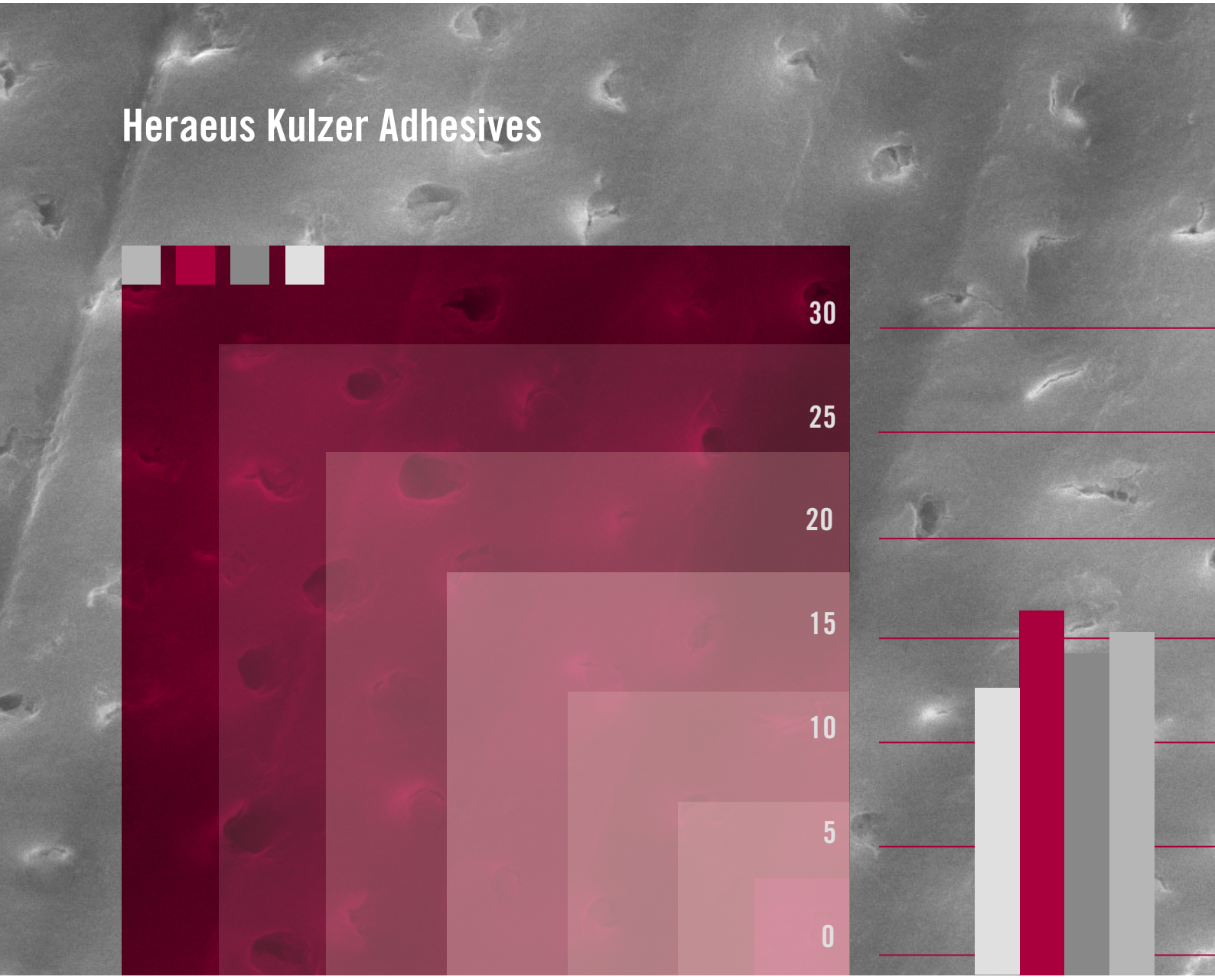
Heraeus

Heraeus Kulzer Adhesives

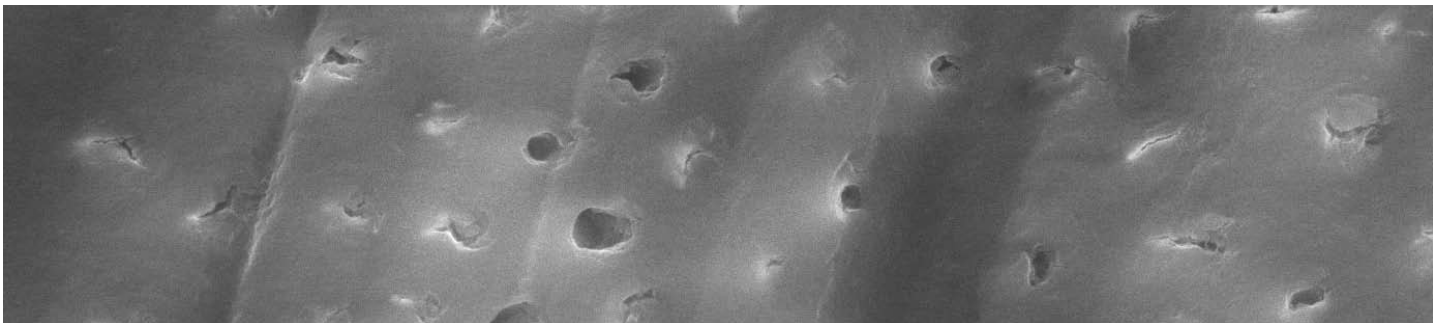


Scientific Information

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Preface



Many patients are familiar with the unpleasant, stabbing pain experienced when they consume hot or cold drinks and food or when the teeth come into contact with cold water or cold air during dental treatment.

Etiologically speaking, hypersensitivity is not a pathological event in the narrower sense of the term. Hypersensitive teeth can, however, have a decidedly negative impact on the day-to-day quality of life of the patient and can also cause the patient considerable discomfort during dental treatment.

GLUMA Desensitizer has been used successfully for the treatment and prevention of hypersensitive dentine since it was first marketed in 1992. The product became very quickly established worldwide because it is easy to use, effective and reliable, both under direct and indirect restorations (e. g. in combination with a standard 3-step adhesive like GLUMA Solid Bond) and with exposed cervical areas. The very wide global acceptance enjoyed by GLUMA Desensitizer has been confirmed by many independent studies.

Hypersensitivity of teeth can also occur after placement of adhesive restorations because of many reasons. This event is known as postoperative hypersensitivity.

The dentine adhesives GLUMA Comfort Bond + Desensitizer (total-etch system) and iBOND Self Etch (self-etch system) also contain the active ingredients for desensitisation and prevention of postoperative sensitivities. Independent studies have demonstrated that use of either product can reduce postoperative problems to a minimum after placement of a filling.

All products – GLUMA Desensitizer, GLUMA Solid Bond, GLUMA Comfort Bond + Desensitizer and iBOND Self Etch– represent many years of cumulative expertise in the adhesive technique and in the treatment of hypersensitivity.

This scientific information is intended to give you an overview of the impressive list of independent and internal data that demonstrate the reliability of these products. Of course, the best way to prove that they are indeed easy to use and effective is to try them out for yourself.

Dr. Marcus Hoffmann
R&D Manager Bonding Materials
Heraeus Kulzer GmbH Wehrheim (Germany)

Dr. Janine Schweppe
Scientific Marketing Manager
Heraeus Kulzer GmbH Hanau (Germany)

Introduction

Dentine hypersensitivity (DHS) is an extremely widespread phenomenon. It is estimated that in the United States of America more than forty million people suffer from dentine hypersensitivity. Statistics produced by the German Dental Association indicate that 10–15 % of patients are treated for dentine hypersensitivity annually and that the trend has increased rapidly during the past few years. In addition, further increases in DHS are predictable as the population increases in age.

Dentine hypersensitivity

Definition

Tooth sensitivity or, to put it precisely, dentine hypersensitivity is defined clinically as being a painful reaction to a non-harmful, sensory stimulus. Hypersensitivity is a chronic condition with acute exacerbation which differs from dentine or pulpal pain in that the patient can localise the pain sensation accurately.

Causes

Dentine hypersensitivity is defined as being pain triggered off by chemical, thermal, tactile or osmotic stimuli which affects exposed dentine rather than by a tooth defect or other pathological cause.

From the etiologic point of view, elimination of the protective enamel layer is often caused by the following:

- Attrition due to forces acting on the occlusal surface
- Abrasion caused by incorrect toothbrushing techniques (depends on the frequency, type of brush and abrasiveness of the toothpaste)
- Eroded areas due to environmental effects or constituents of foodstuffs

Not only elimination of the enamel, but also elimination of the cementum in the root region may cause DHS. The following may eliminate the cementum:

- Acute or chronic periodontal diseases
- Incorrect toothbrushing techniques
- Chronic trauma due to habits
- Periodontal surgery

Prior to commencing topical treatment for DHS, the etiologic and/or predisposing factors must be diagnosed and, if possible, modified or eliminated.

Theories about sensitivity

Theories about odontoblasts

Experts are not quite in agreement about what triggers off DHS. Up until a few decades ago, the theory that the pain reaction was a conventional, neural reply to a stimulus was popular ("Odontoblast Theory").

This theory is countered by the fact that, to date, no neurons have been found in dentine. Although nerve ends are in contact with the pulpal sections of the odontoblasts and possibly extend into the predentine, one has to assume that there is no nerve tissue in dentine.

Hydrodynamic theory

Dentine only becomes sensitive/hypersensitive when exposed in the mouth. Dentine hypersensitivity does not occur as long as the dentine is covered with enamel or cementum. The majority of oral physiologists are of the opinion that DHS is caused by liquid moving in open dentine tubules ("Hydrodynamic theory"). Dentine tubules are filled with liquid. Once the tubules on the surface are exposed to a stimulus, the liquid pillars transfer it hydraulically to the nerve receptors on the pulp/dentine boundary. For example, a stream of air passing over an exposed area of dentine moves the liquid pillar – the movement is transferred to the odontoblasts and exerts a direct or indirect stimulus on the nerve fibres thus causing pain.

Although this theory of hydraulics or hydrodynamics was published by Brännström during the sixties and has yet to be proven (Brännström 1966), it is the only hypothesis with which all scientific observations coincide. What also speaks in favour of this theory is that every reduction in or elimination of DHS coincides with the dentine tubules being sealed.

Methods of treating hypersensitive areas of teeth

Conventional treatment
The objective of all DHS treatment is to seal exposed dentine tubules. Should the dentine be exposed to such a degree that restorative treatment is required, this may also seal the tubules. A wide range of topical treatment is available for eliminating DHS, including:

- Special toothpaste
- Local fluoridation
- Precipitation of small-grained, antisoluble salts
- Sealing the surface with polymerising substances
- Intratubular obturation by precipitating proteins

(Duroux & Cimasoni 1991, Prati et al. 2001)

Treating with GLUMA Desensitizer
GLUMA Desensitizer is an especially effective alternative type of treatment. It functions by reducing the permeability of the dentine by precipitating plasma proteins to seal the peripheral dentine tubules. This halts movement of the tubule liquid which causes the pain. This is also referred to as "Intradentinal Sealing" (Schüpbach et al. 1997).

Postoperative hypersensitivity

Placing adhesive restorations may lead to postoperative hypersensitivity meaning that the restored tooth is sensitive to occlusal loading and is irritated by temperature changes. Postoperative sensitivity can be caused by inadvertently etching exposed dentine and/or inadequate sealing of the dentine surface with bonding agent resulting in the dentine liquid rushing out and associated irritation of the nerve ends. This movement of liquid can be blocked by applying GLUMA Desensitizer.

Preventing postoperative hypersensitivity
There are various causes of postoperative hypersensitivity with adhesive filling techniques. Working carefully with the use of a rubber dam is always recommended to prevent contamination of the operating area.

Possible problems in the techniques used for adhesive filling treatment:

- Overetching the dentine: The longer the dentine is etched, the deeper the woven collagen fibrils which the adhesive must penetrate are exposed. If the dentine is etched for too long, the bonder cannot fully permeate the etched area, resulting in hydrolysis of the non-impregnated woven collagen fibrils.
- Dehydrating the dentine: After etching, the decalcified area of the dentine is mainly made up of a layer of loose collagen fibrils, which is supported by the stored water. If the dentine is dried excessively after etching and rinsing, this collagen matrix collapses to a dense, matted layer. These collapsed woven fibrils prevent the adhesive penetrating the exposed collagen matrix.
- Inadequate marginal seal: Inadvertent saliva contamination during filling treatment can cause marginal gaps. The use of a rubber dam is therefore recommended to prevent the cavity from becoming contaminated by saliva and blood.

- Exceeding the expiry date: Adhesives exhibit a limited shelf life, particularly if they contain chemical compounds for self-curing. The materials should be stored according to instructions to ensure an optimum shelf life. Dispose of the materials immediately after the expiry date.
- Failure of the dentine bonder: Using unsuitable products and ignoring the manufacturer's recommendations, e.g. with regard to times and working procedure, can impair the dentine bond resulting in pain. Ensure that the practice personnel adhere to the correct working procedure.
- Problems when light curing: Inadequate light output from the polymerisation lamp, e.g. due to an old bulb, a contaminated fibre optic or deterioration in the performance of the filter, can affect the quality of polymerisation and consequently that of the whole restoration. Check the output of the polymerisation unit regularly.
- Contamination caused by moisture or oil: Lubricating oil from the compressor or handpieces can contaminate a preparation and prevent successful bonding. The air used for drying the tooth structure and adhesive should not contain any oil or moisture. To check that the air does not contain any oil, test the air jet on a sheet of filter paper.
- Cavity linings: (e.g. glass ionomer cement) can detach from the dentine beneath the filling, after the filling has been placed. This can result in microcracks, which lead to complaints when occlusal loading is applied. Applying a suitable bonder normally eliminates the need for additional cavity lining.

iBOND® Self Etch



iBOND® Self Etch

Description of the product

iBOND Self Etch is a light-curing self-etching one component bonding agent for use in combination with adhesive restorations. Separate conditioning (etching) of the enamel and dentine is not required; however, the use of an additional etching gel on the enamel before application of iBOND Self Etch will not have a negative influence on the bond strength. iBOND Self Etch was developed for bonding composite resin materials (e.g., composite, compomer and Polyglas®) to the hard tooth structure. iBOND Self Etch etches, primes, bonds, and desensitises in one step.

Composition:

- iBOND Self Etch is an acetone/water-based formulation of light-activated methylacrylate resins.

Indications:

- Bonding of direct light-cured composite restorations (including Polyglas and compomers)
- Bonding of indirect restorations in combination with a light-curing luting cement: porcelain, Polyglas, and composite restorations (inlays, onlays, veneers, crowns)
- Sealing hypersensitive areas of teeth

Advantages:

- Based on Heraeus Kulzer bonding expertise and more than 4 years market experience with self-etching, all-in-one adhesives
- High bond strength to enamel and dentine
- Excellent marginal sealing
- Proven worldwide in over 15 research centres
- Easy, fast and safe application with only one coat
- Etching, priming, bonding and desensitising in a single step
- Improved bottle nozzle enables a precise dosage avoids dripping
- Storage at room temperature after first use

Clinical application

Application of iBOND Self Etch



Shake



Dispense



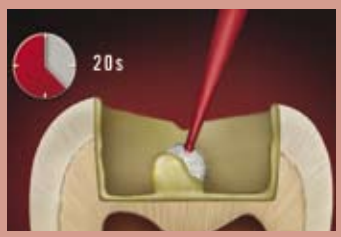
Close immediately



Dip brush



Apply 1x



Agitate for 20 seconds



Air dry



Glossy surface
(if not, apply additional coats)



Light cure for 20 seconds

Clinically proven worldwide – Study Overview

External Testing of iBOND Self Etch by 15 Study Groups Worldwide

Dr. Miller,
Reality Research Lab,
USA

Prof. van Meerbeek,
University of Leuven,
Belgium

Prof. Frankenberger,
University of Erlangen,
Germany

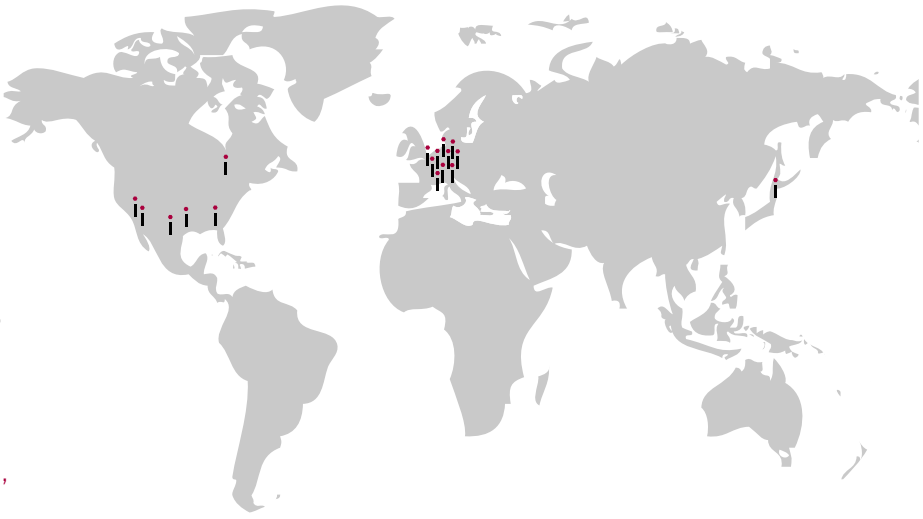
Prof. Finger,
University of Cologne,
Germany

Prof. Lee,
University of
Loma Linda,
USA

Dr. Lu,
University of
Loma Linda,
USA

Prof. Thompson,
University of
San Antonio,
USA

Prof. Soderholm,
University of
Florida,
USA



Prof. Ernst,
University of Mainz,
Germany

Prof. Haller,
University of Ulm,
Germany

Prof. Hannig,
University of Saarland,
Germany

Prof. Uno,
University of Tokyo,
Japan

Prof. Degrange,
University of Paris,
France

Dr. Yapp,
The Dental Advisor,
USA

Dr. Ilie,
University of Munich,
Germany

Prof. Cerutti,
University of Brescia,
Italy

Dr. Rupf,
University of Leipzig,
Germany

in vivo
in vitro

First clinical results with iBOND® Self Etch

Clinical evaluation of a new all-in-one adhesive in class V restorations

Source: Karl-Johan M. Soderholm, University of Florida, Gainesville, USA

Data on file

Objective:
The objective of this study was to evaluate the clinical performance of class V restorations bonded with iBOND Self Etch over an observation time up to 48 months.

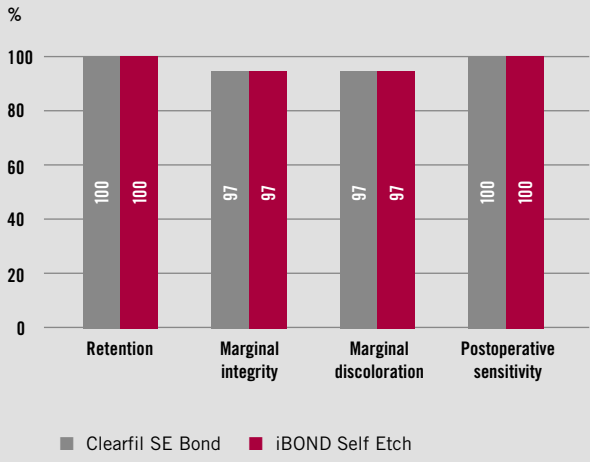
Materials and Methods:
A total of 84 restorations (42 per adhesive) were placed in a total of 21 patients and are evaluated after 3, 12, 24, and 48 months.
The adhesive to be evaluated was iBOND Self Etch (Heraeus Kulzer) in comparison to Clearfil SE Bond (Kuraray). The restorative material in both cases was Venus (Heraeus Kulzer).

Conclusion:
After 3 months, all the placed restorations are still in use and perform without any signs of postoperative symptoms. Comparing the restorations regarding marginal differences and aesthetic performance does not suggest that there are any differences in performance between these two adhesive materials after 3 months of clinical service. After 3 months, one cannot draw any conclusions about the true clinical performance over time of the two products, but there is no doubt that the results are encouraging.

Results

Until July 2007, 70 (35 per group) of 84 placed restorations have been evaluated after 3 months.

Alpha-ratings in class V after 3 months



Clinical results with iBOND® Self Etch in anterior teeth

Use of a self-etching all-in-one adhesive in class III cavities in the permanent dentition – 6-month report

Source: Claus-Peter Ernst, Anke Schattenberg, University of Mainz, Germany

Data on file

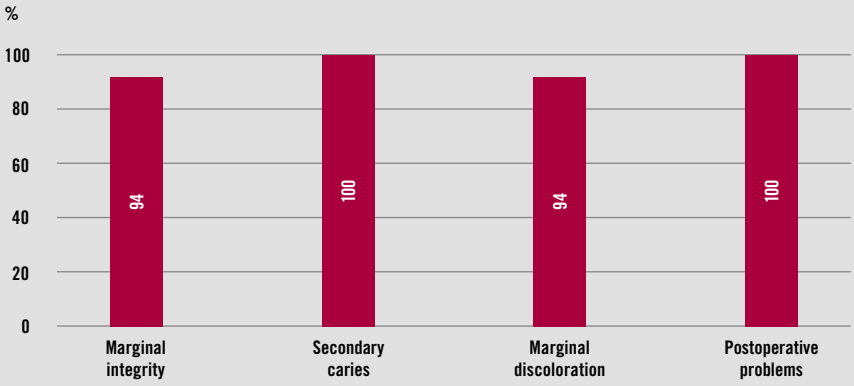
Objective:
The aim of the study was to establish whether iBOND Self Etch self-etching adhesive could guarantee clinical and aesthetic marginal integrity of filled class III cavities over a two-year study period.

Materials and Methods:
A total of 72 fillings were placed in 38 patients up to March 2007; it was possible to carry out a follow-up examination of all the fillings after three months in July 2007. The class III cavities were preconditioned with iBOND Self Etch self-etching adhesive (Heraeus Kulzer) according to the manufacturer's instructions and filled with Venus microhybrid composite (Heraeus Kulzer), after determining the correct tooth shade for each patient. The fillings were assessed according to Ryge and CDA criteria by two examiners.

Conclusion:
Based on the very limited assessment period of 6 months, the initial conclusion is that there does not seem to be any problem with marginal discoloration when using iBOND Self Etch. The assessment criterion of marginal gap was always within the anticipated parameters of an effective adhesive system with assessments A and B. In the case of postoperative sensitivity assessment A also indicates excellent sealing of the dentin surface and a reduction in technique sensitivity.

Results

Assessment A after 3 months in %



Microtensile bond strength to dentine

µ-TBS trials on dentine
Source: Roland Frankenberger, Sergej A. Nikolaenko,
University of Erlangen, Germany
Data on file

Objective:
The objective of this in vitro study was to measure the microtensile bonding strength of five different adhesives.

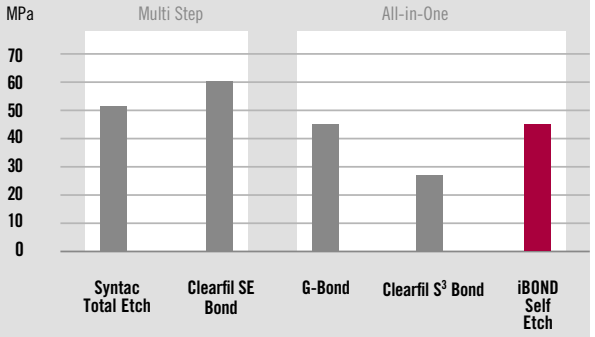
Materials and Methods
The bonding strength of the composite Filtek Z250 (3M ESPE) when bonded to dentine using different adhesives was measured. The following adhesives were used: iBOND Self Etch (Heraeus Kulzer), G-Bond (GC), Clearfil SE Bond (Kuraray), Clearfil S^3 Bond (Kuraray), and Syntac Total Etch (Ivoclar Vivadent). Adhesive and composite were applied to a class I cavity, and then adhesion to the cavity floor was determined. The tests were carried out after storage in water for 24 hours at 37 °C using a microtensile machine at a displacement speed of 1 mm/min. The mean bond strengths were analysed using the Kolmogorov-Smirnov test and the Wilcoxon test (p= 0.05). Samples that fractured before the test were included in the measurement using 0 MPa.

Conclusion:
In this study, iBOND Self Etch shows equivalent or substantially better bond strength than Syntac Total Etch and G-Bond or Clearfil S^3 Bond and demonstrates the best results in the all-in-one group of adhesives.

Results

The mean microtensile bond strengths in MPa with standard deviation on dentine were:
iBOND Self Etch, 45.2±8.2
G-Bond, 44.4±7.4
Clearfil SE Bond, 59.4±6.3
Clearfil S^3 Bond, 27.2±2.9
Syntac Total Etch, 50.4±8.4
The differences between iBOND Self Etch and Syntac Total Etch, as well as between iBOND Self Etch and G-Bond, were not significant.

Microtensile bond strengths on dentine in MPa



Marginal integrity at the enamel and dentine

Marginal integrity of class II composite fillings with iBOND Self Etch
Source: Bernd Haller, University Hospital Ulm, Germany
Data on file

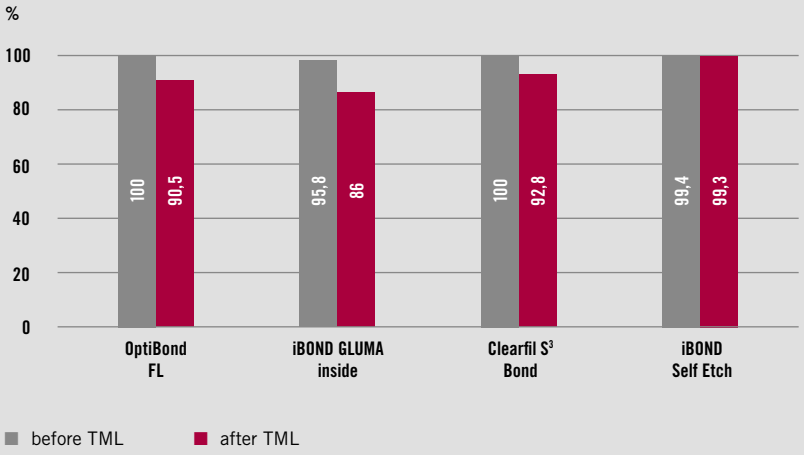
Objective:
The aim of this in vitro study was to investigate, with the aid of quantitative SEM marginal analysis, the extent to which iBOND Self Etch could prevent the formation of marginal gaps at the proximal enamel margins and cervical dentine margins in class II composite fillings with a dentine interface.

Materials and Methods:
Two two-surface class II cavities were prepared in 20 caries-free extracted third molars and each cavity was filled with composite (Venus, Heraeus Kulzer). One of the following bonding systems was used for 10 of the test cavities: Clearfil S^3 Bond (Kuraray), iBOND GLUMA inside (Heraeus Kulzer), iBOND Self Etch (Heraeus Kulzer) and OptiBond FL (Kerr). After the fillings were finished and polished, the teeth were stored in water for 24 h at 37 °C. An impression was then taken of the restored proximal surfaces using a low viscosity A-silicone (Flexitime, Heraeus Kulzer). The test teeth were then subjected to thermocycling (1500x, 55/5 °C, 25 s) and mechanical loading (TML) in a masticatory load simulator (50,000x, 50 N) and a new impression was then taken. The silicone impressions were used for fabricating plastic resin replicas, which were sputtered with gold. The replicas were assessed in the SEM at 300–500 x magnification based on the marginal criteria of seamless transition, marginal gap, tooth margin fracture and composite margin fracture. Furthermore, a dye penetration test was performed on the test teeth using 0.5 % basic fuchsin solution (24 h, 37 °C). The Kruskal-Wallis H test and the Wilcoxon test were used for statistical analysis.

Conclusion:
The marginal adaptation of iBOND Self Etch at the dentine margins was not only very good initially but also stable after loading. The dentine marginal integrity in the SEM after thermomechanical loading was comparable to that of Clearfil S^3 Bond and it was significantly superior not only to that of its forerunner iBOND GLUMA inside but also to that of the OptiBond FL multi-step, etch-and-rinse system. Phosphoric acid etching (OptiBond FL) at the enamel margins produced optimal marginal integrity without any marginal gaps, though there was no significant difference in enamel marginal integrity between iBOND Self Etch and Clearfil S^3 Bond.

Results

Perfect integrity at cervical dentine margins before and after TML in %



Shear bond strength of iBOND® Self Etch on primary tooth dentine

SBS comparison of one-step dentin bonding systems on primary tooth dentin

Source: B. Nelson, R. Grabowsky, H. Lu, W. Okumura, J. Peterson, Loma Linda University, Loma Linda, USA

IADR 2007 New Orleans, Poster 1992

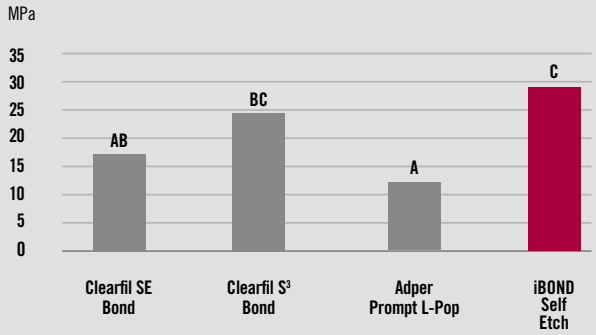
Objective:
To compare shear bond strengths (SBS) of composite materials to primary dentin when used with various one-step dentin bonding agents.

Materials and Methods:
Extracted primary teeth were divided into 4 groups of 15 specimens each. The teeth were mounted in phenolic rings with acrylic resin and wet-ground to expose an experimental dentin testing surface of at least 2.5 mm in diameter. The following bonding agents were used in each group: group I (control) – Clearfil SE Bond (Kuraray), group II – Adper Prompt L-Pop (3M ESPE), group III – iBOND Self Etch (Heraeus Kulzer), and group IV – Clearfil S³ Bond (Kuraray). A 2.38 mm projection of Herculite XRV Unidose composite (Kerr) was bonded to the dentin surface. After 1000 cycles of 5 – 55 °C thermocycling, the specimens were tested in MTS machine with shear force until failure occurred. Load at failure was recorded in Newton, and bond strength was calculated into Mega-Pascal. The debonded surfaces were evaluated for cohesive or adhesive failures.

Conclusions:
Different dentin bonding agents created different shear bond strengths between the composite and the primary dentin. iBOND Self Etch appears to have the highest bonding strength on primary tooth dentin, when taking cohesive failure into account.

Results

Shear bond strength of the tested adhesives



6 specimens in iBOND Self Etch group had cohesive failures in dentin, while all the other specimens broke in the bonding interface. Means of SBS (MPa) are listed in the following table with standard deviation in parentheses. A 1-way ANOVA test showed that the bonding agent had a statistically significant influence on SBS.

Shear bond strength (standard deviation) in MPa

Clearfil S³ Bond	Clearfil SE Bond	Adper Prompt L-Pop	iBOND Self Etch
24 (6)[bc]	17 (10)[ab]	12 (6)[a]	29 (6)[c]

Means with the same superscripted letter are not statistically different from each other at $p<0.05$.

Microtensile bond strength of iBOND® Self Etch

In vitro microtensile strength of different bonding systems to human enamel and dentin

Source: Jeffrey Y. Thompson, University of Texas, San Antonio, USA, Erica Teixeira, University of North Carolina, Chapel Hill, USA

Data on file

Objective:

The objective of this in vitro study was to examine microtensile bond strengths to human dentin and enamel of different adhesives.

Materials and Methods:

Human teeth were cleaned of debris. In half of the teeth, the occlusal surface was ground flat until exposure of the dentin, and the other half, until exposure of enamel. The bonding procedures followed the manufacturers' recommendations. The adhesive systems evaluated in this study were: GLUMA Comfort Bond (Heraeus Kulzer), Prime&Bond NT (Dentsply), Xeno IV (Dentsply), G-Bond (GC), Clearfil SE Bond (Kuraray), Clearfil S^3 Bond (Kuraray), and iBOND Self Etch (Heraeus Kulzer). Six to seven teeth (min. three for enamel and three for dentin groups) were prepared for each material. A crown was built up incrementally over the adhesive resin using a resin composite (Venus, Heraeus Kulzer) for all groups. The roots were then removed, and the pulp chambers were sealed with composite resin. The bonded assemblies (n=20 per group) were stored in water for one day at 37 °C and then sectioned perpendicular to the bonded interface into approximately 1 mm thick beams with a diamond saw. Microtensile bond tests were performed for all specimens using a table-top material tester (EZ test, Shimadzu Co., Kyoto, Japan) at a crosshead speed of 1 mm/min. Bond strength data was subjected to one-way ANOVA followed by Tukey test at 95 % level of confidence.

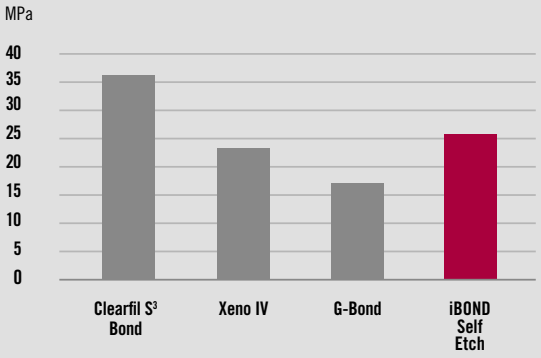
Conclusion:

iBOND Self Etch was equivalent to the other self-etching bonding agents in regard to microtensile bond strength to enamel, except for Clearfil SE Bond, which had a statistically higher mean strength. For microtensile bond strength to dentin, iBOND Self Etch was statistically the same as the other self-etching bonding agents, except for Clearfil SE Bond and Clearfil S^3 Bond.

Results

The mean results with standard deviation for microtensile bond strength to enamel/dentin were:
GLUMA Comfort Bond, 28.4±9.6/46.3±10.2
Prime&Bond NT, 28.7±12.3/42.1±9.8
Clearfil SE Bond, 28.8±9.8/54.7±16.4
Clearfil S^3 Bond, 19.5±9.9/36.2±12.5
Xeno IV, 18.0±7.2/23.2±12.6
G-Bond, 17.8±7.3/17.1±7.6
iBOND Self Etch, 17.4±7.0/25.7±9.6

Microtensile bond strength to dentin of tested all-in-one adhesives



Marginal integrity of iBOND® Self Etch

In vitro investigation on the marginal and internal adaptation of different bonding agents and composites in class II cavities
Source: Matthias Hannig, University of Saarland, Homburg, Germany
Data on file

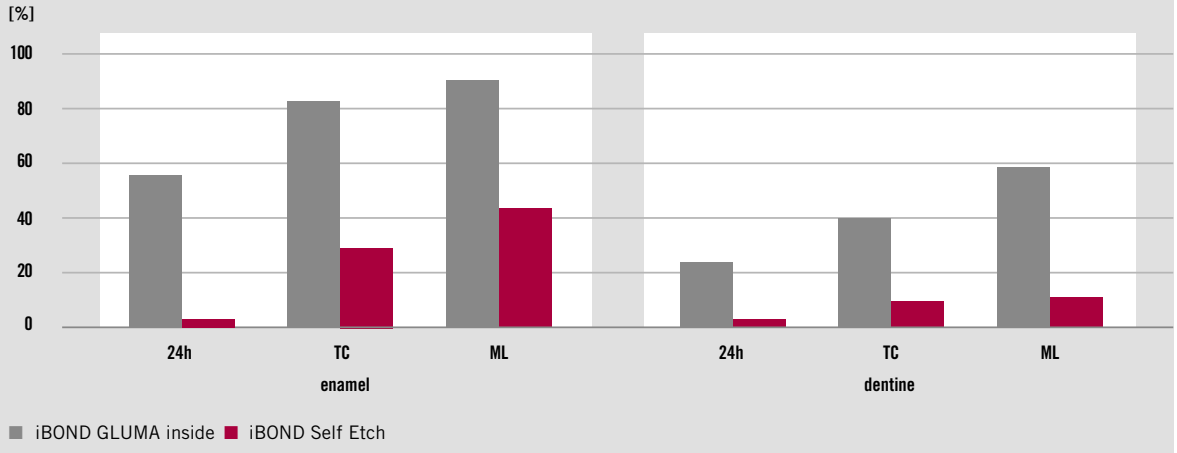
Objective:
The purpose of this in vitro study was to investigate the marginal and internal adaptation of different bonding agents and composites.

Materials and Methods:
Class II cavities with small occlusal cavity, cervical margin in cementum, and chamfered proximal enamel margins were prepared using caries-free, extracted human teeth. The two adhesives were applied according to the manufacturer's instructions, and the composite restoration was prepared using the incremental technique. Inspection then took place using the incident light microscope. The analysis of marginal adaptation was performed by SEM marginal gap analysis by means of the replica method after storage for 24 hours in water (24h), thermocycling (TC) (1500 x, 2/60 °C, 45/7/45 s), and chewing simulation (ML) (200,000 x). Analysis of internal adaptation was done using the dye penetration test after chewing simulation. Here, discontinuity was defined as follows: an interruption in the transition from composite to dental substance (e.g., marginal gaps, hairline cracks, crevices). The following adhesives were examined: iBOND GLUMA inside (Heraeus Kulzer) and iBOND Self Etch (Heraeus Kulzer). Venus A3 (Heraeus Kulzer) was used as the composite material.

Conclusion:
In strain tests, iBOND Self Etch demonstrates more than 50 % fewer marginal gaps compared to iBOND GLUMA inside. With iBOND Self Etch, after storage in water for 24 hours, no marginal gaps were found on enamel or dentine.

Results

Percentage of discontinuity in enamel and dentine



Microtensile bond strength on enamel and dentine

µ-TBS on enamel and dentin

Source: Bart van Meerbeek, University of Leuven, Belgium

Data on file

Objective:

The objective of this in vitro study was to investigate the bonding effectiveness and interaction with enamel and dentin of iBOND Self Etch compared to iBOND GLUMA inside.

Materials and Methods:

The adhesives iBOND Self Etch (Heraeus Kulzer) and iBOND GLUMA inside (Heraeus Kulzer) were examined. The enamel samples were produced by grinding the lingual and buccal enamel from extracted human third molars. The occlusal third of the teeth was removed to produce the dentin samples. A thin layer was removed at the surface using a high speed medium-grit (100 µm) diamond grinder in order to obtain a standardized application layer. The adhesives were applied according to the manufacturer's instructions, and the composite Z100 (3M ESPE) was built up to a height of 5 – 6 mm. The samples were then stored in water for 24 hours at 37 °C. The teeth were cut perpendicular to the bonding surface into rectangular samples. The 48 samples obtained were shear-loaded to failure using an LRX test machine at a displacement speed of 1 mm/min.

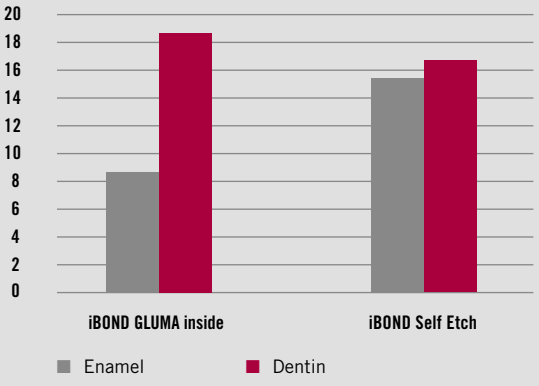
Conclusion:

Compared with iBOND GLUMA inside, iBOND Self Etch demonstrates better bond strength to enamel, whereby a clinical improvement of the marginal integrity is to be expected.

Results

The microtensile bond strengths in MPa with standard deviation for enamel/dentin were 15.6±11.8/16.2±4.3 for iBOND Self Etch and 8.3±15.2/18.7±10.0 for iBOND GLUMA inside.

Microtensile bond strength to enamel/dentin in MPa



Shear bond strength and marginal adaptation to dentine

Test on the shear bond strength and marginal adaptation at the dentine of AdheSE One, Xeno V and iBOND Self Etch
Source: Research & Development, Heraeus Kulzer Wehrheim, Germany
Data on file

Objective:
The aim of this in vitro study was to test the shear bond strength and marginal adaptation at the dentine of three new self-etching all-in-one adhesives.

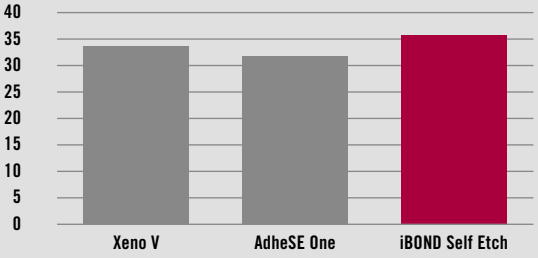
Materials and Methods:
The self-etching all-in-one adhesives tested were AdheSE One (Ivoclar Vivadent), Xeno V (Dentsply) and iBOND Self Etch (Heraeus Kulzer). The adhesives were used according to the manufacturer's instructions in both tests.
The shear bond strength was determined using the Ultradent technique (template with a 2.38 mm diameter) on extracted human molars with an exposed dentine surface (n=8). The composite used for the tests was Venus (Heraeus Kulzer). Following preparation, the test teeth were stored in water for 24 h at 37 °C. The shear strength was determined in a universal testing machine (Zwick Z010) with a thrust speed of 1 mm/min. In order to test the marginal gap, extracted human molars (n=8) were cut down to the dentine; class I cavities were prepared in the dentine and filled with Venus composite (Heraeus Kulzer) after application of the adhesive. The test teeth were then stored for 10 minutes in water. The marginal gap was determined by surface analysis of the digitised images using the Analysis Soft Imaging programme (Olympus) with measurement of the largest marginal gap respectively.

Conclusion:
iBOND Self Etch exhibited the best results at the dentine with regard to shear bond strength and marginal adaptation.

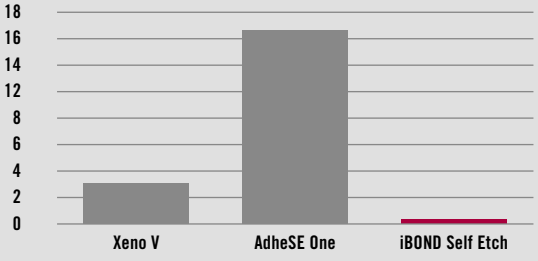
Results

The shear bond strength at the dentine was 31.2 ± 10.7 MPa for AdheSE One, 34.1 ± 8.6 MPa for Xeno V, and 35.7 ± 2.1 MPa for iBOND Self Etch. With regard to gap-free marginal adaptation at the dentine of the teeth tested, AdheSE One attained 0 %, Xeno V 50 % and iBOND Self Etch 100 %.

Mean shear bond strength at the dentine in MPa



Mean of the maximum marginal gaps at the dentine in µm



"Battle of the Bond" – Shear bond strength of iBOND® Self Etch

In vitro evaluation of the dentin bond strength of the experimental self-etching system iBOND Self Etch
Source: Michel Degrange, Biomaterials Lab, University of Paris, France
Data on file

Objective:
The objective of this in vitro study was to assess the dentin bond strength of iBOND Self Etch.

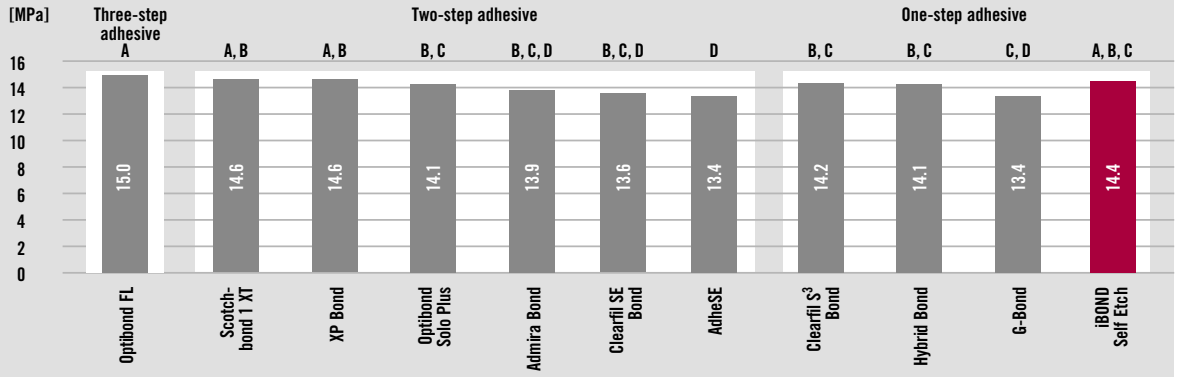
Materials and Methods:
iBOND Self Etch was tested in four practical courses of the "Battle of the Bond". The trials took place in meeting rooms especially equipped for this experiment. Sufficient specimens (extracted human molars) were prepared in advance for each series of tests according to the numbers of participants. The teeth were embedded in acrylic resin, and flat dentin surfaces were produced by wet grinding on SiC paper # 800. To achieve the specimens, the practitioners used Teflon split molds. After the application of the adhesive, the molds were filled in 2 increments (light-cured for 20 seconds each) with a composite resin. Only one composite material was used for all the trials (Z 100, 3M ESPE). The light intensity emitted by the available units was checked before using (a threshold of 600 mW/cm^2 was required). The bonded samples were stored in water and tested approximately 10 minutes after bonding. Shear bond strength was measured using a guillotine-type device on the tensile machine at a cross-head speed of 5 mm/min until fracture occurred. The shear bond strength values were recorded in an EXCEL table as the tests were conducted. Shear bond data were statistically analyzed with a Student's test at the level of p=0.05.

Conclusion:
The main advantage of the "Battle of the Bond" was to record a large database extracted from tests made by general practitioners. In this study, more than one hundred tests were performed with iBOND Self Etch. Recently, a publication grouping together all the clinical trials of dentin bonding systems has shown a positive correlation between this data and the clinical behavior of the same dentin bonding systems (Peumans et al., 2005).

Results

In total, 106 specimens of iBOND Self Etch were tested. The shear bond strength of iBOND Self Etch was 14.39 ± 4.5 MPa.

Initial shear bond strength to dentin in MPa in comparison to other tested adhesives*



*Results with the same superscripted letter are not statistically different from each other ($p < 0.05$).
The other adhesives were tested at least 100 times with the same method in at least five courses of the "Battle of the Bond".

GLUMA® Comfort® Bond + Desensitizer



GLUMA® Comfort® Bond + Desensitizer

Description of the product

GLUMA Comfort Bond + Desensitizer is a light cured, single component, wet-bonding agent for use in combination with adhesive restorations. With its programmed re-wetting action, it compensates for minor variations in the moisture content of the conditioned dentine surface. With the added benefit of ethanol as solvent, GLUMA Comfort Bond + Desensitizer was developed for bonding composite, compomer and Polyglas resins to the tooth structure as well as for bonding amalgams and indirect restorations. The patented chemistry of GLUMA Comfort Bond + Desensitizer combines the excellent adhesive bonding with the desensitising action of GLUMA Desensitizer.

Composition:

- Methacrylate
- 4-META
- Polyacrylic acid
- Ethanol
- Photoinitiators
- Glutaraldehyde

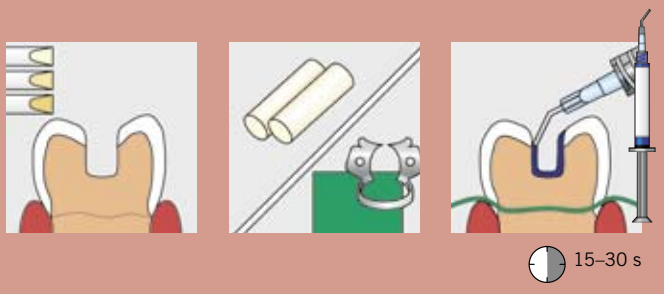
Indications:

- Bonding of direct composite, Polyglas and compomer restorations
- Bonding of indirect restorations (such as ceramic veneers, ceramic crowns, inlays and onlays) using light-curing or dual-curing cements
- Bonding of fresh amalgam
- Sealing hypersensitive areas of teeth

Advantages:

- Priming, bonding and desensitising in only one bottle
- Simple application without prior mixing
- Suitable both for moist and dry bonding techniques
- Excellent adhesive strength

Clinical application



Awards

2003 REALITY Four Star Award

THE DENTAL ADVISOR ++++½

Received a 4.5 @ 92 % rating in Vol. 17, No. 8

2-year results with GLUMA® Comfort® Bond + Desensitizer

Clinical Evaluation of a New Microhybrid Composite Study (Venus)

Authors: Dunn, J. R., Munoz, C.A., University of Loma Linda/USA

Publication: report to Heraeus Kulzer, data on file

Abridged version

Objective

The purpose of this clinical trial was to evaluate the in vivo performance of the combination of GLUMA Comfort Bond + Desensitizer/Venus for anterior restorations over a two-year period.

Materials und Methods

A total of 53 restorations (classes III, IV, V, diastema restorations, veneers) using Venus (Heraeus Kulzer) were placed in the anterior teeth of 28 subjects. GLUMA Comfort Bond + Desensitizer was used as the dental adhesive. At two-year, 40 restorations were evaluated. They were evaluated by using modified USPHS evaluation criteria for anatomic form, color match, marginal adaptation, retention, marginal discoloration, surface staining and secondary caries.

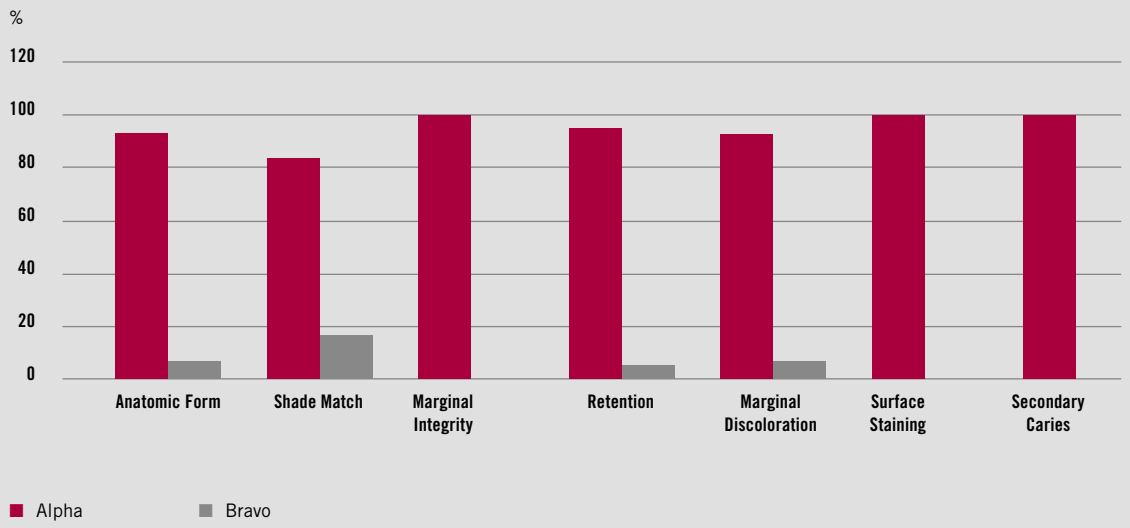
Conclusion

In all categories all restorations were ranked Alpha or Beta. None of the subjects exhibited postoperative sensitivity or exaggerated gingival response.

Based on the two-year findings of this study, the combination GLUMA Comfort Bond + Desensitizer/Venus is a very good choice for anterior restorations.

Results

Alpha/Bravo results after 2 years



Desensitising effect of GLUMA® Comfort® Bond + Desensitizer

Clinical Evaluation of the Role of Glutardialdehyde in a One-Bottle Adhesive

Authors: Dondi dall'Orologio, G., Lone, A., Finger, W. J.

Publication: Am J Dent 2004; 15: 330–334

Abridged version

Objective

To evaluate clinically whether the addition of glutardialdehyde to the one-bottle enamel-dentin adhesive GLUMA Comfort Bond (GCB) has a desensitising function, as insinuated by the brand name GLUMA Comfort Bond + Desensitizer (GCB+D).

Materials und Methods

Two pain studies following identical protocols were conducted in Abu Dhabi (A) and Bologna (B). Each of the 60 and 59 patients selected, respectively, had two sensitive cervical tooth sites, characterized by a score three or higher on a five-step pain scale: 1 (no), 2 (slight), 3 (mild), 4 (severe). 5 (very severe) discomfort upon application of a 2-second cold air stimulus. The buccal sensitive sites treated in A were generally small, in B larger and in most cases extending into the proximal tooth area. The patients indicated their discomfort level according to the pain scale prior to and immediately after topical application of GCB and GCB+D, respectively, and then at recalls after 1 week, 1 (A) or 3 (B) months, and 6 months. The data was statistically analyzed by A^2-tests ($p<0.05$).

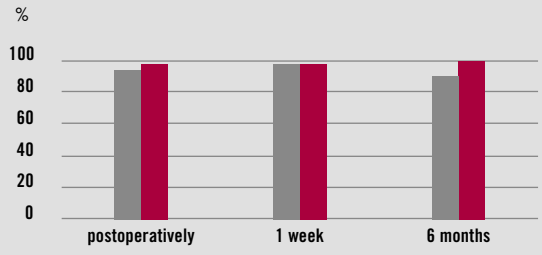
Conclusion

Glutardialdehyde was a suitably active and effective component in GLUMA Comfort Bond + Desensitizer to prevent post-operative sensitivity when adequate dentin sealing with the adhesive was not obtained.

Results

In the A-study, GCB+D was significantly more effective than GCB after 1 week, 1 month, and 6 months, in the B-study at all recall sessions.

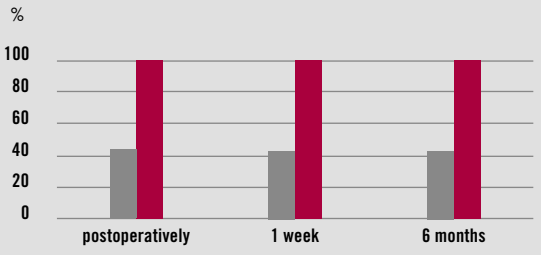
Percentage success rate (scores 1 and 2) – Abu Dhabi



GLUMA Comfort Bond

GLUMA Comfort Bond + Desensitizer

Percentage success rate (scores 1 and 2) – Bologna



GLUMA Comfort Bond

GLUMA Comfort Bond + Desensitizer

Shear bond strength to dentine

Shear Bond Strengths of GLUMA Bonding Systems to Dentin
Authors: Ritter, A. V., Bertoli, C. and Swift, E.F. Jr.
Publication: J Dent Res 2000; 79: 1852

Objective
GLUMA One Bond (GOB, Heraeus Kulzer) is a one-bottle adhesive containing UDMA, HEMA, and 4-META in acetone. To reduce the potential for technique sensitivity, the manufacturer has recently developed two adhesives containing the same resin monomers in ethanol. One of the new materials (GLUMA Comfort Bond + Desensitizer, Heraeus Kulzer, GCBD) contains glutaraldehyde, and one does not (GLUMA Comfort Bond, GCB). The purpose of this study was to evaluate the shear bond strength of the new ethanol-based adhesives versus GOB and a conventional three-step adhesive (Scotchbond Multi-Purpose, 3M Espe) as a control.

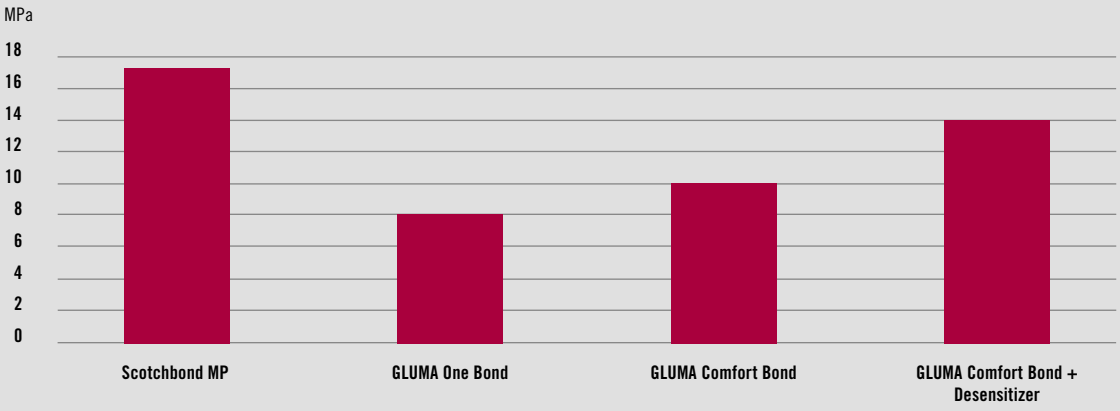
Materials und Methods
Forty bovine incisors were mounted in acrylic, polished to 600-grit, and randomly assigned to four groups (n=10). Dentin was etched for 15 s using 37 % phosphoric acid, rinsed, and lightly dried. After adhesive application and curing, Charisma composite (Heraeus Kulzer) was applied in a #5 gelatin capsule and light-cured. Specimens were loaded in shear using an Instrom at 5 mm/min. Shear bond strengths were calculated by dividing failure load by bonded surface area. ANOVA showed a significant difference in means at $p<0.01$, so Tukey's test was used for pairwise comparisons.

Conclusion
The results indicate that GLUMA Comfort Bond + Desensitizer provides bond strengths to dentin similar to the control Scotchbond Multi-Purpose and higher than its counterparts GLUMA One Bond and GLUMA Comfort Bond.

Results

Mean values SBS (±SD, MPa) were: GLUMA One Bond – 8.0 (4.4); GLUMA Comfort Bond – 10.0 (4.4), GLUMA Comfort Bond + Desensitizer – 14.0 (6.0); Scotchbond MP – 17.7 (6.4).

Shear bond strength in MPa



The references to the manufacturer's name have been amended by Heraeus Kulzer.

Shear bond strength of GLUMA® Comfort® Bond + Desensitizer

Shear Bond Strength to Dentin of New One-Bottle Adhesives
Authors: Quagliatto, P.S. Jang, K.-T., Días-Siohl, J. A., Garcia-Godoy, F.
Publication: J Dent Res 80, Special Issue (AADR-Abstracts 2001, Chicago)

Objective
To evaluate the shear bond strength to dentin of new one bottle enamel-dentin adhesives.

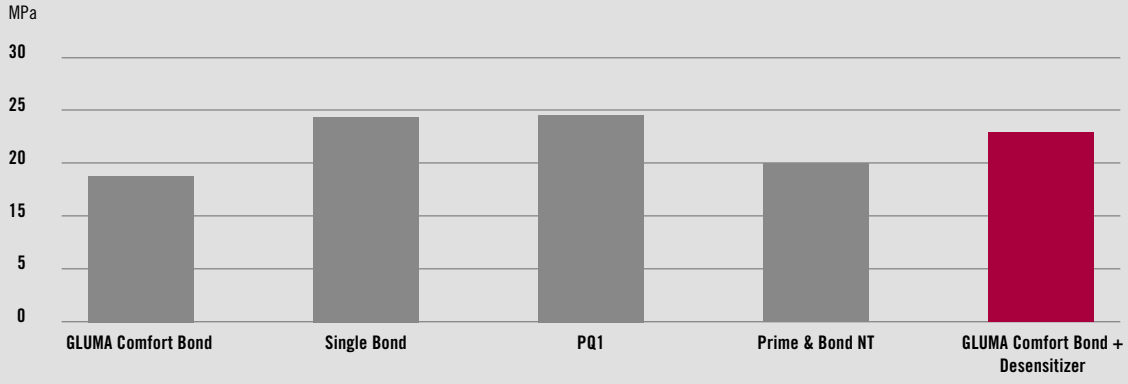
Materials und Methods
A total of 60 healthy human premolars were selected. Flat facial surfaces were made with a series of SiC paper into the superficial-to-middle dentin. The following groups were established (12 teeth per group): (1) Single Bond (3M ESPE); (2) PQ1 (PQ); (3) Prime & Bond NT (Dentsply); (4) GLUMA Comfort Bond (Heraeus Kulzer); (5) GLUMA Comfort Bond + Desensitizer (Heraeus Kulzer). For all groups P60 resin-based composite (3M Espe) was used. All adhesives were handled according to the manufacturers' instructions. Immediately after bonding, the specimens were stored in water for 48 hrs and then thermocycled (500x, 5–55 °C). Specimens were sheared at a crosshead speed of 1 mm/min in an Instron/MTS machine. The results were analyzed with an ANOVA and Student-Newman-Keuls (SNK) test.

Comment of Heraeus Kulzer
GLUMA Comfort Bond + Desensitizer showed very good results in shear bond strength.

Results

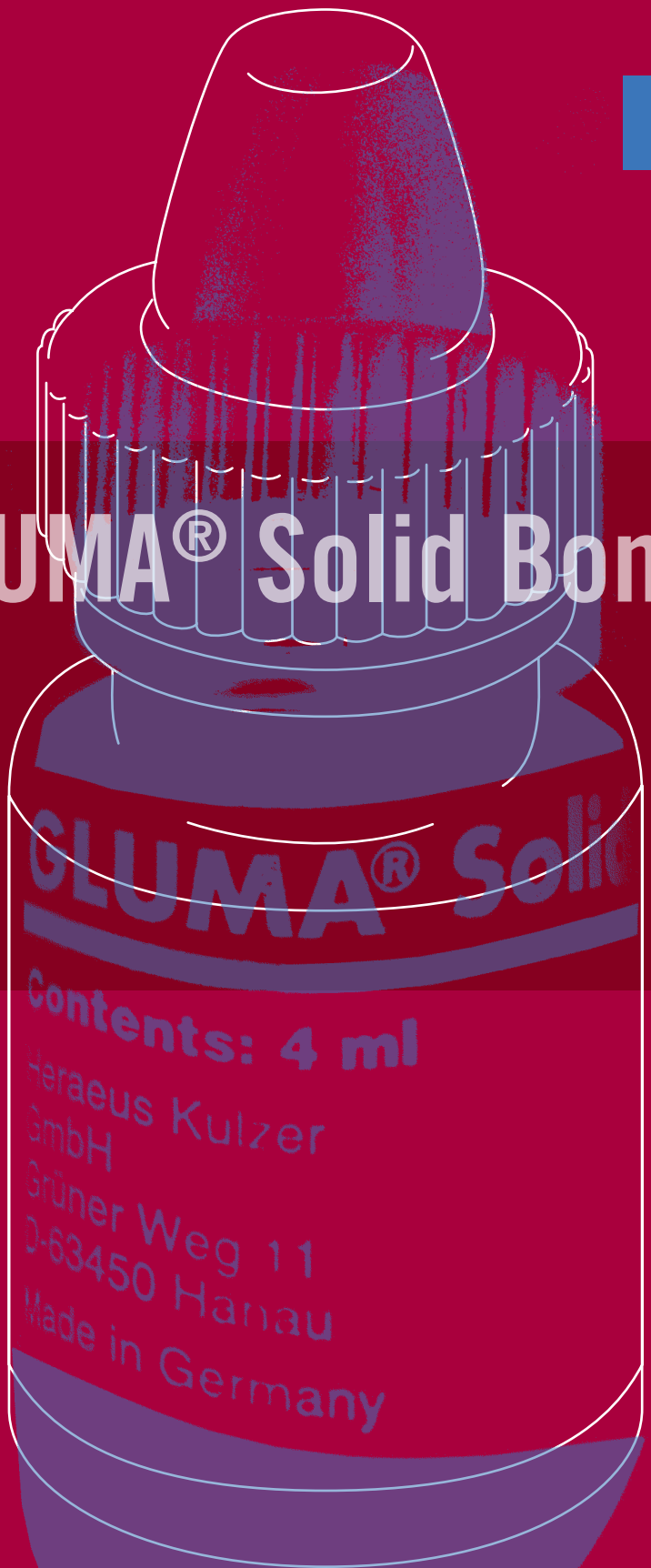
In MPa: Single Bond: 24.9 ± 5.1; PQ1: 24.6 ± 4.3; Prime & Bond NT: 19.8 ± 4.7; Gluma Comfort Bond: 18.0 ± 2.5; Gluma Comfort Bond + Desensitizer: 23.0 ± 3.6. ANOVA showed a statistically significant difference ($p<0.05$) among the groups. SNK test showed that groups 1 vs 4, 1 vs 3, 2 vs 4, 2 vs 3 and 5 vs 3 were statistically significantly different ($p<0.05$).

Shear bond strength in MPa



The references to the manufacturer's name have been amended by Heraeus Kulzer.

GLUMA® Solid Bond



GLUMA® Solid Bond

Description of the product

GLUMA Solid Bond is a bonding agent system for the adhesive filling therapy consisting of GLUMA Solid Bond P and GLUMA Solid Bond S. GLUMA Solid Bond P is a dentine-primer, whereas GLUMA Solid Bond S is a X-ray opaque sealer yielding fluoride ions. GLUMA Desensitizer can be applied after etching and before applying GLUMA Solid Bond P to prevent unwanted hypersensitivities.

Composition:

GLUMA Solid Bond P:

- Ethanol
- (2-hydroxyethyl-)methacrylate
- Maleic acid
- TEGDMA

GLUMA Solid Bond S:

- Bisphenol A – diglycidildimethacrylate
- TEGDMA

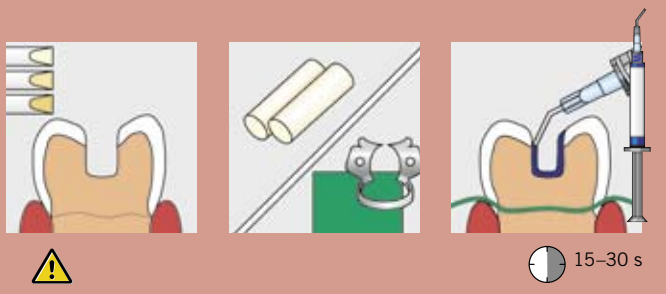
Indications:

- Bonding of all direct and indirect restorations
- Improvement of adhesion of fissure sealers to enamel and dentine
- Sealing exposed tooth necks

Advantages:

- 25 % filler loading
- X-ray opaque for significantly simplified X-ray diagnostics
- Excellent adhesive strength

Clinical application



Awards

Solid Bond (former name for GLUMA Solid Bond) received a 4.5 @ 88 % rating in Vol. 15, No. 8

Clinical evaluation of GLUMA® Solid Bond for 18 months

Clinical Evaluation of an All-In-One Self-Etching Dental Adhesive*

Authors: Ritter, A.V., Heymann, H., Pereira, P., Sturdevant, J. Swift, E. Jr., Wilder, A.

Publication: J Dent Res 84 (Spec Iss A): Abstract #2568, 2005

Abridged version

Objective

The purpose of this randomized clinical trial was to evaluate the clinical performance of an all-in-one self-etching dental adhesive (iBOND GI, Heraeus Kulzer) versus that of a multi-step total-etch dental adhesive (GLUMA Solid Bond, Heraeus Kulzer) when applied to non-carious Class V lesions.

Materials und Methods

Lesions were characterized preoperatively relative to height, width, depth, percent of margin in enamel, internal angle, and degree of sclerosis. Fifty-five non-carious Class V lesions were randomly assigned to two treatment groups according to the adhesive used: GLUMA Solid Bond (n=27) or iBOND GI (n=28). Tooth preparation consisted of roughening the exposed walls of the lesion with a diamond instrument. No retentive grooves or bevels were used. Durafill VS (Heraeus Kulzer) was used as the restorative material. Adhesives and composite were applied according to manufacturer's directions and light-cured using a Translux Energy unit (Heraeus Kulzer). The restorations were evaluated at baseline and at 18 months for retention, secondary caries, marginal adaptation/integrity, and marginal discoloration using modified USPHS criteria for clinical evaluation of dental restorations. Data were analyzed using Fisher Exact's Test (p=0.05) for significant differences between treatments.

Comment of Heraeus Kulzer:

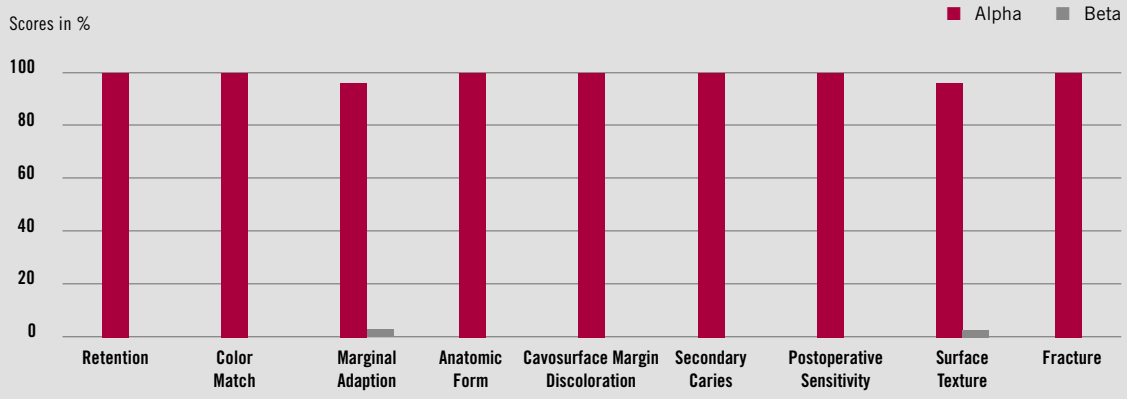
The multi-step total-etch dental adhesive GLUMA Solid Bond presented in all categories very good results after 18 months.

* see study also on page 13

Results

Overall lesion characteristics were similar, and all baseline scores were Alpha for all restorations in both treatment groups. The 18-month recall rate was 95 %. No retention failures or secondary caries were observed, and all restorations were clinically acceptable. No significant differences were detected between Gluma Solid Bond and iBond GI regarding marginal adaptation/integrity (p=0.09).

Results of GLUMA Solid Bond after 18 months



Bond strength of GLUMA® Solid Bond on dentine

Bond Strength of Single- and Multi-Component Bonding Agents in Dry and Moist Bonding Trials in vitro

Authors: B. Haller, A. Fritzenschaft

Publication: Dtsch Zahnärztl Z 54 (1999): 225–230

Abridged version

Objective

The effect of moist bonding on the bond strength and marginal adaptation of 8 single- and multi-component bonding systems was tested in a push-out test.

Materials und Methods

The products tested were one multi-component system with a self-etching primer (Condiprimer, A.R.T. Bond, Catène), three multi-component systems with separate acid-etching (EBS EF, 3M Espe; OptiBond FL, Kerr; GLUMA Solid Bond, Heraeus Kulzer) three primer/adhesive systems with phosphoric acid etching (Prime & Bond 2.1 Dentsply; Scotchbond 1, 3M Espe; Syntac Single Component, Ivoclar Vivadent), and one experimental self-etching primer/adhesive (Condiprimer-adhesive, Degudent). For each bonding agent ten specimens were processed according to the dry bonding protocol with careful drying of the dentin, and another ten according to the moist bonding protocol, where excessive water was removed with a cotton pellet. Bond strength was assessed in a push-out test, and the marginal adaptation of the composite was determined by SEM using acrylic replicas of the push-out specimens.

Conclusion

According to these results moist bonding can be recommended for all single-component and multi-component bonding agents studied, except for A.R.T. bond.

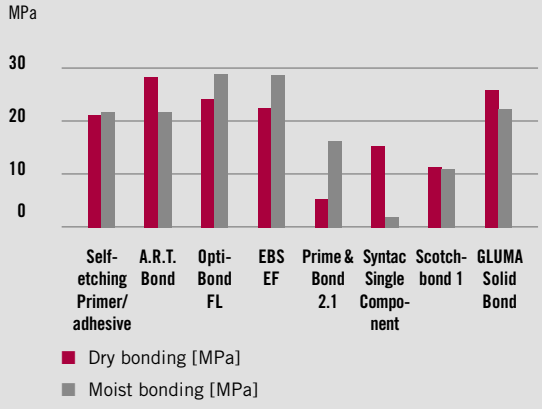
Comment of Heraeus Kulzer:

GLUMA Solid Bond showed the best marginal adaptation (100 % gap-free) and very good bond strength.

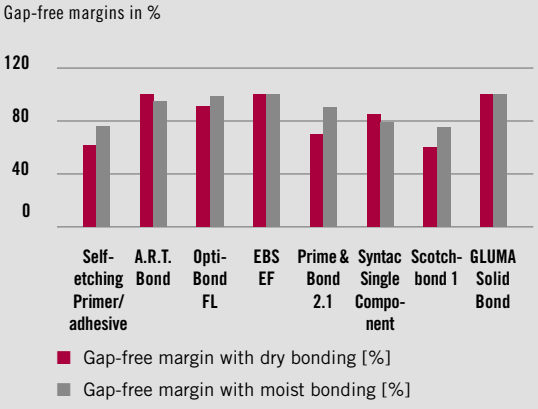
Results

After 24 hours of immersion in 0.9 % NaCl solution the multi-component bonding agents exhibited significantly higher bond strengths both on dry and on moist dentin (22.7–28.9 MPa, or respectively, 22.1–29.6 MPa) than the primer/adhesives (5.3–13.9 MPa, or respectively, 11.0–15.7 MPa). SEM analysis showed that some of the multi-component products are associated with a superior marginal adaptation as compared to some of the single-component systems.

Bond strength



Marginal adaption



The references to the manufacturer's name have been amended by Heraeus Kulzer.

Shear bond strength to enamel

Moist Bonding: Effect on Composite Bond Strength to Enamel
Authors: Moll, K., Gärtner, T., Haller, B.
Publication: J Dent Res 1998, 77: Special Issue B 1998
[Abstract 1254]
Abridged version

Objective
Moist bonding is recommended for dentin adhesives in order to prevent the collapse of the demineralized collagen. The purpose of this in vitro study was to investigate the effect of moist bonding on the shear bond strength of composite to enamel.

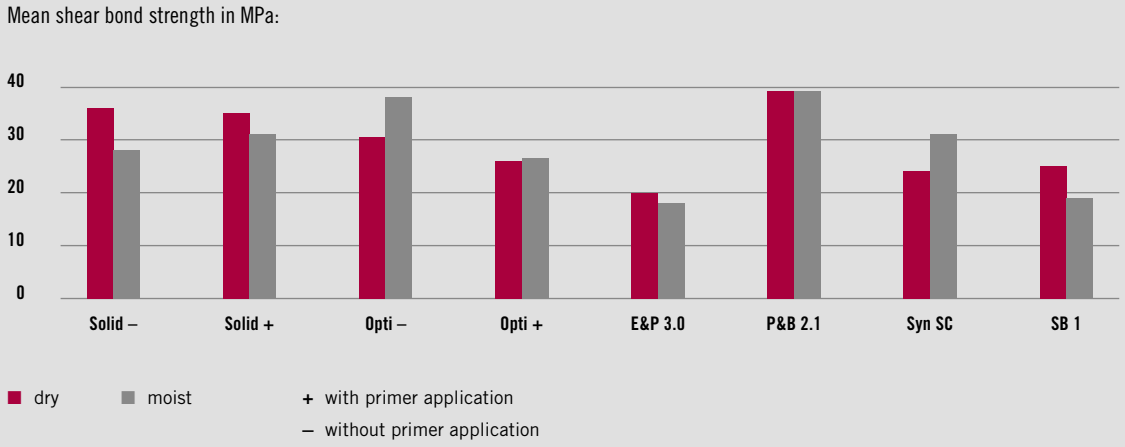
Materials und Methods
Enamel of extracted molars (n=160) was ground flat, etched with phosphoric acid and treated with the bonding agents according to the manufacturers' instruction. Six restorative systems were tested: OPTI OptiBond FL/Herculite (Kerr), SOLID GLUMA Solid Bond/Charisma F (Heraeus Kulzer), E&P 3.0 Etch&Prime 3.0/Degufill Mineral (Degudent), P&B 2.1 Prime&Bond 2.1/Spectrum TPH (Dentsply), SYN SC Syntac Single Component/Tetric (Ivoclar Vivadent), SB1 Scotchbond 1/Z100 (3M Espe). OPTI and SOLID were tested without (–) and with (+) primer application. For each system 20 specimens were prepared. The enamel was either carefully dried with compressed air (dry: n=10), or blot dried with a cotton pellet (moist: n=10). Shear bond strength (SBS) was determined after 24h (0.9 % NaCl, 37 °C) in a universal testing machine (Zwicki 1120) at a crosshead speed of 0.5 mm/min.

Conclusion
SBS of composite to enamel seems not to be affected by moist bonding. However, considerable differences were found between the bonding systems tested. Cavity tests and clinical studies are necessary to evaluate the effect of these differences on marginal adaptation and retention.

Comment of Heraeus Kulzer:
GLUMA Solid Bond showed one of the best shear bond strength results with and without primer application. Dry bonding showed better results for GLUMA Solid Bond.

Results

Results of GLUMA Solid Bond after 18 months



The references to the manufacturer's name have been amended by Heraeus Kulzer.

Microtensile bond strength of GLUMA® Solid Bond

Effect of Desensitizer on Microtensile Bond Strength to Dentin
Authors: Geraldeli, S., Castilhos, N., Mandelli, A., Fulani, J. C. G., Perdigão, J.
Publication: J Dent Res 79: Special Issue, Book of Abstracts 78th General Session of the IADR, Washington 2000
Abridged version

Objective

The purpose of this in-vitro study was to evaluate the effect of GLUMA Desensitizer on the dentin µ-tensile bond strengths (µTBS).

Materials und Methods

The occlusal third of 16 extracted human molars was removed to expose a flat dentin surface. Specimens were randomly assigned to four dentin adhesives: OptiBond SOLO (Kerr); Prime&Bond 2.1 (Dentsply); Single Bond (3M Espe); and GLUMA Solid Bond (Heraeus Kulzer). After acid-etching, half of the specimens were treated with GLUMA Desensitizer (GD). Crowns were built-up with a hybrid composite from the same manufacturer of the adhesive. After storage in saline at 37 °C for 24 h, specimens were prepared for µtensile bond testing according to Shono et al., J. Dent Res 78: 699, 705. Mechanical testing was performed in a Universal Testing Machine with a crosshead speed of 1 mm/min. Mean results were subjected to one-way ANOVA and Tukey's post-hoc test. Student's t-test was used to compare mean results for each adhesive (control vs. GD).

Conclusion

Within the limitations of this in-vitro project, the use of GLUMA Desensitizer, an aqueous solution of 35 % HEMA and 5 % glutaraldehyde, may increase µTBS when used prior to the application of some simplified dentin adhesives.

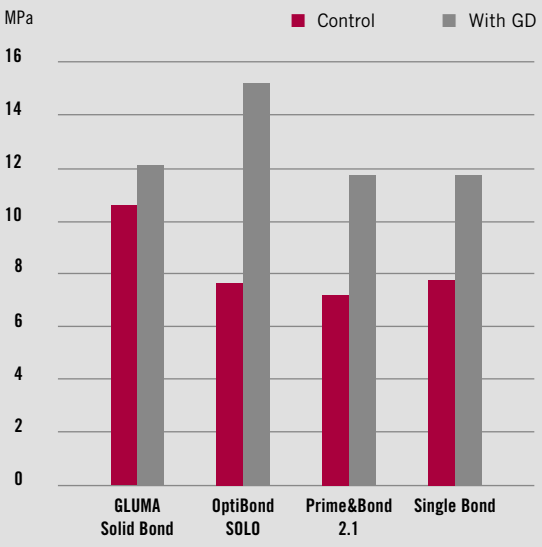
Comment of Heraeus Kulzer:
GLUMA Solid Bond showed the best results in the control group.

Results

The variable "adhesive system" did not result in any significant statistical difference between pairs of mean values for the control and for the GD sub-groups. For each adhesive system, GD resulted in statistically higher µTBS than the control group, except for GLUMA Solid Bond.

	GLUMA Solid Bond	OptiBond SOLO	Prime&Bond 2.1	Single Bond
Control	10.7 ± 8.0	7.5 ± 6.2	7.1 ± 4.4	7.8 ± 5.8
With GD	12.1 ± 8.2	15.1 ± 10.6	11.5 ± 7.8	11.6 ± 9.8

Microtensile bond strength in MPa



The references to the manufacturer's name have been amended by Heraeus Kulzer.

GLUMA®
Desensitizer



GLUMA® Desensitizer

Description of the product

GLUMA Desensitizer has been in the market for over 10 years and has been used in over 45 million restorations worldwide to reduce hypersensitivity.
GLUMA Desensitizer penetrates up to 200µm into the exposed dentine tubuli where it forms multiple layers of protein septa thereby preventing intratubular movement following osmotic changes and preventing hypersensibilities.

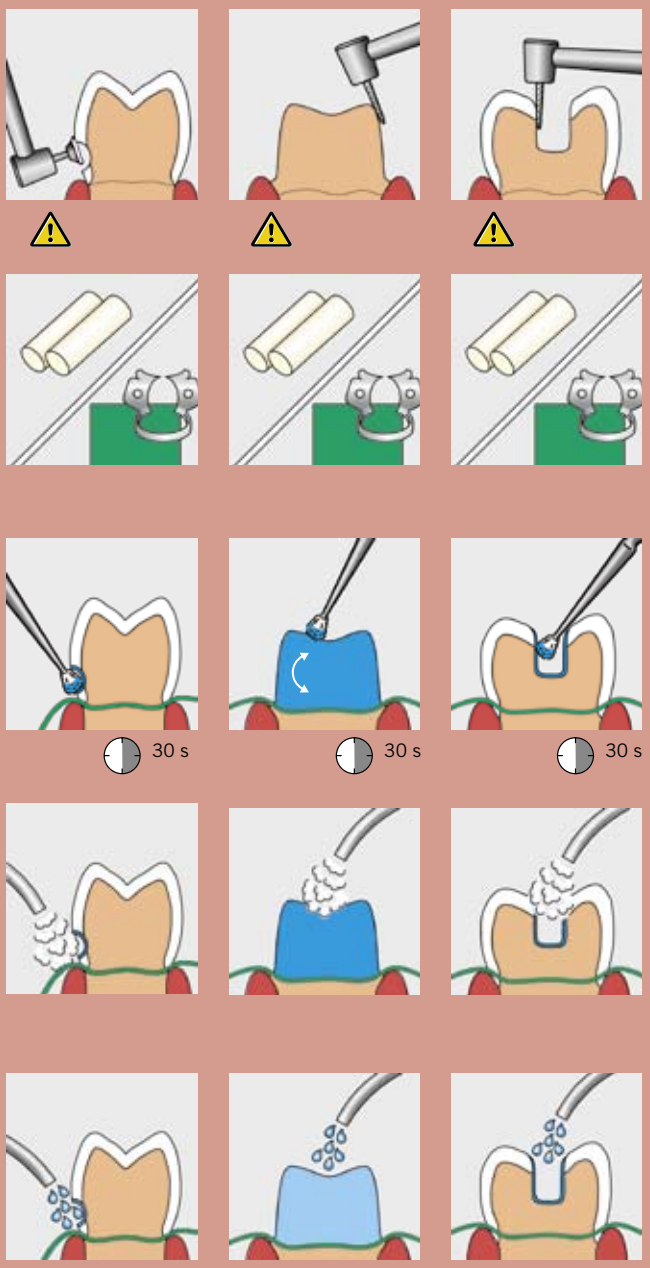
Composition:
- (-hydroxyethyl-)methacrylate
- Glutardialdehyde
- Purified water

Indications:
- Reduction of sensitivity of exposed cervical areas which do not require restoration
- Reduction or prevention of postoperative sensitivity following preparation of teeth for direct or indirect restorations

Advantages:
- Highly effective yet easily handled
- No mixing, at a reaction time of only 30–60 secs., no light-curing required
- Initial efficacy
- Immediate pain reduction
- More effective than pure fluoridation
- Intradentinal effect, no surface film
- Clinically proven to be effective for at least 12 months
- Also used to good effect in combination with bonding agents

Clinical application

Hypersensitivity | **Crown preparation** | **Inlay**



Awards

THE DENTAL ADVISOR ++++½

Received a 4.5 @ 91 % rating in Vol. 18, No. 10
Received a 4.0 @ 88 % rating in Vol. 7, No. 1

2006 REALITY Five Star Award ★★★★★ REALITY'S CHOICES

Desensitising effect of GLUMA® Desensitizer on prepared teeth

Evaluation of the Desensitizing Effect of GLUMA Dentin Bond* on Teeth Prepared for Complete-Coverage Restorations

Authors: Felton, D.A., Bergenholtz, G., Kanoy, B.

Publication: Int J Prosthodont 1991; 4:292–298

Abridged version

Objective

The clinical trial assessed the ability of GLUMA Dentin Bond* (= GLUMA Desensitizer) to inhibit dentinal sensitivity in teeth prepared to receive complete cast restorations.

Materials und Methods

20 patients provided 76 teeth for the study. Following tooth preparation, dentinal surfaces were coated with either sterile water (control) or two 30-second applications of GLUMA Dentin Bond* (test) on either intact or removed smear layers. Patients were recalled after 14 days for a test of sensitivity of the prepared dentin to compressed air, osmotic stimulus (saturated $CaCl_2$ solution), and tactile stimulation via a scratch test under controlled loads.

Conclusion

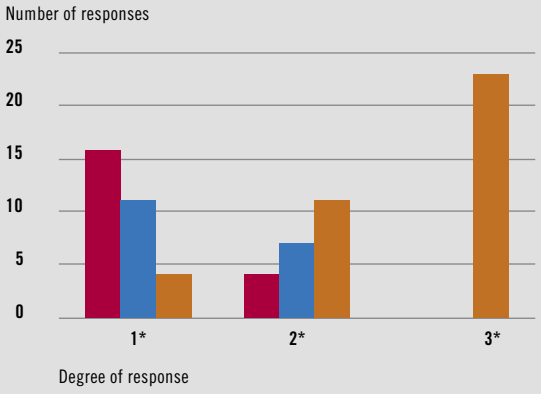
Within the experimental limitations of this investigation, the following conclusions can be drawn: 1. Compared to sterile water, GLUMA Dentin Bond* provided a significant reduction in dentin sensitivity when placed on exposed dentin of complete veneer crown preparations. 2. The presence of a dentinal smear layer had no appreciable effect on dentin sensitivity responses for either GLUMA treatment group.

* GLUMA Dentin Bond was the former name of GLUMA Desensitizer

Results

A siginificantly lower number of teeth responded to the test stimuli for both Gluma groups when compared to the controls ($p<0.01$). No difference was noted between teeth with smear layers intact or removed prior to treatment with GLUMA Dentin Bond*.

Response to air stimulus



1*: No sensation to stimulation

2*: Mild to moderate sensation, but little discomfort (nonlingering)

3*: Severe sensation or discomfort (lingering)

- GLUMA Desensitizer/smear layer intact
- GLUMA Desensitizer/smear layer removed
- Controls

The desensitising effect of GLUMA® Desensitizer on hypersensitive dentine

Desensitizing Effects of Gluma Primer and Gluma 2000 on Hypersensitive Dentin

Authors: Dondi dall'Orologio, G., Malferrari, S.

Publication: Am J Dent 1993; 6: 283–286

Abridged version

Objective

The aim of this clinical trial was to investigate the effects of topical applications of GLUMA 3 Primer* (= GLUMA Desensitizer) or GLUMA 2000 conditioning solutions on hypersensitive erosion/abrasion lesions.

Materials und Methods

Thirty-four patients were included in the trial with at least two teeth each presenting severe sensitivity. From a total of 116 teeth, 40 were treated with GLUMA 3 Primer* (Heraeus Kulzer), 42 with GLUMA 2000 Conditioner and 34 served as the control. Sensitivity was recorded as response to tactile and cold air stimuli prior to treatment as baseline, immediately after the topical application of the agents, after 1 week, 1 month and 6 months.

Conclusion

Single topical treatments of hypersensitive erosion/abrasion lesions with GLUMA 3 Primer* and GLUMA 2000 conditioning solutions, respectively, eliminated or at least significantly reduced dentin sensitivity throughout the 6 month observation time.

* identical to GLUMA Desensitizer

Results

Both GLUMA groups showed a highly significant reduction in sensitivity between baseline and postoperative pain scores ($p<0.05$) and between the postoperative and the 1-week responses ($p<0.05$). The sensitivity scores were not different between 1 week and 6 months. In the control group, no pain reduction was registered between baseline and up to 1-month recall. After 6 months, however, the sensitivity was spontaneously slightly reduced. At the end of the 6-month observation time, 29 GLUMA 3 Primer* and 31 GLUMA 2000 treated teeth no longer showed dentin sensitivity.

Sensitivity score	Baseline			Post-treatment			1 week			1 month			6 months		
	GL	GT	CO	GL	GT	CO	GL	GT	CO	GL	GT	CO	GL	GT	CO
0	–	–	–	10	19	–	28	31	–	29	31	–	29	31	–
1	–	–	–	16	13	–	8	9	–	7	9	–	7	9	2
2	18	18	24	14	10	24	4	2	26	4	2	27	4	2	30
3	22	24	10	–	–	10	–	–	8	–	–	7	–	–	2

GL: GLUMA 3 Primer*

GT: GLUMA 2000 Conditioner

CO: Control Group

Efficiency of desensitising treatments with GLUMA® Desensitizer

Efficiency of Desensitising Treatments of Hypersensitive Dentine with Gluma and GLUMA 2000

Authors: Blunck, U., Roulet, J.-F.

Publication: internal report to Heraeus Kulzer, data on file

Abridged version

Objective

The purpose of this clinical investigation was to evaluate the effectiveness of four different treatments for teeth with severe sensitivity.

Materials und Methods

30 patients who already suffered from hypersensitive dentine for at least two months with unsuccessful treatments before that time were included in the study. 58 severe sensitive teeth were randomly assigned to four different treatment groups. A: 60s application of GLUMA Primer* (= GLUMA Desensitizer), B: 60s application of GLUMA Primer* after using GLUMA Cleanser, C: 60s application of GLUMA 2000 Conditioner, and D: application of the entire GLUMA bonding system (Cleanser, Primer and Adhesive). The treatment as described under D was used as a control since it was unethical to observe untreated hypersensitive dentine for one year. The sensitivity was recorded as a response to tactile and cold air stimuli before treatment, after the different topical applications, after one week, one month, six and twelve months.

Conclusion

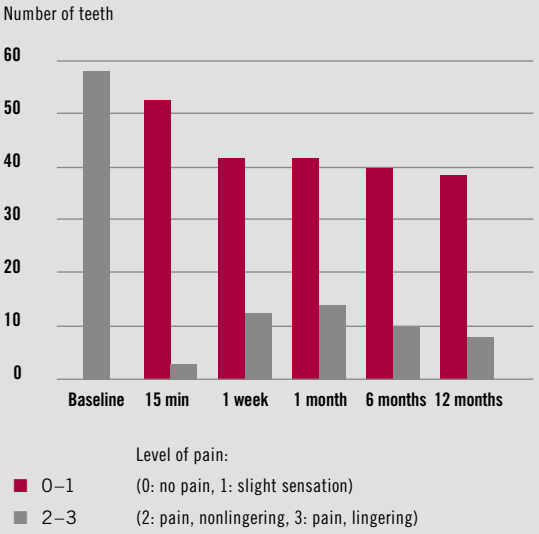
Even a single topical application of GLUMA Primer* without prior cleansing significantly reduced the severe hypersensitivity of exposed cervical dentine and was as effective as the more time consuming application of a total dentine adhesive system.

* identical to GLUMA Desensitizer

Results

All treatments showed a significant reduction of hypersensitivity between baseline and directly after application. No statistically significant difference could be calculated by Chi-square-tests between the four different groups up to the reevaluation after three months. The recording of the sensitivity after 6 and 12 months showed significantly more severely sensitive teeth in the group tested with GLUMA 2000 Conditioner (group C). After one year for the group A (GLUMA Primer*) 39 out of 48 teeth (81%), for group B (GLUMA Cleaner + GLUMA Primer*) 36 out of 44 (82%) and for group D (GLUMA Bording System) 37 out of 48 teeth (77%) were still recorded without severe sensitivity but only 6 out of 49 teeth (11%) in group C (GLUMA 2000 Conditioner). In this group the number of reapplications also was highest.

Efficiency of GLUMA Primer*



Clinical evaluation to dentine hypersensitivity

Clinical Evaluation of Gluma 3 Primer to Dentine Hypersensitivity

Autoren: Inoue, M., Yoshikawa, K., Okamoto, A., Kota, K., Fujii, B., Iwaku, M.

Publication: Japanese Journal of Conservative Dentistry 1996; 39: 768–776

Abridged version

Objective

The objective of this study was to evaluate pain reduction in hypersensitive cervical regions immediately after applying GLUMA 3 Primer* (= GLUMA Desensitizer) and during the following 8 weeks.

Materials und Methods

This study was carried out at the conservative dentistry departments of the Universities of Osaka and Niigata, using the same protocol. A total of 82 teeth (60 patients) with severe dentine hypersensitivity symptoms were involved in this study. The pain causing stimulants were an air blast, cold water or scratching with a dental probe. GLUMA 3 Primer* was applied for 60 seconds. The effectiveness was evaluated after intervals of 15 minutes, 1, 4 and 8 weeks.

Conclusion

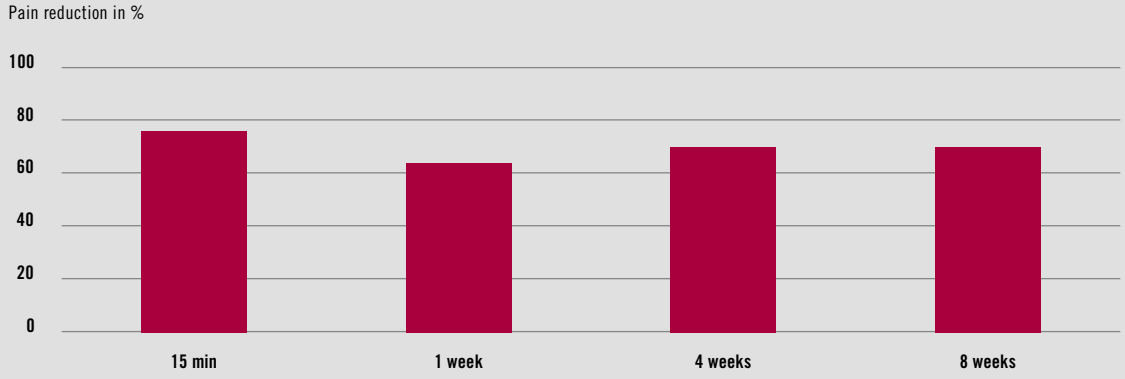
The authors confirmed that GLUMA 3 Primer* is an effective and reliable topical desensitiser for treating dentine hypersensitivity. No side-effects were recorded in cases where the site was kept completely dry with a rubber dam or where it was kept relatively dry with cotton rolls.

* identical to GLUMA Desensitizer

Results

15 minutes after topical application, the dentine hypersensitivity had already been reduced considerably or eliminated in 79 % of the teeth. This high initial effectiveness remained unchanged throughout the ensuing 8 week observation period.

Pain reduction (stimulant air blast)



Clinical effectiveness of GLUMA® Desensitizer on tooth cervical hypersensitivity

Clinical Effectiveness of Two Agents on the Treatment of Tooth Cervical Hypersensitivity

Authors: Kakaboura, A., Rahiotis, CH., Thomaidis, S., Doukoudakis, S.

Publication: Am J Dent 2005; 18: 291–295

Abridged version

Objective

To investigate the desensitising ability of a one-bottle agent and a glutaraldehyde-based HEMA formulation on sensitive tooth cervical areas for a period up to 9 months.

Materials und Methods

The sample consisted of 40 patients with cervical hypersensitivity. Three sensitive teeth per patient were treated; one received One-Step (one-bottle bonding agent, Bisco), the other GLUMA Desensitizer (glutaraldehyde-based agent, Heraeus Kulzer) and the third distilled water (control group). The hypersensitivity level was determined before, immediately after the desensitising session, at 8 weeks, and 9 months post-treatment. Measurements of sensitivity were determined by the patient's response to tactile and air-blast stimuli. A verbal rating scale was used and scored as follows: 0, no discomfort; 1, discomfort but no severe pain; 2, severe pain during stimulation; 3, severe pain after stimulation. The results were subjected to statistical analysis by Kruskal-Wallis test (a=0.05).

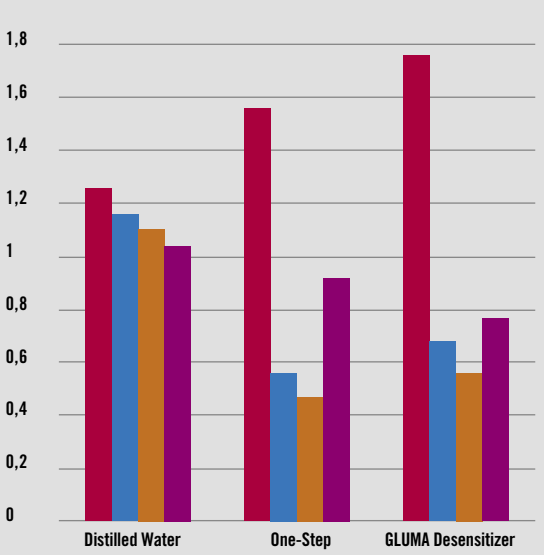
Conclusion

Even though the one-bottle agent tested may offer a short-term, adequate reduction of hypersensitivity, a significant reversal of the sensitivity may occur long-term, particularly for air-blast stimulation. The glutaraldehyde-based agent was proven more efficient in treating cervical sensitivity up to the 9-month follow-up.

Results

Both treatment procedures resulted in reduction of hypersensitivity to both stimuli, for up to 9 months. No significant differences were recorded between One-Step and GLUMA Desensitizer at immediate and 8-week examinations, whereas GLUMA Desensitizer produced lower hypersensitivity than One-Step at the 9-month assessment. In general, a lower level of reduction was found for the 9-month interval compared to the 8-week hypersensitivity score for both agents tested. A placebo effect was effected with water treatment, ranging from 4.7 to 27.5 % reduction of hypersensitivity.

Mean hypersensitivity scores for air-blast stimulus



The references to the manufacturer's name have been amended by Heraeus Kulzer.

Effectiveness after periodontal therapy

Effectiveness of Desensitizing Agents for Dentin Hypersensitivity after Periodontal Therapy

Authors: Tenorio, S. B., Santos, R. L., Gusmão, E. S.

Publication: J Dent Res (Spec Iss B) 2002, 48: 54

Abridged version

Objective

The effectiveness of two desensitising agents were analyzed on 48 teeth of male and female patients who had presented with hypersensitive dentin after periodontal therapy.

Materials und Methods

Teeth were selected and divided into two groups of twenty-four according to the substance applied: group I (Oxagel, Art Dent) and group II (GLUMA Desensitizer, Heraeus Kulzer). For the first section, all patients were instructed in oral hygiene, prophylaxis and their sensibility was evaluated using criteria proposed by Uchida et al. (J. Periodontol., 51: 10, p. 578–81, 1980). For evaluation tactile stimulus (pathfinder), air jet and thermic stimulus (cold) were employed. Solutions were applied and after seven days the patients returned for measuring the degree of sensitivity again and re-applying the desensitizing agents. This was continued for a period of four weeks and after this period a new evaluation was carried out after 60 days.

Conclusion

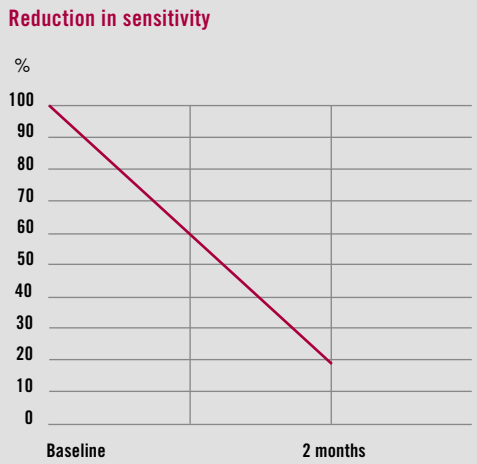
These data indicate that desensitising agents were efficient to decrease hypersensitive dentin after periodontal therapy.

Comment of Heraeus Kulzer:

GLUMA Desensitizer effectively reduces hypersensitivity of dentine after periodental therapy.

Results

Results of the present study corroborate that both groups underwent a medium percentual decrease exceeding 81% between initial and final analysis (two months).



The references to the manufacturer's name have been amended by Heraeus Kulzer.

Influence of retention of cemented castings

Crown Retention with use of a 5 % Glutaraldehyde Sealer on Prepared Dentin

Authors: Johnson, G. H., Lepe, L., Bales, D. J.

Publication: J Prosthet Dent 1998; 79: 671–6

Abridged version

Objective

This study determined whether a non-resin sealer applied to prepared dentin affected the retention of cemented castings.

Materials und Methods

Extracted molars were prepared with a flat occlusal, 20-degree taper and 4 mm axial length. The axial surface area of each preparation was determined and samples were distributed to achieve equivalent groups. Gluma Desensitizer (Heraeus Kulzer) sealer was used to seal the dentin before provisionalization and again before crown cementation. An Olympia alloy casting was produced for each preparation and cemented with a seating force of 20 KG with either Mizzy's zinc phosphate (Mizzy Inc.), Ketac Cem glass ionomer (3M ESPE) or Resinomer material (Bisco) in combination with One Step adhesive (Bisco). Castings were thermocycled, then removed along the path of insertion with an Instron testing machine. A two-factor analysis of variance was used with α=0.05 and n=9–10.

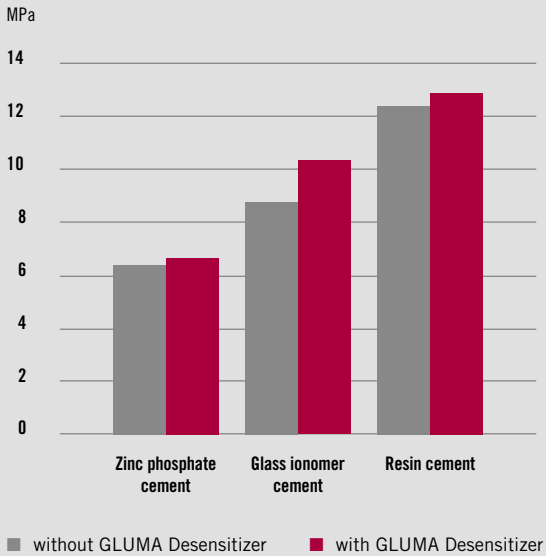
Conclusion

The use of the glutaraldehyde-based system as a desensitizing treatment for prepared teeth had no effect on crown retention for any of the three cements evaluated and the modified resin cement produced the highest mean dislodgement stress that exceeded the strength of the tooth.

Results

Mean dislodgement stresses for unsealed and sealed conditions were 6.3 and 6.4 MPa for zinc phosphate, 9.1 and 10.1 MPa for glass ionomer, and 12.1 and 12.6 MPa for the resin cement. The means for the three cements were statistically different ($p<0.001$). The effect of sealer ($p=0.369$) and cross product interactions ($p=0.820$) were not significant.

Crown retention with and without GLUMA Desensitizer



The references to the manufacturer's name have been amended by Heraeus Kulzer.

Influence of GLUMA® Desensitizer on bond strength

Influence of Desensitizers on Bond Strength of 2 Adhesive Systems at Dentin

Authors: Bedran de Casgtro, A.K.B.; Aramal, C.M.; Shinohara, M.S.; Ambrosano, G.M.B.; Pimenta, L.A.F.

Publication: J Dent Res 2002 ; 81: B–176

Abridged version

Objective

The aim of this study was to evaluate the influence of desensitizer agent treatment on the bond strength of two adhesive systems.

Materials und Methods

One hundred and fifty bovine incisors were mounted, their dentin polished, and divided into 10 groups (n=15): G1 – Singlebond/3M (SB); G2 – Excite/Vivadent (EX); G3 – Oxagel (OXA)+ SB; G4 – OXA + EX; G5 – GLUMA Desensitizer/Heraeus Kulzer (GLU) + SB; G6 – GLU + EX; G7 – Desensibilizer/FGM (DES) + SB; G8 – DES + EX; G9 – Experimental/FGM (EXP) + SB; G10 – EXP + EX. In all groups, the dentin was etched with 37 % phosphoric acid. Soon after, the desensitiser, respectively the adhesive, was applied according to manufacturers' instructions. Then a resin (Z100, 3M ESPE) was inserted in a teflon matrix and cured. The specimens were stored under humidity for 7 days at 37 °C. The SBS tests were performed in an EMIC universal test machine with a crosshead speed at 0.5 mm/min. The mean values were analyzed with two-way ANOVA and Tukes Test ($p<0.05$) and the differences were expressed by different letters ($p<0.05$).

Conclusion

No significant difference was observed between the adhesive, the use of GLUMA Desensitizer presented the higher values and OXA presented the lower values. It could be concluded that the use of desensitizer agents does not interfere with the bond strength of two adhesives.

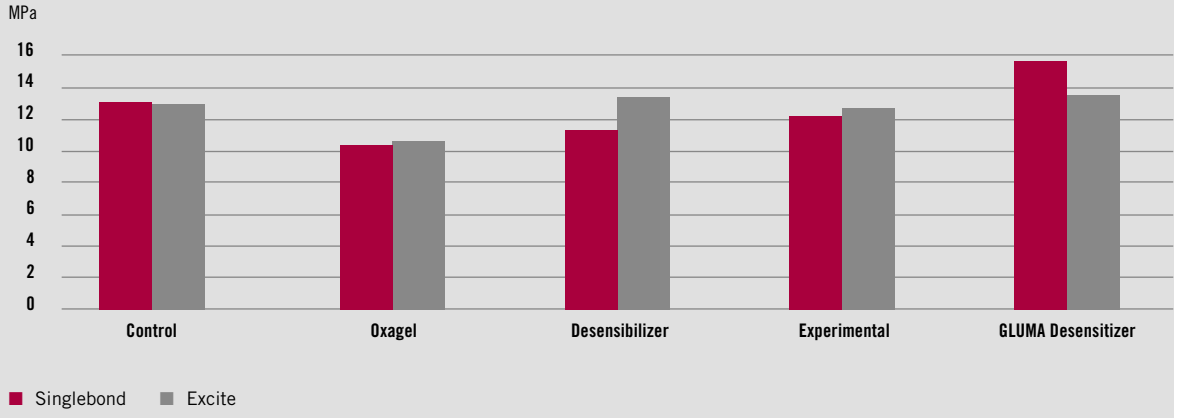
Comment of Heraeus Kulzer:

The adhesives showed the highest bond strength in combination with GLUMA Desensitizer.

Results

The values in MPa (SD) were: G1 = 13.07 (5.82); G2 = 13.00 (4.83); G3 = 10.21 (5.01); G4 = 10.57 (3.94); G5 = 15.77 (4.09): G6 = 13.55 (4.19); G 7 = 11.17 (4.17); G 8 = 13.31 (3.11); G 9 = 12.18 (5.22); G10 = 12.57 (4.43).

Bond strength in MPa



References

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Notes

All graphs and page titles were provided by Heraeus Kulzer.

The studies were chosen with the objective of resuming bond strength results and desensitising effects of the Heraeus Kulzer products iBOND Self Etch, GLUMA Comfort Bond + Desensitizer, GLUMA Solid Bond and GLUMA Desensitizer.

The studies on pages 12, 13, 14, 17, 19, 42, and 43 were translated into English.

In compliance with the European guideline 93/42/EWG our medical devices are CE-marked according to the classifications.
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