



Technical Profile

Rev. 01 - May/10

Adhesive System to
Enamel and Dentin



amber

You're Worth It.



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1. Introduction

Adhesive Systems: General Considerations

The development of adhesive systems has contributed significantly for the scientific advance of the modern dentistry. Most current conservative approaches with their superior results rely on the wide range of applications of this category of dental materials. However, the mechanisms involved in the bonding protocol are rather complex, being this the target of several elaborate studies.

Currently, the adhesive systems are classified according to the way they interact with the smear layer (etch-and-rinse or self-etch approach) and by the number of steps involved in hybridization process. Studies have shown that although self-etch systems have a user-friendly protocol by eliminating the separate conditioning step, they may present inferior long-term clinical results owing to the lower chemical stability of the cured polymer making them highly prone to the hydrolytic degradation. Two- and three-step adhesives have greater acceptance in the clinical field and have been considered superior in terms of longevity. However the bonding protocol is still challenging regardless the adhesive system category selected.

The dental substrates involved in bonding protocol are quite different in terms of composition. This is a challenge itself since a single adhesive solution needs to reach reliable bond to both substrates. Enamel is mainly composed of hydroxyapatite (96% by weight), contrasting with the moist and organic composition of dentin, which contains approximately 50% water and organic substances, including an intricate type I collagen network. When bonded to dentin, the mixture of hydrophobic monomers must infiltrate the clean and demineralized dentin structure to form a homogeneous and resistant hybrid layer. Within this context, the balanced composition of solvents + monomers + photoinitiators is of paramount importance to improve the material compatibility with the moist substrate and to allow the achievement of a high quality hybrid layer. Currently, the technology behind the adhesive systems formulation considers the solubility parameters of monomer mixtures to improve/optimize the affinity of the adhesive with the dental substrates.

As critical as good affinity with dental substrates and adhesive infiltration in the dental structure is the quality of the polymer produced after light curing. In order to obtain a strong polymer it is essential to have a good combination of monomers, a proper technique to ensure proper removal of solvents and also an adequate monomer conversion through the light curing process. The inclusion of nanoparticles into the adhesive's formulation improves the strength of the polymer.

The clinical significance of a resistant hybrid layer formation is the longevity of the bonding. Failures in the hybridization process lead to nano-, micro- or macro-leakage, which may cause degradation of the bonding by hydrolysis of collagen fibers just below the hybrid layer or even lead to caries lesions formation adjacent to the gap. From a clinical standpoint such failures are reported on the long run as marginal infiltration or lack of retention.

In addition to all the challenges the adhesives are prone to, difficulties still arises to reach a successful bonding technique. The process of adhesive application is considered a simple step, but the technical protocol requires careful attention as they are also responsible for final quality of bond. The mode the adhesive is rubbed, the homogeneity of the adhesive film, the solvent evaporation step, the maintenance of surface moisture among other factors must be controlled according to the type and formulation of the adhesive system. Thus, the manufacturer's recommendation should be strictly followed.

Due to the high complexity of the adhesive system, they require an elaborate process of development which includes evaluation of bond strength immediately and after aging, nano- and microleakage pattern, ultimate tensile strength of the adhesive itself (cohesive strength) and clinical studies. The formation of the hybrid layer should also be evaluated under scanning

electron microscopy to analyze the quality of the hybrid layer and the formation of resin tags inside the dentin tubules. The tests performed with the Ambar (FGM) can be seen in detail in the item 6 of this technical profile.

Ambar (FGM)

Ambar is a single-component, light-curing, two-step etch-and-rinse adhesive system (complete removal of the smear layer). After acid etching, the adhesive (bottle containing primer + adhesive) is then applied onto the substrates. The adhesive formulation was developed to ensure adequate infiltration of monomers into the moist, demineralized dentin collagen fibrils. After light-curing, Ambar produces a stable and strong adhesive film, which contributes to long-lasting results. The addition of nanoparticles into the adhesive formulation increases the mechanical strength and chemical stability of the cured polymer film. Some specific components were added to the adhesive composition to allow an adequate polymerization of the product when in contact with moist substrates, such as dentin.

The adhesive is designed for direct procedures such as composite and resin-modified glass ionomer cement restorations and indirect applications when combined with AllCem cement (FGM).

2. Basic Composition

Active Ingredients: Methacrylate monomers, photoinitiators, co-initiators, stabilizers

Inactive Ingredients: Inert filler (silica nanoparticles) and solvent (ethanol)

3. Product Presentation

Single bottle containing 6 mL of primer+adhesive solution and the instructions for the professional.

4. Indications for Use

- Direct light-cured composite restorations (class I, II, III, IV and V);
- Adhesive luting procedures (when combined with a resin luting cement) of prosthetic pieces made of glass fibers, ceromers, ceramics, resins and metal (i.e., intra-radicular core and posts, crowns, onlays and inlays, veneers, etc.);
- Ceramic and composite repair.

5. Main Characteristics and Advantages

- High bond strength;
- Contains treated-silica nanoparticles, which provides high stability and increases the strength of the adhesive film;
- Presents chemical features that ensure adequate polymerization even in a high wet environment and thus ensure high longevity of the adhesive film;
- Balanced formulation with solvents and monomers with high affinity with the wet demineralized dentin, which contributes to the adequate infiltration of the adhesive and good hybrid layer formation. This allows high bond strength and high quality of the bonding interface;
- Simplification of the bonding procedure – combines the primer and adhesive in a single bottle;
- Contains ethanol as solvent;
- There is no need to shake the bottle before use.

6. Physical-Chemical Properties

6.1 Bond Strength

Several methodologies have been employed to evaluate the bond strength of adhesive systems to enamel and dentin. Conventional tensile and shear bond strength tests and more recently microtensile bond strength tests are the most commonly used. The clinical success of a restoration depends on the ability of the adhesive to maintain the restoration bonded to the tooth structures and this feature is directly associated with bond strength.

Dr. Loguercio and Dr. Reis along with their team evaluated the bond strength of the **Ambar** (FGM) to human dentin using the Opallis (FGM) composite.

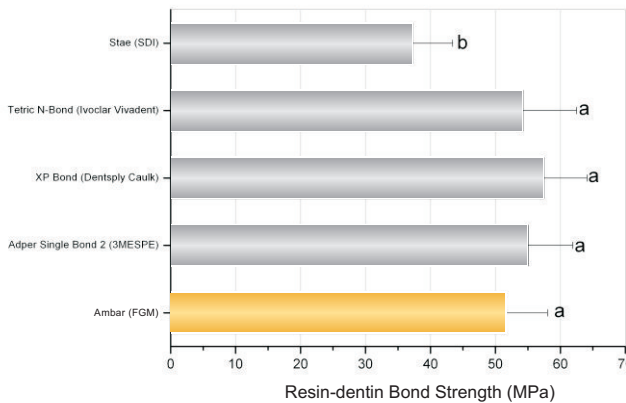


Figure 1: Microtensile resin-dentin bond strength (MPa) of different adhesive systems.

Courtesy of Dr. Alessandro Loguercio and Dra. Alessandra Reis, State University of Ponta Grossa – UEPG-PR, 2009 (Different letters indicate statistically different means ($p < 0,05$)).

One can observe that **Ambar** (FGM) showed a resin-dentin bond strength mean statistically similar to their main competitive products and superior to Stae (SDI).

The resin-dentin bond strength of different simplified adhesive systems was evaluated by Dr. Jorge Perdigão and his co-workers (University of Minnesota, USA). The immediate bond strength values as well as the values after thermo-cycling are depicted in Figure 2.

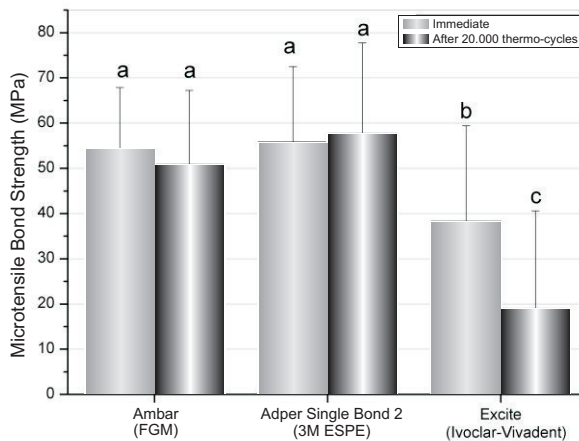


Figure 2: Bond strength of different adhesive systems to human dentin (MPa): immediate data (in light grey) and after 20,000 thermo-cycles (in dark grey).

Courtesy Dr. Jorge Perdigão – University of Minnesota – USA, 2009 (Different letters indicate statistically different means ($p < 0,05$)).

After aging the adhesive interface with 20,000 thermo-cycles one can observe that the adhesives **Ambar** (FGM) and Adper Single Bond 2 (3M ESPE) showed stable bond strength, while Excite (Ivoclar Vivadent) showed a significant reduction of the mean value.

The storage of the microtensile specimens in deionized water or artificial saliva is another way to accelerate the degradation of the adhesive interface. Some authors correlate this aging method with the thermo-cycling procedure (Sabóia *et al.* 2009).

The figure below shows the resin-dentin bond strength values of some adhesive systems. With the aim to evaluate the stability of the adhesive interface, some specimens were stored in deionized water at 37°C for 70 days, being the water exchanged twice a week.

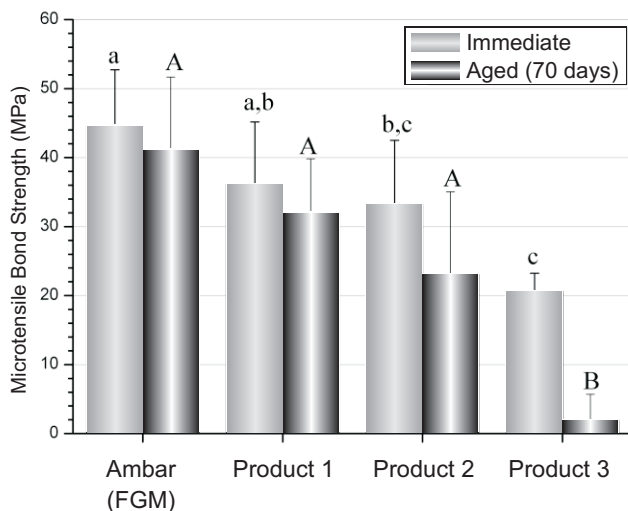


Figure 3: Bond Strength values (MPa) of composite and bovine dentin mediated by different brands of adhesive systems: immediate value (light grey) and after storage in deionized water for 70 days at 37°C (dark grey). Different letters indicate statistically different means between groups ($p < 0,05$); uppercase letters compare the 70-day groups while lowercase letters state the comparison between immediate groups.

Source: FGM Produtos Odontológicos Ltda. (Different letters indicate statistically different means ($p < 0,05$)).

The data presented in Figure 3 showed that the storage of the specimens for 70 days in deionized water produced a significant degradation of the resin-dentin bond strength of Product 3. For the other materials, including Ambar (FGM), the bond strength was quite stable.

Ambar (FGM) showed excellent resin-enamel bond strength as can be seen in Figure 4, where the mean values of shear bond strength to enamel are demonstrated.

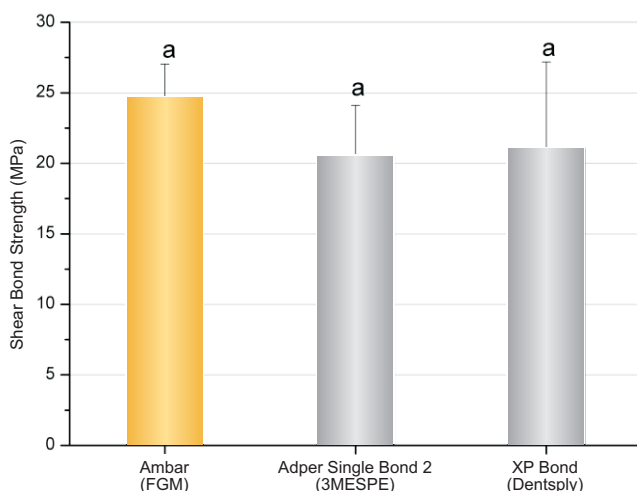


Figure 4: Shear Bond Strength between bovine enamel and composite resin mediated by different adhesive systems.

Source: FGM Produtos Odontológicos Ltda. (no significant difference was detected among groups ($p > 0,05$)).

Bonding to phosphoric acid-conditioned enamel is less challenging. On enamel, the main mechanism of bonding relies on the mechanical interlocking of the adhesive in the porosities created by the previous demineralization. On dentin, however, the solubility parameters of the adhesive system should be compatible with that of the moist demineralized dentin.

Ambar (FGM) is compatible with different brands of methacrylate composite resins available in the market as can be seen in the following Figure.

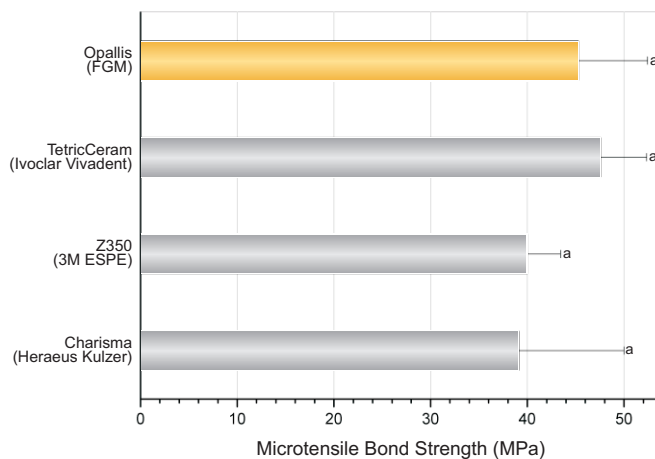


Figure 5: Microtensile bond strength between bovine and different composite resins mediated by Ambar (FGM).

Source: FGM Produtos Odontológicos Ltda. (no significant difference was detected among groups ($p > 0,05$)).

In the context of compatibility, it is very important to know if the cement indicated to be used with the adhesive is indeed compatible with it. Resin cements of dual or chemical cure contain amines involved on the initiation of chemical polymerization reaction. Acid environments can cause protonation of these molecules, reducing or impeding the chemical cure from occur. Thus, the acidity of adhesives is a critical aspect for the success of resin luting cement's complete polymerization and consequent longevity of the cementation.

In order to evaluate the compatibility between Ambar and Allcem (FGM, resin cement), shear bond strength was measured considering the system: dentin/adhesive/resin cement. In this test, indirect restorations made of laboratory resin were luted with Allcem (FGM) to bovine dentin, intermediated by different adhesives. The cement was cured in absence of light, and the results are shown below.

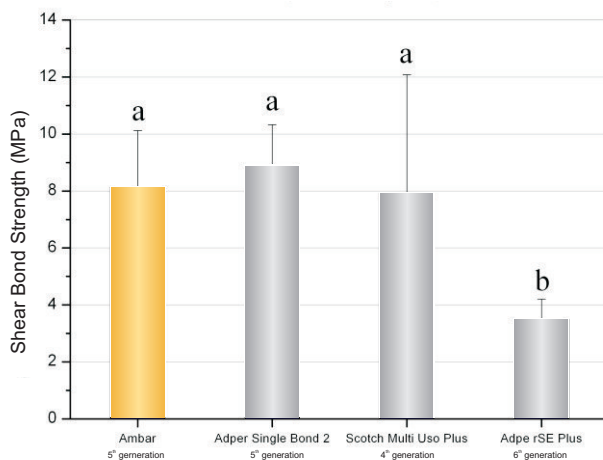


Figure 6: Shear Bond Strength between laboratory resin luted to bovine dentin, mediated by Allcem (FGM) and different adhesive systems.

Source: FGM Produtos Odontológicos Ltda. (Different letters indicate statistical difference ($p < 0,05$)).

By the results of Figure 6, one can observe that only the 6th generation adhesive presented low bond strength, possibly because of its high acidity. The adhesives of 5th generation, including Ambar, and the 4th generation adhesive have shown to be compatible with Allcem, presenting no statistical difference between these groups. Thus, Ambar can be used safely with Allcem resin cement.

6.2 Ultimate Tensile Strength of the Adhesive (Cohesive Strength)

The quality of the polymer produced after the light curing step is critical for the bonding protocol since it has important implications in the stability of the adhesive interface and consequently in the durability of the restorative procedure. The amount of residual solvent entrapped in the adhesive layer, the amount of energy density supplied during the curing step and hydrophilicity of the adhesive film can affect the final quality of the adhesive layer.

An effective way to evaluate the quality of the polymer network is through the measurement of its

ultimate tensile strength. The test methodology and the results described below were conducted by Dr. Reis and Dr. Loguercio's team.

With the aid of an hourglass shape metallic matrix with smallest cross sectional area of 1.0 mm², adhesive specimens were prepared (40s, 500mW/cm²) to be tested into tensile mode at 0.5 mm/min in a universal testing machine (Takahashi *et al.*, 2002 and Loguercio *et al.*, 2009).

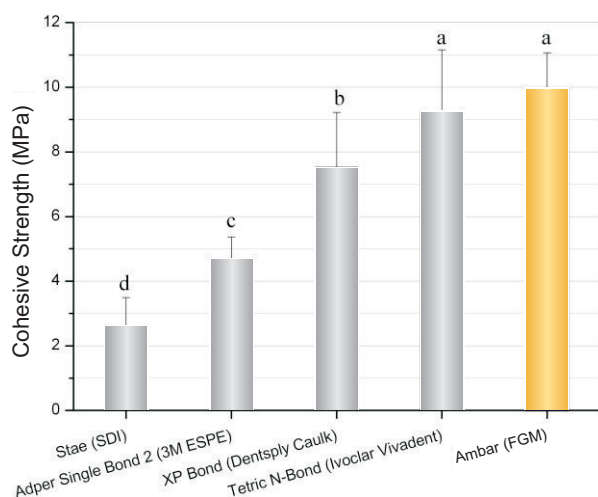


Figure 7: Ultimate Tensile Strength (MPa) of different adhesive systems.

Courtesy of Dr. Alessandro Loguercio e Dra. Alessandra Reis – State University of Ponta Grossa, UEPG-PR (different letters indicate statistically different means ($p < 0,05$)).

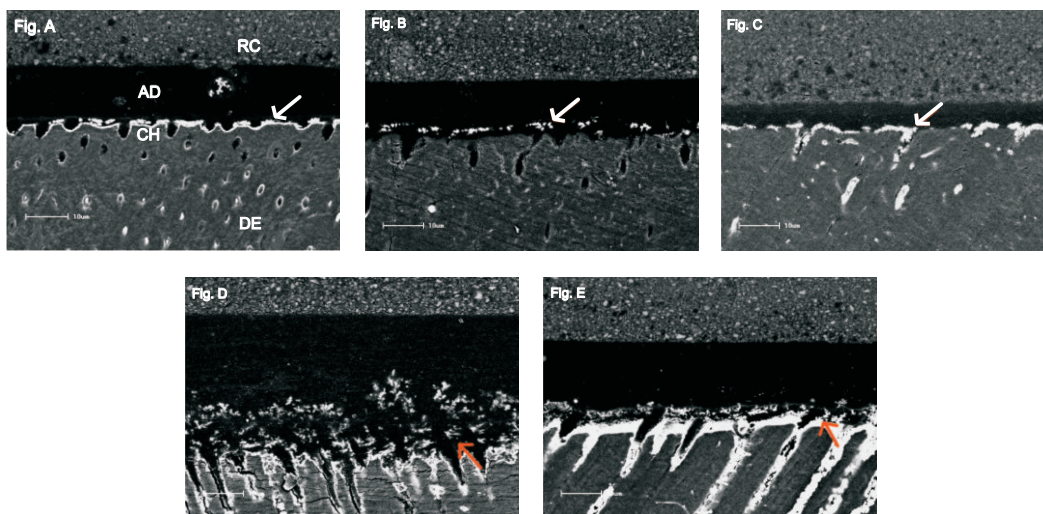
The ultimate tensile strength of **Ambar** (FGM) was statistically superior to most of the competitive products and similar to Tetric N-Bond (Ivoclar Vivadent). These results indicate the high quality of the polymer produced by **Ambar** (FGM) and reflects the clinical longevity of the bonding procedure. These findings are in agreement with the immediate and aged microtensile bond strength results demonstrated earlier. The addition of nanoparticles to **Ambar** (FGM) formulation also contributes to the increase in polymer cross-linking and in the ultimate tensile strength of the product.

6.3 Nanoleakage

It is known that the quality of the bond between dentin and composite is affected by the infiltration of monomers within the collagen mesh. Different patterns of silver nitrate uptake are considered morphological evidence of nanometers voids or nanoleakage within the hybrid layer after impregnation.

The incomplete impregnation of resin monomers at the bottom of the hybrid layer was originally described as nanoleakage. This term was used to describe traces of silver nitrate tracer in the hybrid layer without any gap formation between the composite resin and dentin structure. The nanoleakage pathway may act as potential sites for hydrolytic degradation of collagen fibrils and cured polymers at the resin/dentin bond and thus may induce restoration failure.

For evaluation of the nanoleakage, composite resin restorations were placed in human third molars. The composite restorations were sectioned into resin-dentin beams and the specimens were coated with two layers of nail varnish applied up to within 1 mm of the bonded interfaces, before being immersed in 50% ammoniacal silver nitrate tracer solution for 24 hours. After this period, specimens were rinsed thoroughly in distilled water, and immersed in a photo-developing solution for 8 h under a fluorescent light to reduce silver ions into metallic silver grains within voids along the bonded interface. The specimens were cleaned, air dried in colloidal silica at 37°C for 24 h before being sputtered with gold. Resin-dentin interfaces were analyzed in a scanning electron microscope operated in the backscattered electron mode at an accelerating voltage of 12 kV. Three pictures of the adhesive interface were taken and the relative silver nitrate uptake within the adhesive and hybrid layers were quantified using the UTHSCSA Image Tool 3.0 software (Department of Dental Diagnostic Science at The University of Texas Health Science Center, San Antonio, Texas, USA). For further details see Reis *et al.* 2007 and Loguercio *et al.* 2009.



Scanning electron microscopy images of 5 conventional adhesives (A=Adper Single Bond 2; B = Ambar (FGM); C = XP Bond; D = Tetric N-bond and E = Stae). The amount of silver nitrate uptake (white arrow) in figures A, B and C is lower than in figures D and E. In figures D and E a higher amount of silver nitrate infiltration is seen both in the hybrid layer as well as the adhesive layer (red arrow). RC = composite resin; AD = adhesive layer; CH = hybrid layer and; DE = dentin.

Courtesy: Dr. Alessandro Loguercio, Dr. Alessandra Reis and co-workers, State University of Ponta Grossa, PR, 2009.

Table 1: Means and standard deviations (%) of silver nitrate uptake within the adhesive interface for five two-step conventional adhesives (n= 6 teeth; 18 resin-dentin beams; 54 pictures).

Adhesive (Brand)	Mean	Standard deviation	Statistical analysis (*)
Ambar (FGM)	12,7	3,5	A
Adper Single Bond 2 (3M ESPE)	16,4	4,2	A
XP Bond (Dentsply Caulk)	15,4	4,7	A
Tetric N-Bond (Ivoclar Vivadent)	25,1	5,1	B
Stae (SDI)	38,4	6,3	C

(*) One way analysis of variance and Tukey's test ($\alpha=0.05$)

Table 2: Means and standard deviations (μm) of the adhesive layer thickness for five two-step conventional adhesive systems (n= 6 teeth; 18 resin-dentin beams; 54 pictures).

Adhesive (Brand)	Mean	Standard deviation	Statistical analysis (*)
Ambar (FGM)	12,3	2,4	A
Adper Single Bond 2 (3M ESPE)	10,9	2,3	A
XP Bond (Dentsply Caulk)	8,9	2,5	A
Tetric N-Bond (Ivoclar Vivadent)	31,1	5,1	B
Stae (SDI)	28,1	5,1	B

(*) One way analysis of variance and Tukey's test ($\alpha=0.05$)

Courtesy: Dr. Alessandro Loguercio, Dr. Alessandra Reis and co-workers, State University of Ponta Grossa, PR, 2009.

The SEM images demonstrate a common nanoleakage pattern. One can observe that **Ambar** (FGM) showed low nanoleakage level as detected by the quantification of the silver nitrate uptake within the adhesive interfaces. As seen in Table 1, **Ambar** (FGM), Adper Single Bond 2 (3M ESPE) and XP Bond (Dentsply Caulk) showed similar nanoleakage uptake which was, in turn, statistically lower than the other tested materials.

Table 2 depicts the adhesive layer thickness produced with the same group of adhesives. Again, **Ambar** (FGM), Adper Single Bond 2 (3M ESPE) and XP Bond (Dentsply Caulk) were statistically similar. They produced a thinner adhesive layer than the other tested adhesives.

A similar nanoleakage study was conducted by Dr. Jorge Perdigão (University of Minnesota – EUA). The obtained SEM image (Figure 8) shows the absence of silver nitrate on the adhesive interface formed by Ambar.

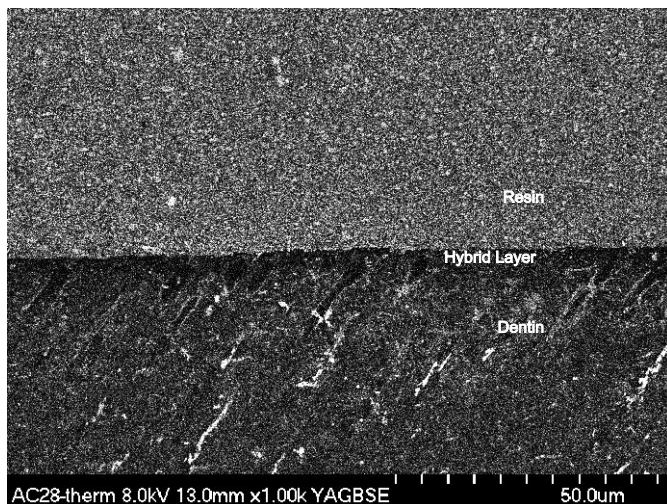


Figure 8: A scanning electron microscope (SEM) image of the hybrid layer formed by Ambar (FGM) on human dentin after thermal challenge (20.000 cycles 5°/55°C), evaluated regarding nanoleakage.

Cortesy Dr. Jorge Perdigão – University of Minnesota – EUA.

6.4 Microleakage

The microleakage is responsible for several problems related to the restoration, such as marginal discoloration, pulp irritation, recurrent caries lesions, post-operative sensitivity among others. Therefore, the evaluation of the microleakage of dentin bonding agents is an important clinical parameter.

Basically, there are two different methods to evaluate the microleakage, which usually requires visual magnification. One of them consists in the impregnation of the adhesive interface with dyes while the other consists in the topographical evaluation of surface with the aid of scanning electron microscope.

On the following study, conducted by Dr. Jorge Perdigão and team, the effect of thermal fatigue on the marginal sealing of ethanol-based etch&rinse 2-step adhesives was verified. Buccal and lingual Class V preparations (occlusal margin in enamel and cervical margin in dentin/cementum) were restored with one of 4 adhesives in 40 extracted human molars: (1) Adper Single Bond Plus (SBP, 3M ESPE); (2) **Ambar** (FGM); (3) Excite (EXC, Ivoclar Vivadent); (4) OptiBond SOLO Plus (OPT, Kerr Dental). For the restoration, Opallis (FGM) composite was placed in two increments. After isolating with nail polish, half of the specimens were thermocycled (TC) for 20,000 cycles (5-55°C), and then teeth were processed with 50% ammoniacal silver nitrate (Tay *et al.*, 2002) followed by photodeveloper. Restorations were sectioned in two halves, scanned at 4,200-pixel resolution in a photo scanner (Epson America) and displayed in a high-resolution monitor to measure silver infiltration around the cervical margins (ranks 0-3). Statistical analysis was computed with SPSS 14.0 (SPSS Inc.) using Kruskal-Wallis and Mann-Whitney non-parametric tests ($p < 0,05$). Results are shown below:

Table 3: Marginal microleakage in Class V preparations (occlusal margin in enamel and cervical margin in dentin/cementum) in human teeth restored with 4 two-step conventional adhesives.

NON-THERMOCYCLED	Excite (Ivoclar Vivadent)	OptiBond SOLO Plus (Kerr Dental)	Adper Single Bond Plus (3M ESPE)	Ambar (FGM)
> Median	10	4	4	2
<= Median	0	6	6	8
THERMOCYCLED				
> Median	5	4	4	2
<= Median	5	6	6	8

Kruskal-Wallis and Mann-Whitney non-parametric tests ($p < 0,05$)

Courtesy: Dr. Jorge Perdigão, Dra. Ana Sezinando and Dr. George Gomes, University of Minnesota – EUA, 2009.

It can be observed that for the non-thermocycled specimens, Excite (Ivoclar Vivadent) resulted in statistically greater silver infiltration than the other three adhesives ($p < 0,002$); Ambar (FGM), Adper Single Bond Plus (3M ESPE) and OptiBond SOLO Plus (Kerr Dental) resulted in statistically similar silver infiltration. For thermocycled specimens, there were no statistically significant differences in silver infiltration ($p > 0,732$). Therefore, it can be concluded that the in vitro marginal sealing of Ambar (FGM) is comparable to that of Adper Single Bond Plus (3M ESPE) and OptiBond Solo Plus (Kerr Dental) regardless of thermal fatigue.

A second marginal microleakage study was performed in the State University of Ponta Grossa - PR. In this study, the marginal microleakage was evaluated in the enamel and dentin margins. The preparation of the specimens followed the ISO TR 11405 (1994) and the results are depicted in the tables below. For statistical purposes, the most prevalent score in each tooth was used to represent the experimental unit. For further details see Loguercio *et al.*, 2002; Loguercio *et al.*, 2004.

Table 4: Microleakage of adhesive/dentin interface of five two-step conventional adhesive systems (n=15 teeth). Percentage values according to the score, medians, means and statistical analysis (*).

Adhesive (Brand)	Score				Median	Mean	Statistical Analysis (*)
	0	1	2	3			
Ambar (FGM)	20,0	23,3	30,0	26,7	2	16,3	A
Adper Single Bond 2 (3M ESPE)	10,0	16,7	43,3	30,0	2	1,93	A,B
XP Bond (Dentsply Caulk)	20,0	23,3	30,0	26,7	2	2,17	A,B
Tetric N-Bond (Ivoclar Vivadent)	13,3	10,0	23,3	53,3	3	1,63	A
Stae (SDI)	13,3	13,3	13,3	60,0	3	2,20	B

(*) Kruskal-Wallis and Mann-Whitney tests ($\alpha = 0,05$)

Table 5: Microleakage of adhesive/enamel interface of five two-step conventional adhesive systems (n=15 teeth). Percentage values according to the score, medians, means and statistical analysis (*).

Adhesive (Brand)	Score				Median	Mean	Statistical Analysis (*)
	0	1	2	3			
Ambar (FGM)	86,7	3,3	6,7	3,3	0	0,27	A,B
Adper Single Bond 2 (3M ESPE)	93,3	3,3	3,3	0	0	0,10	A
XP Bond (Dentsply Caulk)	66,7	23,3	10,0	0	0	0,43	B
Tetric N-Bond (Ivoclar Vivadent)	86,7	10,0	3,3	0	0	0,17	A,B
Stae (SDI)	80,0	6,7	13,3	0	0	0,33	A,B

(*) Kruskal-Wallis and Mann-Whitney tests ($\alpha = 0,05$)

Courtesy: Dr. Alessandro Loguercio and Dr. Alessandra Reis, State University of Ponta Grossa, Ponta Grossa, PR, 2009.

Ambar performance was similar to its competitors, being statistically superior to Stae (SDI) on the dentin evaluation (Table 5) and to XP Bond (Dentsply Caulk) on the enamel tests (Table 6).

6.5 Morphological Characterization of the Hybrid Layer

Some scanning electron microscopy images of the hybrid layer produced with Ambar (FGM) in human dentin can be seen below. Specimens were demineralized in hydrochloric acid and deproteinized in sodium hypochlorite to remove the collagen fibrils not encapsulated by the adhesive, as described in the method by Perdigão *et al.* (1995).

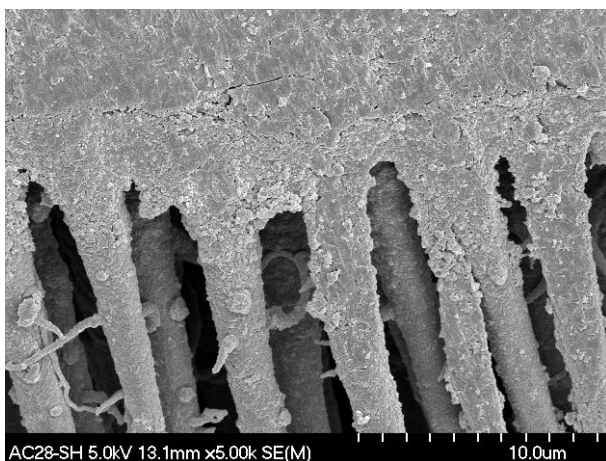


Figure 9a: Scanning electron photomicrograph (SEM) of the hybrid layer produced with Ambar (FGM) when bonded to human dentin.

Courtesy: Dr. Jorge Perdigão – University of Minnesota – USA.

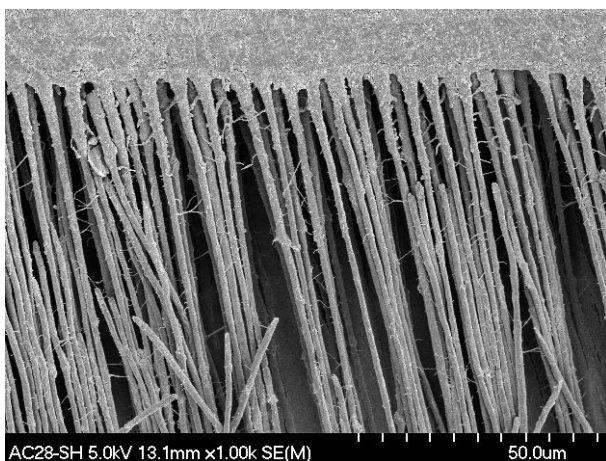


Figure 9b: Scanning electron photomicrograph (SEM) of the hybrid layer produced with Ambar (FGM) when bonded to human dentin in low magnification.

Courtesy: Dr. Jorge Perdigão – University of Minnesota – USA.

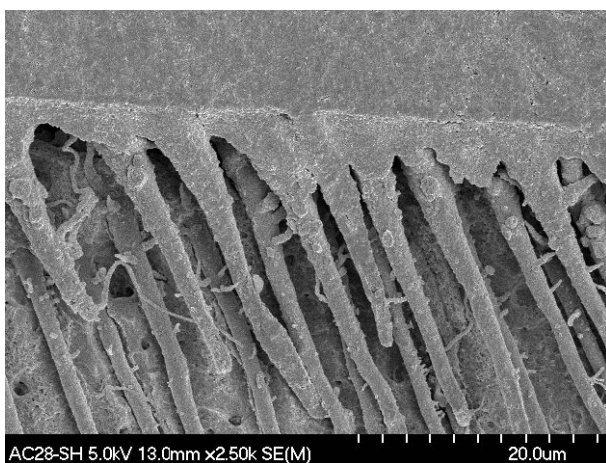


Figure 9c: Ambar adhesive interface after 20,000 thermo-cycles (5-55°C).

Courtesy: Dr. Jorge Perdigão – University of Minnesota – USA.

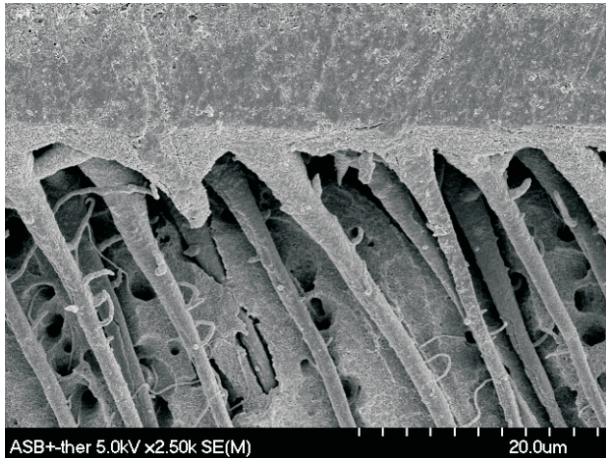


Figure 10a: Adper Single Bond Plus (3M ESPE).

Courtesy: Dr. Jorge Perdigão – University of Minnesota – USA.

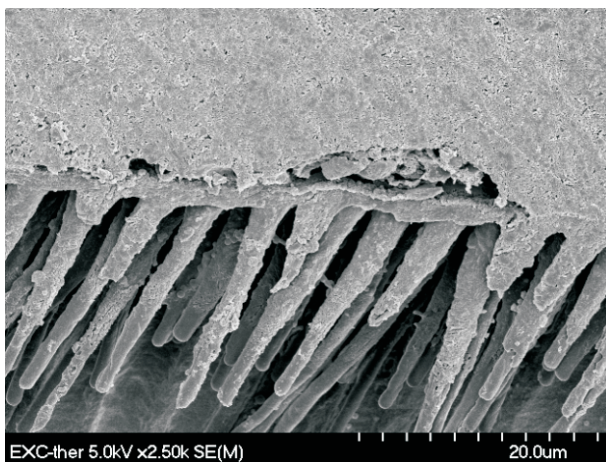


Figure 10b: Excite (Ivoclar Vivadent).

Courtesy: Dr. Jorge Perdigão – University of Minnesota – USA.

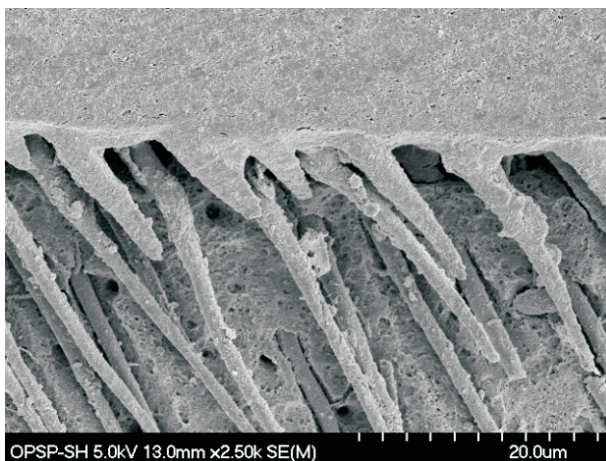


Figure 10c: OptiBond SOLO Plus (Kerr Dental).

Courtesy: Dr. Jorge Perdigão – University of Minnesota – USA.

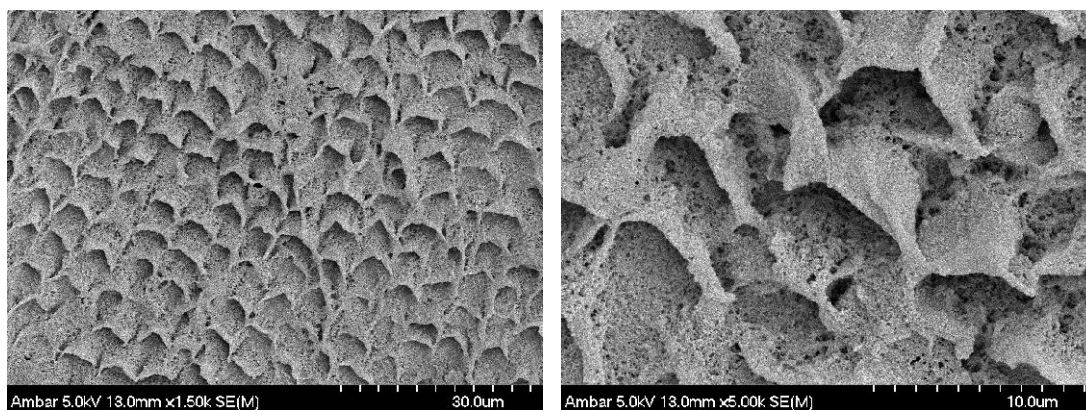
Figures 10a-c: Scanning electron photomicrograph (SEM) of the hybrid layer produced by other two-step adhesives available on market, after 20.000 thermo-cycles (5-55°C). It can be observed that one of the group presented partially filled regions of the hybrid layer, corroborating to its bond strength values.

The SEM images show the integrity of the hybrid layer even after sodium hypochlorite challenge. This reveals the effectiveness of **Ambar** (FGM) to infiltrate within the demineralized collagen mesh. The collagen fibrils were encapsulated by the polymer produced with the adhesive (FGM), protecting them from the deproteinization effect of sodium hypochlorite. The adequate penetration of the adhesive and the formation of the hybrid layer justifies the bond strength values observed in the previous Figures and reflects the stability of the bond after thermo-cycling and aging in water.

Figure 9b highlights the long resin tags produced with **Ambar** (FGM) – including the filling of the anastomosis, forming a polymeric net inside the tubules - after penetrating into the dentin tubules. This finding demonstrates the high affinity of **Ambar** (FGM) with the hydrophilic surface the dentin. After thermo-cycling, the hybrid layer remained stable corroborating with the data of bond strength after this challenge.

6.6 Morphological Characterization of the Adhesive on Enamel

The following images depict the morphological aspect of enamel surface after acid etching and bonding with **Ambar**. The enamel was conditioned with phosphoric acid during 15 seconds, air-dried and two coats of the adhesive were applied as per manufacturer’s instructions. The restorative interface was then sectioned and the specimens were immersed in hydrochloride acid to dissolve the dental structure and expose the polymer produced with the adhesive.



Figures 11a and 11b: SEM images showing the polymer topography produced with **Ambar** after enamel acid etching. Low magnification image and high magnification images.

Courtesy: Dr. Jorge Perdigão - University of Minnesota, USA, 2009.

The images demonstrate the ability of **Ambar** to penetrate in the micropores of the demineralized enamel producing the mechanical interlocking responsible for bonding.

6.7 Clinical Evaluation

Clinical trials are of paramount importance to evaluate the performance of dental materials. Even the more complex and elaborated laboratory study cannot predict the clinical behavior of a given material under in vivo condition. The performance of **Ambar** is being clinically evaluated by the researchers Dr. Alessandro Loguercio, Dr. Alessandra Reis, Dr. Letícia Ferri and Dr. Thays Costa, from State University of Ponta Grossa – PR, as described below.

Material and Methods

Thirty five participants were selected for this study. They should have at least 20 teeth in occlusion and present a good general and oral healthy (without periodontal disease or active caries lesions). Patients with heavy bruxism (wear facets in the incisal/occlusal edge) were not included in the research study.

Each participant had at least two similar sized non-carious cervical lesions. The lesions had to be expulsive with no undercuts and no more than 50% of the cavosurface in enamel; the cervical margin should be located in dentin/cementum. Cervical lesions with previous dentin hypersensitivity or any degree of dentin sclerosis were not excluded from this clinical trial. For further details refer to Loguercio & Reis (2008) and Reis & Loguercio (2009).

Two previously calibrated operators placed all restorations. The bonding protocols were randomly allocated on each patient by tossing a coin. The lesions were prepared as follow:

- 1) Anesthesia;
- 2) Cleaning with pumice and water in a rubber cup followed by rinsing and drying;
- 3) Composite shade selection using the FGM shade guide;
- 4) Rubber dam isolation with dental clamps;
- 5) No additional preparation was performed (surface roughening, bevel or any other retentive approach);
- 6) The adhesives Adper Single-Bond 2 (3M ESPE) and Ambar (FGM) were applied according to the instructions in Table 6;
- 7) The composite resin was incrementally placed in three 1-mm increments. Each layer was light-cured for 40 seconds using a LED light curing unit at 1200 mW/cm² (SDI, Radium-cal);
- 8) Immediately after the end of the restorative procedure, all restorations were finished with diamond finishing burs;
- 9) One week later, the restorations were polished with medium, fine and extra fine grit finishing disks (Diamond Pro - FGM) and diamond paste (Diamond Excel - FGM).

Tabela 6: Adhesive systems, composition and mode of application.

Adhesive Systems	Composition	Mode of application
Adper Single Bond 2 (3M ESPE)	<ol style="list-style-type: none"> 1. CondAc 37: 37% phosphoric acid 2. Adhesive bottle: bis-GMA, HEMA, dimethacrylate monomers, polyalkenoic acid copolymer, initiators, water and ethanol. 	<ol style="list-style-type: none"> a- acid etching (15s) b- rinsing (15s) c- air drying, leaving dentin visible moist (5s) d- application of one coat of adhesive (10s) with gentle agitation e- air drying (20s) at distance f- application of another coat of the adhesive (10s) with gentle agitation g- air drying (20s) at distance h- light curing (10s)
Ambar (FGM)	<ol style="list-style-type: none"> 1. CondAc 37: 37% phosphoric acid 2. Adhesive bottle: methacrylic monomers, photoinitiators, coinitiators, stabilizer, inert load (silica nanoparticles) and vehicle (ethanol). 	<ol style="list-style-type: none"> a- acid etching (15s) b- rinsing (15s) c- air drying, leaving dentin visible moist (5s) d- application of one coat of adhesive (10s) vigorously e- application of another coat of the adhesive (10s) with gentle agitation f- air drying (20s) at distance g- light curing (10s)

Two other experienced and blinded examiners performed the evaluation in the immediate time (after polishing) and after 6 months of clinical service. The evaluation was performed according to Hickel *et al* (2007) criteria, which is a modified and improved version of the known USPHS (United States Public Health Service). As the main factor under evaluation was the adhesive performance only the following criteria were pre-selected: fracture and loss of retention; marginal adaptation (also includes marginal discoloration), post-operative sensitivity and caries adjacent to restorations.

The results of this clinical trial are depicted in Table 7. One can observe that 02 restorations were lost after 6 month of clinical service (01 **Ambar** and 01 Adper Single Bond 2). Twelve restorations (05 **Ambar** and 07 Adper Single Bond 2) required a new polishing due to the presence of small fractures at the enamel margins.

According to the American Dental Association (2001), non carious cervical lesions are considered the clinical model to evaluate dentin bonding systems. As per ADA guidelines, to obtain 'provisional acceptance' loss of retention and marginal discoloration should be lower than 5%. This indicates that both adhesives met the provisional acceptance guidelines of ADA to be used clinically. The results are shown in the table below:

Table 7: Number of restorations evaluated according to each criteria in the baseline and in the 6-month period.

Time	Criterion according to Hickel <i>et al.</i> 2007	Immediate		6 months	
		Adper Single Bond 2	Ambar	Adper Single Bond 2	Ambar
Fracture / Retention	A	35	35	27	29
	B	--	--	05	05
	C	--	--	02	--
	D	--	--	--	--
	E	--	--	01	01
Adaptation	A	35	35	35	35
	B	--	--	--	--
	C	--	--	--	--
	D	--	--	--	--
	E	--	--	--	--
Marginal Discoloration	A	35	35	35	35
	B	--	--	--	--
	C	--	--	--	--
	D	--	--	--	--
	E	--	--	--	--
Caries adjacent to restoration	A	35	35	35	35
	B	--	--	--	--
	C	--	--	--	--
	D	--	--	--	--
	E	--	--	--	--
Post-operative hipersensitivity	A	32	32	35	35
	B	03	03	--	--
	C	--	--	--	--
	D	--	--	--	--
	E	--	--	--	--

A – Clinically excellent/very good; B – Clinically good (after polishing); C – Clinically sufficient/satisfactory (minor shortcomings, no unacceptable effects but not adjustable w/o damage to the tooth); D – Clinically unsatisfactory (but reparable); E – Clinically poor (replacement necessary).

Courtesy: Dr. Alessandro Loguercio, Dra. Alessandra Reis, Dra. Leticia Ferri and Dra. Thays Costa, State University of Ponta Grossa, Ponta Grossa, PR, 2009.

One can observe in the table that the retention rate of Ambar was 97% after 6 months of clinical service. In the other items (marginal adaptation and discoloration, caries adjacent to restoration and post-operative sensitivity), **Ambar** received the best scores.



Figures 12A, B and C: The picture on the left shows teeth # 24 and # 25 with non-carious cervical lesions. In the middle one can see the restorations immediately after being placed (tooth # 24 with Ambar and tooth # 25 with Adper Single Bond 2). The picture on the right shows the same restorations after 6 months of clinical service. Observe their excellent clinical performance.

Courtesy: Dr. Alessandro Loguercio, Dra. Alessandra Reis, Dra. Leticia Ferri and Dra. Thays Costa, State University of Ponta Grossa, Ponta Grossa, PR, 2009.

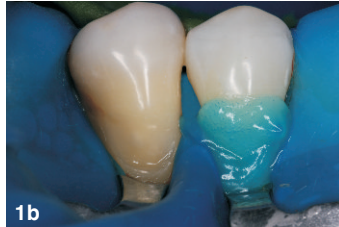
The commercial brands SDI, Ivoclar Vivadent, Dentsply Caulk and 3M ESPE are not registered by FGM Dental Products.

7. Instruction for Use

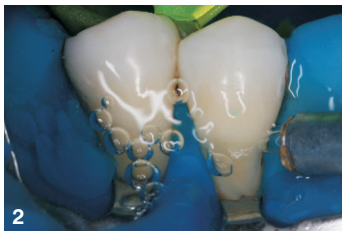
Read carefully the Warnings, Precautions, Contra-Indications and Possible Side Effects written in the Product information sheet, before the beginning of the treatment.

The product is indicated for direct and indirect adhesive restorations (when associated with the resin luting cement) and also for the repair of indirect restorations.

The next pictures describe a clinical case to illustrate the mode of **Ambar** application in dental surfaces (enamel and dentin). This application should be preceded by the restorative steps required for each treatment plan. Each clinical situation requires a different clinical protocol.



1a - b: After cleaning, the dental surfaces should be acid etched with phosphoric acid for 15s.



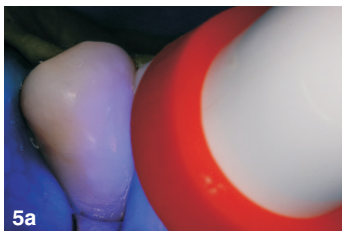
2: The acid gel is removed with vigorous water spray. The substrate is left slightly moist. In case the surface is too dry, a wet cotton pellet can be applied to rewet the surface.



3: One drop of **Ambar** (FGM) should be dispensed in the Cavibrush (FGM) applicator. The first coat should be vigorously agitated for 10s. Then another adhesive drop is dispensed on the applicator and applied for more 10s.



4: Gently air dry for 10 seconds to evaporate the solvent and improve the bonding.



5a - b: The adhesive is then light-cured for 10s (or 20s when applied inside the root canal) using a light curing unit with minimum light intensity of 400 mW/cm². Then, the clinician can proceed with the specific clinical steps (direct restoration, adhesive luting procedures, etc.).

8. Side Effects

Patients may experience some degree of dentin hypersensitivity. This side effect often occurs in deep cavity preparations, in case of over-etching, contamination during the adhesive procedure, inadequate light curing of the adhesive (undercuring), etc. Some restorative-related factors such as the placement of thick increments and failure in occlusal adjustments can also lead to post-operative sensitivity.

9. Conservation and Storage

- **Ambar** (FGM) should be stored at temperature between 15 e 30°C.
- Keep out of external contamination.
- **Ambar** (FGM) should be immediately capped after use to avoid solvent evaporation.
- Keep out of intense light or elevated temperatures.
- Do not use the product after the expiration date.
- For cleanup, **Ambar** (FGM) can be removed with alcohol.
- Shelf life of **Ambar** (FGM) is 3 years from the fabrication date described in the package.

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