# G-ænial
## Bond from GC

TECHNICAL MANUAL

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G-ænial Bond
KIT

## 1.0 Introduction

The increased popularity of aesthetic dentistry in the last 50 years has driven the need for durable aesthetic restorative materials that provide ease-of-use, give confidence in clinical outcomes and result in patient satisfaction. The advent of adhesive dentistry has made possible the creation of beautiful direct aesthetic restorations using a conservative approach. To improve application techniques and the longevity of adhesive restorations, considerable focus has been placed on developing new bonding systems that support adhesion of the restorative materials to the remaining tooth structure.

Two major categories of adhesive systems are currently available (Table 1):

- Etch-and-rinse systems: these require etching of enamel and dentin with phosphoric acid prior to application of the primer and adhesive
- Self-etch systems: these offer the ability to demineralise the tooth surface without the use of an etching agent.

Table 1: Currently available adhesive systems

| Category | Technique/generation | Etching | Priming | Bonding |
|---|---|---|---|---|
| Etch-and-rinse | 3-step $4^{th}$ generation | 1) Etchant | 2) Primer | 3) Adhesive |
| | 2-step $5^{th}$ generation | 1) Etchant | 2) Single bottle primer/adhesive | |
| Self-etch | 2-step $6^{th}$ generation | 1) Self-etching primer | | 2) Adhesive |
| | 1-step $7^{th}$ generation | 1) Self-etching primer/adhesive | | |

Both techniques have known advantages and disadvantages (Table 2).
The technique selected is often based on the clinical situation:

- For preparations with margins that are mainly in enamel (e.g., class IV preparations with large bevels) the etch-and-rinse technique is often preferred.
- For surface areas that consist mainly of dentine (e.g., class I preparations) the need for more reliable adhesion to dentine often results in the self-etch technique being preferred.

Table 2: Advantages and disadvantages of the etch-and-rinse and self-etch techniques

| | Advantages | Disadvantages |
|---|---|---|
| Etch-and-rinse | • High bond strength to enamel | • High risk of post-operative sensitivity<br>• Potential nano-leakage when used on dentine |
| Self-etch | • Ease-of-use<br>• Reduced post-operative sensitivity<br>• Chemical bond to dentine | • Lower bond strength to enamel<br>• Potential nano-leakage when used on enamel |

The ideal product would deliver high adhesion to enamel whilst being "safe" on dentine, offering the advantages of both techniques. With these objectives in mind, GC has developed G-ænial Bond, a new adhesive system.

## 2.0 Product description

G-ænial Bond is a one component self-etching light-cured adhesive, specially developed for the selective etching approach in which only the enamel is etched prior to application of the self-etching adhesive. Therefore, the bond strength to enamel can be increased, while the quality of the bond to dentine remains optimal. As a truly flexible adhesive system, G-ænial Bond will also provide excellent bond strengths when used in the self-etch technique on enamel and dentine.

G-ænial Bond is designed to be used with the G-ænial range of restorative products; however it can also be used with other products such as composite resins (see Indications for use below).

## 3.0 Indications for use

G-ænial Bond is recommended for the following indications:

1. Bonding of light-cured composites and acid-modified composites (compomers) to tooth structure.

2. Bonding of dual-cured luting and core build-up composites to tooth structure provided these materials are light-cured.

## 4.0 The selective etching technique

The development of G-ænial Bond focused on offering a bonding system that can be adapted to all clinical situations, offering flexibility and the option to select the most clinically appropriate technique:

- The self-etch technique: for all clinical indications where adhesion is mainly to dentine; avoids the risk of nano-leakage and hypersensitivity.
- The selective etching technique: acid etching the enamel only for 10 seconds before applying G-ænial Bond. This is indicated for uncut and cut enamel surfaces.

In fact, using selective etching offers the benefits of both techniques and avoids their respective disadvantages.

### 4.1 Why selective etching on enamel?

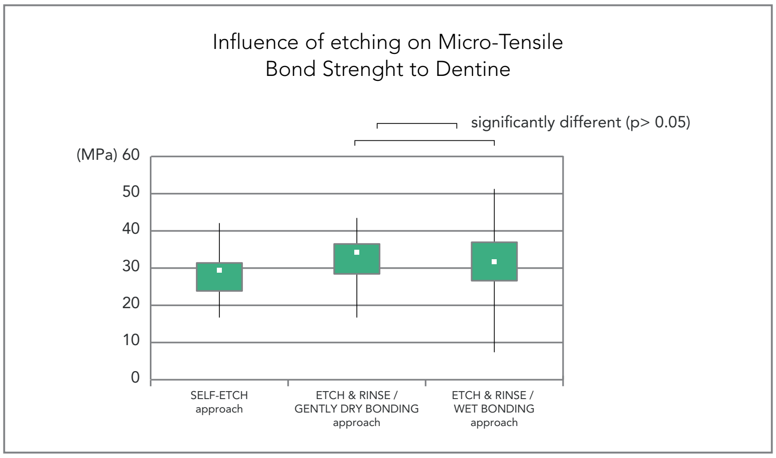
G-ænial Bond used with the self-etch technique provides sufficient bond strength to enamel. In some clinical situations, it may be preferred to further enhance bond strength. This can be achieved by selectively etching the enamel with phosphoric acid for 10 seconds prior to application of G-ænial Bond. Test results have demonstrated that the bond strength will then be comparable to etch-and-rinse products. This will also decrease the risk of marginal staining.

## 4.2 Why self-etching on dentine?

**Etching of dentine does not give any additional benefit for bond strength, as demonstrated by the independent studies below.**

- Microtensile bond strength tested by Professor B. van Meerbeek at the KUL, Leuven, Belgium

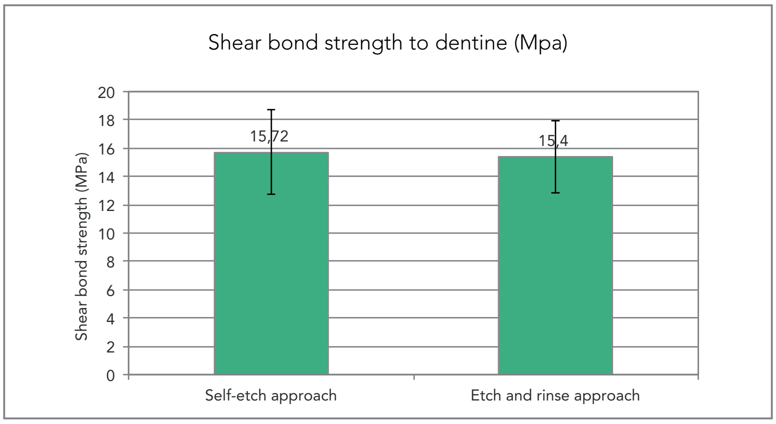
Figure 1: Microtensile bond strength to dentine (test set up: page 17). Source: Adapted except from Prof B. van Meerbeek, KUL Leuven, Belgium, 2010




The results of this test show that there is no statistical difference in the microtensile bond strength to dentin whether using G-ænial Bond in the self etch or in the etch-and-rinse mode.

- Shear Bond strength tests with both self-etch and etch-and-rinse techniques by Professor M. Degrange† at the University of Paris Descartes, France

Figure 2: Shear Bond Strength to Dentine (Test set up page 18). Source: Adapted excerpt from Prof. M. Degrange†, Université Paris Descarte, France, 2010




No statistical differences were found between the two techniques (self-etch and etch-and-rinse) when using G-ænial Bond.

**In conclusion, the results of these two studies prove that there is no added value in etching dentine when using G-ænial Bond.**

## Disadvantages of etching with phosphoric acid

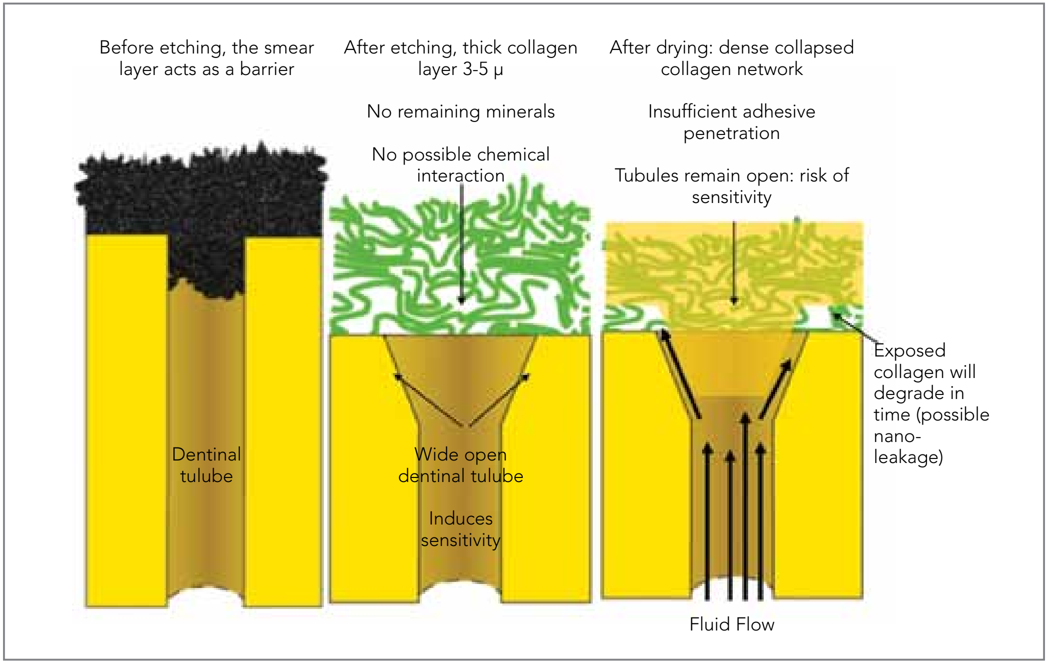
It is now common consensus that phosphoric acid etching of dentine is aggressive, resulting in dentinal tubules that are widely opened, an excessively thick demineralised layer and leaving collagen fibres without any minerals.

- Etching of Dentine can result in post-operative sensitivity
  The major problem in this situation is sealing the dentinal tubules correctly in order to avoid post-operative sensitivity. The collagen fibres collapse easily when drying the cavity, thereby creating a layer of thick and dense fibres that can not be thoroughly impregnated with the bonding agent, this can result in the dentinal tubules remaining open and the patient experiencing post- operative sensitivity.

- Etching of Dentine induces risk of nano-leakage
  It is documented in the literature that the collagen in dentine that becomes exposed by an etch-and rinse procedure is highly vulnerable to hydrolytic and enzymatic degradation processes[1]. If the bonding agent does not fully penetrate into the demineralised collagen network, degradation of exposed collagen fibres can occur, leading to possible nano-leakage.

- Etching of Dentine reduces the potential for chemical interaction.
  Etching of Dentine dissolves hydroxyapatite crystals and removes minerals required for chemical interaction. Chemical interaction is believed to improve the bond durability[2].

Figure 3: Concerns associated with the use of acid etchants on dentine




[1] Pashley DH et al. Collagen degradation by host-derived enzymes during aging. J Dent Res 2004;83:216-21.

[2] Van Meerbeek B. et al., State of the art self-etch adhesives, Dent. Mat. 2011;27:17-28.

# 5.0 Features and benefits

Adopting a dentist oriented approach, GC formulated G-ænial Bond to offer ease of handling and excellent clinical performance of the adhesive. The result is a bonding system providing the following features:

- High performance in self-etch and selective etch approaches
- High bond strength to dentine
- Excellent marginal integrity
- Long-term, durable bond
- Reduced post-operative sensitivity
- Easy handling

# 6.0 Composition

## 6.1 A unique formulation

The following table describes the various components contained in G-ænial Bond and their clinical relevance.

Table 3: Composition of G-ænial Bond

| Component | Function | Clinical relevance |
|---|---|---|
| 4-MET<br>Phosphoric acid ester monomer | Functional monomer:<br>• Etching agent<br>• Wetting agent<br>• Promotes adhesion | • Dissolves the smear layer<br>• Demineralises and creates space for monomer infiltration<br>• Infiltrates the demineralised surface (micro-mechanical adhesion)<br>• Initiates the interaction between the tooth structure and the monomers (chemical adhesion) |
| Dimethacrylate monomers | Resin Monomer:<br>• Linking agent<br>• Networking agent | • Links with the composite resin which is hydrophobic<br>• Promotes cross-linking between the dimethacrylate monomers |
| Distilled water | • Promotes etching<br>• Solvent | • Participates in the etching process<br>• Takes in the residues from the etching process in order to remove them while being blown off |
| Acetone | Solvent | • Evaporates water from the adhesive interface, aiding long-term adhesion |
| Silicon dioxide | • Adjusts the viscosity<br>• Reinforcing material | • Eases the application of the bonding agent<br>• Strengthens the adhesive layer |
| Photo-initiator | Photo-initiator | • Polymerises the resin monomers upon light energy activation |

## 6.2 The HEMA-free Principle

### 6.2.1 Why exclude HEMA from the formulation?[3]

HEMA (2-hydroxyethyl methylmethacrylate) is added to many commercially available adhesives. Adding HEMA provides certain benefits for those products:

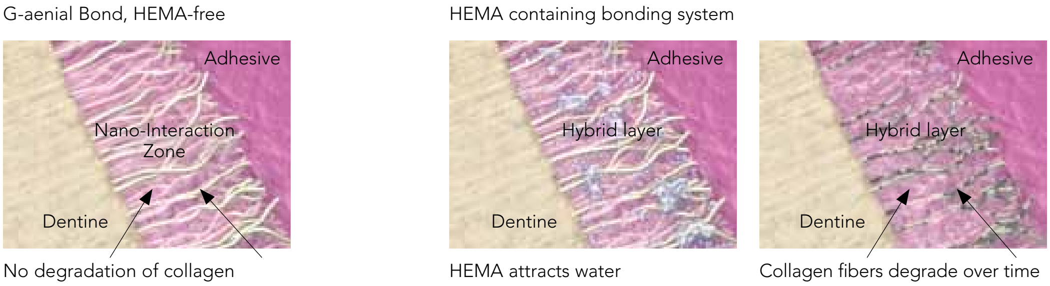
- Excellent infiltration capacity of up to several millimeters into the etched dentine surface. This is particularly useful when the dentine is deeply etched with strong acidic etching agents, such as orthophosphoric acid or with self-etching systems with a very low pH
- HEMA helps mix hydrophobic and hydrophilic components into a single solution (avoiding a phase separation)
- HEMA improves wetting of the adhesive on the tooth surface
- HEMA acts as a co-solvent

However, the inclusion of HEMA also results in some noticeable disadvantages:

- HEMA enhances water uptake from the tooth and the intra-oral environment, rendering the bond more prone to degradation over time
- From a chemical perspective, HEMA has only one polymerizable group, reducing its polymerization efficiency (only linear polymerization without cross-linking), thus resulting in a weaker interface
- HEMA has also been shown to retain water in the adhesive layer, which could reduce polymerisation
- HEMA has been reported in the literature as being able to induce contact allergic reactions, and can also quickly penetrate through dental gloves.

Based on these observations, as with G-Bond, GC decided to use a HEMA-free formulation for G-ænial Bond. After application of the adhesive, water is separated from the other ingredients upon acetone evaporation. The HEMA-free G-ænial Bond formulation makes it possible to avoid the substantial amount of water that is kept within the adhesive layer in HEMA-containing adhesives. As mentioned above, residual water along with the presence of HEMA leads to greater water sorption, and thus weaker bond stability (Figure 4). **In contrast, the long-term hydrolytic resistance and stability of the bond will be improved when using HEMA-free G-ænial Bond adhesive. In addition, the risk of allergic reactions associated with HEMA is avoided with G-ænial Bond.**

Figure 4: Schematic representation of hydrolytic degradation of the collagen network in HEMA-containing bonding systems




G-ænial Bond has a pH of around 1.5, enabling the creation of a 500 nm hybrid layer. Furthermore, the use of adequate resin monomers ensures a simultaneous demineralisation and complete infiltration by the resin monomers into the collagen network even though no HEMA is present into the composition. This in turn avoids the creation of voids at the dentine/ bond interface, thereby decreasing the risk of nano-leakage and increasing long-term durability of the bond.

[3] The science behind G-Bond, The unique concept of a HEMA-free adhesive; Bart Van Meerbeek et al., Leuven BIOMAT Research Cluster,Department of Conservative Dentistry, Catholic University of Leuven (KULeuven), Belgium, June 2009

## 6.2.2 Influence of HEMA on bond strength over time

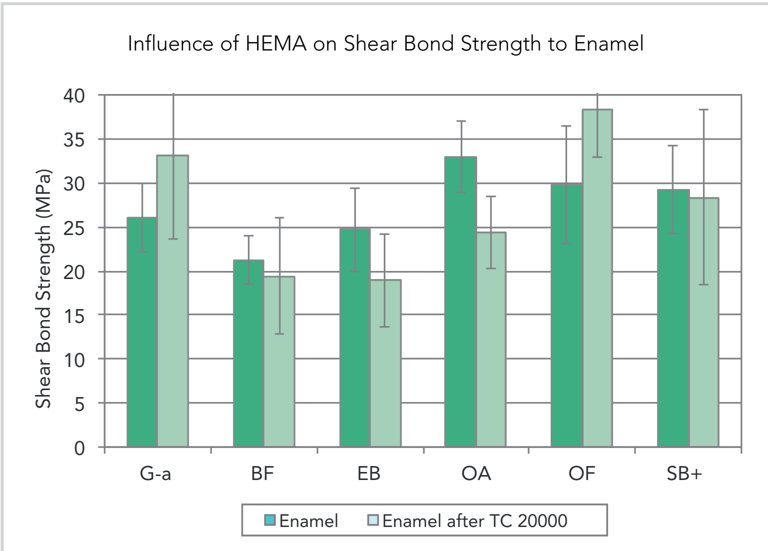
In order to assess the long-term durability of the bond and the influence of HEMA, thermocycling tests were performed by GC R&D (2010), comparing the HEMA-free G-ænial Bond to commercially available HEMA-containing adhesive systems.

**Test set-up:** Bovine enamel and dentine samples were embedded in acrylic resin (Unifast III) and polished with #320-grit SiC paper. Adhesives were applied to the surface according to the respective manufacturer's recommendations as detailed below in Table 4. Clearfil AP-X (Kuraray) was placed on the surface using an Ultradent mould (D=2.38 mm) and light-cured for 20 seconds using G-light (GC). The specimens (n=5) were stored in 37°C water for 24 hours, after which the specimens (n=5) were subjected to thermocycling (5°C-55°C, 20000 cycles). Shear bond strength (SBS) was measured at a cross-head speed of 1 mm/min. The statistical analysis was conducted using the Tukey test ($P<0.05$).

Table 4: Tested materials, HEMA-free or containing HEMA

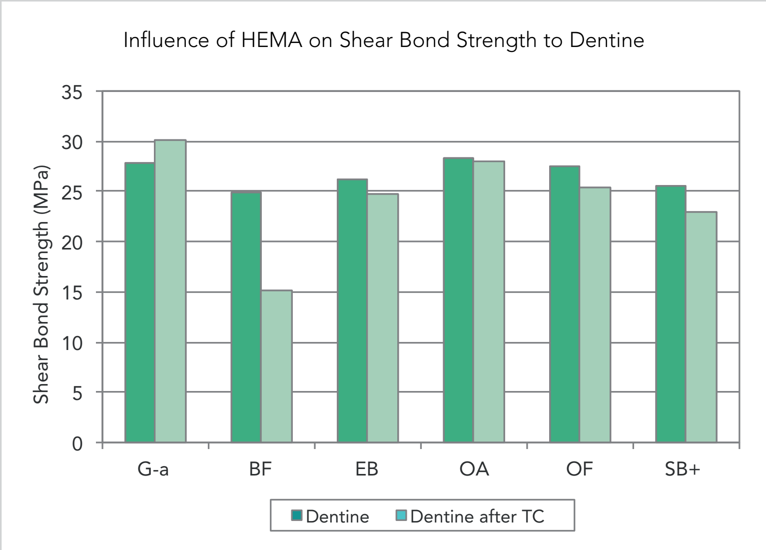
| Code | Product Name | Manufacturer | Application time | Air drying | Light-curing | HEMA |
|---|---|---|---|---|---|---|
| G-a | G-ænial Bond | GC | 10 s | strong 5s | 5s | No |
| BF | Bond Force | Tokuyama | 20 s | weak 5 s and moderate 5 s | 10 s | Yes |
| EB | Easy Bond | 3M ESPE | scrub for 20 s | weak 5 s | 10 s | Yes |
| OA | OptiBond All-in-One | Kerr | scrub for 20 s (X2) | weak 5 s | 10 s | Yes |
| OF | OptiBond FL | Kerr | etch and scrub for 15 s | weak 5 s | 10 s | Yes |
| SB+ | Single Bond Plus | 3M ESPE | etch and apply for 15 s (x2) | weak 5 s | 10 s | Yes |

Figure 5: Shear bond strength to enamel of the HEMA-free G-ænial Bond (G-a) in comparison to various HEMA-containing bonding materials. Source: GC Corporation, Japan, 2010




The shear bond strength to enamel increased after thermocycling for G-ænial Bond (G-a) and Optibond FL (OF). In contrast, the shear bond strength to enamel decreased after thermocycling for all other HEMA-containing adhesives.

Figure 6: Shear bond strength to dentine of the HEMA-free G-ænial Bond (G-a) in comparison to various HEMA-containing bonding materials. Source:GC Corporation, Japan, 2010




The shear bond strength to dentine increased after thermocycling for G-ænial Bond and decreased for all the HEMA containing adhesives.

It is hypothesized that the presence of HEMA in the composition leads to water sorption and degradation of the bonding layer during thermocycling. **Thanks to its HEMA-free composition, G-ænial Bond is expected to provide a long-term, durable bond both and dentine and enamel.**

# 7.0 Physical properties – Results of in Vitro Studies

## 7.1 The mechanisms of adhesion to enamel and dentine

The adhesion of G-ænial Bond relies on both micro-mechanical retention and chemical bonding principles.

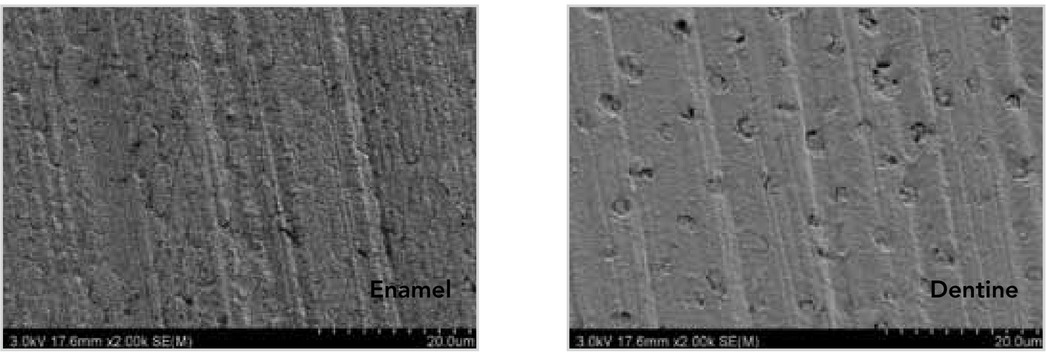
### 7.1.1 Micro-mechanical interlocking

Under aqueous conditions, the two functional monomers (4-MET and phosphoric acid ester) dissolve the smear layer and mildly etch enamel and dentine surfaces, thereby creating micro-porosities on enamel and increasing the surface available for bonding. At the same time, it will partially demineralise the outer dentine layer, leaving space between the collagen networks for resin infiltration which leads to the formation of a hybrid layer. The depth of the demineralised zone is the same as the depth of the resin infiltration, which means that the collagen network will remain protected (rather than part of it becoming exposed), therefore there is no risk of hydrolytic degradation or associated nano-leakage.

**SEM observations - Tests conducted by GC R&D, Japan**
SEM observations were conducted in order to characterise the demineralisation patterns after application of G-ænial Bond to enamel and dentin.

**Test set-up:** G-ænial Bond was applied to the tooth surface, after the surface had been polished with #600 grit SiC paper. After 10 seconds, the adhesive was washed out with acetone, and the SEM images were taken.

Figure 7: Observation of demineralisation patterns on enamel (left) and dentine (right) under SEM microscopy, magnification x2000. Source: GC Corporation, Japan, 2009




The demineralisation patterns generated by application of G-ænial Bond on enamel can be observed in Figure 7 left. Due to its relatively low pH of 1.5, G-ænial Bond induced effective demineralisation of enamel (also demonstrated by the small amount of remaining smear layer) and the creation of micro-porosities.

The SEM of dentine (Figure 7 right) also demonstrates good demineralisation with the application of G-ænial Bond. Nevertheless, the dentinal tubules remain occluded, reducing the risk of post-operative sensitivity.

## 7.1.2 Chemical interaction

While micro-mechanical interlocking is hypothesized to be the basis for good adhesion, recent publications have demonstrated that additional chemical interaction between the functional monomers and the tooth substrate could improve the bond durability.[4] This is known as the "Adhesion-Decalcification" (or AD) concept.

The two functional monomers can form a complex with the remaining calcium salts of the hydroxyapatite crystals, which is the basis for the chemical interaction. This results in the formation of an extremely strong layer with low solubility, known as the nano-interaction zone (NIZ). The amount of residual apatite crystals is of great importance in ensuring the subsequent quality of adhesion.

**TEM observations**
**Tests conducted by GC R&D, Japan**
To assess the quality of the dentine/ adhesive interface of various bonding agents, Transmission Electron Microscope (TEM) observations were conducted on non-demineralised and on demineralised specimens.

**Test set-up:** Two 0.8 mm-thick specimens of human dentine/ adhesive interface were prepared. One of the specimens was left untreated, i.e., non-demineralised (Figure 8), while the other specimen was demineralised with EDTA solution (Figure 9 and Figure 10). Each specimen was embedded in an epoxy resin and ultrathinned to 80-90 nm thickness. After carbon-spattered, the interfacial zone was observed using TEM.

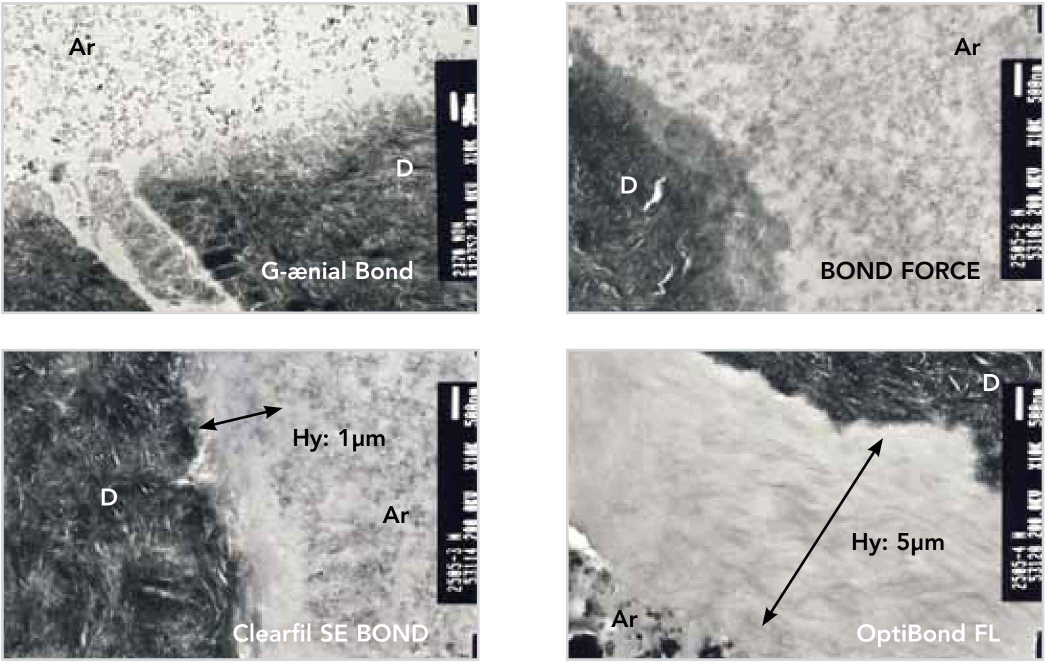
Table 5: Application technique of adhesives tested

| Product Name | Manufacturer | Category | Etching and rinsing | Bottle 1 | Air drying | Bottle 2 | Air drying | Light-curing |
|---|---|---|---|---|---|---|---|---|
| G-ænial Bond | GC | 1-step self-etch | / | 10 s application | strong 5 s | / | / | 10 s |
| Bond Force | Tokuyama | 1-step self-etch | / | 20s application | weak 5 s and moderate 5 s | / | / | 10 s |
| Clearfil SE Bond | Kuraray | 2-step self-etch | / | 20 s | mild | apply | gently | 10 s |
| Optibond FL | Kerr | 3-step etch-and-rinse | 15 s + 15 s | 15 s | 5 s | 15 s | 3 s | 20 s |

In the specimens that were not demineralised (Figure 8), no hybrid layer was observed for either the G-ænial Bond or Bond Force TEM samples. A hybrid layer of 1μ and one of 5μ was observed with Clearfil SE Bond and Optibond FL respectively.

4 Van Meerbeek B. et al., State of the art self-etch adhesives, Dent. Mat. 2011;27:17-28.

Figure 8: TEM photomicrographs of the dentine/adhesive interface of non-demineralised specimens (x10 000). Hy: Hybrid Layer; Ar: Adhesive resin; D: Dentine. Source: GC Corporation, Japan, 2009




In the demineralised specimens treated with G-ænial Bond or Clearfil SE Bond (Figure 9 and Figure 10), a nano-interaction zone (NIZ) was observed between the adhesive resin (Ar) and the underlying dentine (D). In contrast, no NIZ was observed in the Bond Force and OptiBond FL specimens.

Figure 9: TEM photomicrographs of the dentine/adhesive interface of demineralised specimens (x10 000). NIZ: Nano-Interaction Zone; Ar: Adhesive resin; D: Dentine. Source: GC Corporation, Japan, 2009

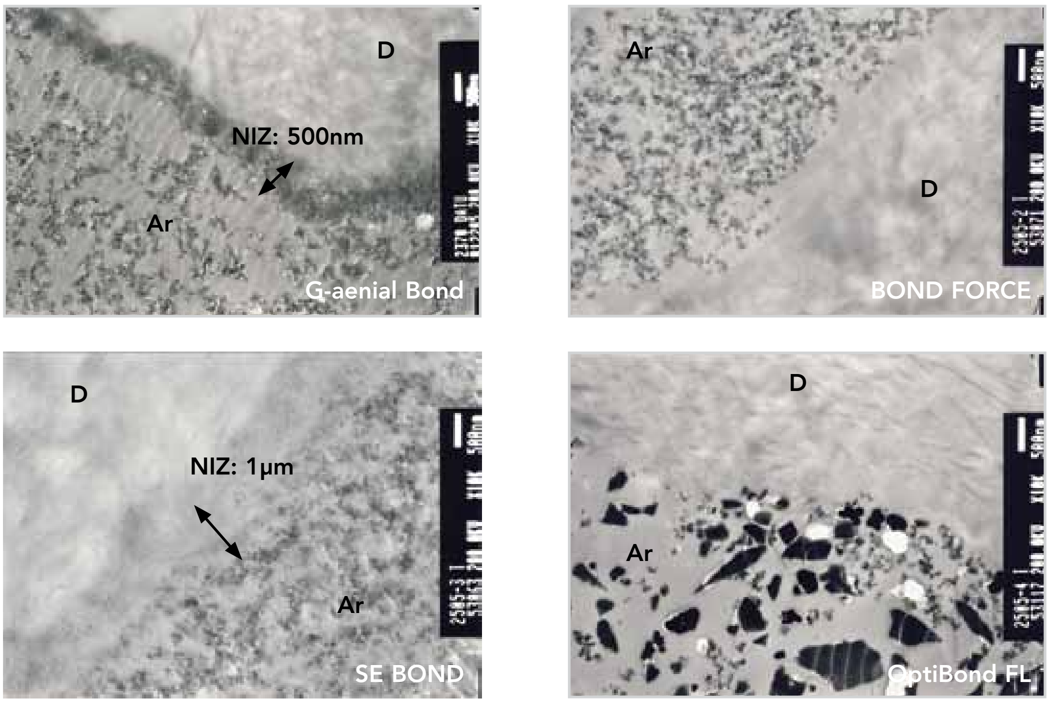
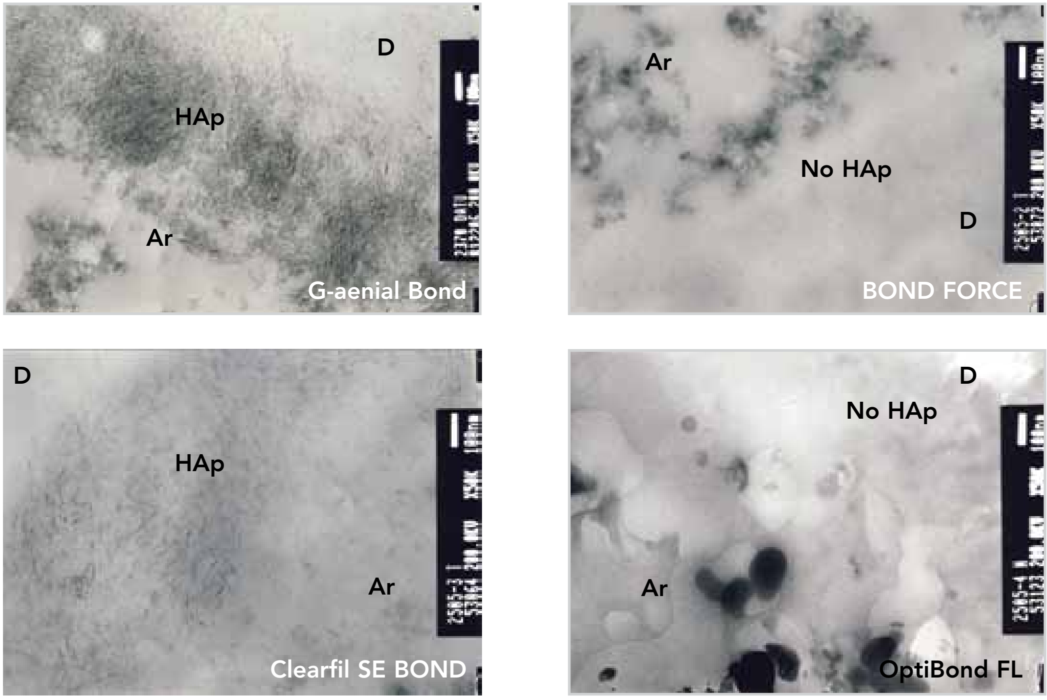


Figure 10 demonstrated the higher density of hydroxyapatite crystals within the approximately 500 nm wide NIZ of G-ænial Bond.

Figure 10: TEM photomicrographs of the dentine/adhesive interface of demineralised specimens (x 50000) HAp: hydroxyapatite; Ar: Adhesive resin; D: Dentine. Source: GC Corporation, Japan, 2009




Bond Force, Clearfil SE Bond and OptiBond FL are not registered trademarks of GC.

Next to the presence of 4-MET, the phosphoric ester monomer in G-ænial Bond improves the demineralisation capacity and chemical reactivity with hydroxyapatite. Additionally, a nano-interaction zone (NIZ) of approximately 500 nm with a high density of hydroxyapatite crystals can be observed, leading to the conclusion that **the hydroxyapatite chemically reacted with the functional monomers and remained within the NIZ**. Since the collagen fibrils in the NIZ are not exposed, they will be resistant to hydrolytic degradation, thus **long-term durability can be expected**.

## 7.2 Bonding performance on dentine

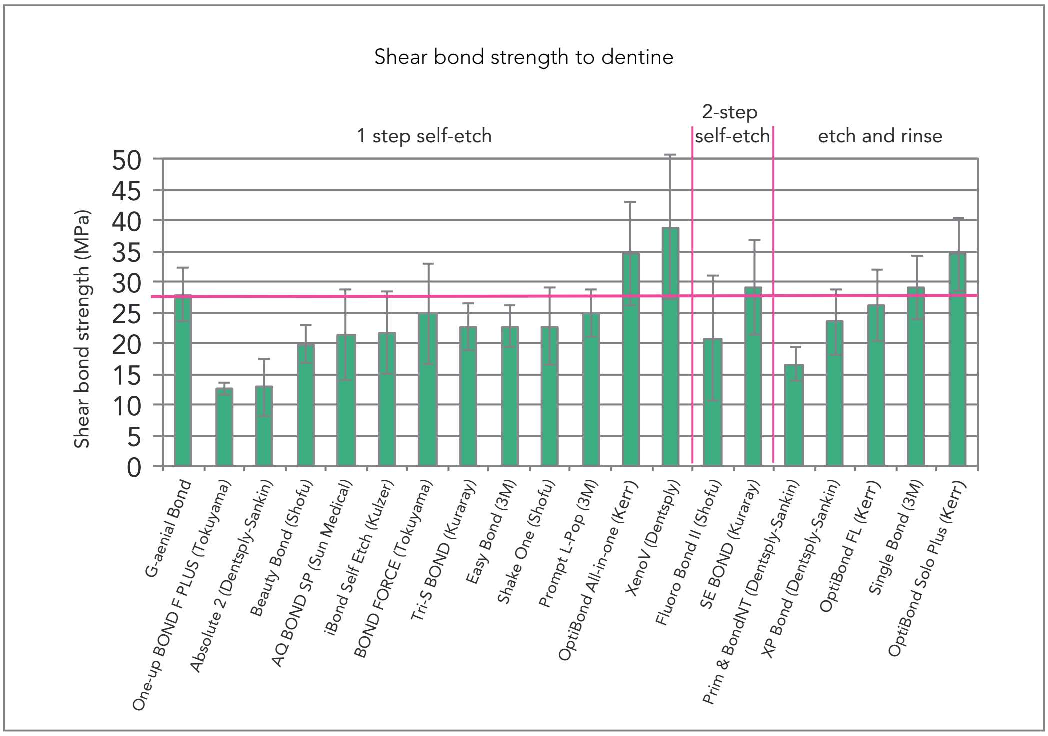
G-ænial Bond is designed for use of the self-etch approach on dentine, meaning that no phosphoric acid etching agent is used prior to application of the adhesive. The bond strength to dentine is optimal in the self-etch mode. In order to confirm the bonding performance of the adhesive layer observed on the SEM and TEM images, shear bond strength (SBS) and microtensile bond strength (μTBS) tests were conducted internally and externally. Furthermore, although etching of dentine is not recommended with G-ænial Bond, some inadvertent etching could occur while selectively etching the enamel. Therefore, the influence of etching on dentine was also analysed, both quantitatively and qualitatively.

### 7.2.1 Shear bond strength to dentine using the self-etch technique

**Tests performed by GC R&D, Japan**
The following test compared the performance of G-ænial Bond to other 1-step self-etch, 2-step self-etch and 3-step etch-and-rinse adhesives, including Clearfil SE Bond (Kuraray) and Optibond FL (Kerr) (which are often quoted in the literature as gold standards).

**Test set-up, Ultradent Method:** Bovine dentine samples were polished with 320-grit SiC paper. Each adhesive tested was used according to the respective manufacturer's instructions. Clearfil AP-X (Kuraray) was placed on the surface using an Ultradent mould (D=2.38 mm) and light-cured. The specimens (n=5) were stored in 37°C water for 24 hours. Shear bond strength (SBS) was measured at a cross-head speed of 1 mm/min. The statistical analysis was conducted using the Tukey test ($P<0.05$).

Figure 11: Comparison of shear bond strength to dentine of various adhesive systems. Source: GC Corporation, Japan, 2009



Within the limitations of this test, G-ænial Bond demonstrates a shear bond strength to dentine higher or equal to the tested group, with the exception of three bonding systems (Optibond Solo Plus, Adper Easy Bond and Optibond All-in-one) which yielded higher results. Compared to the two reference standards in their respective categories (Clearfil SE Bond and Optibond FL), G-ænial Bond performed equally well. **G-ænial Bond demonstrates excellent bonding to dentine using the self-etch technique.**

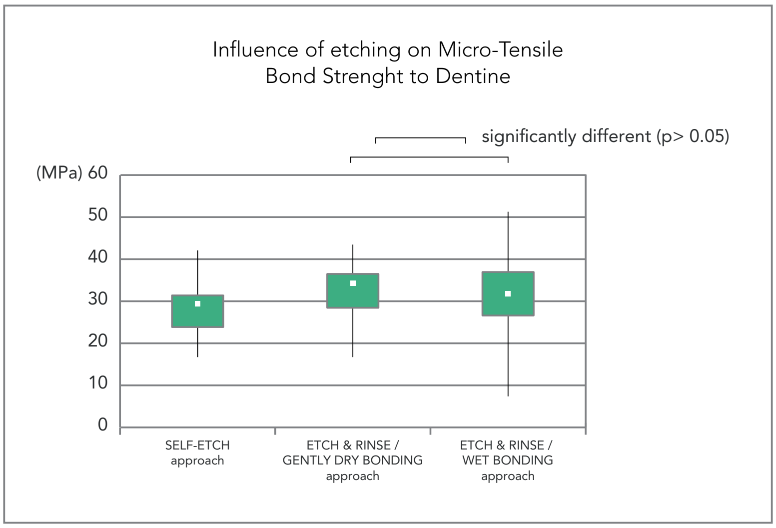
### 7.2.2 Quantitative influence of etching on bond strength to dentine

Several studies were conducted internally and externally in order to investigate the potential influence of etching on bond strength to dentine. The goals were to confirm that etching of dentine is not necessary when using G-ænial Bond, and to understand what would happen if inadvertent etching of dentine occurred during the selective etching procedure.

**Microtensile Bond Strength to Dentin**
**Tests performed by Professor van Meerbeek, Leuven, Belgium**
In order to assess the effect of etching on bond strength to dentine, microtensile bond tests were conducted by Professsor van Meerbeek, Leuven BIOMAT Research Cluster, Department of Conservative Dentistry, Katholic University of Leuven (KULeuven), Belgium

**Test set-up:** Bur-cut dentine surfaces prepared from human molars were partially split in 3 groups (n=45 specimens per group). One group was first etched with 37.5% phosphoric acid gel (Kerr) for 10 seconds, rinsed and gently dried (the etch-and-rinse gently dry bonding approach), the second group was first etched with 37.5% phosphoric acid gel (Kerr) for 10 seconds, then rinsed and the surface was left wet (etch-and-rinse wet bonding approach); in the third group, no etching agent was applied (the self-etch approach). Next, G-ænial Bond was applied strictly following the manufacturer's instructions, after which the surface was built up using Clearfil AP-X (Kuraray). After storage in water for 24 hours, micro-specimens were prepared with the interface circularly constricted using a Micro-Specimen Former, prior to microtensile bond strength (MPa) measurement.

Figure 12: Tensile bond strength of G-ænial Bond to dentine. Source: Adapted excerpt from Prof. van Meerbeek, KU Leuven, Belgium, 2010




**No statistical difference was observed between the self-etch and the etch-and-rinse treatment of dentine.** The only significant differences observed were between the wet bonding and the gently dry etch-and-rinse approaches, with higher results obtained with the gently dried specimen.

### Shear Bond Strength to Dentine

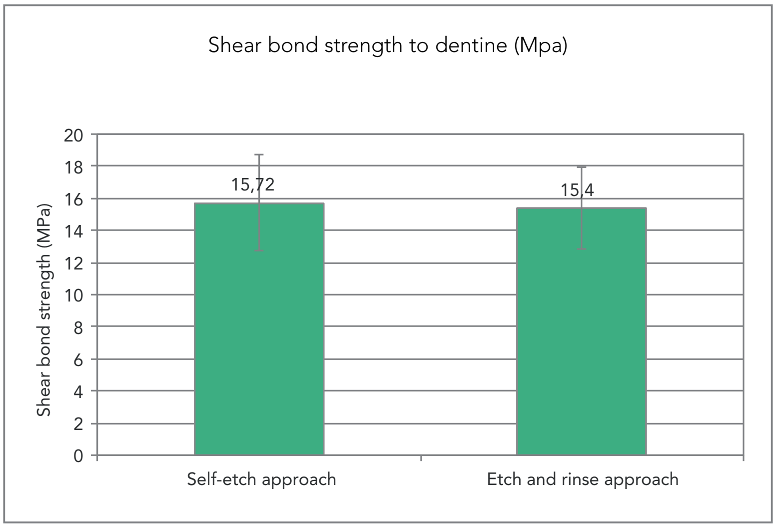
### Tests performed by M. Derbanne, S. Le Goff and M. Degrange†, Paris, France

Another in vitro study conducted by Mathieu Derbanne, Stéphane Le Goff and **Michel Degrange†**, University of Paris Descartes, France, evaluated the early bond strength to dentine of G-ænial Bond using either the self-etch or the etch-and-rinse technique.

**Test set-up:** Samples were prepared from human 3rd molars and split into 2 groups. In the self-etch group (SES, n=30), GBA 400 (commercially available under the brand name G-ænial Bond) was applied directly to the dentine surface as described in the table below. In the etch-and-rinse group (E&R, n=30), the dentine surface was first etched with a 37.5% phosphoric acid gel (Gel Etchant, Kerr) for 15 seconds prior to the application of G-ænial Bond as described in the table below. Three composites were used in 10 samples of each group: Kalore (GC), G-ænial (GC) and Z100 (3M ESPE). The composites used were placed in two layers of less than 2 mm each and light-cured for 20 seconds by layer (BluePhase 2 (Kerr Hawe), light intensity >1300 mW.cm-2). The samples were then stored at 37°C in water for 24 hours, after which the shear test was performed at a speed of 0.5 mm.min-1.

| Technique | Etching | Rinsing & drying | Air drying | Application | Waiting | Air drying | Light-curing |
|---|---|---|---|---|---|---|---|
| Self-etch | / | / | light | apply + brush 15 s | 10 s | 5 s | 5 s |
| Etch-and-rinse | 15 s | 30 s | light | apply + brush 15 s | 10 s | 5 s | 5 s |

Figure 13: Early shear bond strength to dentine using the self-etch and etch-and-rinse techniques.
The chart below represents pooled results with all three tested composites. Source: Adapted excerpt from Prof. M. Degrange†, Univeristy Paris Descartes, France, 2010



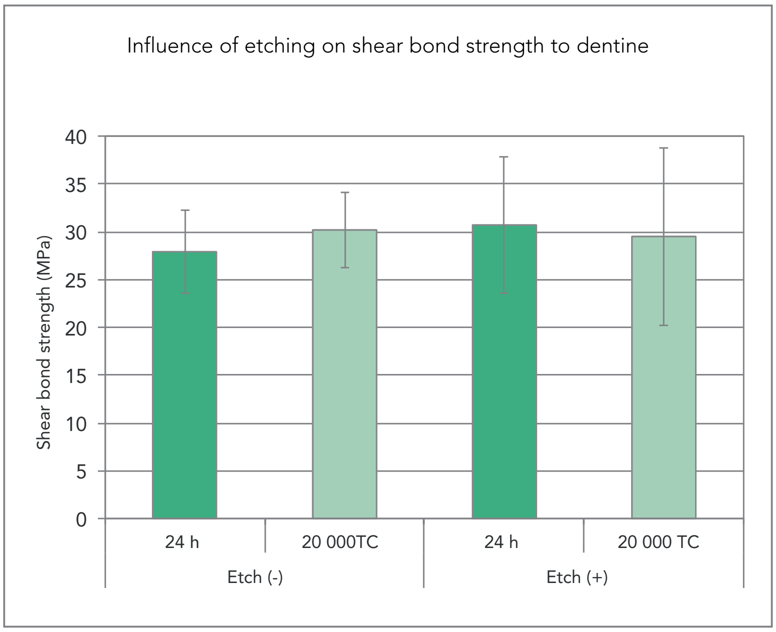

Statistical analysis (ANOVA 1) shows that **there is no significant difference** (p = 0.65) **between the two methods** (self-etching and etch-and-rinse) with respect to the adhesion to dentine (Figure 13).

**Shear Bond Strength to Dentine after Thermocycling**
**Tests performed by GC R&D, Japan**

Etched and unetched samples were stored in water and a shear bond strength (SBS) test was conducted at 24 hours after 20 000 cycles of thermocycling (Etch +group only).

**Test set-up:** Bovine dentine specimens were polished with 320-grit SiC paper. For the Etch(+) group, etching was conducted for 10 seconds with a 37% phosphoric acid etching gel (Link Master Etchant, GC). No etching agent was apply to the Etch (-) surfaces. G-ænial Bond was then applied to the surfaces of the Etch (+) and Etch (-) groups according to the manufacturer's instructions. Clearfil AP-X (Kuraray) was placed on the surface using an Ultradent mould (D=2.38mm) and light-cured. The specimens were then stored in 37°C water for 24 hours. The specimens were subjected to thermocycling (5°C-55°C, 20000 cycles) after water storage. Shear bond strength (SBS) was measured at a cross-head speed of 1 mm/min. The statistical analysis was conducted using the Tukey test ($P<0.05$).

Figure 14: Influence of etching on shear bond strength to dentine. Source: GC Corporation, Japan, 2009
Etch (-): Self-etching; Etch (+): Etch-and-rinse; TC: Thermocycling




**No significant differences in shear bond strengths were found under the four test conditions** (self-etching at 24 hours; self-etching after thermocycling; etch-and-rinse at 24 hours; or etch-and-rinse after thermocycling).

From the above sets of tests results, it can be concluded that **the bonding values of G-ænial Bond to dentine were not influenced by etching (neither positively nor negatively)**. Therefore, there is no added value in etching dentine and, additionally, inadvertent etching of dentine would not affect bond strength. However, tests performed at the KUL showed that although etching of dentine does not affect bond strength, it could result in the procedure becoming more technique sensitive. Therefore, the recommendation from GC is to not etch the dentin in order to avoid any risk of nano-leakage or post-operative sensitivity.

## 7.2.3 Qualitative influence of etching on bond strength to dentine

The following tests were performed to further assess the influence of etching on the quality of the dentine-adhesive interface and its potential for chemical adhesion.

**SEM observation of failure modes in dentine**
**Tests performed by M. Derbanne, S. Le Goff and M. Degrange†, Paris, France**
Following the shear test (test set-up page 18), samples from each batch were observed using scanning electron microscopy in order to assess the fractured surfaces; the SEM images can be seen in Figure 15 and Figure 16.

| Technique | Etching | Rinsing & drying | Air drying | Application | Wainting | Air drying | Light-curing |
|---|---|---|---|---|---|---|---|
| Self-etch | / | / | light | apply + brush 15 s | 10 s | 5 s | 5 s |
| Etch-and-rinse "dry bonding" | 15 s | 30 s | light + stronger on enamel (chalky effect) | apply + brush 15 s | 10 s | 5 s | 5 s |
| Etch-and-rinse "wet bonding" | 15 s | 30 s | light + humidification with cotton pellet | apply + brush 15 s | 10 s | 5 s | 5 s |

Figure 15: Fracture surface, G-ænial Bond, etch-and-rinse, Dentine. Source: Adapted excerpt from Prof. M. Degrange†, Univeristy Paris Descartes, France, 2010

Fig 15 a: G-ænial Bond, etch-and-rinse, dry bonding

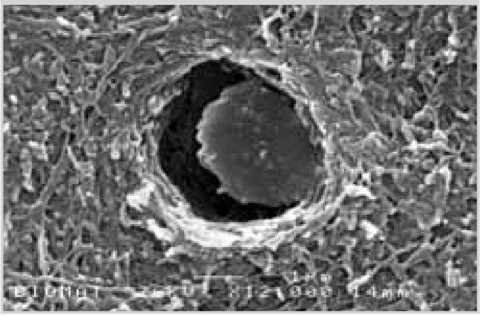
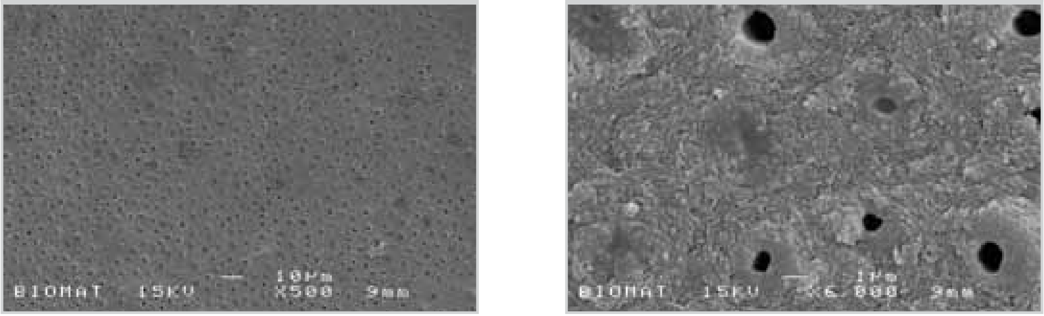


Fig 15 b: G-ænial Bond, etch-and-rinse, wet bonding

When an etching agent was used prior to application of G-ænial Bond, the fracture surface was observed to differ in samples that were wet bonded treatment (where the dentine is left humid prior to adhesive application) compared to those that were dry bonded (where dentine is dried prior to application of the adhesive). Dry bonding (Figure 15 a) appears to provide less infiltration of the adhesive into the collagen network compared to wet bonding (Figure 15 b). In both cases, however, **the visible collagen network indicates that adhesive infiltration into the collagen network remained incomplete when etching was used**. Some collagen fibers remained unprotected and at risk for degradation over time.

Figure 16: Fracture surface, G-ænial Bond, self-etch, dentine. Source: Adapted excerpt from Prof. M. Degrange†, Univeristy Paris Descartes, France, 2010

G-ænial Bond, self-etch | G-ænial Bond, self-etch




**The fractured surfaces of the self-etched sample show good impregnation into the superficial dentine.** The failures observed at the interface are located between the hybrid layer and the bonding layer.

As a result, even though the SBS of G-ænial Bond to dentin was not affected by etching, the observations of failure modes show that **a better quality of infiltration of the collagen network and the superficial dentine is obtained using the self-etch technique. Therefore, the self-etch approach without the use of etching on dentine is preferred with G-ænial Bond**.

**TEM observations on dentine**
**Test performed by GC R&D, Japan**

In order to better understand the influence of etching on the adhesion mechanism to dentine, interfaces of G-ænial Bond with dentine prepared with and without prior acid etching were examined using TEM by GC R&D.

**Test set-up:** Bovine dentine specimens were polished with 320-grit SiC paper. For the Etch(+) group etching was conducted for 10 seconds with a 37% phosphoric acid etching gel (LINK MASTER ETCHANT, GC). No etching agent was apply to the Etch(-) surfaces. G-ænial Bond was then applied to the surfaces of the Etch (+) and Etch (-) samples according to the manufacturer's instructions. Clearfil AP-X (Kuraray) was placed on the surface using an Ultradent mould (D=2.38mm) and light-cured. The TEM specimen used to assess the interface between the etched dentine and G-ænial Bond was demineralised with EDTA and embedded in epoxy resin. The specimen was then cut with a microtome in 80-90 nm thickness. Then, the surface was carbon-spattered and observed by TEM.

Figure 17: TEM images of etched dentine/adhesive interface of G-ænial Bond. (left X10K, right X50K)
Hy: Hybrid layer; Ar: Adhesive resin; Ud: Unaffected dentine; NIZ: Nano-interaction zone; Source: GC Corporation, Japan, 2009

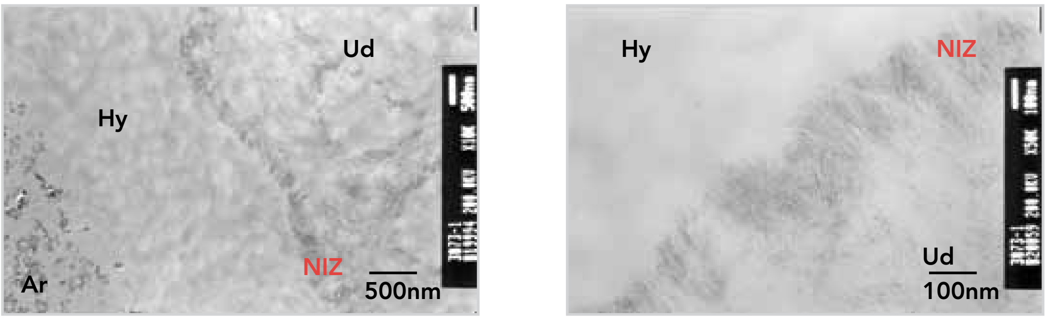
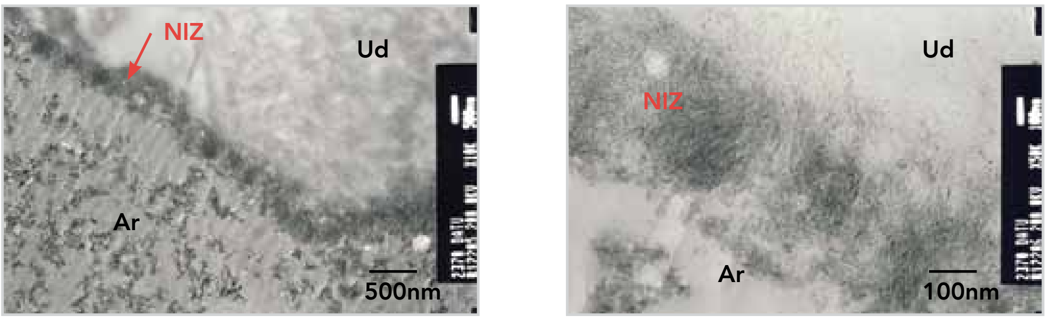



Figure 18: TEM images of dentine/adhesive interface of G-ænial Bond without etching of the dentine. (left X10K, right X50K)
Hy: Hybrid layer; Ar: Adhesive resin; Ud: Unaffected dentine; NIZ: Nano-interaction zone; Source: GC Corporation, Japan, 2009




TEM observations on the etched specimen (Figure 17) revealed the presence of a nano-interaction zone (NIZ) at the interface between the hybrid layer and the unaffected dentine, which means that adhesive monomers certainly penetrated into the base of the demineralized dentine, even when the dentine was etched. A comparison with the adhesive/ dentine interface in the self-etch technique can be made when looking at Figure 18. Inadvertent etching will still allow the formation of a nano-interaction zone at the base of the hybrid layer, however the amount of residual hydroxyapatite will decrease. Residual hydroxyapatitie crystals are important to ensure the quality of the chemical adhesion and the durability of the bond. **Therefore, the quality and longevity of the chemical adhesion will be improved when no etching is used prior to the application of G-ænial Bond on dentine.**

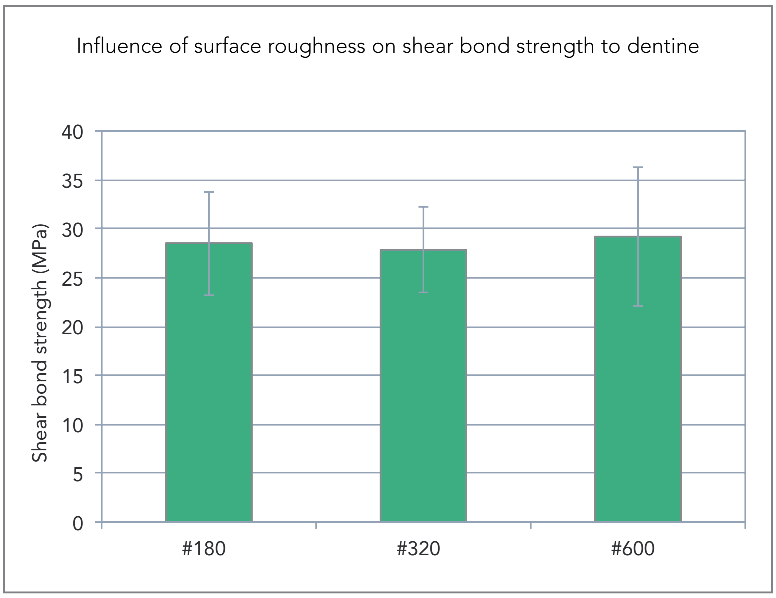
## 7.2.4 Influence of surface roughness on bond strength to dentine

**Shear bond strength to dentine**
**Tests performed by GC R&D, Japan**

The following test was performed in order to assess the potential influence of surface roughness in bur cut dentine on shear bond strength.

**Test set-up:** Bovine teeth were embedded in acrylic resin (Unifast III) and the exposed enamel and dentine surfaces were polished with #180, 320 and 600 grit SiC paper respectively. G-ænial Bond was applied on the surface of the samples. After 10 seconds, the samples were dried thoroughly and light-cured for 5 seconds using a GC G-Light. Clearfil AP-X (Kuraray) was placed on the surface using Ultradent mold (D=2.38mm) and light-cured for 20 seconds. The bonding specimens (n=5) were stored in water at 37°C for 24 hours. Shear bond strength (SBS) was measured at a cross-head speed of 1 mm/min. The statistical analysis was conducted using the Tukey test ($P<0.05$).

Figure 19: Influence of surface roughness on shear bond strength to dentine. Source: GC Corporation, Japan, 2009




The shear bond strength of G-ænial Bond to dentine was not affected by surface roughness. **G-ænial Bond is able to offer consistent results independent of the bur type used for dentine preparation.**

## 7.3 Bonding performance on enamel

G-ænial Bond has been designed for use in the selective and self-etch techniques. To confirm the bonding performance of G-ænial Bond on enamel, the following tests were performed.

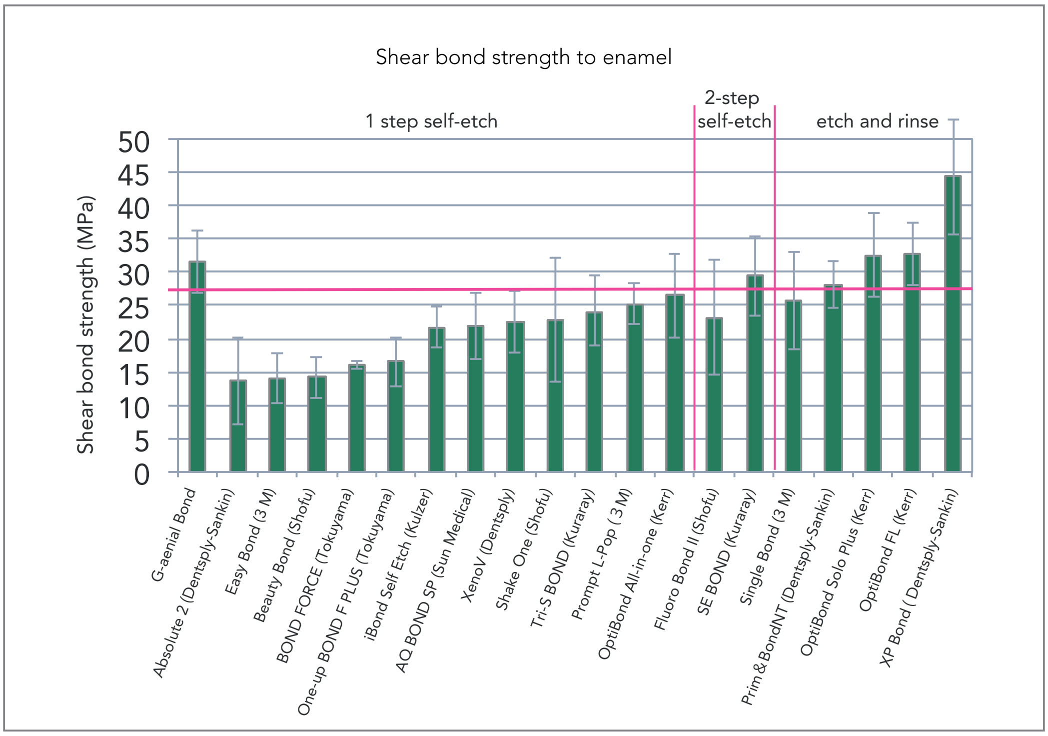
### 7.3.1 Shear bond strength to enamel using the self-etch technique

**Tests performed by GC R&D, Japan**

The following test compared the performance of G-ænial Bond to other 1-step self-etch, 2-step self-etch and 3-step etch-and-rinse adhesives, including Clearfil SE Bond (Kuraray) and Optibond FL (Kerr). These last 2 products are often quoted as gold standards in the literature.

**Test set-up, Ultradent Method:** Bovine enamel samples were polished with 320-grit SiC paper. Each adhesive tested was used according to the respective manufacturer's instructions. Clearfil AP-X (Kuraray) was placed on the surface using an Ultradent mould (D=2.38 mm) and light-cured. The specimens (n=5) were stored in 37°C water for 24 hours. Shear bond strength (SBS) was measured at a cross-head speed of 1 mm/min. The statistical analysis was conducted using the Tukey test ($P<0.05$).

Figure 20: Comparison of shear bond strength to enamel of various adhesive systems. Source: GC Corporation, Japan, 2009




Within the limitations of this test, G-ænial Bond demonstrates higher shear bond strength to enamel than all of the 1-step self-etch adhesives tested. G-ænial Bond demonstrated better or equal performance compared to the 2-step self-etch and etch-and-rinse adhesives, with the exception of XP Bond which had significantly higher results.

**G-ænial Bond demonstrated very good bonding performance to enamel using the self-etch technique.**

## 7.3.2 Influence of etching on bond strength to enamel

While G-ænial Bond demonstrates good bonding values to enamel, etching of the enamel is preferred if the surface to which the adhesive will be applied consists mainly of enamel rather than dentin, and particularly if the surface consists of intact (uncut) enamel.

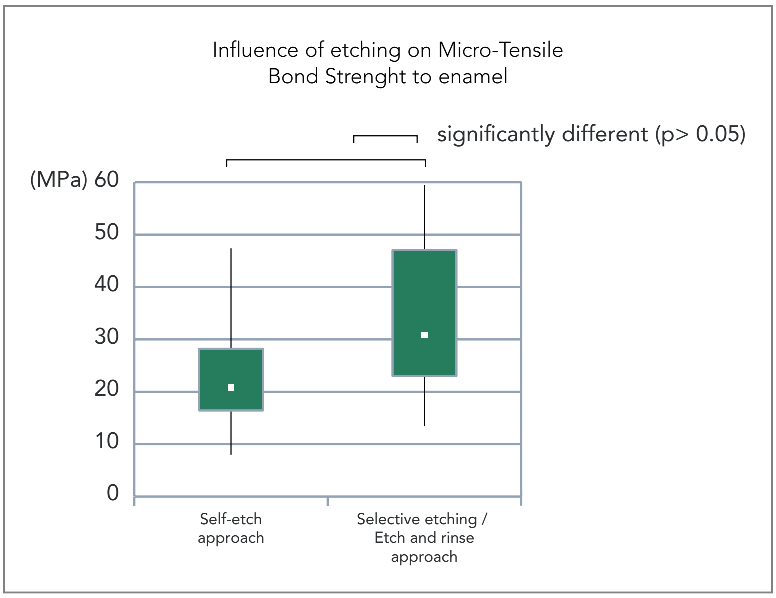
**Micro-Tensile Bond Strength to Enamel**

**Tests performed by Professor van Meerbeek, Leuven, Belgium**

In order to assess the effect of phosphoric acid etching (AET) on enamel, the following microtensile bond strength tests were conducted by Professor van Meerbeek, Leuven BIOMAT Research Cluster, Department of Conservative Dentistry, Katholic University of Leuven (KULeuven), Belgium

**Test set-up:** Bur-cut enamel surfaces prepared from human molars were partially split into 2 groups (n=30 specimens per group). One group was first etched with 37.5% phosphoric acid gel (Kerr) for 10 seconds (selective etch/ etch-and-rinse approach), while no etching agent was applied to the second group (self-etch approach). Next, G-ænial Bond was applied following the manufacturer's instructions, after which the surface of the samples was built up using Clearfil AP-X (Kuraray). After storing in water for 24 hours, micro-specimens were prepared with the interface circularly constricted using a Micro-Specimen Former, prior to microtensile bond strength (MPa) measurement.

Figure 21: Micro-tensile bond strength of G-ænial Bond to enamel. Source: Adapted excerpt from Prof. van Meerbeek, KU Leuven, Belgium, 2010




A statistically significant difference was found between the bond strength of etched and un-etched enamel prior to the application of G-ænial Bond, with higher results obtained with the etched samples.

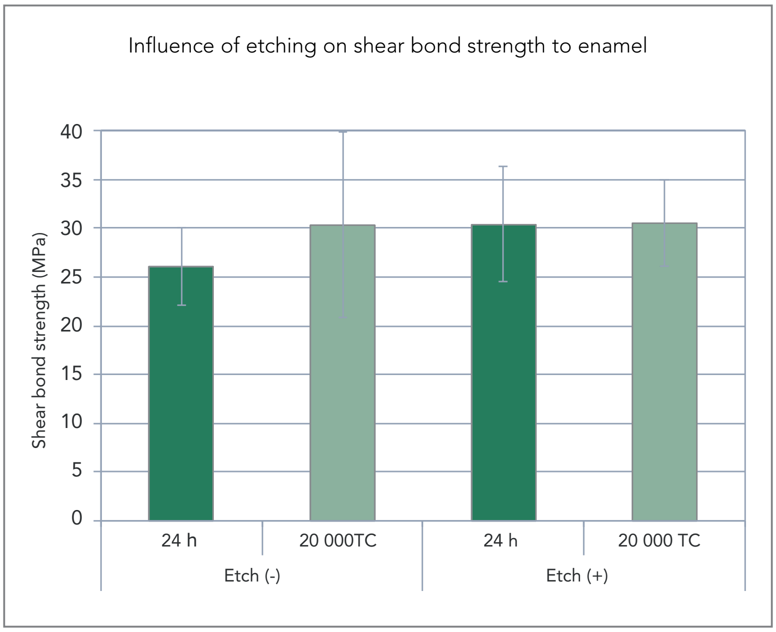
**G-ænial Bond is offering high bond strength to enamel in self etch mode. These results are enhanced when the selective etching technique is used.**

**Shear bond strength to enamel**
**Tests performed by GC R&D, Japan**

The purpose of the following study was to assess the adhesion properties of G-ænial Bond with and without phosphoric acid etching (AET). The resulting shear bond strength (SBS) tests were conducted at 24 hours and after 2000 cycles of thermocycling.

**Test set-up:** Bovine enamel specimens were polished with 320-grit SiC paper. For the Etch(+) group, etching was conducted for 10 seconds with a 37% phosphoric acid etching gel (Link Master Etchant, GC). No etching agent was apply to the Etch (-) surfaces. G-ænial Bond was then applied to the surfaces of the Etch (+) and Etch (-) groups according to the manufacturer's instructions. Clearfil AP-X (Kuraray) was placed on the surface using an Ultradent mould (D=2.38mm) and light-cured. The specimens were stored in 37°C water for 24 hours. The thermocycling specimens were subjected to thermocycling (5°C-55°C and 20,000 cycles) after water storage. Shear bond strength (SBS) was measured at a cross-head speed of 1 mm/min. The statistical analysis was conducted using the Tukey test ($P<0.05$).

Figure 22: Influence of etching on shear bond strength to enamel. Source: GC Corporation, Japan, 2009




Shear bond strengths (SBSs) to enamel increased with phosphoric acid etching.

**Phosphoric acid etching (AET) improved the bond strength of G-ænial Bond to enamel.** However, after thermocycling, there were no significant differences in the bonding values.

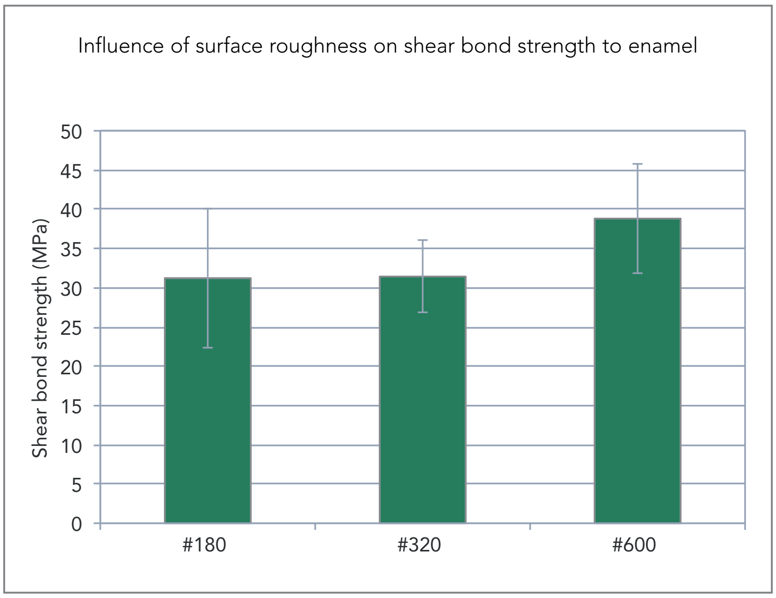
### 7.3.3 Influence of surface roughness on bond strength to enamel

**Shear bond strength to enamel**
**Tests performed by GC R&D, Japan**

The test described below was conducted to assess the influence of bur cut-induced surface roughness on shear bond strength.

**Test set-up:** Bovine teeth were embedded in acrylic resin (Unifast III) and the exposed enamel and dentine surfaces were polished with #180, 320 and 600 grit SiC paper respectively. G-ænial Bond was then applied on the surface. After 10 seconds, the samples were dried thoroughly and light-cured for 5 seconds using a GC G-Light. Clearfil AP-X (Kuraray) was then placed on the surface using an Ultradent mould (D=2.38mm) and light-cured for 20 sec. The bonding specimens (n=5) were stored in water at 37°C for 24 hours. Shear bond strength (SBS) was measured at a cross-head speed of 1 mm/min. The statistical analysis was conducted using the Tukey test (P<0.05).

Figure 23: Influence of surface roughness on shear bond strength to enamel. Source: GC Corporation, Japan, 2009




The shear bond strength of G-ænial Bond to enamel was not affected by surface roughness. Since G-ænial Bond is indicated for use on etched enamel and enamel that has only been bur cut, **this novel adhesive is able to offer consistent results independent of the bur type used for enamel preparation.**

## 7.4 Quantitative marginal analysis

In order to assess the quality of restorations bonded with G-ænial Bond, using the self-etch and selective etching (etch-and-rinse of enamel) techniques, quantitative marginal analyses were conducted by Dr Uwe Blunck - Charité Universitätsmedizin Berlin, for both Class V and Class I restorations. (2008 & 2010)

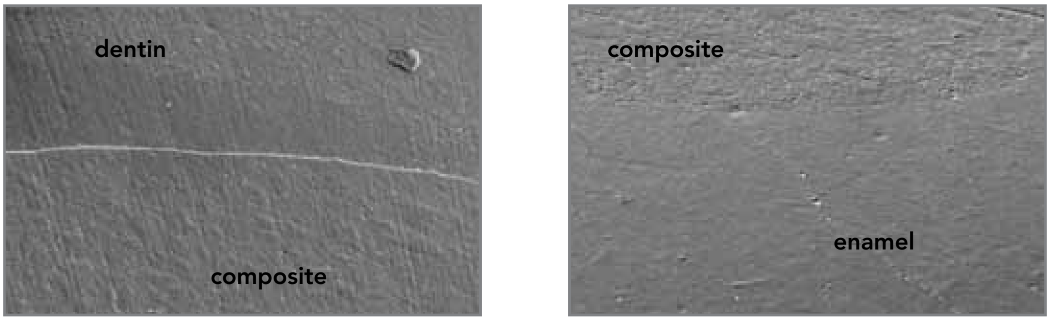
**Test set-up:**

- Standardised Class V or I preparations were made in extracted human teeth stored in 0.5 % chloramine-T solution (8 per group).
- When relevant (etch-and-rinse technique), an etching agent was applied and rinsed off prior to use of the bonding systems. The tested adhesive systems were applied according to the manufacturer's instructions for use, and the preparations were restored with the chosen composite(s) using an incremental technique.
- After finishing and polishing, the samples were stored in water for 21 days.
- Replicas were taken before and after thermocycling for the Class I and Class V restorations (2000 cycles between 5 and 55 °C), as well as after mechanical occlusal loading for the Class I restorations (150.000 cycles at 49 N).
- The margins of the restorations at the enamel- and/ or dentine-composite interface(s) were examined and quantified with a scanning electron microscope (SEM) at a magnification of x200, using defined criteria (Table 6) to assess the quality of the margins.

Table 6: Criteria for the marginal assessment in the SEM at x200 magnification

| Margin-quality | Definition |
|---|---|
| 1 | Margin not visible or barely visible. No, or slight, marginal irregularities. No gap |
| 2 | No gap but severe marginal irregularities |
| 3 | Gap visible (hairline crack up to 2 µm). No marginal irregularities |
| 4 | Severe gap (more than 2 µm). Slight and severe marginal irregularities |
| | The term "marginal irregularities" means:<br>- porosities<br>- marginal restoration fracture<br>- bulge in the restoration |

Figure 24: SEM of marginal adaptation in dentine (left) and enamel (right), margin quality 1 (original magnification: x200) after TC (white bar = 100 µm). Source: Adapted excerpt from Dr U. Blunck, Charité Universitätsmedizin Berlin, Germany, 2008




### 7.4.1 Marginal analysis of Class V restorations after thermocycling

**Tests performed by Dr Uwe Blunck, Charité Universitätsmedizin Berlin**

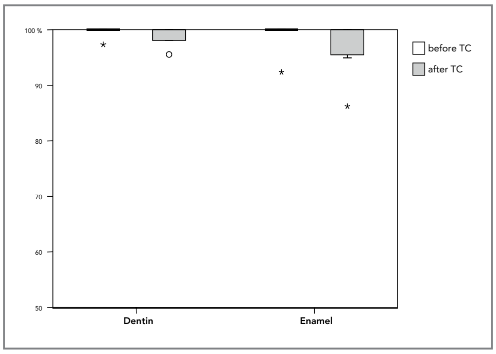
The purpose of the following studies was to evaluate the effectiveness of GBA 400 (commercially available as G-ænial Bond) adhesive in Class V composite resin restorations that had margins in dentine and in enamel. The marginal behaviour of the restorations, which were filled using an incremental technique, was evaluated before thermocycling and then after thermocycling in order to simulate clinical conditions.

## Self-etch technique: Class V

**The study followed the test set-up as defined page 28:**

- Standardised Class V preparations were made in extracted incisors (8 per group).
- The adhesive system GBA 400 (commercially available as G-ænial Bond) was applied in combination with GC Gradia Direct Posterior according to the manufacturer's instructions.

Figure 25: Amount of "continuous margin" (MQ1) in % of the entire margin length in enamel and dentine in Class V restorations, before and after thermocycling (TC) for G-ænial Bond using the self-etch technique in combination with Gradia Direct. Source: Adapted excerpt from Dr U. Blunck, Charité Universitätsmedizin Berlin, Germany, 2008



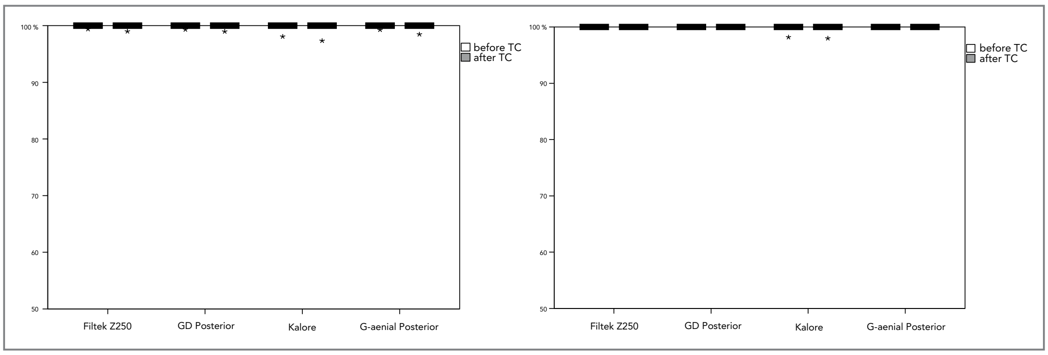

SEM evaluation of the samples after thermocycling demonstrated excellent marginal adaptation of G-ænial Bond to both enamel and dentine using the self-etch technique (Figure 25), with median values of 100 % "continuous margin" and mean values of about 97% to 99%.

## Etch-and-rinse technique: Class V

**The study followed the test set-up as defined page 28:**

- Standardised Class V preparations were made in extracted incisors (8 per group).
- The Class V preparations were treated with G-ænial Bond after phosphoric acid etching the entire preparation for 10 s, then restored with either GC Gradia Direct Posterior, GC G-ænial Posterior, GC Kalore or Filtek Z250 (3M ESPE) using an incremental technique.

Figure 26: Amount of "continuous margin" (MQ1) in % of the entire margin length in enamel (left) and dentine (right) in Class V restorations, before and after thermocycling (TC) for G-ænial Bond along with the etch-rinse-technique, restored with one of four composite resins. Source: Adapted excerpt from Dr U. Blunck, Charité Universitätsmedizin Berlin, Germany, 2010




SEM evaluation of the marginal adaptation after thermocycling demonstrated a "continuous margin" in both dentine and enamel, with median and mean values of about 99% to 100 % margin quality. This result was achieved for all restorations applied with G-ænial Bond after phosphoric acid etching, irrespective of the composite used for the restoration.

**Conclusion of the Class V study**

Within the limitations of this study, the adaptation of G-ænial Bond in class V preparations has proven to be very effective using either the self-etch or the etch-and-rinse technique, independent of the composite used. **It is therefore expected that the long-term marginal adaptation of G-ænial Bond restorations will also be very effective under similar clinical conditions.**

### 7.4.2 Marginal analysis in Class I restorations after thermocycling and mechanical loading

**Tests performed by Dr Uwe Blunck- Charité Universitätsmedizin Berlin**

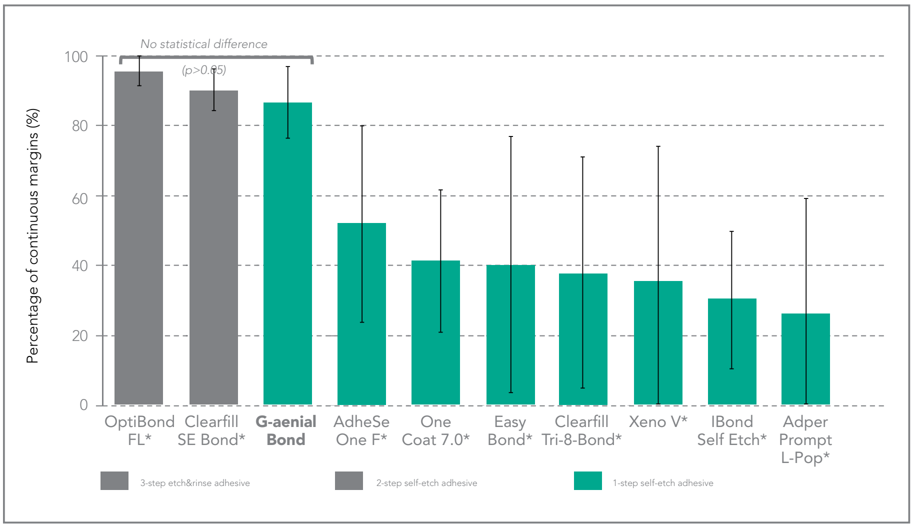
The purpose of this study was to examine the marginal integrity of composite resin restorations in Class I preparations with margins in enamel treated using either a self-etch or an etch-and-rinse technique. Testing was conducted before and after thermocycling procedures and after mechanical loading.

**Self-etch technique, class I**

**The study followed the test set-up as defined page 28:**

- Eight Class I preparations per group were prepared and filled in extracted human molars
- Various adhesives were applied and the preparations were filled with Filtek Z250 (3M ESPE) using an incremental technique.

Figure 27: Amount of "continuous margin" in % of the entire margin length in enamel of class I restorations after thermocycling and mechanical loading for GBA 400 (G-ænial Bond) in comparison to contemporary adhesive systems (all in combination with Filtek Z250). G-ænial Bond (GBA 400) was applied using the self-etch technique. Source: Adapted excerpt from Dr U. Blunck, Charité Universitätsmedizin Berlin, Germany, 2011




* Not a registered trademark of GC.

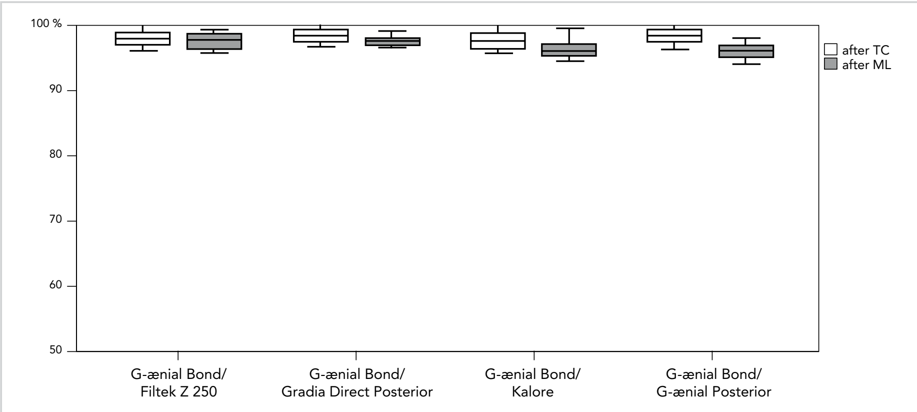
For the self-etching technique (Figure 27), comparison with the results of contemporary adhesive systems, including the standard references for in-vitro tests (etch-and-rinse system OptiBond FL and two-step self-etching adhesive Clearfil SE Bond), demonstrated the effectiveness of the GBA 400 adhesive (commercially available as G-ænial Bond). There were no statistically significant differences in the results for G-ænial Bond compared to the etch-and-rinse adhesive system or the two-step self-etching adhesive.

### Etch-and-rinse technique, Class I

**The study followed the test set-up as defined on page 28**

- Eight Class I preparations per group were prepared and filled in extracted human molars
- After phosphoric-acid etching of the enamel and dentine portions of the preparations for 10 seconds with 37% phosphoric acid (Omni-Etch, Omnident), the preparations were filled with G-ænial Bond in combination with either GC Gradia Direct Posterior, GC G-ænial Posterior, GC Kalore or Filtek Z250 (3M ESPE) using an incremental technique.

Figure 28: Amount of "continuous margin" (MQ1) in % of the entire margin length in enamel of class I restorations (TM 1 = after thermocycling (TC), TM 2 = after mechanical loading (ML)) for the tested self-etch adhesive G-ænial Bond using the etch-and-rinse technique in combination with one of four composite resins. Source: Adapted excerpt from Dr U. Blunck, Charité Universitätsmedizin Berlin, Germany, 2010




When used with the etch-and-rinse technique, the marginal adaptation of class I restorations after thermocycling (TC) and mechanical loading (ML) showed very high amounts of “continuous margin” in enamel, demonstrating a high quality margin and independent of the composite used (median and mean values 96% to 98%).

### Conclusion of the class I study

Within the limitations of this study, the adaptation of **G-ænial Bond to enamel in class I preparations has proven to be very effective** using either the self-etch or the etch-and-rinse technique, independent of the composite used.

### Conclusion from the above studies

**The self-etch and selective etching techniques both demonstrated effective marginal adaptation of G-ænial Bond to enamel in class I and to enamel and dentine in class V preparations. Long-term clinical marginal adaptation and durability of the bond can be expected to be excellent, based on the results of the thermocycling and mechanical loading tests conducted in these studies.**

## 8.0 Summary of Technical Data

Etching has proven to provide higher bond strength to enamel but has no added value for dentine, as shown by test results. Thus, etching of dentine is not recommended. However, the selective etching approach is very safe with G-ænial Bond. Test results have shown that there is no decrease in bond strength to etched dentine; therefore, there is no adverse effect if the etchant inadvertently reaches the dentine while etching the enamel.

Using the selective etching approach, G-ænial Bond safely offers the best of both worlds: the simplicity and reduced post-operative sensitivity of a self-etch adhesive together with the greater bond strength to enamel that was traditionally found only with etch-and-rinse adhesives.

**Self-etch technique**

- Microtensile bond strength to enamel : 23.1 MPa
- Microtensile bond strength to dentine: 30.5 MPa

**Selective etch technique**

Ten seconds etching of enamel with 37% orthophosphoric acid prior to G-ænial Bond application

- Microtensile bond strength to enamel: 34.5 MPa

Direct application to dentine

- Microtensile bond strength to dentine: 30.5 MPa

pH: 1.5

# 9.0 Clinical Study

## 9.1 Class V Clinical Study

**Study conducted by Professor M. Ferrari, University Siena, Italy**

Purpose: Post-operative sensitivity is a common complication when Class V restorations are placed on vital teeth. The aim of the first part of this prospective clinical trial was to evaluate the early post-operative sensitivity of Class V restorations placed using GBA 400, available commercially under the brand name G-ænial Bond, in combination with Gradia Direct LoFlo. The aim of the second part of this clinical study was to evaluate clinical parameters of Class V restorations at 1, 1.5, 2, 3, 4 and 5 years. Results are currently available at 18 months post-placement.

Materials and methods: Forty patients were selected who required at least one and no more than two restorations. A total of 50 restorations were made. The restorations were placed between September 2008 and December 2008. Adhesive procedures were performed following the manufacturer's instructions. Before applying the bonding material, pain was measured utilizing a simple response-based pain scale. Pain responses to a one-second application of air from a dental unit syringe, directed perpendicular to the root surface at a distance of 2 cm, as well as to tactile stimuli with a sharp #5 explorer, were determined. The restorations were placed by the same operator, while the clinical evaluations at recall visits were performed by a second operator (double blind approach). The restorations were evaluated immediately following placement, after 1 day, 1 week and 1 month for post-operative sensitivity, marginal discolouration, marginal integrity, secondary caries and fractures. The other clinical parameters evaluated were vitality and retention. Clinical parameters were also evaluated for the second part of the study at 1 year and 18 months.

Results: Seven of fifty preparations showed moderate sensitivity at baseline before placing restorations and 2 remained sensitive immediately after placing the restorations. Post-operative sensitivity diminished and had completely disappeared by the 7-day recall. After 18 months, all fifty restorations scored alpha for the tested parameters.

Conclusion: **The combination of G-ænial Bond and Gradia Direct LoFlo resulted in no post-operative sensitivity at 18 months post-placement and the marginal integrity was excellent for all restorations.**

Table 7: Performance criteria according to Ryge. For post-operative sensitivity, mean value and standard deviation is provided (1 = lowest sensitivity, 10 = highest sensitivity). Source: Adapted excerpt from Prof. M. Ferrari, University of Siena, Italy, 2010

| Criteria and number of restorations evaluated at **18 months recall** | | G-ænial Bond [n=50] | | | |
|---|---|---|---|---|---|
| | | alpha | bravo | charlie | delta |
| Marginal discoloration and integrity | 50 | 50 | 0 | 0 | 0 |
| Secondary caries | 50 | 50 | 0 | 0 | 0 |
| Vitality test | 50 | 50 | 0 | 0 | 0 |
| Retention | 50 | 50 | 0 | 0 | 0 |
| Fracture | 50 | 50 | 0 | 0 | 0 |
| | | No | Yes | Mean | SD |
| Post-operative sensitivity | 50 | 50 | 0 | 0 | 0 |

## 9.2 Class II Clinical Study

**Study conducted by Professor M. Ferrari, University Siena, Italy**

Purpose: The aim of this clinical study was to evaluate the post-operative sensitivity and clinical performance of Class II restorations placed using GBA 400, commercially available under the brand name G-ænial Bond, in combination GDLS-200 resin composite, commercially available under the brand name Kalore.

Materials and methods: Patients were selected who required at least one and no more than two restorations. A total of 40 restorations were placed using the material combination GBA 400 and GDLS 200. The restorations were placed between September 2008 and December 2008. Adhesive procedures were performed following the manufacturer's instructions. Before applying the bonding material, pain due to sensitivity was measured utilizing a simple response-based pain scale. Pain responses to a one-second application of air from a dental unit syringe (at 40-65 psi and approximately 20°C), directed perpendicular to the root surface at a distance of 2 cm, as well as to tactile stimuli with a sharp #5 explorer were determined. The restorations were placed by the same operator, while the clinical evaluations at recall visits were performed by a second operator (double blind approach). The restorations were evaluated immediately following placement and at day 1 and day 7, then after 1 and 12 months, for post-operative sensitivity, marginal discolouration, marginal integrity, secondary caries, maintenance of interproximal contacts and fractures. The other clinical parameters evaluated were vitality and retention.

Results: Seven of forty preparations showed moderate sensitivity at baseline before restorations were placed, and 1 remained sensitive immediately after placing the restoration. Post-operative sensitivity progressively reduced over time and had completely disappeared by the one-year recall. After 12 months, all forty restorations scored alpha for the tested parameters.

Conclusion: **The combination of GBA (commercial name G-ænial Bond) and GDLS 200 (commercial name Kalore) resulted in no post-operative sensitivity and demonstrated perfect marginal integrity 1-year post-placement.**

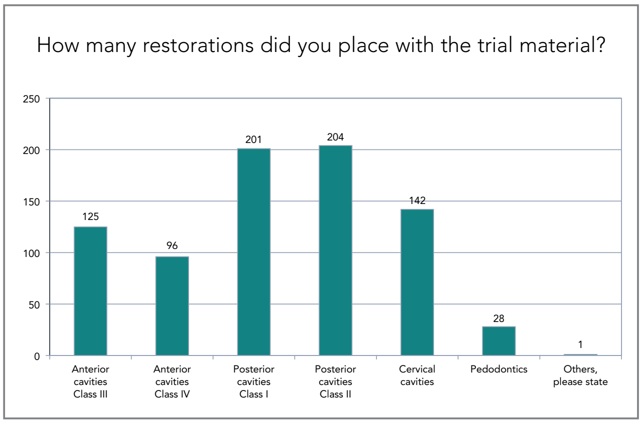
Table 8: Performance criteria according to Ryge. For post-operative sensitivity, mean value and standard deviation is provided (1 = lowest sensitivity, 10 = highest sensitivity). Source: Adapted excerpt from Prof. M. Ferrari, University of Siena, Italy, 2010

| Criteria and number of restorations evaluated at **1-year recall** | | GBA 400 [n=40] | | | |
|---|---|---|---|---|---|
| | | alpha | bravo | charlie | delta |
| Marginal discoloration and integrity | 40 | 40 | 0 | 0 | 0 |
| Secondary caries | 40 | 40 | 0 | 0 | 0 |
| Vitality test | 40 | 40 | 0 | 0 | 0 |
| Interproximal contacts | 40 | 40 | 0 | 0 | 0 |
| Retention | 40 | 40 | 0 | 0 | 0 |
| Fracture | 40 | 40 | 0 | 0 | 0 |
| | | No | Yes | Mean | SD |
| Post-operative sensitivity | 40 | 40 | 0 | 0 | 0 |

# 10.0 Field evaluation

Thirty dentists from all over Europe tested G-ænial Bond in 2010, placing in total almost 800 restorations. Most of the dentists were using different bonding systems in their surgeries.

Figure 29: Number of restorations in each indication type

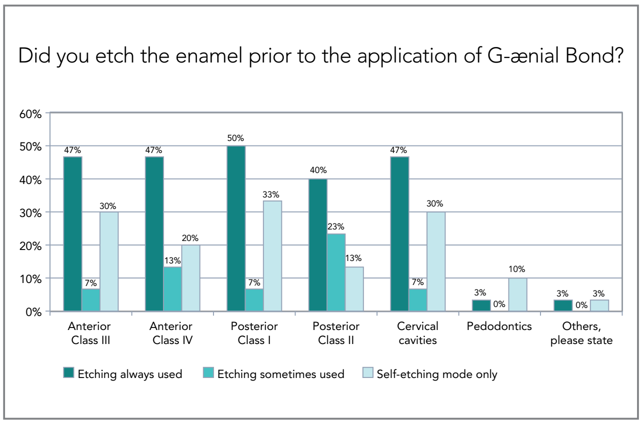



G-ænial Bond was used to restore all types of preparations. In total, almost 800 restorations were placed.

## 10.1 Technique used by testers

One of the major objectives in the development of G-ænial Bond was to make the bonding suitable both for the self-etch and the selective etching technique.

Figure 30: Choice of selective or self-etch technique

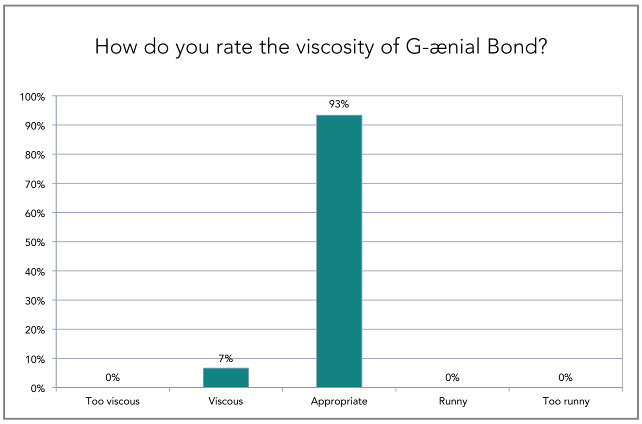



40% to 50% of users always applied phosphoric acid on enamel prior to bonding, while 20% to 30% used the self-etching mode only.

## 10.2 Handling Results

G-ænial Bond has been designed to require only a very limited number of application steps, thereby offering ease and simplicity of use and avoiding the risk of errors during application. The bottle dispenser, viscosity, and the surface appearance were all designed to fulfil these objectives.

Figure 31: Evaluation of the viscosity of G-ænial Bond




93% of users found the viscosity of the product appropriate. The viscosity of G-ænial Bond helps to ensure an even distribution of the adhesive on the tooth surface.

The results in Table 9 show that the product was easy to dispense (90% good or excellent), the surface could easily be wetted (93% good or excellent) and the bonding layer was easily visible upon application (83% good or excellent). Users also appreciated the application time (80% good or excellent). Thanks to the frosty surface (see Figure 32), placement of the first composite layer was found to be very easy (97% good or excellent); the material did not slide and adhered well to the bonded surface.

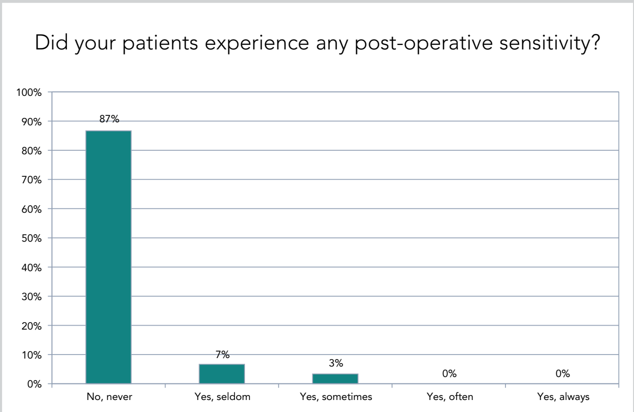
Table 9. Evaluation of the handling of G-ænial Bond

| | Good or excellent | Fair | Poor or very poor |
|---|---|---|---|
| Ease of dispensing from the bottle | 90% | 7% | 3% |
| Wetting of the surface | 93% | 7% | 0% |
| Easily visible on the surface | 83% | 10% | 7% |
| Application time | 80% | 20% | 0% |
| Placement of the first composite layer | 97% | 3% | 0% |

Figure 32: Appearance of frosty surface after application and drying of the G-ænial Bond layer. Courtesy: Dr J. Tapia Guadix, Dentist, Spain, 2010

## 10.3 Post-operative sensitivity

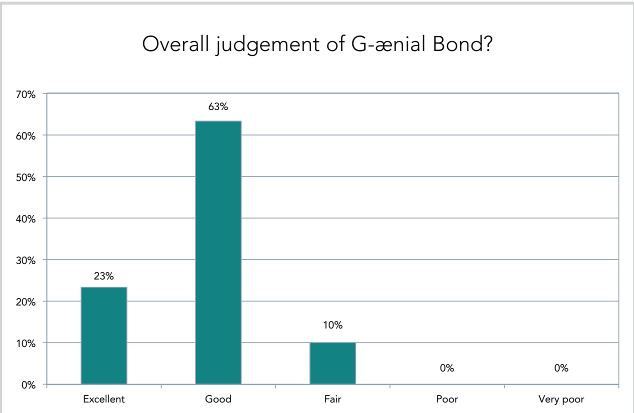
Figure 33: Incidence of post-operative sensitivity




One of the major reasons for using a self-etching adhesive is to ensure a low incidence of post-operative sensitivity. Even though etching of the enamel was often performed - which could have led to some inadvertent etching of dentine - very few cases of post-operative sensitivity were reported.

## 10.4 Overall evaluation

Figure 34: Overall evaluation of G-ænial Bond by the testers




G-ænial Bond was very well accepted by users, with 86% judging the product good or excellent.

# 11.0 Technique Guide

The application of G-ænial Bond requires only a very limited number of steps:

**In self-etch mode**


Application


Waiting 10 sec.


Drying 5 sec. with max air


Light-curing

**In selective etch mode**


Phosphoric acid application for 10s on enamel only


Rinsing


Drying


Application of bonding agent to the entire area


Waiting 10 sec


Drying 5 sec. with max air


Light-curing

# 12.0 Instructions For Use

**G-ænial Bond**
ONE COMPONENT SELF-ETCHING LIGHT-CURED ADHESIVE

For use only by a dental professional in the recommended indications.

**Recommended Indications**
1. Bonding of light-cured composites and acid-modified composites (compomers) to tooth structure.
2. Bonding of dual-cured luting and core build-up composites to tooth structure, provided these materials are light-cured.

**Contraindications**
1. Pulp capping.
2. In rare cases, this product may cause sensitivity. If any such reactions are experienced, discontinue use of the product and refer the patient to a physician.

**Not to be used**
1. In combination with chemically cured composite resin.
2. In combination with eugenol-containing materials as eugenol may hinder G-ænial Bond from setting or bonding properly.
3. In combination with desensitisers as these may hinder G-ænial Bond from setting or bonding properly.
4. In combination with dual cured luting and core build up composites in case these materials will not be light cured.

**Directions for Use**

1. CAVITY PREPARATION
   Prepare tooth using standard techniques. Make sure that any temporary material is thoroughly removed from the surface. Use rubber dam for protection. Dry the prepared tooth surfaces by gently blowing with an air syringe.
   Note: For pulp capping, use calcium hydroxide.

Fig. 1

2. TECHNIQUE OPTIONS
   Select from the following 2 technique options
   a) Self-etch technique – apply G-ænial Bond to bur cut enamel and dentine, without a separate etching step.
   b) Selective etching of enamel – prior to applying G-ænial Bond to enamel and dentine, etch (bur cut) enamel with 35-40% phosphoric acid gel for 10 seconds, rinse for 5 seconds and gently dry.
   Note: Non-bur cut enamel should always be treated with a 35-40% phosphoric acid gel for 10 seconds, rinsed with water for 5 seconds and gently dried.

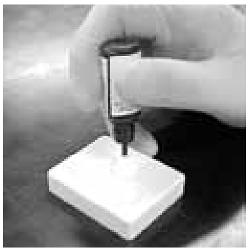


Fig. 2

3. APPLICATION
   a) Prior to dispensing, shake the bottle of G-ænial Bond thoroughly (Fig. 1). Dispense a few drops into a clean dispensing dish (Fig. 2). Replace bottle cap immediately after use (Fig. 3).

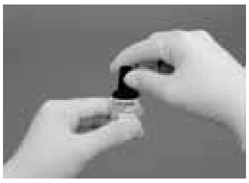


Fig. 3

b) IMMEDIATELY apply to the prepared enamel and dentine surfaces using the disposable applicator (Fig. 4).
c) Leave undisturbed for 10 seconds after applying (Fig.5).
d) Then, dry thoroughly for 5 seconds with oil-free air under MAXIMUM air pressure. Use vacuum suction to prevent splatter of the adhesive (Fig. 6). The final result should be a thin adhesive film with the appearance of frosted glass and that does not visibly move under further air pressure.

Note:

1) When removing from the refrigerator after long-term storage, leave G-ænial Bond to stand at room temperature for several minutes prior to use.
2) Apply G-ænial Bond immediately as the material contains a volatile solvent.
3) Remove excess material remaining on the tooth (other than the surfaces to be bonded) using a sponge or cotton pellet, as residue material is hard to remove after light-curing.
4) Should the applied material be contaminated with water, blood or saliva prior to light-curing, rinse and dry the tooth and repeat the procedure by re-applying material.


Fig. 4


Fig. 5


Fig. 6

4. LIGHT-CURING

Light-cure using a visible light curing unit (Fig. 7).

Exposure time

Halogen / LED (700 mW/cm²) : 10 seconds
Plasma Arc (2000 mW/cm²) : 3 seconds
G-Light (1200 mW/cm²) : 5 seconds


Fig. 7

In cases where the light guide tip is more than 10mm away from the surface to be treated, light-cure for the following times:

Halogen / LED (700 mW/cm²): 20 seconds
Plasma Arc (2000 mW/cm²): 6 seconds
G-Light (1200 mW/cm²): 10 seconds

Note:

1) Light-cure completely for an effective bonding strength. Lower light intensity may cause insufficient adhesion.
2) Use a protective light shield or similar protective eye wear during light-curing.

5A. PLACEMENT OF LIGHT-CURED COMPOSITES AND COMPOMERS

After light-curing the adhesive, follow manufacturer's instructions for use in order to place, contour and light-cure the selected composite resin material.

5B. PLACEMENT OF DUAL-CURED COMPOSITES

After light-curing the adhesive, be sure to light-cure the dual-cured composite material separately. Self-curing only will result in insufficient bonding strength.

6. FINISHING

Adjust restoration, finish and polish using standard techniques.

## Storage

Store at room temperature (1-28°C) (33.8-82.4°F).
If not in use for a prolonged period of time, store in refrigerator.
Shelf life: 2 years from date of manufacture.

## Package

1. G-ænial Bond Bottle Kit:
   5 mL liquid (1), disposable dispensing dish (20), disposable applicator fine (50)
2. G-ænial Bond Bottle Refill:
   5 mL liquid (1)
3. G-ænial Bond 3-bottle Pack:
   5 mL liquid (3)

## Caution

1. G-ænial Bond is flammable. Do not use near naked flame. Keep away from sources of ignition. Do not store large quantities in one area. Keep away from direct sunlight.
2. G-ænial Bond is volatile. Use in a well ventilated place. Advise patients to breathe through their nose.
3. In case of contact with eyes, flush immediately with water and seek medical attention.
4. In case of contact with oral tissue or skin, immediately remove G-ænial Bond with a sponge or cotton pellet. After the restorative treatment is finished, rinse thoroughly with water.
5. If tissue is contacted by the material and turns white or forms a blister, advise the patient to leave the affected area undisturbed until the mark disappears, usually in 1-2 weeks. To avoid contact, it is recommended to apply cocoa butter to any area the rubber dam cannot cover.
6. Avoid inhalation or ingestion of material.
7. When spilt on the table or floor, immediately wipe off with a dry cloth.
8. Do not mix with other products.
9. Dispose of all waste according to local regulations.

Last revision of Instruction for Use: 07/2010

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