily clinical use. A standard class I plastic cavity model was used for each adhesive application. A precision scale with a sensitivity of 0.0001g was used to weigh the bottles/VivaPen®, applicators, mixing wells and plastic cavity model before and after each use. For Adhese® Universal, three clicks with the VivaPen were used per application. One drop of adhesive was used per application for the adhesive products in conventional bottle delivery. Mixing wells were used for all bottle-delivered adhesives as indicated by the manufacturer's instructions for use.

## Results:

With over 190 single-tooth applications per 2 millilitre VivaPen, Adhese Universal in the VivaPen demonstrated the highest number of applications, at 96 per millilitre – almost 3 times more applications per millilitre than other conventional bottle delivery systems. Correspondingly, it also exhibited the lowest amount of material loss compared to conventional bottle delivery systems.



## Conclusion:

Simple "click activation" dispenses the exact amount of material needed for each procedure. Dispensing of adhesive material into a mixing well is no longer required, which results in a significant reduction in material waste. Compared to conventional bottle delivery forms, Adhese Universal in the VivaPen demonstrated greater efficiency compared to conventional bottle delivery forms.





# Clinical investigations

# Clinical effectiveness of bulk-filled versus incremental-layered composite restorations using Adhese® Universal with Tetric EvoCeram® Bulk Fill

## Interim baseline report for a practice-based, randomized, controlled, prospective clinical study

*Study coordination:* Continental European Division of the International Association for Dental Research Practice Based Research Network in Croatia, Hungary, Serbia  
*Study period:* Sept. 2013–Oct. 2015  
*Study author(s):* Miletic V., Tarle Z., Stájer A., Ferrari M., Peschke A., Hickel R., Van Meerbeek B.

### Objective:

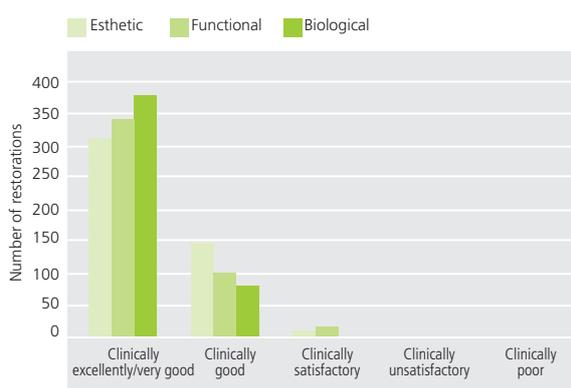
To evaluate the clinical effectiveness of "Bulk-Filled" versus "Incremental-Layered" composite restorations in class II cavities using Adhese® Universal (selective-enamel-etch) with Tetric EvoCeram® Bulk Fill. The research hypothesis states that "Bulk-Filled" composite restorations perform clinically as good as traditional "Incremental-Layered" composite restorations.

### Method:

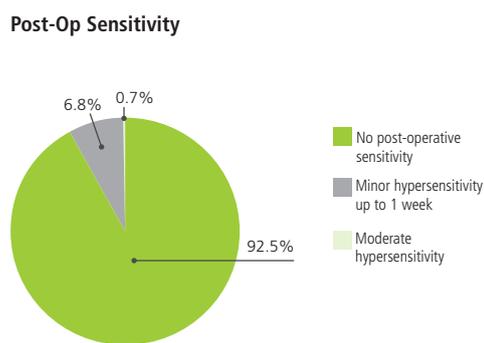
Two class II composite restorations per patient were prepared: 1 restoration using the "Bulk-Fill" technique and the other using the "Incremental-Layered" technique. Recalls were completed after 14 days and 1 year. Additional recalls will be conducted after 2 years, 3 years, 5 years and 8 years.

### Results:

A total of 254 patients were treated with 488 restorations placed. The baseline evaluations were completed. Both techniques demonstrated excellent or very good esthetic, functional and biological properties. Post-operative sensitivity: 92.5% demonstrated no post-operative sensitivity and were rated as clinically excellent (FDI rating: 1), 6.8% showed minor hypersensitivity up to 1 week and were rated as clinically good (FDI rating: 2) and only 0.7% showed moderate hypersensitivity and were rated as clinically sufficient (FDI rating: 3).



Overview of the esthetic, functional and biological properties for all placed restorations



Frequency of post-operative sensitivity

### Conclusion:

Adhese Universal applied using the "selective-enamel-etch" protocol with Tetric EvoCeram Bulk Fill for the "Bulk-Filled" or "Incremental-Layered" composite restorations demonstrated excellent results with regard to the esthetic appearance. A very low rate of postoperative sensitivity was also reported.

# Adhese® Universal

## One-year clinical performance report

*Study location:* The Dental Advisor – Ann Arbor, Michigan USA  
*Study period:* 2014–2015

### Objective:

To evaluate the clinical performance of Adhese® Universal after 1 year.

### Method:

Adhese Universal was used to place a total of 83 direct and indirect restorations. At 1 year, 73 of these restorations (1 zirconia crown, 5 IPS e.max® veneers, 67 universal composite restorations) were available for recall. Restorations bonded with Adhese Universal were evaluated in the following categories: lack of postoperative sensitivity, resistance to marginal discolouration and retention. The restorations were evaluated on a 1–5 rating scale: 1 = poor, 2 = fair, 3 = good, 4 = very good, 5 = excellent.

### Results:

No sensitivity was reported by patients in any of the retained restorations placed with Adhese Universal. 95% of the restorations showed no signs of marginal staining. 3 anterior composite restorations exhibited slight marginal staining. 99% of the restorations were retained after 1 year in service. One large anterior composite restoration debonded and was replaced.



The Dental Advisor rating (1 – 5) for Adhese Universal at 1 year  
(1 = poor, 2 = fair, 3 = good, 4 = very good, 5 = excellent)

### Conclusion:

The clinical outcomes for this one-year evaluation of 73 restorations using Adhese Universal were exceptional. All restorations received excellent ratings for lack of postoperative sensitivity, resistance to marginal discolouration and retention. Adhese Universal received a 99% clinical performance rating at 1 year.

**Reference:** The Dental Advisor, Vol. 32, Nr. 10, Dec. 2015<sup>4</sup>

## Clinical evaluation of Adhese® Universal as an etch & rinse adhesive in direct restorative therapy

Study location: University of Turin – Turin, Italy  
Study period: 6 months, 2015  
Study author(s): Scotti N.

### Objective:

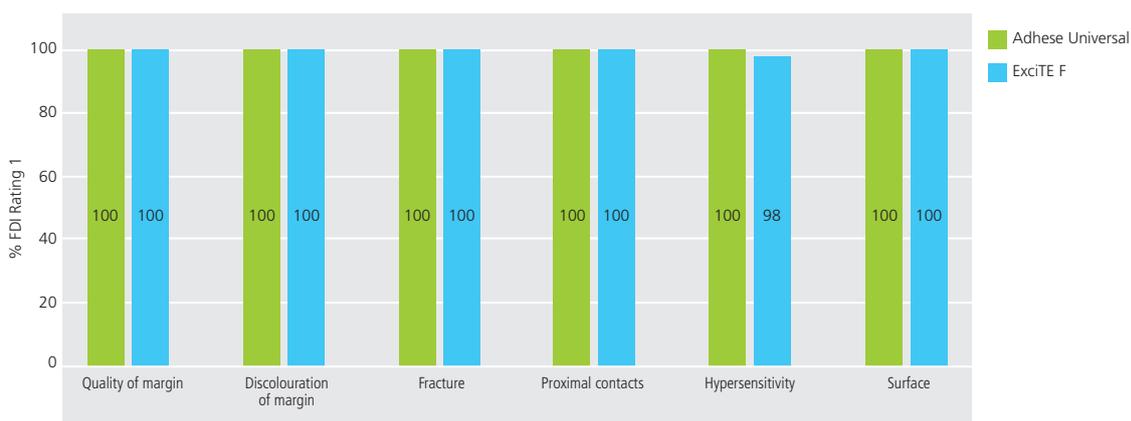
To evaluate the clinical behaviour of Adhese® Universal using the etch&rinse technique in combination with Tetric EvoCeram® Bulk Fill for the restoration of class I and II cavities; and compare it to the clinically proven Excite® F (Ivoclar Vivadent) etch & rinse adhesive. In particular, the occurrence of post-operative sensitivity should be evaluated in addition to the semi-quantitative analysis of the marginal behaviour.

### Method:

103 class I and II restorations were placed with Tetric EvoCeram with Adhese Universal and Excite F using the etch&rinse technique. At the 6 months recall, 101 restorations were available for recall (51 with Adhese Universal, 50 with Excite F). Restorations completed with both adhesive systems were evaluated in accordance with the Semi-Quantitative Clinical Evaluation Method (SQUACE) and FDI criteria. Differences between SQUACE and FDI values were performed using the one-way ANOVA test and Bonferroni post-hoc test. Statistical significance was set at  $p < 0.05$ .

### Results:

Statistical analyses showed that both SQUACE and FDI values were not influenced by the two adhesive systems employed at the 6 month recall. Patients did not experience any complications. Post-operative sensitivity: 100% of the restorations using Adhese Universal and Excite F were evaluated as “excellent” (100% FDI rating: 1) according to the FDI evaluation criteria. Fracture of material and retention: 100% of the restorations using Adhese Universal were rated as “clinically excellent” (FDI rating: 1) according to the FDI evaluation criteria while 2% of the restorations using Excite F were rated as “clinically good” (FDI rating: 2). The SQUACE results are presented in the table below.



Overview of the esthetic, functional and biological properties for all placed restorations.  
Percentage of FDI Rating 1 "clinically excellent/very good"

### Conclusion:

In conjunction with the etch & rinse protocol and the clinically proven restorative material Tetric EvoCeram, Adhese Universal demonstrated excellent clinical performance and a comparable level of restorative quality compared to a clinically-proven adhesive system with regard to the defined criteria. No postoperative sensitivity was reported for Adhese Universal.

# Clinical evaluation of a universal adhesive in non-carious cervical lesions

*Study location:* Indiana University School of Dentistry – Indianapolis, Indiana USA  
*Study period:* 6 months, 2015  
*Study author(s):* Platt J., Diefenderfer K., Rouse M., Cook N.B., Capin O., Adams B., Kirkup M.

**Objective:**

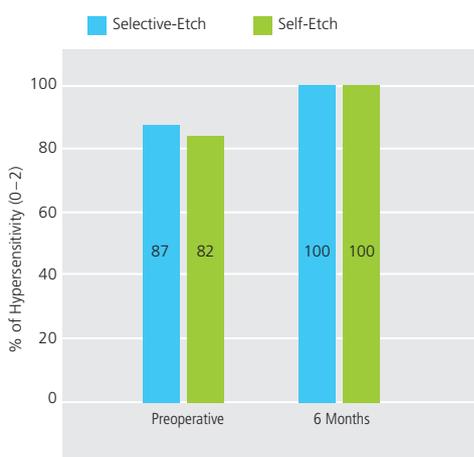
To evaluate the clinical performance of Adhese® Universal using the self-etch and selective-etch technique in combination with Tetric EvoCeram® in patients with at least 2 non-carious cervical lesions present in canine or premolar teeth.

**Method:**

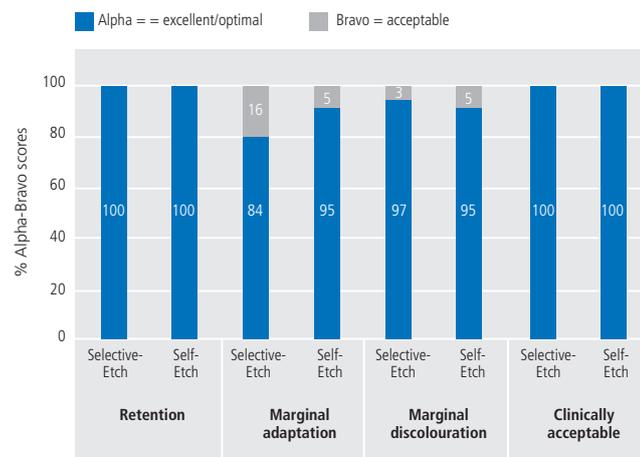
81 lesions were restored in 33 patients using Adhese Universal with the self-etch and selective-etch technique in combination with Tetric EvoCeram. If the lesion was greater than 2 mm in any dimension, which was the case for most of the restorations, incremental placement was performed using Tetric EvoCeram with the first incremental layer being placed against enamel. Pre-operative sensitivity was performed using a blast of air (from approximately 1 cm for 1 second) and evaluated with the "0–10 Numeric Pain Scale" (0=no hypersensitivity, 10=maximum hypersensitivity). Each restoration was evaluated with regards to retention, marginal adaptation and discolouration.

**Results:**

At the 6 month recall, 76 restorations were available for recall in 31 patients. No significant differences were observed between the groups. Marginal adaptation was significantly worse at 6 months than at baseline for the selective-etch group ( $p=0.0094$ ), but there was no difference for the self-etch group ( $p=0.51$ ). Marginal discolouration did not change significantly from baseline to 6 months for the selective-etch group ( $p=0.32$ ) or self-etch group ( $p=0.16$ ). In 27 cases, preoperative sensitivity improved from baseline to 6 months for the selective-etch group ( $p=0.0024$ ) and the self-etch group ( $p=0.0010$ ). 1 restoration improved from a sensitivity of 10 to 2 (low hypersensitivity), and 3 restorations improved from 6 to 0 (no hypersensitivity). No change was observed in 46 restorations, and sensitivity increased from 0 to 1 (low hypersensitivity) for 3 restorations. All restorations were retained and clinically acceptable.



Percentage of low hypersensitivity (0–2) on a Numeric Pain Scale from 0–10 at preoperative and after 6 months



Percentage of "Alpha" rating after 6 months: USPHS criteria

**Conclusion:**

Adhese Universal applied using both etching protocols demonstrated excellent results in class V fillings after 6 months with regard to retention, marginal quality and clinical acceptance. Virtually no postoperative sensitivity was reported for both groups after 6 months.

## Clinical behaviour of direct-placed composite restorations after 2 years using Adhese® Universal

*Study location:* R&D Clinic, Ivoclar Vivadent AG – Schaan, Liechtenstein  
*Study period:* 2013–2015  
*Study author(s):* Huth S., Enggist L., Peschke A., Watzke R.

### Objective:

The objective of this clinical observation was to evaluate the clinical performance of the universal adhesive Adhese® Universal in cavity classes I and II using the etch & rinse protocol for direct-placed composite restorations after 2 years.

### Method:

A total of 40 fillings (16 class I, 24 class II) were placed using Adhese Universal with the etch & rinse-technique in combination with the composite filling material Tetric EvoCeram® Bulk Fill (Ivoclar Vivadent). All 40 of the restorations were evaluated at baseline and after 6, 12 and 24 months of clinical service with regards to the esthetic, functional and biological properties using the FDI criteria (Hickel et al. 2010). The semi-quantitative clinical evaluation method (SQUACE) was also used.

### Results:

After 2 years, 36 restorations were available for evaluation. 100% of the restorations were still in place (i.e. no debondings). All restorations showed an FDI rating that ranged between “excellent” and “good” (FDI rating criteria 1 & 2). In reference to post-operative sensitivity, 100% of the restorations were evaluated as excellent (FDI rating 1) at the baseline evaluation and after 24-months, i.e. no hypersensitivity/normal vitality after testing by the dentist with cold spray and mechanical disturbance. In reference to marginal staining, 99.0% of the total margin length observed reported as “clinically excellent” (FDI rating 1) and 1.0% as “clinically good” (FDI rating 2). Documented marginal flaws (marginal irregularities) concerned only a small portion of the total margin length, representing an average of 24.6% of the total margin length. These sections were rated as “clinically good” (FDI rating 2). 75.4% of the total margin length was evaluated as “clinically excellent” (FDI rating 1) in reference to marginal irregularities.



Overview of the esthetic, functional and biological properties for all placed restorations  
 Percentage of FDI Rating 1 "Excellent/Very Good" & FDI Rating 2 "Good"

### Conclusion:

The combination of Adhese Universal using the etch & rinse technique with Tetric EvoCeram Bulk Fill demonstrated reliable and effective results for class I and II cavities. Tetric EvoCeram Bulk Fill showed excellent to good esthetic results in reference to marginal quality, surface lustre, surface staining and colour match. Due to effective bonding, no debondings or post-operative sensitivity was reported after 2 years of service.

**Reference:** Huth et al. Academy of Dental Materials 2015<sup>5</sup>

## Clinical observation involving Tetric EvoFlow® Bulk Fill / Tetric EvoCeram® Bulk Fill

*Study location:* R&D Clinic, Ivoclar Vivadent AG – Schaan, Liechtenstein  
*Study period:* 6 month clinical observation, 2015  
*Study author(s):* Huth S., Enggist L., Peschke A., Watzke R.

### Objective:

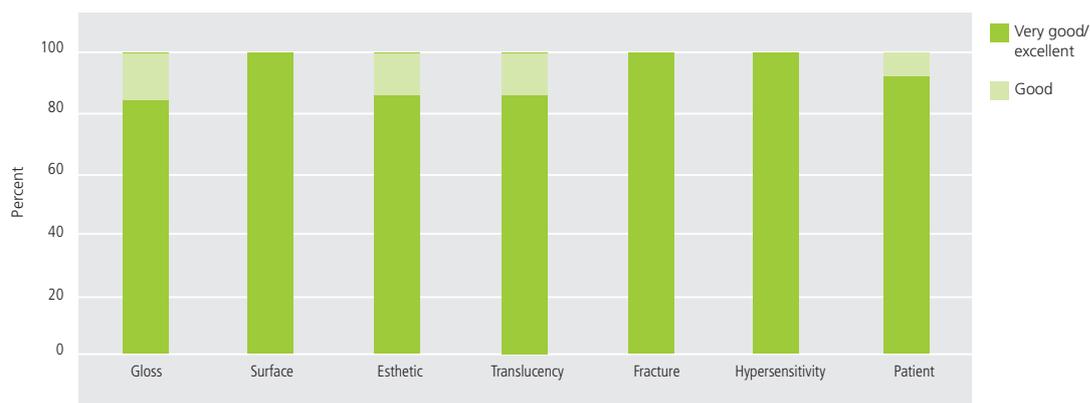
The objective of this clinical observation was to evaluate the clinical performance of the universal adhesive Adhese® Universal in cavity classes I and II using the etch & rinse and self-etch protocols for direct-placed composite restorations with Tetric EvoCeram® Bulk Fill after 6 months.

### Method:

The 6 month clinical performance of Tetric EvoFlow® Bulk Fill in posterior cavities was examined based on selective FDI criteria<sup>6</sup>. The FDI evaluation criteria covered the esthetic, functional and biological properties of the material. Thirty (6 class I and 24 class II) cavities were restored using Adhese Universal as the bonding agent (15 self-etch technique / 15 etch & rinse technique). Tetric EvoFlow Bulk Fill was applied to each cavity in a layer of up to 4 mm and subsequently light-cured. This was followed by a capping layer of Tetric EvoCeram Bulk Fill.

### Results:

After 6 months, 100% of the fillings examined were intact. There were no reports of hypersensitivity. All the fillings were rated "very good, excellent" or "good" according to the FDI recall criteria. With regard to "Gloss", 86.7% of the restorations were rated "very good" and 13.3% "good". None of the fillings showed discolouration of the surface. "Esthetics" were rated "very good" in 86.7% of the cases and "good" in 13.3% of the cases. The clinicians used the universal shades <sup>IV</sup>A (23 fillings) and <sup>IV</sup>B (7 fillings). The translucency of the fillings was rated "very good" in the majority of the cases (86.7%). A slight deviation of the translucency was observed in four fillings (13.3%, FDI rating 2). No filling fractures or loss of retention occurred. The patients themselves also gave the fillings an "excellent" (93.3%) or "good" (6.7 %) rating.



Overview of the esthetic, functional and biological properties for all placed restorations  
 Percentage of FDI Rating 1 "Excellent/Very Good" & FDI Rating 2 "Good"

### Conclusion:

One hundred per cent of the restorations were still intact after 6 months. There were no cases of hypersensitivity. Even though only two universal shades were used (<sup>IV</sup>A, <sup>IV</sup>B), the esthetic appearance of the fillings was rated "very good" (86.7%) or "good" (13.3%). Tetric EvoFlow Bulk Fill and Tetric EvoCeram Bulk Fill in combination with Adhese Universal appear to be appropriate materials for efficiently and adequately restoring posterior teeth.





# Clinical product evaluations

## Adhese® Universal – Clinical product evaluation

Study location: The Dental Advisor – Ann Arbor, Michigan USA

Study period: 2015

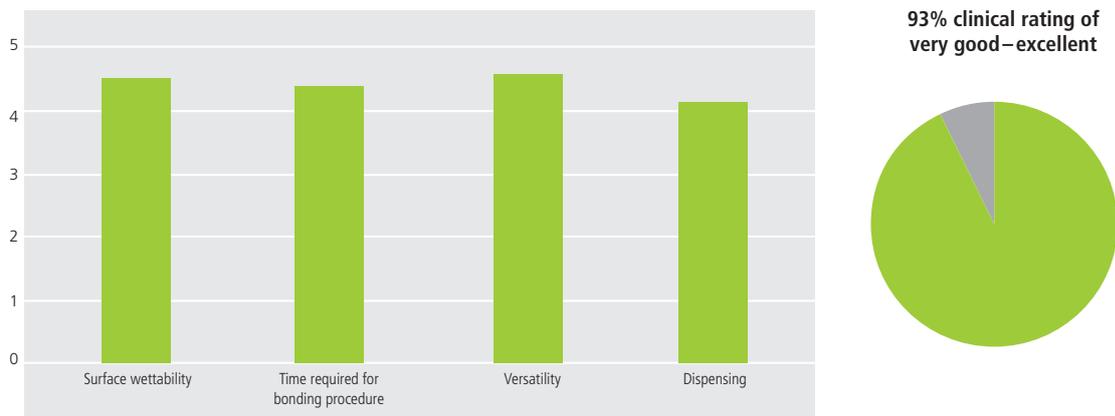


### Method:

32 consulting dentists for The Dental Advisor evaluated Adhese® Universal in the VivaPen® delivery form in 1158 uses. The consultants rated the surface wettability, time required for the bonding procedure, versatility and dispensing. They were also asked to compare Adhese Universal to their current brand of adhesive and whether or not they would switch to using it or recommend it to a colleague.

### Results:

Adhese Universal in the VivaPen received a 93% clinical rating (very good-excellent) after 1158 uses. Consultants commented positively about its low film thickness, absence of post-operative sensitivity, lower waste compared to bottle or unit-dose delivery, precise application, versatile material for most bonding applications, and no separate brushes or wells needed. 41% of consultants rated Adhese Universal as better than their current adhesive and 50% as equivalent. 69% said they would switch to Adhese Universal and 88% would recommend it.



The Dental Advisor Editor's Choice rating for Adhese Universal (n=32 dentists, 1158 applications)  
(1=poor, 2=fair, 3=good, 4=very good, 5=excellent)

### Conclusion:

Adhese Universal in the VivaPen achieved a 93% clinical rating for the Editors' Choice Award in March 2015.

**Reference:** The Dental Advisor, Vol. 32, No. 02, March 2015<sup>7</sup>

# Adhese® Universal Clinical product evaluation

Study location: Barometer Verlagsgesellschaft mbH – Leipzig, Germany  
Study period: 2014

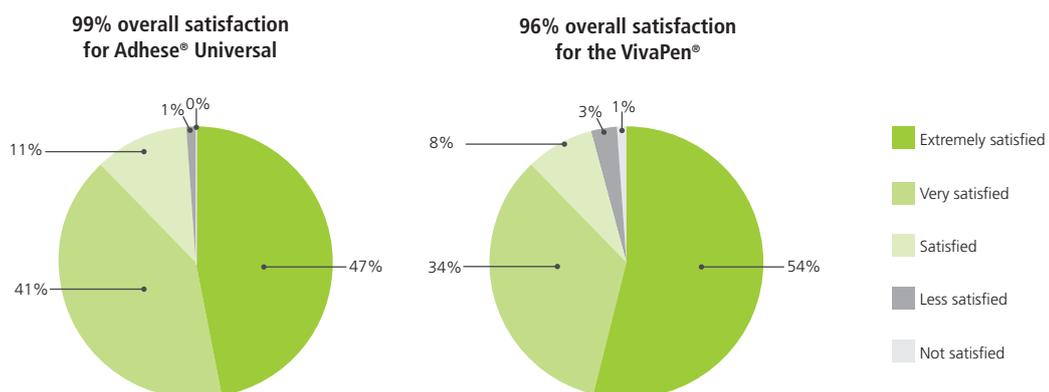


## Method:

66 dentists in Germany evaluated Adhese® Universal in the VivaPen® delivery form in their practice. Participants rated their overall satisfaction for Adhese Universal and the VivaPen. They were also asked whether or not they would switch to using it afterwards.

## Results:

99% of the participants were positively satisfied with the performance of Adhese Universal (47% extremely satisfied, 41% very satisfied, 11% satisfied). 96% of the participants were positively satisfied with the VivaPen delivery form (54% extremely satisfied, 34% very satisfied, 8% satisfied). Participants commented positively about Adhese Universal's simple handling, good retention and time savings. 59% of the participants would switch to using Adhese Universal. No post-operative sensitivity was reported.



Clinical product evaluation for Adhese Universal (n = 66 dentists) in Germany.

## Conclusion:

Adhese Universal achieved a high satisfaction rate after clinical evaluation with regard to its clinical performance as well as the efficiency of the VivaPen compared to conventional bottle delivery forms.

**Reference:** Barometer Verlagsgesellschaft, September 2014<sup>8</sup>

## Adhese® Universal – Clinical product evaluation of the VivaPen® versus bottle

*Study location:* Marketing Ivoclar Vivadent AG – Schaan, Liechtenstein  
*Study period:* 2014  
*Study author(s):* Scheftner M.

### Method:

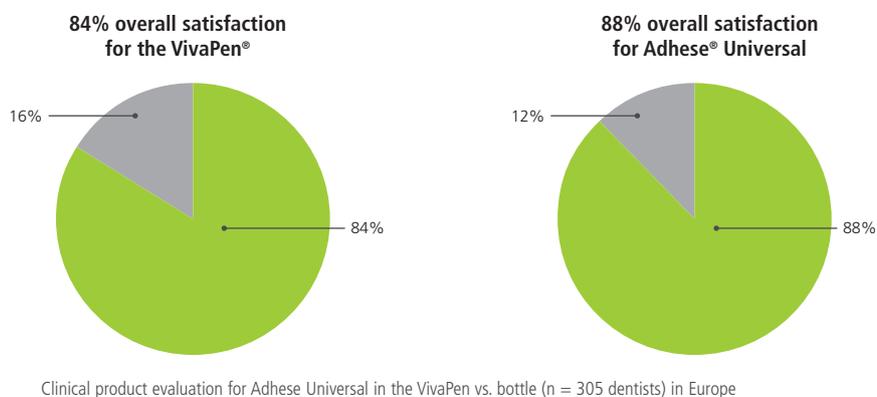
305 dentists in Europe evaluated Adhese® Universal in the VivaPen® versus bottle delivery form in their practice. Participants rated their overall satisfaction for Adhese Universal and the VivaPen. They were also asked whether or not they would switch to using it afterwards.

### Results:

84% of the participants were positively satisfied with the VivaPen delivery form with regard to its easy and quick direct intraoral application, ergonomic pen-like design, exact dispensing of fresh material every time with the click mechanism, angled shape of the snap-on cannula brush, hygiene, integrated fill-level indicator, flocked cannula brush, and waste of material.

88% of the participants were positively satisfied with the performance of Adhese Universal with regard to its ease of use/application, good esthetic results, compatibility with any application protocol for direct and indirect bonding procedures, low film thickness and no post-operative sensitivity.

78% of the participants would switch to using Adhese Universal. No post-operative sensitivity was reported.



### Conclusion:

The results revealed a high preference towards the use of Adhese Universal in the VivaPen compared to conventional bottle delivery. Adhese Universal also achieved a high satisfaction rate with regard to its clinical performance.



# Terminology/ Literature

## Terminology

### Bulk fill

Dental composites denoted as bulk fill are restorative materials that can be applied in thick increments i.e. typically in increments of 4 mm or more, as opposed to standard composites which are traditionally applied in up to 2 mm increments. Bulk-fill materials are available in sculptable and flowable form depending on the manufacturer. Sculptable bulk fill composites can be applied in one layer, while flowable composites require additional application of a sculptable composite in order to create the natural tooth topography.

### Cvar and Ryge/ USPHS criteria

The Cvar and Ryge method of evaluation is interchangeably referred to as Cvar & Ryge criteria, Ryge criteria or the USPHS criteria. The criteria were drawn up at a time when the longevity of direct restorative materials, other than amalgam, was limited. Therefore, many modifications of this criteria have been made by various authors in an attempt to make the criteria more discriminating for modern restorative materials. This is referred to as the modified Ryge or modified USPHS criteria. Virtually every modification is slightly different (Hickel et al, 2007). The criteria uses the Alpha, Bravo, Charlie, Delta evaluation scale. These scores have different meanings depending on the criteria being assessed:

- Alpha = excellent/optimal
- Bravo = acceptable
- Charlie = unacceptable/insufficient
- Delta = needs replacing

### Desiccated dentin

Excessive drying of dentin (over-drying  $\geq 10$  s) can result in the collapse of the collagen mesh or network, which typically forms a dense film that is difficult to penetrate by the bond agent.

### FDI criteria (Hickel et al, 2007)

As part of the FDI World Dental Federation Science Committee, Hickel et al published a paper in 2007 outlining a proposal for a more modern clinical evaluation of composite restorations. They presented evaluation criteria related to the original Ryge criteria. Restorations were evaluated accordingly:

- Score 1 = Excellent
- Score 2 = Very good but not ideal
- Score 3 = Sufficient with minor shortcomings
- Score 4 = Unacceptable but repairable
- Score 5 = Unacceptable and needs replacing

Hickel et al compare their scoring system with Cvar and Ryge accordingly:

Cvar & Ryge	Hickel/FDI	
<b>Alpha</b>	Scores 1 & 2	Clinically excellent/good
<b>Bravo</b>	Score 3	Clinically satisfactory
<b>Charlie</b>	Score 4	Clinically unsatisfactory
<b>Delta</b>	Score 5	Clinically poor

### *In vitro* studies

*In vitro* refers to examinations conducted in a laboratory. Many materials science or toxicological tests are carried out *in vitro*, since they cannot be conducted on human beings or animals 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.

<b><i>In vivo</i> studies</b>	<i>In vivo</i> in this report refers to clinical studies on human beings. The advantage is that they are conducted under clinical conditions. They are typically complex due to several possible influential factors. They require exact planning, systematic methods and statistically correct evaluation. Randomised controlled studies are considered the gold standard.
<b>ISO 29022</b>	An international standard that defines a shear bond test in order to monitor the adhesive bond strength. Process steps such as substrate selection, storage and handling are prescribed by this standard.
<b>Self-etch technique</b>	The process of conditioning the surface of the enamel and dentin without the use of phosphoric acid by using self-etch adhesive systems that contain acidic monomers to etch/prime the enamel and dentin.
<b>Selective-enamel-etch technique</b>	The process of cleaning and roughening the surface of the enamel margins of the preparation with phosphoric acid and thoroughly rinsing the residue off with water to promote micromechanical bonding of an adhesive to enamel.
<b>Shear bond strength</b>	A preformed cylinder (e.g. polymerized composite) is bonded to a substrate (tooth or restorative material) and then sheared off by application of a force parallel to the bonding surface.
<b>Studies</b>	Studies are conducted to forecast or examine the behaviour of materials when used for the intended application. Most frequently, the aspects of functionality, reliability and safety, compatibility or user-friendliness are of interest.
<b>Tensile bond strength</b>	A preformed cylinder (e.g. polymerized composite) is bonded to a substrate (tooth or restorative material) and then sheared/pulled apart by application of a pull-out force from the bonding surface. Different methods of bond strength testing highlight different aspects of the adhesive properties and are best used in combination to maximize the significance of data. The absolute values obtained depend on the exact test methodology employed and should only be compared using samples prepared by the same lab using the same methodology.
<b>Thermal cycling</b>	Test samples are thermal cycled (e.g. 5,000 times) between 5°C and 55°C to simulate aging and thermal stress on the adhesive bond induced by eating, drinking and breathing. Afterwards, test specimens are subjected to either shear or tensile bond strength testing.
<b>Thermo-mechanical loading</b>	Test samples are thermal cycled (e.g. 5,000 times) between 5°C and 55°C and loaded with a force to simulate aging and thermal stress on the adhesive bond induced by chewing, eating, drinking and breathing. Afterwards, test specimens are subjected to either shear or tensile bond strength testing.
<b>Total-etch or etch &amp; rinse technique</b>	The process of cleaning and roughening the surface of the enamel and dentin with phosphoric acid and thoroughly rinsing the residue off with water to promote micromechanical bonding of an adhesive to enamel and dentin.

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- [10] *Dental Economics* 2014, December, Vol 104, Nr 12



# Testimonials

”

*The in-vitro test results of Adhese Universal demonstrate comparable results to multi-component Gold Standard systems. After long-term testing, universal adhesives have the potential to become the future Gold Standard in dentistry.*

”



**Dr med. dent. Uwe Blunck**  
Charité – Universitätsmedizin  
Berlin, Germany

”

*At present, the ideal way of creating a durable bond to the dental hard tissues is by combining selective-enamel-etching with a self-etch adhesive. As this can be very difficult to implement in practice, the best solution available for the adhesive technique are either conventional, multi-bottle adhesives or universal adhesives. The latter help to significantly reduce technique sensitivity and error proneness, and they are capable of establishing a chemical bond to dentin.*

Excerpt from Quintessenz 2015; 66(11):1261-1267 <sup>9</sup>

”



**Univ.-Prof. Dr Roland Frankenberger**  
Universitätsklinikum Giessen und  
Marburg – Marburg, Germany

” *The Adhese® Universal VivaPen® by Ivoclar Vivadent is my favorite product of the year! This nifty little delivery system (VivaPen) enables the clinician to dispense only the exact amount of adhesive needed for each restoration. The adhesive itself is kept in a hermetically sealed compartment that eliminates evaporation and other adverse effects from oxygen. The single-use, tufted tip applicator can be attached to the pen to allow for the adhesive to be dispensed directly to the preparation in the mouth.... I was very loyal to my former bonding system, but the Adhese Universal VivaPen broke up my relationship with my old bonding agent. I couldn't be happier!* ”

Excerpt from Dental Economics 2014, December, Vol 104, Nr 12 <sup>10</sup>



**Dr Joshua Austin**  
San Antonio,  
Texas USA

” *I think one of the things I like about it a lot is the simplicity. What's nice about the universal generation of adhesives is you can do either direct or indirect restorations with it, and whether you do total-etch, selective-etch or self-etch, it really, in that way, simplifies things, and it often saves in cost. That is a huge thing.* ”



**Dr Amanda Seay**  
Park West Dentistry  
Mount Pleasant, South Carolina  
USA

” *First what comes to my mind is the flexibility. Because it is a universal adhesive. So if I want to do a total-etch I can use this, if I want self-etch, I can use my Adhese® Universal and if I want selective-etch I can use that same adhesive. So having one thing my assistant has to put out without thinking about it. For me it means great flexibility.* ”



**Dr Lee Ann Brady**  
Desert Sun Smiles Dental Care  
Glendale, Arizona USA





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