Adhese® Universal

The universal adhesive

Scientific Documentation

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passion vision innovation

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1. Introduction

Adhesive dentistry has undergone remarkable and constant progress over recent decades - and has undoubtedly co-revolutionized restorative dental practice.[1]

Dental adhesives have developed hand in hand with dental composites. Composite materials first became available in dentistry in the 1960s,[2] and initially were mainly used in the anterior region, where amalgam fillings were deemed unaesthetic. In the 1990s, they began to substitute amalgam as a universal filling material and composite restorations heralded a new minimally invasive era in dentistry. The retentive aspect of amalgam fillings was no longer necessary as the cavity to be filled, had only to be as large as the demineralized tissue to be removed. This "new" development in restorative dentistry was only possible due to the simultaneous development of clinically reliable enamel/dentin adhesives. The nature of these adhesives and composites has continued to change over time.

1.1 Mechanism of dental adhesion

Two basic types of adhesion are possible:

Mechanical: via the penetration of adhesive resin into the tooth surface.

Chemical: via chemical bonding to the inorganic component (hydroxyapatite) or organic components (collagen) of the tooth structure.

Irrespective of adhesive type, a combination of the above is usually responsible for bonding with all modern adhesives.

1.1.1 Substrate

Adhesive systems must establish a bond to both the restoration and the dental hard tissue. Composite restoratives consist of a hydrophobic matrix in which different filler particles are embedded. Teeth are comprised of two very different substrates: enamel and dentin. Enamel is essentially 96% hydroxyapatite, crystalline calcium phosphate, and 4% organic material and water[3] whereas dentin consists of 70% hydroxyapatite, 20% collagen and 10% water.[4] Enamel is thus an essentially dry substrate, whilst dentin is moist, though both can be considered essentially hydrophilic in comparison to restorative materials. Adhesives therefore need to possess both hydrophobic and hydrophilic properties in order to establish a bond to both tooth and restorative substrates.

1.1.2 Smear layer

The smear layer refers to a layer of dental "debris" about one micron thick lying over the prepared sections of tooth after instrumentation. It may have a protective function as it lowers dentin permeability; however as it partly penetrates the dentin tubuli it can pose a challenge to effective bonding.[1] With early composite materials, it was observed that bonding agents that removed the smear layer, achieved better retention rates in clinical trials than those that merely modified it.[5,6] Removal of the smear layer appeared to be a prerequisite for adhesion to dentin, and remains a largely accepted concept. Studies found that if the smear layer was left in place, only about 5 MPa of bond could be achieved prior to cohesive fracture within the smear layer.[7,8]

This led to the establishment of the group of bonding materials referred to as "total-etch" and later on "etch-and-rinse" adhesives.

Etching enamel: Buonocore (1955) was the first to demonstrate the acid etch technique on enamel.[9] It increases the surface area, by leaving an irregular white etch pattern (Fig. 1). The enamel prisms of enamel are cut either transversely or vertically during preparation and a micro-retention pattern forms during etching because the central and peripheral parts of the prisms feature different degrees of acid-solubility.[10] A resin-based fluid, aided by capillary action is then able to flow into the micro-porosities created. Monomers polymerize and become interlocked with the enamel as resin tags. A stronger acid or longer exposure to acid is required to obtain an optimal retentive pattern on enamel than is needed to expose dentinal collagen in dentin bonding.

Etching dentin: Etching dentin enlarges the tubular openings, removes or dissolves the smear layer and demineralizes surface dentin (Fig. 2). Demineralization of peri- and inter-tubular dentin results in a cup shaped expansion of the dentin tubules to a depth of approximately 10 µm[11], creating porous zones with exposed collagen fibrils. This is fundamental to achieving an effective bond.[12] Initially, etching dentin was problematic as the first adhesive materials were hydrophobic. They worked sufficiently on enamel, but were unable to penetrate and bond to "wet" dentin successfully. Modern hydrophilic resins however, penetrate moist etched dentin surfaces and form a hybrid layer whereby resin tags extending into the tubuli form a micro-mechanical bond. The hybrid layer seals the exposed dentin and is linked covalently to the composite restoration during polymerization of the first increment.

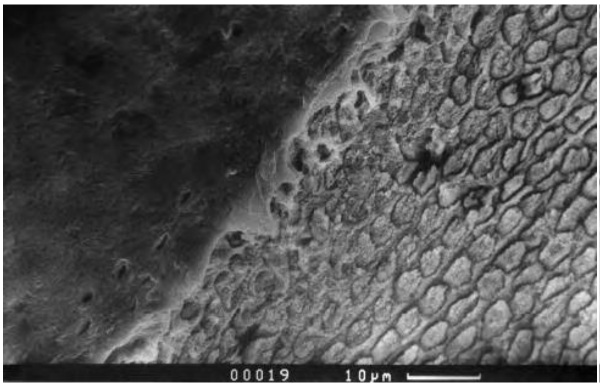


Fig. 1: **SEM Etched enamel:** Left side shows unetched enamel with smear layer intact. Right side shows etch pattern. *Dr P Gabriel, University of Leipzig*

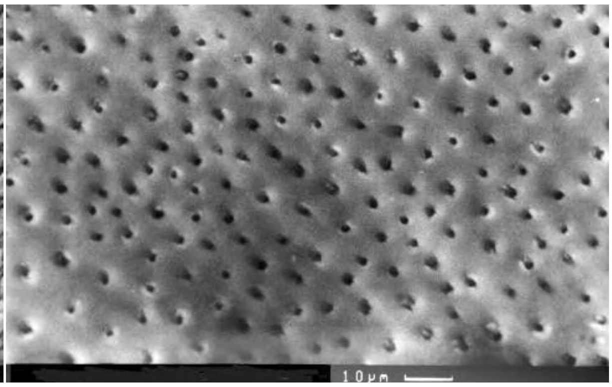


Fig. 2: **SEM Etched dentin:** Dentinal surface showing open tubuli after conditioning with the phosphoric acid Total-Etch. *Dr P Gabriel, University of Leipzig*

Hybridized dentin is a mixture of adhesive polymers and dental hard tissues, differing from the original tooth structure at a molecular-level. The fundamental principle therefore of adhesion to tooth substrates is based on an exchange process by which inorganic tooth material is exchanged for synthetic resin.[13]

1.2 Adhesive techniques

1.2.1 The "Total-Etch" or "Etch-and-Rinse" Technique

The "total-etch" term refers to the procedure whereby both enamel and dentin are etched before bonding. Total-etch adhesives involve an initial etching step with phosphoric acid (H_3PO_4) which removes the smear layer and conditions the preparation. The total-etch technique is also often referred to synonymously as the "etch-and-rinse" technique. The phosphoric acid is rinsed off with water together with the smear layer and the exposed dental tissue is carefully dried. Enamel is usually etched for longer than dentin. The *"how wet is wet?"* discussion refers to the necessity of not over-drying the dentin after etching and rinsing.

Dentin should remain moist and slightly glossy in appearance, such that the collagen fibrils do not collapse as this would make the surface less permeable to hydrophilic monomers in the adhesive and create a weak interface, potentially leading to a poor bond and postoperative sensitivity.

For this reason, plus the multi-step nature of the technique, total-etch adhesives are often referred to as technique-sensitive.[14] They are however very well established and clinically successful.[15, 16]

1.2.2 Selective-Etch Technique

This refers to the conventional etching technique whereby only the enamel edges of a preparation are etched with phosphoric acid and then rinsed with water. The dentin is then conditioned using either an acidic primer or all-in-one self-etching adhesive. The smear layer is modified but not removed as the surfaces are not rinsed with water after the primer application. This method can also be seen as an etch-and-rinse method for enamel only. This technique originally employed with total-etch adhesives (see Table 1), has enjoyed a resurgence in use with both self-etch adhesives and the new “universal” adhesives.

1.2.3 Self-Etch Technique

Self-etch adhesives are intended for use without a separate etching step. Self-etch systems contain acidic monomers that etch/prime the enamel and dentin. In contrast to total-etch systems, there is less danger of excessive demineralization of the dentin as self-etch systems have a milder pH level. The potentially technique-sensitive step of drying the dentin to just the right degree after etching is also not required; thus the danger of collagen-fibre collapse can be excluded. Each of these factors should reduce the risk of postoperative complaints. As mentioned above, some dentists choose to acid-etch the enamel selectively prior to using self-etch adhesives.

The new universal adhesives are usually indicated for use with any one of the above-mentioned etching techniques – depending on the clinical situation.

2. A brief History of Adhesives

In order to understand the current situation with adhesive dentistry, it is important to look to the past and how and why the various generations of adhesives developed. The concept of bonding to enamel and dentin was first considered over 50 years ago by Buonocore.[9] Extrapolating from industrial bonding techniques, he postulated that acids could be used as a surface treatment before the application of resins, and found that etching enamel with phosphoric acid increased the duration of adhesion under water. In 1963, he demonstrated further insight in discussing the differences of bonding to enamel vs. dentin.[17] In the late 1960s, he suggested it was the formation of resin tags in the micro-porosities of etched enamel that were principally responsible for adhesion; with adhesion to dentin proving more elusive due to its composition, water content and the smear layer.

The first dental adhesives therefore only bonded resins to enamel, with little or no adhesion to dentin. Adhesives then evolved step by step with changes in chemistry, application, mechanism of adhesion, technique and effectiveness – an evolution that accompanied the development of increasingly aesthetic dental materials, notably composite resins and ceramics.

3. Classification of Adhesives

Classifying adhesives into neat categories is nigh on impossible. Over the years, adhesives have been classified variably according to generation, method of etching, the number of bottles involved or the number of individual steps necessary for the entire bonding procedure. In addition to this, authors/dentists often define generations differently, they may or may not include etching in calculating the number of bottles or steps involved and some authors allocate specific adhesives to different groups, e.g. the classification of a multi-step adhesive with a separate primer (traditionally viewed as an etch-and-rinse adhesive) as a self-etch adhesive. Comparative analysis is undoubtedly hindered by these not inconsiderable and inconsistent overlaps in attempts at classification and differences in interpretation. The following paragraphs and Table 1 attempt to clarify the situation.

3.1 Classification by generation

Dental adhesives can to a degree be categorized chronologically according to generation - a historical system of identification commonly used by adhesive manufacturers. The generation simply refers to when and in what order this type of adhesive was developed by the dental industry, ranging from 1st generation in the 1960s to modern 7th generation adhesives.

1st and 2nd generation bonding agents are no longer used, due mainly to failed attempts to bond with a loosely bound smear layer. They achieved poor bond strengths of 2-8 MPa [18] and failed to prevent marginal gaps.[19] Manufacturers currently produce so-called 7th generation products, however 3rd, 4th, 5th and 6th generation adhesives remain popular and offer various advantages depending on the clinical situation and the clinician's personal preferences and experience. The new "universal" adhesives can be applied either using the total-etch, selective-etch or self-etch technique. Thus they fall rather into a new side class of adhesives rather than a totally new generation. The approximate timescale and principle differences between generations are shown in Table 1:

Generation	Developed	Mechanism / Steps		Description
1	1960s	**No Longer in Use**		Enamel etch only – poor adhesion
2	1970s			Enamel etch only – improved adhesion
3	1980s/1990s	**Etch & Rinse**	**Selective-Etch/ Multi-Step**	Selective enamel etch/etch-and-rinse with H_3PO_4. Dentin conditioned with primer to modify or remove smear layer
4	1990s		**Total-Etch/ Multi-/3-Step**	Total-etch/etch-and-rinse: separate primer and adhesive
5	Mid 1990s		**Total-Etch/ 2-Step**	Total-etch/etch-and-rinse: combined primer and adhesive
6	Late 1990s	**Self-Etch**	**Self-Etch/ 2-Step**	Self-etch: etch and primer combined then hydrophobic bonding i.e. self-etch/multi-component
7	2000 +		**Self-Etch/ 1-Step**	Self-etch: etch, primer and adhesive combined i.e. self-etch/single component
Universal	2011 +	**All-Etch**	**Total-/Self-/Selective-Etch/ 1 or 2-Step**	Total or selective etch procedure followed by universal adhesive or universal adhesive only in self-etch mode

Table 1: Classification overview of adhesives according to generation, mechanism of adhesion and number of clinical steps.

3.1.1 Generations of Ivoclar Vivadent adhesives

The multi-step system Syntac can be seen as belonging to both the 3rd and 4th generation of adhesives as it can be used with the selective-etch technique (3rd generation) or the total-etch technique (4th generation). ExciTE F is a typical one bottle (or VivaPen) adhesive involving a separate total-etch step and belongs to the 5th generation. AdheSE as a two-step self-etch system belongs to the 6th generation and AdheSE One F a single component self-etching adhesive to the 7th generation. Adhese Universal belongs to the new universal class of adhesives that allows for all the etching techniques described in section 1.2.

3.2 Classification by mechanism of adhesion / clinical steps

Whilst the generational system of classification is helpful for looking at adhesives from a historical perspective, with regard to adhesives currently on the market (generations 3-7), it may be more meaningful to classify them according to how they work and how many working steps are involved.

Modern dental adhesives can be classified into two basic types: **etch-and-rinse** and **self-etch** adhesives. Although the etch-and-rinse term is often used synonymously for total-etch adhesives, theoretically it covers both total-etch and selective-etch adhesives (i.e. total-etch: both enamel and dentin are etched and rinsed; selective-etch: just the enamel is etched and rinsed). These systems can then be sub-categorized based on the number of clinical steps involved: e.g. multi-step, three-step and two-step etch-and-rinse systems and two-step and one-step self-etch systems.

The etch-and-rinse system is distinct in that it has a separate etch-and-rinse step prior to the priming and bonding steps. The three-step etch-and-rinse/total-etch system (using fourth-generation adhesives) follows the conventional “etch-rinse-prime-bond” approach. The two-step etch-and-rinse system (using fifth-generation adhesives, also known as one-bottle adhesives) combines the primer and the bonding agent into one application. The self-etch adhesive system eliminates the rinsing phase after etching by using non-rinse acidic monomers to etch and prime dentin simultaneously. The two-step self-etch system (involving sixth-generation adhesives) uses acidic monomers as self-etch primers in the initial step and an adhesive resin in the second step. The one-step self-etch system (using seventh generation adhesives, also known as all-in-one adhesives) combines the (self-etch) acidic primer with the adhesive resin in one application step. This allows for simultaneous infiltration of adhesive resin to the depth of demineralization, which may reduce postoperative sensitivity. The universal adhesives differ in terms of their claimed universality (see section 4). However, in general they too combine the acidic primer with the adhesive resin in one step, can be used with all etching techniques and are suitable for use with both direct and indirect restorations.

To provide an overview of adhesives from both a historical and current perspective, Table 1 attempts to combine both methods of classification.

Perception and trends in adhesive use

It is generally accepted that the more time given to adhesive technique, the better the clinical results; and that phosphoric acid etching remains the most effective way of pre-treating enamel due to the consistently better marginal quality achieved with this method.[20]
GfK (Gesellschaft für Marktforschung) figures from 2014 indicate that conventional bonding has fallen to approximately 42% of the market with self-etching accounting for approximately 40%. Universal adhesives however represent the fastest growing segment comprising approximately 18% of the market.

Due to differences in the ability of self-etch and total-etch adhesives in etching enamel and dentin, many dentists intuitively still prefer total-etch adhesives, notably if a major fraction of the bonding area is enamel e.g. aesthetically sensitive anterior restorations. Self-etch adhesives however have shown to provide superior and more predictable bond strengths to dentin and are, consequently, recommended for *direct* composite resin restorations, especially when predominantly supported by dentin.[21] There has also been considerable discussion about the "resurrection" of selective-etching for self-etch adhesives. Frankenberger compared dentin and enamel bond values for self-etch adhesives used according to manufacturer instructions and again after an initial total-etch step. Whereas enamel values were shown to increase considerably the values on dentin tended to worsen. Selective-etching would therefore appear sensible when bonding to both enamel and dentin.[20,22] According to Frankenberger, selective-etching always makes sense in combination with self-etch adhesives.[23]

This apparent reluctance to forego phosphoric etching entirely has led to the next classification of adhesives - universal adhesives which are not only less technique sensitive, but allow for the possibility of using the total- or selective-etching techniques as well.

4. Universal Adhesives

Universal adhesives appeared on the market in 2011. This new (largely 1-step) adhesive category helps simplify the complexity surrounding the many types and categories of bonding procedures, offering products that can be used with all etching protocols, for direct and indirect bonding procedures and with light-, dual- and self-cure materials. The table below taken from The Dental Advisor [24] gives a general overview of the varying indications for five different "universal" adhesives.

Product	**Company**	**Total-Etch Technique**	**Self-Etch Technique**	**Dual-cure materials** without separate activator	**Bonds to lithium disilicate** without separate primer	**Bonds to zirconia and metal** without separate primer
All-Bond Universal	Bisco Dental Products	✓	✓	✓	✓**	✓**
Peak Universal	Ultradent Products Inc.	✓	✓	✗	✗	✗
Scotchbond Universal	3M ESPE	✓	✓	✗*	✓	✓
Optibond XTR	Kerr Corporation	✗	✓	✓	✓	✓
Prime&Bond Elect	Dentsply Caulk	✓	✓	✗	✗	✗

Table 2: A summary of indications for universal bonding agents on the market. Adapted from The Dental Advisor, March 2013. [24]

* Requires separate activator unless it is used with RelyX Ultimate Adhesive Resin Cement.
** All-Bond Universal does bond to lithium disilicate and zirconia, but the manufacturer recommends using a pure silane with lithium disilicate and Z-Prime Plus with zirconia for optimum bond strengths.

As table 2 indicates, it is important to note that the meaning of the term “universal” differs from manufacturer to manufacturer. Universal usually relates to one or more of the following issues:

- compatibility with total-, selective- and self-etch techniques
- compatibility with direct and indirect bonding procedures
- ability to bond to different substrates
- ability to be used with dual- and self-cure materials (without the use of a separate activator)
- use as a primer for silica-based and/or zirconia-based and metallic restorations.

Universality is at times debateable. Although acceptable bond strengths were demonstrated to both enamel and dentin for the five universal adhesives noted in table 2 (in both total- and self-etch modes) [24] - some products have drawbacks e.g. Scotchbond Universal/3M ESPE requires a separate activator when used for indirect restorations unless it is used with one particular cement - RelyX Ultimate Adhesive Resin Cement/3M ESPE. Prime & Bond Elect/Dentsply can be used with all etching techniques, but is not alone compatible with dual-cure materials. Optibond XTR/Kerr is not indicated for the total-etch technique.

Adhese Universal is indicated for use with the total-etch, self-etch techniques and with dual-cure materials without a separate activator. It is not however indicated as a separate primer for restorative substrates - as incorporating silane components into the adhesive has failed to render convincing in-vitro data. An external investigation by Lehmann and Kern at the University Clinic Schleswig-Holstein, Germany evaluated the adhesive bond achieved with “universal” adhesives to lithium disilicate ceramic - compared to a system using a dedicated primer. Four groups were compared: Monobond Plus + Multilink Automix vs. Scotchbond Universal + RelyX Ultimate/3M ESPE, Optibond XTR + NX 3/Kerr and All-Bond Universal + Duo-Link/Bisco. Although the initial bonding values were acceptable in all groups, the group using Monobond Plus indicated the highest values initially and these values also remained stable after 150 days’ water-storage and thermocycling. The All-Bond Universal group de-bonded after 30 days and the remaining groups exhibited very low bonding values of approximately 10 MPa.[25] As priming the indirect restoration represents a separate step anyway, the advantage of using the same product here is debateable. For optimal results with indirect restorations, the use of a dedicated ceramic / metal primer, such as Monobond Plus is strongly recommended.

5. Ivoclar Vivadent Adhesive Range

Ivoclar Vivadent produces both total-etch and self-etch adhesives. The current range is depicted in table 3. There are valid pros and cons to both types of adhesive and of the multi-bottle/single bottle variants within these groups. Total-etch adhesives offer longer clinical experience, a more pronounced etch pattern in enamel and extensive removal of the smear layer. Self-etch adhesives on the other hand, may be less technique sensitive[26], reducing the danger of collagen collapse and can be applied in fewer steps. Adhese Universal aims to combine the advantages of both types of adhesive, offering dentists simplicity both in terms of application and the amount of practice-inventory required.

Total-Etch Adhesives		**Self-Etch Adhesives**
Light-Cure	**Dual-Cure**	**Light-Cure**
Syntac	Syntac	AdheSE
ExciTE F	ExciTE F DSC	
Universal Adhesives		
Adhese Universal		

Table 3: Ivoclar Vivadent adhesive range and associated category.

6. Adhese® Universal

Adhese Universal is a single-component, light-cured adhesive for direct and indirect bonding procedures. Adhese Universal is based on the know-how accumulated from the long standing performance of ExciTE (F), the AdheSE product family and Multilink Primer. It contains methacrylates, ethanol, water, highly dispersed silicon dioxide, initiators and stabilizers.

It is compatible with all etching protocols: total-etch, selective-etch and self-etch.

Fig. 3: Total-Etch (a), Selective-Etch (b) and Self-Etch (c) techniques with Adhese Universal. R&D Clinic Ivoclar Vivadent, FL, 2013.

The choice of tooth conditioning technique depends on the dentist's assessment of the clinical situation i.e. which will achieve superior clinical longevity and patient satisfaction. Adhese Universal is then applied to the cavity and rubbed into the surfaces for at least 20 seconds. Thereafter it is dispersed with oil/moisture-free compressed air until a thin glossy immobile film-layer results. Adhese Universal is always light-cured prior to use - for both direct and indirect bonding procedures.

6.1 Indications

Adhese Universal is indicated for bonding or repairing light-cured composite and compomer restorations, for core build ups with light-, self- and dual-curing composites, for the adhesive cementation of indirect restorations with light- or dual-curing luting composites, for sealing prepared tooth surfaces before the temporary/permanent cementation of indirect restorations (e.g. immediate dentin sealing/dual-bonding technique) and for desensitizing hypersensitive cervical areas. As Adhese Universal is always light-cured, it is contraindicated in situations where sufficient illumination cannot be ensured e.g. the cementation of root canal posts.

6.2 Mode of action

6.2.1 Bonding

The breakthrough in dentin bonding came with the multi-/three-step systems, which bridged the gap between the hydrophilic dentin and the hydrophobic resin-based filling materials, via the sequential application of the components. In essence, the multi-component systems meant that each bonding issue could be dealt with in turn enabling the practitioner to achieve a transition between the hydrophilic dentin and hydrophobic composite. Syntac is a classic example of a 3rd/4th generation adhesive. After etching and rinsing, the hydrophilic Syntac Primer is applied to the entire cavity (enamel and dentin) followed by the hydrophilic Syntac Adhesive and then a layer of the hydrophobic Heliobond. The table below illustrates the chronological advancement of Ivoclar Vivadent adhesives and the reduction in steps involved to achieve a bond between the restorative material and the tooth structure:

<table>
<tr><th>Working Step</th><th>Purpose</th><th>Syntac (1990)</th><th>ExciTE (F) (1999)</th><th>AdheSE (2002)</th><th>AdheSE One (F) (2007)</th><th>Adhese Universal (2014)</th></tr>
<tr><td>Enamel conditioning</td><td>Expose retentive etching pattern</td><td>Total Etch H_3PO_4</td><td rowspan="2">Total Etch H_3PO_4</td><td rowspan="3">AdheSE Primer</td><td rowspan="4">AdheSE One F</td><td rowspan="4">Adhese Universal</td></tr>
<tr><td>Dentin conditioning</td><td>Modify smear layer and expose collagen and tubules, infiltration and hydrophilic wetting</td><td>Syntac Primer</td></tr>
<tr><td>Wetting</td><td>Infiltrate collagen with hydrophilic resin. Create transition between hydrophilic substrate and restoration via tag formation</td><td>Syntac Adhesive</td><td rowspan="2">ExciTE (F)</td></tr>
<tr><td>Bonding</td><td>Hydrophobic bonding agent to bond to restoration via co-polymerization with restorative material</td><td>Heliobond</td><td>AdheSE Bonding</td></tr>
</table>

Table 4: Bonding steps and how Ivoclar Vivadent adhesives work.

Clearly adhesive development has aimed at providing dentists with products that are faster and easier to apply. Adhese Universal essentially belongs to a new class of adhesives rather than a new generation. In essence, it is also a one-bottle, self-etch adhesive (1-step) which can also be used according to the total-etch or selective-etching techniques (2-step) and for direct and indirect bonding procedures.

Adhese Universal and universal adhesives in general, contain low levels of acidic monomer, and are therefore “mild-etching” adhesives. Adhese Universal has a pH of approximately 2.5 – 3.0. The Adhese Universal matrix is based on a combination of monomers of hydrophilic (hydroxyethyl methacrylate/HEMA), hydrophobic (decandiol dimethacrylate/D3MA) and intermediate (bis-GMA) nature. This combination of properties allows Adhese Universal to reliably bridge the gap between the hydrophilic tooth substrate and the hydrophobic resin restorative, under a variety of surface conditions. Table 5 details the monomer matrix of Adhese Universal.

Monomer Name	Type	Purpose
MDP Methacryloyloxydecyl dihydrogen phosphate	Phosphoric acid methacrylate	Forms strong bond to hydroxyapatite surfaces. Promotes adhesion to tooth surface by formation of non-soluble Ca^{2+} salts.
MCAP	Methacrylated carboxylic acid polymer	Carboxylic acid functional polymer reacts with and bonds to hydroxyapatite. The presence of many carboxylic acid groups along a polymeric backbone/chain allows multiple bonds to the tooth surface.
HEMA Hydroxyethyl methacrylate	Hydrophilic mono-functional methacrylate	Promotes wetting of polar / inorganic and moist surfaces. Assists penetration of liquid filled dentinal tubuli.
Bis-GMA Bisphenol A glycidyl methacrylate	Hydrophilic / hydrophobic crosslinking dimethacrylate	Facilitates compatibility of hydrophilic HEMA and hydrophobic D3MA in the presence of water, thereby preventing phase separation of adhesive. Imparts high mechanical strength and resilience to adhesive layer.
D3MA Decandiol dimethacrylate	Hydrophobic crosslinking dimethacrylate	Enables the reaction of the adhesive with the less polar monomers of the filling or luting composite.

Table 5: Type and purpose of monomers contained in Adhese Universal.

Table 6 describes the bonding mechanism of Adhese Universal in more detail i.e. how the different bonding steps/conditions are achieved by the balanced composition of specific components within the formulation. Adhese Universal is considered here when used alone i.e. according to the **self-etch technique.**

For clarity, the traditional working/bonding “steps” as previously set out in table 4 are used. However, it should be made clear that with a one-step/one-liquid system, the steps are achieved simultaneously, not consecutively.

Working Step	Purpose	Adhese Universal
Enamel conditioning	Forms a stable bond via strongly bound monomer layer on enamel surface	• Hydrophilic phosphate group of MDP facilitates mild acid demineralization and formation of stable calcium salts and chemical bond to hydroxyapatite. • Agitation of adhesive for 20s maximizes contact of acid monomers (MDP and MCAP) with enamel surface. • Reliable wetting of hydroxyapatite due to synergistic effect of MDP and MCAP promotes higher bond strengths to enamel. • Precipitation of MDP as calcium salt provides stable bond to hydroxyapatite and promotes marginal integrity.
Dentin conditioning	Hybridisation and stabilising of smear layer Forms a stable bond via strongly bound monomer layer on dentinal surface	• Hydrophilic phosphoric acid group of MDP facilitates mild acid demineralization and formation of chemical bond with hydroxyapatite. • Agitation of adhesive for 20s maximizes contact of acid monomers (MDP and MCAP) with dentin surface. • Infiltration of dry and moist dentin is facilitated by hydrophilicity of HEMA – due to mild etching nature, dentin is not over-demineralized.
Wetting	Infiltrates collagen with hydrophilic resin	• Infiltration of hydrophilic surfaces is facilitated by hydrophilic monomers.
Bonding	Creates compatibility and transition between hydrophilic tooth substrate and hydrophobic composite	• Transition between hydrophilic tooth substrate and hydrophobic restorative aided by the hydrophilic/intermediate/hydrophobic monomer combination of HEMA, BisGMA and D3MA respectively.

Table 6: How Adhese Universal components achieve a bond as a one-step universal adhesive.

6.2.2 Desensitization

Dentin hypersensitivity is a common condition, notably after dental restorative work. It is generally agreed that hypersensitivity occurs due to fluid movements within the dentin tubuli in response to stimuli such as cold, warmth or osmotically active substances such as sugar.[27]

The water/ethanol solvents and the integrated micro-fillers used in Adhese Universal are designed to enhance penetration into the dentin tubuli to ensure the formation of a reliable dentin seal by a homogenous adhesive layer with defined resin tags. In addition, the acidic monomers contained in Adhese Universal trigger a coagulation of the proteins in the dentinal fluid - so contributing to the mechanical sealing of the tubuli by helping to prevent fluid movement and thus postoperative sensitivity associated with that movement. A combination of thixotropic silica and carboxylic acid functionalized polymer also facilitates the uniform film-formation of Adhese Universal. During the recommended 20 second scrubbing application, the adhesive flows over, penetrates and covers the dentine uniformly. Diffusion through the smear layer aids mechanical sealing and thus desensitization. (See section 8.8 Adhese Universal – dentin penetration and desensitization).

6.2.3 Adhesive cementation of indirect restorations

Adhesive layer thickness is an issue when seating indirect restorations. Adhese Universal is always “thinned out” with compressed air to form a thin layer – aided by the thixotropic silica filler. The adhesive layer is light-cured before seating indirect restorations – eliminating the need for an additional dual-cure activator. Curing Adhese Universal immobilizes the acid monomers and allows good polymerization at the adhesive/luting composite interface without a separate dual-cure activator (see section 8.7 for tests with indirect restorations).

The mild etching formulation also renders Adhese Universal compatible with the initiator systems of light- and dual-curing luting composites and light-, dual- and self-curing core build up composites.

6.3 Advanced delivery via VivaPen®

Adhese Universal is available in the unique VivaPen for precision dispensing as well as quick and easy intraoral application for optimum efficiency with minimum waste. The VivaPen features an easy-to-use click mechanism and enables targeted, single-handed deployment of the adhesive exactly where it is needed. A few clicks are sufficient to saturate the brush tip of the snap-on cannula. The amount of adhesive left in the VivaPen can be checked via the fill-level-window at the end.

Fig. 4: Adhese Universal VivaPen with snap-on brush cannulas.

The VivaPen is designed to keep solvent loss by evaporation to an absolute minimum. This is in contrast to adhesives dispensed from bottles where a higher degree of solvent loss is simply unavoidable. As such, the VivaPen delivery form helps to keep the liquid sealed ensuring maximal applications per ml and consistent adhesive viscosity. In a study by Berndt & Partner regarding the efficiency of the VivaPen and other adhesive delivery forms, it was found that the VivaPen delivered up to 190 single tooth applications per pen.

Benchmarking: VivaPen Universal Evaluation, Berndt + Partner, August 2013

The packaging engineers Berndt + Partner, conducted an independent evaluation to analyse the amount of waste and efficiency generated by the VivaPen compared to conventional bottle delivery systems using comparative, gravimetric/weight analysis during simulated daily clinical use.

Methods: Adhese Universal supplied in the VivaPen was compared with Scotchbond Universal/3M ESPE, Optibond XTR/Kerr, All-Bond Universal/Bisco, Prime & Bond Elect/ Dentsply and iBond Self Etch/Heraeus Kulzer – all supplied in bottles.

The products were used 5 times a day to simulate daily clinical use. A standard Class I plastic cavity model was used for each adhesive application and precision scales (Kern ABJ 120-4M) with a sensitivity of 0.0001g, were used to weigh the bottles/VivaPen, the applicators, the mixing wells and cavity models before and after use. For Adhese Universal, three clicks of the VivaPen were used per application. One drop of adhesive was used per application for Scotchbond Universal/3M ESPE, All-Bond Universal/Bisco, Prime & Bond Elect/Dentsply and iBond Self Etch/Heraeus Kulzer. For the Optibond XTR/Kerr 2-bottle system, 1 drop of primer and 1 drop of the adhesive was used per application. Mixing wells (two separate wells for Optibond XTR) were used for all bottle-adhesives as indicated by the manufacturers' instructions for use. "Adhesive used" refers to the weighed material actually applied onto the cavity model and "adhesive wasted" refers to that material weighed found on the applicator(s), mixing plates, etc.

Results:

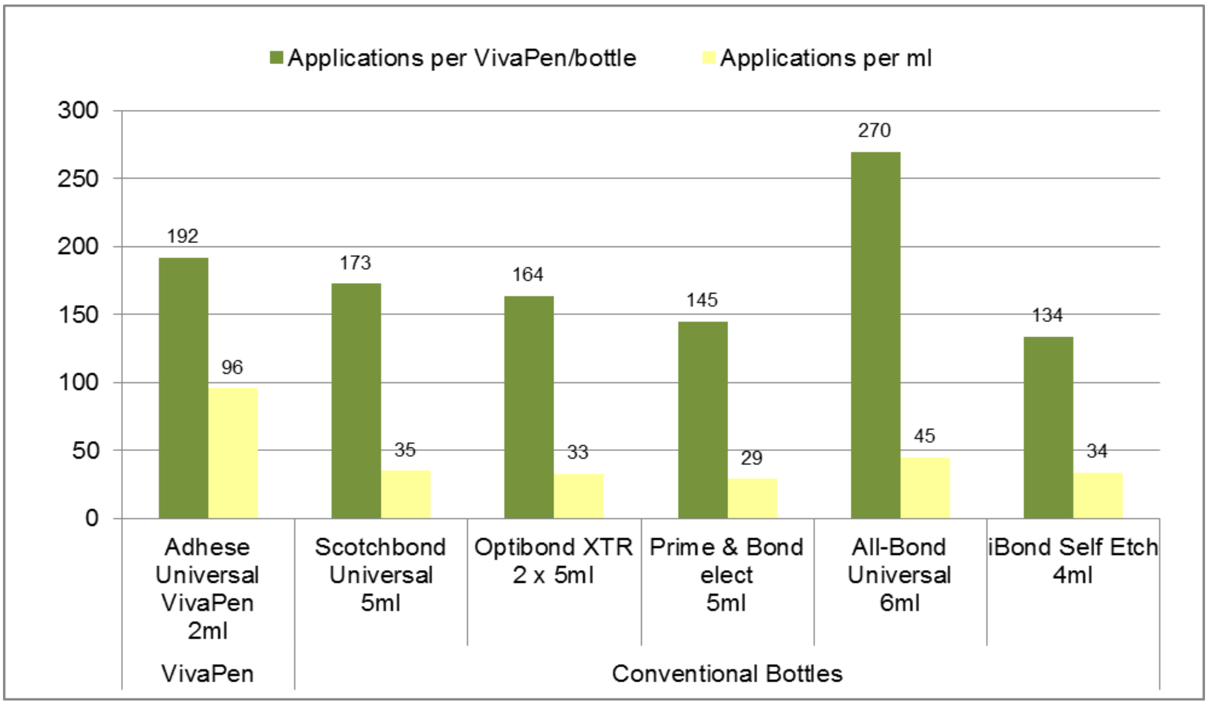


Fig. 5: The number of applications per VivaPen/bottle and ml for various universal adhesives. Berndt & Partner 2013.

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

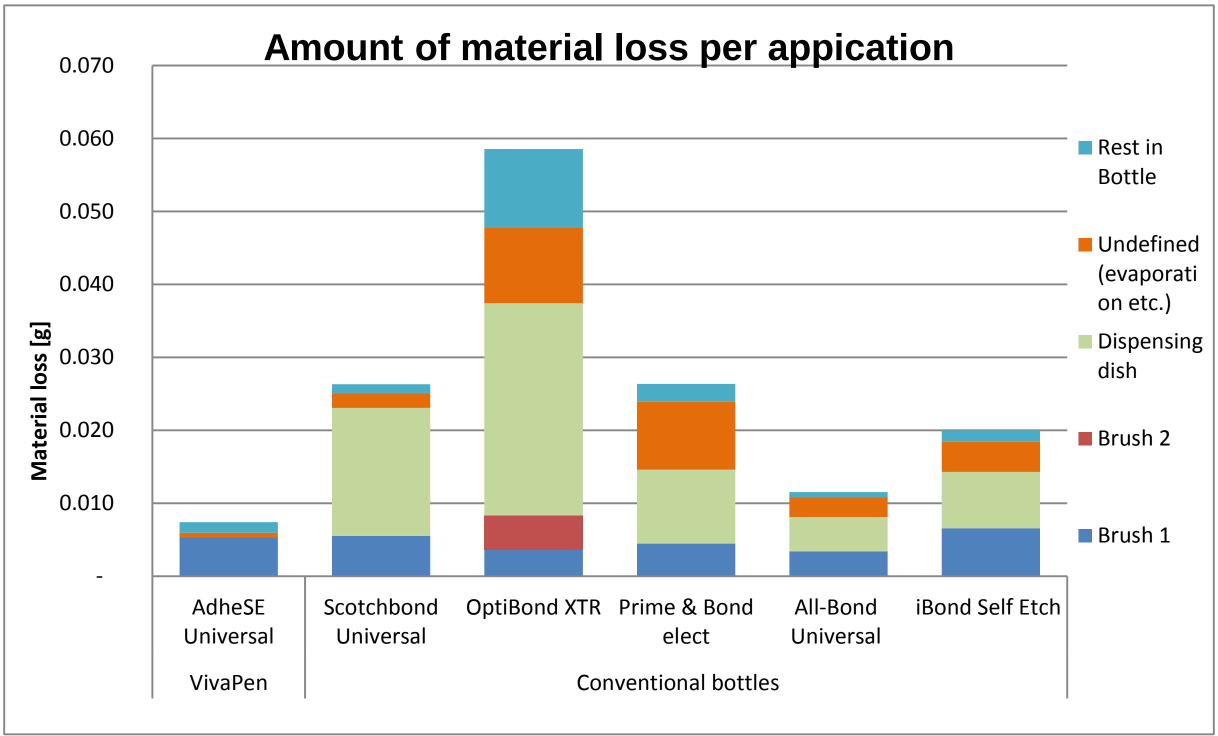


Fig. 6: Material loss for various universal adhesives. Berndt & Partner 2013.

Precision click dispensing: The comparatively low waste associated with the VivaPen is largely due to the fact that the product can be applied intra-orally directly in the patient`s mouth without the need for a mixing well; thus eliminating the discarded material commonly left over in the dish.

The VivaPen's precise click mechanism and safety-cap also facilitate low levels of unknown waste e.g. evaporation, crusting on the lid, involuntary expulsion of adhesive, etc.

6.4 "Universality" of Adhese Universal

The specially tuned composition of Adhese Universal, as described in the previous sections enables its use for both direct and indirect restorations and all etch techniques:

Suitability for both direct and indirect restorations: The low film thickness after dispersing with air and curing of the adhesive, avoids possible negative effects when fitting indirect restorations. Adhese Universal is a light-cured adhesive that co-polymerizes well with composites, core build up and luting composites and has proven to be technique-tolerant.

Compatibility with all etching protocols: Adhesives need to combine both hydrophobic and hydrophilic properties in order to establish a sufficient bond between the tooth substrate (hydrophilic) and the restorative material (hydrophobic). Adhese Universal possesses optimized mild-etching characteristics which effectively condition both un-etched and etched tooth surfaces; and due to its optimal balance of hydrophilic and hydrophobic monomers, it is highly tolerant towards dentin moisture rendering it suitable for use with all etching protocols.

7. Technical Data

Adhese Universal

Standard - Composition	(in weight %)
Methacrylates	67.0
Water, Ethanol	25.0
Highly dispersed silicon dioxide	4.0
Initiators and Stabilisers	4.0

Physical properties:

Shear bond strength

In combination with:

- **direct restorative composites**
- **light-curing composite cements**
- **light-curing core build-up composites**

		Test method	Specification	Example value**
Dentin	MPa	ISO 29022	≥ 25*	33.1 ± 3.9
Enamel	MPa	ISO 29022	≥ 17*	21.5 ± 3.3

* 4 from 5 test pieces
** Self-etch modus in combination with Tetric EvoCeram (light-curing)

In combination with:

- **self-curing core build-up composites**

		Test method	Specification	Example value***
Dentin	MPa	ISO 29022	≥ 25*	28.0 ± 5.6
Enamel	MPa	ISO 29022	≥ 14*	29.8 ± 3.7

* 4 from 5 test pieces
*** Total-etch modus in combination with MultiCore Flow (self-curing)

8. In Vitro Investigations

Numerous in vitro investigations are carried out during the development phase of a dental product. Though not capable of predicting clinical success directly, they are useful indicators – notably in predicting tolerance towards handling influences. In the development of dental adhesives, the adhesive strength and marginal quality are of primary importance. Tests are characteristically carried out on extracted human or bovine teeth and usually take place with the counterpart i.e. direct/indirect restorations intended to bond to the tooth structure.

8.1 Adhesives and bond strength tests

In general, for shear bond strength tests, a composite test specimen is bonded to a substrate with the adhesive to be tested and is sheared off parallel to the bonding surface. In a micro-tensile strength test, the load is applied at a right angle to the bonding surface.

The standard ISO 29022, released in 2013 on dentistry adhesion, details a shear bond strength testing method used to determine the adhesive bond strength between direct dental restorative materials and tooth structure.

Shear bond strength testing protocols for direct and indirect restorations are shown schematically in the diagrams below.

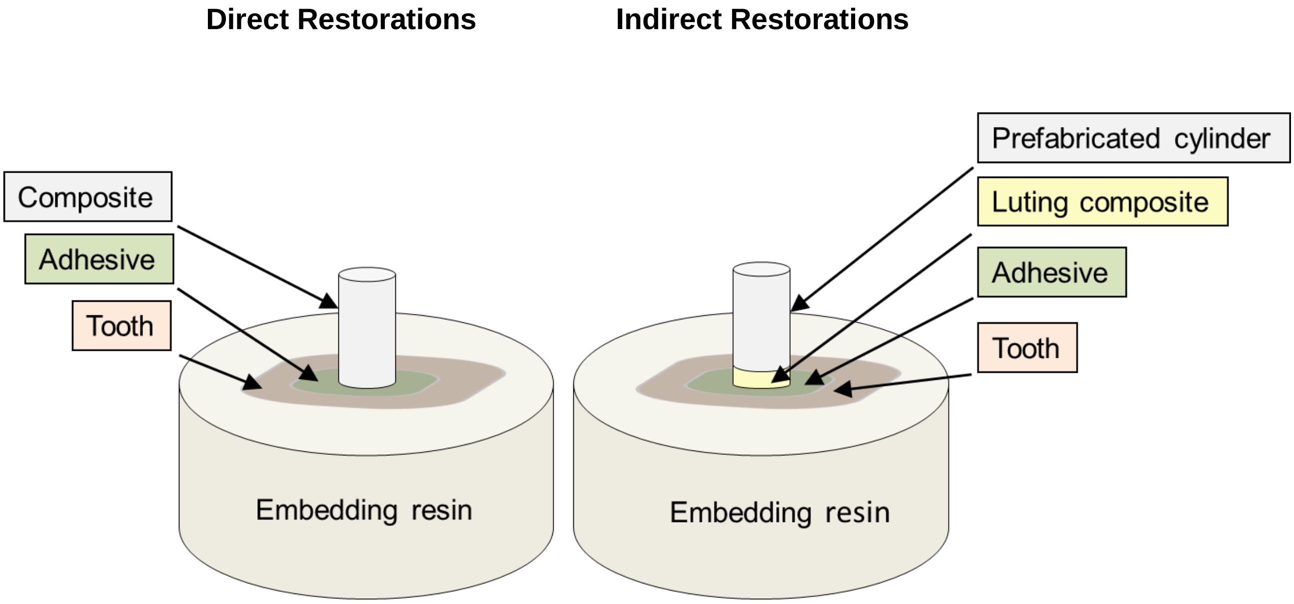


Fig. 7: Schematic representation of shear bond strength testing for direct (left) and indirect (right) restorations.

The different methods of bond strength testing illuminate different aspects of adhesive properties and are best used in combination to maximize significance of data. The absolute values obtained depend on the exact test method employed and can only be usefully compared with samples prepared by the same lab using the same method.

8.2 Adhese Universal and direct restorations

8.2.1 Bond strengths to dentin and enamel

Bond strength of two bonding agents.
The Dental Advisor Investigation. R. Yapp, J. M. Powers. July 2013

Method: This shear bond strength test, with directly placed composites, was carried out in an investigation by The Dental Advisor. Human extracted third molars, previously stored in sodium azide solution and then in saline, were embedded in acrylic resin discs and ground with 600 grit SiC paper to form bonding substrates of ground enamel and superficial dentin. The bonding agents – Adhese Universal or Scotchbond Universal/3M ESPE were applied to the substrate and cured according to the manufacturer's instructions for use. TPH Spectra/Dentsply or Tetric EvoCeram composite was then placed on top of the bonding agent, utilising a shear test mould and jig to produce a 2.38 mm diameter cylinder according to ISO 29022. The composite cylinder was then light-cured according to the manufacturer's instructions for use whilst in the mould. The specimens were tested immediately (6.5 minutes) after fabrication. Shear bond strength testing was performed on a universal testing machine (Instron 5866) at a crosshead speed of 1mm/min.

Results: The following graph shows the 6.5 minute immediate bond strengths to dentin from one tester using Adhese Universal and Scotchbond Universal/3M ESPE in self-etch mode, with the two composites Tetric EvoCeram and TPH Spectra/Dentsply.

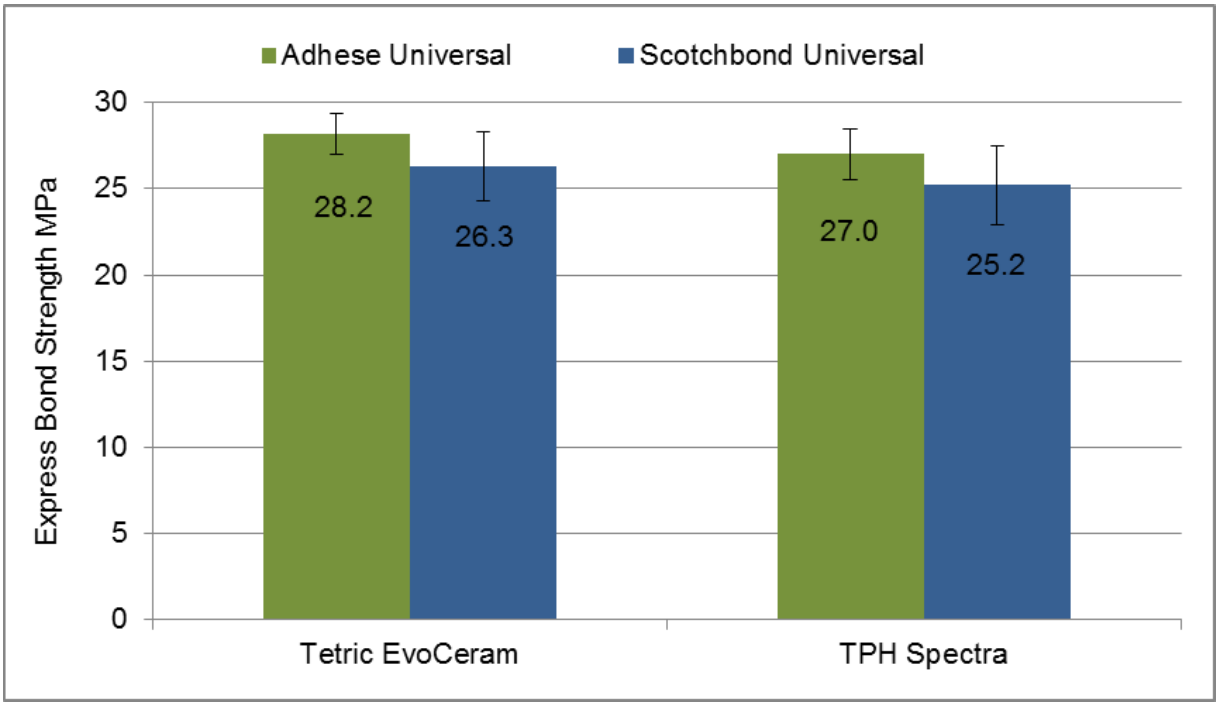


Fig. 8: 6.5 minute immediate bond strengths on dentin for Adhese Universal and Scotchbond Universal with Tetric EvoCeram and TPH Spectra using the self-etch mode. *The Dental Advisor, July 2013.*

Conclusion: Comparable "immediate" bond strengths to dentin for Adhese Universal and Scotchbond Universal were exhibited when bonding direct restorative materials.

Immediate and 24 hour bond strengths for Adhese Universal and Scotchbond Universal – Self-etch technique.

R&D (Ivoclar Vivadent, FL, and Amherst Test Center USA), May 2013

The goal was to test user-sensitivity by testing the shear bond strength with different universal adhesives: Adhese Universal and Scotchbond Universal/3M ESPE plus the composite Tetric EvoCeram Bulk Fill were measured immediately (after 60 seconds) on human dentin and after 24 hours on both enamel and dentin at both the Ivoclar Vivadent R&D department in Schaan (Liechtenstein) and the Test Center in Amherst (USA). Human teeth were used in Amherst and bovine teeth in Schaan. The graph below shows a similar pattern left and right i.e. Schaan vs. Amherst.

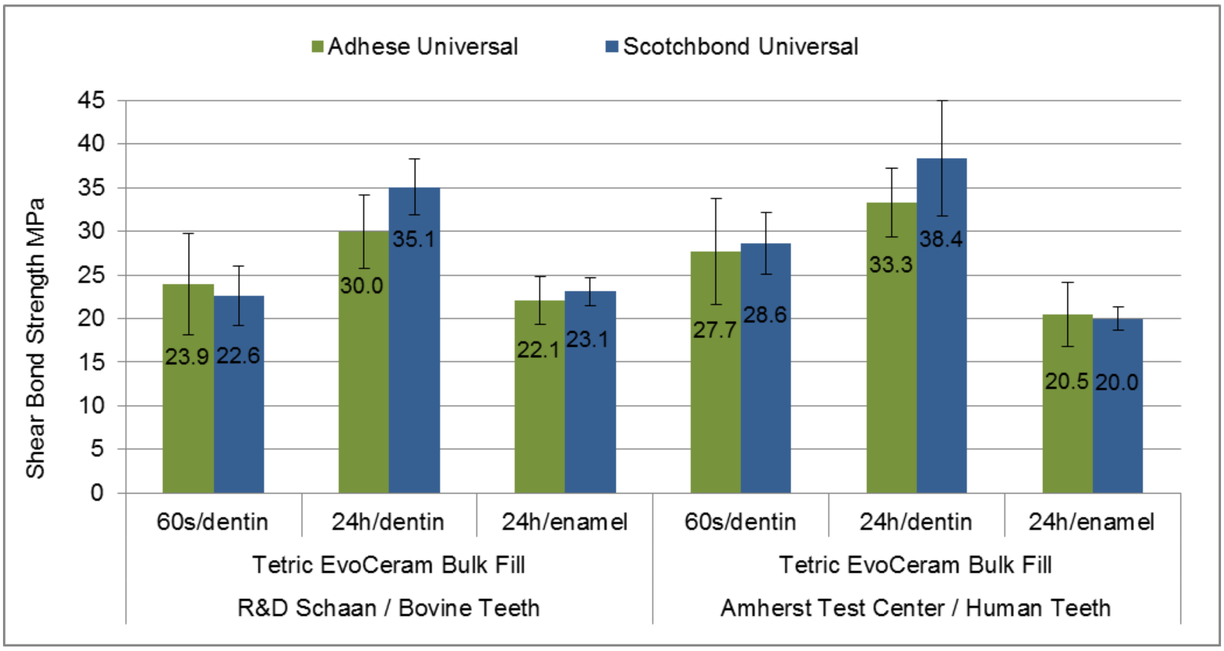


Fig. 9: Shear bond strengths on dentin and enamel for Adhese Universal and Scotchbond Universal with Tetric EvoCeram Bulk Fill using the self-etch mode at different test centres. *R&D Schaan/Amherst, May 2013.*

Conclusion: Comparable bond strength values for Adhese Universal and Scotchbond Universal with Tetric EvoCeram Bulk Fill – both 60 seconds and 24 hours after bonding independent of substrate and with comparable results between test centres.

Immediate and 24 hour bond strengths Adhese Universal and Scotchbond – Self-etch technique with different operators.

Amherst Test Center, May 2013

Shear bond strength tests with the previously mentioned products were also carried out at the Ivoclar Vivadent Amherst (USA) Test Center by four different operators, in order to further test the existence or non-existence of user-sensitivity. Human dentin/enamel was used for all tests. Both products elicited comparable bond strengths, however the bond strengths on enamel after 24 hours were considerably and consistently higher for Adhese Universal for operators 1, 2 and 3. Scotchbond Universal was unfortunately not measured by Operator 4 on enamel due to time constraints.

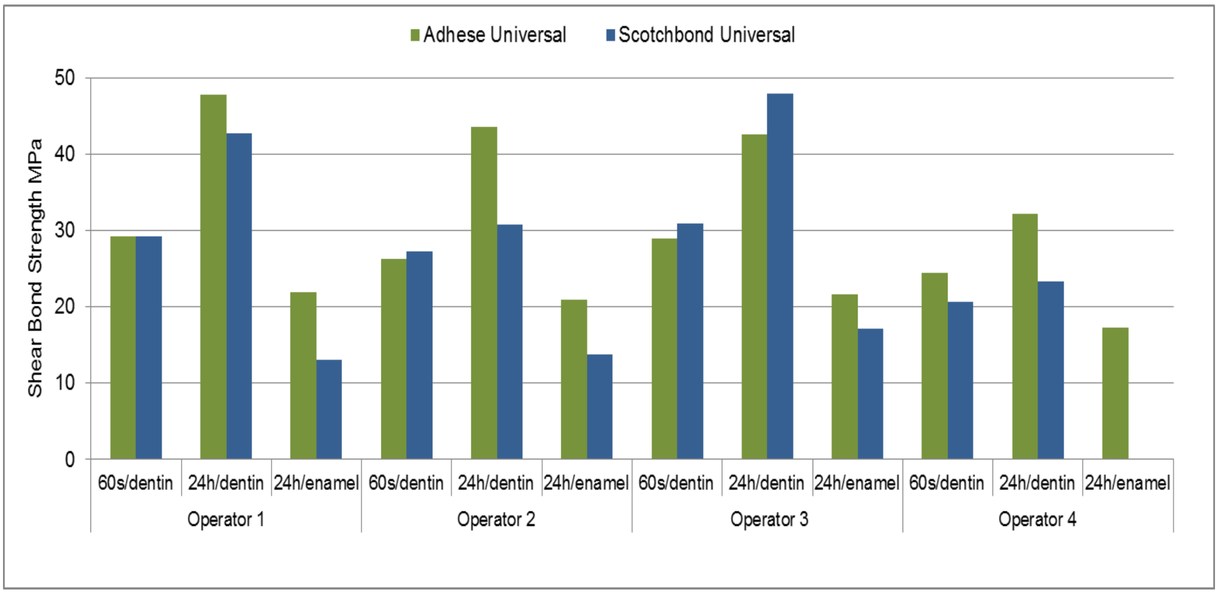


Fig. 10: Shear bond strengths on human dentin and enamel with Adhese Universal and Scotchbond Universal measured by four different operators *Amherst Test Center, July 2013.*

Conclusion: Similar bond strength values were measured between operators – notably 1, 2 and 3.

User influence on shear bond strength for Adhese Universal and Scotchbond Universal

R&D Ivoclar Vivadent, FL, January 2014.

Nine internal dentists in Schaan carried out a product comparison test with Adhese Universal and Scotchbond Universal/3M ESPE on bovine dentin, showing similar results. Each dentist prepared 7 samples per adhesive. Bond strength values were determined and the 2 lowest values for each adhesive were discarded from the evaluation (n=5).

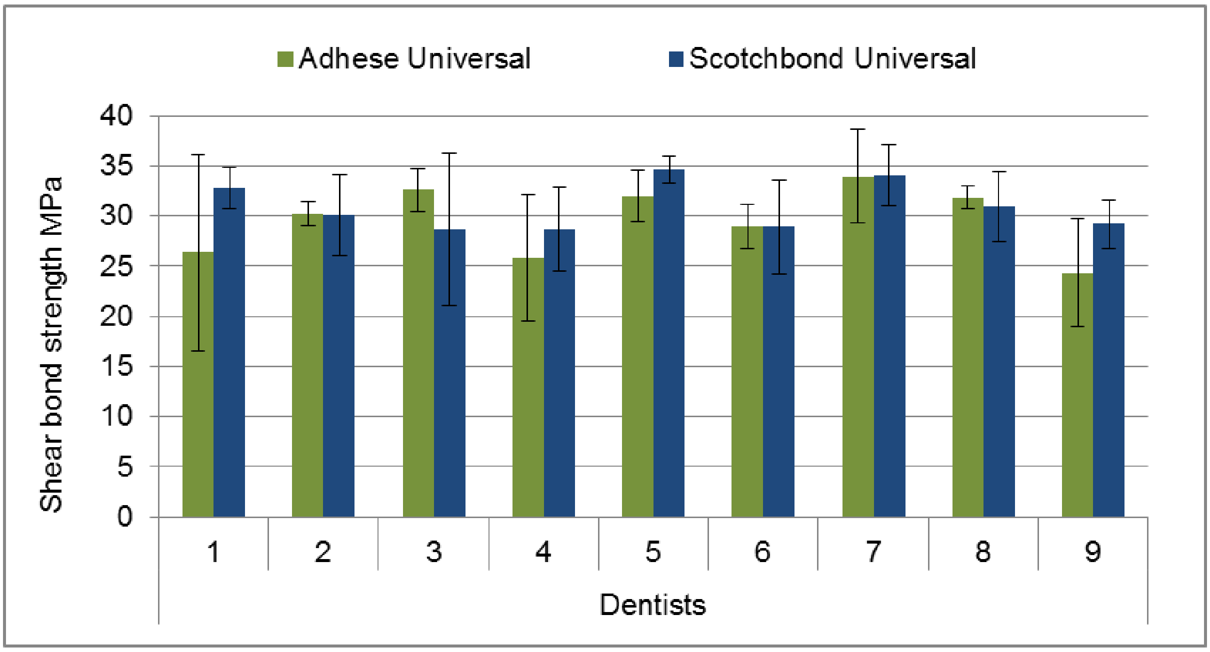


Fig. 11: Bond strengths for Adhese Universal and Scotchbond Universal - measured by nine different dentists on bovine dentin. *R&D Ivoclar Vivadent, FL, January 2014*.

Conclusion: Comparable bond strengths were achieved with both materials by all dentists – supporting the considerable technique/user-tolerance of the products.

Shear bond strength before and after thermocycling

R&D Ivoclar Vivadent, FL, 2014

The bond strengths of five adhesives were tested on dentin and enamel. To simulate aging, the test samples were thermocycled.

Method: The adhesives were applied to the bovine tooth substrate using the total-etch or 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 thermocycles between 5 and 55°C.

Results:

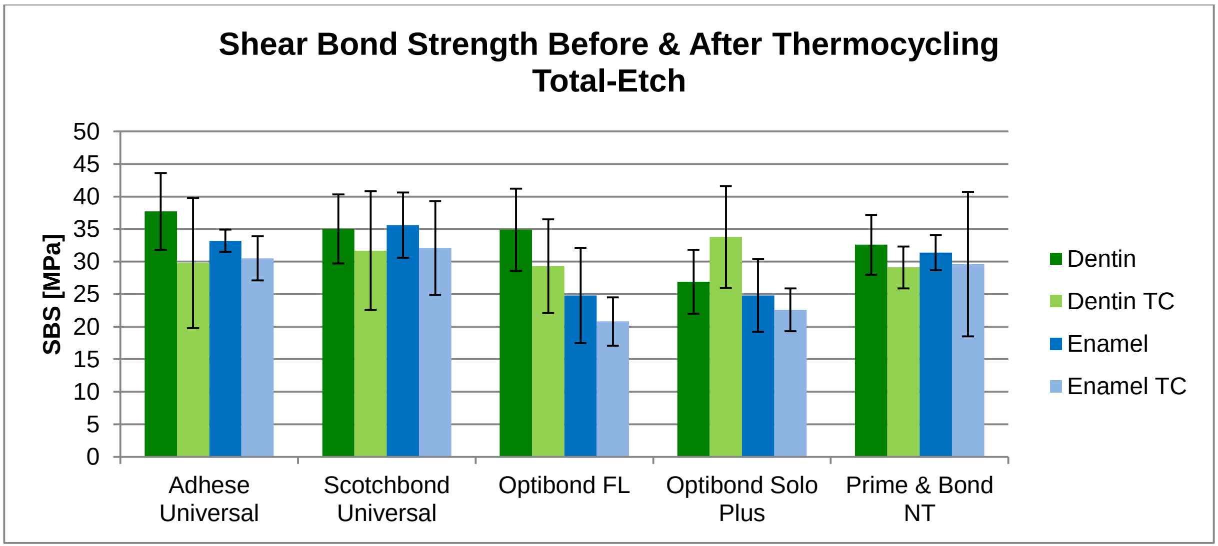


Fig. 12: Shear bond strength of universal adhesives in total-etch technique on dentin and enamel, before and after thermocycling. *R&D Ivoclar Vivadent, FL, March 2014*

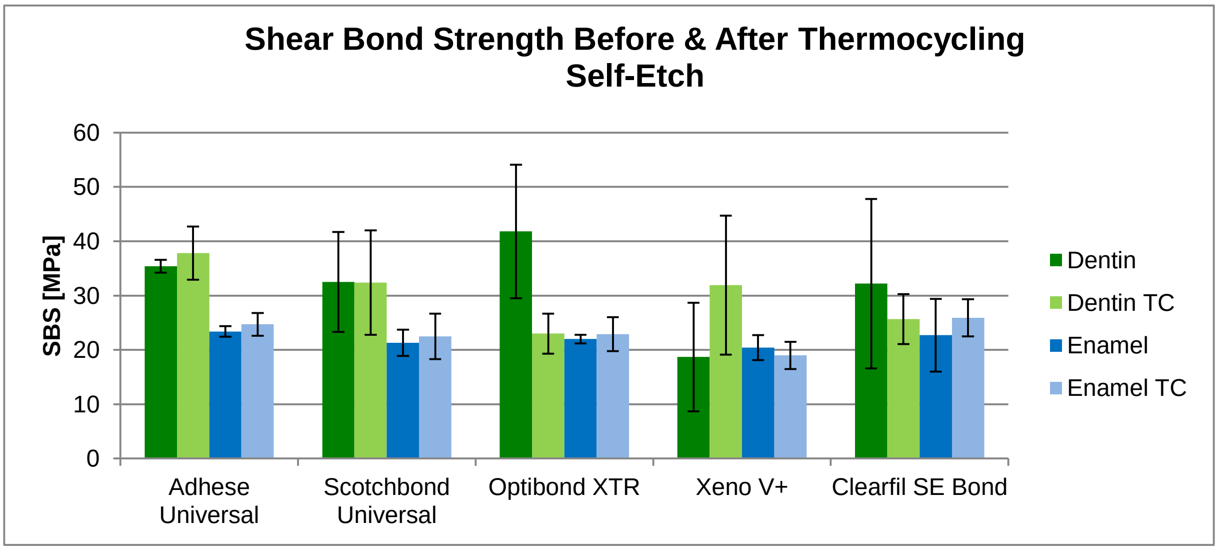


Fig. 13: Shear bond strength of universal adhesives in self-etch technique on dentin and enamel, before and after thermocycling. *R&D Ivoclar Vivadent, FL, March 2014*

Conclusion: With both etching techniques, Adhese Universal achieved high bond strengths that were stable even after aging.

Micro-tensile bond strength of Adhese Universal to dentin.
B Van Meerbeek, Department of Oral Health Sciences, KU Leuven, Belgium, 2013 – 2014 and ADM 2014

The purpose of this study was to evaluate the effect of smear layer, hybridization mode, adhesive and aging on the micro-tensile bond strength (µTBS) to human dentin.

Micro-tensile bond strength was tested before and after aging on three adhesives: Adhese Universal, Scotchbond Universal/3M ESPE and the two-step self-etch adhesive Clearfil SE Bond/Kuraray as control. Testing was carried out using the self-etch and total-etch modes (test parameter "hybridization mode") according to the instructions for use. The teeth were either prepared with a diamond bur or SiC ground (test parameter "smear layer") to evaluate differences in the preparation method. The results below show the "bur-cut" results on flat dentin surfaces prepared using the Micro-Specimen Former equipped with a medium grit (107µm) diamond bur to produce a clinically relevant smear layer. Tetric EvoCeram Bulk Fill was used as the composite. Ten teeth per adhesive were tested. These were cut in half - each half treated according to the total-etch or self-etch technique. Specimens were stored for one week in water at 37°C before micro-tensile bond strength testing was carried out. Additionally, the samples were aged for 3 and 6 months in water at 37°C.

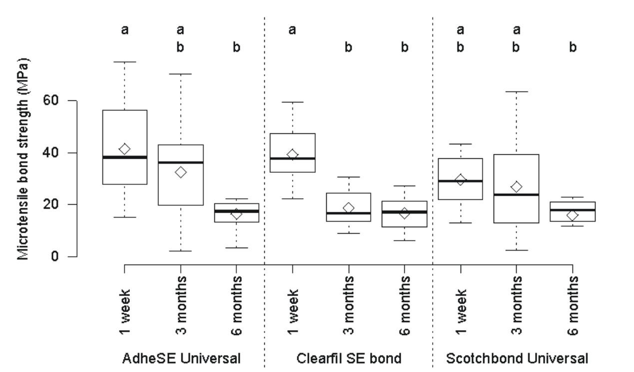
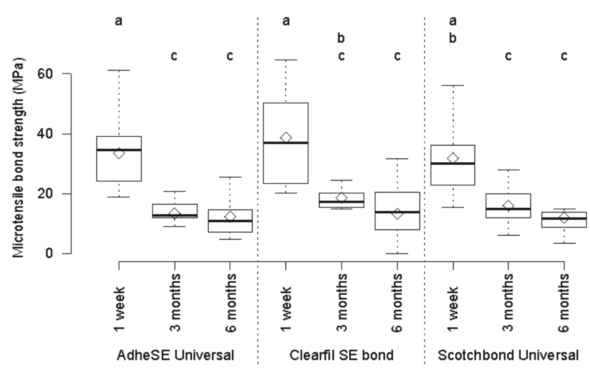
TOTAL-ETCH / bur-cut dentin	**SELF-ETCH / bur-cut dentin**
	

Fig. 14: Micro-tensile bond strengths on bur-cut dentin with various adhesives using the total-etch and self-etch techniques. B. *Van Meerbeek, KU Leuven, 2013 - 2014.* * (Clearfil SE Bond is not indicated for total-etch technique)

Conclusions: Initially, there was no statistically significant difference between the adhesives using either etch technique. Overall, the variables 'hybridization mode' (p=0.0079) and 'aging' (p<0.0001) had a significant effect on the bonding performance, while the variables 'smear layer' (p=0.73) and 'adhesive' (p=0.49) did not. Planned contrasts revealed no significant difference in micro-tensile bond strength after 6-month water storage, except for Adhese Universal and Scotchbond Universal (3M-ESPE) which both revealed a significantly higher micro-tensile bond strength with the total-etch technique versus the self-etch technique when applied to BUR-CUT dentin (p<0.05).

Bond strength comparison for several bonding agents using the self-etch* and total-etch* technique.

The Dental Advisor Investigations. R. Yapp, J M. Powers, A. Baumann. November 2013 and The Dental Advisor Vol. 31, No 07 September 2014 (* 2 separate reports)

The shear bond strengths were tested according to both the self-etch and total etch techniques for six different universal adhesives: Adhese Universal, Scotchbond Universal/3M ESPE, ALL-BOND Universal/Bisco, Prime & Bond Elect/Dentsply, Optibond XTR/Kerr and Peak Universal Bond/Ultradent.

Method: Human extracted third molars were embedded in acrylic resin discs and ground through 600 grit SiC paper to form bonding substrates of ground enamel and superficial dentin. The total-etch technique was only tested on enamel. The enamel was etched with 37% phosphoric acid and rinsed according to the etchant`s instructions for use. The bonding agents were then applied and cured according to the manufacturer's instructions for use. The self-etch technique was used on both dentin and enamel whereby the bonding agent was applied directly to the substrate and cured according to the manufacturer's instructions for use. The composite TPH Spectra/Dentsply was then placed on top of the bonding agent utilising the utilising a shear test mould and jig to produce a 2.38 mm diameter cylinder according to ISO 29022. The composite cylinder was then light-cured according to the manufacturer's instructions for use whilst in the mould. The specimens were tested after being stored in 37°C water for 24 hours. Shear bond strength testing was performed on a universal testing machine (Instron 5866) at a crosshead speed of 1mm/min.

Results: These results combine the results from two separate Dental Advisor Reports, using exactly the same methods, as detailed above. The shear bond strength values on dentin and enamel in the self-etch and total-etch modes are shown in the figure below.

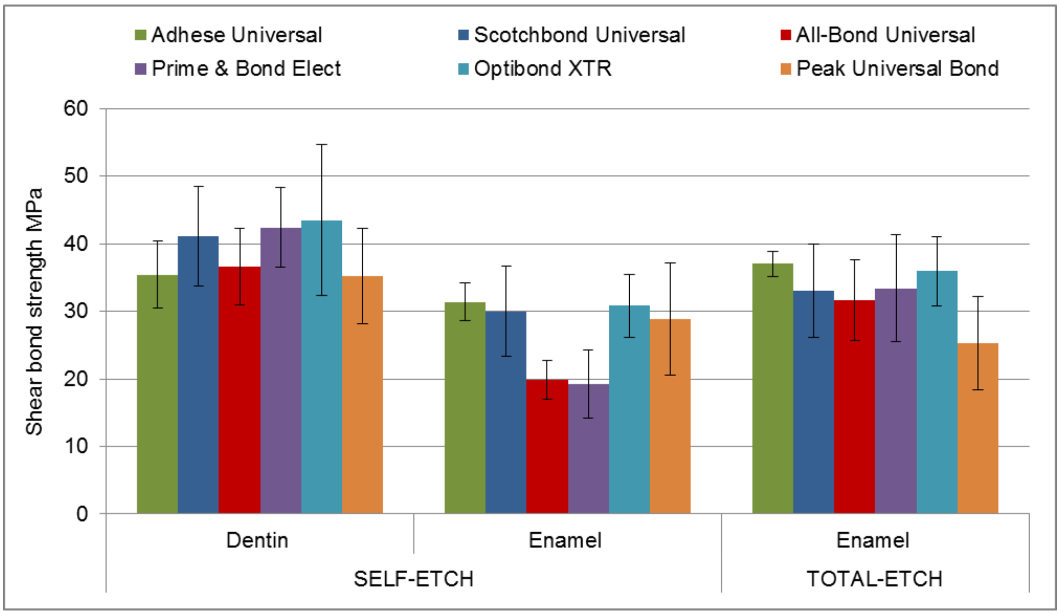


Fig. 15: Shear bond strengths of various "universal" adhesives when used with the self-etch and total-etch techniques. *The Dental Advisor July 2013 and November 2013* and The Dental Advisor Vol. 31, No 07 September 2014.*

(* 2 reports: 1 SE & 1 TE) (Optibond XTR not indicated for total etch technique)

Adhese Universal exhibited average bond strengths of over 30 MPa on all substrates under all conditions. The other products showed greater variation in bond strengths. Within technique and substrate, the greatest variance was found on enamel in the self-etch mode between Adhese Universal (31.4 MPa) and Prime & Bond Elect (19.2 MPa). All products exhibited comparative values on dentin i.e. the differences between products were not statistically significant.

Conclusion: High average bond strengths on all substrates, under all etching conditions were observed for Adhese Universal. Adhese Universal exhibited the highest mean values on enamel using both self-etch and total-etch techniques.

Adhesive shear bond strength to tooth structure – 24 hour bond.
J. O. Burgess. University of Alabama, Birmingham USA. November 2013

Similar testing as at The Dental Advisor using the same adhesives was performed - measuring the 24 hour bond strengths on both enamel and dentin after the total-etch procedure and self-etch procedure.

Method: The tests were carried out on 240 freshly extracted human teeth which were ground down to expose a flat bonding surface. These flattened enamel and deep dentin samples were ground using a series of abrasive discs, finishing with a grit 320 to establish a standardized surface. Sixty teeth were tested per technique i.e. 12 per adhesive/technique. After application of the etching gel (total-etch technique) and adhesive, a 1.5 mm diameter cylinder of the composite Z100/3M ESPE was bonded to each tooth surface and light-cured. Specimens were then stored in an incubator at 37°C for 24 hours. Shear bond strengths were calculated using a universal testing machine (Instron 5565 MA USA) at a crosshead speed of 1mm/min. Peak Universal Bond was tested later in exactly the same way, but with half the samples.

Results: The average shear bond strength values for each adhesive in each technique-group are shown in the graph below. The values in this test series were lower than those of The Dental Advisor for all products. It should be noted that values are affected by the size of the composite cylinder used, which was 1.5 mm here compared to 2.38 mm in The Dental Advisor test series.

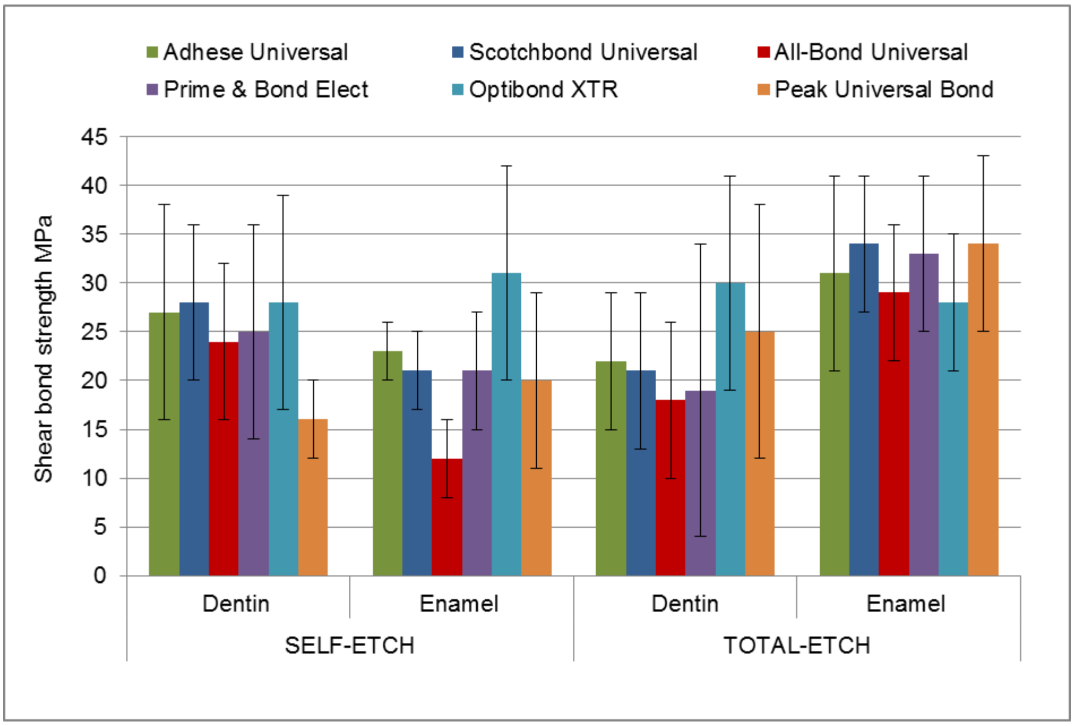


Fig. 16: Shear bond strengths on dentin and enamel for various “universal” adhesives when used with the self-etch and total–etch techniques. *J. Burgess. University of Alabama. November 2013.*

(Optibond XTR is not indicated for the total etch technique. Peak Universal Bond was tested later with fewer samples).

Conclusion: There were no statistically significant differences between the adhesives within the different technique groups: Self-etch on dentin and total-etch on dentin and enamel. However, the self-etch on enamel group showed greater variation. Adhese Universal exhibited the lowest standard deviation on enamel using the self-etch mode, which can be an indicator for reliable performance.

Shear bond strength with Tetric Family composites – Self-etch and total-etch techniques.
R&D Ivoclar Vivadent, FL, October 2013

Adhese Universal was tested with the Ivoclar Vivadent composites, Tetric EvoFlow, Tetric EvoCeram and Tetric EvoCeram Bulk Fill. As the graph below shows, there was no statistically significant difference between the composites for each individual substrate and technique. The bond strength to dentin was comparable independent of the etching technique; and as would be expected, the bond strengths to enamel were somewhat higher in the total-etch group. The values shown are the immediate values after bonding.

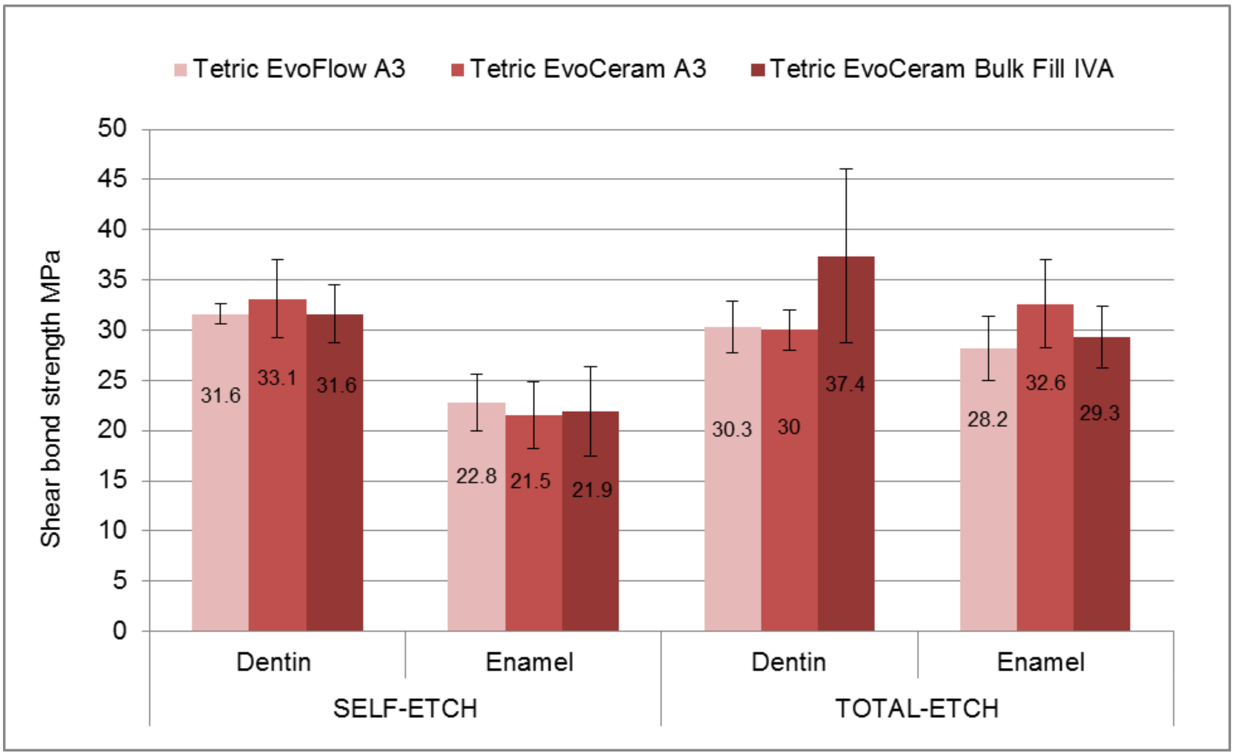


Fig. 17: Shear bond strengths on dentin and enamel for Ivoclar Vivadent composite materials after using the self-etch or total-etch technique with Adhese Universal. *R&D Ivoclar Vivadent, FL, October 2013.*

Conclusion: Similar results were observed for Tetric EvoFlow, Tetric EvoCeram and Tetric EvoCeram Bulk Fill on dentin and enamel using both etching protocols.

Shear bond strength to enamel and dentin substrate
M Irie, Okayama University Japan*, December 2013*

Irie investigated shear bond strengths to human enamel and dentin substrates when bonding the composite Clearfil AP-X/Kuraray with the following "universal" adhesives: Adhese Universal, Scotchbond Universal/3M ESPE, Prime & Bond Elect/Dentsply, OptiBond XTR/Kerr, All-Bond Universal/Bisco and BeautiBond Multi/Shofu. After application of the adhesives according to the manufacturer`s instructions for use, a Teflon mould was clamped to the substrate surfaces and filled with the composite. Shear bond strength values were measured immediately after light-curing and after one day storage in water at 37°C. The figure below shows the shear bond strengths after one day storage.

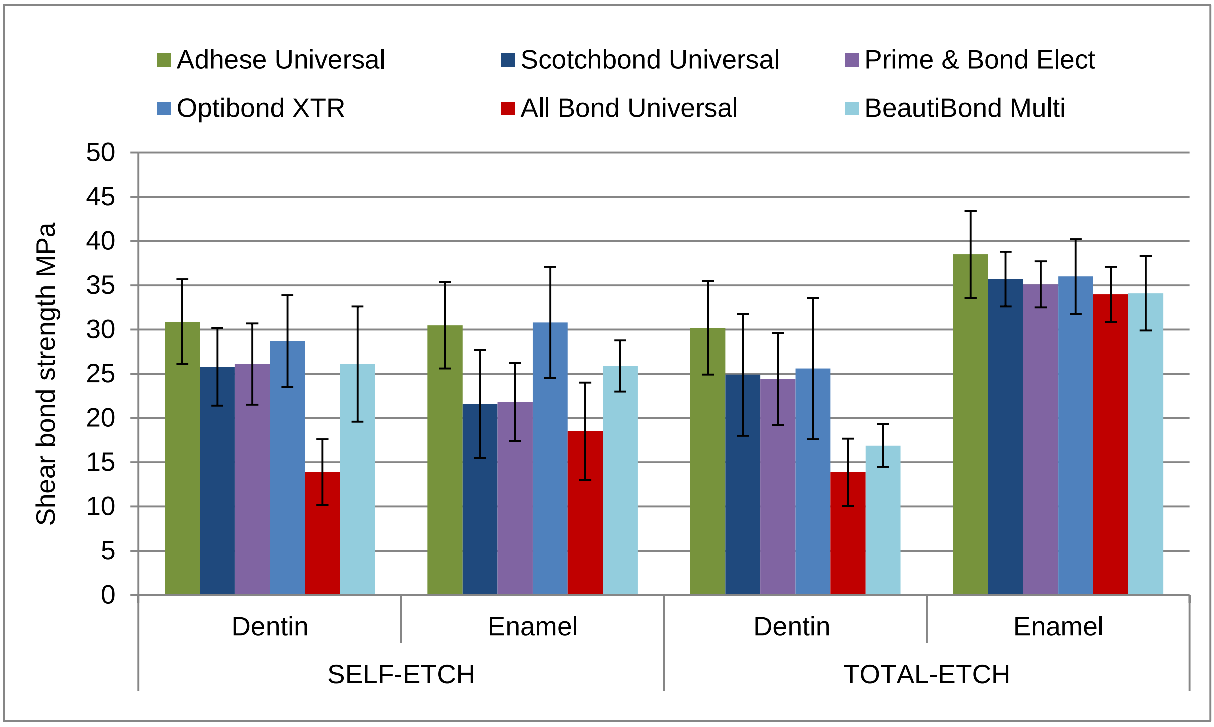


Fig. 18: Shear bond strengths of various universal adhesives when used with the self-etch and total-etch techniques. *M Irie, Okayama University, December 2013*

(Optibond XTR is not indicated for total etch technique)

Conclusion: Adhese Universal exhibited the highest average bond strengths independent of etch protocol (equal to Optibond XTR on enamel in the self-etch mode). All-Bond Universal exhibited the lowest average values under all circumstances. As in most studies, the bond strengths to enamel were highest for all products in the total etch mode - however this was not seen across the board e.g. The Dental Advisor study depicted in Fig. 15.

8.3 Bonding on wet and dry dentin

When etched dentin is over-dried, collagen may collapse and many adhesives are unable to sufficiently rewet over-dried collagen. Other adhesives are unable to establish a stable bond to dentin that is left too wet after etching. Therefore determining the right degree of moisture for reliable bonding can be challenging for the dentist. Ideally, an adhesive should be able to establish a strong and reliable bond to dentin with different levels of moisture. To test moisture tolerance, the bond strength of Adhese Universal to dentin was tested on wet and dry dentin by several investigators.

Immediate and 6-month microtensile bond strength on dry and wet dentin
M. Lopes. University of Lisbon, Portugal. 2014, final report.

The objective of this study was to evaluate the 24 hour and 6-month resin-dentin bond strength of three universal adhesive systems, with different modes of application and dentin conditions.

Method: Sixty extracted human third molars were randomly distributed across 12 groups. Three adhesives [Adhese Universal (Ivoclar Vivadent), Futurabond U (Voco) and Scotchbond Universal (3M ESPE)], two application methods [Total-Etch versus Self-Etch] and two dentin conditions [wet / dried] were tested (n=5).

The occlusal enamel was removed to expose superficial to middle dentin. The exposed dentin surface was polished on wet #600-grit SiC sandpaper for 60 seconds in order to standardize the smear layer.

The adhesives were applied according to the manufacturer‘s instructions for use, and light-cured with a Bluephase 20i curing light (Ivoclar Vivadent) for 10 seconds (2,000 mW/cm2). Then a 4-mm thick layer of composite resin (Tetric EvoCeram, Ivoclar Vivadent) was applied to the treated dentin and light-cured for 20 seconds.

After storage in distilled water at 37°C for 24 h, restored teeth were sectioned across the bonded interface with a diamond saw under water with an Isomet 1000 machine in order to obtain 2 rectangular 1mm x 1mm sticks. The diameter of each stick was measured with a digital caliper (Digimatic caliper, Mitutoyo Corporation). The sticks obtained from each tooth were randomly divided in two groups. Half of the sticks were tested immediately. The other half was tested after storage for 6-month at 37° in distilled water with 0.1% sodium azide. Micro-tensile bond (µTBS) tests were performed with a Universal Testing Machine (Instron 4500) at a crosshead speed of 1 mm/min. Each tooth was considered as a statistical unit. Samples that debonded prematurely were included in the tooth mean, attributing them the average value between zero and the lowest bond strength obtained in the respective experimental group. Sticks with cohesive failures were excluded. Data were analyzed with ANOVA followed by Tukey post-hoc tests (alfa 0.05).

Results:

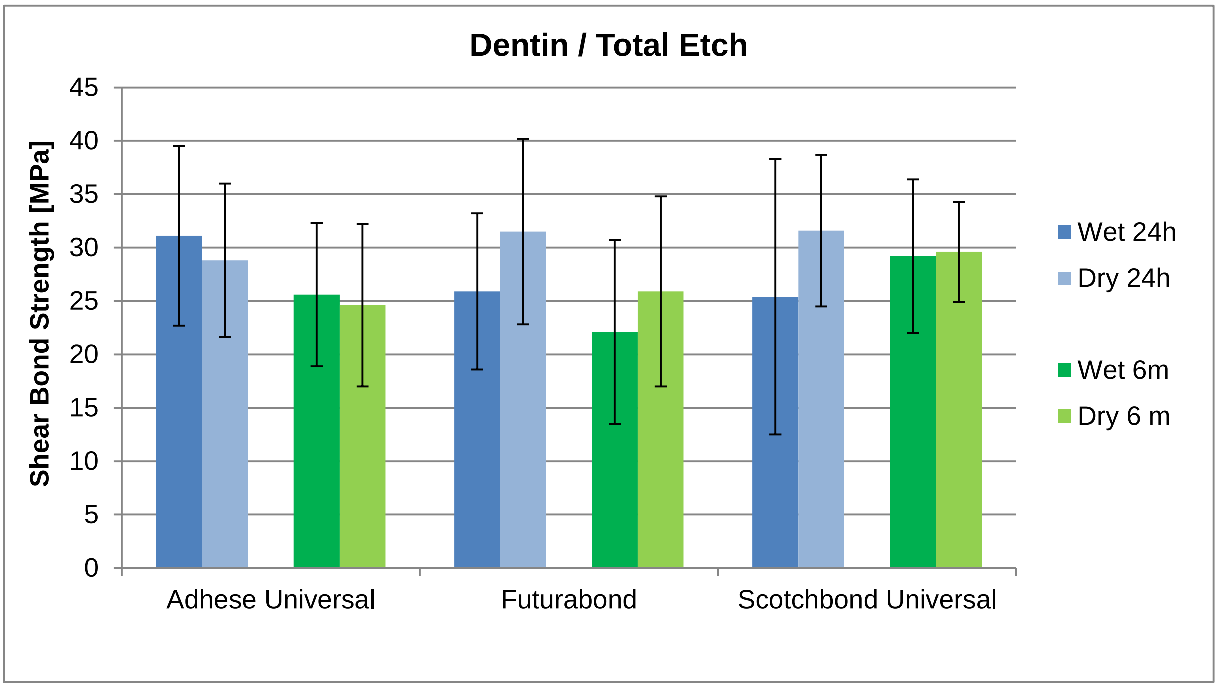


Fig. 19: Microtensile bond strength on wet and dry dentin, 24h and 6 months after sample preparation, total-etch protocol. *M. Lopes, University of Lisbon, September 2014*.

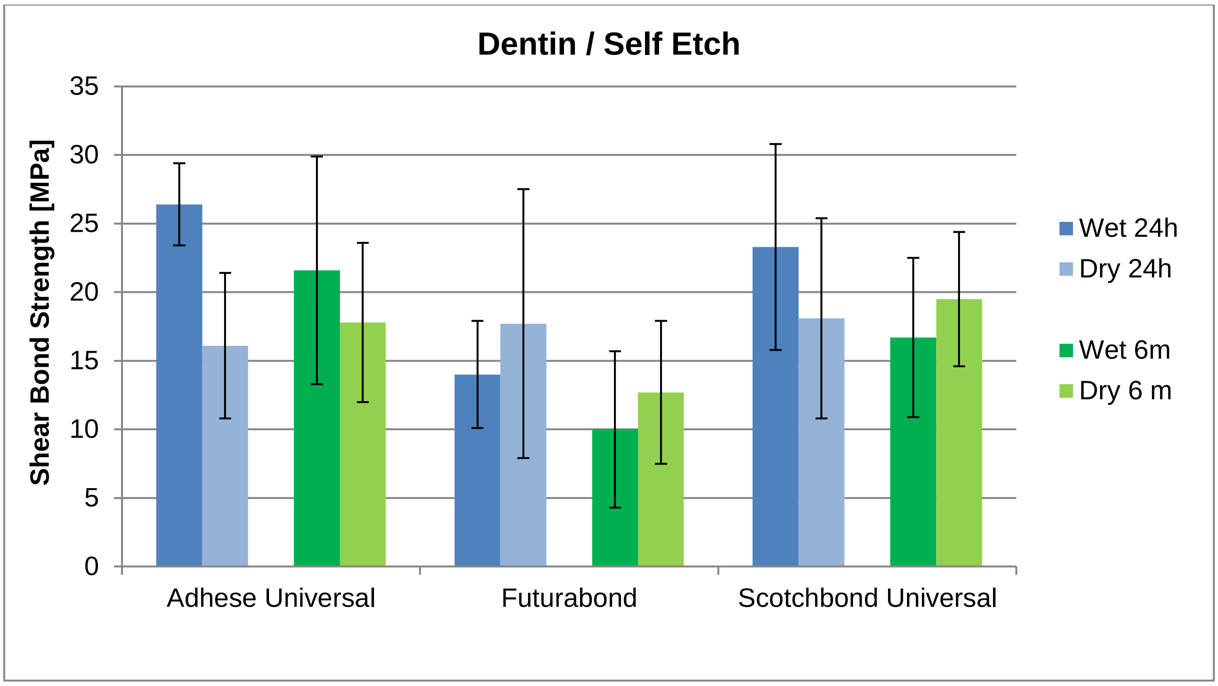


Fig. 20: Microtensile bond strength on wet and dry dentin, 24h and 6 months after sample preparation, self-etch protocol. *M. Lopes, University of Lisbon, September 2014.*

There were statistical differences among the 3 adhesives. The µTBS values of Adhese Universal and Scotchbond Universal were significantly higher than Futurabond U ($p=0.017$). The total-etch technique showed significantly higher values of adhesion versus the self-etch technique ($p<0.001$). The microtensile values were significantly lower after 6 months compared to the 24 hour results ($p=0.034$). For these adhesives, no significant differences between the wet and dry dentin techniques were found ($p=0.891$).

Effect of moist, dry and desiccated dentin on shear-bond strength of universal Adhesives

S. Singhal, S. A. Antonson, D. E. Antonson and P. Bush, University at Buffalo, Buffalo, NY, USA; ADM 2014

The aim of this study was to evaluate the shear bond strength of Universal bonding agents on moist, dry and desiccated dentin surfaces.

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

Results

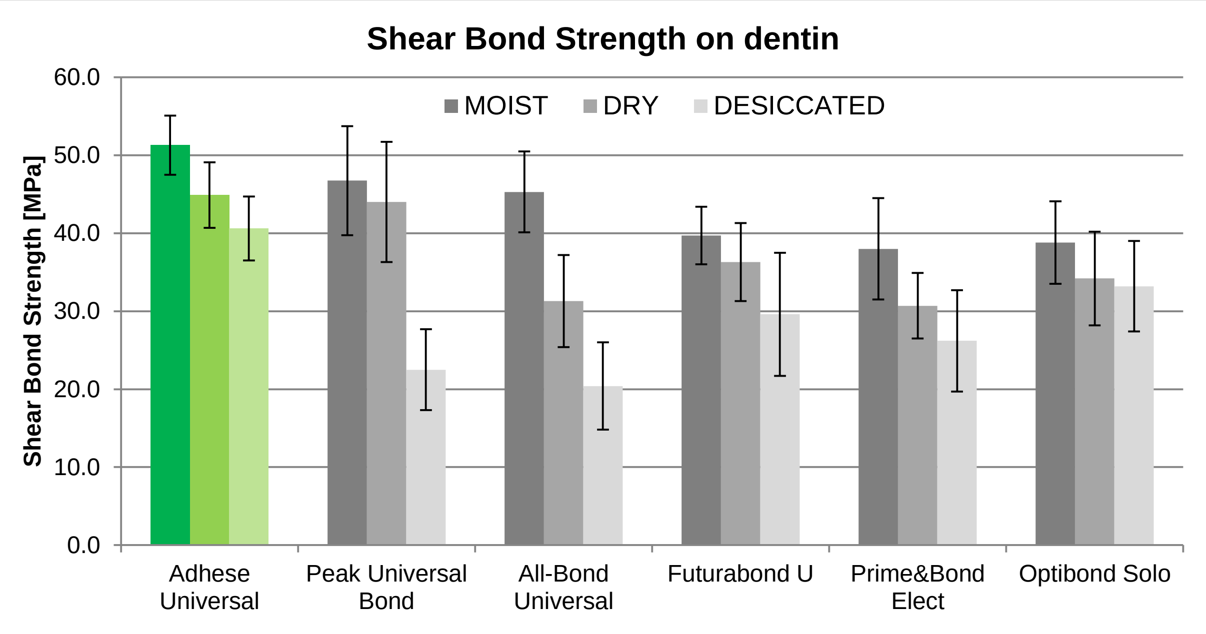


Fig. 21: Shear bond strength of universal adhesives on moist, dry and dessicated dentin. *S. Singhal, S. A. Antonson, D. E. Antonson and P. Bush, University at Buffalo, Buffalo, NY, USA; ADM 2014.*

Conclusion: Different surface treatments affected the shear bond strength of all tested adhesives. Adhese Universal was least affected by dentin surface treatment compared to the other universal bonding agents tested.

In vitro shear bond strength of adhesives to dentin substrates with varying moisture content.

JA. Sorensen and Yen-Wei Chen, Laboratory For Biomimetics, Biomaterials, Biomechanics & Technology, School of Dentistry, University of Washington, USA, 2015

The purpose of the study was to evaluate the effect of dentin moisture content on the shear bond strength of dentin bonding agents (DBA) used with direct filling materials. The four levels of dentin moisture content ranged from a layer of water to classic "moist" dentin to air-dried and over air-dried dentin.

Method: Dentin and enamel samples were prepared from extracted human molar teeth using a low speed diamond saw, followed by grinding with SiC 600 paper and rinsing thoroughly with water. After conditioning the dentin with phosphoric acid and thoroughly rinsing with an air/water syringe, four surface moisture conditions were created:

1. Water Layer: To produce a controlled water layer that clinically would be considered over-wet, an automated micropipette was used to deliver 2.5 uL of sterile water onto the dentin surface.
2. Moist Dentin (the classic technique): Blotted to absorb moisture, and if necessary any excess water absorbed with clean microbrush(es).
3. Dry: air dried for 3 seconds.
4. Over-dried: air dried for 10 seconds.

As control substrate, enamel was etched with phosphoric acid for 30 seconds, thoroughly rinsed with air/water syringe, and then air dried for 10 seconds.

The adhesives were applied and cured according to manufacturers' instructions for use.

Results:

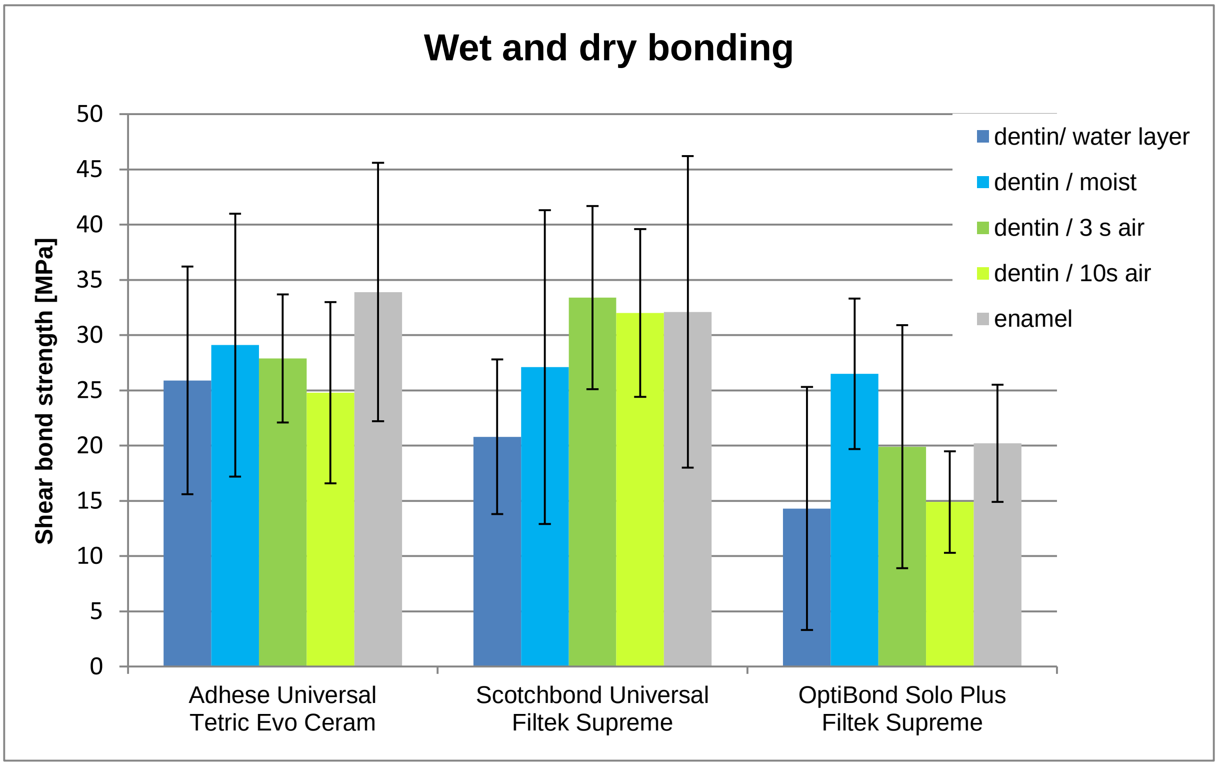


Fig. 22: Shear bond strength on enamel and on dentin with varying moisture content. *JA Sorensen, University of Washington, USA, 2015*

In his report, Sorensen summarised the results as follows:

Adhese Universal had excellent control bond strength to enamel at about 34 MPa. It demonstrated high tolerance to excess water on the dentin surface with only a 24% lower bond strength than the enamel control. Similarly, under ideal "moist" dentin conditions, the bond strength was at 85% of the bond strength of enamel.

Scotchbond Universal had poor tolerance to excess water on the dentin surface with a 23% reduction in bond strength to dentin compared to moist dentin conditions. The moist dentin bond strength was similar to Adhese Universal. Scotchbond demonstrated excellent bond strengths on dried dentin that were equal to its enamel control.

OptiBond had poor tolerance of excess water on the dentin surface. It was similar in bond strength to the other two adhesives on moist dentin, but recorded a substantial reduction in bond strength on dried dentin surfaces.

Conclusion: Adhese Universal applied under dry dentin conditions was found to have bond strengths in the range of the ideal moist dentin conditions. Adhese Universal also proved to be an outstanding dentin adhesive attaining 85% of the bond strength of the enamel control. Adhese Universal had a high tolerance to excess water on the dentin surface able to achieve about 75% of the enamel control.

Effect of moist and dry dentin on the shear-bond strength of universal adhesives
R&D Ivoclar Vivadent, FL, 2014

Bovine teeth were prepared to expose dentin according to ISO 29022. The dentin was etched with phosphoric acid for 15 seconds to expose collagen. After rinsing with water, the surface was blot dried (Wet-Bond) and additionally dried with blown air for 5 seconds (Dry-Bond). All materials were applied according to the manufacturer`s instructions for use. Sample preparation and measurements were conducted according to the Ultradent protocol. The shear bond strength was tested before and after 10'000 thermocycles between 5 and 55°C.

Results:

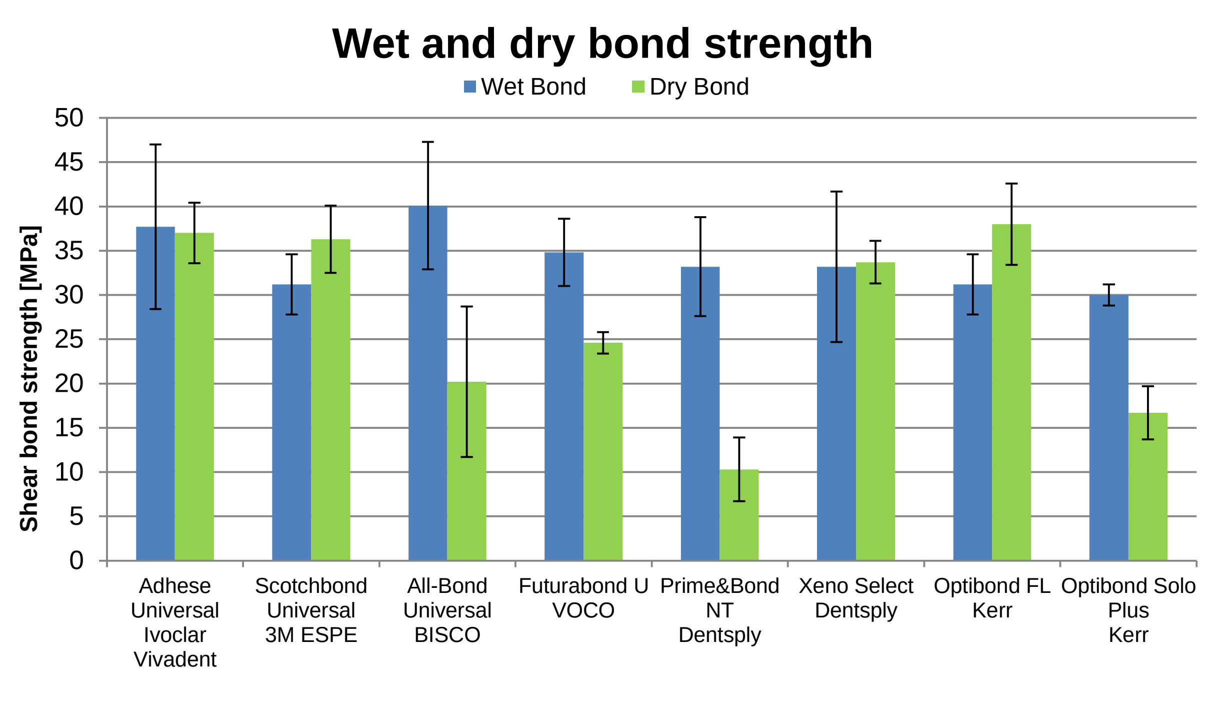


Fig. 23: Shear bond strength of universal adhesives on wet and dry dentin. *R&D Ivoclar Vivadent 2014.*

Conclusion: Adhese Universal demonstrated high bond strengths on wet and dry dentin, whereas some other adhesives were very sensitive to dry dentin.

8.4. Marginal quality

In-vitro test of the effectiveness of Adhese Universal in combination with Tetric EvoCeram and Tetric EvoCeram Bulk Fill in Class-V cavities
Dr. Uwe Blunck, Charité - Universitätsmedizin Berlin, Germany, May 2014

The marginal quality of Adhese Universal was evaluated in combination with Tetric EvoCeram and Tetric EvoCeram Bulk Fill and compared to other self-etch and total etch adhesives in combination with Tetric EvoCeram.

Methods: Extracted, caries-free, anterior human teeth were used in this study. For each of the six groups, 8 oval-shaped cavities approx. 4 mm (incisal-apically), 3 mm (mesio-distally) and 1.5 mm deep were prepared. The cavities were then treated with Adhese Universal (both self-etch and total-etch technique) and with either Tetric EvoCeram (in 2 layers) or Tetric EvoCeram Bulk Fill (1 layer). Each layer was polymerised for 40 seconds with Bluephase Style. The adhesive Syntac (TE, total-etch technique) and Clearfil SE Bond (SE, self-etch technique) were employed as controls in combination with Tetric EvoCeram.

The restorations were stored in water for 21 days. Silicone impressions were taken before and after thermocycling (2,000 cycles between 5°C and 55°C) to prepare a replica for surface quality evaluation in SEM. Marginal quality was evaluated at a magnification of 200x according to a previously defined quality scale MQ:1-4:

Margin Quality	Definition
1	Margin hardly detectable no marginal gaps observable
2	no marginal gaps massive margin irregularities
3	marginal gaps up to 2 µm no margin irregularities
4	large marginal gaps of > 2µm

Table 7: Marginal quality rating

Results:

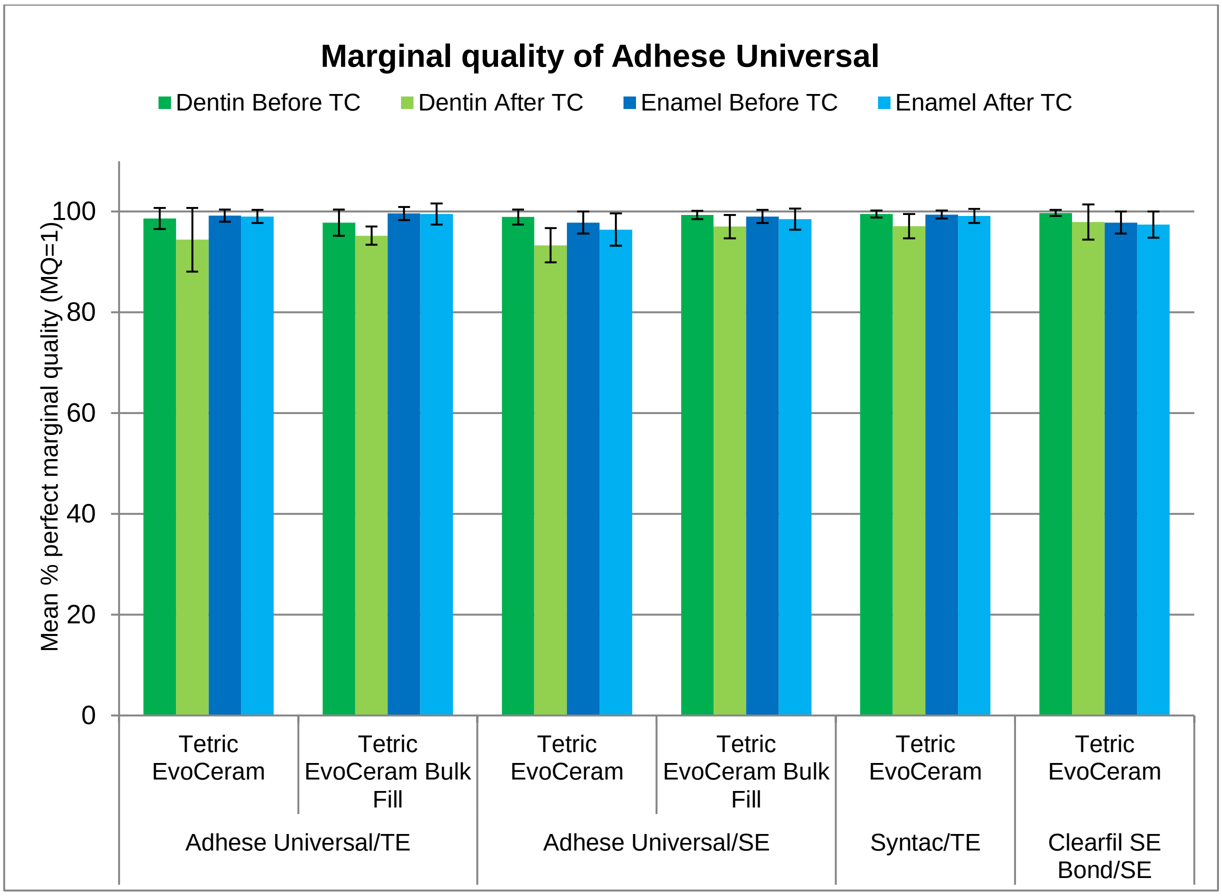


Fig. 24: Marginal quality of Adhese Universal on dentin and enamel before and after thermocycling (TC). *U. Blunck, Charité - Universitätsmedizin Berlin, Germany, May 2014*

Conclusion: No statistically significant difference in the quality of margins was observed in dentin and enamel before and after thermocycling.

Adhese Universal proved to be highly effective in class V cavities on dentin and enamel when tested with different composite materials using either the total-etch or self-etch protocol.

Marginal sealability of modern self-etch adhesives in composite restorations.

M Irie, J Tanaka, T Matsumoto, Y Maruo, G Nishigawa, S Minagi, D Watts*. Okayama University Japan, *University of Manchester UK. IADR Charlotte USA, March 2014

The percentage of perfect margins i.e. no marginal gap when bonding the composite Clearfil AP-X/Kuraray with various modern self-etch and "universal" adhesives was also investigated by M. Irie et al.: Prime&Bond Elect/Dentsply, Scotchbond Universal/3M ESPE, OptiBond XTR/Kerr, G-aenial Bond/GC, BeautiBond Multi/Shofu, Bond Force/Tokuyama and Clearfil SE Bond 2/Kuraray.

Method: Cylindrical Class I cavities (diameter 3.5 mm, depth 1.5 mm) were placed in premolars. A restorative procedure was performed according to manufacturer`s instructions for use. The restored tooth was polished immediately after light-curing and marginal gap formation was assessed using a microscope (x 400) and expressed as a percentage of the measured teeth (n=10 per group).

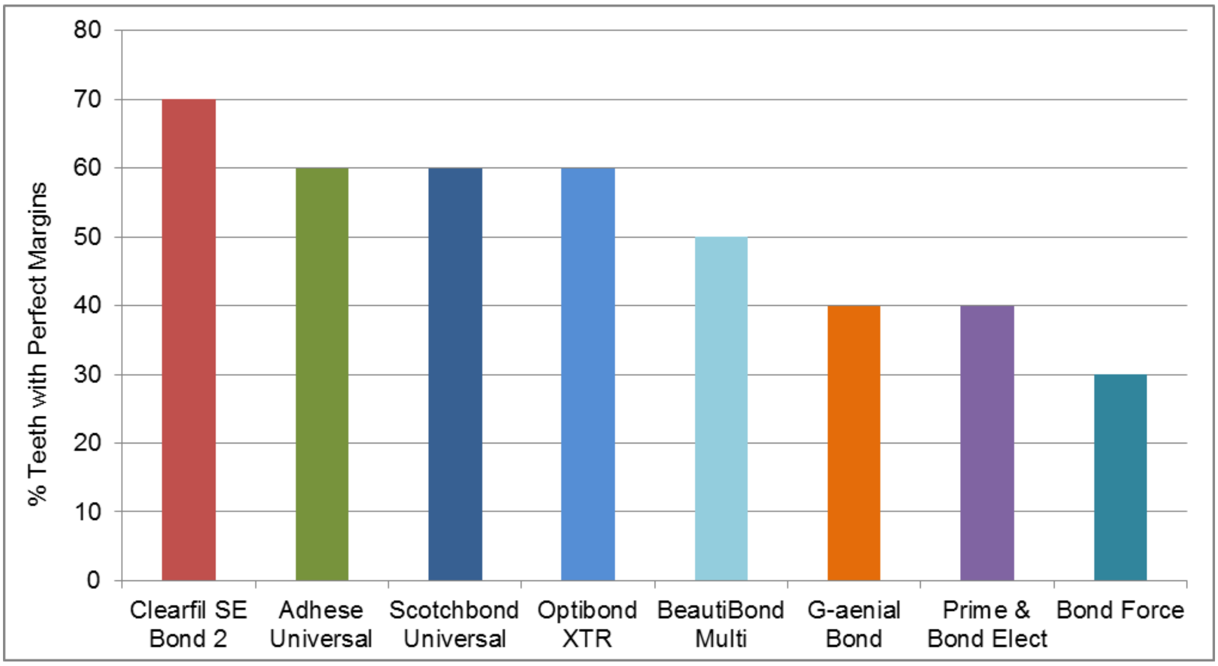


Fig. 25: Percentage of teeth with perfect marginal integrity when bonded with various adhesives. *M.Irie et al. IADR, March 2014.*

Conclusion: Of the teeth bonded with Adhese Universal, 60% had perfect margins. Clearfil SE Bond 2 showed a slightly higher percentage in this investigation.

Marginal quality of universal adhesives before and after thermo-mechanical loading

R. Frankenberger, University Marburg, Germany. 2014

The marginal quality of direct composite restorations in MOD-cavities was evaluated on enamel and dentin for universal adhesives. Thermo-mechanical loading was applied to simulate aging.

Method: 32 MOD cavities with one proximal box beneath the CEJ were prepared in extracted human third molars. Direct resin composite restorations (Tetric EvoCeram Bulk Fill) were bonded with the adhesives Scotchbond Universal or Adhese Universal using either the self-etch technique or after phosphoric acid etching (etch-and-rinse technique). Before and after thermo-mechanical loading (100,000 × 50 N, 2500 thermocycles between 5°C and 55°C), marginal gaps were analysed using SEM of epoxy resin replicas. Results were analysed with Kruskal–Wallis and Mann–Whitney U-tests ($p < 0.05$). After thermo-mechanical loading, specimens were cut longitudinally in order to investigate internal dentin adaptation by epoxy replicas under a SEM (200× magnification).

Results:

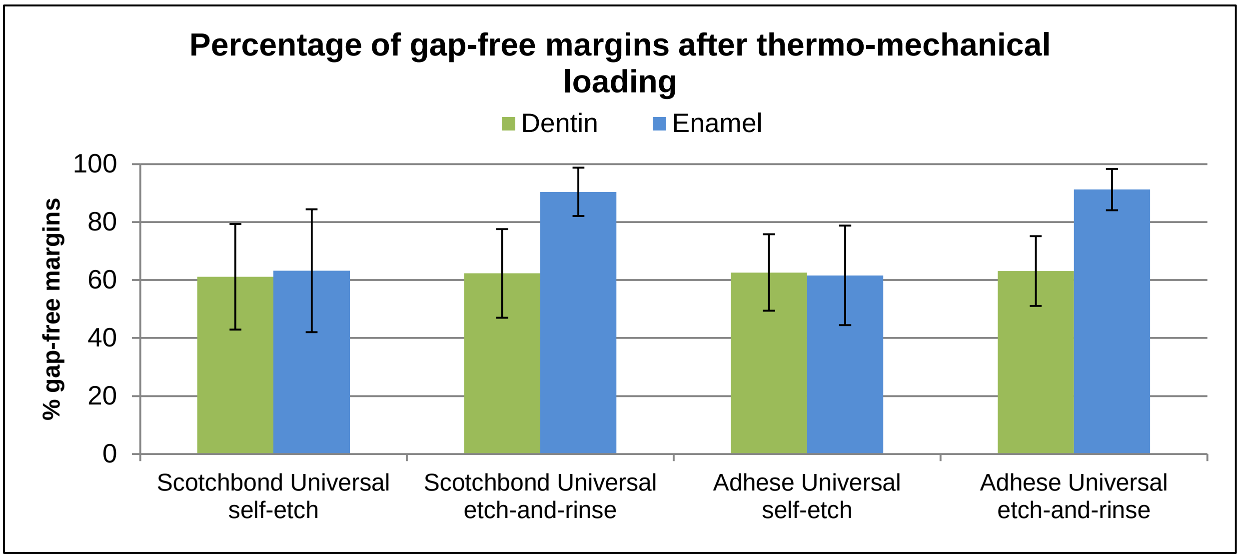


Fig. 26: Percentage of gap-free margins after thermo-mechanical loading. *R. Frankenberger, University Marburg, Germany. 2014*

A high percentage of gap-free margins were initially identified under all conditions in enamel and dentin for both adhesives. After thermo-mechanical loading, no significant differences were observed between both adhesives using the Total-Etch and Self-Etch protocol.

Conclusion: When compared to adhesives and filling composites previously tested under equal conditions [28], Adhese Universal performed very well on dentin and enamel using the Total-Etch and Self-Etch protocol.

In vitro evaluation of adhesive defects by optical coherence tomography (OCT) and scanning electron microscopy (SEM)

R. Haak and H. Schneider, University Leipzig, 2015

The aim of this study was to compare the marginal quality of three self-etch universal adhesives with a multi-component total-etch adhesive as reference in class V cavities. Using spectral domain optical coherence tomography (SD-OCT), adhesive defects at the interface of the composite and tooth structure can be detected in a non-destructive way. Using OCT, the bond quality can be quantified over the entire tooth-restoration interface, not just at the restoration margin, as with microscopic analysis of replica.

Method: Standardized class V cavities were prepared in enamel and dentin with diamond burs in 40 extracted incisors. The cavities were restored using the adhesives and Tetric EvoCeram according to the instructions for use.

The prepared teeth were analysed after storage in water for 24 hours and after 180 days plus 2,500 thermocycles between 5 and 55°C (TC). Adhesive defects were assessed by OCT for 8 teeth per adhesive at each time point.

Additionally, 2 prepared teeth per adhesive were analysed by SEM before TC and all teeth were analysed by SEM after TC and OCT.

Thirty-one of the 200 OCT-B-Scans per filling were used to quantify the adhesive defects as percentage of the interface.

Using SEM, the adhesive defects were evaluated and scored according to following table:

Score	Adhesive defects evaluated by SEM
1	0 - 25 %
2	>25 - 50 %
3	>50 - 75 %
4	> 75 - 100 %

Table 8: Score regarding the length of adhesive defects evaluated by SEM

Results:

a) OCT

Example of OCT B-scan image with adhesive defects at the tooth-composite interface:

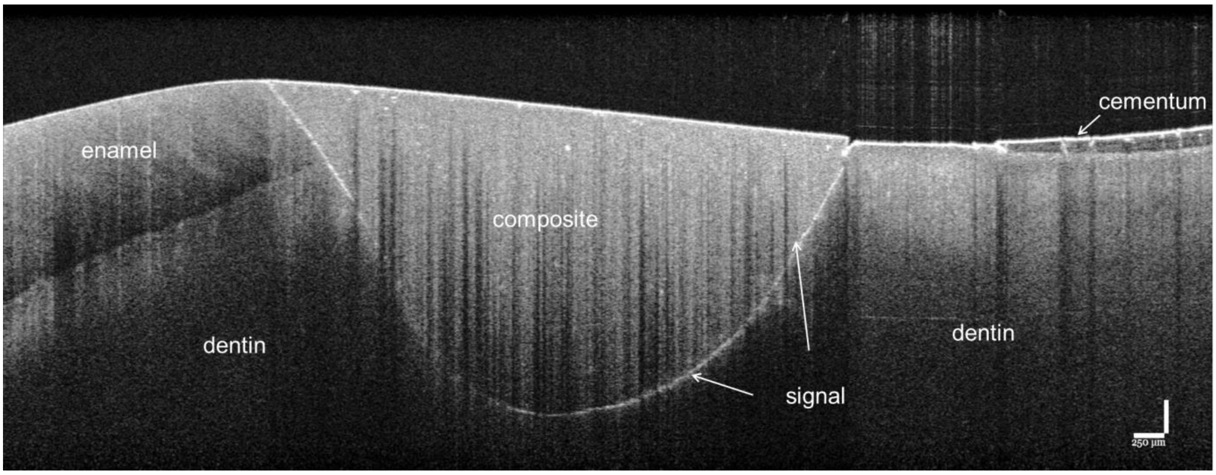


Fig. 27: Example OCT B-scan of class V filling. Signals (white line) can be seen at gaps between composite and tooth structure (arrows). *R. Haak and H. Schneider, University Leipzig, 2015*

Adhesive defects at the enamel-composite interface

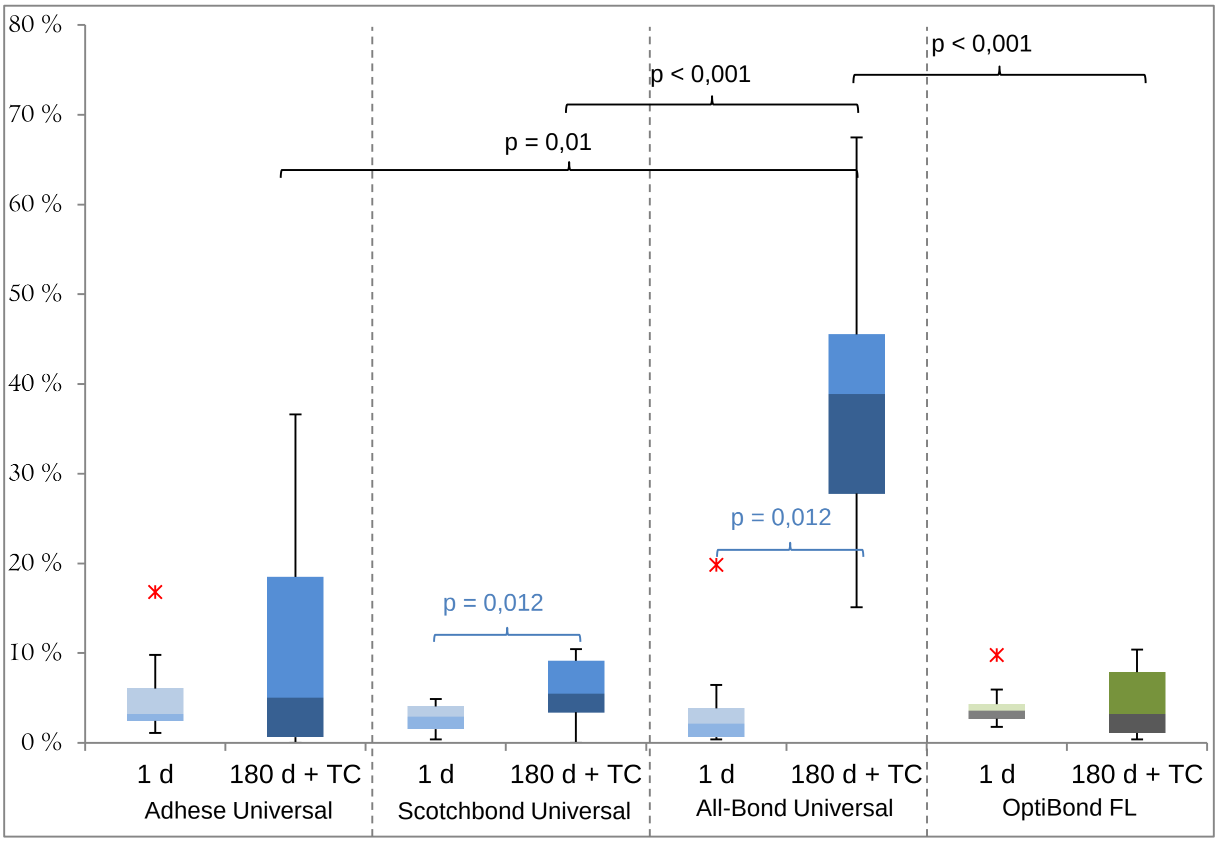


Fig. 28: Quantification of adhesive defects at the enamel-composite interface by OCT before and after thermocycling (TC). *R. Haak and H. Schneider, University Leipzig, 2015*

At the enamel-composite interface, All-Bond Universal showed the most adhesive defects after aging. The difference to the other adhesives was significant. The median values were comparable for Adhese Universal, Scotchbond Universal and the multi-component total-etch adhesive OptiBond FL.

Adhesive defects at the dentin/cementum-composite interface

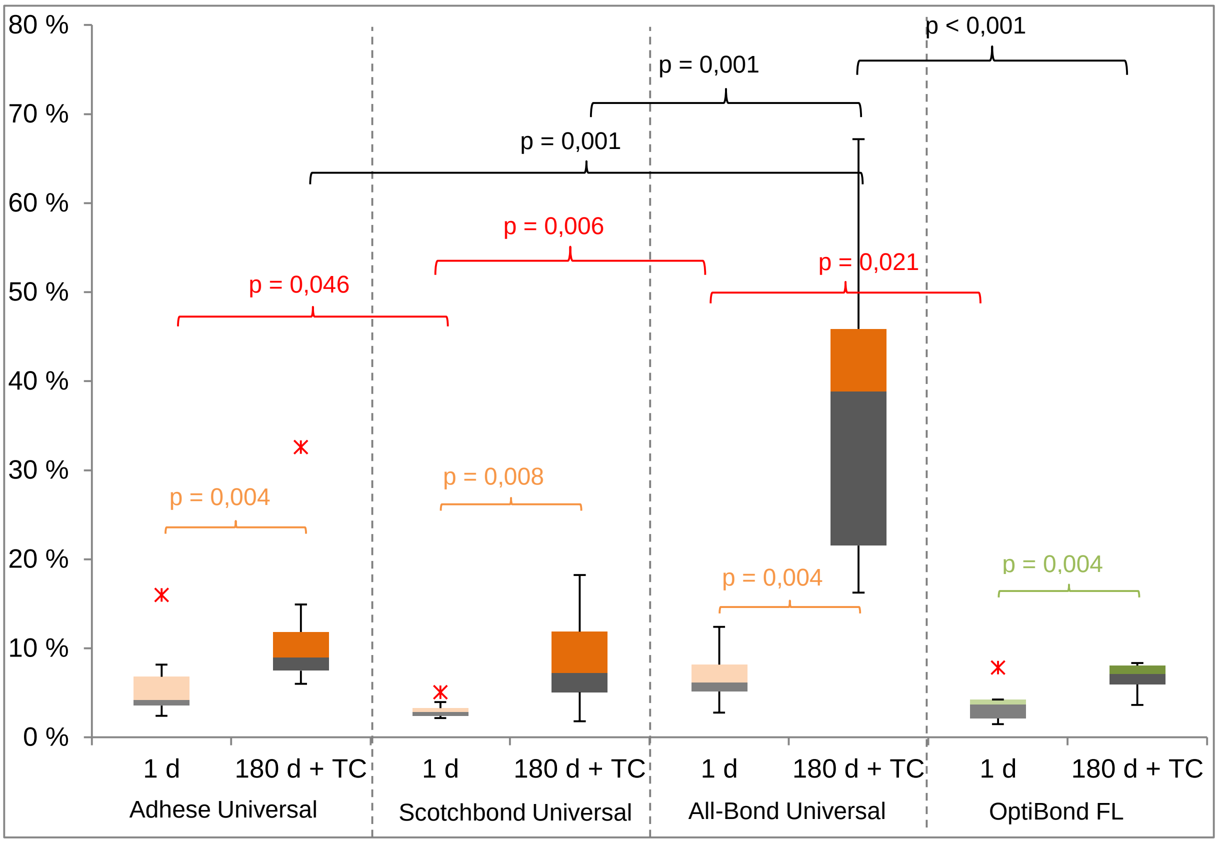


Fig. 29: Quantification of adhesive defects at the dentin-composite interface by OCT before and after thermocycling (TC). *R. Haak and H. Schneider, University Leipzig, 2015*

Also at the dentin-composite interface, All-Bond Universal showed most adhesive defects after aging, the differences to the other adhesives were significant. Adhese Universal and Scotchbond Universal showed comparable adhesive defects to the multi-component total-etch adhesive OptiBond FL.

b) Scanning electron microscopy evaluation (SEM):

The scores of length of adhesive defects obtained by SEM interpretation according to Table 8 were analysed statistically, Table 9 below summarizes the results.

	Adhese Universal		**Scotchbond Universal**		**All-Bond Universal**		**OptiBond FL**	
	Enamel	**Dentin**	**Enamel**	**Dentin**	**Enamel**	**Dentin**	**Enamel**	**Dentin**
Marginal gap	$1.7^{a,c}$	1.4^{e}	1.8^{b}	1.5^{f}	$3.0^{a,b,d}$	$2.9^{e,f,g}$	$1.1^{c,d}$	$1,4^{g}$

Table 9: Score regarding the length of adhesive defects after thermocycling (same superscript letters indicate significant differences between two average values, p_i<0,05).

All-Bond Universal revealed significantly higher adhesive defect scores than all the other adhesives tested on enamel and dentin. There was no statistical significant difference in the adhesive defect scores between Adhese Universal and Scotchbond Universal on enamel and dentin. In dentin, the adhesive defect scores of Adhese Universal and Scotchbond

Universal did not differ significantly from those of OptiBond FL. On enamel, the difference was significant, but minor.

8.5 Composite repair – bond strengths to aged composite material

Adhese Universal is indicated for the repair of fractured composite and compomer restorations. Daily wear and tear due to saliva, thermal change, foods of varying acidity and the abrasive forces of occlusion and mastication affect teeth and dental materials alike. [29] The interface of dentin and enamel and restorative materials is dynamic – different substances have different coefficients of thermal expansion and react differently under the same circumstances/exposure. Chipping, breakage and thus composite repair is therefore a standard part of daily dental practice.

Composite repair with Adhese Universal
R&D Ivoclar Vivadent, FL, December 2013

Adhese Universal was tested with regards its suitability as a bonding agent for the direct repair of composite fillings.

Method: Composite disc samples made of Tetric EvoCeram Bulk Fill (n=14), Heliomolar (n=15) and Tetric EvoCeram (n=15) (diameter 20 mm, height 2 mm) were prepared. To represent aged-composite, the discs were stored for 3 months in water at 37°C, then embedded in resin. The composite surface was sanded using P400 SiC paper under water-cooling, then rinsed and dried. Adhese Universal was applied to the composite discs and left for 20 seconds before being dispersed with compressed air to a thin film-layer. The adhesive layer was light-cured for 10 seconds with Bluephase Style. Tetric EvoCeram was used as the repair-composite. It was applied in one increment onto the adhesive surface and light-cured for 20 seconds with Bluephase Style. The samples were then stored for 24 hours in water at 37°C and thermocycled (1000x) before being tested for bond strength. Shear bond strength tests were carried out according to ISO 29022 (using the composite surface as the bonding surface instead of the tooth substrate).

Results:

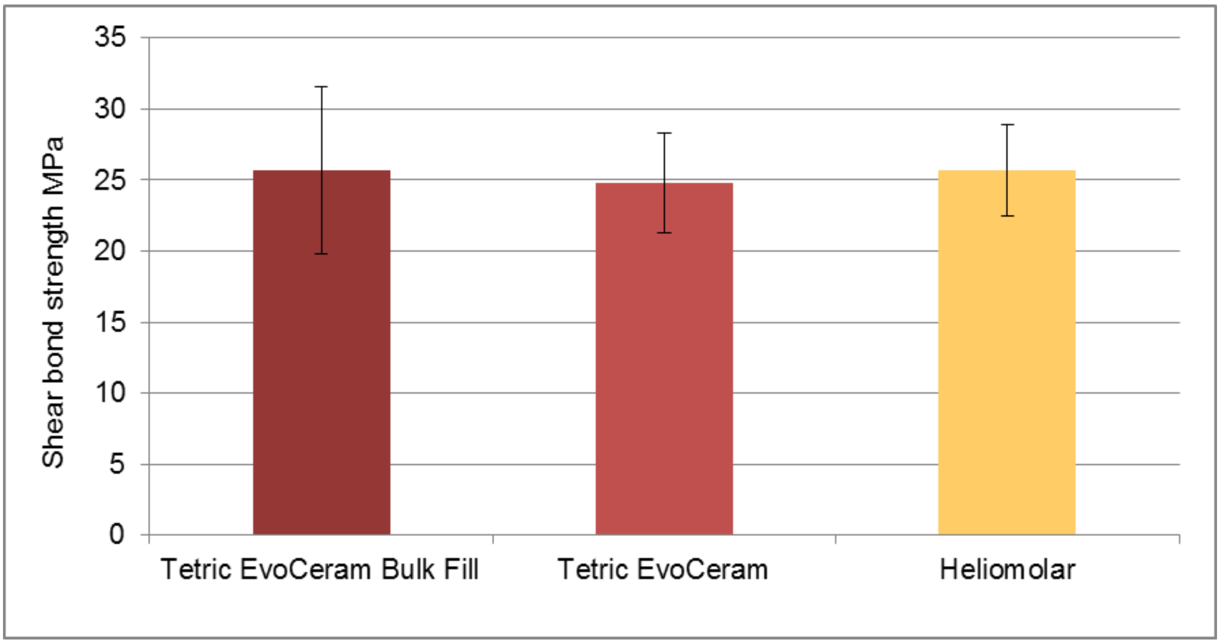


Fig. 30: Shear bond strengths with Adhese Universal and Tetric EvoCeram to three different aged composite materials. *R&D Ivoclar Vivadent, FL, December 2013*

All the composites achieved shear bond strength values of around 25-26 MPa. The bond strength exceeded the cohesive strength of the material with 100% of the samples undergoing cohesive failure in the test.

Conclusion: There was no statistically significant difference between the substrates/composites. Respectable bond strengths were achieved with Tetric EvoCeram on all aged-composite substrates supporting the suitability of Adhese Universal for composite repairs.

8.6 Adhese Universal and core build up materials

R&D Ivoclar Vivadent, FL, October 2013

Adhese Universal was tested together with the core build-up material MultiCore Flow (self-curing composite with light-curing option) in both the self-cure and light-cure mode. The graph below shows that although the values in light-cure mode are consistently higher than those using the self-cure mode, the difference is not statistically significant. The bond strengths were higher on dentin and enamel using the total-etch technique for MultiCore Flow in both the self-cure and light-cure modes. The values shown are immediate values after bonding.

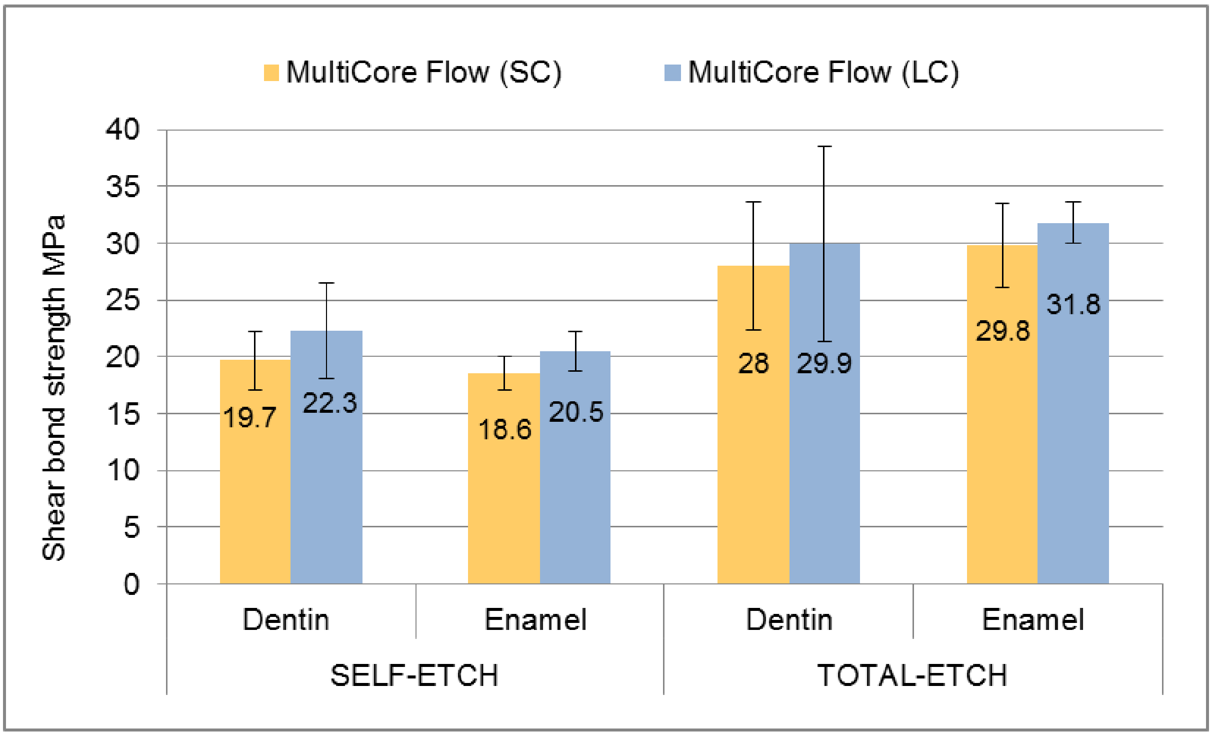


Fig. 31: Shear bond strengths of Adhese Universal plus MultiCore Flow in self-cure (SC) and light-cure (LC) mode on dentin and enamel. *R&D Ivoclar Vivadent, FL, October 2013*

Conclusion: Compatibility of Adhese Universal with MultiCore core build up material using the self- and light-cure modes and self- and total-etch techniques was observed.

8.7 Adhese Universal and indirect restorations

8.7.1 Shear bond strength of adhesive/luting composite system on dentin and enamel

R&D Ivoclar Vivadent, FL, January 2014

To assess performance with indirect restoratives, Adhese Universal was tested together with the luting composite Variolink II. Bond strength tests were carried out according ISO 29022 (see also the schematic diagram in figure 7b). Variolink II was used in the dual-cure mode (DC) i.e. the base and catalyst pastes were mixed prior to application; and in the light cure mode (LC) i.e. using the base paste only.

The graph below shows the shear bond strengths to dentin and enamel using Adhese Universal according to the self-etch and total-etch techniques and Variolink II in the dual-cure or light-cure mode - as indicated in the instructions for use. The values were measured after 24-hour storage in water at 37°C. The shear bond strengths were high in all situations.

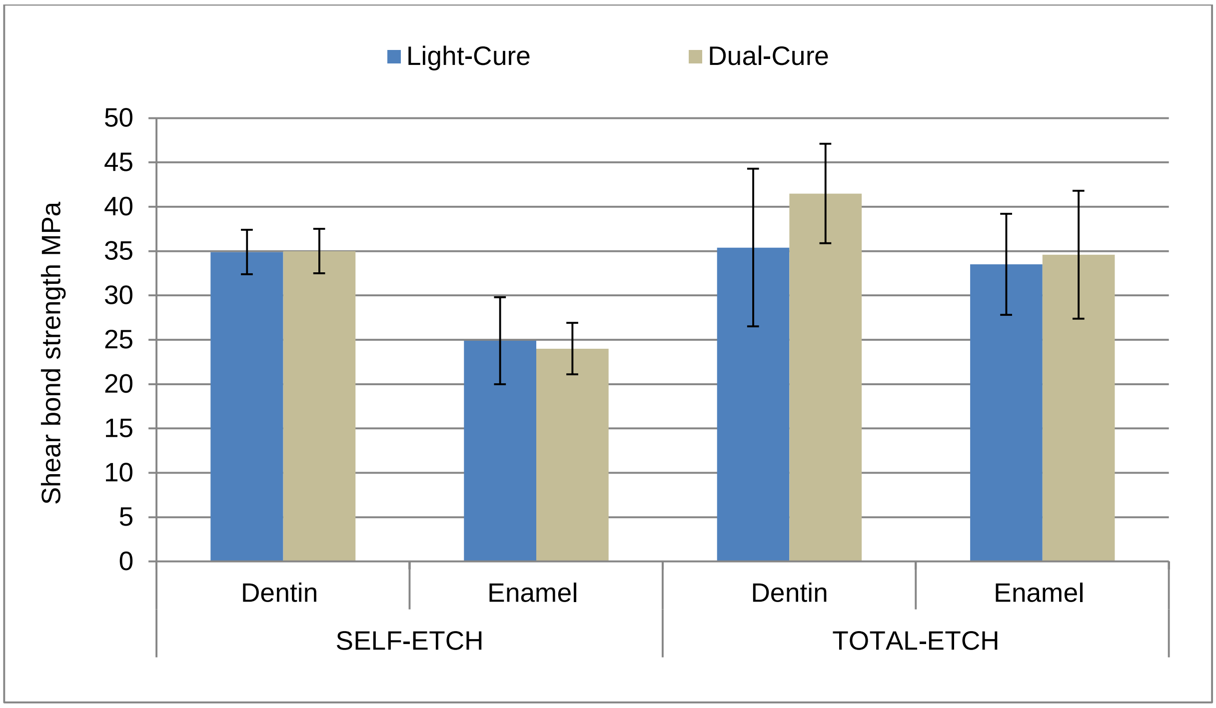


Fig. 32: Shear bond strengths for Adhese Universal with Variolink II on dentin and enamel using the self-etch and total-etch techniques after light-curing (LC) or dual- curing (DC). *R&D Ivoclar Vivadent, FL, January 2014*

Conclusion: Consistent bond strengths for Adhese Universal with Variolink II luting composite on dentin and enamel, independent of the curing mode, were observed.

8.7.2 Shear bond strengths of adhesive / luting composite systems on dentin and enamel before and after thermocycling (TC)

R&D Ivoclar Vivadent, FL, July 2014

The bond strengths for indirect restorations were tested on dentin and enamel for five adhesives in combination with the respective dual curing luting composite of the same manufacturer.

The adhesives were applied to bovine tooth substrate using the self-etch technique followed by the application of the luting material from the same manufacturer. 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 thermocycles between 5 and 55°C.

Results:

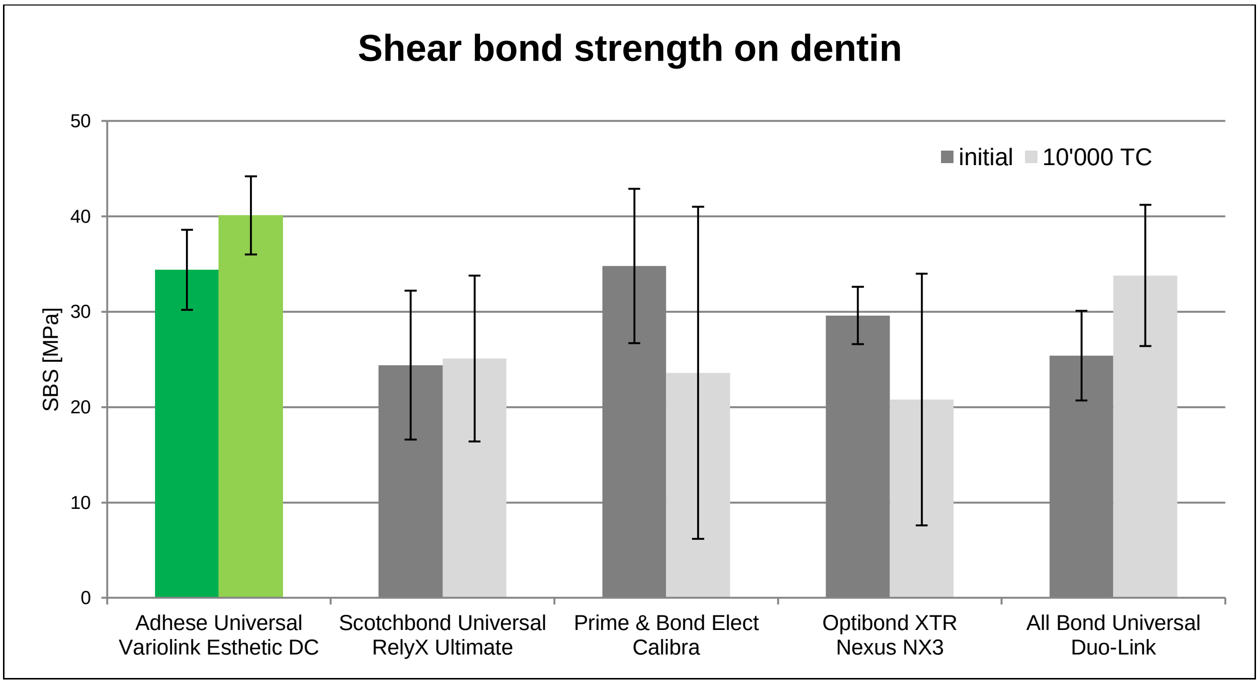


Fig. 33: Shear Bond Strength of the adhesive/luting composite system (dual-cure mode) on bovine dentin before and after thermocycling. *R&D Ivoclar Vivadent, FL, July 2014*

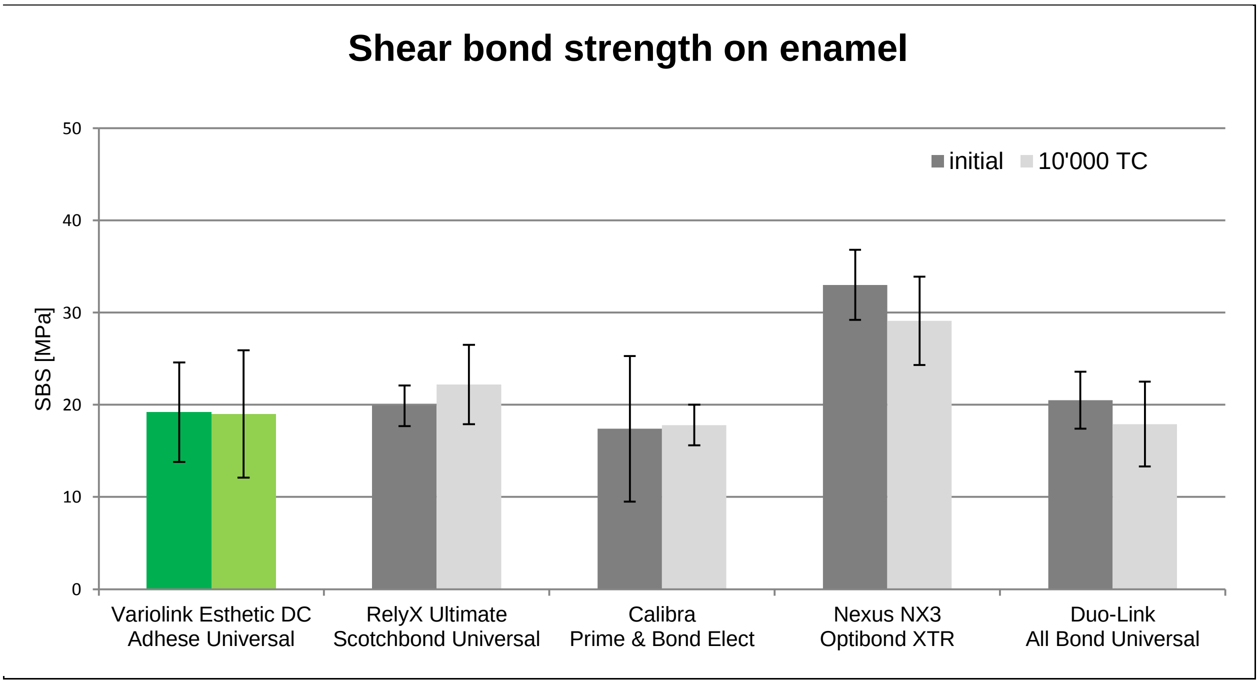


Fig. 34: Shear Bond Strength of the adhesive/luting composite system (dual-cure mode) on bovine enamel before and after thermocycling. *R&D Ivoclar Vivadent AG, Ivoclar Vivadent, FL, July 2014*

Since spontaneous debonding during thermocycling was valued at 0 MPa, this explains the high standard deviations observed for some of the competitive materials.

Conclusion: The combination of Adhese Universal with Variolink Esthetic DC showed high and consistent bond strengths before and after thermocycling on both tooth substrates.

8.7.3 Immediate Dentin Sealing / Dual Bonding Technique and bond strength

Immediate Dentin Sealing (IDS) refers to the immediate application and polymerization of the bonding agent, prior to impression taking for the indirect restoration. The additional bonding that takes place when seating the final restoration has also led to the expression “Dual Bonding Technique.” Magne carried out a review in 2005 that concluded that IDS appears to achieve improved bond strength, fewer gap formations, decreased bacterial leakage and reduced dentin sensitivity. [30]

Influence of temporary cementation on the bond strength of Adhese Universal.
R&D Ivoclar Vivadent, FL, August 2013

An internal investigation in Schaan tested the effect on bond strength of carrying out immediate dentin sealing involving the use of either Liquid Strip glycerine gel or Vaseline petroleum jelly as isolation materials.

Method: To mimic the clinical situation, Adhese Universal was applied to bovine dentin and light-cured. Ten samples were covered with a fine layer of either glycerine (n=5) or vaseline (n=5). The temporary cement Telio CS Link was applied and the samples were stored for 2 weeks in water at 37°C. The temporary material was then removed and the surface cleaned using a rotating brush and Proxyt fine prophy paste for 15 seconds. The paste was rinsed off and dried with dispersed air. Standard bonding was then carried out using Adhese Universal and Variolink II in dual-cure mode - as if for the permanent restoration. As a reference, fifteen samples were prepared without temporary cementation.

Results:

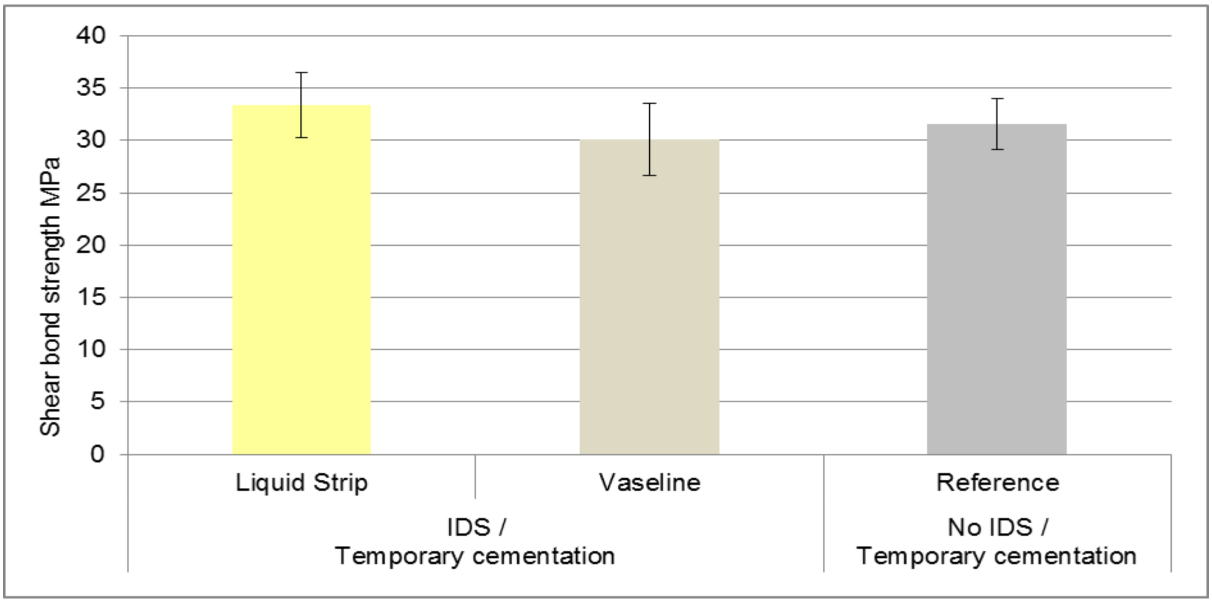


Fig. 35: Shear bond strength values on dentin after immediate dentin sealing/temporary cementation using either glycerine gel or Vaseline compared to a control without immediate dentin sealing and temporary cementation. *R&D Ivoclar Vivadent, FL, August 2013*

No irreversible contamination of the adhesive surface was observed due to contact with either glycerine gel or Vaseline or due to the 2-week water storage.

Conclusion: Adhese Universal is suitable for sealing cavity surfaces before impression taking and the application of temporary restorations. All of the bond strength values were over 30 MPa. No significant difference was observed between the reference teeth (no IDS or temporary cementation) and the teeth undergoing immediate dentin sealing and temporary cementation.

8.7.4 Film-thickness and accuracy of fit

Investigation of film-layer thickness of Adhese Universal using white light interferometry.
R&D Ivoclar Vivadent, FL, May 2013

Adhesive layer thickness can be an issue when seating indirect restorations. Adhese Universal is always “thinned out” with dispersed air (which is aided by the inclusion of thixotropic silica) and subsequently light-cured before seating indirect restorations – eliminating the need for an additional dual-cure activator. Curing Adhese Universal immobilizes the acid monomers and allows good polymerization at the adhesive-cement interface without a separate activator. As shown below, the cured adhesive exhibits a layer thickness of < 10µm on bovine dentin enabling the seating of even very tight-fitting indirect restorations.

Fig. 36a represents a tooth surface (as seen from above) embedded in resin, which has been coated with Adhese Universal, dispersed with air and light-cured. After curing, any unpolymerized material (inhibition layer) was rinsed away with ethanol. The film-thickness profile was calculated via the use of white light interferometry. This is a non-contact optical method for surface height measurement on 3-D structures with surface profiles varying between a few micrometers and a few centimeters. The pale circular ring around the outside Fig. 36a shows where the adhesive rises in height due to dispersion with an air stream. Fig. 36b depicts this profile graphically. At the very left, the level is set at 0 where the tooth surface has no adhesive. On the left and right side, the profile is also higher (graphically equivalent to the pale ring in Fig. 36a which represents how the layer was blown to both sides. The middle of the graph however (which represents the clinical situation) shows a consistently low film thickness of <10µm.

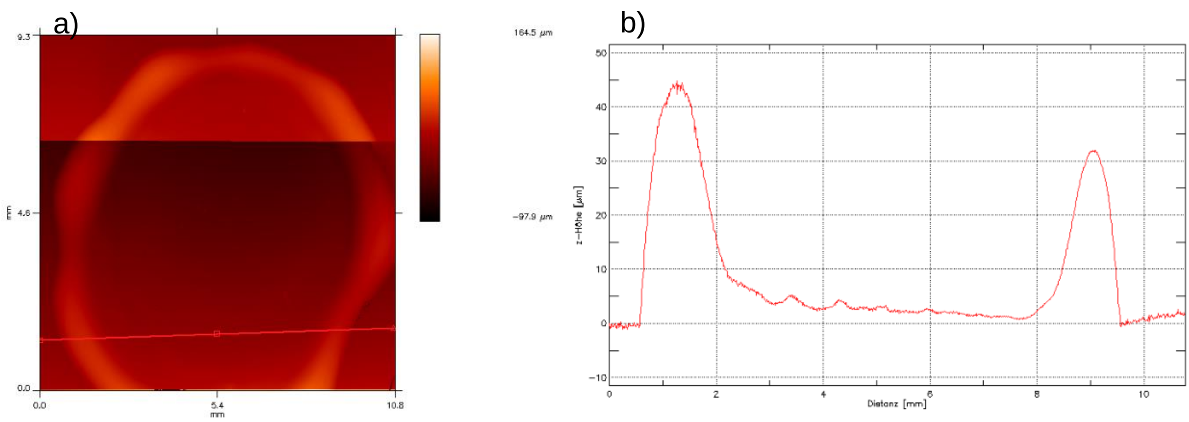


Fig. 36 The Adhesive Universal layer on tooth surface sample viewed from above (a) and film-layer thickness profile (b). *R&D Ivoclar Vivadent, FL, May 2013*

Conclusion: This investigation shows that the thin film layer thickness of Adhese Universal is consistent with providing for accuracy of fit with indirect restorations. The graph also emphasizes the importance of dispersing the adhesive with oil- and moisture-free compressed air until a glossy immobile film layer results – as indicated in the instructions for use.

Accuracy of fit with indirect restorations

R&D Ivoclar Vivadent, FL, October 2013

The influence of Adhese Universal on accuracy of fit when used for bonding indirect restorations was investigated by three Ivoclar Vivadent dentists.

Method: Nine extracted, caries-free human molars of similar size (3 per dentist) were prepared with inlay cavities of the same size. Inlays were prepared using IPS e.max Press (LT). A spacer varnish (Tru Fit Stumpflack/G. Taub Dental) was used and fitted to the cavities. With the non-adhesively-fixed inlay in each tooth, a mould and plaster die for each was made. This was used as a baseline model to quantify any changes in inlay elevation after adhesive bonding. The nine teeth were treated with Adhese Universal, according to the instructions for use and light-cured. Variolink II luting composite was applied to the pre-treated inlays and the inlays were placed and light-cured with Bluephase Style for 20 seconds in the cavities. Further moulds and plaster dies of the adhesively-bonded inlays were made for comparison. Both dies were scanned using a 3D-laser scanner, compared and differences in the inlay elevation were calculated. As shown in table 10, none of the teeth exhibited an increase in inlay elevation over 50 µm (related to the application of both the adhesive and the luting composite) which was set as the acceptance limit for not negatively affecting accuracy of fit.

Inlay	Dentist 1	Dentist 2	Dentist 3
1	34 µm	32 µm	29 µm
2	38 µm	36 µm	21 µm
3	39 µm	31 µm	20 µm

Table 10: Calculated increase in inlay elevation after bonding IPS e.max Press inlays with Adhese Universal and Variolink II for different dentists/teeth. *R&D Ivoclar Vivadent, FL, October 2013*

No excessive increase in inlay elevation was observed after bonding together with Variolink II i.e. no negative effect on the accuracy of fit.

Conclusion: Minimal inlay elevation supports the thin film-building qualities of Adhese Universal and thus its suitability for use with indirect restorations.

8.8 Adhese Universal – dentin penetration

An ultra-morphological characterization of dentin using an experimental adhesive – Adhese Universal.

M. Lopes. University of Lisbon, Portugal. August 2013

Manuela Lopes, at the University of Lisbon, studied the ultra-morphological effects of Adhese Universal on dentin using electron microscopy.

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 Ltd) and 56 dentin discs with a thickness of 800 ± 200 µm 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.

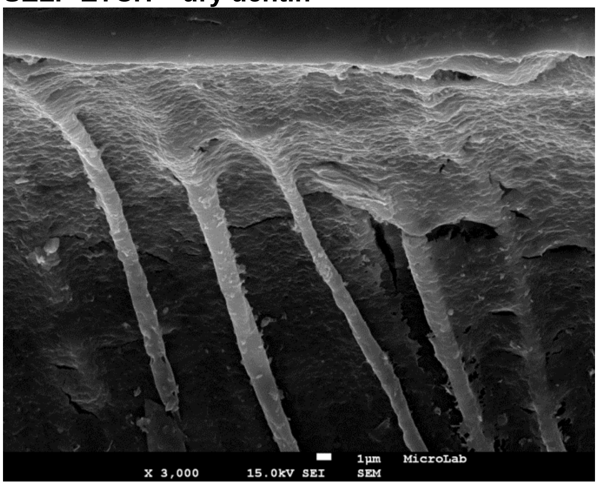
Group 1	Group 2	Group 3	Group 4
Self-Etch		Total-Etch	
Dry	Wet	Dry	Wet
Dentin dried with compressed air for 5 seconds.	Excess water blotted dry using a moist cotton pellet.	Phosphoric acid applied for 15 seconds and rinsed off for 10 seconds. Dried with compressed air for 5 seconds.	Phosphoric acid applied for 15 seconds and rinsed off for 10 seconds. Excess water blotted dry a using moist cotton pellet.
Adhesive was scrubbed into the dentin surface for 20 seconds and dispersed with compressed air for 10 seconds.			

Table 11: Groupings of human teeth according to Self-Etch, Total-Etch using the wet or dry techniques. *M. Lopes, University of Lisbon, August 2013*

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 (dry and wet) exhibited a sealed acid-resistant resin-dentin inter-diffusion zone. Adhese Universal penetrated profusely into dentin tubuli up to 100 µm in all specimens analysed (see figure. 37). The hybrid layer was 0.6 - 0.8 µm thick. In both total-etch groups (dry and wet), the hybrid layer was thicker at 3.5 - 5.0 µm, and densely infiltrated (see figure 38). Resin tags were funnel shaped with peri-tubular triangular hybridisation which is characteristic of most total-etch systems.

SELF-ETCH – dry dentin



SELF-ETCH - wet dentin

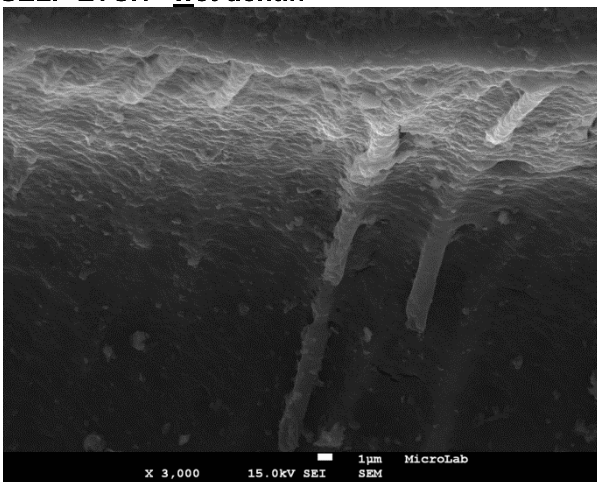


Fig. 37: SEM (x 3000) of dentin tubuli after application of Adhese Universal using the self-etch technique under dry (left) and wet (right) conditions. *M. Lopes, University of Lisbon, August 2013.*

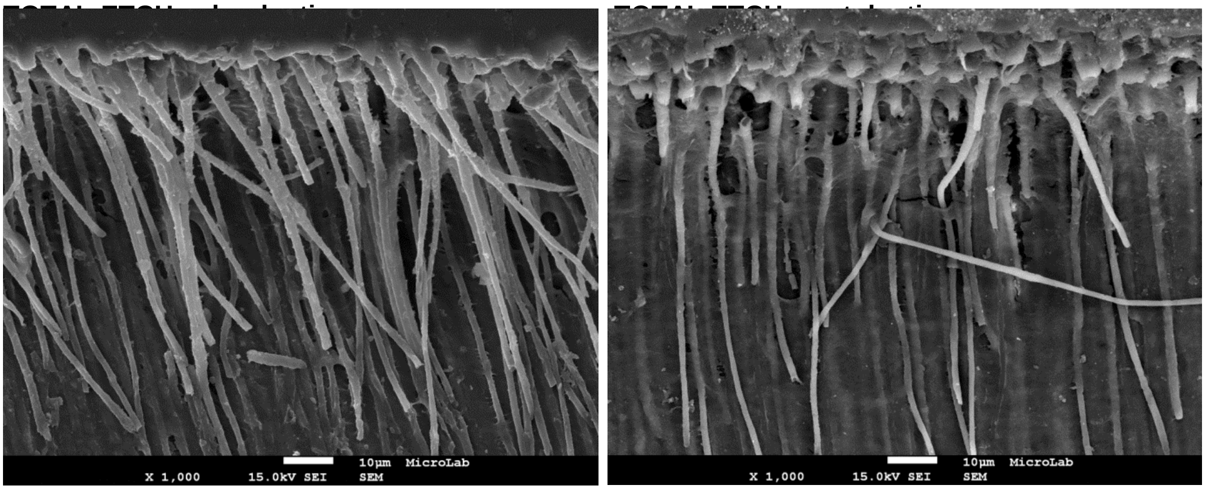


Fig. 38: SEM (x 1000) of dentin tubuli after application of Adhese Universal using the total-etch technique under dry (left) and wet (right) conditions. *M. Lopes, University of Lisbon, August 2013.*

Conclusion: The SEM photos show relatively uniform sealing/mechanical blockage of the dentin tubuli under all conditions – supporting the ability of Adhese Universal to form a strong bond to dentin whilst providing protection from hypersensitivity. More sealed tubuli are visible in Fig. 37 than Fig. 38 (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.

9. Clinical Investigations

Clinical investigations remain the ultimate way to collect scientific evidence on the clinical effectiveness of an adhesive/restorative treatment.[31] The clinical performance of Adhese Universal has been investigated at the Ivoclar Vivadent R&D clinic since its market release.

9.1 Clinical observations with Adhese Universal in Class I and Class II cavities

9.1.1 Etch and rinse technique

R&D Clinic Ivoclar Vivadent, FL. 12 month report, 2015

The main objective of this observation-study was to monitor bonded fillings using Adhese Universal with the etch & rinse (total-etch) technique in Class I and II cavities - since this technique represents the highest risk with regard to postoperative sensitivity. Baseline, 6-month and 12-month recall data are available.

Method: Forty fillings were applied to vital teeth by four different internal dentists at Ivoclar Vivadent using Adhese Universal in the etch & rinse i.e. total-etch-technique; 16 were Class I and 24 Class II fillings. The choice of delivery form i.e. VivaPen or bottle was left up to the clinician. All 40 restorations were evaluated at baseline. 38 restorations were evaluated after 6 months and 37 restorations after 12 months.

Adhesive: The enamel margins of the cavities were conditioned with phosphoric acid (Total Etch) for 30 seconds and the dentin for 15 seconds. The etchant gel was removed with water and the cavity dried until a chalky-white etch pattern was visible on the enamel surface. Starting with the enamel, Adhese Universal was then scrubbed into the surfaces of the cavity for 20 seconds, dispersed with air and polymerized with Bluephase Style for 10 seconds.

Composite: An optional layer of Tetric EvoFlow could be applied to the cavity floor which was polymerized separately. All fillings were then completed with Tetric EvoCeram Bulk Fill in layers using a maximum thickness of 4 mm. Each layer was cured for 10 seconds with Bluephase Style.

A clinical baseline evaluation was carried out by the respective dentist, approximately 1 week after placement of the filling. Esthetic integration and marginal quality were evaluated and patients were asked about their personal experience regarding post-operative sensitivity and occlusion. FDI evaluation criteria[32] were used to rate the restorations i.e. 1 = clinically excellent, 2= clinically good, 3=clinically satisfactory, 4=clinically unsatisfactory (but repairable) and 5= clinically poor (replacement necessary). Any problems with occlusion were checked and corrected as necessary.

Results: The results relevant to the adhesive are presented here. Aspects such as the aesthetic ratings of the fillings are not discussed.

Application of Adhese Universal: Application with the VivaPen and brush cannula was unproblematic, as was the bottle delivery form. The viscosity of the material allowed for rapid wetting of all required surfaces with a visible thin film remaining after dispersion with a strong stream of air. No pooling of material was observed. Light sensitivity proved unremarkable with no premature polymerization of the material observed. The composites Tetric EvoFlow and Tetric EvoCeram Bulk Fill were easy to apply on the adhesive and exhibited good adaptation.

Postoperative Sensitivity: At the baseline evaluation and at the evaluations after 6 and 12 months, all available restorations were evaluated as excellent (100% FDI criteria rating: 1) i.e. stimulation with cold spray or percussion revealed no hypersensitivity and normal vitality.

Marginal quality of the restoration: At the 12-month recall, all restorations were rated “excellent” or “good” according to the FDI evaluation criteria (table 12). With regard to marginal staining, an average of 99.5% of the total marginal length evaluated was reported as „clinically excellent“ (FDI rating: 1) and 0.5% as “clinically good” (FDI rating: 2). Marginal flaws (marginal irregularities) documented in the form of whitish margins concerned only a small portion of the total marginal length, representing an average of 10.9% of the total marginal length. These sections were rated as “clinically good” (FDI rating: 2).

Aesthetic, functional and biological properties after 12 months		**Mean % of total margin length (SQUACE)**					
		A = aesthetic	B= functional				C= biological
FDI Grading	Corresp. USPHS-grading	Marginal Staining	Submargination	Marginal fracture	Marginal gaps	Marginal Irregularities	Secondary Caries
1. Excellent	A	99.5±2.3	99.7±1.6	100.0	99.9±0.8	89.1±13.2	100.0
2. Good	A	0.5±2.3	0.3±1.6	0	0.1±0.8	10.9±13.2	0
3. Satisfactory	B	0	0	0	0	0	0
4. unsatisfactory (but repairable)	C	0	0	0	0	0	0
5. poor (replacement necessary)	D	0	0	0	0	0	0

Table 12: FDI ratings of restorations with Adhese Universal (etch and rinse) in class I/II-cavities. *R&D Clinic, Ivoclar Vivadent, FL, 2015*

Figure 39 shows one of the restorations with Adhese Universal and Tetric EvoCeram BulkFill rated 1:

Fig. 39a: Initial situation – insufficient amalgam filling in tooth 26 (mirror image)

Abb. 39b: Applikation von Adhese Universal

Fig. 39c: Situation after restoration with Adhese Universal and Tetric EvoCeram Bulk Fill. Fissures have been characterized and margins polished.

Fig. 39d: Baseline situation after approximately one week. Excellent (1) margins and clinically faultless performance.

Fig. 39e: Situation after 6 months. The restoration is still perfect (1).

Abb 39f: Clinical Situation after 12 months with excellent marginal quality.

F&E Klinik, Ivoclar Vivadent, FL, 2014 - 2015

Conclusion: In combination with the standard etch & rinse (total-etch) protocol, Adhese Universal exhibited excellent results in Class I and II cavities. It can be assumed from the clinical data that the adhesive is uncritical with regard to postoperative sensitivity. The composite fillings prepared with Adhese Universal show very good marginal quality. Application via the VivaPen was easy and trouble-free.

9.1.2 Self etch technique

R&D Clinic Ivoclar Vivadent, FL, 6 month report

Method: Twenty class I/II cavities were restored by four clinicians using Adhese Universal in the self-etch mode with Tetric EvoCeram BulkFill (7 class I and 13 class II).

Adhesive: Starting with the enamel, Adhese Universal was scrubbed into the surfaces of the cavity for 20 seconds, dispersed with air and polymerized with Bluephase Style for 10 seconds.

Composite: An optional layer of Tetric EvoFlow could be applied to the cavity floor which was polymerized separately. All fillings were then completed with Tetric EvoCeram Bulk Fill in layers using a maximum thickness of 4 mm. Each layer was cured for 10 seconds with Bluephase Style.

All restorations were evaluated after 6 months of clinical service concerning their aesthetic, functional and biological properties (FDI criteria). Furthermore a semi-quantitative clinical evaluation-method (SQUACE) was used.

Results:

None of the restorations caused material-related postoperative hypersensitivity.

After 6 months all restorations were still in place and showed FDI scores ranging from excellent (FDI grading 1) to satisfactory (FDI grading 3) (table 13). With regard to marginal staining 99.5% of the total margin length was rated as very good. Marginal irregularities affected only small portions of the total margin length (28.0%). 72.0% were rated as clinically excellent.

Aesthetic, functional and biological properties after 6 months		**Mean % of total margin length (SQUACE)**					
		A = aesthetic	B= functional				C= biological
FDI Grading	Corresp. USPHS-grading	Marginal Staining	Submargination	Marginal fracture	Marginal gaps	Marginal Irregularities	Secondary Caries
1. Excellent	A	**99.5±2.2**	**100.0**	**100.0**	**100.0**	**72.0±27.6**	**100.0**
2. Good		**0**	**0**	**0**	**0**	**28±27.6**	**0**
3. Satisfactory	B	**0.5±2.2**	**0**	**0**	**0**	**0**	**0**
4. unsatisfactory (but repairable)	C	**0**	**0**	**0**	**0**	**0**	**0**
5. poor (replacement necessary)	D	**0**	**0**	**0**	**0**	**0**	**0**

Table 13: FDI ratings of restorations with Adhese Universal (self-etch) in class I/II-cavities. *R&D Clinic Ivoclar Vivadent, FL, 2015*

Conclusion

Adhese Universal applied with the self-etch mode showed excellent results regarding marginal quality in Class I and II cavities after 6 months and no postoperative sensitivity were reported.

9.2 Adhese Universal (self-etch) in class V restorations

R&D Clinic Ivoclar Vivadent, FL, 6 month report 2015

Method: Twenty class V cavities were restored by four clinicians using Adhese Universal in the self-etch mode with Tetric EvoCeram, Tetric EvoFlow or Empress Direct.

Starting with the enamel (if existing), Adhese Universal was scrubbed into the surfaces of the cavity for 20 seconds, dispersed with air and polymerized with Bluephase Style for 10 seconds. Referring to the clinical situation Tetric EvoFlow, Tetric EvoCeram or Empress Direct were applied by using the layering technique. The maximum increment thickness was considered. Each layer was cured for 10 seconds with Bluephase Style (1100mW/cm2).

18 restorations (2 drop outs) were evaluated by the respective dentist after 6 months of clinical service concerning their aesthetic, functional and biological properties (FDI criteria). Furthermore a semi-quantitative clinical evaluation-method (SQUACE) was used.

Results: After 6 months none of the restorations caused material-related postoperative hypersensitivity. All 18 available class V- restorations showed excellent clinical function. Marginal imperfections were limited to small sections of the margins (table 14).

Aesthetic, functional and biological properties after 6 months		**Mean % of total margin length (SQUACE)**					
		A = aesthetic	B= functional				C= biological
FDI Grading	Corresp. USPHS-grading	Marginal Staining	Submargination	Marginal fracture	Marginal gaps	Marginal Irregularities	Secondary Caries
1. Excellent	A	**96.7±11.8**	**100.0**	**100.0**	**100.0**	**84.2 ±19.1**	**100.0**
2. Good		**3.3±11.8**	**0**	**0**	**0**	**15.0±19.5**	**0**
3. Satisfactory	B	**0**	**0**	**0**	**0**	**0.8±3.5**	**0**
4. unsatisfactory (but repairable)	C	**0**	**0**	**0**	**0**	**0**	**0**
5. poor (replacement necessary)	D	**0**	**0**	**0**	**0**	**0**	**0**

Table 14: FDI ratings of restorations with Adhese Universal (self-etch) in class V-cavities. *R&D Clinic Ivoclar Vivadent, FL, 2015*

a) Initial situation, tooth 22

b) Application of Adhese Universal with the VivaPen

c) Situation immediately after treatment with Adhese Universal and Empress Direct. The margins are perfectly polished.

d) Situation after 6 months. The filling is clinically excellent and shows perfect marginal quality.

Fig. 40: Class V restoration with Adhese Universal and Empress Direct. *R&D Clinic Ivoclar Vivadent, FL, 2015*

10. Biocompatibility

Introduction

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

Cytotoxicity

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

Uncured Adhese Universal was tested for cytotoxicity *in vitro* (I). As is to be expected on the basis of its monomer composition, uncured Adhese Universal exhibited cytotoxic potential in the XTT assay with an XTT_{50} value of 138.1µg/ml. When the adhesive is polymerized, the cytotoxic compounds (monomers) react and are immobilized; i.e. the cytotoxic effect of the uncured adhesive is limited in time. To reduce the risk of any cytotoxic effect on the pulp in very deep cavities, areas close to the pulp must be selectively coated with calcium hydroxide liner (e.g. ApexCal); and subsequently covered with a pressure-resistant cement (e.g. a glass ionomer cement such as Vivaglass Liner). Most dental adhesives in clinical use exhibit a similar initial cytotoxic potential; however negative effects have not been observed. When used according to the instructions for use, the risk for patients or users is negligible when compared to the overall benefit of the product.

Genotoxicity

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

Adhese Universal has been examined regarding its potential gene changing properties via Ames mutagenicity tests (II). Adhese Universal did not induce gene mutations by base pair changes or frameshifts in the genome of the strains used. Adhese Universal is not considered genotoxic.

Sensitization and irritation

Like all resin-based dental materials, Adhese Universal contains methacrylate and acrylate derivatives. Such materials may have an irritating effect and may cause sensitization. This 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.[33-39] These reactions can be minimized by clean working conditions and by avoiding contact of unpolymerized material with the skin. Commonly employed gloves made of latex or vinyl, do not provide effective protection against sensitization to such compounds.

Conclusion

Having tested the toxicity and mutagenicity of Adhese Universal, the following conclusions can be drawn:

- Uncured Adhese Universal is cytotoxic due to its monomer composition. After polymerization, the monomers are immobilized within the polymer network; thus the cytotoxic effect is minimized shortly after application of the adhesive.
- Adhese Universal, particularly in the uncured state, may cause sensitization to methacrylates. This is typical for all resin-based dental materials.
- According to the data available, Adhese Universal is not genotoxic.

In summary, Adhese Universal is safe for use in humans if it is used according to the instructions for use provided. Possible side effects, such as the sensitising property of methacrylates, occur infrequently in patients and the risk is negligible compared to the overall benefit of Adhese Universal.

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