Technical Manual

GC UniFil Bond

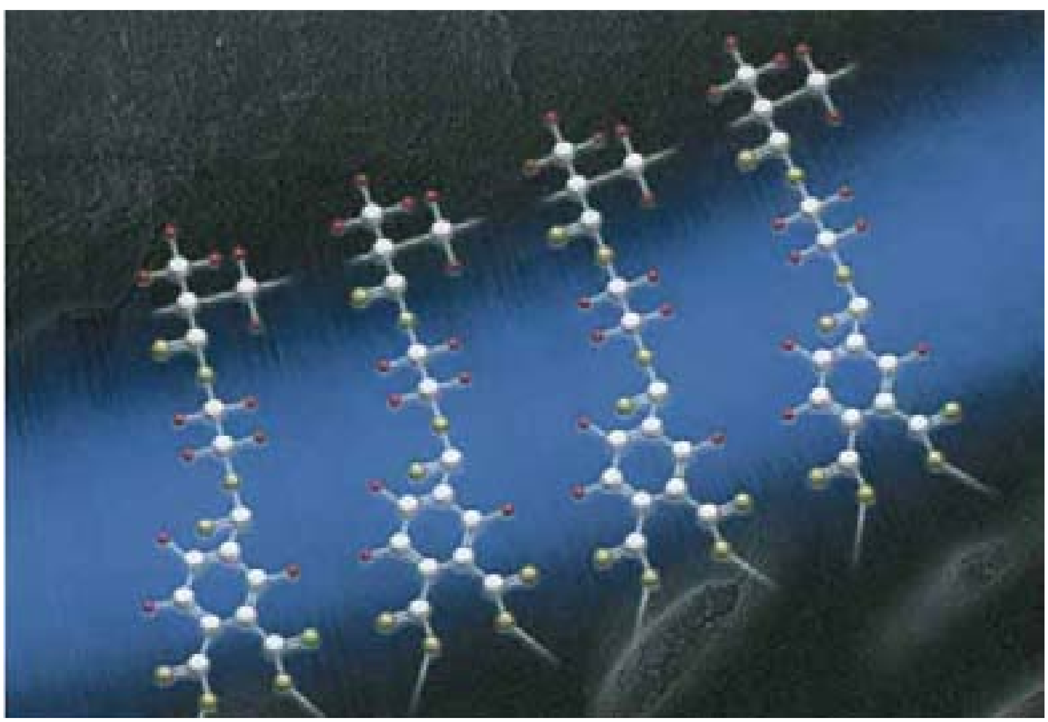


Table of contents

1.0 Introduction

The development of GC UniFil Bond is the result of GC's commitment to understanding and seeking solutions to the variable success parameters currently restricting certain indications for composite resin restoratives.

While long-term success has been achieved with composite resin bonded to all enamel surfaces, the same cannot be said for bonded composite where margins are in dentine. Composite restoration failure often occurs at the interface between the composite and dentine leading to staining, microbial leakage and progression of caries.

Improvements therefore focused on solutions to the problems experienced at this interface. The many causes of interface failure include application factors (variable placement techniques, over etching, over drying, fluid contamination, surface contaminants like excess acetone), site factors (variable dentin structure i.e. tubule orientation, degree of mineralization) and stress factors (occlusal loading, tooth flexure, polymerization shrinkage stress and variable coefficients of thermal expansion).

GC UniFil Bond was developed seeking to provide solutions to many of these problems and focused on three primary objectives:

- Provide strong adhesion via simple application procedures with minimal opportunity for compromised results caused by technique variation

- Provide strong adhesion to a wide variety of dentine surfaces

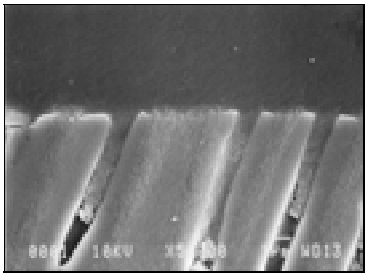
Maintain an effective seal by utilizing both micromechanical interlocking and chemical adhesion.

2.0 Currently available adhesion concepts

At present several adhesion concepts are considered for bonding to tooth surfaces. The adhesion mechanisms are divided into three major categories

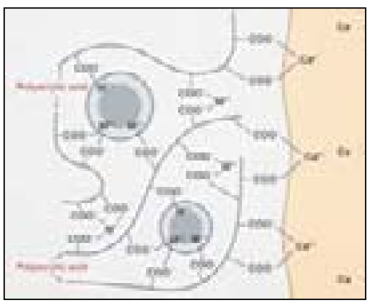
- micromechanical interlocking
- chemical (ion-exchange) adhesion
- combination of above two

- Micromechanical interlocking is achieved by etching both enamel and dentine surfaces followed by application of resin bonding systems that contain functional monomers with both hydrophilic and hydrophobic groups. These monomers are able to penetrate and diffuse throughout the etched dentine surface layer to form a hybrid zone that adheres to the dentin surface. Strong micromechanical interlocking to enamel is also achieved where the resin penetrates the irregularities in the etched enamel surface forming micro resin tags.



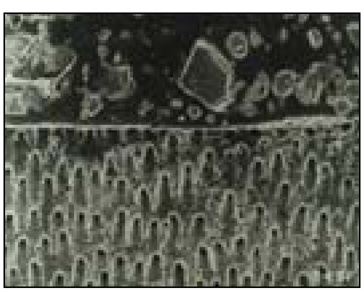
Mechanical retention due to resin tag formation

- Chemical adhesion is the main mechanism by which glass ionomer cements are bonded to dentine and enamel surfaces. The carboxyl group (COOH) of polyalkenoic acids (the liquid component of glass ionomer cement) is ionized by reaction with powder into carboxylic acid ions (COO^-). These ions have extremely strong ionic bonds with calcium ions (Ca^{2+}) in the tooth apatite. The adhesion is so strong that laboratory testing often shows cohesive failure within the cement rather than adhesive failure at the interface. Class V retention studies have shown that long term stability of this adhesion is clinically relevant.

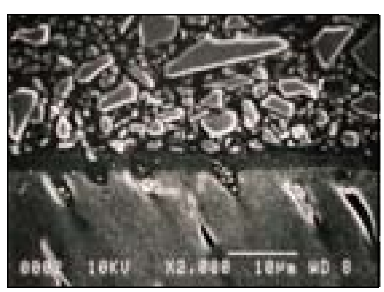


Chemical adhesion of glass ionomers to tooth structure

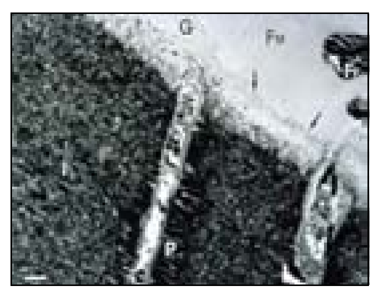
- A combined chemical adhesion / mechanical interlocking can be observed by using resin reinforced glass ionomers in combination with the appropriate conditioners. These resin reinforced glass ionomer cements have grown quickly in popularity as highly successful adhesive materials for crown and bridge cementation (GC Fuji PLUS), composite lining and bonding (GC Fuji Bond LC) and for orthodontic bonding of brackets and bands (GC Fuji ORTHO LC).



GC Fuji BOND LC
Interface with dentine



GC Fuji PLUS
Interface with dentine



GC Fuji BOND LC
Interface with dentine

GC UniFil Bond represents the result of GC's application of glass ionomer adhesion concepts into an advanced, user-friendly, resin bonding system.

3.0 Composition

SELF-ETCHING PRIMER	WT%
4-Methacryloxyethyl trimellitic acid (4-MET)	10
Ethanol	48
Distilled water	40
HEMA	2
Initiator	Trace

BONDING AGENT	WT%
UDMA	50
TEGDMA	30
HEMA	16
Silica Filler	4
Initiator	Trace

<u>Initiators used</u>

In GC UniFil Bond, a combination of camphorquinone and amine is used as the catalyst. Light activation can be carried out with quartz halogen, plasma or LED curing units.
To reinforce the outer enamel surface and the collagen network with a firm and stable adhesive resin layer it is crucial that monomers from both the primer and bonding agent are converted from a liquid into a solid state. When the initiators, as in GC UniFil Bond, are contained in both the primer and bonding agent solutions, the co-polymerization of available monomers occurs more efficiently than when contained only in either one of the solutions. Although in the latter case the initiator might diffuse through both the primer and bonding agent immediately after coming into contact with each other, it is preferable that both liquids include the initiator separately.

Silica

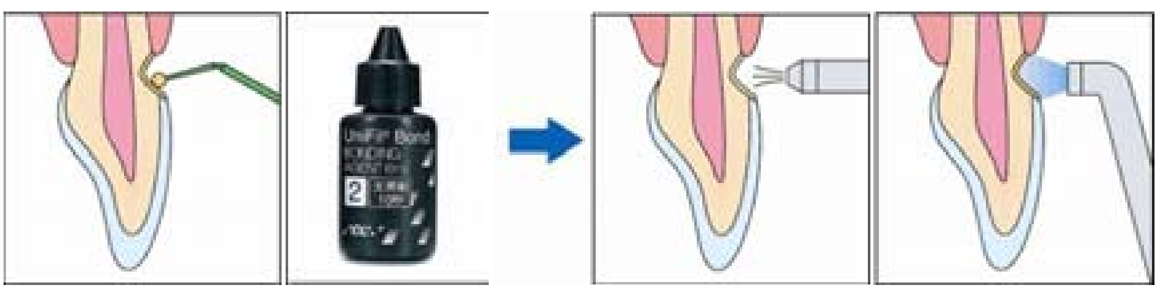
Colloidal silica is added to control the flow of the bonding agent. This will ensure that the operator has a better control during the application.
In addition to this practical advantage, a slight increase in the modulus of elasticity could be obtained – 2.8 (0.1) GPa with silica, versus 2.6 (0.1) GPa without.

4.0 Application

- Self – etching primer

Apply GC UniFil Bond self-etching primer to the dentine and enamel surfaces and leave undisturbed for 20 seconds. Then gently dry with an air syringe for 5 seconds and ensure that the primed surface has a glossy appearance. Do not rinse with water.

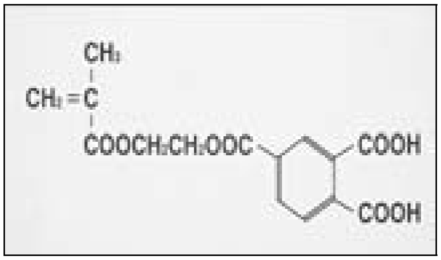
- Bonding agent



GC UniFil Bond bonding agent is immediately applied to the primed enamel and dentine surfaces. Then gently dry with an air syringe to form a thin film and light cure for 10 seconds. GC GRADIA DIRECT composite can now be applied to the treated surface.

5.0 Adhesion mechanism

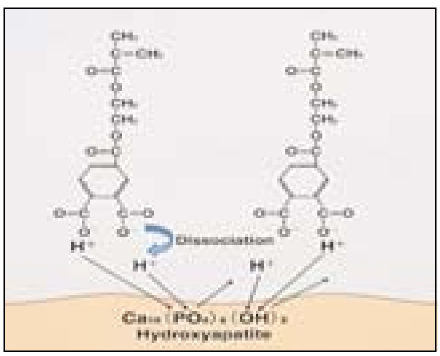
At the heart of GC UniFil Bond's performance is the 4-MET molecule in the primer solution.
4-MET is derived from 4-META by hydrolysis during the manufacturing process and compared to the latter is more hydrophilic and acidic. The functional monomer 4-MET is characterized by self etching and adhesive properties and inherently has very good diffusion properties.



4-MET

Self-etching primer / 4 - MET

As can be seen from the figure below, the carboxyl group (COOH) of 4-MET can dissociate into hydrogen (H^+) and carboxylic (COO^-) ions.

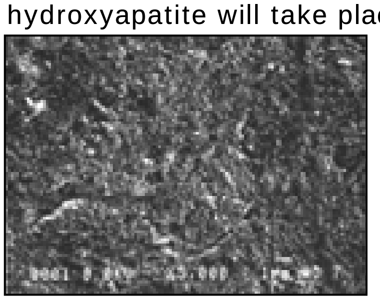


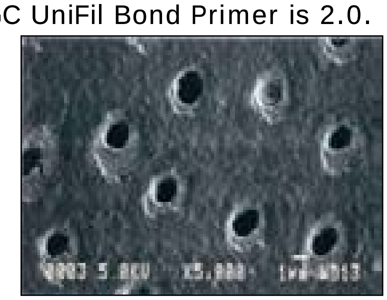
Dissociation of 4-MET when applied to tooth surfaces

This dissociation will result in both (self) etching of tooth surfaces and chemical adhesion to calcium.

- Self-etching properties

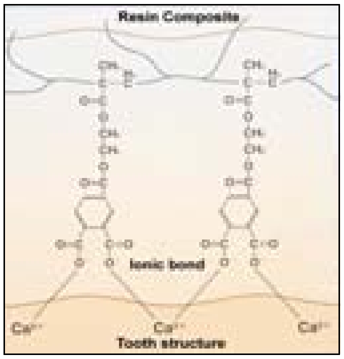
  Both enamel and dentine surfaces will be decalcified due to the freely available hydrogen ions and consequently dissolution of the outer surfaces (≤1µm) of the hydroxyapatite will take place. The pH of GC UniFil Bond Primer is 2.0.



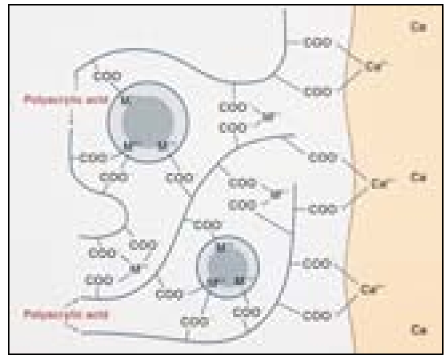


Enamel *Dentine*

- Chemical adhesion to calcium
  The carboxylic ions have the potential to bond chemically to available calcium.
  NOTE: this adhesion mechanism is very similar to the ionic bonding of glass ionomer cements to tooth structure.



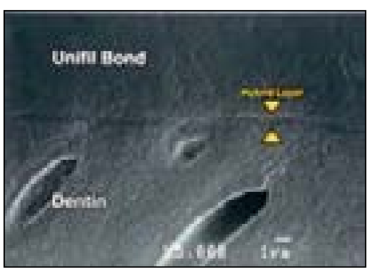
Chemical adhesion of GC UniFil Bond

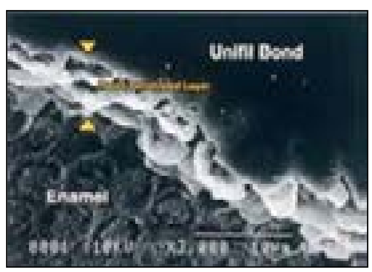


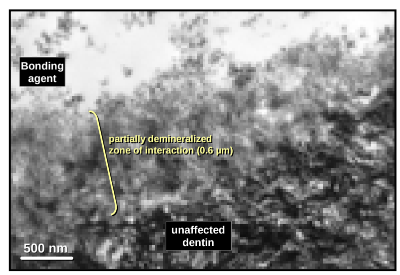
Chemical adhesion of glass ionomer cements

Bonding agent

The bonding agent applied will not only blend with the monomer component of the self-etching primer but also a chemical interaction induced by light curing between the monomer groups of the primer and bonding agent will take place. Light curing will further enhance the bond strength to enamel and dentine.





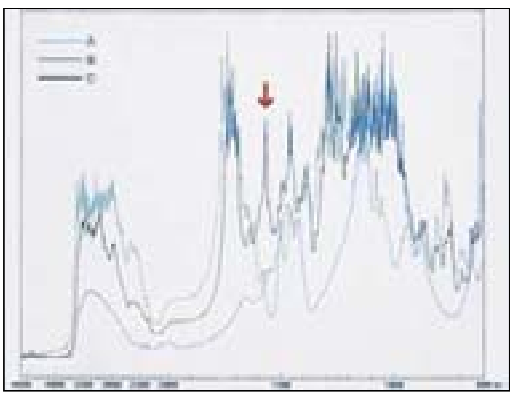


6.0 Test results

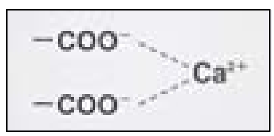
GC UniFil Bond is part of the GC UniFil range of products, successfully introduced in 1998 by GCC in the domestic market, Japan.
GC UniFil comprises a high quality range of resin bonding agents and composite materials and is well appreciated, like GC Fuji glass ionomers, for ease of use and reliable results. In Europe only GC UniFil Bond and GC UniFil Flow are sold.
Due to the availability in Japan for a long period, several publications can be found in the literature. In the chapter 8 a small selection taken from available data is listed.

IR analysis

To verify the formation of calcium carboxylate, IR analysis was performed. Bovine enamel was ground into apatite powder (A). GC UniFil Bond self etching primer was kept in a container at 45 °C and alcohol and water were removed. After light curing, the hardened primer was ground and used as control powder (B). Self etching primer was applied to apatite powder, kept and stored in a container at 45 °C and water and alcohol were removed. Primed powder was light cured and ground into test powder (C) .



From the IR analysis it can be concluded that only powder C shows a peak near 1550 cm^{-1}. This peak represents the formation of Calcium carboxylate when the self etching primer comes into contact with hydroxyapatite from the tooth.



XPS analysis

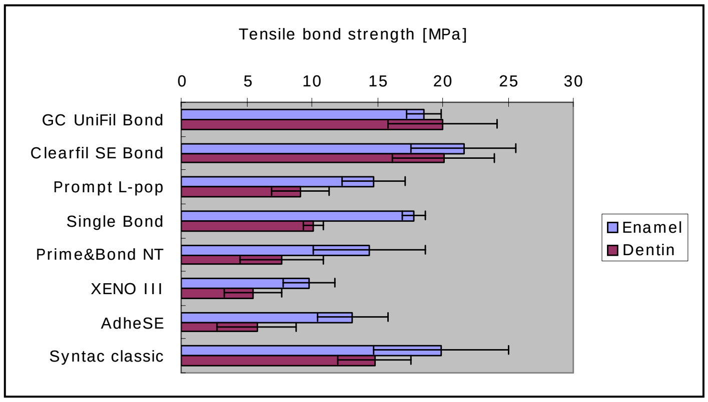
In the study “Bonding Mechanism and Micro-Tensile Bond Strength of a 4-MET based self-Etching Adhesive“, B.Van Meerbeek, Y.Yoshida and others analyzed the bonding mechanism chemically using XPS. It was concluded that the bonding mechanism of UniFil Bond to dentine is twofold. Micro-mechanical bonding was established by monomer interdiffusion into a shallow, partially demineralized dentine layer. Chemical bonding was obtained by ionic interaction of the carboxyl group of 4-MET with calcium of hydroxyapatite that remained around collagen.

Tensile bond strength

The tensile bond strength of 8 state of the art bonding systems to bovine enamel and dentine was measured in house according to the following protocol.

1) The labial surfaces of extracted bovine anterior teeth are polished with SiC (silicon carbide) paper (#600). The polished surface is used for the measurement of tensile bond strength.
2) The bonding test area (4.91 cm^2) is marked with plastic tape (2.5 mm in diameter).
3) The self-etching primer is dispensed onto the polished tooth surface, and left undisturbed for 20 seconds.
4) The surface is dried with gentle air blowing for 5 seconds.
5) The bonding agent is applied to the primed enamel or dentine surfaces and light cured for 10 seconds.
6) Composite resin is placed onto the cured bond, and light cured.

NB. For competitive bonding systems, the respective instructions of the manufacturer were used. Step 3 to 6 applies for GC UniFil Bond.



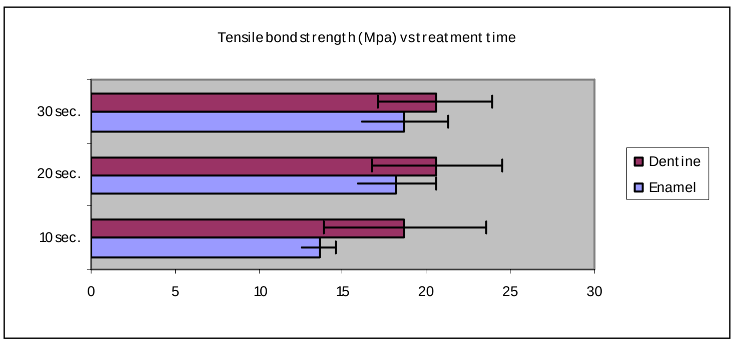
Within the limitations of this test it can be concluded that:
1) Compared to Prompt L-Pop, Prime&Bond NT, XENO III and AdheSE, the bond strength to enamel of UniFil Bond is higher.
2) Compared to Clearfil SE Bond, Single Bond and Syntac classic, the bond strength to enamel of UniFil Bond is similar.
3) Compared to Prompt L-Pop, Single Bond, Prime&Bond NT, XENO III, AdheSE and Syntac classic, the bond strength to dentin of UniFil Bond is higher.
4) Compared to SE Bond, the bond strength to dentin of UniFil Bond is similar.

Consequence of technique variables

Many factors contribute to unstable long term adhesive strengths due to technique variables. These include application times, over dry/wet bonding conditions, air drying conditions, film thickness of adhesive and variable dentine tubule orientation. GC UniFil Bond shows minimal sensitivity to these variables which will contribute to the overall success of this adhesive material.

- Relationship between self-etching primer application time and tensile bond strength to tooth structure

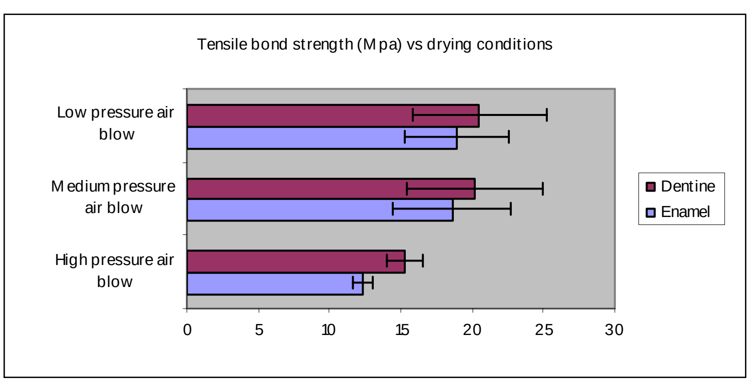
The etching time is often quoted as having a potential influence on the bond strength to tooth structure. In this experiment, the influence of different application times of the self-etching primer on the tensile bond strength of GC UniFil Bond was measured. For details on the tensile bond strength testing protocol, see above.



Within the limitations of this test it can be concluded that:
1) Application time of 10 sec. is not sufficient to etch enamel properly.
2) Application time of 20 sec. is sufficient to etch enamel and dentine correctly.
3) Application time of 30 sec. is not increasing the results on either enamel or dentine.

- Relationship between drying of GC UniFil Bond self-etching primer and tensile bond strength to tooth structure

To measure the influence of the air pressure whilst drying the self-etching primer, tensile bond strength measurements were done under different air pressure conditions. For details on the tensile bond strength testing protocol, see above.

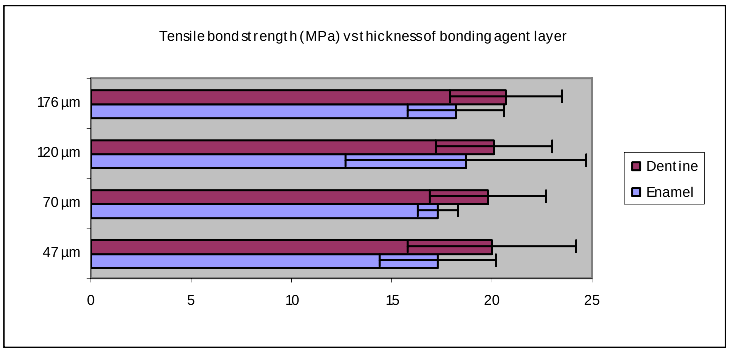


Within the limitations of this test it can be concluded that:
1) When high pressure air blow is applied, the bond strength decreases noticeably. This weaker adhesion is probably caused by insufficient blending of monomers from primer and bonding agent due to excessive dispersion of

monomers.
2) In both cases of medium and low pressure air blow, the results are not significantly different.

- <u>Relationship between film thickness of GC UniFil Bond and tensile bond strength to tooth structure.</u>

The film thickness of the bonding agent will vary from case to case, depending on the manner in which it is applied. To measure if any influence exists on the tensile bond strength of GC UniFil Bond, tape with varying thickness to mark the surface area, see protocol above, was used. After application of the primer, bonding agent was applied up to the level of the tape height.



Within the limitations of this test it can be concluded that: Film thickness does not have an influence on the tensile bond strength.

<u>Consequence of variables in tooth structures</u>

The achievement of the bond to dentine depends on the penetration of the self-etching primer and bonding agent into the demineralised dentine surface in order to form the so-called hybrid layer. This penetration can however be effected by site and location of the prepared dentinal surface. In the study called ‘An evaluation to determine the effect of dentin location and tubule orientation on the bond strengths between UniFil Bond and dentin’ from Phrukkanon S, Burrow MF, Tyas M.J., The University of Melbourne, GC UniFil Bond was applied to 6 different dentin locations on extracted human premolars, either parallel or perpendicular to the tubule orientation. Micro-tensile bond strength measurements were then completed and compared to a so called one bottle adhesive system, Single Bond, 3M Espe.

Dentin position	Single Bond		UniFil Bond	
	Perpendicular	Parallel	Perpendicular	Parallel
Cusp	19.8 (2.8)	21.1 (7.0)	22.0 (5.9)	25.3 (5.9)
Fissure	22.8 (3.5)	21.5 (4.9)	20.8 (5.7)	25.4 (7.9)
Buccal	22.2 (4.2)	18.3 (3.9)	24.6 (6.3)	26.4 (7.0)
Bucco-cervical	22.3 (5.4)	19.2 (2.3)	20.3 (5.3)	24.9 (6.2)
Cervical root	21.7 (7.4)	19.4 (5.5)	21.3 (6.6)	25.9 (5.4)
Mid root	17.3 (5.1)	14.8 (3.9)	24.9 (6.7)	30.1 (6.4)

( ): Standard deviation

From this study it can be concluded that GC UniFil Bond exhibited no significant variation in bond strengths despite variations in dentine location for the teeth tested. Although not statistically significant, GC UniFil Bond specimens bonded parallel to the tubule orientation produced slightly higher adhesive strengths than those specimens bonded perpendicular. These results could be attributed to the increased surface area of mineral available for chemical bonding when tubule orientation is parallel.

In contrast, Single Bond showed slightly lower bond strengths when bonded parallel to tubule orientation and significantly lower bond strengths to mid root dentine.

7.0 Clinical investigations

One-year clinical trial of Gradia direct Class II restorations by M. FERRARI , A. FABIANELLI, S. GRANDINI, C. GORACCI
School of Dental Medicine, University of Siena, Italy

Objective: The objective of this study is to evaluate the safety, longevity, aesthetics and efficacy of Gradia Class II restorations placed under clinical conditions. Methods: 40 Class II OM or OD restorations were placed using experimental Gradia Direct material in combination with UniFil self-etching adhesive system (GC). No bevel or macromechanical retention was placed. The performance of Class II restorations was assessed at baseline and at the 1 and 7 days and 1-month (for post-op sensitivity) 6-month, 12-month recalls.Cervical margins were located primarily in dentine. A rubber dam was applied and the restorations were placed following an incremental technique. The patients were recalled for evaluating post-operative sensitivity and other clinical parameters such as Marginal Integrity (MI), marginal discoloration (MD), Color stability (CS), Surface staining (SS), Retention (R) and Secondary caries (SC) according the Ryge criteria. Results: only one restoration showed moderate post-op sensitivity after 1 year. Another restoration showed slight but still acceptable discoloration (CS and SS) not requiring replacement, with a slight discoloration at the interface (MI, MD). All restorations showed proper retention and no secondary caries. Conclusions: The restorative material used in this study showed acceptable clinical performance after 1 year of clinical service. Longer clinical trials will elucidate clinical behavior of Gradia direct resin composite in combination with UniFil bonding system.

8.0 Literature

1. K. Matsunae, S. Akahane, K. Hirota. Effect of bonding layer thickness on tensile bond strength. R&D Dept. GC Corporation, Tokyo, Japan. Data on file.

2. S. Phrukkanon, M.F. Burrow, M.J. Tyas. The effect of dentine location and tubule orientation on the bond strengths between resin and dentine. Journal of Dentistry 27 (1999) 265-274.

3. S. Phurukkanon, M.F. Burrow, M.J. Tyas. The effect of dentin location and tubule orientation on Bond strengths. Abstract 2110 – 77th General Session of the IADR, 1999, Vancouver, Canada.

4. H. Inoue, S. Inoue, S. Uno, H. Komatsu and H. Sano. Adhesion of new simplified adhesive systems to human dentin. Abstract 2998 – 77th General Session of the IADR, 1999, Vancouver, Canada.

5. T. Yamada, J. Sugizaki, S. Horiguchi, M. Okuda. Tensile bond strength of newly designed self-etching primer Bonding system. Abstract 3428 – 77th General Session of the IADR, 1999, Vancouver, Canada.

6. Y. Yoshida, B. Van Meerbeek, Y. Nakayama, J. Snauwaert, L. Hellemans, P. Lambrechts, G. Vanherle and K. Wakasa. Evidence of chemical bonding at biomaterial-hard tissue interfaces. Journal of Dental Research, Vol. 79, 790-714, 2000.

7. B. Van Meerbeek, Y. Yoshida, S. Inoue, M. Vargas, Y. Abe, R. Fukuda, M. Okazaki, P. Lambrechts, G. Vanherle. Bonding mechanism and micro-tensile bond strength of a 4-MET-based self-etching adhesive. Abstract 845 - 78th General Session of the IADR, 2000, Washington, USA.

8. M.A. Vargas, B. Van Meerbeek, Y. Yoshida, C. Bergeron, P. Lambrechts, G. Vanherle. TEM evaluation of self-etching adhesives resin-dentin interfaces. Abstract 999 - 78th General Session of the IADR, 2000, Washington, USA.

9. N. Akimoto, G. Yokoyama, A. Kohno & C.F. Cox. Nanohardness and Bond Strength with new self-etching primer systems. Abstract 1705 – 78th Session of the IADR, 2000, Washington, USA.

10. S.B.V. Trevisan, R.R. Silveira, J.F. Soares, R.M. Carvalho, D.H. Pashley. Factors affecting the use of the microtensile bond strength technique. Abstract 1741 – 78th General Session of the IADR, 2000, Washington, USA.

11. A. Urayama, T. Kimochi, M. Yoshiyama, T. Matsuo, D.H. Pashley. Resin Bonding to in vitro artificial carious dentin. Abstract 1836 – 78th General Session of the IADR, 2000, Washington, USA.

12. C. Bergeron, M.A. Vargas, P. Gelinas and B. Van Meerbeek. Bond strength of self-etching adhesives to enamel. Abstract 2386 – 78th General Session of the IADR, 2000, Washington, USA.

13. G. Ibarra, M.A. Vargas, S.R. Armstrong. Microtensile bond strength of self-etching adhesives to unprepared enamel. Abstract 2387 - 78th General Session of the IADR, 2000, Washington, USA.

14. A. Koiwa, H. Terano, M. Okuda, R. Kishikawa, N.Inai, M. Otsuki, J. Tagami. Effect of high-powered curing lights on dentin bonding of composites. Abstract 2468 - 78th General Session of the IADR, 2000, Washington, USA.

15. A. Takahashi, Y. Sato, C. Kawamoto, M. Hashimoto, S. Uno, H. Komatsu. Effect of ultimate tensile strength of adhesives on bond strength. Abstract 2919 – 78th General Session of the IADR, 2000, Washington, USA.

16. M. Yoshiyama, T. Kimochi, A. Urayama, T. Matsuo and D.H. Pashley. Resin adhesion to caries-infected dentin. Abstract 2930 - 78th General Session of the IADR, 2000, Washington, USA.

17. S. Inoue, M.A. Vargas, Y. Abe, Y. Yoshida, P. Lambrechts, G. Vanherle, H. Sano, B. Van Meerbeek. Microtensile Bond Strength of Eleven Contemporary Adhesives to Dentin. The Journal of Adhesive Dentistry, Vol. 3, No 3, 2001.

18. G. Eliades, G. Mountouris. Bonding mechanism of a 4-MET self-etching primer with dentin. A combined XPS and FTIR study. Abstract 372 – 37th Annual Session of the EADR, 2001, Rome, Italy.

19. S. Uno, H. Inoue, W.J. Finger, S. Inoue, H. Sano. Microtensile Bond Strength Evaluation of Three Adhesive Systems in Cervical Dentin Cavities. The Journal of Adhesive Dentistry, Vol. 3, No 4, 2001.

20. G. Honjo, M. Miyazaki, H. Onose and B.K. Moore. Effect of self-etching primer application method on enamel bond strength. Abstract 204 – 30th Annual Meeting of the AADR, 2001, Chicago, USA.

21. T. Maseki, M. Miyamato, I. Kizuki, T. Kimshima, Y. Nara, H. Tanaka and I.L. Dogon. Microleakage of one-step and two-step adhesive systems under thermocycling and simultaneous repeated load. Abstract 562 – 30th Annual Meeting of the AADR, 2001, Chicago, USA.

22. R. Fukada, Y. Yoshida, B. Van Meerbeek, P. Lambrechts, G. Vanherle, M. Okazaki, H. Shintani. Analysis of chemical bonding potential of poly-acids to enamel and dentin. Abstract 1066 - 79th General Session of the IADR, 2001, Chiba, Japan

23. B. Van Meerbeek, Y. Abe, Y. Yoshida, P. Lambrechts, G. Vanherle, H. Sano. Micro-tensile bond strength of eleven modern adhesive systems to enamel. Abstract 0132 - 79th General Session of the IADR, 2001, Chiba, Japan

24. T. Ikeda, A. Takahashi, Y. Sato, C. Kawamoto, H. Sano. Micro-tensile strengths of adhesives before and after irradiation through composite. Abstract 0494 - 79th General Session of the IADR, 2001, Chiba, Japan

25. K.J. Ryu, H.Y. Choi, S.J. Park, G.W. Choi, K.K. Choi. Effect of salivary contamination of teeth on bonding efficacy of various dentin bonding systems. Abstract 1049 - 79th General Session of the IADR, 2001, Chiba, Japan

26. A. Takahashi, C. Kawamoto, S. Inoue, R. Ominato, Y. Sato, T. Tanaka, S. Uno and H. Sano. Long-term durability of two adhesive systems in vivo. Abstract 1442 - 79th General Session & Exhibition of the IADR, 2001, Chiba, Japan.

27. B. Van Meerbeek, M. Peumans, P. Lambrechts, G. Vanherle, M. Vargas, S. Inoue, Y. Yoshida. Adhesives and cements to promote preservation dentistry. Operative Dentistry, Supplement 6, 2001, 119-144.

28. M. Otsuki, M. Yamauti, J. Tagami, R.M. Carvalho, N.R.F.A. Silva and M.V. Fuentes. Dentin bond strength of auto-cured composite with/without flowable composite. Abstract 360 - 80th General Session of the IADR, 2002, Chicago, USA.

29. A. Takahashi, Y. Sato, S. Uno, P.N.R. Pereira, H. Sano. Effects of mechanical properties of adhesive resins on Bond strength to dentin. Dental Material 18 (2002) 263-268

30. J.-I. Seo, K.-Ch. Cho, Y.-G. Cho. Marginal Microleakage of Self-Etching Primer Adhesive and a Self-Etching Adhesive. Poster-presentation P-7 - Annual Session of the Japanese Society of Conservative Dentistry, November 2002

31. E.J. Swift Jr. Glass ionomers. Journal of esthetic and restorative dentistry, Volume 14, Number 6, 2002.

32. A. Takahashi, S. Inoue, C. Kawamoto, R. Ominato, T. Tanaka, Y. Sato, H. Sano, P.N.R. Pereira. In vivo long-term durability of the bond to dentin using two adhesive systems. Journal of Adhesive Dentistry 2002, 4: 151-159.

33. A. Itthagarun, F.R. Tay, D.H. Pashley, J. Wefel, S.H.Y. Wei, S.H.Y. Wei and S.H.Y. Wei. Single-step adhesives are semi-permeable membranes. III. Fluoride-releasing evidence. Abstract 3830 - 80th General Session of the IADR, 2002, San Diego, USA.

34. W.J. Finger, M.Bakenhol. Comparative in vitro evaluation of self-etching primer adhesives. Abstract 2430 - 80th General Session of the IADR, 2002, San Diego, USA.

35. J.M. Kwon, H.-Y. Choi, S.-J. Park, G.-W. Choi and K.-K. Choi. Microtensile bond strength of bonding agents added microfiller to bovine teeth. Abstract 1989 – 80th General Session of the IADR, 2002, San Diego, USA.

36. T. Itota, Y. Torii, S. Nakabo, M. Yoshiyama. Effect of fluoride application on tensile bond strength of self-etching adhesive systems to demineralized dentin. The Journal of Prosthetic Dentistry, November 2002, Vol.88, Number 5, p.503-510

37. Y. Yoshida, B. Van Meerbeek, M. Okazaki, H. Shintani and K. Suzuki. Comparative study on adhesive performance of functional monomers. Abstract 0051 – 81st General Session of the IADR, 2003, Göteborg, Sweden.

38. G. Vougiouklakis, A. Ntasi and G. Eliades. A comparative study of the effect of water storage on conventional, self-etching, and adhesive liquid resins. Abstract 0056 – 81st General Session of the IADR, 2003, Göteborg, Sweden.

39. M. Chakmakchi, G. Eliades and T. Eliades. Effects of self-etching primers on the conversion of adhesive resin components. Abstract 0056 – 81st General Session of the IADR, 2003, Göteborg, Sweden.

40. J.C. Chang, L.M. Pinzon, T.M. Vuu, C.D. Johnson and S.H. Koh. Tensile bond strengths of bonding agents with composite and enamel. Abstract 0345 - 81st General Session of the IADR, 2003, Göteborg, Sweden.

41. M. Giannini, M.F. De G"Es, T. Nikaido, Y. Shimada and J. Tagami. Influence of acidic monomers on dentin bond strength of composite resin cores. Abstract 0348 - 81st General Session of the IADR, 2003, Göteborg, Sweden.

42. K. Kida, Y. Momoi and A. Kohno. Water sorption and disintegration of various dental adhesives containing fluoride. Abstract 0372 - 81st General Session of the IADR, 2003, Göteborg, Sweden.

43. K. Fujita, S. Sugiyama, N. Yamamoto, T. Ikemi, N. Nishiyama, K. Nemoto and T. Ishizaki. Adhesion mechanism of self-etching primer adhesives. Abstract 0858 - 81st General Session of the IADR, 2003, Göteborg, Sweden.

44. K. Koshiro, S. Inoue, T. Tanaka, K. Koase, M. Hujita, M. Hashimoto, J. De Munck, B. Van Meerbeek and H. Sano. In vivo long-term durability of adhesives bonded to monkey dentin. Abstract 0905 - 81st General Session of the IADR, 2003, Göteborg, Sweden.

45. M. Irie, R. Tjandrawinata and K. Suzuki. Effect of one-day storage on gap formation in direct restorations. Abstract 1972 - 81st General Session of the IADR, 2003, Göteborg, Sweden.

46. T. Ikeda, A. Takahashi, T. Tanaka, S. Inoue and H. Sano. Mechanical properties of adhesive resins at 5 minutes after light-curing. Abstract 2600 - 81st General Session of the IADR, 2003, Göteborg, Sweden.

47. GC UniFil Bond – rating; The Dental Advisor, Vol.20, No.7, September 2003

48. M. Yamada, M. Miyazaki, K. Hinoura and B.K. Moore. Influence of interchanging primers and bond agents on dentin bond. Abstract 1733 – 82nd General Session of the IADR, 2004, Honolulu, Hawaii.

49. S. Hirabayashi. Effect of grinding condition on bond strength of self-etching system. Abstract 1738 – 82nd General Session of the IADR, 2004, Honolulu, Hawaii.

50. B. Maxson, N.P. Mutch, A.L. Neme, F.E. Pink. Microleakage comparison of adhesive systems in Class V composite restorations. Abstract 2827 – 82nd General Session of the IADR, 2004, Honolulu, Hawaii.

51. M.L. Cannon, R. Jurado. Flexural strangth and modulus of interface between composite and RMGI. Abstract 3128 – 82nd General Session of the IADR, 2004, Honolulu, Hawaii.

52. C.A.G. Arrais, A.F. Reis, P.D. Novaes, R.M. Carvalho, M.F. De Goes and M. Giannini. Ultramorphological SEM/TEM analysis of the resin-dentin bond degradation: nanoleakage expression. Abstract 3225 – 82nd General Session of the IADR, 2004, Honolulu, Hawaii.

53. M. Irie and K. Suzuki. Effect of delayed polishing on gap formation in flowable composites. Abstract 3131 – 82nd General Session of the IADR, 2004, Honolulu, Hawaii.

54. S. Chersoni, P. Suppa, S. Grandini, C. Goracci, F. Monticelli, C. Yiu, C. Huang, C. Prati, L. Breschi, M. Ferrari, D.H. Pashley and F.R. Tay. In vivo and in vitro permeability of one-step self-etch adhesives. J Dent Res 83 (6):459-464, 2004

55. Y. Yoshida, K. Nagakane, R. Fukuda, Y. Nakayama, M. Okazaki, H. Shintani, S. Inoue, Y. Tagawa, K. Suzuki, J. De Munck and B. Van Meerbeek. Comparative study on adhesive performance of functional monomers. J Dent Res 83 (6):454-458, 2004

56. K. Koshiro, S. Inoue, T. Tanaka, K. Koase, M. Fujita, M. Hashimoto, H. Sano. In vivo degradation of resin-dentin bonds produced by a self-etch vs. a total-etch adhesive system. Eur J Oral Sci; 12: 368-375

57. A. Itthagarun, F.R. Tay, D.H. Pashley, J.S. Wefel, F. García-Godoy, S.H.Y. Wei. Single-step, self-etch adhesives behave as permeable membranes after polymerization. Part III. Evidence from fluid conductance and artificial caries inhibition. American Journal of Dentistry, Vol.17, No.6,December,2004

58. R.N. Garcia, M. Giannini, M.F. de Goes. Effect of water storage on bond strength of self-etching adhesives to dentin. Japan Society for Adhesive Dentistry – Vol.22, N°4, 2005

59. H. Ibayashi, K.K. Chen, K. Sadakata, T. Ooki and M. Terashita. Effect of air blow pressure on tensile bond strength of a new one bottle bonding system. Japan Society for Adhesive Dentistry – Vol.22, N°4, 2005

60. R.S. Hayes, W. De Rijk. Shear bond strength of self etching adhesives to resin cements. Abstract 1678 - IADR, March 2005, Baltimore, Maryland, USA *

61. S. Sautter, J. Lindblom, N. McElwee, D. Ajdic, S.S. Khajotia. Quantitative analysis of streptococcus mutans adherence to various dental materials. Abstract 2710 - IADR, March 2005, Baltimore, Maryland, USA *

62. M.T. Oliveira, P. Freitas, C.D.P. Eduardo, G.M.B. Ambrosano, M. Giannini. Effect of cavity preparation techniques on bond strength to dentin. Abstract 2953 - IADR, March 2005, Baltimore, Maryland, USA *

63. Y. Nishitani, S. Ito, M. Hashimoto, M. Yoshiyama, D. Pashley. Effects of eccentric/concentric specimen attachment on micro-tensile bond strength. Abstract 2961 - IADR, March 2005, Baltimore, Maryland, USA *

64. F. Papacchini, C. Goracci, F. Tranchesi Sadek, F. Monticelli, F. Garcia-Godoy, M. Ferrari. Microtensile bond strength to ground enamel by glass-ionomers, resin-modified glass-ionomers, and resin composites used as pit and fissure sealants. Journal of Dentistry (2005) 33, 459-467

9.0 Packaging

1. Kit:
   Self-Etching Primer 6ml, Bonding Agent 6ml, 50 micro-tip applicators (25 each pink/yellow), applicator holder, dispensing dish (No.2) and protective cover (No.1)

2. Replacement packages
   a. Self-Etching Primer 6ml
   b. Bonding Agent 6ml

   Option:
   Box of Micro-tip applicator (250 each pink/yellow) with applicator holder (4)
   Other items are available separately.

10.0 Instructions for use

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

RECOMMENDED INDICATIONS
Bonding of light cured composites to tooth structure.

CONTRAINDICATIONS

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

DIRECTIONS FOR USE

1. CAVITY PREPARATION
   Prepare tooth in usual manner. Dry the prepared tooth surfaces by gently blowing with an air syringe.

   Note: For pulp capping, use calcium hydroxide.

2. APPLICATION OF UniFil®Bond SELF-ETCHING PRIMER
   Dispense 1 or 2 drops of UniFil® Bond SELF ETCHING PRIMER into the dispensing dish provided. Apply the primer to the enamel and dentin surfaces on the prepared tooth using a pink disposable micro-tip applicator provided, leave undisturbed for 20 seconds.

   Note:
   1) Prior to use, leave the primer bottle at room temperature for 5 minutes after removing from refrigerator.
   2) After dispensing, use as quickly as possible.
   3) Do not allow the primer to contact oral tissues. In case of contact, immediately remove with a sponge or cotton. Rinse thoroughly with water after placing composite.
   4) Replace bottle cap immediately after use.

3. DRYING THE SELF-ETCHING PRIMER
   20 seconds after application, gently dry with an air syringe for 5 seconds and ensure that the primed surface has a glossy appearance. Do not rinse away.

   Note: Should the applied Primer be rinsed away, dry the cavity and re-apply primer.

4. APPLICATION OF UniFil® Bond BONDING AGENT
   Dispense 1 or 2 drops of UniFil® Bond BONDING AGENT into the dispensing dish. Immediately apply to the primed enamel and dentin surfaces using a yellow colored micro-tip applicator. Blow gently with an air syringe to form a thin film.

   Note:
   1) Prior to use, leave the bottle of Bonding agent at room temperature for 5 minutes after removing from refrigerator.

2) Take care not to mix with SELF-ETCHING PRIMER.
3) After dispensing, protect from light and use as quickly as possible.
4) Replace bottle cap immediately after use.
5) Prior to blowing gentle air, make sure that no water or oil is injected from the air syringe as this can adversely affect bonding effectiveness.
6) Be sure to use UniFil® Bond Self-etching Primer with Bonding Agent. Do not use other primers.

5. LIGHT CURING OF BONDING AGENT
Light cure for 10 seconds using a visible light curing unit (470nm wavelength)*.
In case of deep cavities, light cure for a minimum of 20 seconds.

*Irradiation time by light curing device

Halogen (GC, Co-bee or Coe Lunar TA)	10 sec.
Plasma arc (GC Flipo)	3 sec.

Note:
When light curing material, wear eye protection glasses.

6. PLACEMENT OF LIGHT-CURED COMPOSITE
For placement of light-cured composite, follow manufacturer's instructions for use.

STORAGE

Store in a refrigerator (2-8°C/35.6-46.4°F) when not in use.
(Shelf life: 2 years from date of manufacture)

CAUTION

1. UniFil® Bond SELF-ETCHING PRIMER is flammable. Do not use near naked flame. Keep away from sources of ignition. Keep away from sunlight. Use in a well ventilated place.
2. In case of contact of UniFil® Bond SELF-ETCHING PRIMER and BONDING AGENT with oral tissues or skin, immediately remove with a sponge or cotton. Flush with water. Note that the primer affected part may turn white. In this situation, instruct the patient to leave undisturbed until the mark disappears in 2-3 days.
3. In case of contact with eyes, flush immediately with water and seek medical attention.
4. Take special care that the patient should not swallow the PRIMER or BONDING agent.
5. Do not mix with other similar products.
6. Do not use with chemically cured composite resins.