Tetric® N-Bond Universal

The tolerant universal adhesive

Selective-Etch

Total-Etch

Self-Etch

Scientific Documentation

ivoclar vivadent

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 hole 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.

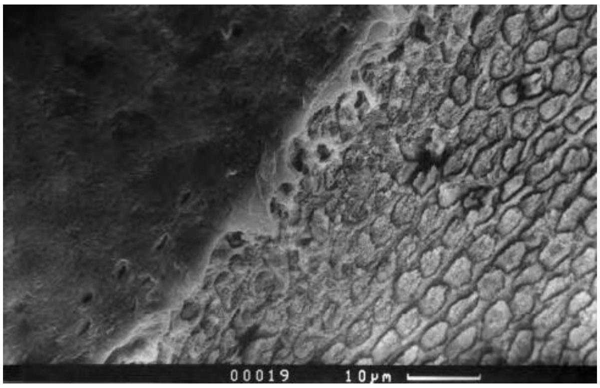

Fig.1: **SEM: Etched enamel:** Left side shows unetched enamel with smear layer intact. Right side shows etch pattern. *Dr P Gabriel, University of Leipzig*

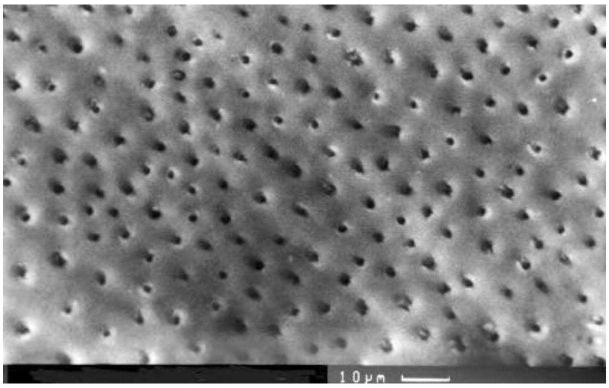

Fig. 2: **SEM: Etched dentin:** Dentinal surface showing open tubuli after conditioning with the phosphoric acid Total-Etch. *Dr P Gabriel, University of Leipzig*

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 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. The dentin is then conditioned using an acidic primer step or an all-in-one self-etching adhesive. The smear layer is modified but not removed as surfaces are not rinsed 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 prime/etch 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 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, 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). Tetric N-Bond is a typical one bottle (or VivaPen) adhesive involving a separate total-etch step and belongs to the 5th generation. Two-step self-etch systems are considered 6th generation. Tetric N-Bond Self Etch as a one-step self-etch system belongs to the 7th generation. Tetric N-Bond 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.

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 recent 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 class of adhesives - universal adhesives which are not only less technique sensitive, but allow for the possibility of using the total or selective-etching technique.

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 etch techniques, 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 current 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.	✓	✓	✗	✗	✗
Single Bond 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 etch and self-etch techniques
- compatibility with direct and indirect bonding procedures
- ability to bond to different substrates
- ability to be used with dual-cure 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. Single Bond 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.

Tetric N-Bond 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. 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. 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,[25] reducing the danger of collagen collapse and can be applied in fewer steps. Tetric N-Bond 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	**Light-Cure**
Tetric N-Bond	Tetric N-Bond Self-Etch
Universal Adhesives	
Tetric N-Bond Universal	

Table 3: Ivoclar Vivadent adhesive range and associated category

6. Tetric® N-Bond Universal

Tetric N-Bond Universal is a single component, light-cured adhesive for direct and indirect bonding procedures. The formulation of Tetric N-Bond Universal consists of proven ingredients from Tetric N-Bond and Tetric N-Bond Self-Etch as well as of new components from other Ivoclar Vivadent products. It contains methacrylates, ethanol, water, highly dispersed silicon dioxide, initiators and stabilizers.

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

Fig. 3a-c: Total-Etch, Selective-Etch and Self-Etch techniques with Tetric N-Bond Universal (left to right). *R&D Clinic Schaan, 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. Tetric N-Bond 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. Tetric N-Bond Universal is always light-cured prior to use - for both direct and indirect bonding procedures.

6.1 Indications

Tetric N-Bond 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 Tetric N-Bond 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 material, 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 this 3rd/4th generation of adhesives. 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 of step</th><th>Syntac (1990)</th><th>Tetric N-Bond (2007)</th><th>Tetric N-Bond Self-Ecth) (2009)</th><th>Tetric N-Bond Universal (2015)</th></tr>
<tr><td>Enamel conditioning</td><td>Expose retentive etching pattern</td><td>Total Etch H_3PO_4</td><td rowspan="2">N-Etch H_3PO_4</td><td rowspan="4">Tetric N-Bond Self-Etch</td><td rowspan="4">Tetric N-Bond 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 planned restoration via tag formation</td><td>Syntac Adhesive</td><td rowspan="2">Tetric N-Bond</td></tr>
<tr><td>Bonding</td><td>Hydrophobic bonding agent to bond to restoration via co-polymerization with restorative material</td><td>Heliobond</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. Tetric N-Bond Universal essentially belongs to a new class of adhesive 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 indirect bonding procedures.

Tetric N-Bond Universal and universal adhesives in general, contain low levels of acidic monomer, and are therefore “mild-etching” adhesives. Tetric N-Bond Universal has a pH of approximately 2.5 – 3.0. The Tetric N-Bond 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 Tetric N-Bond 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 Tetric N-Bond 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 Tetric N-Bond Universal

Table 6 describes the bonding mechanism of Tetric N-Bond Universal in more detail i.e. how the different bonding steps/conditions are achieved by the balanced composition of specific components within the formulation. Tetric N-Bond 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 of step	Tetric N-Bond Universal
Enamel conditioning	Formation of 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 promoting 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 Formation of 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 facilitated by hydrophilicity of HEMA – and due to mild etching nature, dentin is not over-demineralized
Wetting	Infiltrate collagen with hydrophilic resin.	• Infiltration of hydrophilic surfaces facilitated by hydrophilic monomers
Bonding	Create 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 Tetric N-Bond 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.[26]

The water/ethanol solvents and the integrated micro-fillers used in Tetric N-Bond 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 Tetric N-Bond 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 Tetric N-Bond 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 8.5 Tetric N-Bond Universal – dentin penetration: bond and desensitization).

6.2.3 Adhesive cementation of indirect restorations

Adhesive layer thickness is an issue when seating indirect restorations. Tetric N-Bond Universal is always "thinned out" with compressed air to form a thin coating – 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 Tetric N-Bond Universal immobilizes the acid monomers and allows good polymerization at the adhesive/luting composite interface without a separate dual-cure activator (see section 8.4 for tests with indirect restorations).

The mild etching formulation also renders Tetric N-Bond 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®

Tetric N-Bond 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: Tetric N-Bond 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, October 2014

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: Tetric N-Bond Universal supplied in the VivaPen was compared with OptiBond All-In-One/Kerr, Clearfil SE Bond/Kuraray, Prime & Bond NT/Dentsply, G-BOND/GC and Single Bond Universal/3M ESPE – 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 Tetric N-Bond Universal, three clicks of the VivaPen were used for one application. One drop was used for OptiBond All-In-One, Prime & Bond NT, G-BOND and Single Bond Universal. For the Clearfil SE Bond 2-bottle system, 1 drop of PRIMER and 1 drop of BOND was used for each application. Mixing wells (two separate wells for Clearfil SE Bond) were used for all bottle-adhesives as indicated by the manufacturers' instructions for use. "Adhesive used" refers to the weighed material actually applied to the cavity model and "adhesive wasted" refers to that material weighed found on applicator(s), mixing plates etc.

Results:

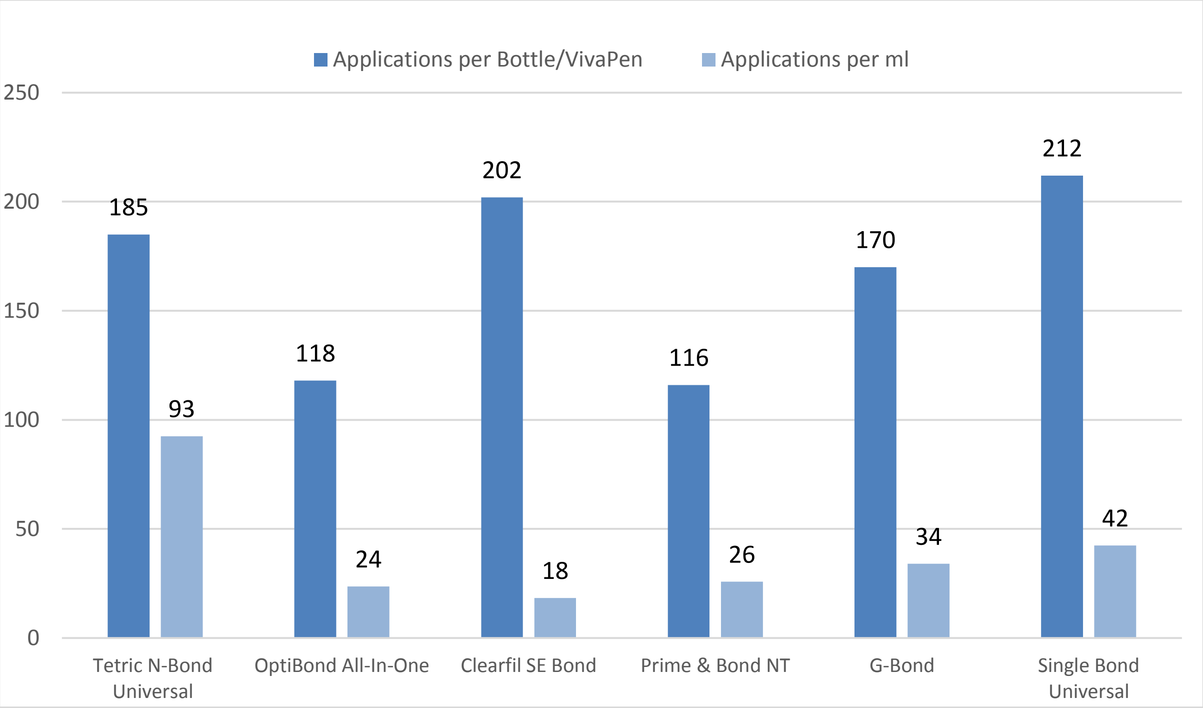

Fig. 5: The number of applications per VivaPen/bottle and ml for various universal adhesives. *Berndt & Partner 2014*

With 185 applications per 2 ml-VivaPen, it exhibited the highest number of applications per ml - 93 per ml – more than twice than average bottle delivery forms.

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

6.4 “Universality” of Tetric N-Bond Universal

The specially tuned composition of Tetric N-Bond 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 dispersed air and curing the adhesive, avoids possible negative effects when fitting indirect restorations. Light-cured adhesive copolymerizes well with composites, core build up and luting composites and has proven to be operator-tolerant.

Compatibility with all etching techniques: Adhesives need to combine both hydrophobic and hydrophilic properties in order to establish a bond between the tooth substrate (hydrophilic) and the restorative material (hydrophobic). Tetric N-Bond 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 of dentin moisture rendering it suitable for use with all etching protocols.

7. Technical Data

Tetric N-Bond Universal

Standard - Composition	(in weight %)
Methacrylates	60 - 70
Water, Ethanol	23 - 28
Highly dispersed silicon dioxide	3 - 5
Initiators and Stabilisers	3 - 5

Physical properties:

Shear bond strength

In combination with:
- **direct restorative composites**
- **light-curing composite cements**
- **light-curing core build-up composites**

		Test method	Specification
Dentin	MPa	ISO 29022	≥ 25*
Enamel	MPa	ISO 29022	≥ 17*

* 4 from 5 test pieces

In combination with:
- **self-curing core build-up composites**

		Test method	Specification
Dentin	MPa	ISO 29022	≥ 25*
Enamel	MPa	ISO 29022	≥ 14*

* 4 from 5 test pieces

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 to 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 restoration they are intending 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 test 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.

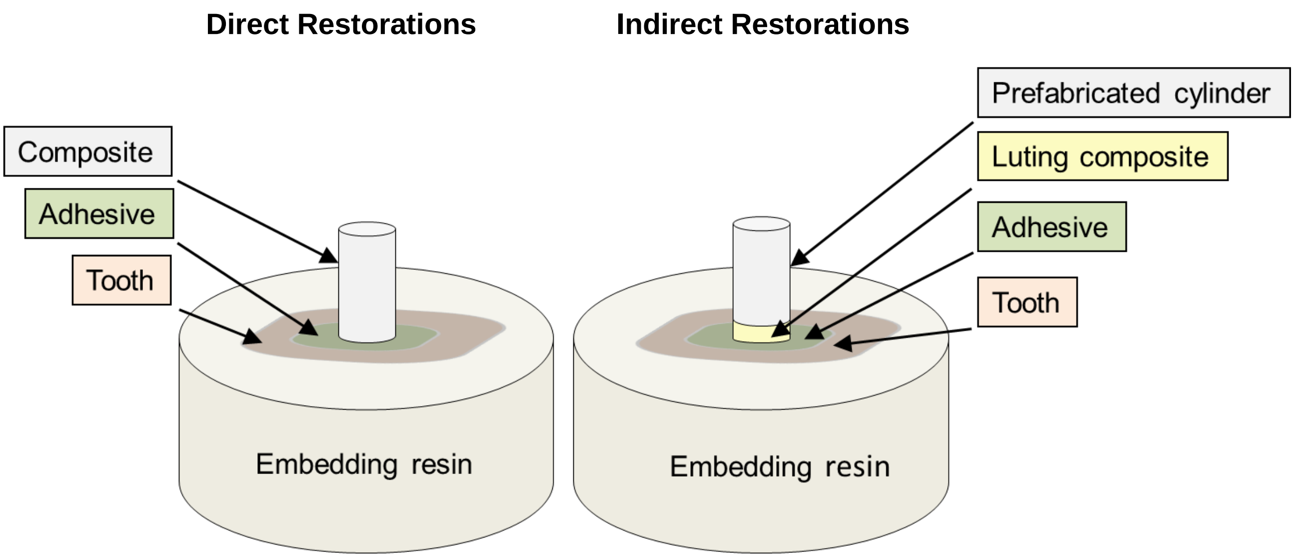

Fig. 6: Schematic representation of shear bond strength testing for direct (left) and indirect (right) Restorations.

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 Tetric N-Bond Universal and direct restorations

8.2.1 Shear bond strength tests for adhesives on dentin using etch and rinse protocol

E. Mahn, Universidad de los Andes, Chile, 2015

Method: Caries free human teeth were embedded in epoxy resin and a flat surface with exposed dentin was created by sanding with an industrial sander with SiC P120 followed by P500 grit paper. The prepared teeth were stored in water until use. After drying with paper, the dentin was etched for 10 s with 37% phosphoric acid, rinsed with water and dried with paper. The following adhesives were then applied to the tooth surface according to their respective instructions for use: Tetric N Bond Universal (Ivoclar Vivadent), Tetric N Bond (Ivoclar Vivadent), Prime & Bond NT (Dentsply), Single Bond Universal (3M ESPE) and Optibond Solo Plus (Kerr). Tetric N-Ceram Bulk Fill (Ivoclar Vivadent) was applied and cured in a cylindrical mold onto the adhesive layer. Fourteen samples were prepared for each adhesive. The samples were stored in water for 48 hours before the shear bond strength was determined using a universal testing machine (Z100®, Zwick Roell, Ulm).

Results: The best and the worst results of each group were removed. The specimens that debonded before the shear test were not considered in the analysis. When that was the case, the worst and best results were not eliminated. None of the samples with Tetric N-Bond Universal and Tetric N-Bond debonded prior to testing.

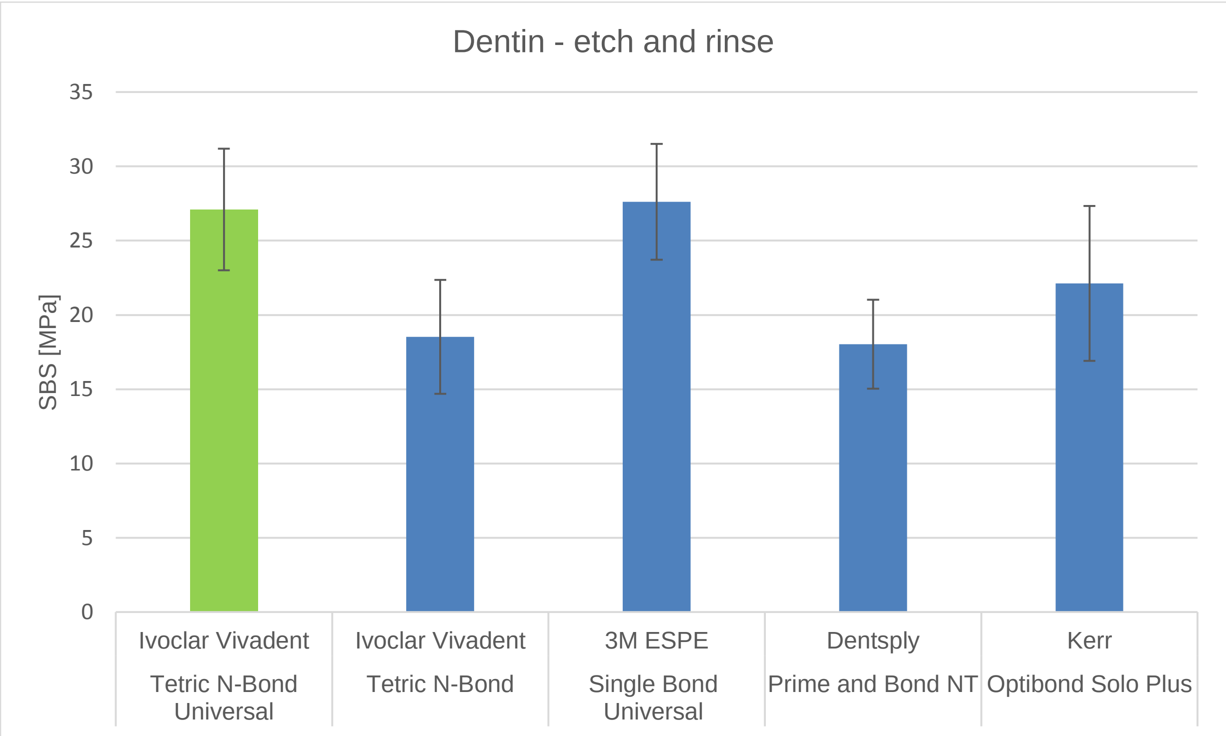

Fig. 7: Shear bond strength values for adhesives on dentin using the etch and rinse protocol

8.2.2 Shear bond strength tests for adhesives on dentin using the self-etch protocol

E. Mahn, Universidad de los Andes, Chile, 2015

Method : The samples were prepared as described in 8.2.1 with the difference that no phosphoric etching was performed. Data were analysed as described in 8.2.1. 6 samples were prepared for each adhesive.

Results:

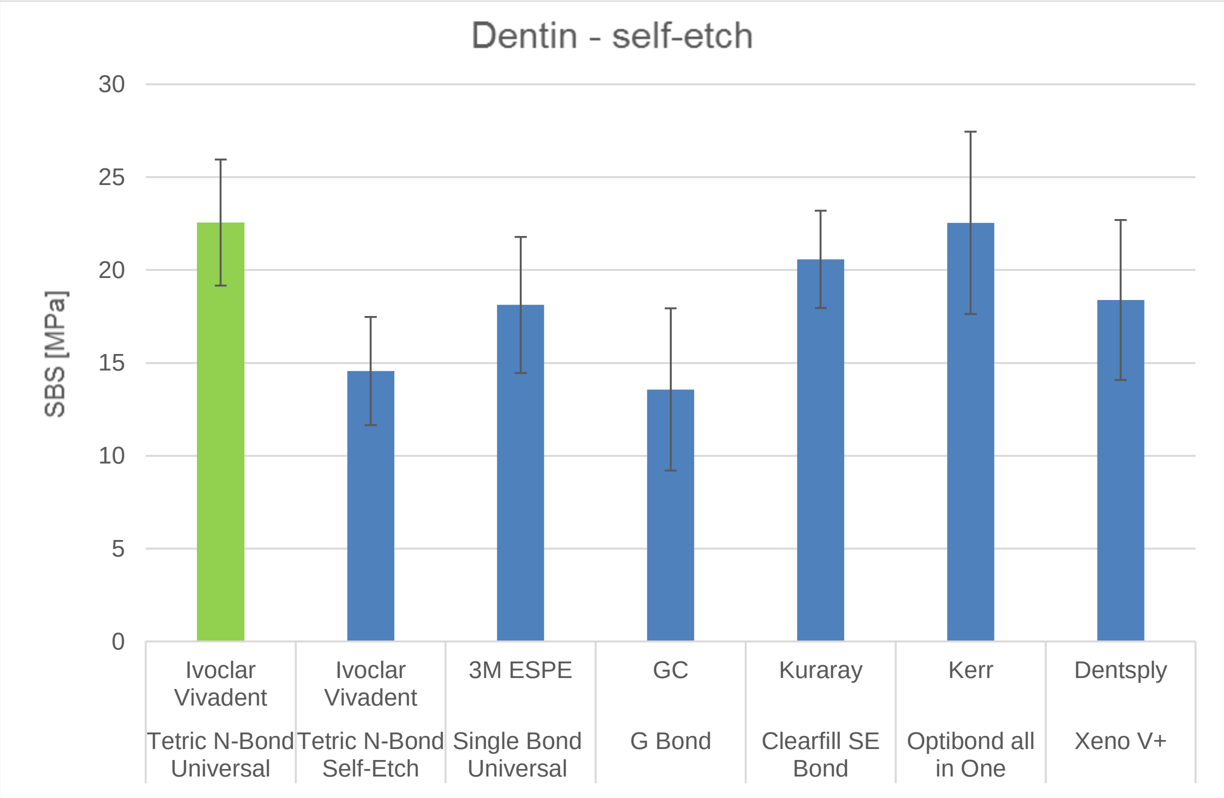

Fig. 8: Shear bond strength values for adhesives on dentin using self-etch protocols

8.2.3 Shear bond strength tests for adhesives on enamel using the etch and rinse protocol

E. Mahn, Universidad de los Andes, Chile, 2015

Method: Samples were prepared as described in 8.2.1 with the difference that an enamel surface was prepared and the enamel was etched for 30 seconds. 6 samples were prepared for each adhesive.

Results:

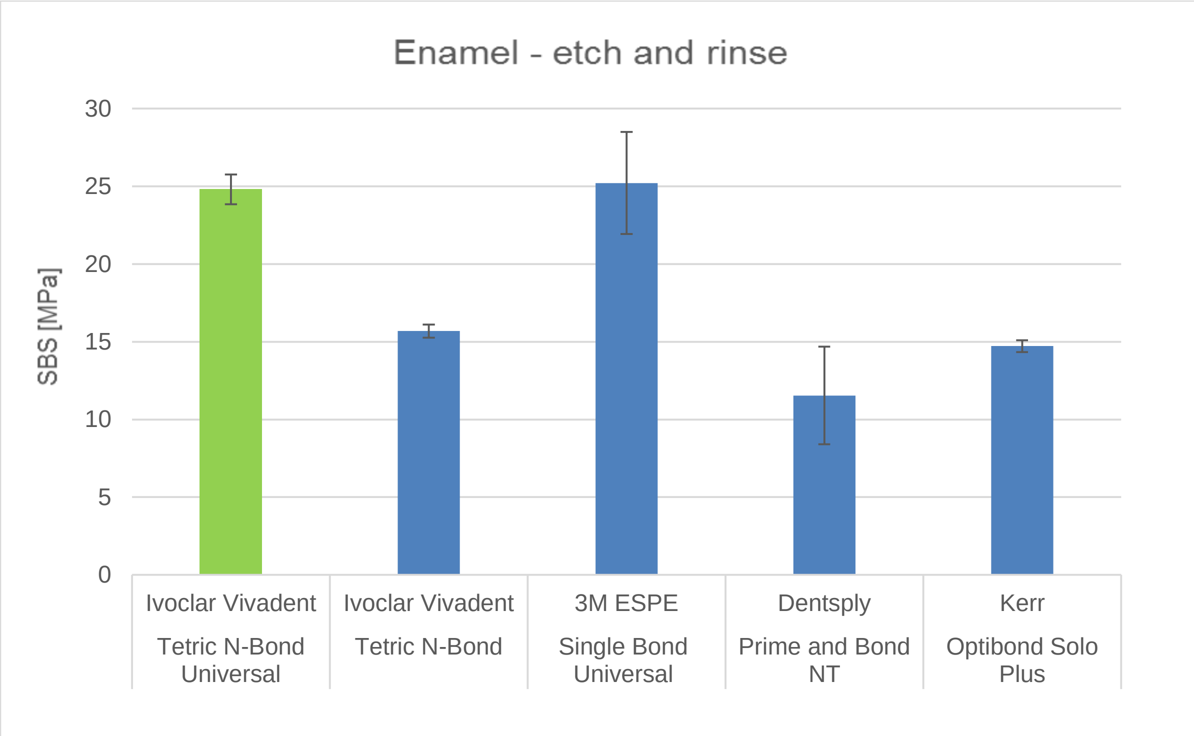

Fig. 9: Shear bond strength values for adhesives on enamel using the etch and rinse protocol

8.2.4 Shear bond strength tests for adhesives on enamel using the self-etch protocol

E. Mahn, Universidad de los Andes, Chile, 2015

Method: Samples were prepared as described in 8.2.1 with the difference that an enamel surface was prepared and no phosphoric acid etching was performed. 6 samples were prepared for each adhesive.

Results:

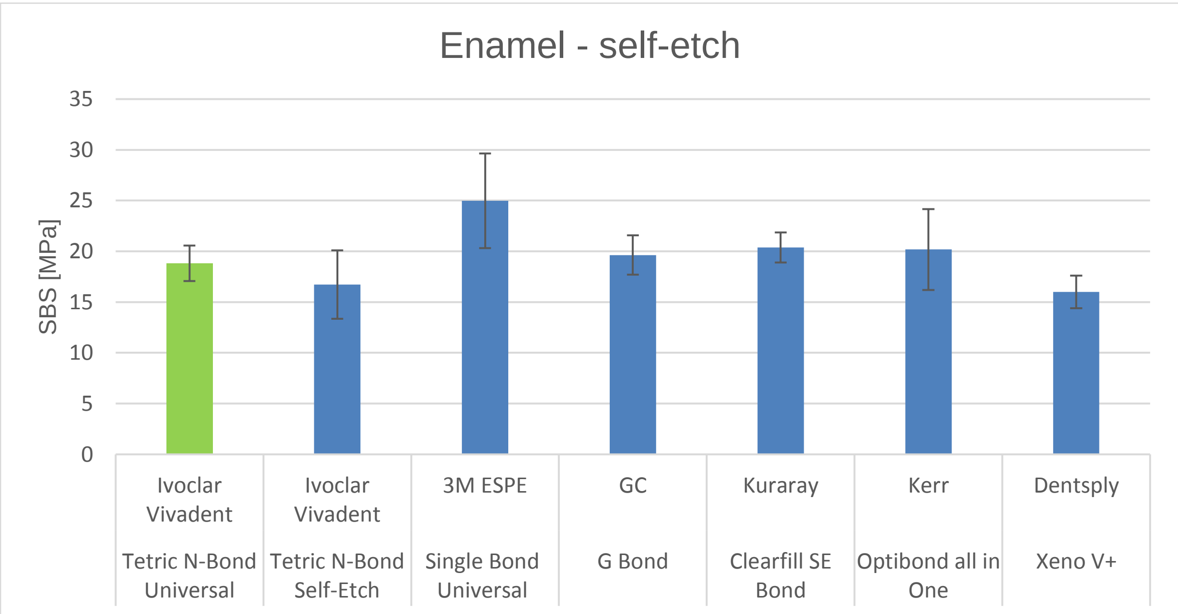

Fig. 10: Shear bond strength values for adhesives on enamel using the self-etch protocol

Conclusion: In all bonding conditions tested, Tetric N-Bond Universal showed high shear bond strength. On enamel, highest bond strength is reached after etching with phosphoric acid (selective etch / etch and rinse).

8.2.5 Micro shear bond testing on enamel and on dentin dried with different modes

M. Erhan Çömlekoğlu/ M. Dündar Çömlekoğlu, Ege University, School of Dentistry, Department of Prosthodontics, Izmir, Turkey.

The bond strength on enamel and on dentin was evaluated for Tetric N-Bond Universal and three other dental adhesives in total-etch mode: Adper Single Bond Plus (3M ESPE) (ADP), OptiBond Solo Plus (Kerr) (OPB) and Prime&Bond NT (Dentsply) (PB). Tetric N-Bond Universal and Adper Single Plus were additionally tested in self-etch mode. On dentin, the effect of two drying modes was compared.

Method: Fifty intact human third molars were sectioned in four quadrants with a diamond saw, creating 200 tooth substrate samples. Flat enamel surfaces were obtained around the vestibular aspects of each tooth portion while flat dentine surfaces were obtained at their mid-coronal areas. After grinding with abrasive (150 to 600-grit SiC abrasive papers), the tooth substrate samples were divided into total-etch and self-etch groups for enamel and dentin. The dentin group was further divided into 2 drying modes: the dentin was dried in an air stream for either 1s without desiccating or for 15 s (dry).

Each subgroup (n=10) was surface-treated with 4 different universal adhesives according to the instructions for use. Then Tetric N-Ceram Bulk Fill was applied in a mould with an internal diameter of 1mm and light cured. Micro shear bond strength was measured using a universal testing machine (Autograph, Shimadzu, cross-head speed: 1 mm/s).

The data were statistically analyzed using SPSS 17.0 software. Micro shear bond strength data (MPa) were subjected to two-way ANOVA with the bond strength as the dependent variable and surface conditioning methods. Multiple comparisons were made using Tukey's test. Statistical significance was set at $p < 0.05$ in all tests.

Additionally, fractographic analysis was performed using optical microscopy at 50X magnification and scanning electron microscopy.

Results:

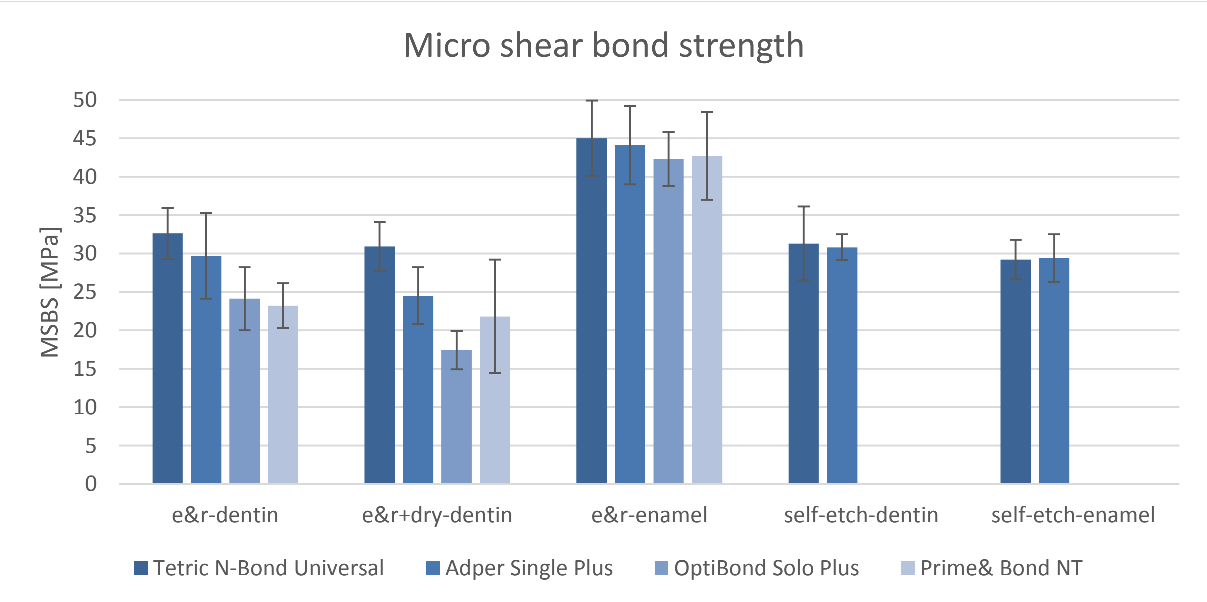

Fig. 11: Micro shear bond strength on dental substrates. Dentin was either blot-dried (e&r dentin) or overdried (e&r + dry dentin) after etching with phosphoric acid.

Pretest failures occurred in no test group. In the etch&rinse and over-dried dentin group, Tetric N-Bond Universal exhibited the highest micro shear bond strength (MSBS) values, while OptiBond Solo Plus showed the lowest (*P*<.05). In the etch&rinse and lightly dried dentin group Tetric N-Bond Universal and Adper Single Bond Plus showed higher bond strength values when compared with OptiBond Solo Plus and Prime&Bond NT subgroups (*P*<.05). Only Tetric N-Bond Universal showed no significant differences between the drying modes (*P*>.05).

	e&r-dentin	e&r+dry-dentin	self-etch-dentin	etch&rinse-enamel	self-etch-enamel
Tetric N-Bond Universal	20.00%	30.00%	20.00%	10.00%	30.00%
Adper Single Plus	40.00%	30.00%		10.00%	
Optibond Solo Plus	40.00%	40.00%	20.00%	0.00%	30.00%
Prime& Bond NT	50.00%	40.00%		10.00%	

Table 7: Frequencies of adhesive failures according to fractographic analysis.

Conclusion: In each condition tested, Tetric N-Bond Universal generated consistently high bond strengths, which was higher or equal to the compared adhesives. All adhesives tested showed highest bond strengths on etched enamel. Over drying of dentin after phosphoric acid etching did not reduce the bond strength of Tetric N-Bond Universal. In this condition, Tetric N-Bond Universal showed the highest bond strength of all adhesives tested. The occurrence of adhesive fractures was very low for Tetric N-Bond Universal.

8.3 Tetric N-Bond Universal and indirect restorations

8.3.1 Shear bond strength tests with indirect cement protocols.

E. Mahn, Universidad de los Andes, Chile, 2015

Universal Adhesives are applied for indirect restorations in combination with a luting composite. This investigation measured and compared the shear bond strengths of various manufacturers' combinations of adhesive and luting composite.

Method: Teeth were prepared as described in 2.2.1. The etch and rinse protocol was applied where indicated. Composite cylinders with a diameter of 2.23 mm were prepared with Tetric N-Ceram Bulk Fill and sandblasted. The adhesives were applied according to the manufacturers' instructions for use. The luting composite was then applied onto the prefabricated composite cylinder and clamped to the prepared tooth surface. Excess composite was removed by wiping with a microbrush, then the luting composite was light cured for 10 s from two sides. Shear bond strength was measured after 48h storage in water.

Results:

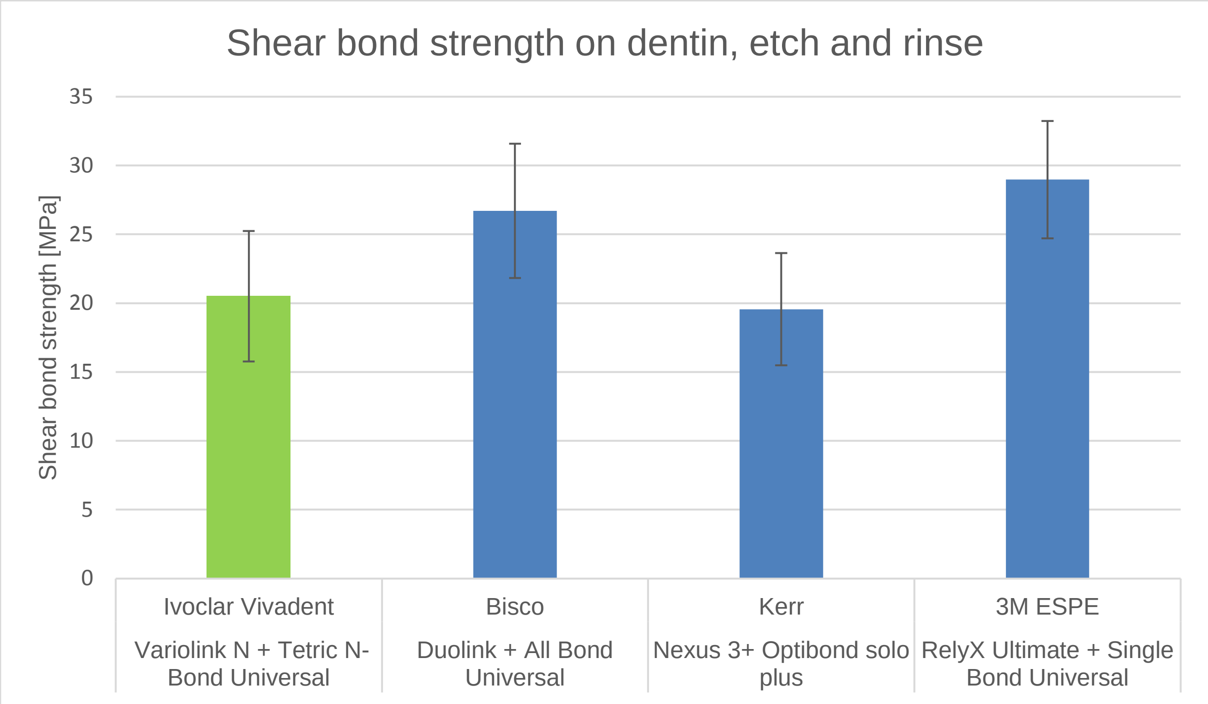

Fig. 12: Indirect shear bond strength on dentin, etch and rinse protocol. 14 samples were measured per adhesive; the highest and the lowest values were discarded, the average of 12 measurements is displayed.

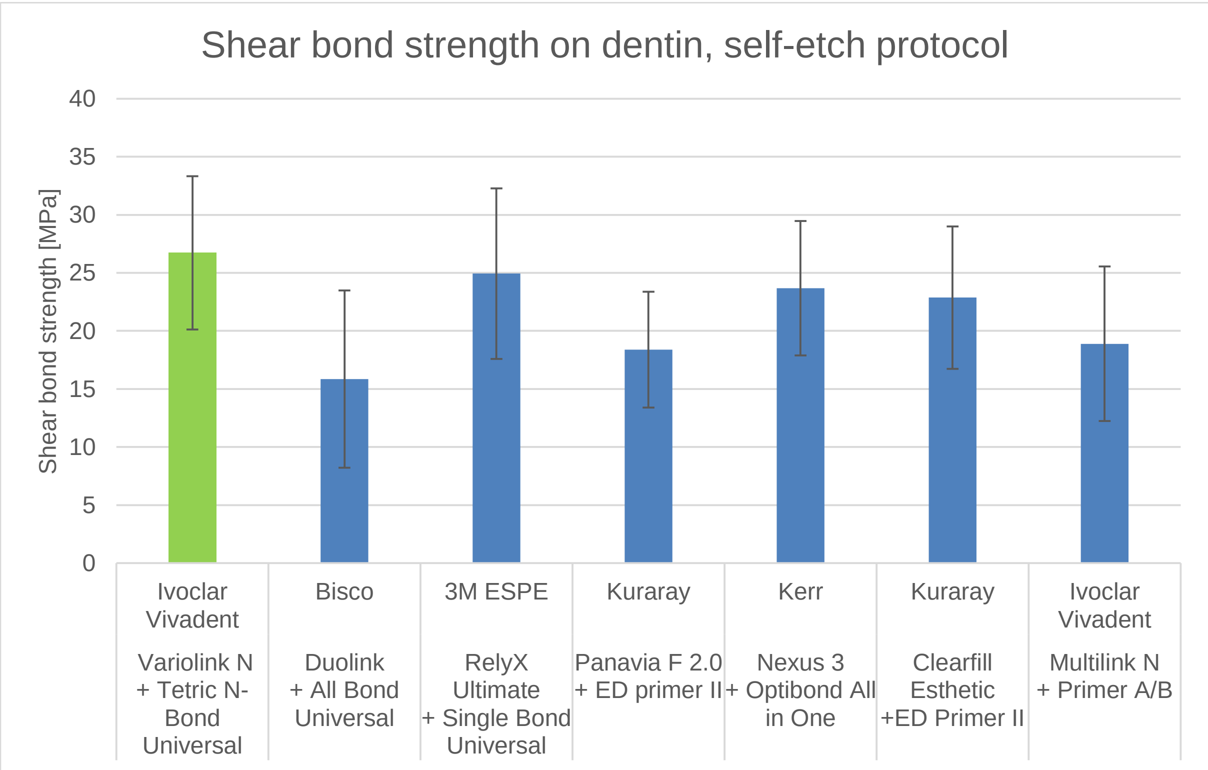

Fig. 13: Indirect shear bond strength on dentin, self-etch protocol. 26 samples were measured per adhesive; the highest and the lowest values were discarded, the average of 24 measurements is displayed.

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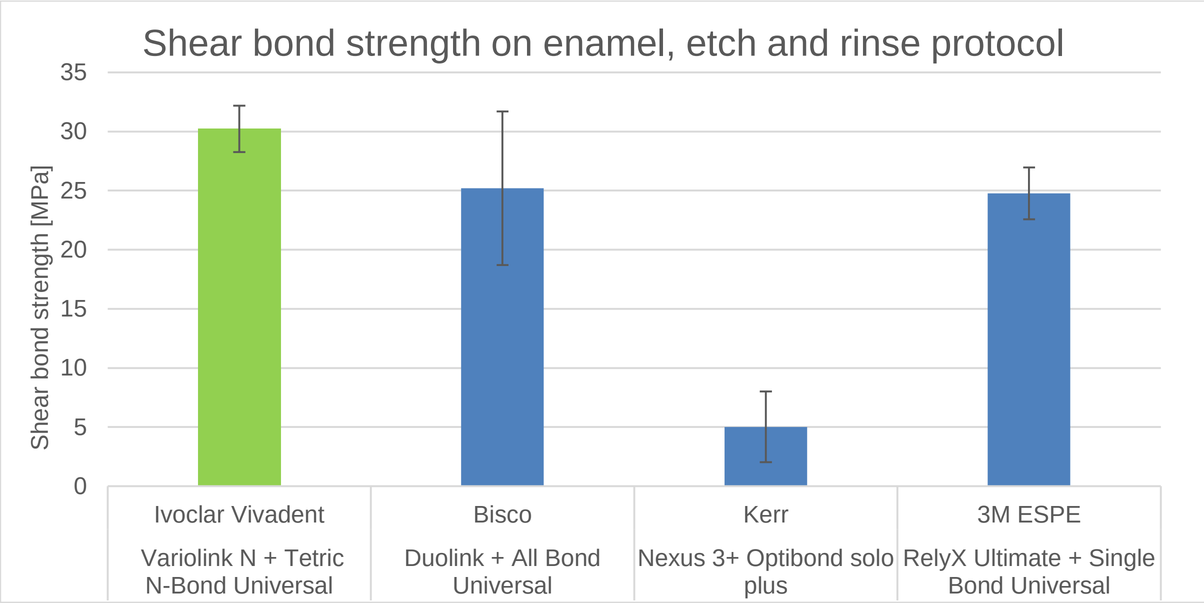

Fig. 14: Indirect shear bond strength on enamel, etch and rinse protocol. 6 samples were measured per adhesive; the highest and the lowest values were discarded, the average of 4 measurements is displayed.

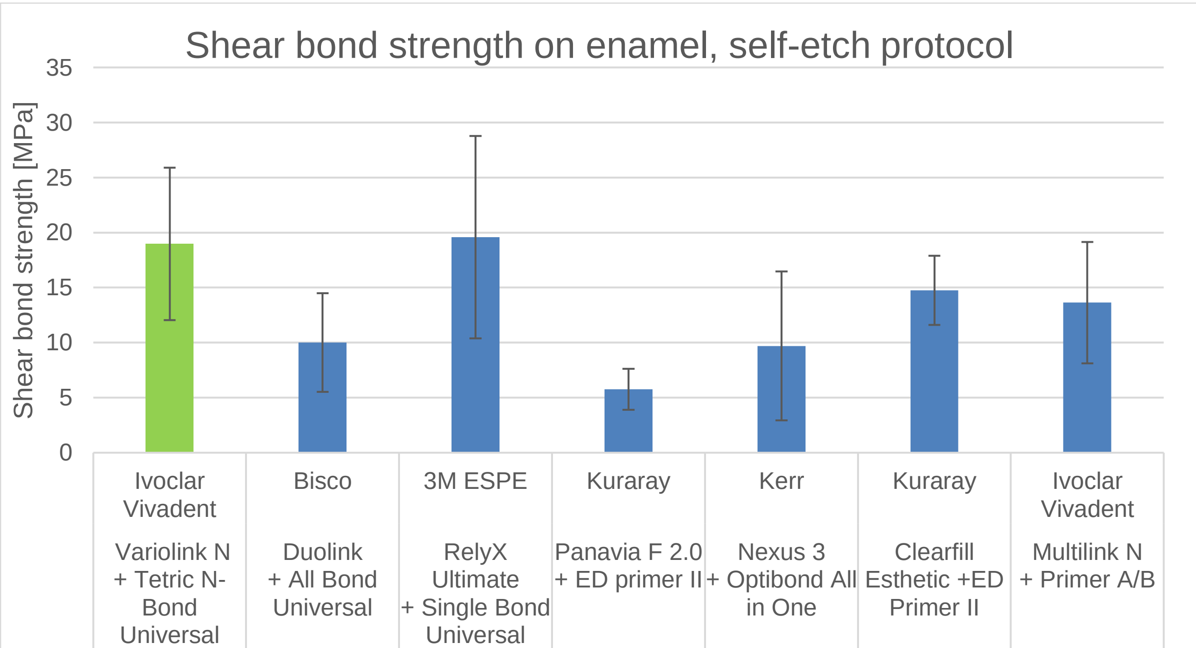

Fig. 15: Indirect shear bond strength on enamel, self-etch protocol. 6 samples were measured per adhesive; the highest and the lowest values were discarded, the average of 4 measurements is displayed.

Conclusion: The combination of Tetric N-Bond Universal and Variolink N performed very well on dentin and enamel in both etching protocols. As with most universal adhesives, the bond strength on enamel was highest after etching with phosphoric acid (etch and rinse / selective etch).

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 Tetric N-Bond Universal has been evaluated 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 Tetric N-Bond Universal was evaluated for cytotoxicity *in vitro*. As is to be expected on the basis of its monomer composition, uncured Tetric N-Bond Universal has a cytotoxic potential. The adhesive has an XTT_{50} value of 138.1µg/ml in the XTT assay [(a)]. 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.

Tetric N-Bond Universal has been evaluated regarding its potential gene changing properties. In the Ames mutagenicity tests [(b)] the unpolymerized adhesive mixture did not induce gene mutations by base pair changes or frameshifts in the genome of the strains used. Tetric N-Bond Universal is not considered genotoxic.

Sensitization and irritation

Like all resin-based dental materials, Tetric N-Bond 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 [27-33]. These reactions can be minimized by clean working conditions and 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 Tetric N-Bond Universal, the following conclusions can be drawn:

- Uncured Tetric N-Bond 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.
- Tetric N-Bond 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 Tetric N-Bond Universal is not genotoxic.

In summary, Tetric N-Bond Universal is safe for use in humans if it is used according to the instructions given. 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 Tetric N-Bond Universal.

Biocompatibility data

(a) Heppenheimer A. Cytotoxicity assay in vitro (XTT-Test). Harlan Report No. 1543002. 2013.

(b) Sokolowski A. Salmonella typhimurium and Escherichia coli reverse mutation assay. Harlan CCR Report No. 1543001. 2013.

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