AdheSE® One F

Click & Bond® with the VivaPen®

Economical and convenient to use

Scientific Documentation

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1. Introduction

Ever since tooth-coloured filling materials have started off their triumphant advance in restorative dentistry, there has been a need for adhesive systems which ensure a reliable bond to the filling material on one side and to the dental hard tissues on the other. These systems must be capable of establishing a bond to both enamel and dentin. As enamel and dentin are two completely different substrates, adhesive systems need to fulfil very different requirements. Initially, the application of adhesives consisted of several steps in order to ensure that all these requirements were met. For each step, a different component was used.

1.1 From multi-step adhesives to all-in-one products

Dental composite restoratives are fundamentally different from the tooth structure:

- Composite material consists of a hydrophobic, i.e. water repellent, matrix into which different filler particles are embedded.
- Enamel essentially consists of 96% hydroxyapatite, crystalline calcium phosphate and only 4% organic material and water [6]. Dentin consists of 70% hydroxyapatite but has a high content of organic material, essentially collagen (20%) and 10% water [7]. Therefore, enamel is essentially a dry substrate, while dentin is a wet hydrophilic substrate.
- Furthermore, after tooth preparation with rotary instruments, the preparation is covered by a layer of debris, called the smear layer.

Individual components are responsible for the different steps required in conjunction with multiple-component adhesives. The simplified products combine either two or all steps in one delivery form.

The following table describes the steps necessary for establishing adhesion between the restorative material and the tooth structure and how multi-step, total-etch, two component self-etch and one-component self-etch all-in-one adhesives accomplish these steps:

<table>
<tr><th>Step</th><th>Task of the step</th><th>Syntac (1990)</th><th>ExciTE (1999)</th><th>AdheSE (2002)</th><th>AdheSE One (2007)</th><th>AdheSE One F (2009)</th></tr>
<tr><td>Enamel conditioning</td><td>Exposure of the retentive etching pattern</td><td>H_3PO_4</td><td rowspan="2">H_3PO_4</td><td rowspan="3">AdheSE Primer</td><td rowspan="4">AdheSE One</td><td rowspan="4">AdheSE One F</td></tr>
<tr><td>Dentin conditioning</td><td>Exposure of the collagen network and dentin tubules</td><td>Syntac Primer</td></tr>
<tr><td>Wetting</td><td>Transition between hydrophilic and hydrophobic tooth structure</td><td>Syntac Adhesive</td><td rowspan="2">ExciTE</td></tr>
<tr><td>Bonding</td><td>Bond to the composite</td><td>Heliobond</td><td>AdheSE Bonding</td></tr>
</table>

Multi-step adhesives, such as Syntac, are still considered to be among the clinically most successful adhesives systems [1-3]. However, the more steps are involved, the more time is required and the more potential sources of error exist. Therefore, the priority of adhesive development has been clearly set on providing dentists with products that are faster and easier to apply. A logical consequence is thus the reduction of the steps in the application of the product. Therefore, multi-step adhesives have been followed by two-step adhesives. These adhesives were initially used in combination with the total-etch technique, while a few years later, two-bottle self-etching adhesives were introduced.

Total-etch adhesives became known as being technique sensitive [4,5]. In contrast, some of the two component self-etching adhesives, e.g. AdheSE, achieved a clinical performance similar to that of earlier multi-step adhesives.

Still a few years later, one-step adhesives appeared on the market. These adhesives require only one coat of liquid to be applied, which is either mixed from several components prior to application or, such as in the case of all-in-one adhesives, is supplied ready-mixed in bottles or, as for the first time AdheSE One, in the unique VivaPen delivery form. Consequently, in the development of AdheSE One F, the focus was placed on the further development not only of the adhesive but also of the delivery form.

1.2 The user-friendly VivaPen

AdheSE One F, the further developed self-etching single-component adhesive from Ivoclar Vivadent continues to be a true innovation also with regard to its delivery form.

The handling of the VivaPen is now even more user-friendly. The new VivaPen features an easy-to-operate click mechanism. A few clicks are sufficient to saturate the brush tip of the novel snap-on cannula with an appropriate amount of material. The yellow discoloration of the tip shows that it has been saturated with adhesive.

Even the fill-level of the VivaPen can now be visually checked. As a result, the user has consistent control over the availability of material.
These innovations make the application of AdheSE One F even easier for the dental team.

1.3 Technical challenges of all-in-one self-etching adhesives

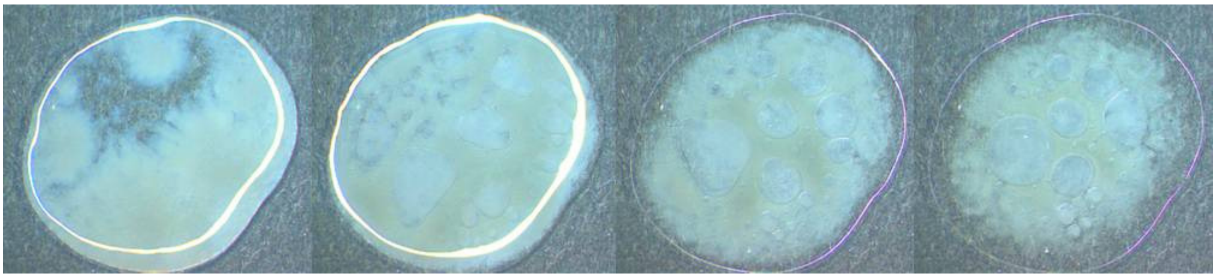
Taking all individual steps together is a challenge with respect to achieving a comparable function with only one liquid rather than with several sequentially applied liquids. Therefore, scientists are continuously working on optimizing all the parameters that influence the bonding capacity of an adhesive. Compared to AdheSE One, AdheSE One F features improved enamel etching, which has been achieved by the addition of sulphonic acid.

In addition, the chemists particularly face the following two problems in the development of all-in-one adhesives:

Solubility of monomers

Both multi-step and two-step systems employ either phosphoric acid or an acidic primer solution for etching. Upon completion of the etching step, a more hydrophobic bonding solution is applied. In one-component self-etching adhesives, the acid and the water necessary for etching must be mixed with the hydrophobic, polymerizable monomers of the bonding agent. For this purpose, some all-in-one products employ acetone, since it forms a mixture both with water and organic solvents and is thus also suitable for dissolving the more hydrophobic monomers. Such products may suffer from phase separation upon evaporation of the organic solvent [8].

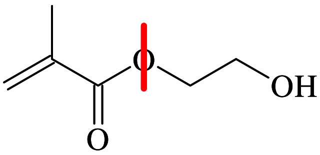
Phase separation means that the acetone starts to evaporate as soon as a drop of material is dispensed onto the mixing pad leading to a separation, i.e. de-mixing, of the water and resin monomers. This is visible by the formation of water drops. This effect is particularly detrimental to the product if it is not used immediately after dispensing.

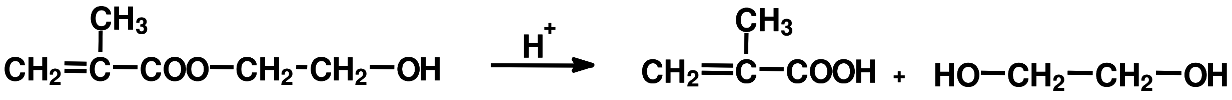


In AdheSE One F, a mixture of water and alcohol is used as the solvent. Consequently, no phase separation occurs, while the elimination of water is simplified when dispersing the adhesive with a stream of air.

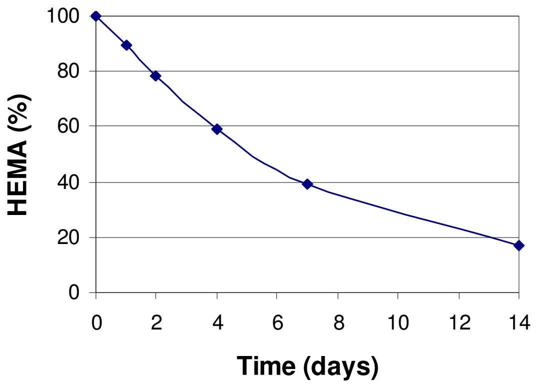
Hydrolytic stability of methacrylate monomers

Commonly used dental methacrylate monomers are not stable under acidic or alkaline conditions, because they contain an ester bond which hydrolyzes, i.e. is broken down, in an aqueous environment. Hydroxyethyl methacrylate (HEMA), a very typical hydrophilic monomer employed in dental adhesives, is such an example. Under acidic conditions, it is hydrolyzed to methacrylic acid and ethylene glycol according to the following reaction:





HEMA Methacrylic acid Ethylene glykole



An extensive study, which compared the hydrolytic stability of methacrylates to that of methacrylamides, found that HEMA largely disintegrates at a pH of 0.94 and a temperature of 37 °C [9] (see Figure on the left). In the same publication, it was stated that methacrylamides are promising monomers for self-etching dental adhesives as far as the stability to hydrolysis is concerned.

Most manufacturers of self-etching adhesives have managed to circumvent this problem in two different ways:

- The acid monomers of the primer and water are mixed just before they are used.
- The product has to be refrigerated to delay hydrolysis.

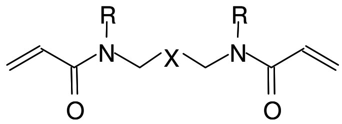
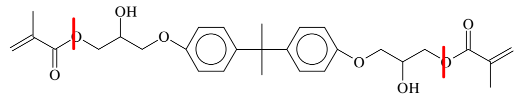
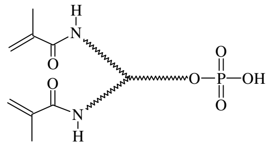
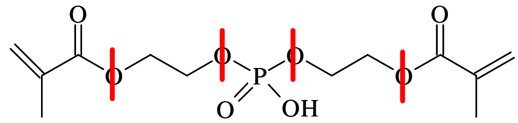
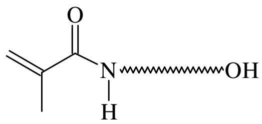
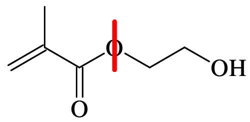
Such measures only partly solve the problem of poor hydrolytic stability. Incorrect storage of the product on its way from the manufacturer to the customer may reduce the shelf life of materials requiring refrigeration. Errors during mixing of two components prior to use may compromise the performance of a product. Furthermore, recent research suggests that hydrolysis within the dentin-adhesive-composite interfaces may even occur after application and polymerization of the product.

A microtensile bond strength study showed that after thermocycling, the bond of a self-etching two-component system remained stable, while the bond strength of two others became lower with an increasing number of thermocycles [10]. Such a decrease of micro-tensile bond strength had previously also been reported during prolonged storage of samples prepared with total-etch adhesives [11]. An in-vitro investigation of Class-V cavities impressively demonstrated that after only 2000 thermocycles most all-in-one self-etching adhesives exhibited an acceptable marginal quality. However, when specimens were stored in water for one year and thermocycled again, some all-in-one adhesives exhibited a substantial decrease in marginal quality [12]. Clearly, this problem can only be solved if adhesive monomers that retain their hydrolytic stability under aqueous acidic conditions are used.

1.4 Hydrolytically stable monomers from Ivoclar Vivadent

Ivoclar Vivadent has consistently pursued the goal of developing hydrolytically stable monomers for dental materials. Previous products already employing such monomers are ExciTE and the primer of the two-component self-etching AdheSE.

In AdheSE One F, the same hydrolytically stable monomers as in the predecessor product AdheSE One were used. The chemical structures of the AdheSE One monomers and commonly employed hydrolytically labile monomers are depicted below:

Function	**AdheSE One F**	**Example of conventional monomers with indication of hydrolytically labile bonds**
Cross-linking monomer		
Acidic monomer with affinity to calcium		
Hydrophilic wetting monomer		

The hydrolytically stable monomers employed in AdheSE One F not only ensure a consistently good bonding performance until the last click, they also enable the product to be stored at room temperature without compromising the quality. Refrigeration is not required.

1.5 Adhesive with fluoride release

The addition of potassium fluoride to AdheSE One F ensures a consistent release of fluoride ions in the first days following placement of the restoration.

Potassium fluoride dissolves well in AdheSE One F and the solution is not affected by temperature fluctuations and sedimentation.

The acidic monomers contained in AdheSE One F can trigger a coagulation of the dentinal fluid proteins and thus contribute to the sealing of the dentinal tubules. The released fluoride can support the sealing of the tubules by forming calcium fluoride: This may help prevent

dentinal fluid movement and the post-operative sensitivities associated with it. The addition of a source of fluoride can thus contribute to avoiding post-operative sensitivities.

2. Technical data

Standard composition	**(in % wt)**
Solvent	20 - 30
Monomers	45 - 55
Acid monomers	20 - 30
Fillers	< 5.0
Catalysts and stabilizers	< 2.0

Physical properties:

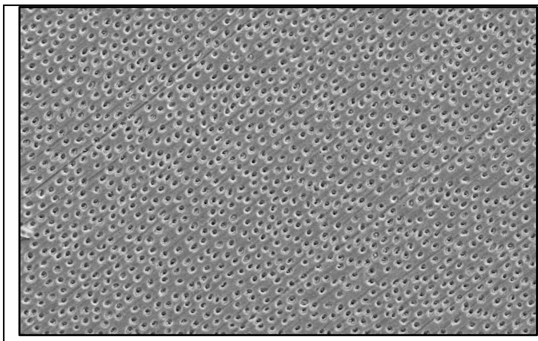
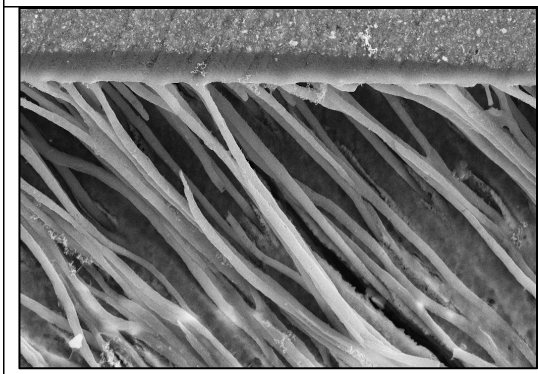
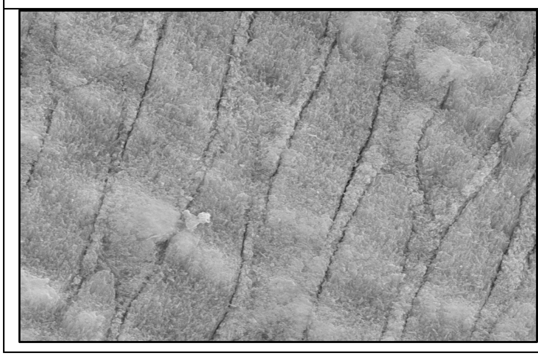
Shear bond strength on dentin	> 20 MPa
Shear bond strength on enamel	> 20 MPa
pH	1.4

3. In-vitro investigations

In the laboratory, the quality of adhesive systems can be tested by means of various methods. In conjunction with dental adhesives, the bond strength achieved on dentin and enamel is of particular importance. As the task of a dental adhesive is to mediate a durable and sound bond between the dental hard tissues and the restorative, marginal analysis is also a useful method to assess the performance. For this purpose, adhesives are tested in combination with restorative materials. With these test set-ups, the performance of the material can be investigated under various conditions. The results of the tests allow conclusions to be drawn on the clinical performance of the adhesive. Micro-morphological investigations under the scanning electron microscope may deliver additional information on the quality of the dentin-adhesive or enamel-adhesive interface.
For this type of *in-vitro* investigations, bovine teeth or extracted human teeth are normally used.

3.1 Dentin and enamel etching

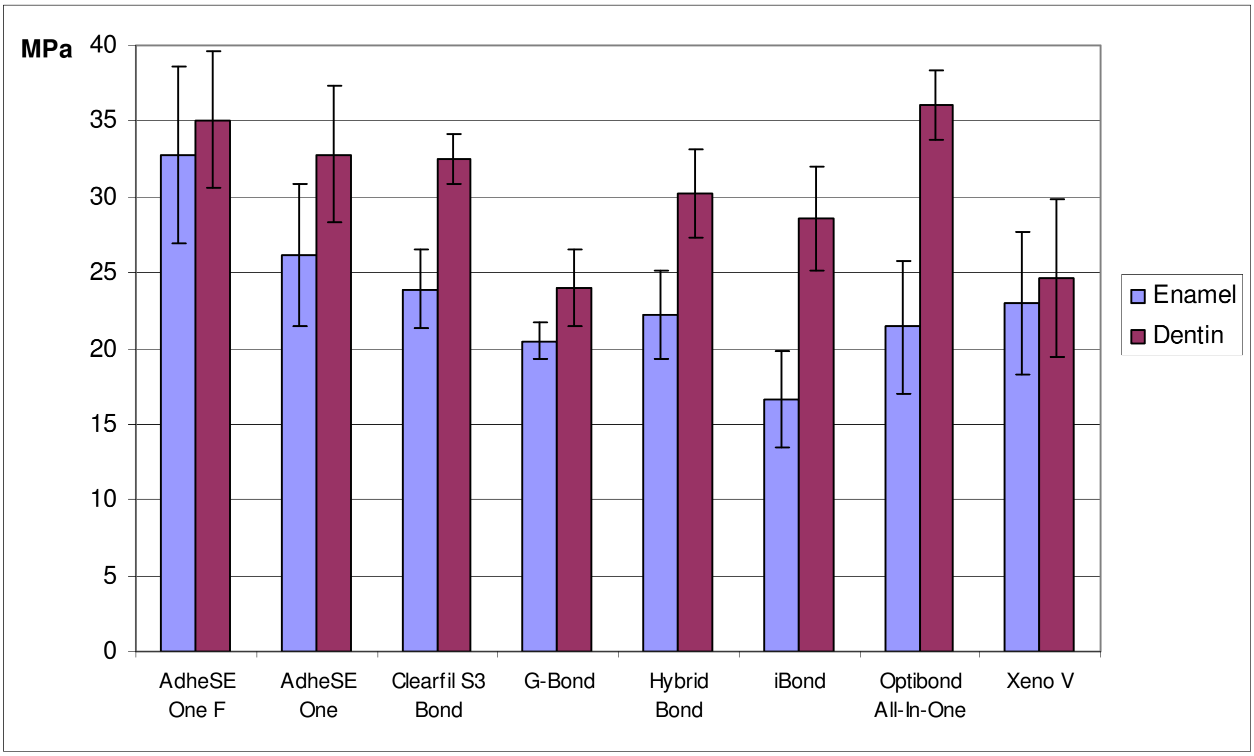
It is customary to use phosphoric acid for enamel and dentin conditioning when etch-and-rinse products are employed. This acid produces a pronounced etching pattern on enamel, which becomes visible after rinsing the acid off. On dentin, it dissolves the smear layer produced during tooth preparation, demineralizes the dentin surface and exposes the collagen network. The self-etching all-in-one product AdheSE One F contains acidic monomers to achieve a sufficiently developed etching pattern.

	Dentin surface with exposed dentinal tubules (R&D Ivoclar Vivadent, Schaan, 2009)
	The adhesive penetrates the dentinal tubules (R&D Ivoclar Vivadent, Schaan, 2009)
	Enamel etching pattern on bovine teeth (R&D Ivoclar Vivadent, Schaan, 2009)

3.2 Shear bond strength to enamel and dentin

In order to test the shear bond strength, bovine teeth are embedded in epoxy resin and enamel or dentin are exposed in several steps by grinding under water cooling using successively smaller-grit abrasive paper. Subsequently, the adhesive is applied according to the instructions for use and a composite cylinder of 3 mm diameter is incrementally built up and light-cured. After 24 hours of water storage at 37 °C, the shear bond strength is measured with a universal testing machine.

AdheSE One F was compared to the predecessor product AdheSE One as well as to other single-component adhesives. It is obvious that the development goal of achieving even higher enamel bond strength with AdheSE One F has been reached. In comparison with competitor products, AdheSE One F achieves far higher shear bond strength values on enamel and the values on dentin are superior to those of most competitors.

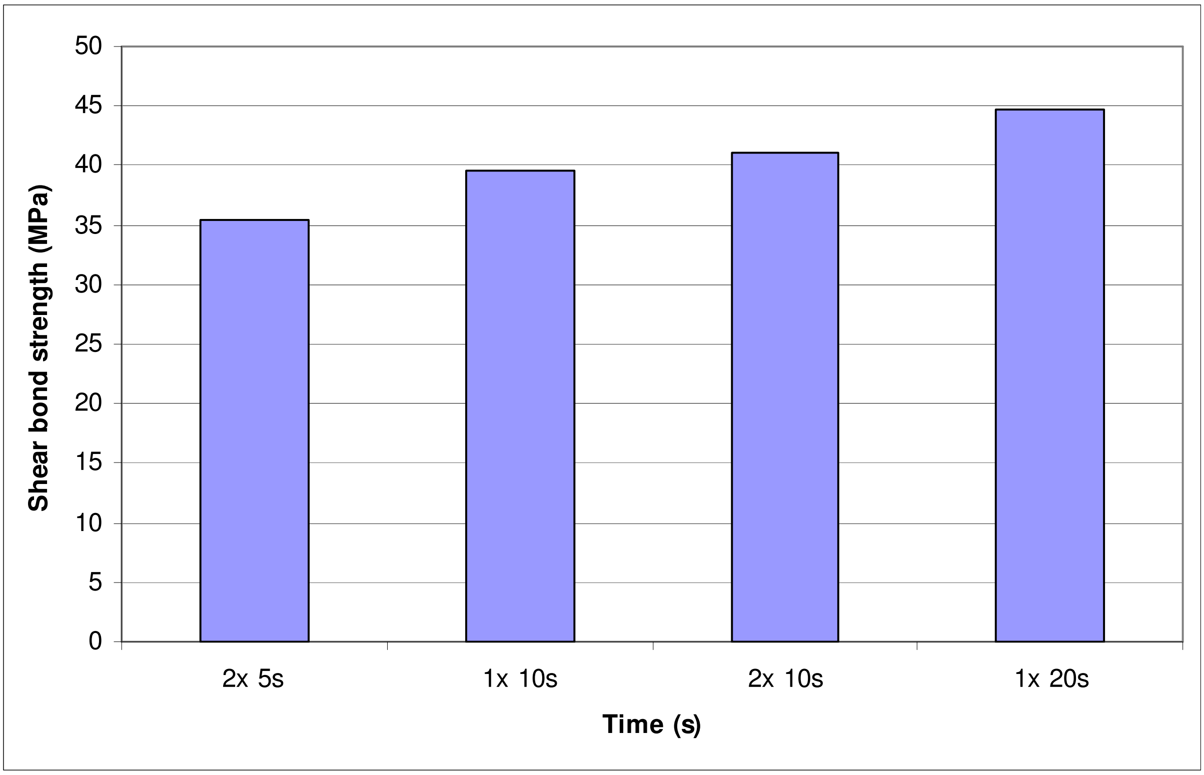


(R&D Ivoclar Vivadent, Schaan, 2009)

3.3 Dentin adhesion – Effect of the application time

In order to determine the optimum way and duration of applying the adhesive, different protocols were tested. The adhesive was applied in different ways for varying periods of time, dispersed with air in different ways and then polymerized with an LED or halogen curing light for different periods of time. Following this, the composite was placed and the shear bond strength was determined according to the procedure described above.

The effect of the application time is presented in the graph below:



(R&D Ivoclar Vivadent, Schaan, 2009)

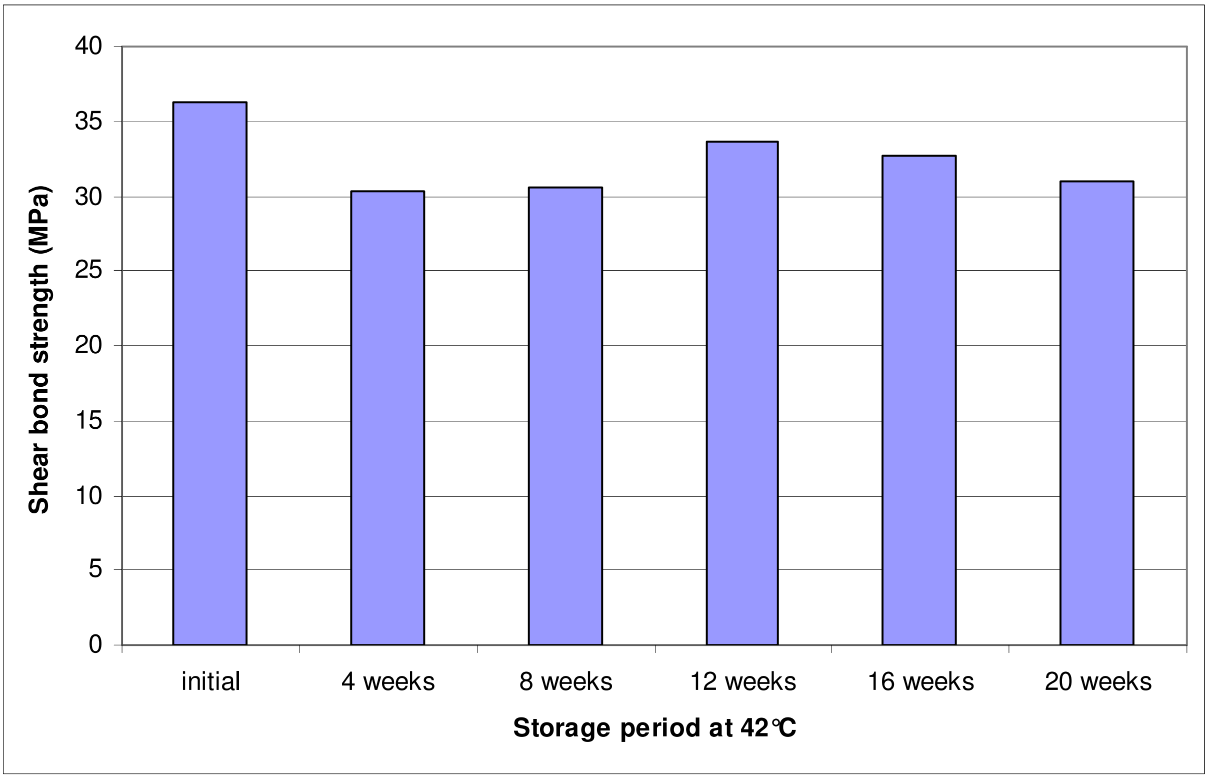
In summary, it can be said that the highest bond strengths are achieved if AdheSE One F is rubbed into the tooth structure for 20 seconds and subsequently dispersed with a strong stream of air until a glossy, immobile liquid film results, which is then light-cured for 10 seconds in the adhesive mode. However, a light intensity of at least 500mW/cm^2 is indispensable.

3.4 Consistently good adhesion to dentin

A statement on the storage stability beyond the shelf life expiry date can be made by storing specimens for a defined period of time and at defined conditions and then determining the corresponding parameters.

In order to prove a consistently good dentin adhesion, specimens were stored at 42 °C for at least 20 weeks. Subsequently, the bond to dentin was assessed by means of a shear bond strength test.

AdheSE One F showed consistent dentin bond strength values, which were within a narrow bandwidth.



(R&D Ivoclar Vivadent, Schaan, 2009)

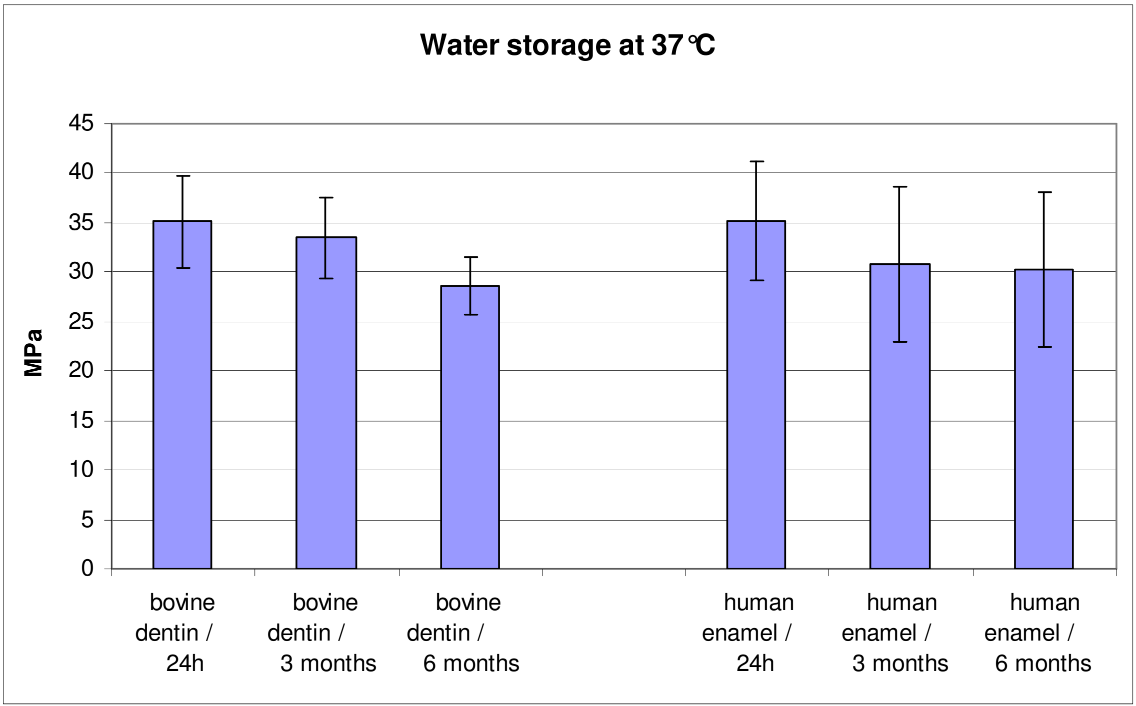
However, not only the shear bond strength is important in the evaluation of the quality of the bond. The type of fracture is equally important. If different adhesives demonstrate similar shear bond strength values, they may still differ in their mode of failure, i.e. the type of fracture.

In general, we distinguish between three different types of fractures. If adhesive fracture occurs, the fracture line runs between two different types of materials, e.g. between the dental hard tissue and the adhesive, or between the adhesive and the composite. In the case of cohesive fracture, the fracture occurs within a material or a tissue, e.g. in dentin or in composite. The combination of adhesive and cohesive fracture is called “mixed” fracture.

In this investigation, all fractures were cohesive and occurred in dentin. This is a clear indication that the bond between dentin, adhesive and composite was stronger than that within the dentin. This is proof of consistently good bond strength of the adhesive on dentin and of the storage stability of the product.

3.5 Adhesion after immersion in water

Long-term immersion in water of bovine and human test specimens with restorations fabricated with AdheSE One F and composite did not result in a notable drop in adhesion, neither on bovine dentin nor on human enamel, during the period of observation.

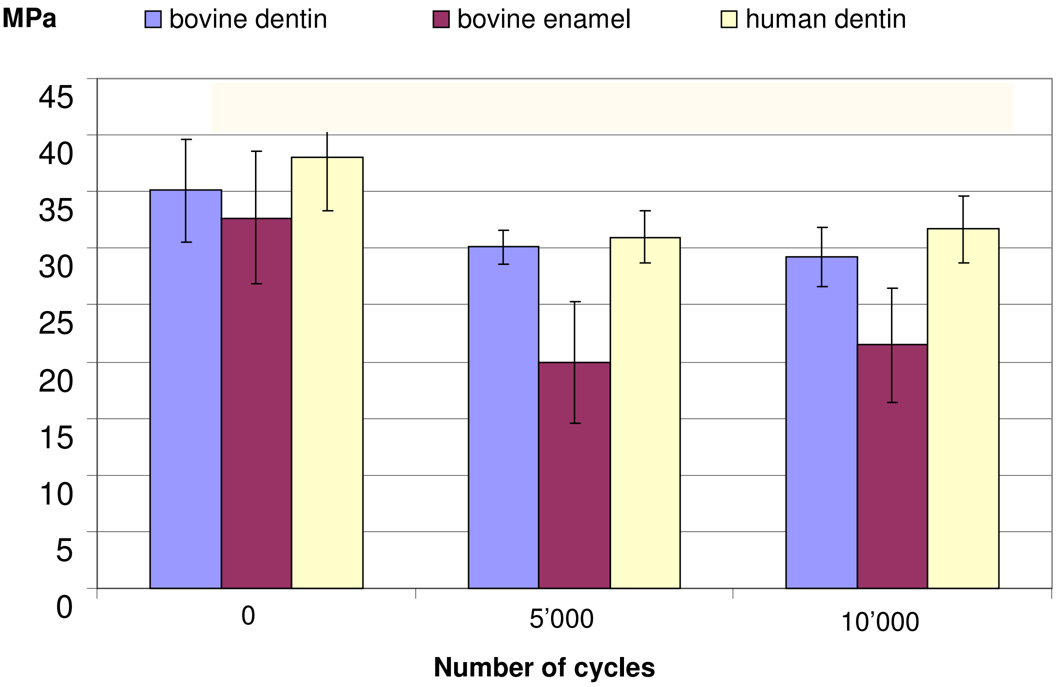


(R&D Ivoclar Vivadent, Schaan, 2009)

Also in this test, the type of fracture observed in the bovine test specimens was cohesive fracture in dentin.

3.6 Adhesion after thermocycling

In order to assess whether and how the adhesion is affected by frequent temperature changes, AdheSE One F test specimens were subjected to thermocycling in water ranging from 5 to 55°C and involving up to 10,000 cycles. Subsequently, the shear bond strength was measured.



(R&D Ivoclar Vivadent, Schaan, 2009)

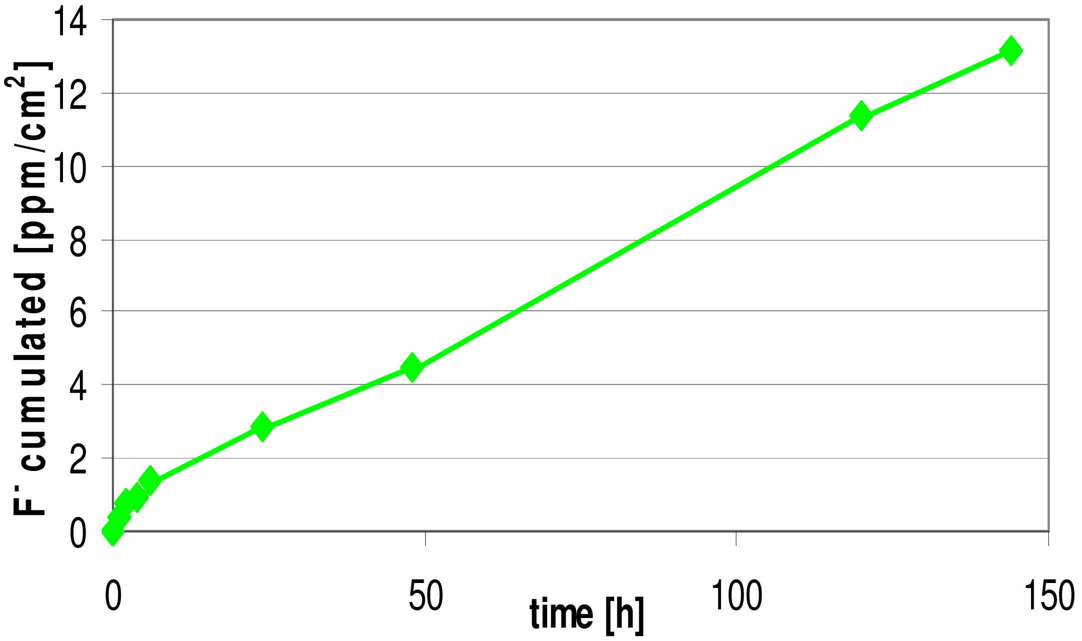
In bovine enamel, a decrease in the shear bond strength of slightly short of 32 MPa to 21.5 MPa was measured, whereas between 5,000 and 10,000 cycles no further decrease was observed. Even after thermocycling, AdheSE One F still showed shear bond strength values which were in the same range as the initial values of several competitor products (cf. section 3.2).

Both on bovine and on human dentin the adhesive strength only changes slightly after up to 10,000 temperature cycles. On bovine dentin, an initial value of 35 MPa was determined, while 29 MPa were still measured after 10,000 cycles. Test specimens involving human dentin showed a decrease from 38 to slightly short of 32 MPa.

As far as bond strength is concerned, the clinical experience gathered with existing adhesives to date has shown that values in this range are certainly sufficient to ensure the clinical success of adhesives.

3.7 Fluoride release

In order to measure the fluoride release, thin tabs of polymerized AdheSE One F were incubated in artificial saliva at 37 °C on a vibrator. The eluation buffer was changed at regular intervals and the fluoride contents determined by means of an ion-selective electrode (ISE). The graph below shows the results in the form of a cumulated release curve:



(R&D Ivoclar Vivadent, Schaan, 2009)

It is obvious that AdheSE One F releases fluoride ions at a nearly constant rate during a period of at least 6 days.

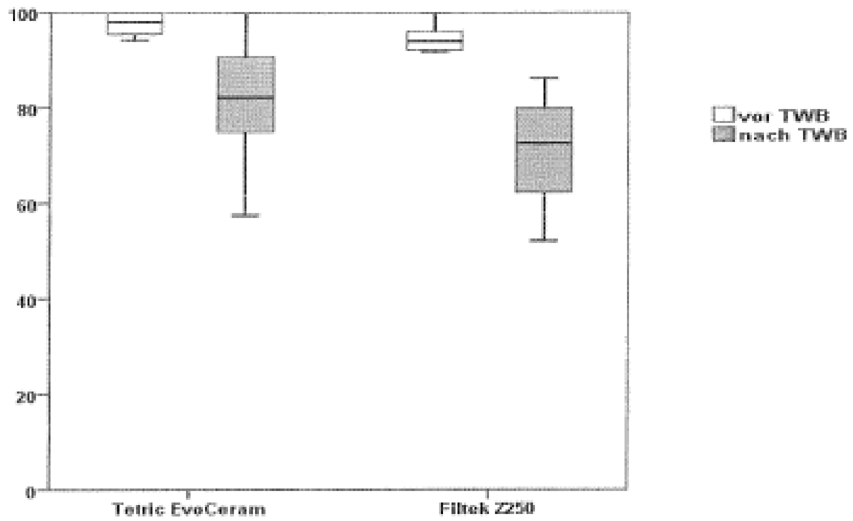
3.8 Quality of margins in Class-V cavities

Quantitative marginal analyses are conducted in the laboratory to establish the quality of restorations. A comparative evaluation of the results of the respective *in-vitro* and *in-vivo* studies has proved that the results of the procedure applied below shows a statistically significant correlation with the clinical assessment, if the tested adhesive systems are combined with the same composite materials [13].

Eight class-V restorations were placed in extracted anterior teeth using AdheSE One F in combination with Tetric EvoCeram or Filtek Z250. Fifty percent of the restoration margin was below the amelo-cement junction, with the depth of the cavity being 1.5 mm. The type of preparation procedure chosen ensured that both the enamel and the dentin were cut with diamond burs. After finishing of the restorations and immersion in water for three weeks, the specimens were subjected to thermocycling involving 2,000 cycles at +5° and +55 ℃. Following this, replicas of the restorations surfaces were made and the marginal seal was assessed by means of quantitative marginal analysis according to defined criteria in the scanning electron microscope (SEM).

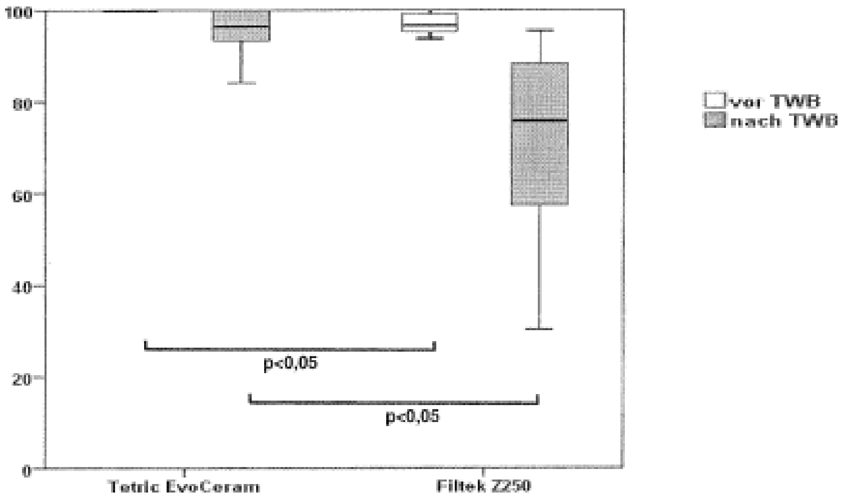
The results showed that a very good marginal quality of the restoration both on dentin and enamel is achieved if AdheSE One F is used in combination with Tetric EvoCeram. Prior to thermocycling, the median scores for “continuous margin” were 98.1% in dentin and 100% in enamel. After themocycling, the median scores for “continuous margin” were 82.3% in dentin and 96.4% in enamel.

Share of continuous margin (%) in dentin prior to and after thermocycling:



(Dr. U. Blunck, Charité, Berlin, 2009)

Share of continuous margin (%) in enamel prior to and after thermocycling:



(Dr. U. Blunck, Charité, Berlin, 2009)

A statistical calculation of the results for restorations fabricated with Tetric EvoCeram or Filtek Z250 in combination with AdheSE One F revealed statistically significant differences ($p<0.05$) in the values achieved in enamel both prior to and after thermocycling, with the AdheSE One F / Tetric EvoCeram combination showing better marginal quality.

4. Clinical investigations (in vivo)

AdheSE One F has been the subject of clinical studies in Europe as well as the USA.

4.1 Dr. Arnd Peschke, R&D Clinic, Ivoclar Vivadent, Schaan, Liechtenstein

Experimental: The aim of this study is the clinical evaluation of AdheSE One F in combination with Tetric EvoCeram and Tetric EvoFlow in Class-I, II and V cavities. At least 40 Class-I and II and at least 40 Class-V cavities will be restored as follows:

<table>
<tr><th colspan="2">Min. 40 Class-I and II restorations</th><th colspan="2">Min. 40 Class-V restorations</th></tr>
<tr><th>Group 1</th><th>Group 2</th><th>Group 3</th><th>Group 4</th></tr>
<tr><td rowspan="2">Application of Selfetch Pen Upgrade (N=20)</td><td>Etching with H_3PO_4 (Total Etch)</td><td rowspan="2">Application of Selfetch Pen Upgrade (N=20)</td><td>Etching with H_3PO_4 (Total Etch)</td></tr>
<tr><td>Application of Selfetch Pen Upgrade (N=20)</td><td>Application of Selfetch Pen Upgrade (N=20)</td></tr>
<tr><td>Application of Tetric EvoFlow as a liner, followed by Tetric EvoCeram</td><td>Application of Tetric EvoFlow as a liner, followed by Tetric EvoCeram</td><td>Application of Tetric EvoFlow; in deep cavities Tetric EvoCeram is used additionally</td><td>Application of Tetric EvoFlow; in deep cavities, Tetric EvoCeram is used additionally</td></tr>
</table>

The evaluation of the restorations is accomplished according to the modified USPHS criteria, whereby the criteria concerning the marginal quality are recorded in terms of a semi-quantitative clinical evaluation (SQUACE method).

Status: So far, slightly short of 30 restorations have been placed using AdheSE One F and Tetric EvoCeram. No postoperative sensitivities or other unacceptable deviations in the clinical performance have been observed.

4.2 Dr. Mark A. Latta, Creighton University School of Dentistry, Nebraska, USA

Experimental: At least 55 Class-V restorations were placed in 28 patients. AdheSE One F was used as the adhesive and Tetric EvoCeram as the restorative material. The restorations were examined at baseline and they will be examined again after 6 and 18 months. The study is being conducted in accordance with the ADA guidelines for dentin and enamel adhesives.

Status: Baseline results are already available. So far, no abnormalities have been observed.

5. Biocompatibility of AdheSE One F

5.1 Introduction

AdheSE One F is a single-component self-etching dental adhesive, which is based on the formulation of AdheSE One. AdheSE One F thus also contains hydrolytically stable monomers, an additional sulphonic acid, which improves the enamel etching effect, as well as potassium fluoride as a fluoride source. In contrast to AdheSE One, which is merely water-based, part of the water has been replaced by alcohol in AdheSE One F. Extensive toxicological testing was carried out with the individual components as well as the complete AdheSE One F formulation in order to evaluate its biocompatibility.

5.2 Tests with the product AdheSE One F

Solid specimens of AdheSE One F were fabricated by placing liquid AdheSE One into a mould of defined size (2 cm diameter and 1 mm height). Then the samples were polymerized between Mylar foils. Subsequenlty, these tabs were incubated in defined, suitable media to produce extracts. Following this, toxicological and mutagenicity tests were carried out with concentrations series of these extracts.

Cytotoxicity

Extracts of the test item AdheSE One possess a cytotoxic potential at concentrations of 100% (undiluted extract) and 70%. No cytotoxic activity was observed at concentrations of 30% and below [14]. For adhesives, which are generally known to be cytotoxic, this is a very favourable result.

Mutagenicity

ISO 10993-3 requires that the mutagenicity of a medical device is tested *in-vitro* by a bacterial test and also by a test employing eukaryotic cells. For these tests, test methods are employed which are in accordance with OECD guidelines.

Ames test

A reverse mutation assay was carried out employing four strains of Salmonella typhimurium and one of Escherichia coli with AdheSE One F. It was found that the test item did not induce gene mutations by base pair changes or frameshifts in the genome of the strains used. Therefore, AdheSE One F is considered to be non-mutagenic in this Salmonella typhimurium and Escherichia coli reverse mutation assay [15].

Mouse lymphoma assay

The study was performed to investigate the potential of extracts of AdheSE One F to induce mutations in the mouse lymphoma thymidine kinase locus using the cell line L5178Y. The assay was performed in two independent experiments using two parallel cultures each. The first main experiment was performed with and without liver microsomal activation and a treatment period of 4 h. The second experiment was solely performed in the absence of metabolic activation with a treatment period of 24 h.

No substantial and reproducible dose-dependent increase in mutant colony numbers was observed in both main experiments. No relevant shift of the ratio of small versus large colonies was observed up to the maximal concentration of the test item which was undiluted extract [16].

Therefore, AdheSE One F is considered to be non-mutagenic in this mouse lymphoma assay.

Conclusion on mutagenicity
All tests carried out with AdheSE One F employing bacteria, eukaryotic cells did not reveal mutagenic activity. Therefore, AdheSE One F is non-mutagenic according to the information available.

5.3 Irritation and sensitization

AdheSE One F contains methacrylamide and acrylamide derivatives. Such materials may have an irritating effect and may cause sensitization. This can lead to allergic contact dermatitis. These reactions can be minimized by clean working conditions and avoiding contact of unpolymerized material with the skin. Commonly employed gloves, e.g., latex or vinyl gloves, do not provide effective protection against sensitization to such compounds. Allergic reactions are extremely rare in patients but are increasingly observed in dental personnel, which handles uncured composite material on a daily basis [17,18].

5.4 Conclusions

The toxicity and mutagenicity of AdheSE One F has been tested. The following conclusions can be drawn:

- AdheSE One F is of low cytotoxicity.
- Sensitization is a common risk of such dental materials. Therefore, AdheSE One F may also cause sensitization and lead to allergic contact dermatitis.
- Extracts of polymerized AdheSE One F specimens were non-mutagenic in all tests carried out.

These results show that according to the available information, AdheSE One F is safe for use in humans with respect to toxicity and mutagenicity when employed correctly as a dental material.

6. Literature

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