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Noritake

CLEARFIL™ SE BOND 2

SCIENTIFIC PRODUCT INFORMATION

Kuraray Noritake Dental Inc.

CLEARFIL™ SE BOND 2

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1 Introduction

Kuraray launched its first bond system, "CLEARFIL™ BOND SYSTEM F," which was a total-etch system, in 1978. This was followed by the introduction of "CLEARFIL™ NEW BOND" and "CLEARFIL™ PHOTO BOND," which were two bond systems that performed even better. After the development of the "CLEARFIL™ LINER BOND SYSTEM," which featured a mild etching agent and primer, a 2-step self-etch system, "CLEARFIL™ LINER BOND 2," was subsequently developed. The self-etching system was then advanced by the introduction of "CLEARFIL™ LINER BOND 2V," which had multiple clinical applications, and "CLEARFIL™ SE BOND" that was designed to be simple to use in the clinic. This has evolved to single-step self-etch systems called "CLEARFIL™ TRI-S BOND," "CLEARFIL™ DC BOND," and "CLEARFIL™ TRI-S BOND PLUS." In addition, Kuraray developed a 2-step self-etch system, "CLEARFIL™ SE PROTECT (CLEARFIL™ PROTECT BOND) ," which contains "MDPB," an antibacterial monomer, and a fluorine-releasing filler to expand adhesive technology and develop high-performance adhesives. "CLEARFIL™ LINER BOND F" was also developed using the fluoride-releasing filler introduced in the "CLEARFIL™ SE PROTECT." Now, Kuraray Noritake Dental Inc. has developed "CLEARFIL™ SE BOND 2." It takes over the features of the "CLEARFIL™ SE BOND," which was evaluated by dental universities to be the gold standard based on outstanding long-term clinical results and scientific evidence, and can be applied for wider indications than ever before.

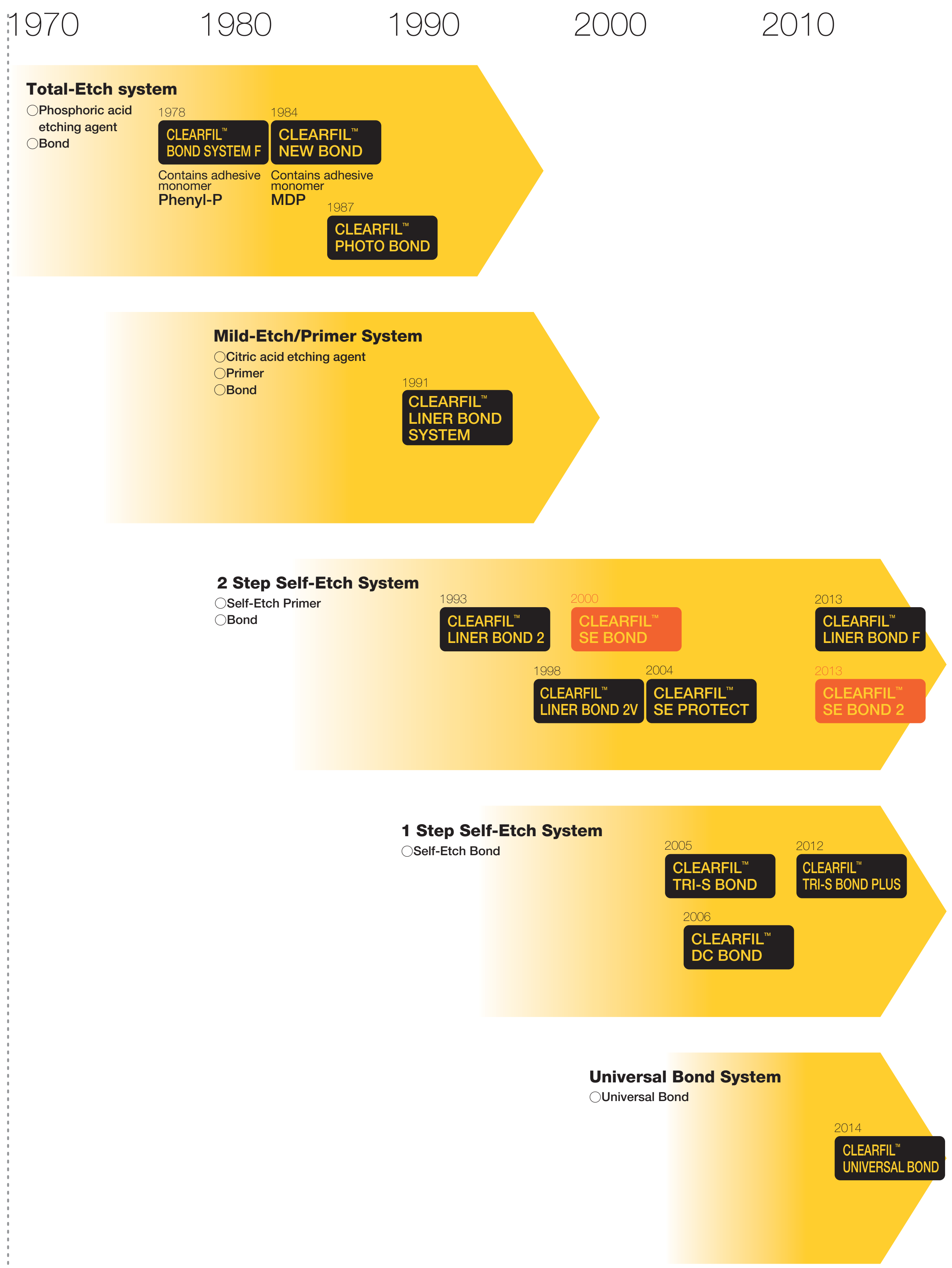


Fig.1 A brief history of the development of bonding materials by Kuraray Noritake Dental

2 History and Technology

2.1 Development of Adhesion Technology

Kuraray first entered the dental business in Japan in the early 1970's, utilizing the "GK-101" system, which selectively removes carious tooth structure without pain, using a chemical solution. At that time, we started to establish a dental treatment system including filling materials that could be applied into a cavity that had been prepared by selectively removing carious tooth structure without any retention form being created.

Kuraray had been working on research and development of new adhesion technologies, on the assumption that adhesion is an essential factor in the achievement of excellent dental restorations, resulting in the development of the phosphate ester monomer, "Phenyl-P"[1]. Based on this discovery, we developed "CLEARFIL™ BOND SYSTEM F", an adhesive resin system designed for tenacious adhesion to tooth structure. "Phenyl-P" came to the forefront again during the development of a self-etching primer because of its acidity and adhesion to tooth structure, and was employed as one of the main ingredients of "CLEARFIL™ LINER BOND 2"[2]. It can be said that the compound "Phenyl-P" played an important role in the advent of an adhesive dental material.

Resin-based dental adhesive materials contain a radically-polymerizable monomer (acrylic monomer) and a polymerization initiator as their basic ingredients, and they contain fillers to improve their physical properties depending on the applications. In resin type adhesive materials, a radically-polymerizable monomer or so-called adhesive monomer that contains a functional group reactive to the adherent plays a key role. Of course, this adhesive function is not attained solely due to the presence of the adhesive monomer. The polymerization and curing technology is also an essential factor in adhesion. Since the conventional BPO/amine polymerization initiator system would not cure phosphate ester adhesive monomer, we also developed a tertiary polymerization initiator containing aromatic sulfinic acid salt along with the development of "Phenyl-P". This completed the first phase of our basic adhesion technology. (**Fig.2**)

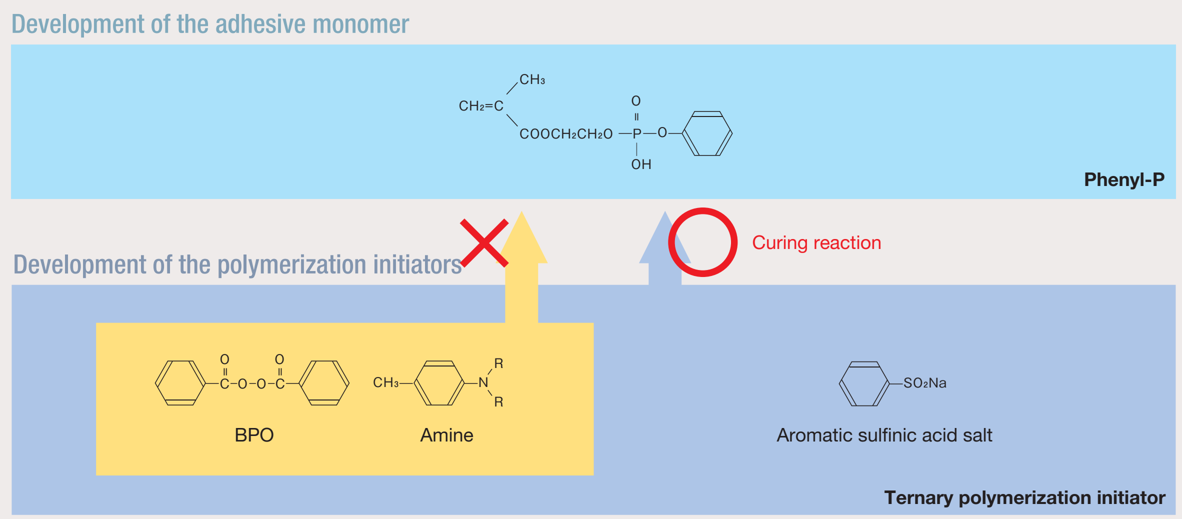


Fig.2 Development of the adhesion technology

2.2 Optimizing the Chemical Structure of the Adhesive Monomers

With the goal of developing a better adhesive monomer than "Phenyl-P," Kuraray analyzed the chemical composition of "Phenyl-P" in detail to gain a deeper understanding of the function of each component in the adhesive monomer and to optimize its chemical composition (**Fig.3**).

The chemical structure of an adhesive monomer can be roughly divided into three categories: (1) polymerizable groups, (2) a spacer, and (3) reactive groups. As an example of how the chemical structure of an adhesive monomer affects its adhesive properties, the relationships between the length of the spacer, the valence number of the reactive group (phosphate group), and the bond strength of the adhesive monomer to dentin and Ni-Cr alloy are shown below. (**Fig.4** and **Fig.5**).

This study provided us with a great deal of insight into the chemical composition of the adhesive monomers and gave us a better understanding of the ideal structure. As a result, we learned that the following are key factors that result in the delivery of a high level of adhesion:

- The spacer must be a hydrophobic group with 4 or more carbon atoms.
- The reactive group must be a divalent phosphate group.
- There must be a radical polymerizable group.

Taking advantage of these findings, we invented "Methacryloyloxydecyl Dihydrogen Phosphate (MDP)" an adhesive phosphate monomer that bonds well to metals as well as to the structure of the tooth (**Fig.6**) [3].

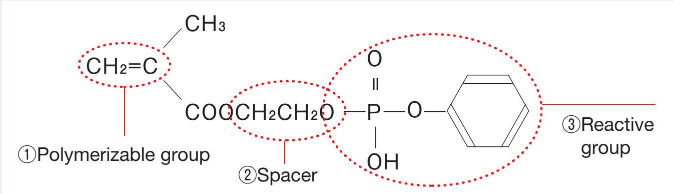


Fig.3 The chemical structure of adhesive monomer (Phenyl-P)

Effect on the bond strength to dentin

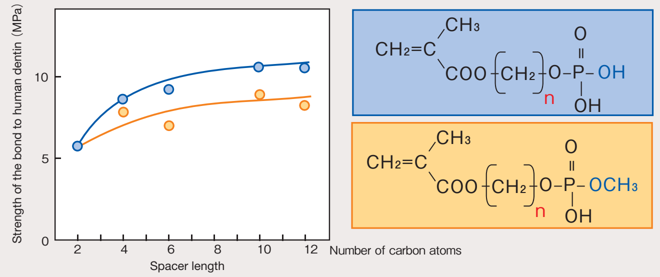


Fig.4 Optimizing the chemical structure of the adhesive monomers (1)

Effect on the bond strength to Ni-Cr alloy

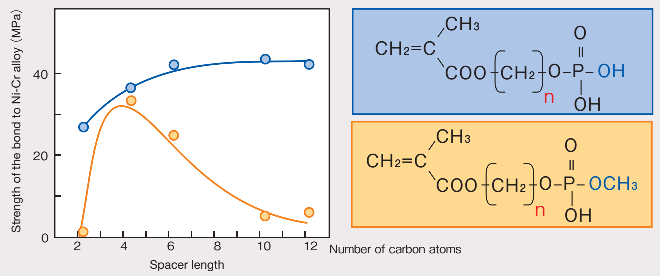


Fig.5 Optimizing the chemical structure of the adhesive monomers (2)

The Chemical structure of the reactive group

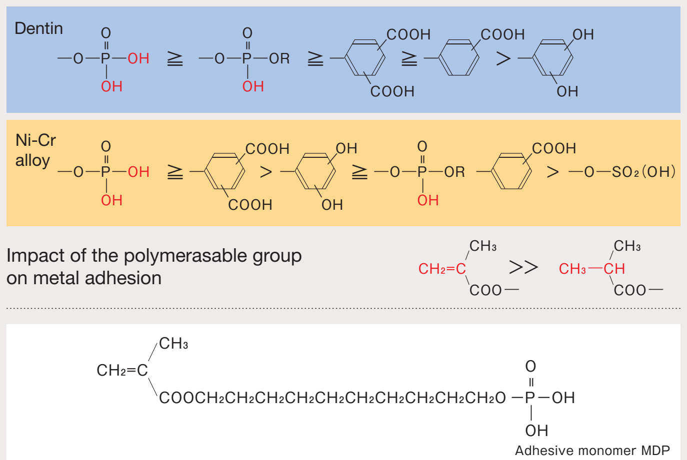


Fig.6 Optimizing the chemical composition of an adhesive monomer (3)

2.3 Characteristics of the Original Adhesive Phosphate Monomer (MDP)

The adhesive phosphate monomer, MDP, exhibits high bond strength for adhesion to tooth structures (e.g., dentin, enamel), metals (e.g., gold, silver, titanium, stainless, aluminum), metal oxides (e.g., zirconia, alumina), and composite resins that include inorganic fillers.

These exceptional adhesive characteristics are due to its unique structural formula, which is composed of a polymerization group, a dihydrogen phosphate group, and a long carbon (long alkylene) chain. Recently, the solubility of the calcium salt of the adhesive monomer has been studied extensively. The presence of a lower solubility in water indicates that a very stable chemical bond is formed with the hydroxyapatite surface. Studies conducted using atomic absorption spectroscopy have demonstrated major differences between the adhesive monomers (Yoshida et al., I Dent Res 83 (6) 454 – 458, 2004) [4].

The solubility rate of the calcium salt of the 4-MET monomer (4-methacryloxyl trimellitic acid), i.e., 1.36 g/L was about 200 times greater than that of the MDP monomer, (6.79 mg/L). The calcium salt created from MDP was thus hardly soluble in water and was effective in chemically bonding to dentin and enamel.

Kuraray has a great deal of experience in using our original MDP. As such, we have utilized it as a key component in our adhesive materials, including "CLEARFIL™ SE BOND 2."

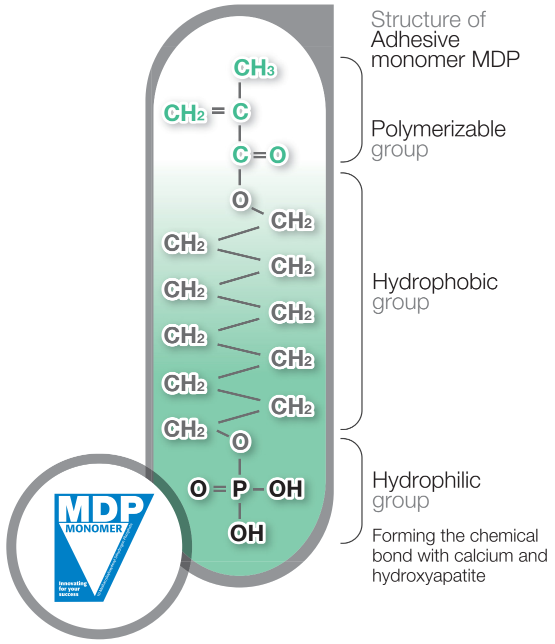


Fig.7 The MDP monomer

MDP is a dihydrogen phosphate adhesive monomer that is mildly acidic.

Its chemical structure contains a unique hydrophobic group, which allows for easy penetration into dentin due to its superior surface-active property.

A chemical bond with hydroxyapatite is established quickly. A stable adhesive bond is thus created during clinical preparation.

This high chemical bonding capacity to hydroxyapatite results in good adhesion to the enamel even without the use of a phosphoric acid etching agent.

The solubility of the calcium salt that is formed is very low. This significantly improves the long-term adhesive effect to tooth structures.

These excellent adhesion durability characteristics are seen not only with tooth structures but also with metals, metal oxides, and composites that include inorganic fillers.

2.4 Development of Total-Etch Systems

Recent advancements in dental bonding material technology are striking and a variety of bonding systems have been developed by many research institutions, including our company, to improve bonding to teeth and to simplify the bonding procedure (**Fig.8**).

The adhesive material in every bonding system fulfills the following three functions: (1) it demineralizes the tooth structure; (2) it penetrates into the tooth structure; and (3) it polymerizes. However, the adhesive performance varies greatly from system to system. In particular, bonding to dentin, which includes many organic and water, depends heavily on not only the adhesive monomer and the polymerization initiator to be used, but also on the bonding system.

A total etching system first etches the tooth surface with a phosphoric acid etching agent. Then a bonding agent is applied to the treated tooth surface. However, the use of an etching agent on the tooth surface often demineralizes the tooth structure so deeply that severe damage to the tooth occurs. Though there is the advantage that the degree of demineralization can be clearly observed, the additional problem is that the collagen exposed by demineralization can shrink during the washing or drying cycle, making it difficult for the bonding agent to penetrate thoroughly into the collagen. It is said that poor penetration of the bonding agent into collagen is one cause of weak bonds.

In order to reduce the damage caused to the tooth structure by the etching agent, in the mid-1980's we embarked on the development of the "CLEARFIL™ LINER BOND SYSTEM," which included a mild etching agent. This bonding system used an etching agent that contained citric acid and calcium chloride, which are milder than phosphoric acid. In addition, the primer of this system contained 5-NMSA. It swells any collagen that is shrunk during washing or drying, thus substantially strengthening the bond between the bonding agent and the dentin [5]).

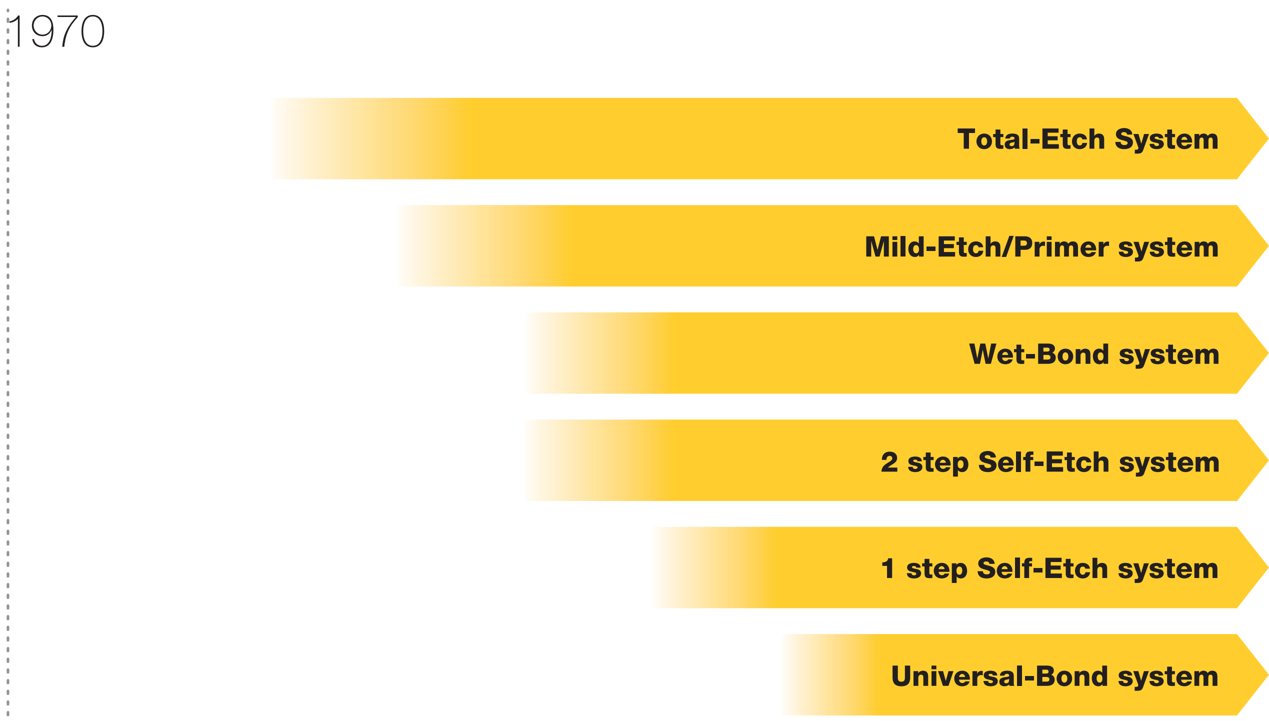


Fig.8 The development of a dental bonding system

2.5 Development of Self-Etch Systems

While the wet bonding system was attaining popularity in the global market, in about 1990, we began to develop a self-etch system with the objective to further improve the bond strength for adhesion to dentin and to create a simpler bonding procedure. The self-etch system that we developed consisted of a self-etch primer that etched and primed the tooth structure and a bonding agent that had excellent curing properties. Kuraray's self-etch primer contains an acidic monomer, water, and a hydrophilic monomer as its main ingredients. As a result, both demineralizing and priming take place simultaneously. In this self-etch system, there is no need to control the water content during the bonding procedure, which ensures a strong and stable bond (**Fig.9**). In addition, since a demineralized layer equates to a resin-penetrated layer, a dense "resin-impregnated layer" is created between the tooth structure and the bonding agent resulting in an ideal bonding situation.

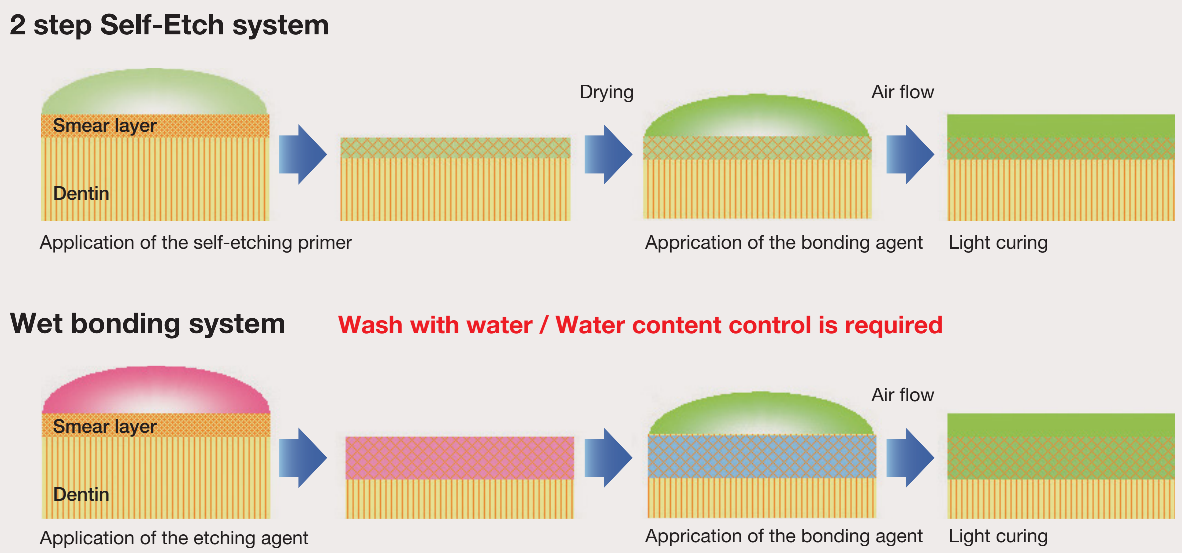


Fig.9 Differences in the clinical procedures used for Self-Etch systems and a Wet bonding systems

In addition, in the self-etching system, the dentinal tubules remain closed and the cavity is securely sealed. As such, there is little movement of the pulp fluid inside the dentinal tubules during biting, resulting in less postoperative sensitivity (**Fig.10**).

As shown above, a self-etching system results in a more reliable resin restoration procedure. Therefore, Kuraray has been improving the system to this day.

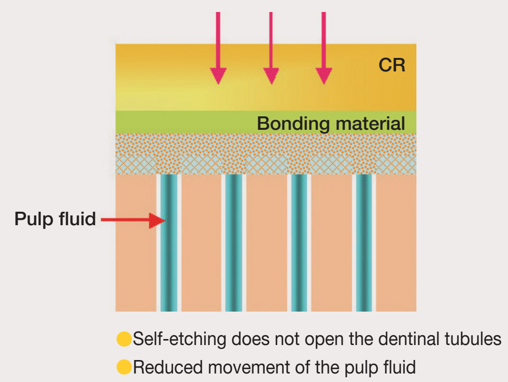


Fig.10 Suppression of postoperative sensitivity in the Self-Etch system

3 Product Description

"CLEARFIL™ SE BOND 2" is a two component, self-etch, light-cured bonding agent, which is intended for universal use for both direct and indirect restorations. The “PRIMER” allows for the simultaneous treatment of both dentin and enamel using a single liquid. The product is activated by a dual-cure mechanism when the “BOND” is mixed with the “CLEARFIL™ DC Activator.” This allows it to be used with dual-cure or self-cure composite filling materials, cements, or core build-up materials.

The excellent features that are inherited from “CLEARFIL™ SE BOND” include:

- Excellent bond strength with long-term marginal sealing
- Virtually no post-operative sensitivity
- Low technique sensitivity
- No need for a separate acid-etching nor a rinsing step
- Less attention to the moisture level of the tooth surface

The newly added outstanding characteristics include:

- New catalyst system for a stronger bond strength
- Versatile clinical applications in combination with the new “CLEARFIL™ DC Activator”
- Low film-thickness with indirect restorations
- Ideal adhesive layer for direct restorations
- Treatment of zirconia and alumina restorations with “CLEARFIL™ SE BOND 2 PRIMER”

3.1 Indications

[1] Direct restorations using light-cured composite resins
[2] Cavity sealing as a pretreatment for indirect restorations
[3] Treatment of exposed root surfaces
[4] Treatment of hypersensitive teeth
[5] Intraoral repairs of fractured restorations
[6] Post cementation using a dual- or self-cured composite resin
[7] Core build-ups using a light-, dual-, or self-cured core material
[8] Cementing inlays, onlays, crowns, bridges, and veneers using a composite resin cement

3.2 Composition and Principle Ingredients

3.2.1 CLEARFIL™ SE BOND 2

1) “PRIMER”

Principal ingredients:

- 10-Methacryloyloxydecyl dihydrogen phosphate (MDP)
- 2-Hydroxyethyl methacrylate (HEMA)
- Hydrophilic aliphatic dimethacrylate
- dl-Camphorquinone
- Water

2) “BOND”

Principal ingredients:

- 10-Methacryloyloxydecyl dihydrogen phosphate (MDP)
- 2-Hydroxyethyl methacrylate (HEMA)
- Bisphenol A diglycidylmethacrylate (Bis-GMA)
- Hydrophobic aliphatic dimethacrylate
- dl-Camphorquinone
- Initiators
- Accelerators
- Silanated colloidal silica

3.2.2 CLEARFIL™ DC Activator

CLEARFIL™ DC Activator is a dual-cure activator that contains alcohol, initiators and unique, advanced catalysts. It’ s indicated for use with CLEARFIL™ SE BOND 2.
When the “CLEARFIL™ SE BOND 2 BOND” is mixed with CLEARFIL™ DC Activator, it is activated by a dual-cure mechanism truly universal adhesives with low film-thickness and high bond strength. Light-curing the mixture is an option for optimum performance.

- Ethanol
- Catalysts
- Accelerators

3.3 Novel Integrated Photo-Initiator

Kuraray introduced a new “Integrated Photo-Initiators” which contributes to the rate of polymerization. Compared to conventional initiators, the new "Integrated Photo-Initiators" can generate more radicals when they are irradiated by a certain amount of light (**Fig.11**), which relates to higher monomer conversion rates and more stable and durable bond (especially when LED lights are used). (**Fig.12**)

Integrated photo initiator

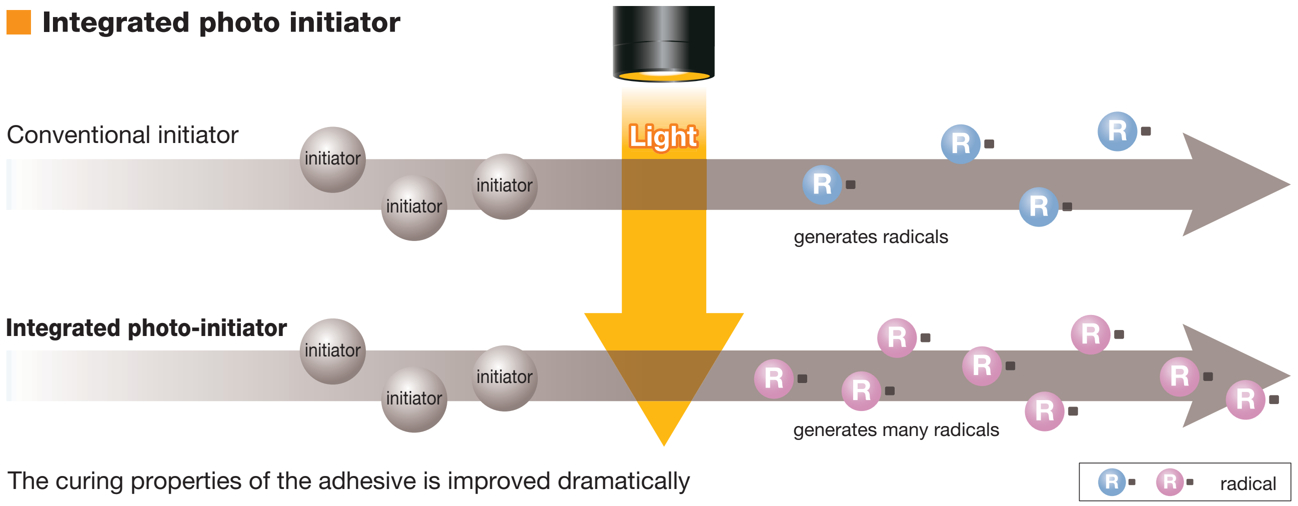
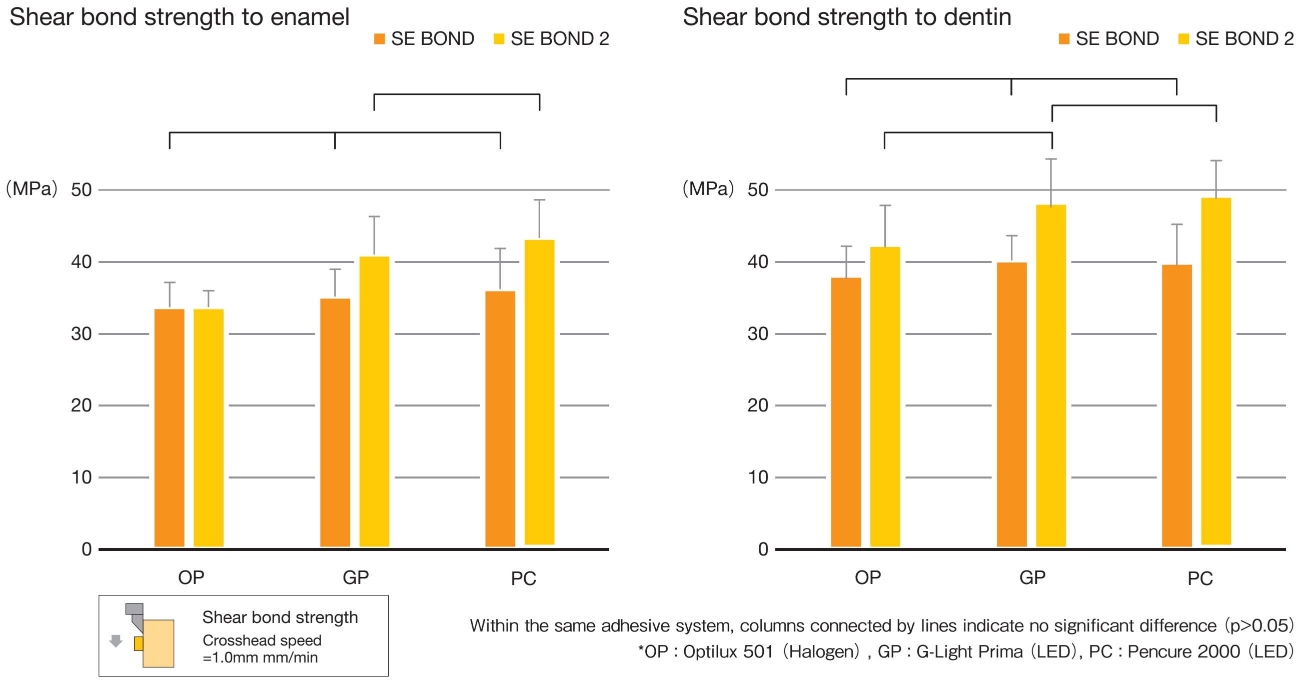


Fig.11 Integrated Photo-Initiator



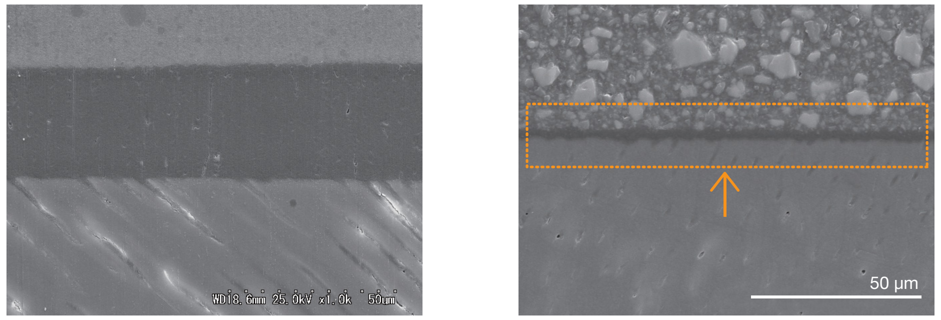
Within the same adhesive system, columns connected by lines indicate no significant difference (p>0.05)
*OP : Optilux 501 (Halogen), GP : G-Light Prima (LED), PC : Pencure 2000 (LED)

Fig.12 Influence of light irradiator for bonding agent on shear bond strength

Source : Data courtesy of Dr. Miyazaki, Nihon University School of Dentistry

3.4 Characteristics of the Combination with the CLEARFIL™ DC Activator

For indirect restorations, simply mix one drop of CLEARFIL™ SE BOND 2 BOND with one drop of CLEARFIL™ DC Activator. The film thickness of the mixture after air-drying is approximately 3-5μm, which is optimal for indirect applications.



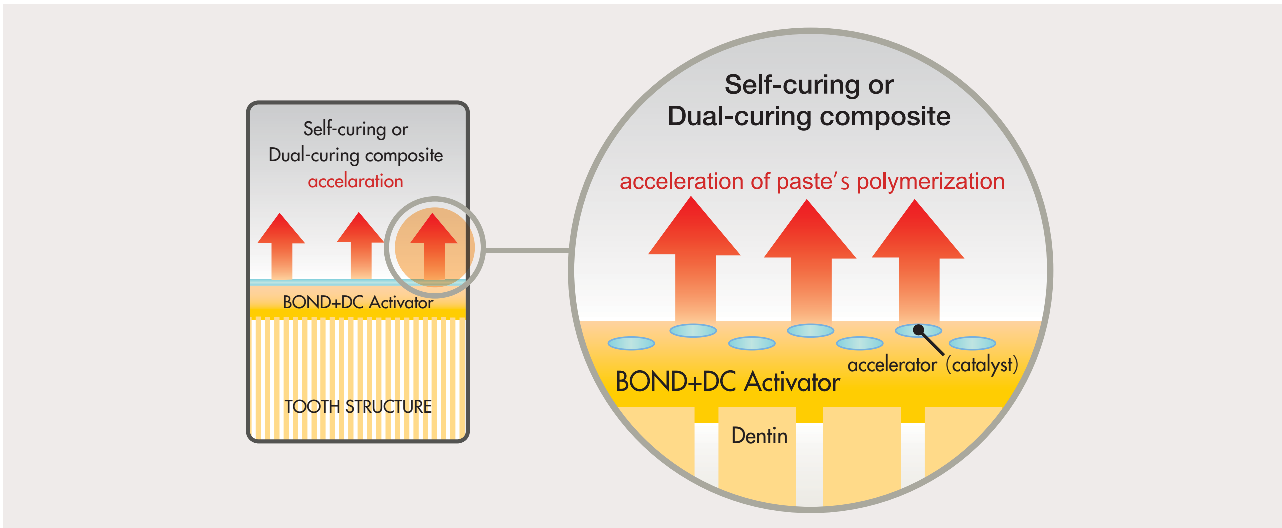
CLEARFIL™ SE BOND 2
50 μm

CLEARFIL™ SE BOND 2
with CLEARFIL™ DC Activator
3 - 5 μm

Fig.13 Bond Film Thickness

Source : Kuraray Noritake Dental Inc.,

CLEARFIL™ SE BOND 2 BOND with CLEARFIL™ DC Activator shows high bond strength to tooth structure with or without light-curing, and due to it’s unique technology, the acceleration of the polymerization starts at the bond-cement interface upon contact. Light-curing the mixture is an option for optimum performance.



4 In Vitro Investigations

4.1 Direct Restorations

4.1.1 Bond Strength for Adhesion to Tooth Structures

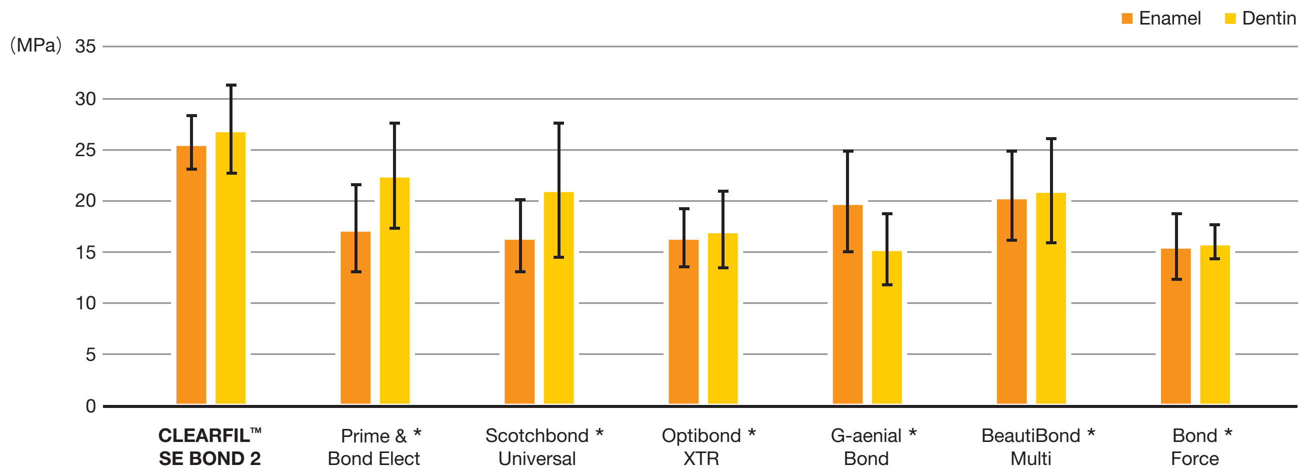


Fig.14 Immediate shear bond strength to enamel and dentin

Source : Data courtesy of Dr.M.Irie, Okayama University, Japan [6].

* Not a trademark of Kuraray Co., Ltd

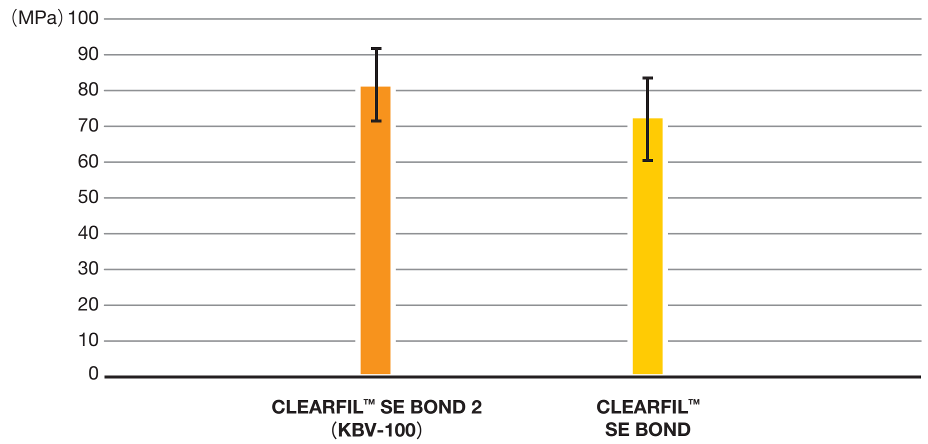


Fig.16 Microtensile Bond Strength to Dentin

Source : Data courtesy of Dr. J Tagami Tokyo Medical and Dental University, Japan [8].

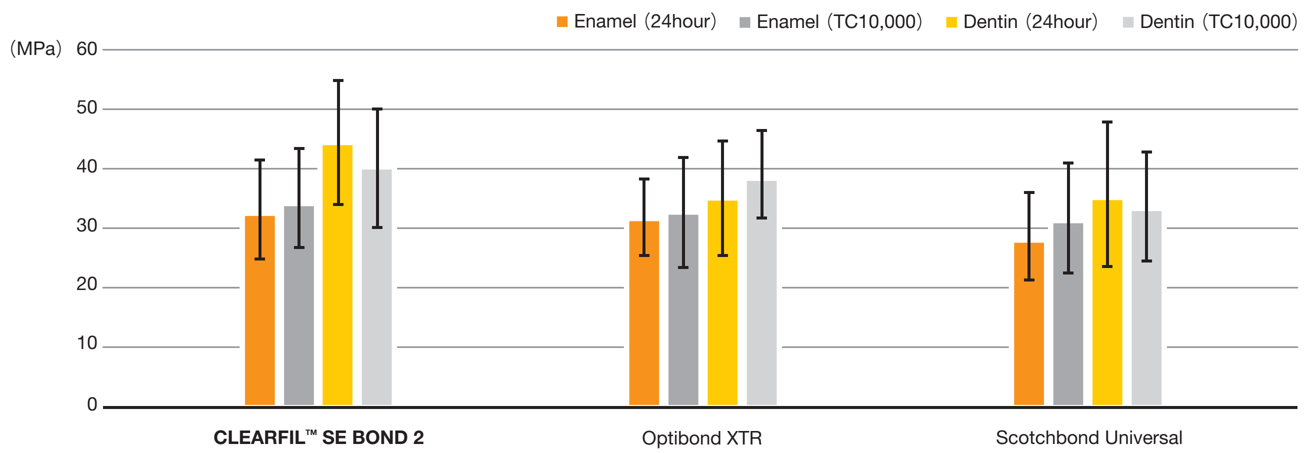
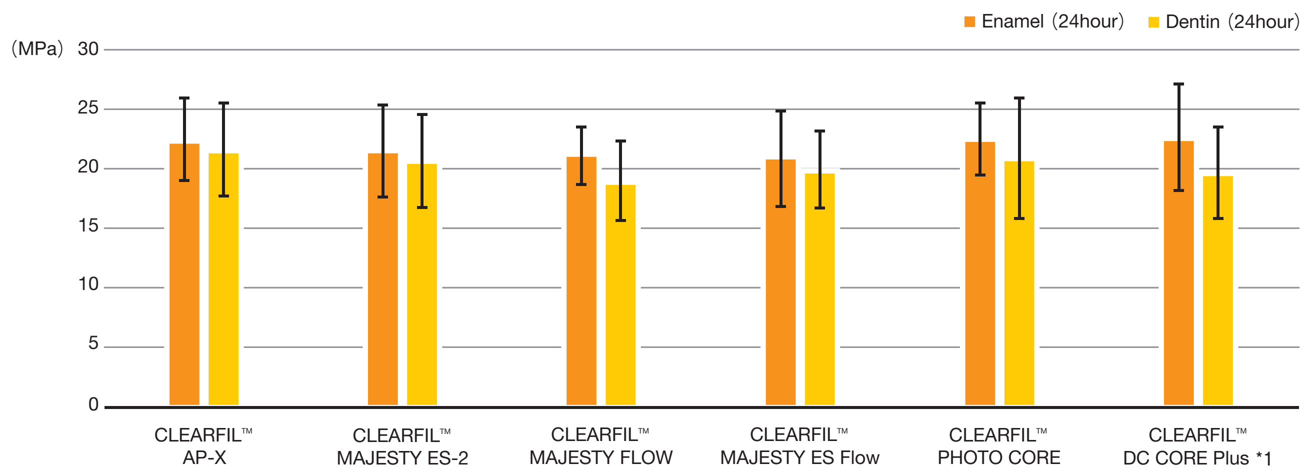


Fig.15 Shear bond strength to enamel and dentin

Source : Data courtesy of Dr. J. Burgess, University of Alabama at Birmingham, U.S.A [7].



*1 CLEARFIL™ SE BOND 2 BOND mixture with CLEARFIL™ DC Activator

Fig.17 Shear bond strength to enamel and dentin with various materials.

Source : Kuraray Noritake Dental Inc.,

4.1.2 Optical Coherence Tomography (OCT) Images

"CLEARFIL™ SE BOND 2" has excellent initial bond strength for adhesion to dentin (with the Original MDP adhesive monomer) & the ideal adhesive layer to withstand the increased polymerization stress with bulk-fill composites. This ideal combination results in GAP-FREE dentin margins when bulk-fill composites are used.

Optical coherence tomography (OCT) can be used for quantitative and qualitative assessment of the composite restorations. This technique can be used in real-time, thereby identifying gaps at the adhesive interface.

Fig.18 **Optical Coherence Tomography (OCT) images of the bonding interface with composite.**

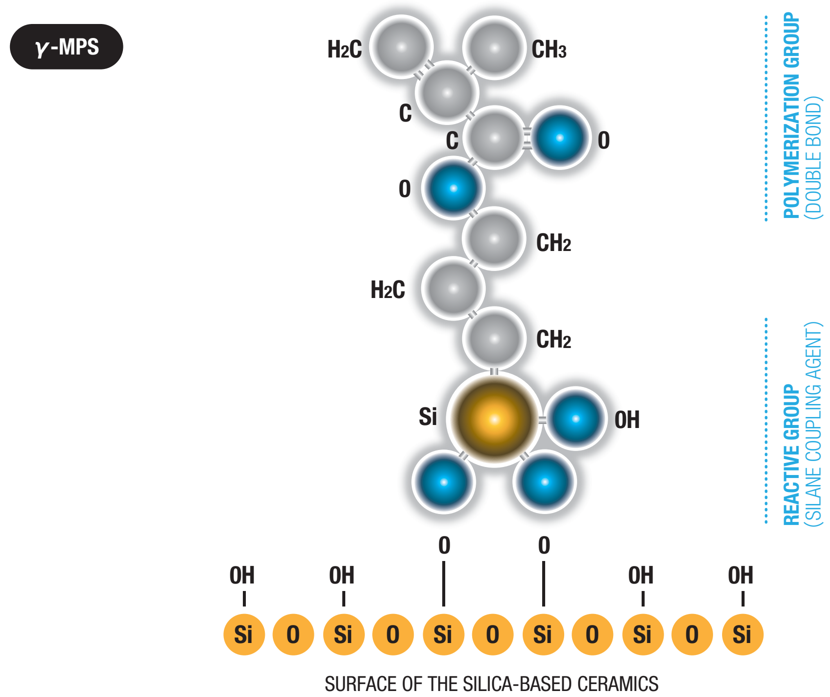
Images courtesy of Dr. Sadr and Dr. Tagami, Tokyo Medical & Dental University.
* Not a trademark of Kuraray Co., Ltd

4.1.3 Pretreatment of Various Materials

CLEARFIL™ PORCELAIN BOND ACTIVATOR

"CLEARFIL™ PORCELAIN BOND ACTIVATOR" is a non-activated, waterless, stable silane coupling agent. When mixed with "CLEARFIL™ SE BOND 2 PRIMER," it is activated and facilitates strong adhesion to glass ceramics and zirconia restorations.

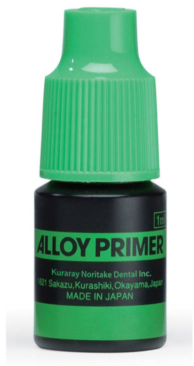
Fig.19 **ADHESION MECHANISM of γ-MPS TO SILICA-BASED CERAMICS**



MDP also results in very high bond strengths to porcelain and cured composite resin.

MDP activates the silane-coupling agent, "CLEARFIL™ PORCELAIN BOND ACTIVATOR," [9]), which promotes chemical bonding with porcelain or cured composite resin surfaces.

By mixing "CLEARFIL™ SE BOND 2 PRIMER" with "CLEARFIL™ PORCELAIN BOND ACTIVATOR," an effective agent for the simultaneous surface treatment of porcelain or cured composite resins, dental metals, and tooth structures, is created.



ALLOY PRIMER

"ALLOY PRIMER" is a metal adhesive primer that adheres to all dental metals. ALLOY PRIMER contains two adhesive monomers (Original MDP & triazine vinyl monomer (VBATDT)). MDP facilitates adhesion to base metal alloys (oxidizing metals) while VBATDT facilitates adhesion to non-oxidizing metals (eg. gold). ALLOY PRIMER is indicated for bonding composite or acrylic resins to metals and can be used for intra-oral & extra-oral bonding.

"CLEARFIL™ SE BOND 2" imparts a high bond strength for adhesion to precious metals following pretreatment with "ALLOY PRIMER." The significantly high affinity of MDP to metal oxides is used to realize bonding of the primer to non-precious metals. Furthermore, it contains VBATDT as an additional monomer, which allows for adhesion to precious metals [10].

Acetone is used as a fast-evaporating solvent.

Fig.20 ADHESION MECHANISM OF MDP TO A BASE METAL ALLOY

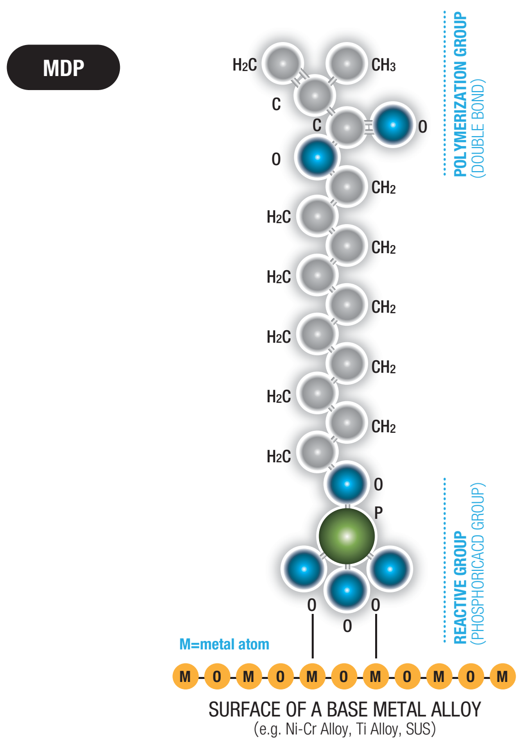
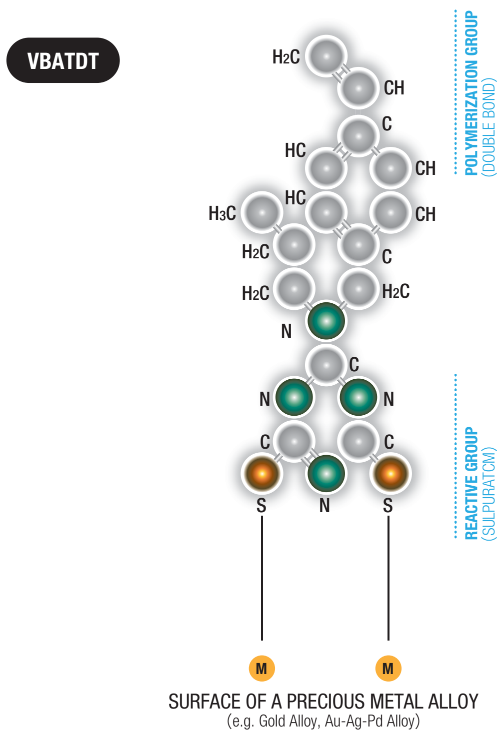


Fig.21 ADHESION MECHANISM OF VBATDT TO A PRECIOUS METAL ALLOY



*Both "CLEARFIL™ SE BOND 2" and "ALLOY PRIMER" contain the MDP monomer.

4.1.4 Bond Strength for Adhesion to Various Materials

To repair prosthesis intraorally, high adhesion to various materials are needed. Shear bond strength of CLEARFIL™ SE BOND 2 to various materials are shown in **Fig.22**.

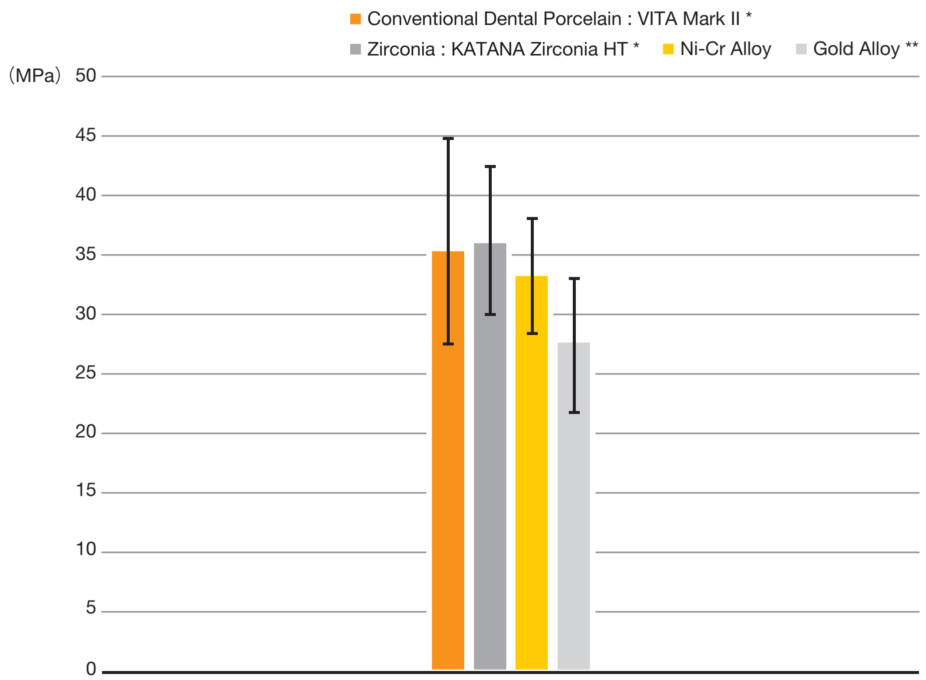
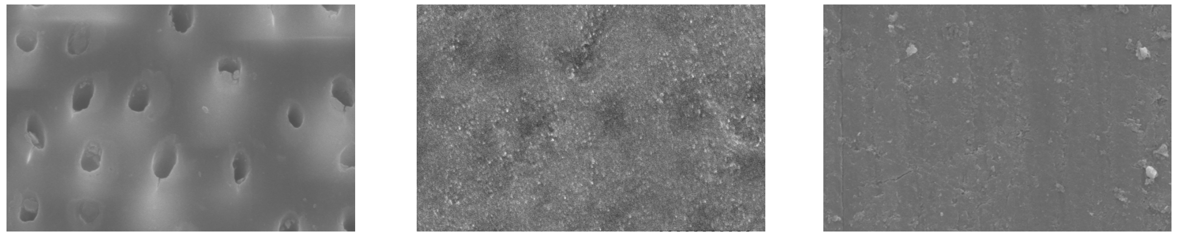


Fig.22 Shear Bond Strength to Various Materials 37℃ 1DAY

These surfaces are treated by the mixture of "CLEARFIL™ SE BOND PRIMER" and "CLEARFIL™ PORCELAIN BOND ACTIVATOR"
* Pretreatment by K-etchant GEL for 5 sec followed by washing and drying
** Pretreatment by "ALLOY PRIMER"
Source : Kuraray Noritake Dental Inc.

4.1.5 SEM Images of Dentin-Sealing

To estimate the efficacy of the indication, "treatment of hyper-sensitive teeth," the sealing performance of the “CLEARFIL™ SE BOND 2” for dentinal tubules was evaluated.
After polishing a bovine tooth with 1000-grit sic paper, we applied “CLEARFIL™ SE BOND 2” as a coat to the dentin surface.



Untreated surface | Initial surface (right after applying a coating) | Treated surface (After TC 10,000, treatment with a tooth brush 500 times)

Fig.23 Sealing durability

Source : Kuraray Noritake Dental Inc.,

Toothbrush abrasion followed by thermal cycling tests confirmed the excellent sealing durability of the “CLEARFIL™ SE BOND 2.”

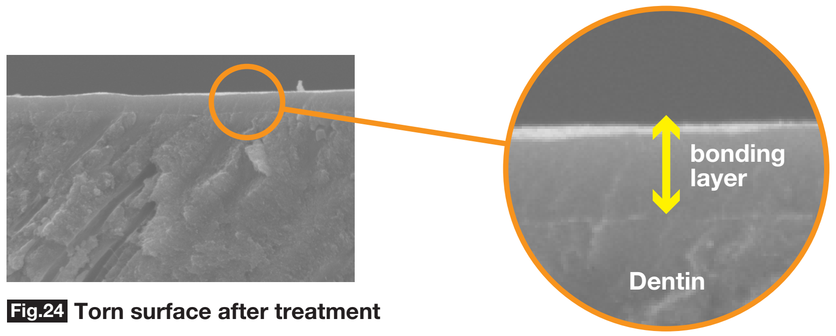


Fig.24 Torn surface after treatment

4.2 Indirect Restorations

4.2.1 Bond Strength for Adhesion to Tooth Structures

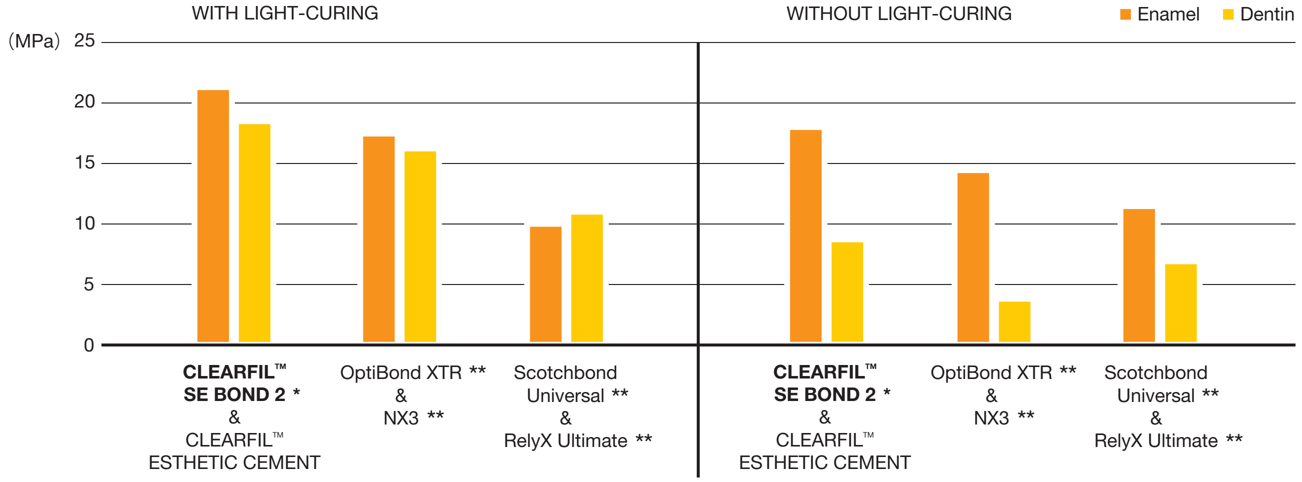


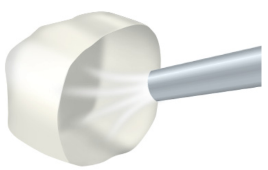
Fig.25 Tensile bond strength to the tooth structure with resin cements

* CLEARFIL™ SE BOND 2* BOND was mixed with CLEARFIL™ DC Activator.
** Not a trademark of Kuraray Co., Ltd
Source : Kuraray Noritake Dental Inc.,

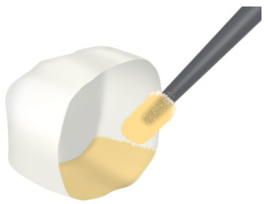
4.2.2 Bond Strength for Adhesion to Various Indirect Restoration Materials

The "CLEARFIL™ SE BOND 2 PRIMER" contains a high concentration of Kuraray's original MDP adhesion monomer and is used to treat the surface of zirconia and metal restorations.
Furthermore, the mixture liquid of the "CLEARFIL™ SE BOND 2 PRIMER" and the "CLEARFIL™ PORCELAIN BOND ACTIVATOR" has superior adhesive properties to etchable glass ceramics and lithium disilicate.

For Zirconia & Metals*

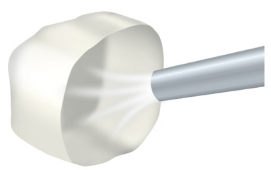


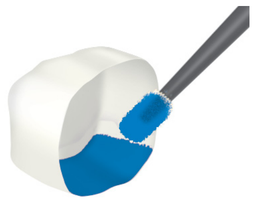
1-a. Blast with alumina powder, then ultrasonically clean and dry



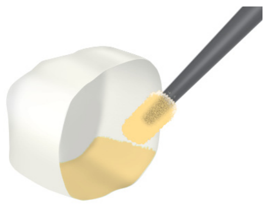
2-a. Apply PRIMER and dry with mild air

For Silica-based Ceramics (e.g. Conventional Porcelain, Lithium disilicate)





1-b. Apply Hydrofluoric acid (HF) or Phosphoric acid, then wash and dry **



2-b. Apply the mixture of PRIMER and CLEARFIL™ PORCELAIN BOND ACTIVATOR, then dry with mild air

* When precious metal is used, apply ALLOY PRIMER after roughening.

**According to the Instructions for Use of the restorative material.

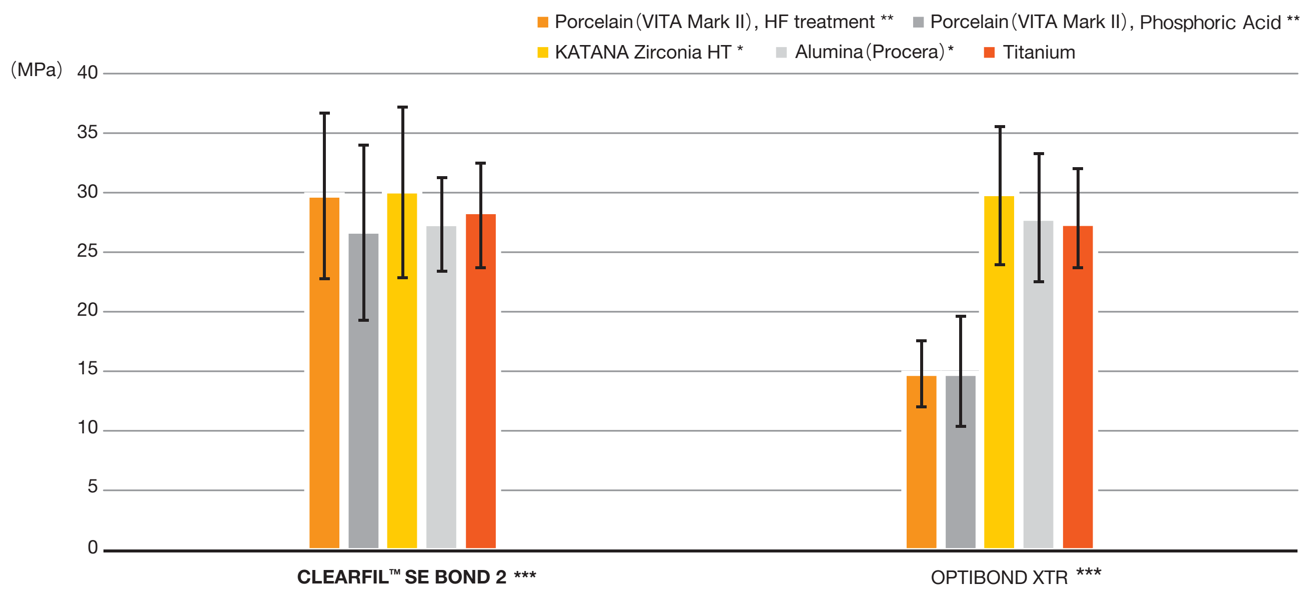


Fig.26 Tensile Bond Strength to various materials (Combination with CLEARFIL™ ESTHETIC CEMENT) 37℃ 1DAY

* Pretreatment by sandblasting
** CLEARFIL™ SE BOND 2 PRIMER was mixed with CLEARFIL™ PORCELAIN BOND ACTIVATOR
*** Light-curing
Source : Kuraray Noritake Dental Inc.,

5 Clinical Procedures

INDICATIONS	[1] Direct restorations using light-cured composite resin	Direct restorations
	[2] Cavity sealing as a pretreatment for indirect restorations*	
	[3] Treatment of exposed root surfaces*	
	[4] Treatment of hypersensitive teeth*	
	[5] Intraoral repairs of fractured restorations	Intraoral repairs
	[6] Post cementation using a dual- or self-cured composite resin*	
	[7] Core build-ups using a light-, dual- or self-cured core material*	
	[8] Cementing inlays, onlays, crowns, bridges and veneers using a composite resin cement	Cementing

*Please refer to the IFU for [2], [3], [4], [6] and [7] of Indications.

Table : Dental curing unit and curing time

Type	Light source	Light Intensity	Light-curing time
Halogen	Halogen lamp	More than 400 mW/cm2	10 seconds
LED	Blue LED*	800-1400 mW/cm2	10 seconds
		More than 1500 mW/cm2	5 seconds

The effective wavelength range of each dental curing unit must be 400-515nm.

Peak of emission spectrum : 450-480nm

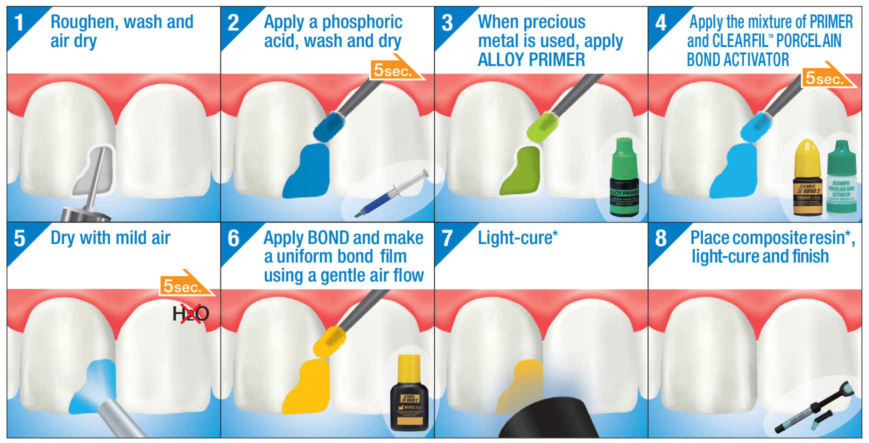
Direct restorations Using Light-cured composite resin.

Follow the standard procedures for isolation, moisture control, cavity preparation and pulp protection

*Before applying PRIMER, selective enamel etch by phosphoric acid is an option.

*Refer to the table for light-curing time.

Intraoral repairs of fractured restorations

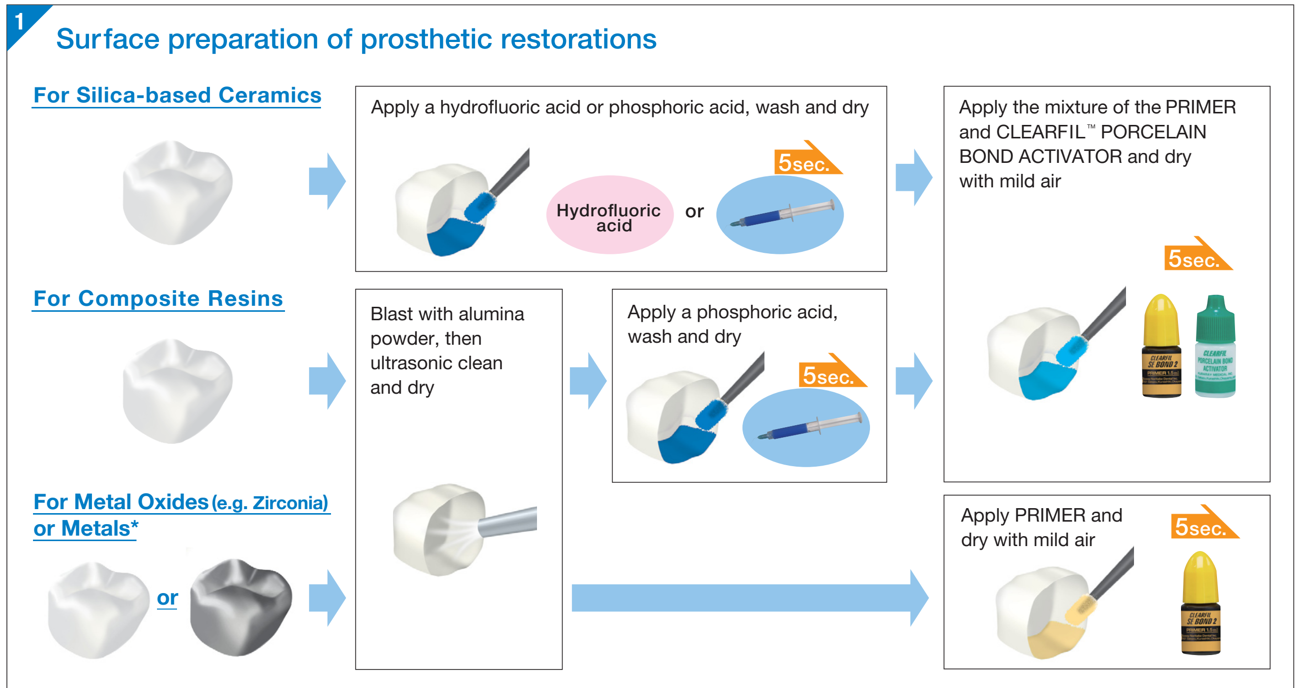


*Refer to the table for light-curing time.

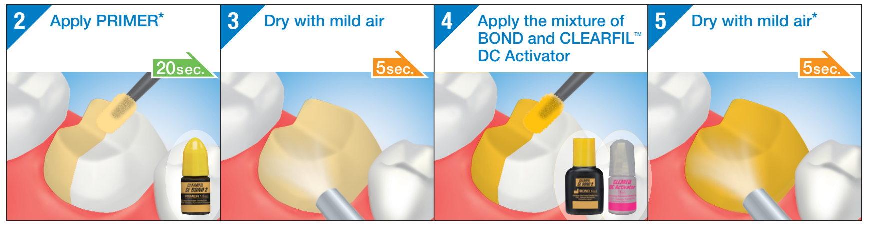
*Use an opaque resin (e.g. CLEARFIL™ ST OPAQUER) to mask metal color.

Cementing Inlays, onlays, crowns, bridges, and veneers, using a composite resin cement

Clean and dry the tooth surface, and then trial fit the prosthetic restoration



*When precious metal is used, apply ALLOY PRIMER after roughening.



*Before applying PRIMER, selective enamel etch by phosphoric acid is an option.

*Light-curing the mixture is an option for optimum performance.

6 Literature

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NOTE: Please read Instructions for use thoroughly before using the product.

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