3M ESPE

Vitrebond™ Plus Light Cure Liner/Base

technical product profile

Vitrebond™

Table of Contents

Introduction

Reasons For Using Liners

Liners are typically fluid materials that, due to their rheology, can adapt more readily to all internal aspects of a cavity preparation. They can be used to create a uniform, even surface that aids in adaptation of more viscous filling materials such as amalgams or composites.

Sensitivity following restorative procedures is, in many cases, associated with an incomplete dentinal seal. Often referred to as "dentinal sensitivity", its origin has been associated with movement of dentinal tubular fluid in a coronal direction at a rate that stimulates pulpal pain receptors.[1] For adhesive restorative procedures, the formation of a fully sealed dentinal hybrid layer will prevent this rapid outward flow of tubule fluid and greatly minimize the risk for post-operative sensitivity if not eliminate it altogether. Additionally, resin-modified glass ionomer liners (RMGI liners) used under amalgams can seal the dentin immediately and have been shown to reduce the incidence of post op sensitivity.[2,3] Liners may also provide thermal insulation to the pulp,[4] which is particularly important for deep amalgam restorations.

Calcium hydroxide use on frank pulpal exposures is the standard of practice in dentistry for two reasons. First, calcium hydroxide has been shown to protect the pulp from thermal insult. Secondly, due to a high pH (11-13), calcium hydroxide stimulates the formation of reparative dentin that eventually forms a bridge once again encasing the pulp in dentin.[5] However, if this type of liner is exposed to the oral environment (e.g., due to leakage) it will dissolve.[6]

Liners are used for indirect pulp-capping procedures. An indirect pulp cap involves leaving a layer of affected dentin (dentin that has been partially demineralized and may be discolored but not infected with bacteria) to maintain pulpal coverage. This dentin is then covered by calcium hydroxide followed by ZOE or a GI (glass ionomer)/RMGI liner.[7] This restoration may be treated as a temporary or a permanent restoration.

Methacrylate composites used as restorative materials shrink upon polymerization creating stress. The amount of stress generated during this polymerization has been shown to be dependent on many properties including the polymerization kinetics, the modulus of the filling material and cavity configuration.[8,9] These stresses generated are transferred to the restorative-tooth interface, which may cause post-operative sensitivity, gap formation, leakage, enamel cracks and cuspal movements. Many methods have been discussed and studied to manage this stress including incremental placement techniques, low shrinkage composites and stronger bond strengths of adhesives.[10] Lining the restoration with low modulus materials can also be a method for managing the stress caused by polymerization shrinkage of composites. This low modulus lining may distribute the stress more uniformly along the cavity wall. One study examined the differences in cuspal deformation for MOD composite restorations with an adhesive layer only vs. three lining techniques – a thin initial layer of the composite, a flowable composite, or a resin-modified glass ionomer liner. The results from this study indicated that the use of an RMGI liner (Vitrebond™ liner/base) reduced the cusp deflection more than the other liners.[11]

Glass ionomer (GI) or resin modified glass ionomer (RMGI) liners have been used as a renewable source of fluoride under restorations. Fluoride has been shown to reduce the incidence of caries.[12]

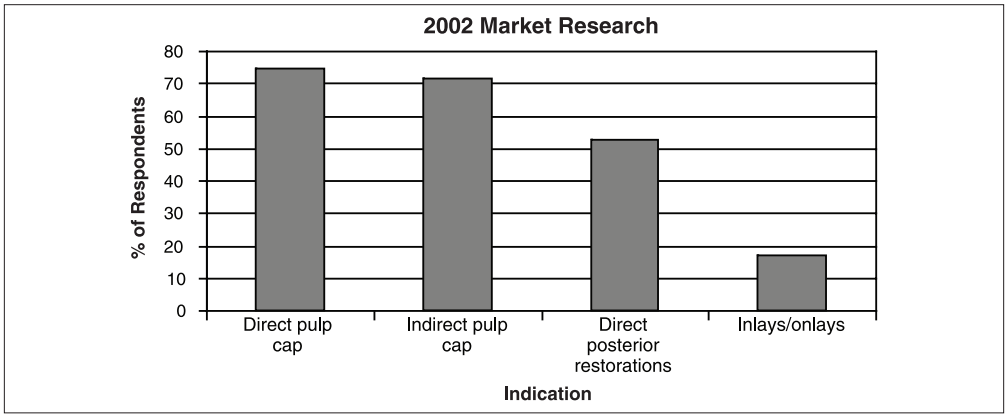
Many dentists do not use liners. They view the liner as an extra step that provides benefits achievable by careful adherence to good clinical techniques and choice of restorative materials.

When and Where are Liners Used

Liners are most frequently used under Class I or II restorations to seal dentin. They are recommended for dentin bonding in areas of deep cavity excavation where the bond with adhesives may be compromised due to increased dentinal fluid.

In a recent customer study, users of lining materials were asked to report their frequency of use of a liner on various types of indications. Most of the respondents listed pulp cap as their most frequent use of a liner.

Source: 3M ESPE Internal Data



In the field evaluation where GI/RMGI users were selected, dentists reported their frequency of using these types of liners in a variety of indications. The following summarizes their use.

- Indirect pulp cap
- Class II composite
- Class I composite, Class II amalgam and other direct restorations
- Indirect restorations
- Class I amalgam

Types of Liners

There are three types of materials most commonly used as liners – calcium hydroxide, flowable composites and GI/RMGIs.

Calcium hydroxide is the material of choice to cover frank pulpal exposure. Studies have shown that calcium hydroxide helps instigate formation of reparative dentin, which will eventually recover the exposure with tooth structure.

Flowables are composites with a lower amount of filler. The reduction in filler content allows for a more fluid consistency, less strength and lower modulus than fully filled composites. Users of flowables cite that they use flowables as liner primarily under composite restorations and to block out undercuts in crown and bridge preparations prior to impressioning. An adhesive must be used prior to application of a flowable. Because of the needs for adhesive application and the maintenance of a contamination-free field during both adhesive and flowable placement, their use under amalgam restorations may be limited. The main reasons dentists cite for using flowables are adaptation (flow), placement ease (the materials are injected directly into the preparation), shade choice is important for highly esthetic restorations, and consistency.

Glass ionomer or resin-modified glass ionomers are the third category of materials used as liners. Dentists using GIs or RMGIs as liners cite the following reasons for using these materials as protection against post-op sensitivity; they don't remove the smear layer, provide stress relief, act as a thermal barrier, seal dentin, prevent microleakage, bond in a moist environment and are easy to use.

Background

History of Vitrebond™ Liner/Base

3M introduced Vitrebond™ Light Cure Glass Ionomer Liner/Base in 1988. It was the first resin-modified glass ionomer on the market. The powder is a radiopaque, ion-leachable fluoroaluminosilicate glass powder, which is made photosensitive by its unique chemistry. The liquid component is a modified polyacrylic acid with pendant methacrylate groups, HEMA (2-hydroxyethylmethacrylate), water and photoinitiator. HEMA is present to aid in the crosslinking and to improve the wetting of the dentin surface.

The chemistry of the setting process of Vitrebond liner/base consists of two independent setting reactions. When powder and liquid are combined, the conventional glass ionomer acid-base reaction begins. The acidic liquid releases cations (Mx^{+}) from the glass, which then react with the carboxylate groups of the polyalkenoic acid resulting in chelation. When irradiated by a curing unit, a photoinitiated crosslinking of the polymer chains occur through a free radical methacrylate polymerization. The light curing mechanism is much faster than the acid-base reaction, which results in command setting of the mixed Vitrebond liner/base mass upon light exposure from a curing unit. The ionic chelation reaction continues over a long period resulting in long-term fluoride release.

Clinical studies using Vitrebond liner/base can be found in the literature. One clinical study involving Vitrebond light cure liner/base reported reduced sensitivity under amalgam restorations.[13,14] Another study compared the level of post-operative sensitivity of restorations lined with Vitrebond liner/base (covering all of the dentin surfaces) to restorations using a dentin adhesive alone. Immediate post-operative sensitivity was less frequent and less severe when Vitrebond liner/base was used.[15]

One study was found for Class V erosion cavities restored with either a conventional glass ionomer, a composite plus bonding system or a composite plus bonding system lined with Vitrebond liner/base. Restorations lined with Vitrebond liner/base showed notably better retention at 3-year recall than those restorations using composite plus bonding system restorations only.[16]

Numerous papers have been published on in-vitro studies using Vitrebond liner/base. Twenty papers reported data on microleakage studies under various types of restorative materials. The majority of the papers (twelve papers) showed superior results for the RMGI liner groups compared with controls for sealing against leakage,[17-28] however four studies reported similar amounts of leakage for restorations lined with RMGI liner and the control[29-31] and four studies showed better results for the control.[32-35]

Product Description

3M™ ESPE Vitrebond™ Plus Light Cure Glass Ionomer Liner/Base is a two-part liquid/paste system. The liquid/paste materials are contained in the 3M™ ESPE™ Clicker™ Dispensing System. This dispensing system provides simultaneous dispensing of each component for a consistent mix.

The composition is based on 3M ESPE Vitrebond light-cure glass ionomer liner/base. Vitrebond Plus liner/base provides the major benefits of glass ionomer cements including adhesion to tooth structure and fluoride release. Additionally, Vitrebond Plus liner/base offers a combination of a prolonged working time with a short set time achieved by light curing.

Composition

The liquid component of Vitrebond™ Plus liner/base consists primarily of the same resin modified polyalkenoic acid, HEMA (2-hydroxyethymethacrylate), water and initiators (including camphorquinone) found in Vitrebond™ liner/base. The paste is a combination of HEMA, BIS-GMA, water, initiators and a radiopaque fluoroaluminosilicate glass (FAS glass). This glass is different than the FAS glass contained in the original Vitrebond liner/base. The change in FAS glasses produces a reduction in the opacity of Vitrebond Plus liner/base compared to the original Vitrebond liner/base. Vitrebond Plus liner/base has been shown to exhibit the true glass ionomer reactions found in the original Vitrebond liner/base.

Indications for Use

Vitrebond Plus liner/base is indicated for lining and basing applications under the following restorations:

- Composite
- Amalgam
- Ceramic
- Metal

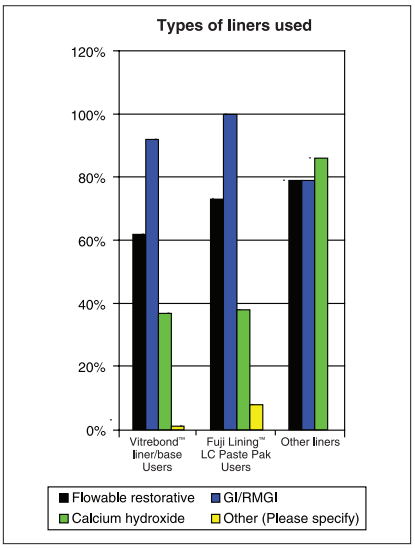
Vitrebond Plus liner/base is not indicated for direct pulp capping.

Customer Response

Source: 3M ESPE Internal Data

Market research studies were conducted to understand GI/RMGI liner use. Vitrebond Plus light cure glass ionomer liner/base was field evaluated with 144 dentists who were currently using either Vitrebond liner/base or Fuji Lining LC Paste Pak across the US. In addition to gaining more understanding of their current liner use, this field evaluation provided feedback on the actual clinical use of Vitrebond Plus liner/base.

Over 60% of the dentists frequently have more than one product in their armamentarium for lining restorations. Flowable composites and GI/RMGI products are the most frequently used materials for lining restorations.



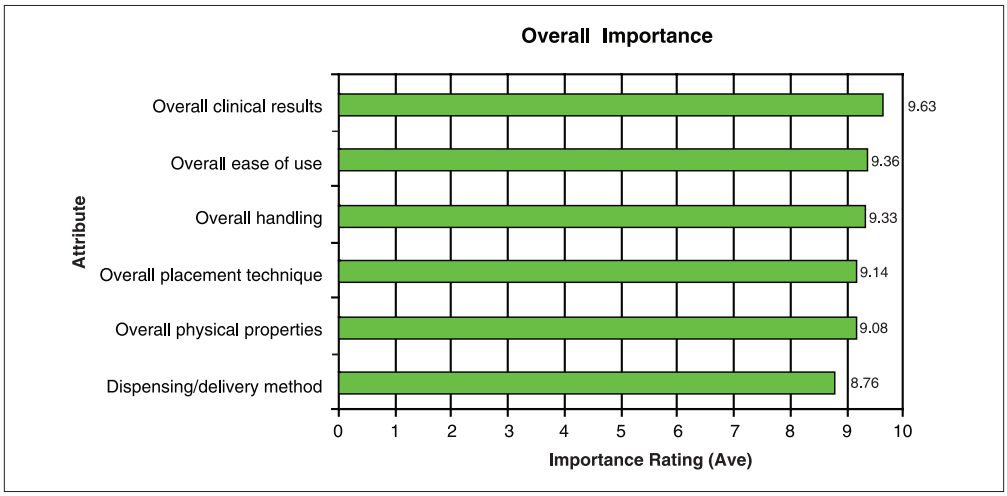
Importance

Dentists were asked to identify the reasons for using their liner of choice.

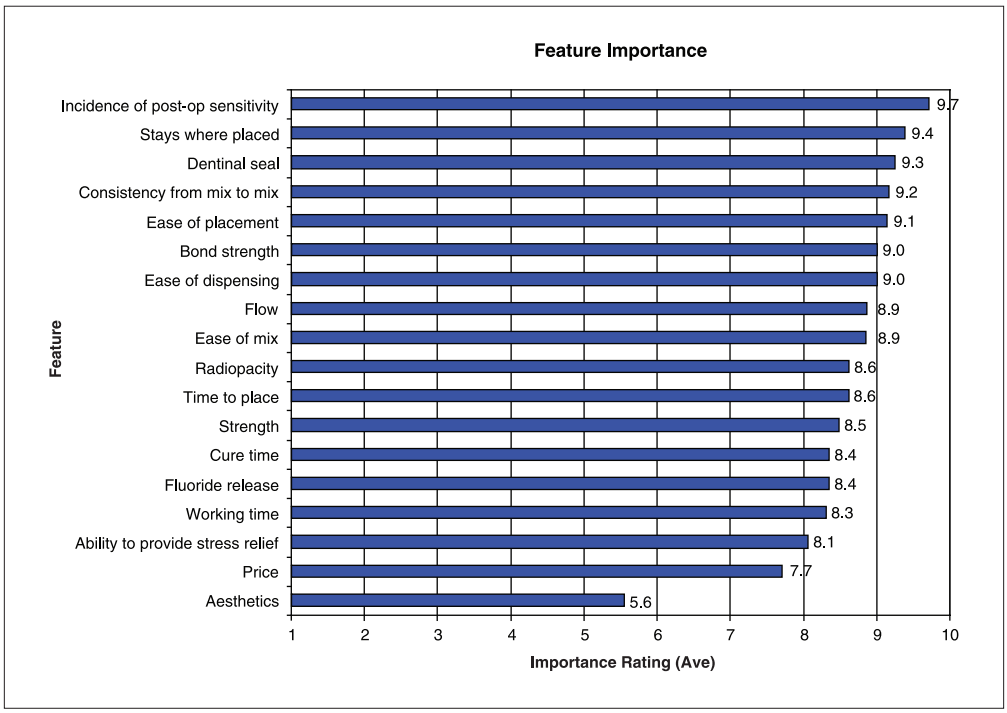
Flowable users commented that the flow (ability to adapt to all internal aspects of the preparation) was most important, closely followed by placement ease and ease of use, shades, consistency and cost.

The dentists using GI/RMGI liners were asked why they chose these products. They listed protection against post-operative sensitivity, ability to seal dentin and prevent microleakage and the ease of handling and placement. The reasons why a particular GI/RMGI product was chosen included brand, clinical results, ease of use and handling. In addition, Vitrebond™ liner/base users listed reduction in post-operative sensitivity while Fuji Lining™ LC Paste Pak users listed ease of dispensing and mix.

Dentists using GI/RMGI liners were asked to rate the importance of a variety of overall product and features associated with liners.



Source: 3M ESPE Internal Data

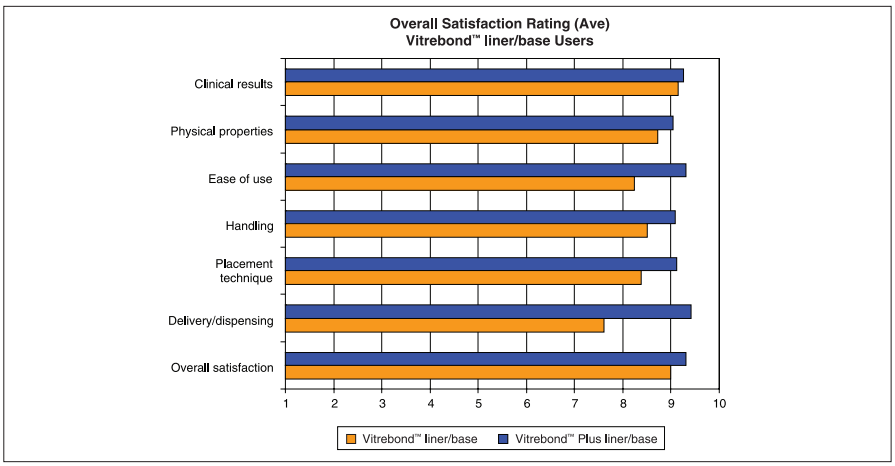


Source: 3M ESPE Internal Data

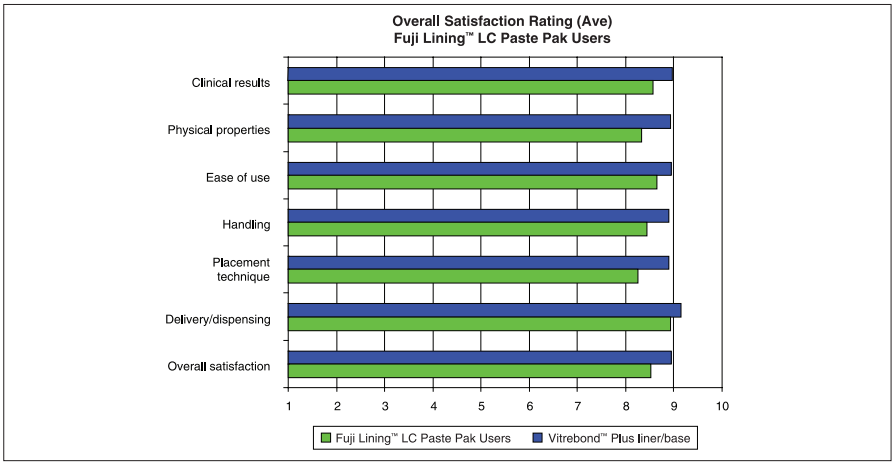
Satisfaction and Preferences

The results of the field evaluation show that Vitrebond™ liner/base users expressed significantly higher satisfaction with the delivery and ease of use of Vitrebond™ Plus liner/base. Fuji Lining™ LC Paste Pak users expressed the greatest increase in satisfaction with the placement technique.

Source: 3M ESPE Internal Data



Source: 3M ESPE Internal Data



On the individual attribute level, Vitrebond liner/base users rated their satisfaction higher on every attribute for the Vitrebond Plus liner/base. Most notably significant improvements were made in:

- ease of dispensing
- ease of mix
- consistency from mix to mix

Fuji Lining LC Paste Pak users reported higher levels of satisfaction with Vitrebond Plus liner/base for:

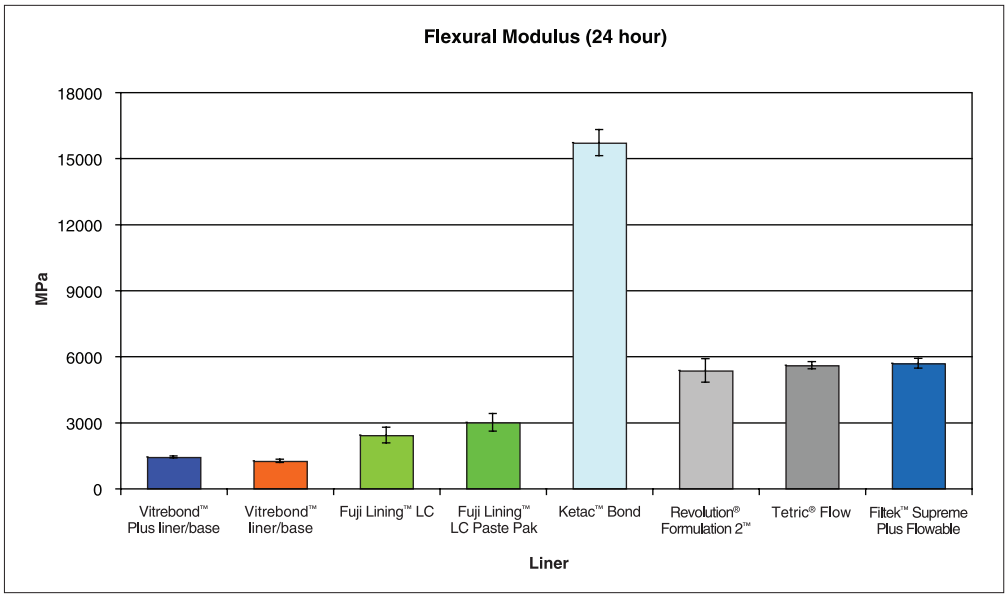
- handling (staying where placed and flow)
- radiopacity

In terms of importance, Fuji Lining LC Paste Pak users rated the importance of the liner staying where placed as their number two product feature (just behind incidence of post-operative sensitivity).

Physical Properties

Flexural Modulus

Flexural modulus is a method of defining a material's stiffness. A low modulus indicates a flexible material. The flexural modulus is measured by applying a load to a material specimen that is supported at each end.

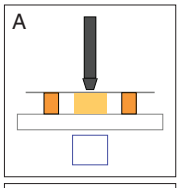


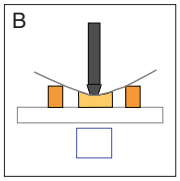
Source: 3M ESPE Internal Data

The flexural modulus of Vitrebond™ Plus liner/base is lower (it is less rigid) than that of GC Fuji Lining™ LC and GC Fuji Lining™ LC Paste Pak, 3M ESPE Ketac™ Bond and Filtek™ Supreme Plus Flowable, Vivadent Tetric® Flow and Kerr Revolution® Formula 2™. The flexural modulus of Vitrebond Plus liner/base is comparable (equivalent) to Vitrebond liner/base.

Polymerization Shrinkage Buffer

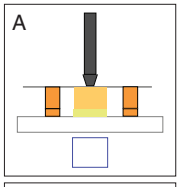
Deflection without liner

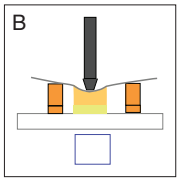




A method for determining polymerization shrinkage was described by Watts and Cash (Meas. Sci. Technol. 2(1991) 788-794). In this method, a disc shaped test specimen is bonded to and sandwiched between two glass plates and light cured through the lower rigid plate. The flexible upper plate is deflected during the polymerization of the test specimen. Deflection is measured and recorded as a function of time. The less the flexible plate bends, the lower the shrinkage. Although this process actually measures linear shrinkage, volumetric shrinkage was closely approximated due to the fact that the dimensional changes were limited to the thickness dimension. The lower the value, the less the shrinkage.

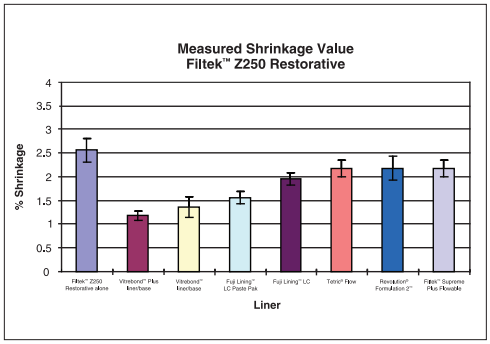
Deflection with liner

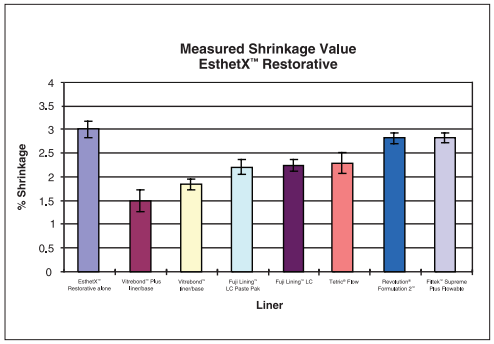


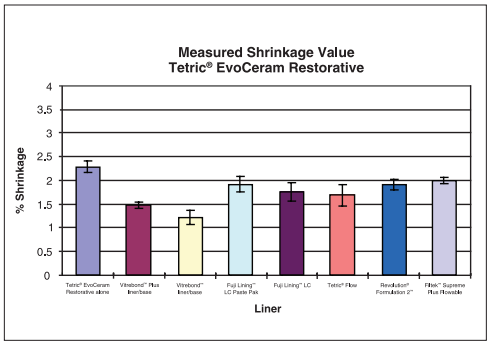


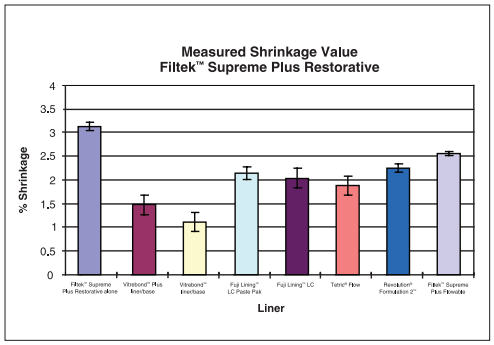
To measure the buffering effect of liners on the polymerization shrinkage this test was modified to include a liner layer between the rigid glass plate and the composite layer. The liner was cured prior to application of the composite. The same volume of composite was used in all samples.[36-38] In this test, composite samples were exposed for length of time that was recommended by the composite manufacturer to a 3M™ Visilux™ 2 Visible Light Curing Unit. The final shrinkage was recorded 5 minutes after the end of light exposure. Results showed differences between liners and composite materials.

Source: 3M ESPE Internal Data









The ability of Vitrebond™ Plus liner/base to buffer an effect of polymerization shrinkage is greater than GC Fuji Lining™ LC and flowable liners when tested using Filtek™ Z250, EsthetX™ or Filtek™ Supreme Plus Universal Restorative.

The ability of Vitrebond Plus liner/base to buffer an effect of polymerization shrinkage is similar to Vitrebond liner/base when tested using Filtek Z250 and Tetric® EvoCeram.

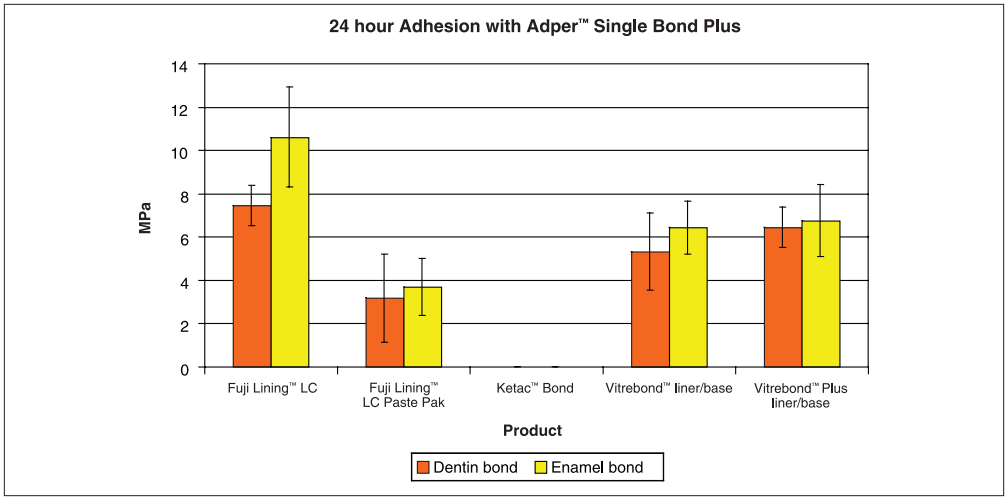
The ability of Vitrebond Plus liner/base to buffer an effect of polymerization shrinkage is greater than GC Fuji Lining™ LC Paste Pak and Revolution® and Filtek™ Supreme Plus Flowable when tested using Tetric EvoCeram.

These results can be closely correlated to the flexural modulus data.

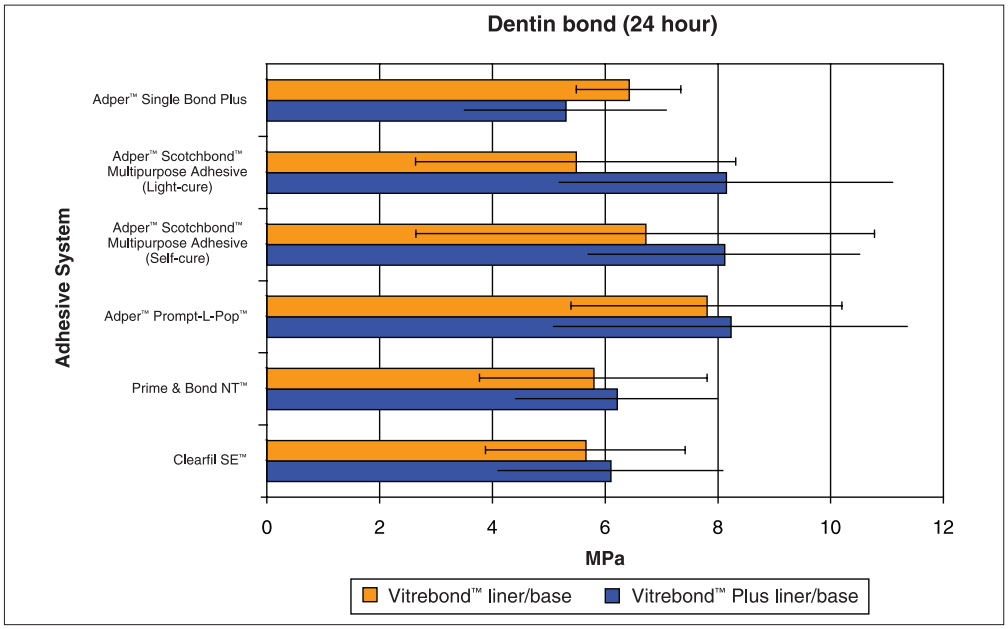
Bond Strength

Vitrebond Plus light cure glass ionomer liner/base was also tested for adhesion to bovine dentin and enamel using a shear wire-loop method. In this method, the liner was placed and cured directly on the prepared bovine tooth. An adhesive was then applied (following the corresponding instructions for use) and cured. Then an approximate 5mm diameter button of 3M ESPE Filtek™ Z250 Universal Restorative is bonded to the adhesive coated liner layer and a shear force is applied with a wire loop until failure.

Source: 3M ESPE Internal Data

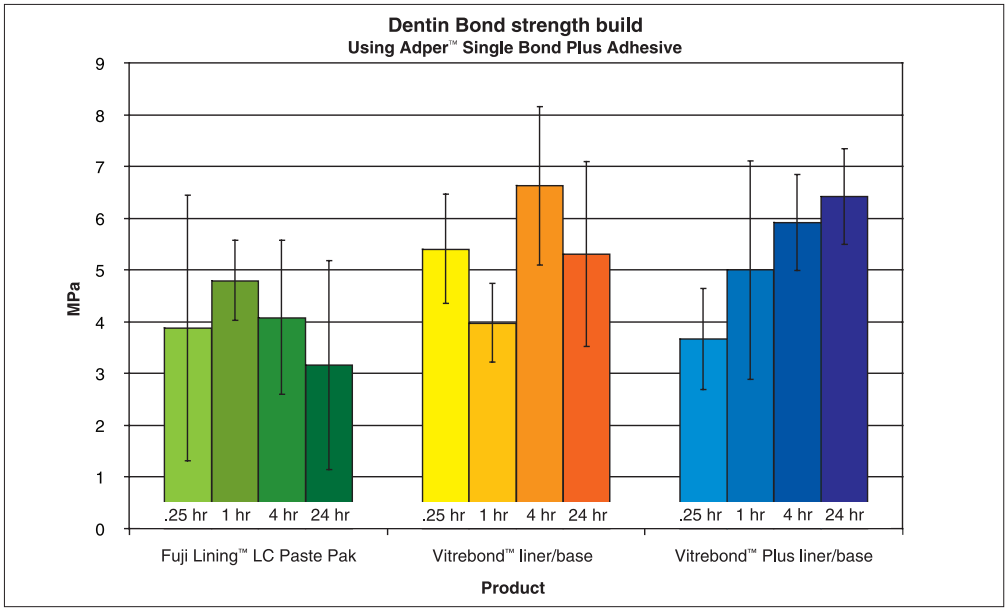


The 24-hour adhesion to dentin of Vitrebond™ Plus liner/base is greater than that for GC Fuji Lining™ LC Paste Pak and 3M ESPE Ketac™ Bond Glass Ionomer Base Material. The 24-hour adhesion to dentin of Vitrebond™ Plus liner/base is comparable to that for GC Fuji Lining LC and Vitrebond Light Cure Glass Ionomer Liner/Base. The enamel bond strength of Vitrebond Plus liner/base is greater than Ketac Bond Glass Ionomer Base Material. The enamel bond strength of Vitrebond Plus liner/base is comparable to Vitrebond Light Cure Glass Ionomer Liner/Base and GC Fuji Lining LC Paste Pak.



Source: 3M ESPE Internal Data

Vitrebond Plus liner/base can be used with any type of adhesive (light or self cured; separate etch or self-etch, i.e. - 4th, 5th or 6th generation adhesives) on dentin or enamel. The bond strength of Vitrebond Plus liner/base to dentin and enamel is comparable to Vitrebond liner/base regardless of adhesive system used.



Source: 3M ESPE Internal Data

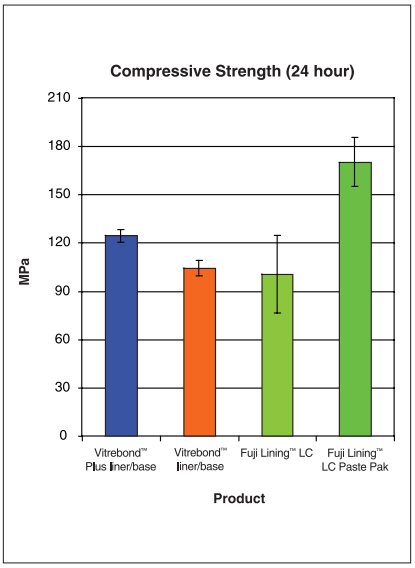
Not only is the 24-hour adhesion important, so is the immediate bond strength. In order for the liner to withstand composite polymerization contraction forces and impression removal forces without pulling away from the dentin to form gaps, the bond has to develop quickly. The (dentin and enamel) bond of Vitrebond Plus liner/base develops quickly (within 15 minutes) which is comparable to the clinically successful Vitrebond liner/base.

Vitrebond Plus liner/base maintains its adhesion to dentin and enamel over time.

Compressive and Diametral Tensile Strength

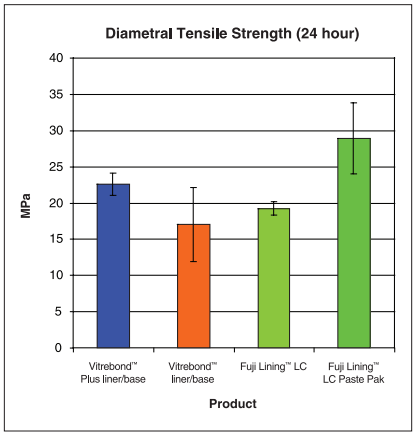
Source: 3M ESPE Internal Data

Compressive strength is particularly important because of chewing forces. Rods are made of the material and simultaneous forces are applied to the opposite ends of the sample length. The sample failure is a result of shear and tensile forces. The compressive strength of Vitrebond™ Plus liner/base is comparable (equivalent) to Vitrebond™ Light Cure Glass Ionomer Liner/Base and GC Fuji Lining™ LC.



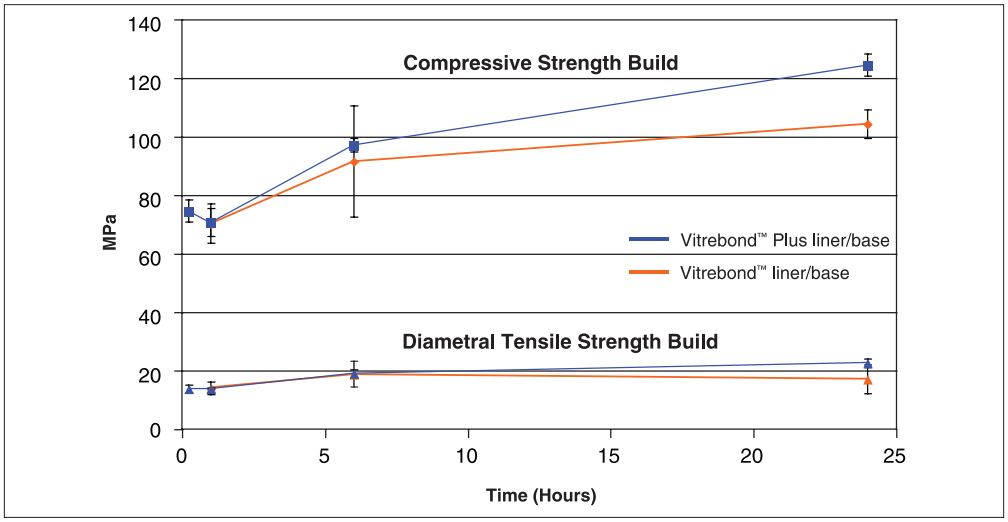
Diametral Tensile strength is measured using a similar apparatus. Compressive forces are applied to the sides of the sample, not the ends, until fracture occurs. The diametral tensile strength of Vitrebond Plus liner/base is comparable (equivalent) to Vitrebond liner/base, GC Fuji Lining LC and Fuji Lining™ LC Paste Pak.

Source: 3M ESPE Internal Data



Because of the two curing mechanisms (rapid polymerization and a slower acid-base reaction) the strength of Vitrebond and Vitrebond Plus liner/bases is more modulated than for methacrylate flowable composites. The rate the compressive and diametral tensile strength of Vitrebond Plus liner/base develops is similar to that of Vitrebond liner/base. This is especially important during the packing of amalgam. If the lining is weak (partially set) this process may cause fracture of the lining. If cavities are deep, this may result is sensitivity to temperature.[39]

Source: 3M ESPE Internal Data

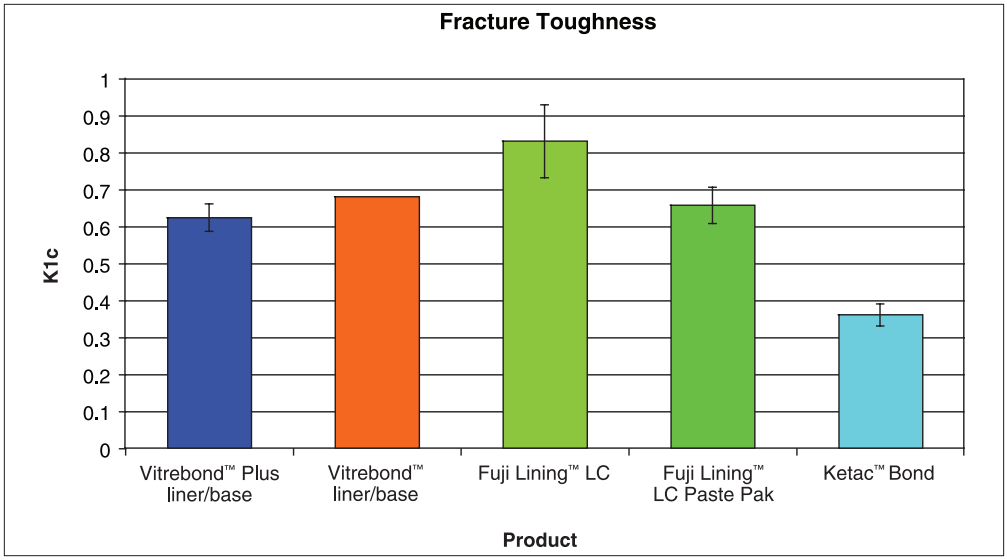


About 60% of the diametral tensile and compressive strength for Vitrebond Plus liner/base develops within 15 minutes.

Vitrebond Plus liner/base maintains its [diametral tensile and compressive] strength over time. [comparable to other RMGI liners]

Fracture Toughness

The values reported for fracture toughness (K1c) are related to the energy required to propagate a crack. In this test a short rod of material is cured. A chevron or notch is cut into the cylinder and the parts on either side of the chevron are pulled apart. Below are the 24-hour values for wet fracture toughness.

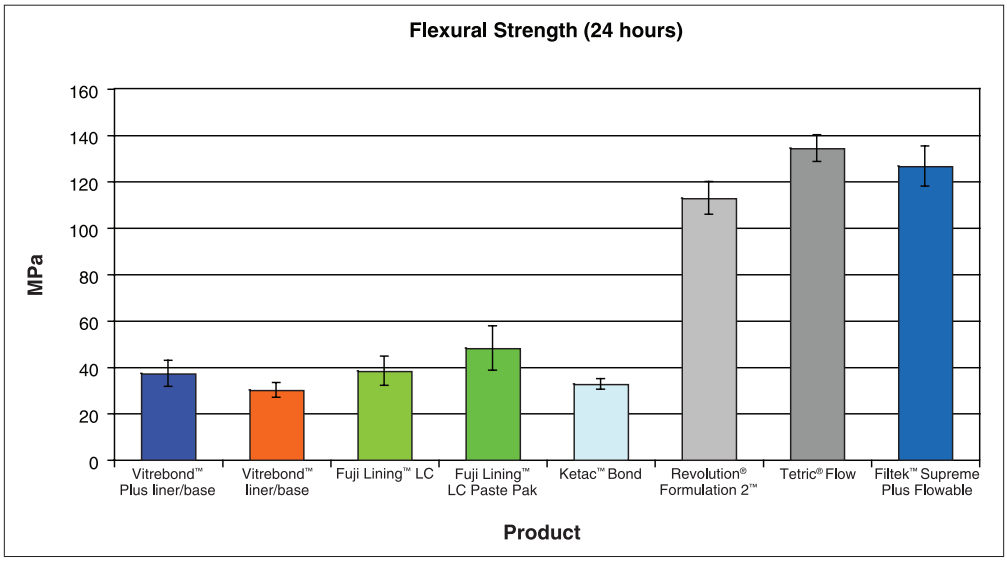


Source: 3M ESPE Internal Data

The fracture toughness of Vitrebond™ Plus liner/base is comparable to Vitrebond™ Light Cure Glass Ionomer Liner/base and GC Fuji Lining™ LC Paste Pak.

Flexural Strength

Flexural strength is determined in the same test as flexural modulus. Flexural strength is the value obtained when the sample breaks. This test combines the forces found in compression and tension.



Source: 3M ESPE Internal Data

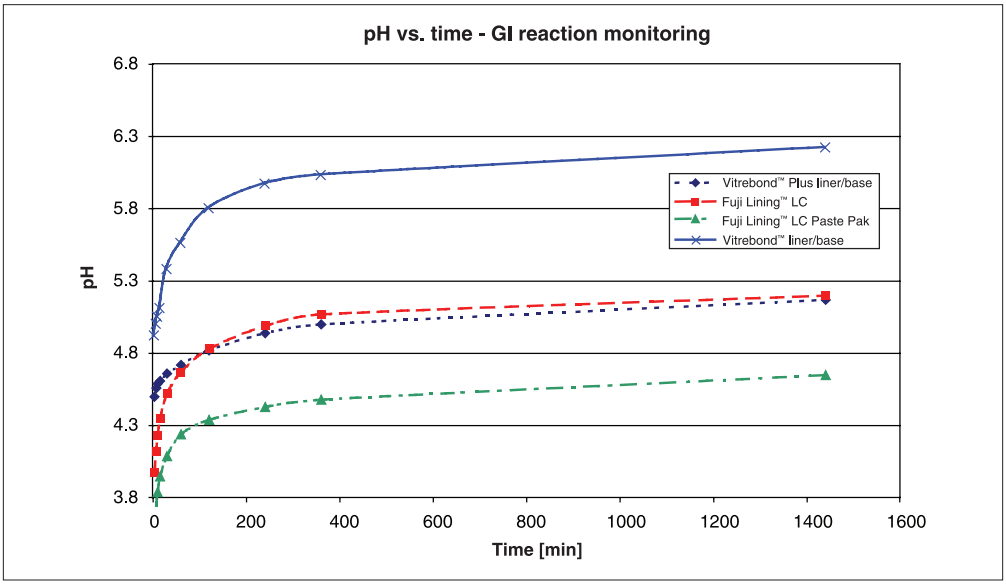
The flexural strength of Vitrebond Plus liner/base is comparable (equivalent) to Vitrebond Light Cure Glass Ionomer Liner/base, Ketac™ Bond Glass Ionomer Base Material and GC Fuji Lining™ LC.

GI Properties

FTIR analysis confirms that Vitrebond™ Plus liner/base exhibits true glass ionomer chemistry.

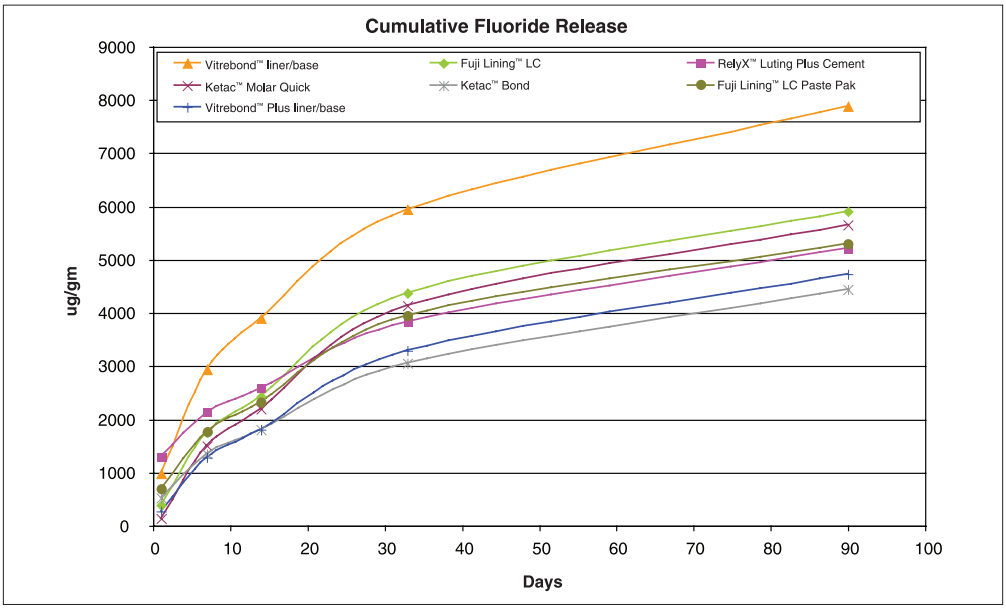
The pH of cured Vitrebond Plus liner/base is significantly more neutral than cured GC Fuji Lining™ LC Paste Pak. The pH was monitored over time by placing freshly light-cured cured discs of the liners in water. A pH electrode was placed on top of the disc and pH readings were taken periodically (from 2 minutes after light cure to 24 hours after light cure).

Source: 3M ESPE Internal Data



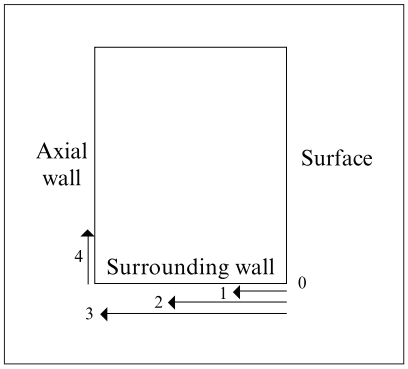
Fluoride Release

Source: 3M ESPE Internal Data



Discs of each liner were prepared. Cured discs were then suspended in distilled water and stored in a 37ºC oven. Fluoride release was measured using a fluoride electrode at specified times for all of the materials. Vitrebond Plus liner/base releases fluoride over time in the range of clinically proven glass ionomers. Fluoride has been shown to reduce the incidence of secondary decay.[40]

Microleakage



Extracted human molars were cleaned and pumiced. Cylindrical cavities (3mm diameter and 2mm deep) were prepared at the CEJ. The teeth were kept slightly moist throughout the entire procedure. The liners included in this study were Vitrebond™ Plus liner/base, Vitrebond™ liner/base, Fuji Lining™ LC Paste Pak and Ketac™ Bond. All liners were placed according to manufacturer's instructions. The teeth were etched, Adper™ Single Bond Plus applied and cured, and a single layer of Filtek™ Z250 Universal Restorative placed and cured. The restoration surface was finished using Sof-Lex™ Coarse and Medium discs to remove flash. The teeth were then placed in a 37ºC, 90%RH chamber for 1 hour then kept in distilled water for a total of 24 hours. The teeth were then thermocycled for 700 cycles (5ºC-55ºC). The teeth were then immersed in 0.5% basic fuschin dye solution. Teeth were sectioned and microleakage was scored as described on the diagram.

Restorations placed using Vitrebond Plus liner/base exhibited low microleakage, comparable to Vitrebond liner/base.

ISO Testing

Passes ISO 9917-2:1998(E) Requirements (Sec 5) for Type II Light Activated cement for use as a liner/base.

Test	Requirement (minimum values)	Vitrebond Plus liner/base
Ambient light sensitivity	No change for at least 30 seconds	Pass
Depth of cure	Not less than 1mm and Not more than 0.5mm below the stated value	Halogen light 20 seconds for 1.5mm
Flexural strength	>10MPa	37.2MPa
Radiopacity	Equal to (or more than) an equivalent thickness of Al	1.03 (pass)

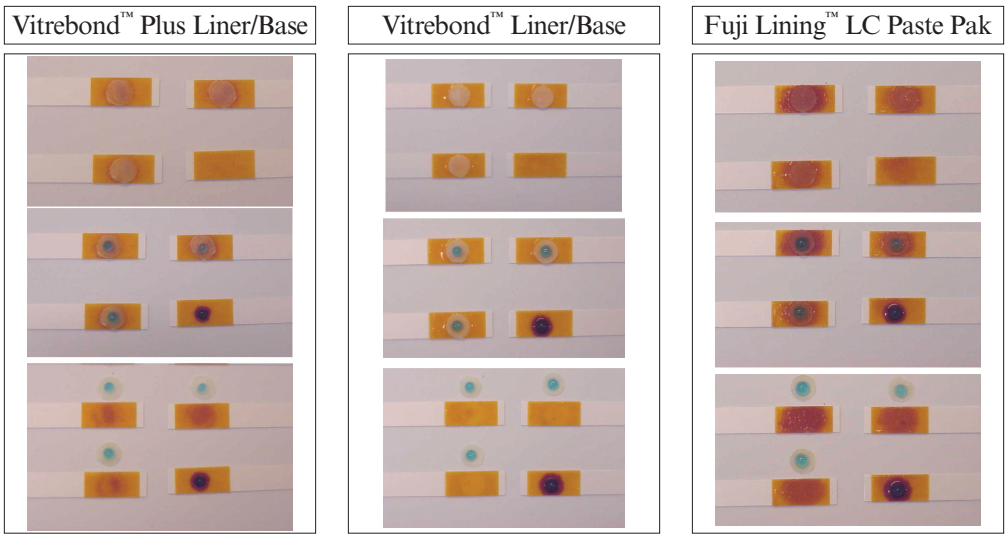
Compatibility with Calcium Hydroxide

In clinical situations where frank pulpal exposure could not be prevented, the use of calcium hydroxide to cover the exposure followed by a layer of Vitrebond Plus to seal in the calcium hydroxide and cover the remaining dentin is recommended. As calcium hydroxide is basic and glass ionomer chemistry relies on an acid-base reaction, the compatibility between these two materials was examined. It was found that Vitrebond Plus liner/base could be used over calcium hydroxide.

Protect Dentin (Thermal and Acid Barrier)

Vitrebond Plus liner/base protects dentin from etchant. Thin discs of Vitrebond Plus were made and cured. These discs were placed on top of wet pH paper (range 2.5-4.5). Etchant was then syringed on top of the disc and let sit for 15 seconds. The discs were removed and the pH paper examined to determine any color change due to the etchant. Only a slight color change was noted with the Vitrebond and the Vitrebond Plus liner/base materials. The discs themselves of Fuji Lining LC Paste Pak caused significant color change of the pH paper.

Source: 3M ESPE Internal Data



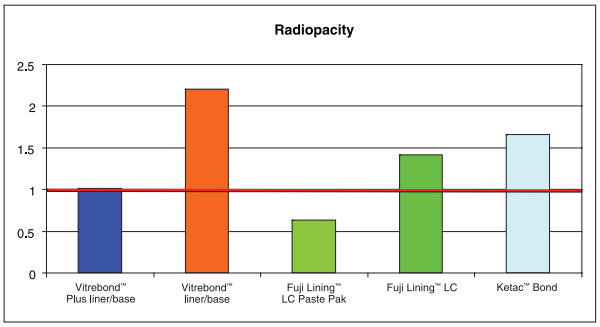
Acid etching Vitrebond™ Plus liner/base is not deleterious. The surface of cured Vitrebond Plus liner/base remains essentially unchanged after acid etching. The surface of a cured disc of Fuji Lining™ LC Paste Pak was significantly altered after exposure to acid etching.

Vitrebond Plus liner/base insulates tooth structure. Vitrebond Plus liner/base acts as a thermal barrier.

Radiopacity

Radiopacity was measured following the ISO 9917-2 1998E methodology. The measured radiopacity of Vitrebond Plus liner/base was lower than Vitrebond™ liner/base but higher than Fuji Lining LC Paste Pak. As part of the field evaluation, participating dentists were asked to take an X-Ray of a restoration lined with Vitrebond Plus liner/base. Dentists reported an equivalent satisfaction with the radiopacity of Vitrebond Plus liner/base and Vitrebond liner/base.

Source: 3M ESPE Internal Data



Working Aspects

In the field evaluation dentists reported that Vitrebond Plus liner/base exhibited an acceptable working time.

The recommended cure time of Vitrebond Plus liner/base is less than GC Fuji Lining LC and Vitrebond™ Light Cure Glass Ionomer Liner/Base. Cure time of Vitrebond Plus liner/base is 20 seconds in (1.5mm or less) increments.

Delivery

Vitrebond Plus liner/base is packaged in the unique 3M ESPE Clicker™ Dispensing System. The Clicker™ Dispensing System provides simultaneous, pre-measured, and uniform amounts of each component. A consistent volume of each component assures a consistent product. The Clicker dispensing system delivers a consistent A:B ratio regardless of amount in the clicker, age of the material, (within its shelf life) or operator. This increases the precision and the accuracy of the amount dispensed for Vitrebond Plus liner/base vs. the conventional dispensing of powder liquid for Vitrebond liner/base. The Clicker dispenser reduces A:B ratio variability of Vitrebond Plus liner/base by about 74% when compared to the traditional powder/liquid dispensing of Vitrebond liner/base.

The Clicker Dispensing System minimizes possible skin contact of dual components.

Management of Post-operative Sensitivity

Sensitivity following restorative procedures is, in many cases, associated with an incomplete dentinal seal. Often referred to as "dentinal sensitivity", its origin has been associated with movement of dentinal tubular fluid in a coronal direction at a rate that stimulates pulpal pain receptors (Brannstrom). For adhesive restorative procedures, the formation of a fully sealed dentinal hybrid layer will prevent this rapid outward flow of tubule fluid and greatly minimize the risk for postoperative sensitivity if not eliminate it altogether.

Isolation with rubber dam is highly recommended. - Contamination of the preparation during adhesive placement of any adhesive may potentially compromise the dentinal seal leading not only to post-operative sensitivity, but also possible margin discoloration and lack of long-term retention.

Use of 3M ESPE Vitrebond™ Plus Liner/Base - The resin-modified glass ionomer, Vitrebond Plus liner/base, is recommended for the management of post-operative sensitivity. Vitrebond Plus liner/base can be used routinely to seal the dentin of class I and II restorations since it is with these restorations where post-operative sensitivity often occurs. It is also recommended for dentin bonding in areas of deep cavity excavation where the bond with total etch adhesives may be compromised due to increased dentinal fluid. Vitrebond Plus liner/base offers several features, which help reduce the risk of post-operative sensitivity:

- Placement on dentin prior to etch so dentinal tubules are more easily sealed and are protected from etch;
- Clearly observable coverage during placement;
- Low viscosity to easily fill all the divots and undercuts created by cavity preparation
- Low microleakage;
- Low modulus
- The layer buffers an effect of polymerization shrinkage;
- Thermal barrier to insulate tooth from temperature variations.

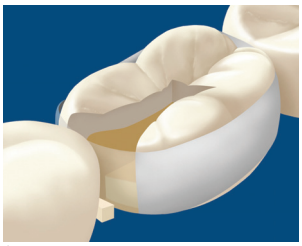
Adhesive Application - For optimum penetration of the adhesive into dentin following the etching step, the dentin must remain moist. Dehydration of the dentinal surface will cause the collagen fibrils to collapse resulting in a reduction in the porosity of this surface. Consequently, the collagen layer in this state will inhibit the penetration of adhesive throughout this layer and compromise the integrity of the dentinal seal. Following the few simple steps described below will promote complete dentinal sealing and minimize potential for post-operative sensitivity.

- Utilize a wet bonding technique.
    - o Use of compressed air is not recommended to remove pooled water remaining after the etch step.
    - o Blot excess moisture from the preparation using a cotton pellet or mini-sponge. The dentinal surface should appear glistening without pooling of water.
    - o Apply adhesive (or primer) immediately after blotting. Evacuators may hasten dentinal surface dehydration. If application is delayed, rewet and blot as above.
- Use a self-etch adhesive.

Technique Guides

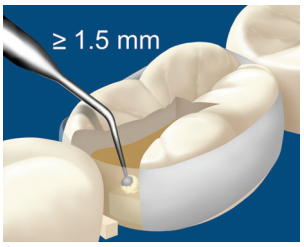
3M ESPE

Liner/Base Application
Vitrebond™ Plus Light-Cure
Glass Ionomer Liner/Base

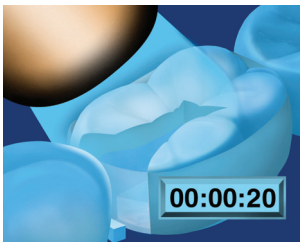

1

2

3



4



5

6

Instructions For Use

3M™ ESPE™ Vitrebond™ Plus Light Cure Glass Ionomer Liner Base in a 3M™ ESPE™ Clicker™ Dispenser

General Information

3M ESPE Vitrebond Plus light cure glass ionomer is a two-part liquid/paste system. The liquid/paste materials are contained in the 3M™ ESPE™ Clicker™ Dispensing System. This dispensing system provides simultaneous dispensing of each component for a consistent mix.

The composition is based on 3M™ ESPE™ Vitrebond™ Light-Cure Glass Ionomer Liner/Base. The paste contains a radiopaque fluoro-aluminosilicate glass. The liquid contains a modified polyalkenoic acid. Vitrebond Plus liner/base provides the major benefits of glass ionomer cements including adhesion to tooth structure and sustained fluoride release. Additionally, Vitrebond Plus liner/base offers a combination of a prolonged working time with a short set time achieved by light curing.

Indications

Vitrebond Plus liner/base is indicated for lining and basing applications under the following restorations:

- Composite
- Amalgam
- Ceramic
- Metal

Contraindications:

Vitrebond Plus liner/base is **not indicated for direct pulp capping**. If a pulp exposure has occurred and if the situation warrants a direct pulp capping procedure use a minimum amount of calcium hydroxide on the exposure followed by an application of Vitrebond Plus liner/base.

Precautionary Information for Patients:

Avoid use of this product in patients with known acrylate allergies. This product contains substances that may cause an allergic reaction by skin contact in certain individuals. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product.

Precautionary Information for Dental Personnel:

This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed.

Instructions for Use

1. **Isolation:** A rubber dam is the preferred method of isolation. Avoid water and saliva contamination during application and setting of the Vitrebond™ Plus liner/base.

2. **Restoration/tooth Preparation.** Remove carious dentin and all amalgam or other base material from the internal form of the preparation. Rinse and dry cavity. Leave tooth surface moist. **Do not overdry.**

3. **Pulp Protection:** Vitrebond Plus liner/base **is not indicated for direct pulp capping.** If a pulp exposure has occurred and if the situation warrants a direct pulp capping procedure use a minimum amount of calcium hydroxide on the exposure followed by an application of Vitrebond Plus liner/base.

4. **Dentin Pretreatment: Dentin pretreatment is not recommended.** The use of smear layer cleansers such as polyacrylic acid based solutions results in decreased adhesion of Vitrebond Plus liner/base.

5. **Dispensing**

   a. **Remove Cap:** Press and hold tab to unlock the protective cap. Slide cap off clicker dispenser.

   b. **Dispense:** Touch dispenser tip to mix pad. Fully depress clicker lever to dispense "1 click" of Vitrebond Plus liner/base on to the mix pad. Release lever when paste stops extruding (1-2 seconds). Repeat dispensing process for additional material. 1-2 clicks will be sufficient for most restorations.

   c. **Clean:** Wipe dispenser tip with alcohol-dampened gauze.

   d. **Replace Protective Cap:** Replace protective cap immediately after dispensing. Hold the sides of the clicker cartridge and slide cap into place until securely latched as indicated by the audible "click".

   Do not depress the clicker lever during cap removal and/or replacement.

   Do not advance the dispenser plunger during cap removal and/or replacement.

   An approximate number of Vitrebond Plus liner/base applications remaining in the 3M™ ESPE™ Clicker™ Dispensing System are indicated on the underside of the plunger adjacent to the black arrow on the cartridge.

6. **Mixing:** Using a small spatula, mix paste/liquid components together rapidly (10-15 seconds). The mixed Vitrebond Plus liner/base should have a smooth consistency and glossy appearance.

   To minimize water evaporation and maximize working time, confine spatulation of the paste/liquid to a small area on the mixing pad, about one inch (2.5 cm) in diameter.

7. **Application and curing:** Avoid water and saliva contamination during application and setting of the liner/base. Rubber dam is the best means of isolation.

   Apply a thin layer (1/2mm or less) of the mixed Vitrebond Plus liner/base material to the dentin surfaces of the prepared cavity using a ball applicator or other suitable instrument. Do not take out to the margins.

   Vitrebond Plus liner/base material has a minimum working time of 2 minutes 30 seconds at a room temperature of about 73ºF (23ºC). Higher temperatures will shorten working time.

   Cure Vitrebond Plus liner/base by exposing **layers of 1.5 mm or less for 20 seconds** to a 3M ESPE curing light or other curing unit of comparable intensity.

The delayed auto-setting mechanism of Vitrebond™ Plus liner/base will ensure an eventual cure of material shielded from light polymerization such as undercut areas.

Where a thicker application of the Vitrebond Plus liner/base is desired, the best adhesion can be achieved by first placing and light curing a thin layer followed by placement of a second layer up to 1.5 mm in depth and light cure for 20 seconds.

8. **Adhesive system:** Continue with the bonding step of the restorative procedure starting with etching. Etchant on the liner/base is not deleterious.

Storage and Use

1. The liner/base is designed for use at room temperature of approximately 21-24ºC or 70-75ºF. Avoid elevated temperatures.
2. Vitrebond Plus liner/base is light sensitive. Protect from ambient light exposure by dispensing just prior to use and replacing Clicker™ dispenser cap immediately after dispensing.
3. Clicker disinfection. Disinfect the capped Clicker using an intermediate level disinfection process (liquid contact) as recommended by the CDC (Centers for Disease Control) and endorsed by the ADA (American Dental Association). Guidelines for Infection Control in Dental Health-Care Settings – 2003 (Vol. 52; No. RR-17), Center for Disease Control and Prevention.
4. Shelf life of the Vitrebond Plus liner/base at room temperature is 24 months. See outer package for expiration dates.
5. Keep Clicker dispensers in foil package until time of initial use. Once the foil pouch is opened, the shelf life of the paste in the Clicker dispenser is 12 months or date of expiry.
6. Storage in refrigerator ensures longest possible shelf life. Allow to reach room temperature prior to use.
7. Do not store materials in proximity to eugenol containing products.

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the products for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Questions and Answers

Q. Can I use Vitrebond™ Plus liner/base with any adhesive system?

A. Yes. The adhesion using Vitrebond Plus liner/base (covering all dentin) was tested using a variety of 4th, 5th and 6th generation adhesives. In all cases the failure occurred either within the dentin or within the liner layer.

Q. Do I have to keep the etchant off the Vitrebond Plus liner/base layer?

A. No, we have found that etchant is not deleterious to a cured Vitrebond Plus liner/base layer.

Q. I use a flowable as my first increment of composite, why would I use Vitrebond Plus liner/base?

A. Particularly in deep cavities where dentinal fluid flow is higher which may compromise the performance of the bonding agent, Vitrebond Plus liner/base seals the dentin.

Q. Can I use Vitrebond Plus liner/base under my esthetic restorations without altering the final esthetic result?

A. Yes. Vitrebond Plus liner/base is much lighter in color (less chroma) than the Fuji Lining LC Paste Pak formulation and is less opaque than the original Vitrebond liner/base. Field evaluators noted the esthetic results were significantly better with Vitrebond Plus liner/base.

Q. The bond strength values are lower than my current adhesive system alone, why should I not be concerned?

A. Bond to tooth structure with glass ionomer materials is very different than methacrylate bonding. Glass ionomers have two bonding mechanisms, a micromechanical bond and a chemical bond to tooth structure that continues to form through the ongoing acid-base setting reaction (typical glass ionomer reaction). As noted above, the adhesion testing resulted in failure either within the Vitrebond Plus liner/base or the dentin layer. The bond strength (and bond failure mode), microleakage and presence of a glass ionomer reaction of Vitrebond Plus liner/base are the same as for the original Vitrebond liner/base. The adequacy of this performance is documented with the clinically successful history of Vitrebond liner/base.

Reference:

[1] Brannstrom M. (1986). The hydrodynamic theory of dentinal pain. Sensation in preparations, caries, and the dentinal crack syndrome. J Endodontics, 12(10)

[2] Gordan VV, Mjor IA, Hucke RD, Smith GE. Effect of different liner treatments on post-operative sensitivity of amalgam restorations. Quintessence Int 1999; 30:55-59

[3] Gordan VV, Mjor IA, Hucke RD, Smith GE. Amalgam restorations: Post-operative sensitivity as a function of liner treatment and cavity design. Quintessence Int 1999; 24:377-383

[4] Christensen GJ. To Base or Not to Base?. JADA 1991:122:61-62

[5] Stanley HR. Pulp capping: Conserving the dental pulp-Can it be done? Is it worth it?. Oral Surg Oral Med Oral Oathol 1989; 68:628-39.

[6] Textbook of Cariology, Edited by Anders Thylstrup & Ole Fejerskov. 1986. 372-375

[7] Antonelli, JR. Acute Dental Pain, Part II: Diagnosis and Emergency Treatment. Compendium Contin Educ Dent; Vol XI (9):526-532

[8] Davidson, CS and Feilzer AJ. Polymserization shrinkage and polymerization shrinkage stress in polymer-based restoratives. J of Dentistry 1997; 25(6):435-440

[9] Ferracane JL. Developing a more complete understanding of stresses produced in dental composites during polymerization. Dent Materials 2005; 21:36-42.

[10] Braga RR, Ferracane JL. Alternatives in Polymerization Contraction Stress Management. Crit Rev Oral Biol Med 2004; 15(3):176-184

[11] Alomari QD, Reinhardt JW, Boyer DB. Effect of liners on cusp deflection and gap formation in composite restorations. Oper Dent 2001; 26:406-411.

[12] CDC. Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States. MWR™ Recommendations and Reports 2001; 50(RR-14)

[13] Gordan VV, Mjor IA, Hucke RD, Smith GE. Effect of different liner treatments on post-operative sensitivity of amalgam restorations. Quintessence Int 1999; 30:55-59

[14] Gordan VV, Mjor IA, Moorhead JE. Amalgam restorations: Post-operative sensitivity as a function of liner treatment and cavity depth. Oper Dent 1999:24:377-383

[15] Akpata ES, Sadiq W. Post-operative sensitivity in glass-ionomer versus adhesive resin-lined posterior composites. Am J Dent 2001; 14:34-38.

[16] Powell LV, Johnson GH, Gordon GE. Factors associated with clinical success of cervical abrasion/erosion restorations. Oper Dent 1995; 20:7-13.

[17] Holtan JR, Nystrom GP, Douglas WH, Phelps RA. Microleakage and marginal placement of a glass-ionomer liner. Quintessence Int 1989; 20: 117-122.

[18] Swift EJ, Hansen SE, Bailey SJ. Effects of the XR bonding system on microleakage. Am J Dent 1990; 3: 143-146.

[19] Sidhu SK, Henderson LJ. In vitro marginal leakage of cervical composite restorations lined with a light-cured glass ionomer. Oper Dent 1992; 17: 7-12.

[20] Tsunekawa M, Usami Y, Iwaku M, Setcos JC, Marshall SJ. A new light-activated adhesive cavity liner: An in vitro bond strength and microleakage study. Dent Mater 1992; 8: 296-298.

[21] Wieczkowski G, Yu XY, Joynt RB, Davis EL. Microleakage evaluation in amalgam restorations used with bases. J Esthet Dent 1992; 4: 37-40.

[22] Youngson CC, Holguin SM. Early in vitro marginal microleakage associated with different materials under Class II amalgam restorations. Eur J Prosthodont Rest Dent 1992;1: 73-77.

[23] Robchinsky J, Donly KJ. A comparison of glass-ionomer cement and calcium hydroxide liners in amalgam restorations. Int J Periodontics Rest Dent 1993; 13: 378-383.

[24] Mason PN, Ferrari M. In vivo evaluation of glass-ionomer cement adhesion to dentin. Quintessence Int 1994; 25: 499-504.

[25] Marchiori S, Baratieri LN, de Andrada MAC, Monteiro S, Ritter AV. The use of liners under amalgam restorations: An in vitro study on marginal leakage. Quintessence Int 1998; 29: 637-642.

[26] Wibowo G, Stockton L. Microleakage of Class II composite restorations. Am J Dent 2001; 14: 177-185.

[27] Gupta S, Khinda VIS, Grewal N. A comparative study of microleakage below cemento-enamel junction using light cure and chemically cured glass ionomer cement liners. J Indian Soc Prev Dent 2002; 20: 158-164.

[28] Howdle MD, Fox K, Youngson CC. An in vitro study of coronal microleakage around bonded amalgam coronal-radicular cores in endodontically treated molar teeth. Quintessence Int 2002; 33: 22-29

[29] Douglas WH, Fundingsland JW. Microleakage of three generically different fluoride-releasing liner/bases. J Dent 1992; 20: 365-369.

[30] Blixt M, Coli P. The influence of lining techniques on the marginal seal of Class II composite resin restorations. Quintessence Int 1993; 24: 203-210.

[31] Trushkowsky RD, Gwinnett AJ. Microleakage of Class V composite, resin sandwich, and resin-modified glass ionomers. Am J Dent 1996; 9: 96-99.

[32] Dietschi D, de Siebenthal G, Neveu-Rosenstand L, Holz J. Influence of the restorative technique and new adhesives on the dentin marginal seal and adaptation of resin composite Class II restorations: An in vitro evaluation. Quintessence Int 1995; 26: 717-727.

[33] Newman JE, Hondrum S, Clem DB. Microleakage under amalgam restorations lined with Copalite, Amalgambond Plus, and Vitrebond. Gen Dent 1996; 44: 340-344.

[34] Haller B, Trojanski A. Effect of multi-step dentin bonding systems and resin modified glass ionomer cement liner on marginal quality of dentin-bonded resin composite Class II restorations. Clin Oral Invest 1998; 2: 130-136.

[35] Opdam NJM, Roeters JJM, Burgersdijk RCW. Microleakage of Class II box-type composite restorations. Am J Dent 1998; 11: 160-164.

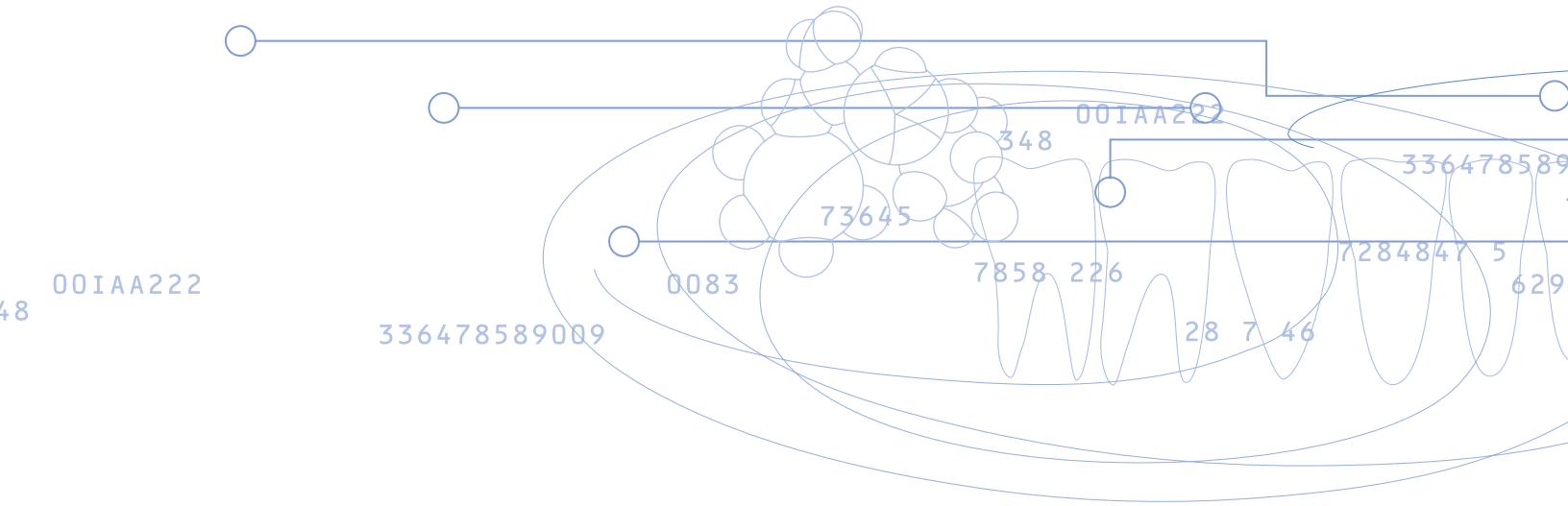
[36] Chang S-F, Jin Y-T, Lin T-S, Chang C-H, Garcia-Godoy F. Effects of lining materials on microleakage and internal voids of Class II resin-based composite restorations. Am J Dent 2003; 16: 84-90.

[37] Tolidis K, Nobecourt A, Randall RC. Effect of a resin-modified glass ionomer liner on volumetric polymerization shrinkage of various composites. Dental Materials 1998; 14:417-423.

[38] Bui HT, Mitra SB, Rolf JC, Rusin RP, Randall R. Effect of a new RMGI liner on polymerization shrinkage. IADR Bisbane 2006 Abstract 2554

[39] Plant CG, Wilson HJ. Forces Exerted on Lining Materials. British Dental Journal 1971; 131:62-66

[40] CDC, MMWR™



3M ESPE

Dental Products

3M Center
Building 275-2SE-03
St. Paul, MN 55144-1000
USA

3M Canada

Post Office Box 5757
London, Ontario N6A 4T1
Canada
1-800-265-1840 ext. 6229

10% post-consumer waste paper

70-2009-3814-3

3M ESPE

Vitrebond™ Plus Light Cure Liner/Base

technical product profile

Vitrebond™

Table of Contents

Introduction

Reasons For Using Liners

Liners are typically fluid materials that, due to their rheology, can adapt more readily to all internal aspects of a cavity preparation. They can be used to create a uniform, even surface that aids in adaptation of more viscous filling materials such as amalgams or composites.

Sensitivity following restorative procedures is, in many cases, associated with an incomplete dentinal seal. Often referred to as "dentinal sensitivity", its origin has been associated with movement of dentinal tubular fluid in a coronal direction at a rate that stimulates pulpal pain receptors.[1] For adhesive restorative procedures, the formation of a fully sealed dentinal hybrid layer will prevent this rapid outward flow of tubule fluid and greatly minimize the risk for post-operative sensitivity if not eliminate it altogether. Additionally, resin-modified glass ionomer liners (RMGI liners) used under amalgams can seal the dentin immediately and have been shown to reduce the incidence of post op sensitivity.[2,3] Liners may also provide thermal insulation to the pulp,[4] which is particularly important for deep amalgam restorations.

Calcium hydroxide use on frank pulpal exposures is the standard of practice in dentistry for two reasons. First, calcium hydroxide has been shown to protect the pulp from thermal insult. Secondly, due to a high pH (11-13), calcium hydroxide stimulates the formation of reparative dentin that eventually forms a bridge once again encasing the pulp in dentin.[5] However, if this type of liner is exposed to the oral environment (e.g., due to leakage) it will dissolve.[6]

Liners are used for indirect pulp-capping procedures. An indirect pulp cap involves leaving a layer of affected dentin (dentin that has been partially demineralized and may be discolored but not infected with bacteria) to maintain pulpal coverage. This dentin is then covered by calcium hydroxide followed by ZOE or a GI (glass ionomer)/RMGI liner.[7] This restoration may be treated as a temporary or a permanent restoration.

Methacrylate composites used as restorative materials shrink upon polymerization creating stress. The amount of stress generated during this polymerization has been shown to be dependent on many properties including the polymerization kinetics, the modulus of the filling material and cavity configuration.[8,9] These stresses generated are transferred to the restorative-tooth interface, which may cause post-operative sensitivity, gap formation, leakage, enamel cracks and cuspal movements. Many methods have been discussed and studied to manage this stress including incremental placement techniques, low shrinkage composites and stronger bond strengths of adhesives.[10] Lining the restoration with low modulus materials can also be a method for managing the stress caused by polymerization shrinkage of composites. This low modulus lining may distribute the stress more uniformly along the cavity wall. One study examined the differences in cuspal deformation for MOD composite restorations with an adhesive layer only vs. three lining techniques – a thin initial layer of the composite, a flowable composite, or a resin-modified glass ionomer liner. The results from this study indicated that the use of an RMGI liner (Vitrebond™ liner/base) reduced the cusp deflection more than the other liners.[11]

Glass ionomer (GI) or resin modified glass ionomer (RMGI) liners have been used as a renewable source of fluoride under restorations. Fluoride has been shown to reduce the incidence of caries.[12]

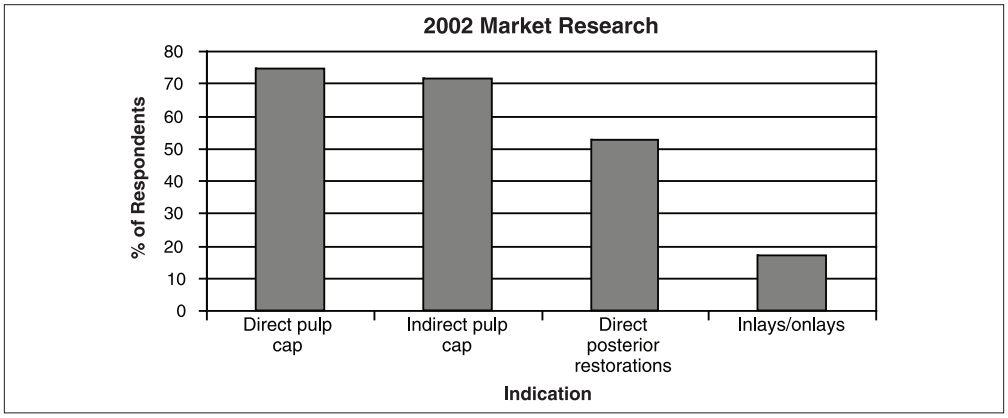
Many dentists do not use liners. They view the liner as an extra step that provides benefits achievable by careful adherence to good clinical techniques and choice of restorative materials.

When and Where are Liners Used

Liners are most frequently used under Class I or II restorations to seal dentin. They are recommended for dentin bonding in areas of deep cavity excavation where the bond with adhesives may be compromised due to increased dentinal fluid.

In a recent customer study, users of lining materials were asked to report their frequency of use of a liner on various types of indications. Most of the respondents listed pulp cap as their most frequent use of a liner.

Source: 3M ESPE Internal Data



In the field evaluation where GI/RMGI users were selected, dentists reported their frequency of using these types of liners in a variety of indications. The following summarizes their use.

- Indirect pulp cap
- Class II composite
- Class I composite, Class II amalgam and other direct restorations
- Indirect restorations
- Class I amalgam

Types of Liners

There are three types of materials most commonly used as liners – calcium hydroxide, flowable composites and GI/RMGIs.

Calcium hydroxide is the material of choice to cover frank pulpal exposure. Studies have shown that calcium hydroxide helps instigate formation of reparative dentin, which will eventually recover the exposure with tooth structure.

Flowables are composites with a lower amount of filler. The reduction in filler content allows for a more fluid consistency, less strength and lower modulus than fully filled composites. Users of flowables cite that they use flowables as liner primarily under composite restorations and to block out undercuts in crown and bridge preparations prior to impressioning. An adhesive must be used prior to application of a flowable. Because of the needs for adhesive application and the maintenance of a contamination-free field during both adhesive and flowable placement, their use under amalgam restorations may be limited. The main reasons dentists cite for using flowables are adaptation (flow), placement ease (the materials are injected directly into the preparation), shade choice is important for highly esthetic restorations, and consistency.

Glass ionomer or resin-modified glass ionomers are the third category of materials used as liners. Dentists using GIs or RMGIs as liners cite the following reasons for using these materials as protection against post-op sensitivity; they don't remove the smear layer, provide stress relief, act as a thermal barrier, seal dentin, prevent microleakage, bond in a moist environment and are easy to use.

Background

History of Vitrebond™ Liner/Base

3M introduced Vitrebond™ Light Cure Glass Ionomer Liner/Base in 1988. It was the first resin-modified glass ionomer on the market. The powder is a radiopaque, ion-leachable fluoroaluminosilicate glass powder, which is made photosensitive by its unique chemistry. The liquid component is a modified polyacrylic acid with pendant methacrylate groups, HEMA (2-hydroxyethylmethacrylate), water and photoinitiator. HEMA is present to aid in the crosslinking and to improve the wetting of the dentin surface.

The chemistry of the setting process of Vitrebond liner/base consists of two independent setting reactions. When powder and liquid are combined, the conventional glass ionomer acid-base reaction begins. The acidic liquid releases cations (Mx^{+}) from the glass, which then react with the carboxylate groups of the polyalkenoic acid resulting in chelation. When irradiated by a curing unit, a photoinitiated crosslinking of the polymer chains occur through a free radical methacrylate polymerization. The light curing mechanism is much faster than the acid-base reaction, which results in command setting of the mixed Vitrebond liner/base mass upon light exposure from a curing unit. The ionic chelation reaction continues over a long period resulting in long-term fluoride release.

Clinical studies using Vitrebond liner/base can be found in the literature. One clinical study involving Vitrebond light cure liner/base reported reduced sensitivity under amalgam restorations.[13,14] Another study compared the level of post-operative sensitivity of restorations lined with Vitrebond liner/base (covering all of the dentin surfaces) to restorations using a dentin adhesive alone. Immediate post-operative sensitivity was less frequent and less severe when Vitrebond liner/base was used.[15]

One study was found for Class V erosion cavities restored with either a conventional glass ionomer, a composite plus bonding system or a composite plus bonding system lined with Vitrebond liner/base. Restorations lined with Vitrebond liner/base showed notably better retention at 3-year recall than those restorations using composite plus bonding system restorations only.[16]

Numerous papers have been published on in-vitro studies using Vitrebond liner/base. Twenty papers reported data on microleakage studies under various types of restorative materials. The majority of the papers (twelve papers) showed superior results for the RMGI liner groups compared with controls for sealing against leakage,[17-28] however four studies reported similar amounts of leakage for restorations lined with RMGI liner and the control[29-31] and four studies showed better results for the control.[32-35]

Product Description

3M™ ESPE Vitrebond™ Plus Light Cure Glass Ionomer Liner/Base is a two-part liquid/paste system. The liquid/paste materials are contained in the 3M™ ESPE™ Clicker™ Dispensing System. This dispensing system provides simultaneous dispensing of each component for a consistent mix.

The composition is based on 3M ESPE Vitrebond light-cure glass ionomer liner/base. Vitrebond Plus liner/base provides the major benefits of glass ionomer cements including adhesion to tooth structure and fluoride release. Additionally, Vitrebond Plus liner/base offers a combination of a prolonged working time with a short set time achieved by light curing.

Composition

The liquid component of Vitrebond™ Plus liner/base consists primarily of the same resin modified polyalkenoic acid, HEMA (2-hydroxyethymethacrylate), water and initiators (including camphorquinone) found in Vitrebond™ liner/base. The paste is a combination of HEMA, BIS-GMA, water, initiators and a radiopaque fluoroaluminosilicate glass (FAS glass). This glass is different than the FAS glass contained in the original Vitrebond liner/base. The change in FAS glasses produces a reduction in the opacity of Vitrebond Plus liner/base compared to the original Vitrebond liner/base. Vitrebond Plus liner/base has been shown to exhibit the true glass ionomer reactions found in the original Vitrebond liner/base.

Indications for Use

Vitrebond Plus liner/base is indicated for lining and basing applications under the following restorations:

- Composite
- Amalgam
- Ceramic
- Metal

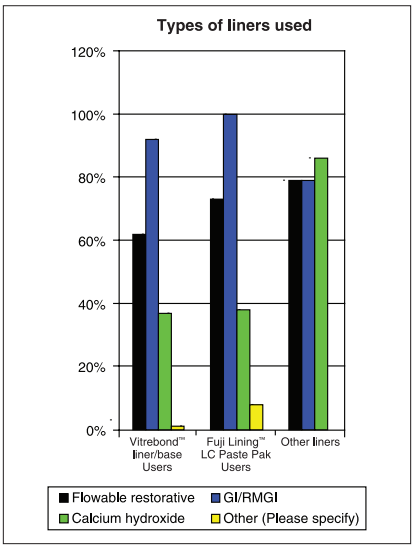
Vitrebond Plus liner/base is not indicated for direct pulp capping.

Customer Response

Source: 3M ESPE Internal Data

Market research studies were conducted to understand GI/RMGI liner use. Vitrebond Plus light cure glass ionomer liner/base was field evaluated with 144 dentists who were currently using either Vitrebond liner/base or Fuji Lining LC Paste Pak across the US. In addition to gaining more understanding of their current liner use, this field evaluation provided feedback on the actual clinical use of Vitrebond Plus liner/base.

Over 60% of the dentists frequently have more than one product in their armamentarium for lining restorations. Flowable composites and GI/RMGI products are the most frequently used materials for lining restorations.



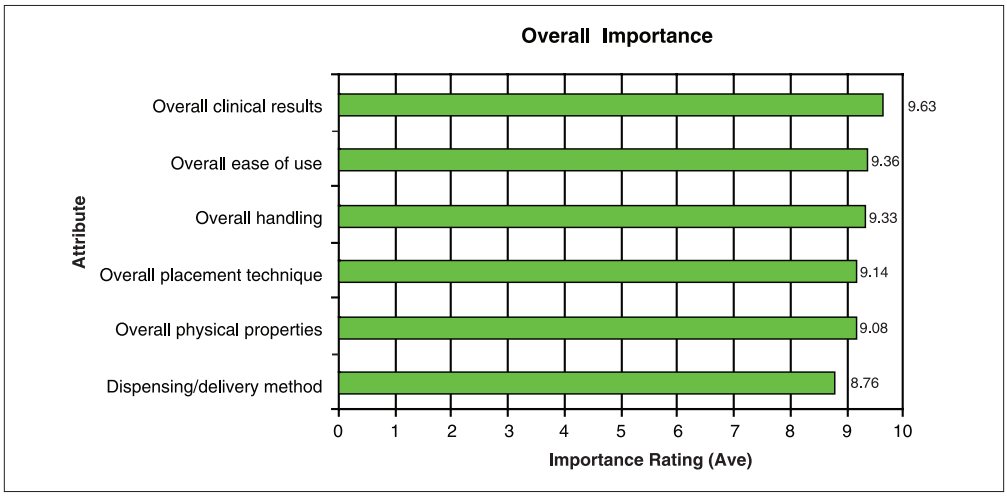
Importance

Dentists were asked to identify the reasons for using their liner of choice.

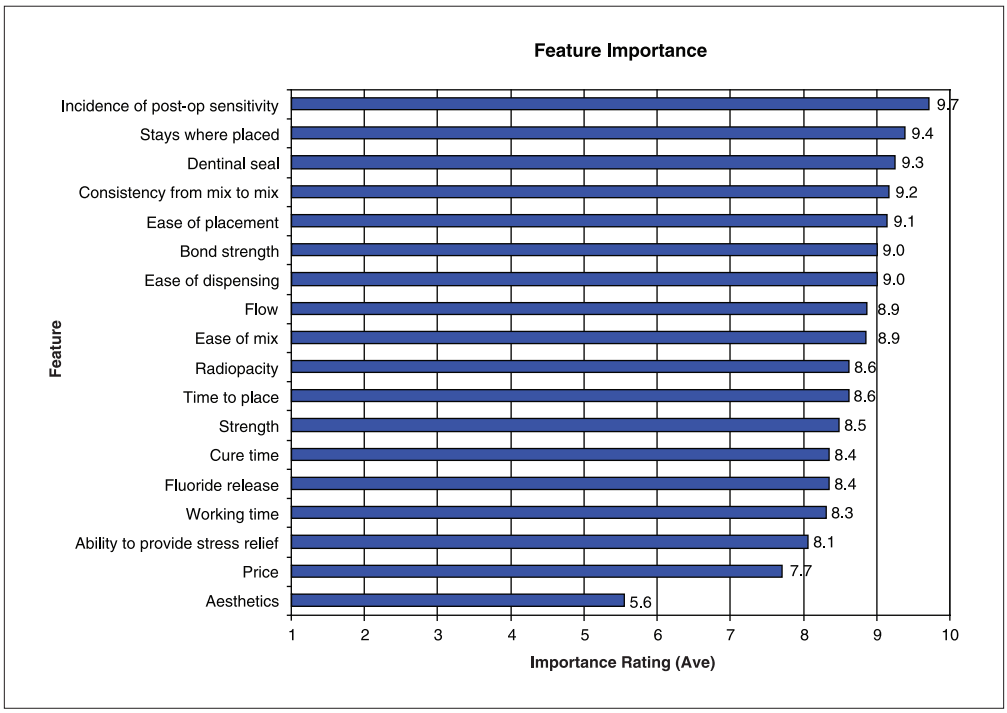
Flowable users commented that the flow (ability to adapt to all internal aspects of the preparation) was most important, closely followed by placement ease and ease of use, shades, consistency and cost.

The dentists using GI/RMGI liners were asked why they chose these products. They listed protection against post-operative sensitivity, ability to seal dentin and prevent microleakage and the ease of handling and placement. The reasons why a particular GI/RMGI product was chosen included brand, clinical results, ease of use and handling. In addition, Vitrebond™ liner/base users listed reduction in post-operative sensitivity while Fuji Lining™ LC Paste Pak users listed ease of dispensing and mix.

Dentists using GI/RMGI liners were asked to rate the importance of a variety of overall product and features associated with liners.



Source: 3M ESPE Internal Data

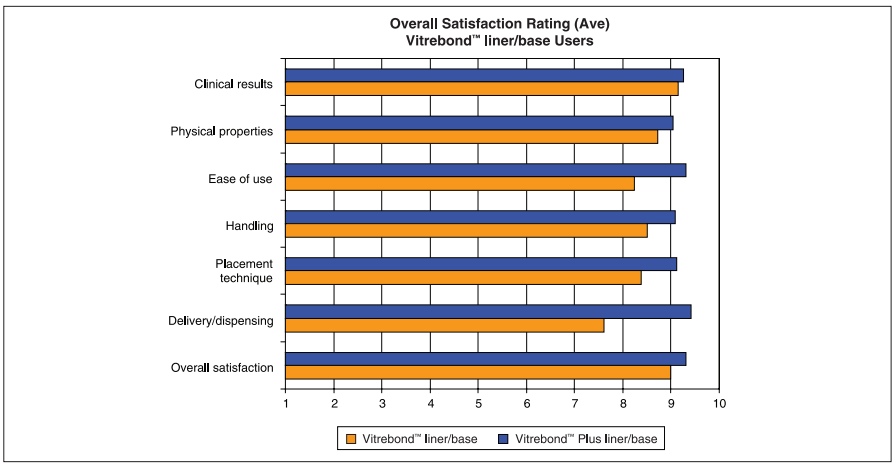


Source: 3M ESPE Internal Data

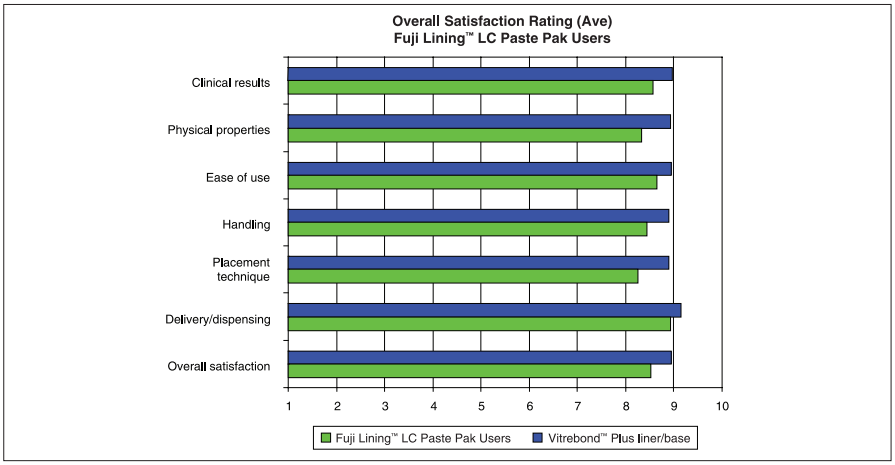
Satisfaction and Preferences

The results of the field evaluation show that Vitrebond™ liner/base users expressed significantly higher satisfaction with the delivery and ease of use of Vitrebond™ Plus liner/base. Fuji Lining™ LC Paste Pak users expressed the greatest increase in satisfaction with the placement technique.

Source: 3M ESPE Internal Data



Source: 3M ESPE Internal Data



On the individual attribute level, Vitrebond liner/base users rated their satisfaction higher on every attribute for the Vitrebond Plus liner/base. Most notably significant improvements were made in:

- ease of dispensing
- ease of mix
- consistency from mix to mix

Fuji Lining LC Paste Pak users reported higher levels of satisfaction with Vitrebond Plus liner/base for:

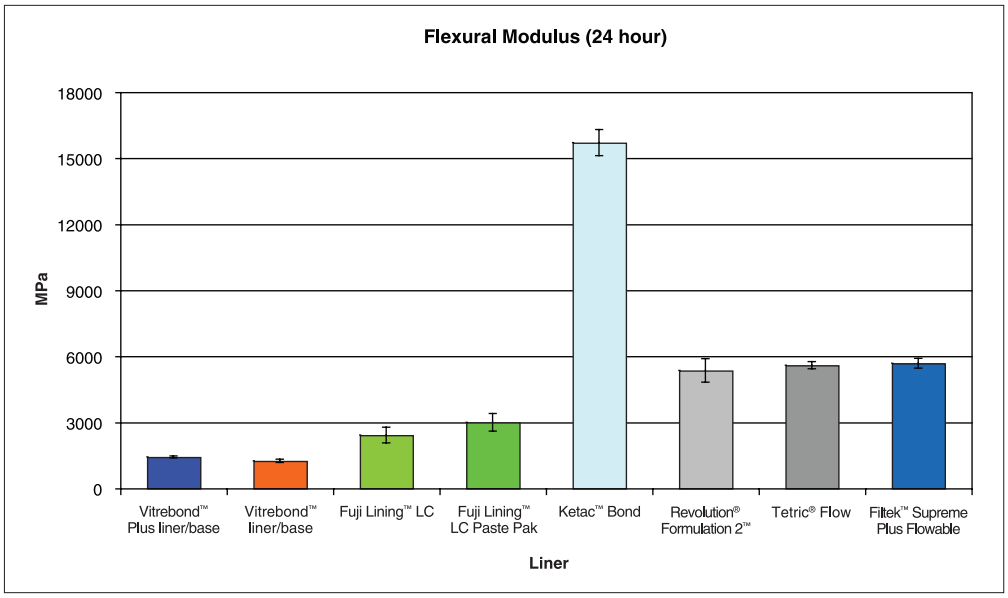
- handling (staying where placed and flow)
- radiopacity

In terms of importance, Fuji Lining LC Paste Pak users rated the importance of the liner staying where placed as their number two product feature (just behind incidence of post-operative sensitivity).

Physical Properties

Flexural Modulus

Flexural modulus is a method of defining a material's stiffness. A low modulus indicates a flexible material. The flexural modulus is measured by applying a load to a material specimen that is supported at each end.

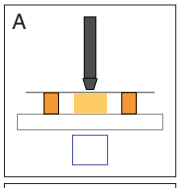


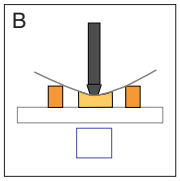
Source: 3M ESPE Internal Data

The flexural modulus of Vitrebond™ Plus liner/base is lower (it is less rigid) than that of GC Fuji Lining™ LC and GC Fuji Lining™ LC Paste Pak, 3M ESPE Ketac™ Bond and Filtek™ Supreme Plus Flowable, Vivadent Tetric® Flow and Kerr Revolution® Formula 2™. The flexural modulus of Vitrebond Plus liner/base is comparable (equivalent) to Vitrebond liner/base.

Polymerization Shrinkage Buffer

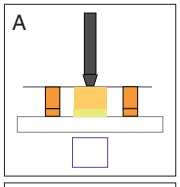
Deflection without liner

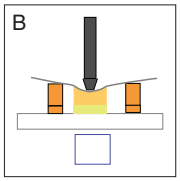




A method for determining polymerization shrinkage was described by Watts and Cash (Meas. Sci. Technol. 2(1991) 788-794). In this method, a disc shaped test specimen is bonded to and sandwiched between two glass plates and light cured through the lower rigid plate. The flexible upper plate is deflected during the polymerization of the test specimen. Deflection is measured and recorded as a function of time. The less the flexible plate bends, the lower the shrinkage. Although this process actually measures linear shrinkage, volumetric shrinkage was closely approximated due to the fact that the dimensional changes were limited to the thickness dimension. The lower the value, the less the shrinkage.

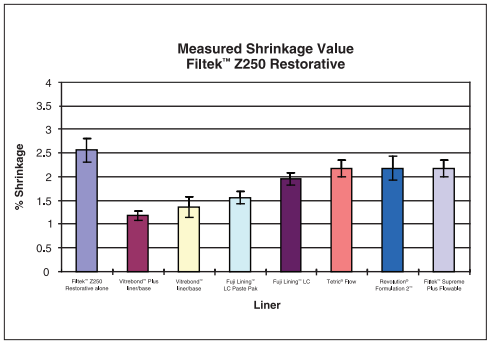
Deflection with liner

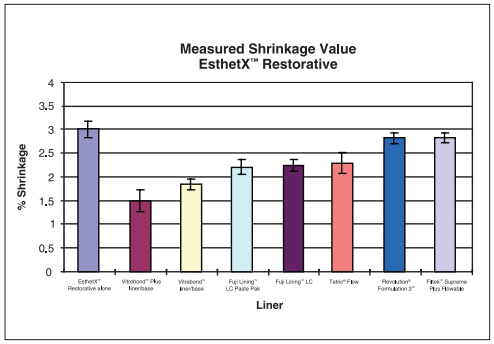


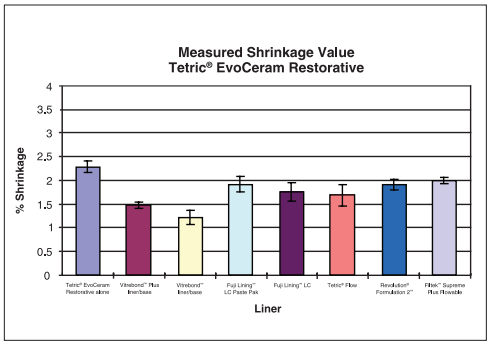


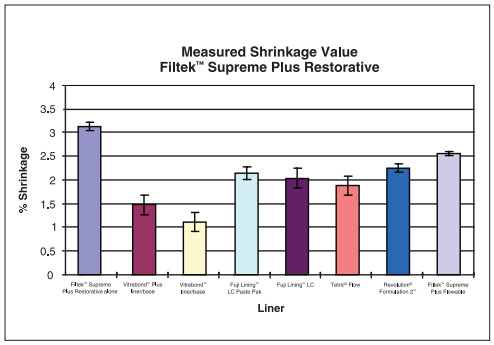
To measure the buffering effect of liners on the polymerization shrinkage this test was modified to include a liner layer between the rigid glass plate and the composite layer. The liner was cured prior to application of the composite. The same volume of composite was used in all samples.[36-38] In this test, composite samples were exposed for length of time that was recommended by the composite manufacturer to a 3M™ Visilux™ 2 Visible Light Curing Unit. The final shrinkage was recorded 5 minutes after the end of light exposure. Results showed differences between liners and composite materials.

Source: 3M ESPE Internal Data









The ability of Vitrebond™ Plus liner/base to buffer an effect of polymerization shrinkage is greater than GC Fuji Lining™ LC and flowable liners when tested using Filtek™ Z250, EsthetX™ or Filtek™ Supreme Plus Universal Restorative.

The ability of Vitrebond Plus liner/base to buffer an effect of polymerization shrinkage is similar to Vitrebond liner/base when tested using Filtek Z250 and Tetric® EvoCeram.

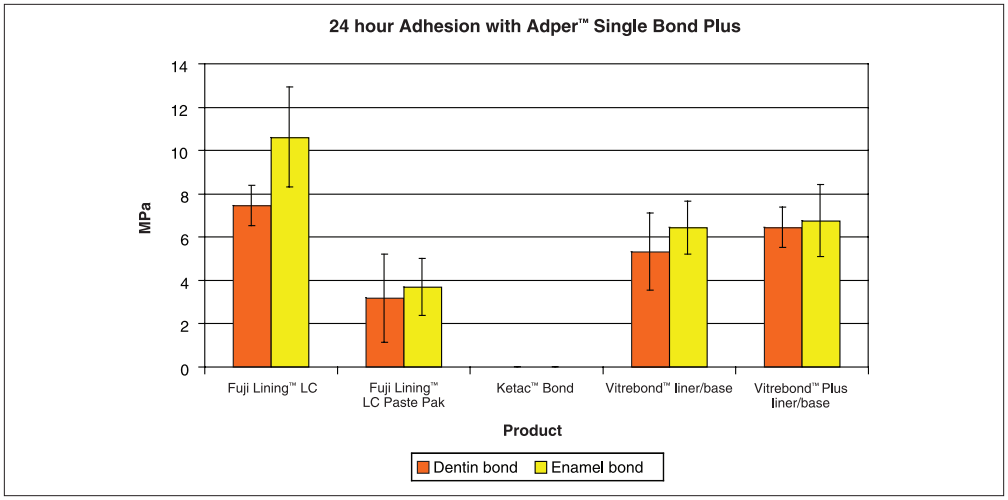
The ability of Vitrebond Plus liner/base to buffer an effect of polymerization shrinkage is greater than GC Fuji Lining™ LC Paste Pak and Revolution® and Filtek™ Supreme Plus Flowable when tested using Tetric EvoCeram.

These results can be closely correlated to the flexural modulus data.

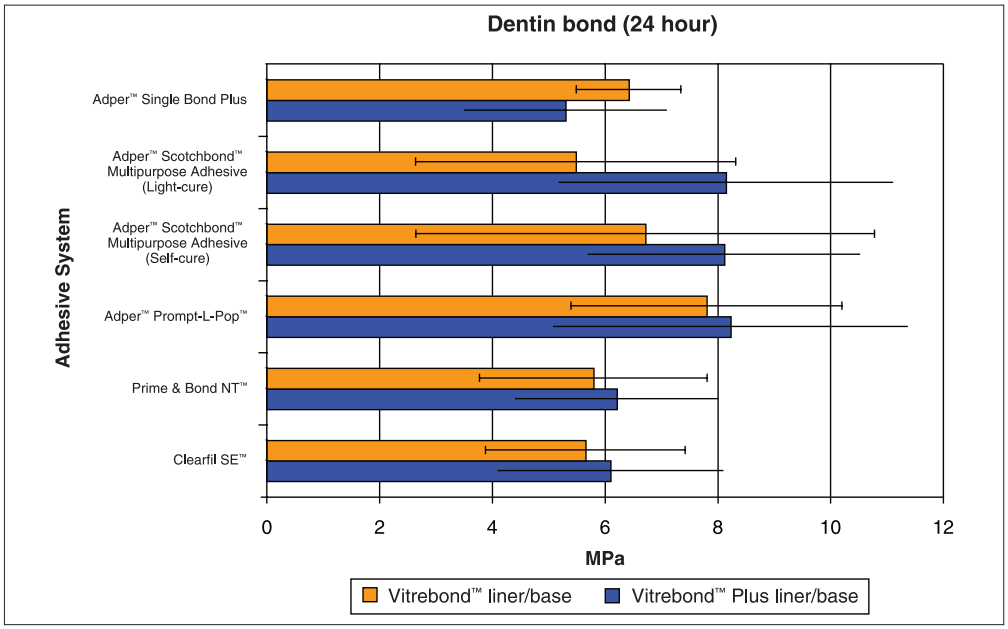
Bond Strength

Vitrebond Plus light cure glass ionomer liner/base was also tested for adhesion to bovine dentin and enamel using a shear wire-loop method. In this method, the liner was placed and cured directly on the prepared bovine tooth. An adhesive was then applied (following the corresponding instructions for use) and cured. Then an approximate 5mm diameter button of 3M ESPE Filtek™ Z250 Universal Restorative is bonded to the adhesive coated liner layer and a shear force is applied with a wire loop until failure.

Source: 3M ESPE Internal Data

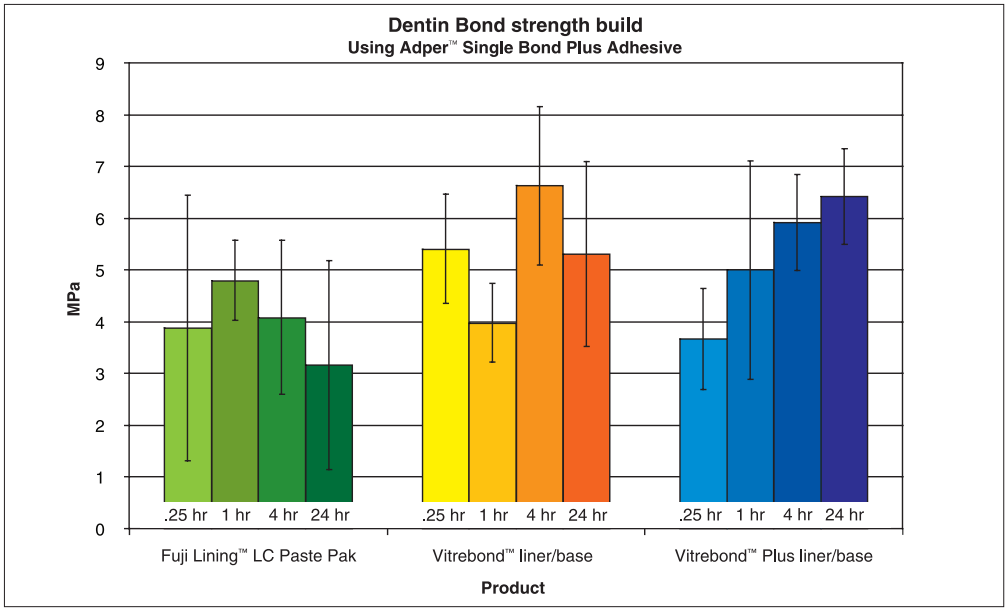


The 24-hour adhesion to dentin of Vitrebond™ Plus liner/base is greater than that for GC Fuji Lining™ LC Paste Pak and 3M ESPE Ketac™ Bond Glass Ionomer Base Material. The 24-hour adhesion to dentin of Vitrebond™ Plus liner/base is comparable to that for GC Fuji Lining LC and Vitrebond Light Cure Glass Ionomer Liner/Base. The enamel bond strength of Vitrebond Plus liner/base is greater than Ketac Bond Glass Ionomer Base Material. The enamel bond strength of Vitrebond Plus liner/base is comparable to Vitrebond Light Cure Glass Ionomer Liner/Base and GC Fuji Lining LC Paste Pak.



Source: 3M ESPE Internal Data

Vitrebond Plus liner/base can be used with any type of adhesive (light or self cured; separate etch or self-etch, i.e. - 4th, 5th or 6th generation adhesives) on dentin or enamel. The bond strength of Vitrebond Plus liner/base to dentin and enamel is comparable to Vitrebond liner/base regardless of adhesive system used.



Source: 3M ESPE Internal Data

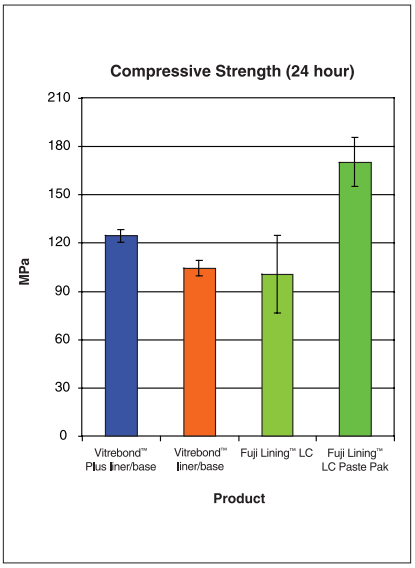
Not only is the 24-hour adhesion important, so is the immediate bond strength. In order for the liner to withstand composite polymerization contraction forces and impression removal forces without pulling away from the dentin to form gaps, the bond has to develop quickly. The (dentin and enamel) bond of Vitrebond Plus liner/base develops quickly (within 15 minutes) which is comparable to the clinically successful Vitrebond liner/base.

Vitrebond Plus liner/base maintains its adhesion to dentin and enamel over time.

Compressive and Diametral Tensile Strength

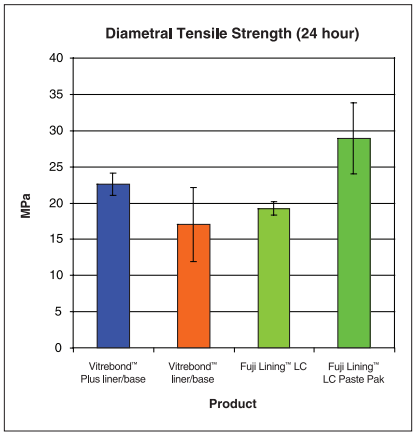
Source: 3M ESPE Internal Data

Compressive strength is particularly important because of chewing forces. Rods are made of the material and simultaneous forces are applied to the opposite ends of the sample length. The sample failure is a result of shear and tensile forces. The compressive strength of Vitrebond™ Plus liner/base is comparable (equivalent) to Vitrebond™ Light Cure Glass Ionomer Liner/Base and GC Fuji Lining™ LC.



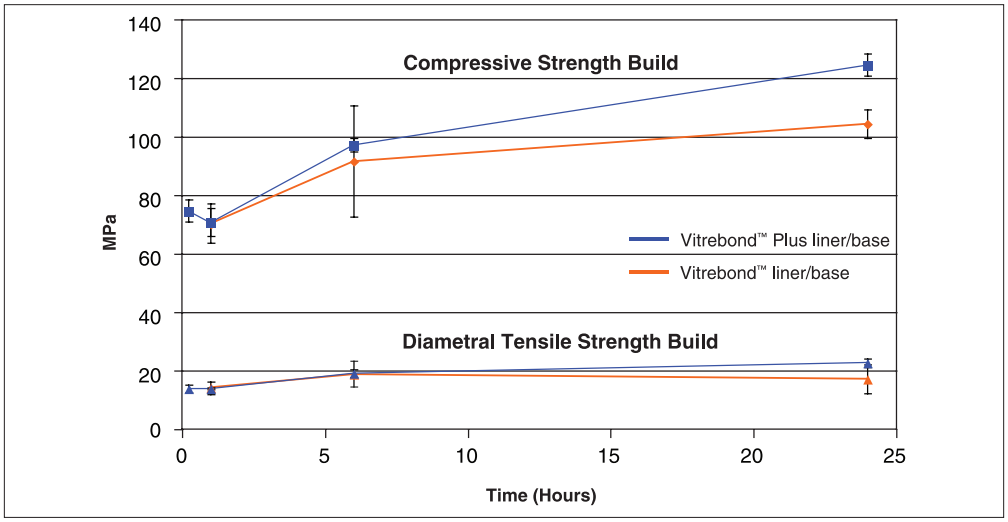
Diametral Tensile strength is measured using a similar apparatus. Compressive forces are applied to the sides of the sample, not the ends, until fracture occurs. The diametral tensile strength of Vitrebond Plus liner/base is comparable (equivalent) to Vitrebond liner/base, GC Fuji Lining LC and Fuji Lining™ LC Paste Pak.

Source: 3M ESPE Internal Data



Because of the two curing mechanisms (rapid polymerization and a slower acid-base reaction) the strength of Vitrebond and Vitrebond Plus liner/bases is more modulated than for methacrylate flowable composites. The rate the compressive and diametral tensile strength of Vitrebond Plus liner/base develops is similar to that of Vitrebond liner/base. This is especially important during the packing of amalgam. If the lining is weak (partially set) this process may cause fracture of the lining. If cavities are deep, this may result is sensitivity to temperature.[39]

Source: 3M ESPE Internal Data

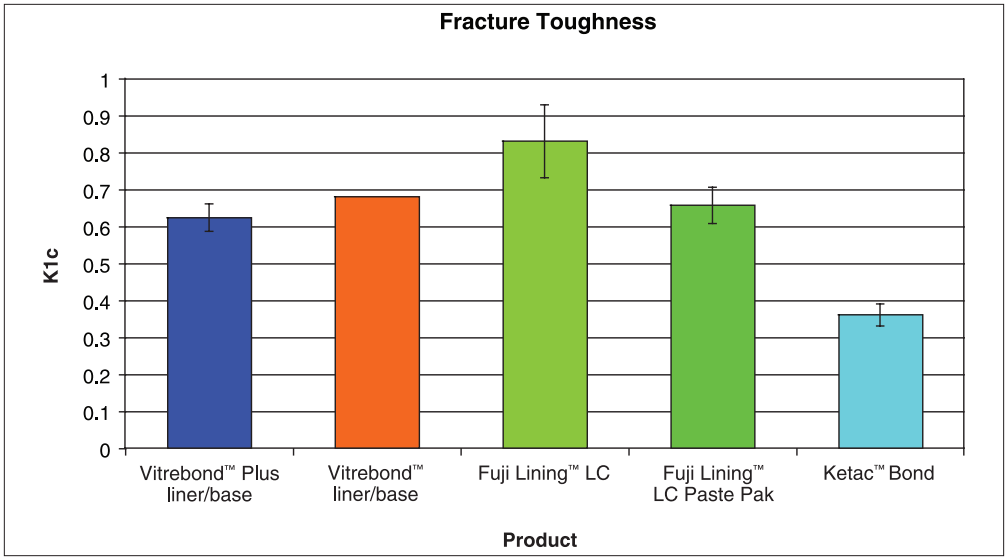


About 60% of the diametral tensile and compressive strength for Vitrebond Plus liner/base develops within 15 minutes.

Vitrebond Plus liner/base maintains its [diametral tensile and compressive] strength over time. [comparable to other RMGI liners]

Fracture Toughness

The values reported for fracture toughness (K1c) are related to the energy required to propagate a crack. In this test a short rod of material is cured. A chevron or notch is cut into the cylinder and the parts on either side of the chevron are pulled apart. Below are the 24-hour values for wet fracture toughness.

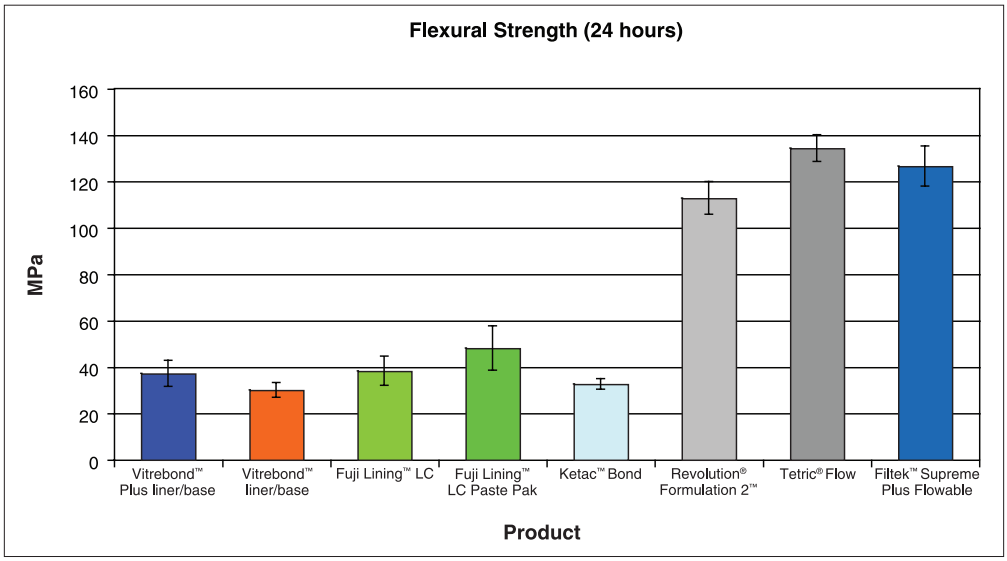


Source: 3M ESPE Internal Data

The fracture toughness of Vitrebond™ Plus liner/base is comparable to Vitrebond™ Light Cure Glass Ionomer Liner/base and GC Fuji Lining™ LC Paste Pak.

Flexural Strength

Flexural strength is determined in the same test as flexural modulus. Flexural strength is the value obtained when the sample breaks. This test combines the forces found in compression and tension.



Source: 3M ESPE Internal Data

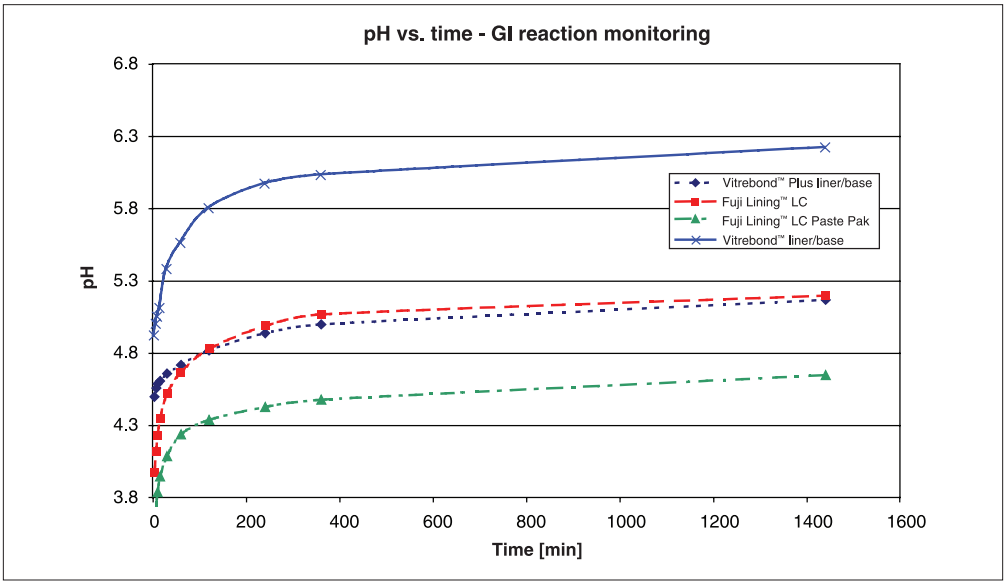
The flexural strength of Vitrebond Plus liner/base is comparable (equivalent) to Vitrebond Light Cure Glass Ionomer Liner/base, Ketac™ Bond Glass Ionomer Base Material and GC Fuji Lining™ LC.

GI Properties

FTIR analysis confirms that Vitrebond™ Plus liner/base exhibits true glass ionomer chemistry.

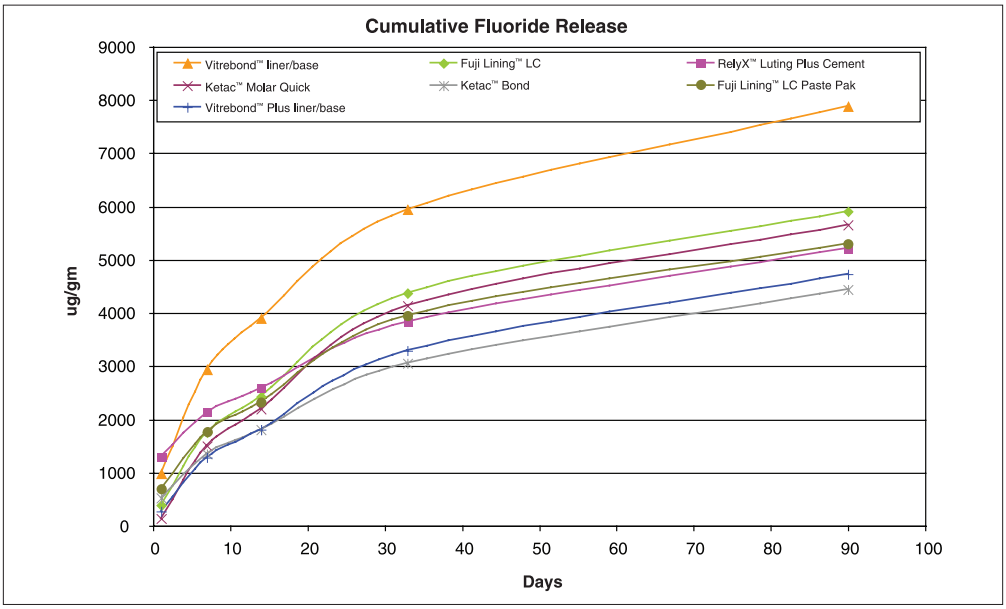
The pH of cured Vitrebond Plus liner/base is significantly more neutral than cured GC Fuji Lining™ LC Paste Pak. The pH was monitored over time by placing freshly light-cured cured discs of the liners in water. A pH electrode was placed on top of the disc and pH readings were taken periodically (from 2 minutes after light cure to 24 hours after light cure).

Source: 3M ESPE Internal Data



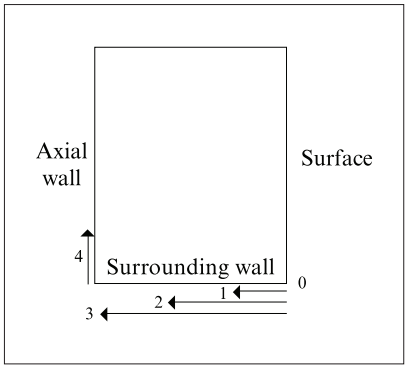
Fluoride Release

Source: 3M ESPE Internal Data



Discs of each liner were prepared. Cured discs were then suspended in distilled water and stored in a 37ºC oven. Fluoride release was measured using a fluoride electrode at specified times for all of the materials. Vitrebond Plus liner/base releases fluoride over time in the range of clinically proven glass ionomers. Fluoride has been shown to reduce the incidence of secondary decay.[40]

Microleakage



Extracted human molars were cleaned and pumiced. Cylindrical cavities (3mm diameter and 2mm deep) were prepared at the CEJ. The teeth were kept slightly moist throughout the entire procedure. The liners included in this study were Vitrebond™ Plus liner/base, Vitrebond™ liner/base, Fuji Lining™ LC Paste Pak and Ketac™ Bond. All liners were placed according to manufacturer's instructions. The teeth were etched, Adper™ Single Bond Plus applied and cured, and a single layer of Filtek™ Z250 Universal Restorative placed and cured. The restoration surface was finished using Sof-Lex™ Coarse and Medium discs to remove flash. The teeth were then placed in a 37ºC, 90%RH chamber for 1 hour then kept in distilled water for a total of 24 hours. The teeth were then thermocycled for 700 cycles (5ºC-55ºC). The teeth were then immersed in 0.5% basic fuschin dye solution. Teeth were sectioned and microleakage was scored as described on the diagram.

Restorations placed using Vitrebond Plus liner/base exhibited low microleakage, comparable to Vitrebond liner/base.

ISO Testing

Passes ISO 9917-2:1998(E) Requirements (Sec 5) for Type II Light Activated cement for use as a liner/base.

Test	Requirement (minimum values)	Vitrebond Plus liner/base
Ambient light sensitivity	No change for at least 30 seconds	Pass
Depth of cure	Not less than 1mm and Not more than 0.5mm below the stated value	Halogen light 20 seconds for 1.5mm
Flexural strength	>10MPa	37.2MPa
Radiopacity	Equal to (or more than) an equivalent thickness of Al	1.03 (pass)

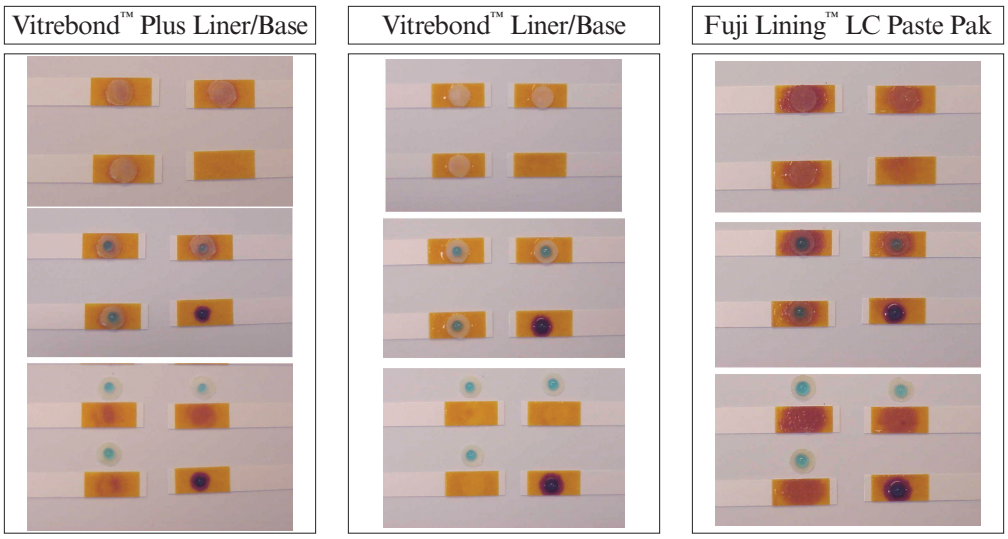
Compatibility with Calcium Hydroxide

In clinical situations where frank pulpal exposure could not be prevented, the use of calcium hydroxide to cover the exposure followed by a layer of Vitrebond Plus to seal in the calcium hydroxide and cover the remaining dentin is recommended. As calcium hydroxide is basic and glass ionomer chemistry relies on an acid-base reaction, the compatibility between these two materials was examined. It was found that Vitrebond Plus liner/base could be used over calcium hydroxide.

Protect Dentin (Thermal and Acid Barrier)

Vitrebond Plus liner/base protects dentin from etchant. Thin discs of Vitrebond Plus were made and cured. These discs were placed on top of wet pH paper (range 2.5-4.5). Etchant was then syringed on top of the disc and let sit for 15 seconds. The discs were removed and the pH paper examined to determine any color change due to the etchant. Only a slight color change was noted with the Vitrebond and the Vitrebond Plus liner/base materials. The discs themselves of Fuji Lining LC Paste Pak caused significant color change of the pH paper.

Source: 3M ESPE Internal Data



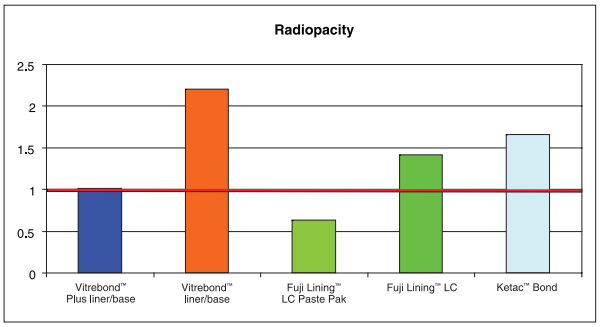
Acid etching Vitrebond™ Plus liner/base is not deleterious. The surface of cured Vitrebond Plus liner/base remains essentially unchanged after acid etching. The surface of a cured disc of Fuji Lining™ LC Paste Pak was significantly altered after exposure to acid etching.

Vitrebond Plus liner/base insulates tooth structure. Vitrebond Plus liner/base acts as a thermal barrier.

Radiopacity

Radiopacity was measured following the ISO 9917-2 1998E methodology. The measured radiopacity of Vitrebond Plus liner/base was lower than Vitrebond™ liner/base but higher than Fuji Lining LC Paste Pak. As part of the field evaluation, participating dentists were asked to take an X-Ray of a restoration lined with Vitrebond Plus liner/base. Dentists reported an equivalent satisfaction with the radiopacity of Vitrebond Plus liner/base and Vitrebond liner/base.

Source: 3M ESPE Internal Data



Working Aspects

In the field evaluation dentists reported that Vitrebond Plus liner/base exhibited an acceptable working time.

The recommended cure time of Vitrebond Plus liner/base is less than GC Fuji Lining LC and Vitrebond™ Light Cure Glass Ionomer Liner/Base. Cure time of Vitrebond Plus liner/base is 20 seconds in (1.5mm or less) increments.

Delivery

Vitrebond Plus liner/base is packaged in the unique 3M ESPE Clicker™ Dispensing System. The Clicker™ Dispensing System provides simultaneous, pre-measured, and uniform amounts of each component. A consistent volume of each component assures a consistent product. The Clicker dispensing system delivers a consistent A:B ratio regardless of amount in the clicker, age of the material, (within its shelf life) or operator. This increases the precision and the accuracy of the amount dispensed for Vitrebond Plus liner/base vs. the conventional dispensing of powder liquid for Vitrebond liner/base. The Clicker dispenser reduces A:B ratio variability of Vitrebond Plus liner/base by about 74% when compared to the traditional powder/liquid dispensing of Vitrebond liner/base.

The Clicker Dispensing System minimizes possible skin contact of dual components.

Management of Post-operative Sensitivity

Sensitivity following restorative procedures is, in many cases, associated with an incomplete dentinal seal. Often referred to as "dentinal sensitivity", its origin has been associated with movement of dentinal tubular fluid in a coronal direction at a rate that stimulates pulpal pain receptors (Brannstrom). For adhesive restorative procedures, the formation of a fully sealed dentinal hybrid layer will prevent this rapid outward flow of tubule fluid and greatly minimize the risk for postoperative sensitivity if not eliminate it altogether.

Isolation with rubber dam is highly recommended. - Contamination of the preparation during adhesive placement of any adhesive may potentially compromise the dentinal seal leading not only to post-operative sensitivity, but also possible margin discoloration and lack of long-term retention.

Use of 3M ESPE Vitrebond™ Plus Liner/Base - The resin-modified glass ionomer, Vitrebond Plus liner/base, is recommended for the management of post-operative sensitivity. Vitrebond Plus liner/base can be used routinely to seal the dentin of class I and II restorations since it is with these restorations where post-operative sensitivity often occurs. It is also recommended for dentin bonding in areas of deep cavity excavation where the bond with total etch adhesives may be compromised due to increased dentinal fluid. Vitrebond Plus liner/base offers several features, which help reduce the risk of post-operative sensitivity:

- Placement on dentin prior to etch so dentinal tubules are more easily sealed and are protected from etch;
- Clearly observable coverage during placement;
- Low viscosity to easily fill all the divots and undercuts created by cavity preparation
- Low microleakage;
- Low modulus
- The layer buffers an effect of polymerization shrinkage;
- Thermal barrier to insulate tooth from temperature variations.

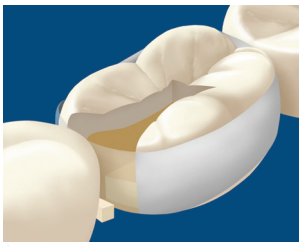
Adhesive Application - For optimum penetration of the adhesive into dentin following the etching step, the dentin must remain moist. Dehydration of the dentinal surface will cause the collagen fibrils to collapse resulting in a reduction in the porosity of this surface. Consequently, the collagen layer in this state will inhibit the penetration of adhesive throughout this layer and compromise the integrity of the dentinal seal. Following the few simple steps described below will promote complete dentinal sealing and minimize potential for post-operative sensitivity.

- Utilize a wet bonding technique.
    - o Use of compressed air is not recommended to remove pooled water remaining after the etch step.
    - o Blot excess moisture from the preparation using a cotton pellet or mini-sponge. The dentinal surface should appear glistening without pooling of water.
    - o Apply adhesive (or primer) immediately after blotting. Evacuators may hasten dentinal surface dehydration. If application is delayed, rewet and blot as above.
- Use a self-etch adhesive.

Technique Guides

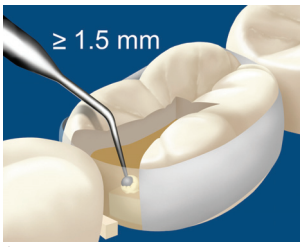
3M ESPE

Liner/Base Application
Vitrebond™ Plus Light-Cure
Glass Ionomer Liner/Base

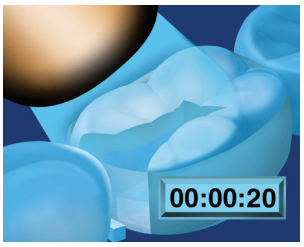

1

2

3



4



5

6

Instructions For Use

3M™ ESPE™ Vitrebond™ Plus Light Cure Glass Ionomer Liner Base in a 3M™ ESPE™ Clicker™ Dispenser

General Information

3M ESPE Vitrebond Plus light cure glass ionomer is a two-part liquid/paste system. The liquid/paste materials are contained in the 3M™ ESPE™ Clicker™ Dispensing System. This dispensing system provides simultaneous dispensing of each component for a consistent mix.

The composition is based on 3M™ ESPE™ Vitrebond™ Light-Cure Glass Ionomer Liner/Base. The paste contains a radiopaque fluoro-aluminosilicate glass. The liquid contains a modified polyalkenoic acid. Vitrebond Plus liner/base provides the major benefits of glass ionomer cements including adhesion to tooth structure and sustained fluoride release. Additionally, Vitrebond Plus liner/base offers a combination of a prolonged working time with a short set time achieved by light curing.

Indications

Vitrebond Plus liner/base is indicated for lining and basing applications under the following restorations:

- Composite
- Amalgam
- Ceramic
- Metal

Contraindications:

Vitrebond Plus liner/base is **not indicated for direct pulp capping**. If a pulp exposure has occurred and if the situation warrants a direct pulp capping procedure use a minimum amount of calcium hydroxide on the exposure followed by an application of Vitrebond Plus liner/base.

Precautionary Information for Patients:

Avoid use of this product in patients with known acrylate allergies. This product contains substances that may cause an allergic reaction by skin contact in certain individuals. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product.

Precautionary Information for Dental Personnel:

This product contains substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove, remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed.

Instructions for Use

1. **Isolation:** A rubber dam is the preferred method of isolation. Avoid water and saliva contamination during application and setting of the Vitrebond™ Plus liner/base.

2. **Restoration/tooth Preparation.** Remove carious dentin and all amalgam or other base material from the internal form of the preparation. Rinse and dry cavity. Leave tooth surface moist. **Do not overdry.**

3. **Pulp Protection:** Vitrebond Plus liner/base **is not indicated for direct pulp capping.** If a pulp exposure has occurred and if the situation warrants a direct pulp capping procedure use a minimum amount of calcium hydroxide on the exposure followed by an application of Vitrebond Plus liner/base.

4. **Dentin Pretreatment: Dentin pretreatment is not recommended.** The use of smear layer cleansers such as polyacrylic acid based solutions results in decreased adhesion of Vitrebond Plus liner/base.

5. **Dispensing**

   a. **Remove Cap:** Press and hold tab to unlock the protective cap. Slide cap off clicker dispenser.

   b. **Dispense:** Touch dispenser tip to mix pad. Fully depress clicker lever to dispense "1 click" of Vitrebond Plus liner/base on to the mix pad. Release lever when paste stops extruding (1-2 seconds). Repeat dispensing process for additional material. 1-2 clicks will be sufficient for most restorations.

   c. **Clean:** Wipe dispenser tip with alcohol-dampened gauze.

   d. **Replace Protective Cap:** Replace protective cap immediately after dispensing. Hold the sides of the clicker cartridge and slide cap into place until securely latched as indicated by the audible "click".

   Do not depress the clicker lever during cap removal and/or replacement.

   Do not advance the dispenser plunger during cap removal and/or replacement.

   An approximate number of Vitrebond Plus liner/base applications remaining in the 3M™ ESPE™ Clicker™ Dispensing System are indicated on the underside of the plunger adjacent to the black arrow on the cartridge.

6. **Mixing:** Using a small spatula, mix paste/liquid components together rapidly (10-15 seconds). The mixed Vitrebond Plus liner/base should have a smooth consistency and glossy appearance.

   To minimize water evaporation and maximize working time, confine spatulation of the paste/liquid to a small area on the mixing pad, about one inch (2.5 cm) in diameter.

7. **Application and curing:** Avoid water and saliva contamination during application and setting of the liner/base. Rubber dam is the best means of isolation.

   Apply a thin layer (1/2mm or less) of the mixed Vitrebond Plus liner/base material to the dentin surfaces of the prepared cavity using a ball applicator or other suitable instrument. Do not take out to the margins.

   Vitrebond Plus liner/base material has a minimum working time of 2 minutes 30 seconds at a room temperature of about 73ºF (23ºC). Higher temperatures will shorten working time.

   Cure Vitrebond Plus liner/base by exposing **layers of 1.5 mm or less for 20 seconds** to a 3M ESPE curing light or other curing unit of comparable intensity.

The delayed auto-setting mechanism of Vitrebond™ Plus liner/base will ensure an eventual cure of material shielded from light polymerization such as undercut areas.

Where a thicker application of the Vitrebond Plus liner/base is desired, the best adhesion can be achieved by first placing and light curing a thin layer followed by placement of a second layer up to 1.5 mm in depth and light cure for 20 seconds.

8. **Adhesive system:** Continue with the bonding step of the restorative procedure starting with etching. Etchant on the liner/base is not deleterious.

Storage and Use

1. The liner/base is designed for use at room temperature of approximately 21-24ºC or 70-75ºF. Avoid elevated temperatures.
2. Vitrebond Plus liner/base is light sensitive. Protect from ambient light exposure by dispensing just prior to use and replacing Clicker™ dispenser cap immediately after dispensing.
3. Clicker disinfection. Disinfect the capped Clicker using an intermediate level disinfection process (liquid contact) as recommended by the CDC (Centers for Disease Control) and endorsed by the ADA (American Dental Association). Guidelines for Infection Control in Dental Health-Care Settings – 2003 (Vol. 52; No. RR-17), Center for Disease Control and Prevention.
4. Shelf life of the Vitrebond Plus liner/base at room temperature is 24 months. See outer package for expiration dates.
5. Keep Clicker dispensers in foil package until time of initial use. Once the foil pouch is opened, the shelf life of the paste in the Clicker dispenser is 12 months or date of expiry.
6. Storage in refrigerator ensures longest possible shelf life. Allow to reach room temperature prior to use.
7. Do not store materials in proximity to eugenol containing products.

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the products for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

Questions and Answers

Q. Can I use Vitrebond™ Plus liner/base with any adhesive system?

A. Yes. The adhesion using Vitrebond Plus liner/base (covering all dentin) was tested using a variety of 4th, 5th and 6th generation adhesives. In all cases the failure occurred either within the dentin or within the liner layer.

Q. Do I have to keep the etchant off the Vitrebond Plus liner/base layer?

A. No, we have found that etchant is not deleterious to a cured Vitrebond Plus liner/base layer.

Q. I use a flowable as my first increment of composite, why would I use Vitrebond Plus liner/base?

A. Particularly in deep cavities where dentinal fluid flow is higher which may compromise the performance of the bonding agent, Vitrebond Plus liner/base seals the dentin.

Q. Can I use Vitrebond Plus liner/base under my esthetic restorations without altering the final esthetic result?

A. Yes. Vitrebond Plus liner/base is much lighter in color (less chroma) than the Fuji Lining LC Paste Pak formulation and is less opaque than the original Vitrebond liner/base. Field evaluators noted the esthetic results were significantly better with Vitrebond Plus liner/base.

Q. The bond strength values are lower than my current adhesive system alone, why should I not be concerned?

A. Bond to tooth structure with glass ionomer materials is very different than methacrylate bonding. Glass ionomers have two bonding mechanisms, a micromechanical bond and a chemical bond to tooth structure that continues to form through the ongoing acid-base setting reaction (typical glass ionomer reaction). As noted above, the adhesion testing resulted in failure either within the Vitrebond Plus liner/base or the dentin layer. The bond strength (and bond failure mode), microleakage and presence of a glass ionomer reaction of Vitrebond Plus liner/base are the same as for the original Vitrebond liner/base. The adequacy of this performance is documented with the clinically successful history of Vitrebond liner/base.

Reference:

[1] Brannstrom M. (1986). The hydrodynamic theory of dentinal pain. Sensation in preparations, caries, and the dentinal crack syndrome. J Endodontics, 12(10)

[2] Gordan VV, Mjor IA, Hucke RD, Smith GE. Effect of different liner treatments on post-operative sensitivity of amalgam restorations. Quintessence Int 1999; 30:55-59

[3] Gordan VV, Mjor IA, Hucke RD, Smith GE. Amalgam restorations: Post-operative sensitivity as a function of liner treatment and cavity design. Quintessence Int 1999; 24:377-383

[4] Christensen GJ. To Base or Not to Base?. JADA 1991:122:61-62

[5] Stanley HR. Pulp capping: Conserving the dental pulp-Can it be done? Is it worth it?. Oral Surg Oral Med Oral Oathol 1989; 68:628-39.

[6] Textbook of Cariology, Edited by Anders Thylstrup & Ole Fejerskov. 1986. 372-375

[7] Antonelli, JR. Acute Dental Pain, Part II: Diagnosis and Emergency Treatment. Compendium Contin Educ Dent; Vol XI (9):526-532

[8] Davidson, CS and Feilzer AJ. Polymserization shrinkage and polymerization shrinkage stress in polymer-based restoratives. J of Dentistry 1997; 25(6):435-440

[9] Ferracane JL. Developing a more complete understanding of stresses produced in dental composites during polymerization. Dent Materials 2005; 21:36-42.

[10] Braga RR, Ferracane JL. Alternatives in Polymerization Contraction Stress Management. Crit Rev Oral Biol Med 2004; 15(3):176-184

[11] Alomari QD, Reinhardt JW, Boyer DB. Effect of liners on cusp deflection and gap formation in composite restorations. Oper Dent 2001; 26:406-411.

[12] CDC. Recommendations for Using Fluoride to Prevent and Control Dental Caries in the United States. MWR™ Recommendations and Reports 2001; 50(RR-14)

[13] Gordan VV, Mjor IA, Hucke RD, Smith GE. Effect of different liner treatments on post-operative sensitivity of amalgam restorations. Quintessence Int 1999; 30:55-59

[14] Gordan VV, Mjor IA, Moorhead JE. Amalgam restorations: Post-operative sensitivity as a function of liner treatment and cavity depth. Oper Dent 1999:24:377-383

[15] Akpata ES, Sadiq W. Post-operative sensitivity in glass-ionomer versus adhesive resin-lined posterior composites. Am J Dent 2001; 14:34-38.

[16] Powell LV, Johnson GH, Gordon GE. Factors associated with clinical success of cervical abrasion/erosion restorations. Oper Dent 1995; 20:7-13.

[17] Holtan JR, Nystrom GP, Douglas WH, Phelps RA. Microleakage and marginal placement of a glass-ionomer liner. Quintessence Int 1989; 20: 117-122.

[18] Swift EJ, Hansen SE, Bailey SJ. Effects of the XR bonding system on microleakage. Am J Dent 1990; 3: 143-146.

[19] Sidhu SK, Henderson LJ. In vitro marginal leakage of cervical composite restorations lined with a light-cured glass ionomer. Oper Dent 1992; 17: 7-12.

[20] Tsunekawa M, Usami Y, Iwaku M, Setcos JC, Marshall SJ. A new light-activated adhesive cavity liner: An in vitro bond strength and microleakage study. Dent Mater 1992; 8: 296-298.

[21] Wieczkowski G, Yu XY, Joynt RB, Davis EL. Microleakage evaluation in amalgam restorations used with bases. J Esthet Dent 1992; 4: 37-40.

[22] Youngson CC, Holguin SM. Early in vitro marginal microleakage associated with different materials under Class II amalgam restorations. Eur J Prosthodont Rest Dent 1992;1: 73-77.

[23] Robchinsky J, Donly KJ. A comparison of glass-ionomer cement and calcium hydroxide liners in amalgam restorations. Int J Periodontics Rest Dent 1993; 13: 378-383.

[24] Mason PN, Ferrari M. In vivo evaluation of glass-ionomer cement adhesion to dentin. Quintessence Int 1994; 25: 499-504.

[25] Marchiori S, Baratieri LN, de Andrada MAC, Monteiro S, Ritter AV. The use of liners under amalgam restorations: An in vitro study on marginal leakage. Quintessence Int 1998; 29: 637-642.

[26] Wibowo G, Stockton L. Microleakage of Class II composite restorations. Am J Dent 2001; 14: 177-185.

[27] Gupta S, Khinda VIS, Grewal N. A comparative study of microleakage below cemento-enamel junction using light cure and chemically cured glass ionomer cement liners. J Indian Soc Prev Dent 2002; 20: 158-164.

[28] Howdle MD, Fox K, Youngson CC. An in vitro study of coronal microleakage around bonded amalgam coronal-radicular cores in endodontically treated molar teeth. Quintessence Int 2002; 33: 22-29

[29] Douglas WH, Fundingsland JW. Microleakage of three generically different fluoride-releasing liner/bases. J Dent 1992; 20: 365-369.

[30] Blixt M, Coli P. The influence of lining techniques on the marginal seal of Class II composite resin restorations. Quintessence Int 1993; 24: 203-210.

[31] Trushkowsky RD, Gwinnett AJ. Microleakage of Class V composite, resin sandwich, and resin-modified glass ionomers. Am J Dent 1996; 9: 96-99.

[32] Dietschi D, de Siebenthal G, Neveu-Rosenstand L, Holz J. Influence of the restorative technique and new adhesives on the dentin marginal seal and adaptation of resin composite Class II restorations: An in vitro evaluation. Quintessence Int 1995; 26: 717-727.

[33] Newman JE, Hondrum S, Clem DB. Microleakage under amalgam restorations lined with Copalite, Amalgambond Plus, and Vitrebond. Gen Dent 1996; 44: 340-344.

[34] Haller B, Trojanski A. Effect of multi-step dentin bonding systems and resin modified glass ionomer cement liner on marginal quality of dentin-bonded resin composite Class II restorations. Clin Oral Invest 1998; 2: 130-136.

[35] Opdam NJM, Roeters JJM, Burgersdijk RCW. Microleakage of Class II box-type composite restorations. Am J Dent 1998; 11: 160-164.

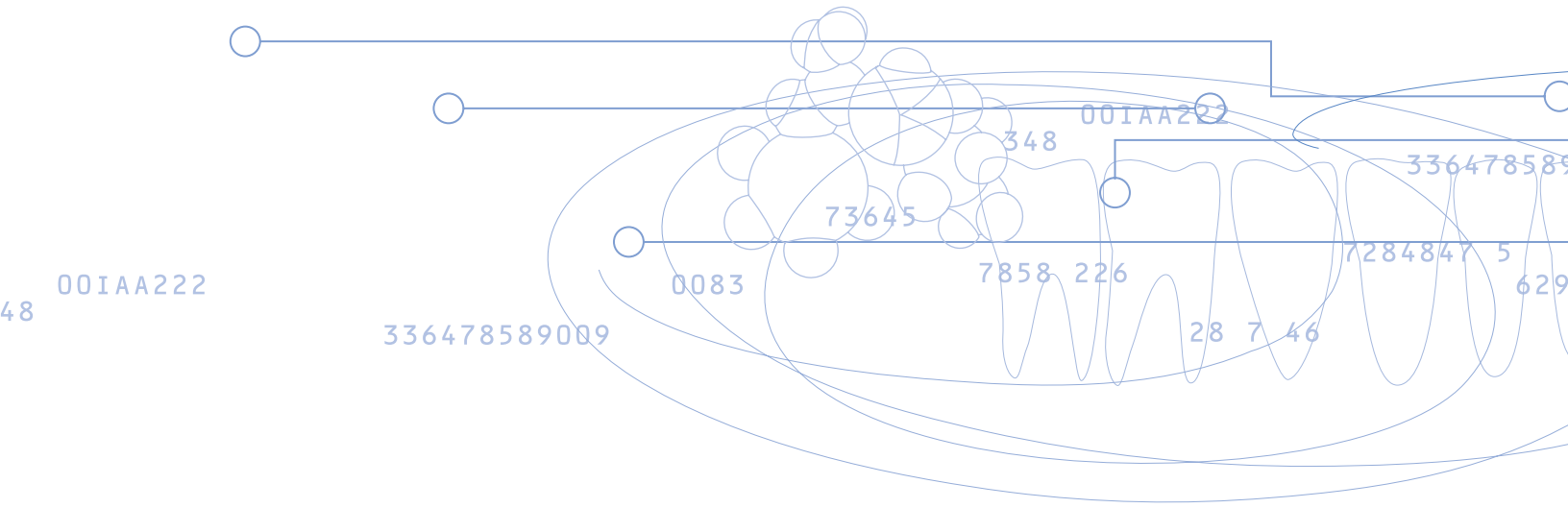
[36] Chang S-F, Jin Y-T, Lin T-S, Chang C-H, Garcia-Godoy F. Effects of lining materials on microleakage and internal voids of Class II resin-based composite restorations. Am J Dent 2003; 16: 84-90.

[37] Tolidis K, Nobecourt A, Randall RC. Effect of a resin-modified glass ionomer liner on volumetric polymerization shrinkage of various composites. Dental Materials 1998; 14:417-423.

[38] Bui HT, Mitra SB, Rolf JC, Rusin RP, Randall R. Effect of a new RMGI liner on polymerization shrinkage. IADR Bisbane 2006 Abstract 2554

[39] Plant CG, Wilson HJ. Forces Exerted on Lining Materials. British Dental Journal 1971; 131:62-66

[40] CDC, MMWR™



3M ESPE

3M Australia Pty Limited

ABN 90 000 100 096
Building A, 1 Rivett Road
North Ryde NSW 2113
Ph: 1300 363 454
www.3MESPE.com.au

3M New Zealand Limited

94 Apollo Drive
Rosedale
Auckland 0632
Ph: 0800 80 81 82
www.3MESPE.co.nz

10% post-consumer waste paper

Printed in USA

70-2009-3814-3