

3M[™] Scotchbond[™] Universal Plus Adhesive

Technical Product Profile



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1. About 3M[™] Scotchbond[™] Universal Plus Adhesive

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In 2011, 3M introduced the first truly universal adhesive – 3M[™] Scotchbond[™] Universal Adhesive – and laid the foundation for a new adhesive category. For the first time, a single adhesive could:

- Work with all etching techniques total-etch, self-etch, and selective enamel etch
- Be used for direct and indirect indications
- Bond to all dental surfaces without the need for separate primers or silans
- Offer virtually no post-operative sensitivity

This revolutionary concept in an award-winning vial quickly gained popularity among dental professionals and spurred the interest of researchers around the world. Now clinically proven, Scotchbond Universal Adhesive has become the industry's most researched universal adhesive.

3M[™] Scotchbond[™] Universal Plus Adhesive also offers all the benefits of its predecessor, as demonstrated by a 3M field evaluation comparing the performance of the two products. The study involved over 300 dentists in Europe and the US, almost half of whom were users of the current Scotchbond Universal Adhesive. 94.5% of current users were satisfied or very satisfied with the new adhesive while 99% of dentists reported the same or less post-operative sensitivity for Scotchbond Universal Plus Adhesive compared to Scotchbond Universal Adhesive.

Thanks to careful formulation, the new Scotchbond Universal Plus Adhesive offers:

- Radiopacity like dentin to reduce the risk of X-ray misdiagnosis and overtreatment
- Ability to bond and seal caries-affected dentin to support minimally invasive preparation guidelines and maximize preservation of natural tooth structure
- Gold standard adhesion to all dental substrates and all direct and indirect materials, including glass ceramics
- Full dual- and self-cure compatibility without the need for an additional dual-cure activator bottle
- A BPA derivative-free formulation to alleviate concerns about BPA in dental materials
 - A fully aligned system with 3M[™] RelyX[™] Universal Resin Cement, offering excellent bond strength for virtually all dual-cure resin cement indications

Scotchbond Universal Plus Adhesive is available in a new streamlined vial with smooth surfaces and free of edges and vents, and in a unit dose for efficient hygiene management.

2. Indications

Direct indications:

- Bonding for all methacrylate-based light-, dual-, and self-cure composite and compomer filling materials
- Root surface desensitization
- Bonding of methacrylate-based fissure sealants
- Protective varnish for glass ionomer fillings
- Repair of composite and compomer fillings
- Sealing of cavities prior to placement of amalgam restorations

Indirect indications:

- Cementation of indirect restorations in combination with 3M[™] RelyX[™] Universal Resin Cement and other resin cements (follow applicable Instructions for Use)
- Bonding for all methacrylate-based light-, self-, and dual-cure core build-up materials and cements
- Cementation of veneers when combined with 3M[™] RelyX[™] Veneer Cement
- Intraoral repair of composite restorations, porcelain fused to metal, and all-ceramic restorations without extra primer
- Sealing of cavities and preparation of tooth stumps prior to temporary cementation of indirect restorations



3. Chemical Composition

3M[™] Scotchbond[™] Universal Plus Adhesive is based on the same chemistry as 3M[™] Scotchbond[™] Universal

Adhesive, the clinically proven and world's most researched universal adhesive.

3M [™] Scotchbond [™] Universal Adhesive	3M [™] Scotchbond [™] Universal Plus Adhesive
MDP Phosphate Monomer	▲ Same gold standard adhesive monomer
HEMA	▲ Same hydrophilic monomer for wetting dentin
3M™ Vitrebond™ Copolymer	▲ Same 3M proprietary technology for moisture tolerance
Filler	▲ Same non-settling silica filler for adjusting viscosity and handling
Ethanol/water	▲ Same solvent, adjusts viscosity, wetting of tooth structure
Initiators	▲ Same photoinitiators based on camphorquinone
Silane	Optimized mixture of silanes for improved bond strength to glass ceramic
3M™ Scotchbond™ Universal Dual Cure Activator (separate vial)	Dual-cure accelerator for improved dual-cure compatibility; no more mixing with DCA from a separate vial
Dimethacrylate resins containing BisGMA	Dimethacrylate resins contain a BPA derivative-free , crosslinking radiopaque monomer – does not contain BisGMA (which is based on BPA)

Table 1: Overview of chemical composition of 3M[™] Scotchbond[™] Universal Plus Adhesive in comparison to 3M[™] Scotchbond[™] Universal Adhesive

Scotchbond Universal Plus Adhesive uses the same high quality MDP Phosphate Monomer as its predecessor for high, durable bond strength and a long shelf life of up to 36 months at room temperature (starting from the manufacturing date). Due to its MDP content, it is a mild and highly effective self-etch formulation with a pH of about 2.7. Quality of the adhesive monomers is crucial to achieve good performance and shelf life (K. Yoshihara, N. Nagaoka, T. Okihara, M. Kuroboshi, S. Hayakawa, Y. Maruo, G. Nishigawa, J. De Munck, Y. Yoshida, B. Van Meerbeek: Functional monomer impurity affects adhesive performance, Dent Mater 2015, 31, 1493-1501).

3M's proprietary 3M[™] Vitrebond[™] Copolymer ensures moisture tolerance and high bond strength to dentin under varying moisture levels. This compound, first invented for resin modified glass ionomers, is a polyalkenoic acid with a large number of carboxylic acid groups, which can interact with hydroxyapatite and collagen via ionic and hydrogen bonding. Furthermore, the polymer can adsorb and release a substantial amount of water, which imparts moisture tolerance to the adhesive formulation.

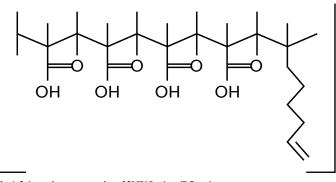


Fig. 1: Schematic representation of 3M[™] Vitrebond[™] Copolymer

3M[™] Scotchbond[™] Universal Plus Adhesive contains an optimized amount of HEMA (2-hydroxyethyl methacrylate). HEMA is a unique monomer that mixes at any ratio with hydrophobic monomers and with water. This property helps prevent phase separation (formation of droplets in the liquid, like in salad dressing) and ensures a homogeneous adhesive layer without voids.

It has been known for quite some time that HEMA free adhesives are prone to phase separation and are especially sensitive with respect to the air-drying technique (N. Hiraishi, L. Breschi, C. Prati, M. Ferrari, J. Tagami, NM. King: Technique sensitivity associated with air-drying of HEMA-free, single-bottle, one-step self-etch adhesives, Dent Mater 2007, 23, 498-505).

Scotchbond Universal Plus Adhesive contains the same camphorquinone-based photoinitiator system as its predecessor. In order to achieve a high degree of conversion (see Chapter 5) and minimize inhibition of the cure by ambient oxygen, it has a higher concentration of camphorquinone, which results in a more vividly yellow uncured adhesive compared to other bonding agents in the market. This yellow color serves as a placement aid when applying Scotchbond Universal Plus Adhesive and disappears when it is air dried and light-cured.

Both Scotchbond Universal Adhesive and its successor contain an ethanol/water solvent system. Ethanol evaporates more slowly than acetone, another commonly used solvent whose fast evaporation may lead to a compromised shelf life. (KL. Van Landuyt, J. Snauwaert, J. De Munck, M. Peumans, Y. Yoshida, A. Poitevin, E. Coutinho, K. Suzuki, P. Lambrechts, B. Van Meerbeek: Systematic review of the chemical composition of contemporary dental adhesives, Biomaterials 2007, 28, 3757-3785).

The stable, pre-hydrolyzed silanes of Scotchbond Universal Adhesive have been further optimized by adding an amino-functional silane to provide bond strength to etched glass ceramic at the level of gold standard traditional silane primers like 3M[™] RelyX[™] Ceramic Primer. The amino group may further stabilize hydrolyzed silanes by intramolecular hydrogen bonding (H. Ishida, S. Naviroj, K. Tripathy, JJ. Fitzgerald, JL. Koenig: The structure of an aminosilane coupling agent in aqueous solutions and partially cured solids, J Polym Sci Polym Phys Ed 1982, 20, 701-718), which will likely increase their availability for reaction with the ceramic surface.

Scotchbond Universal Plus Adhesive contains a small amount of a transition metal salt as a dual-cure accelerator. This compound achieves compatibility with all dual- and self-cure composite materials by catalyzing the decomposition of the peroxide component of the dark cure initiator system. It therefore makes the separate dual-cure activator bottle (3M[™] Scotchbond[™] Universal Dual Cure Activator) of its predecessor obsolete. However, like its predecessor, Scotchbond Universal Plus Adhesive is not a self- or dual-cure adhesive. The adhesive must be light-cured before the next material is applied unless it is combined with 3M[™] RelyX[™] Universal Resin Cement.

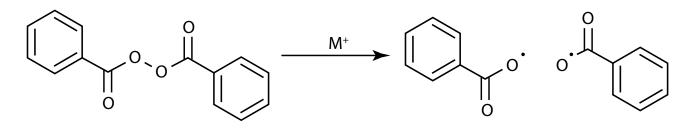


Fig. 2: Transition metal catalyzed decomposition of a peroxide to form reactive radicals

A novel crosslinking BPA free radiopaque resin has been developed that allows for a BisGMA-free formulation and a radiopacity similar to that of dentin. Unlike conventional radiopaque fillers, it remains homogeneously mixed and does not settle. This helps ensure that every drop of adhesive has the same quality and properties – without having to shake the bottle before each use. Also, it ensures that Scotchbond Universal Plus Adhesive has a low viscosity for favorable handling. If a similar radiopacity was to be achieved by conventional inorganic fillers, viscosity would be in the range of flowable composites.

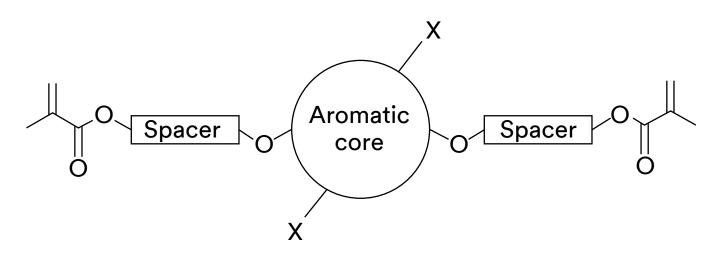


Fig. 3: Schematic formula of the radiopaque resin, X = heavy element, enabling radiopacity

4. Biocompatibility

The medical devices sold by 3M Oral Care Solutions undergo comprehensive evaluations to ensure biocompatibility. The biocompatibility evaluations are performed according to ISO 10993 "Biological evaluation of medical devices" and ISO 7405 "Preclinical evaluation of biocompatibility of medical devices used in dentistry" as part of our overall risk management process for medical devices. All raw materials and ingredients for the medical devices are included in these assessments. The biocompatibility of Scotchbond Universal Plus Adhesive has been evaluated according to these international standards by a board-certified toxicologist and found to be safe for its intended use. Accordingly, Scotchbond Universal Plus Adhesive has been cleared by regulatory agencies and approved for sale in applicable markets.

5. Material Properties

3M[™] Scotchbond[™] Universal Plus Adhesive is a unique universal adhesive. This section will demonstrate its adhesive properties to various dental substrates and direct and indirect restoration materials, as well as its performance under different conditions. It will also present data to support the use of Scotchbond Universal Plus Adhesive for different indications.

Bond strength of universal adhesives

Shear bond strength (SBS) was measured using the notched-edge method according to ISO 29022:2013 on bovine incisors. The labial surface of each tooth was ground to prepare a flat enamel or dentin surface. A cylindrical button of composite (3M[™] Filtek[™] Supreme Ultra / XTE Universal Restorative) was cured on the tooth surfaces treated with Scotchbond Universal Plus Adhesive or selected competitor universal adhesives according to manufacturers' instructions.



Fig. 4: Specimen for shear bond strength testing according to ISO 29022:2013 (bovine dentin)

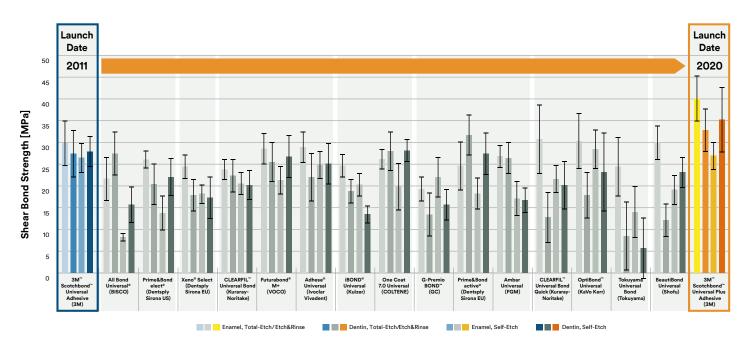


Fig. 5: Shear bond strength of 3M[™] Scotchbond[™] Universal Plus Adhesive in comparison to selected universal adhesives (3M internal data, partly published in M. Schuckar, C. Thalacker, K. Dede, B. Anich. Performance of an experimental universal adhesive, J Dent Res (Spec Iss B): 444 (CED-IADR), 2019)

Since the introduction of the original 3M[™] Scotchbond[™] Universal Adhesive in 2011, few of the later universal adhesives afforded higher shear bond strength to enamel or dentin – until Scotchbond Universal Plus Adhesive, which has significantly higher shear bond strength to etched enamel, etched dentin, and unetched dentin than its predecessor.

Bond strength to human teeth under various conditions

Bond strength to primary and permanent teeth

The intention of this investigation was to evaluate the shear bond strength of 3M[™] Scotchbond[™] Universal Plus Adhesive on primary and MIH (Molar Incisor Hypomineralization) affected human teeth. Bond strength to human primary teeth and teeth affected by MIH was measured using the notched-edge shear bond method according to ISO 29022:2013, using Scotchbond Universal Plus Adhesive in self-etch and total-etch modes. Sound

permanent human teeth were used as a control. The substrates yielded statistically the same bond strength for etched enamel, etched dentin and unetched dentin. On unetched enamel, bond strength was significantly lower for primary teeth and MIH teeth, although still at a high level of over 25 MPa. This difference may be due to the different mineralization versus sound, permanent enamel. Based on this *in vitro* data, Scotchbond Universal Plus Adhesive is suitable for bonding to primary and MIH affected teeth and and therefore supports pediatric dentistry.

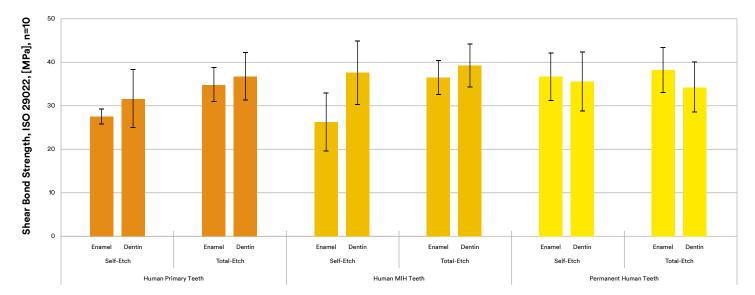


Fig. 6: Shear bond strength of 3M[™] Scotchbond[™] Universal Plus Adhesive on human teeth with 3M[™] Filtek[™] Universal Restorative (3M internal data, 2020)

Bond strength to sclerotic dentin

With its higher degree of mineralization, it is sometimes considered difficult to bond to sclerotic dentin. A high degree of sclerotic dentin is present at cervical non-carious wedge-shaped lesions. Scotchbond Universal Plus Adhesive, 3M[™] Scotchbond[™] Universal Adhesive and competitor universal adhesives were used for this study. Dentin of cervical abrasion lesions in extracted human premolars was cleaned with a polishing brush and water. Sound enamel and dentin surfaces from intact premolars were prepared in the form of standardized V-shaped buccocervical cavities as control substrates. Immediate tensile bond strength was measured using the adhesives in the self-etch application mode.

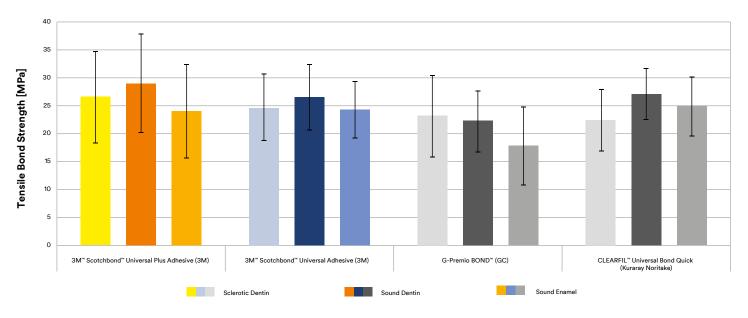


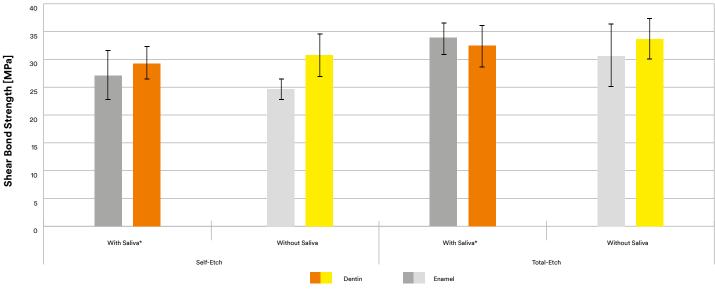
Fig. 7: Bonding Performance of Recent All-in-One Adhesive Systems to Cervical Tooth Substance, Y. Nara, M. Okada, M. Maeno, T. Kawai, T. Murata, I.L. Dogon, J Dent Res 98 (Spec Iss A): No. 1910, 2019

There was no significant difference in immediate tensile bond strength to abrasion lesion / sclerotic dentin, sound dentin and sound enamel between 3M[™] Scotchbond[™] Universal Plus Adhesive, 3M[™] Scotchbond[™] Universal Adhesive, and CLEARFIL[™] Universal Bond Quick. Scotchbond Universal Plus Adhesive affords similar high bond strength in self-etch mode to sclerotic dentin as its predecessor Scotchbond Universal Adhesive. Based on this *in vitro* data, Scotchbond Universal Plus Adhesive is suitable for bonding to sclerotic dentin in self-etch mode.

Dentin bond strength with saliva contamination

Moisture management is one of the major issues a dentist faces every day. A moisture tolerant adhesive can help alleviate this problem.

To show the influence of saliva contamination, shear bond strength (SBS) was measured using the notched-edge method according to ISO 29022:2013. Human saliva was applied to etched or unetched enamel or dentin and slightly blotted with a paper towel. A cylindrical button of 3M[™] Filtek[™] Z250 Universal Restorative was cured on the tooth surface and treated with Scotchbond Universal Plus Adhesive according to manufacturers' instructions. Uncontaminated substrates were used as a control. Shear bond strength with saliva contamination prior to application of Scotchbond Universal Plus Adhesive was statistically not different from uncontaminated. These results demonstrate that Scotchbond Universal Plus Adhesive is not sensitive to saliva contamination before application of the adhesive – which is beneficial in situations where isolation is difficult.



*Saliva was applied, slightly blotted with a paper towel, then 3M™ Scotchbond™ Universal Plus Adhesive was applied according to the Instructions for Use.

Fig. 8: Shear bond strength of 3M[™] Scotchbond[™] Universal Plus Adhesive with and without saliva contamination (3M internal data)

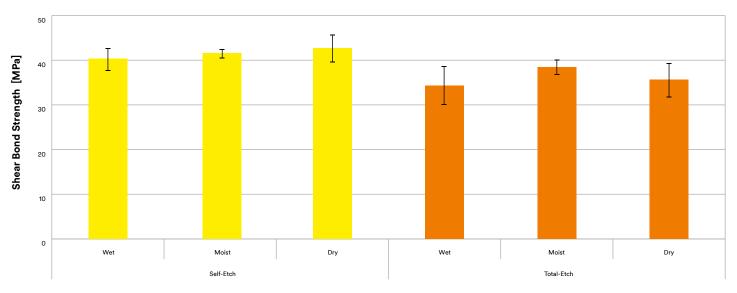
Dentin bond strength at different moisture levels

Shear bond strength (SBS) was measured using the notched-edge method according to ISO 29022:2013. Surfaces were treated with 3M[™] Scotchbond[™] Universal Plus Adhesive according to manufacturers' instructions. A cylindrical button of 3M[™] Filtek[™] Z250 Universal Restorative was cured on the tooth surface at different moisture levels:

- Wet: teeth were taken out of demineralized water and bonded without any further drying step
- Moist: teeth were blotted dry with tissue before application of adhesive
- Dry: teeth were dried with pressurized air for 30 seconds

Moisture level did not have a significant effect on dentin shear bond strength within the self-etch groups or the total-etch groups. Some self-etch groups had significantly higher dentin shear bond strength than total-etch groups. All groups had very high bond strength with means exceeding 30 MPa.

Scotchbond Universal Plus Adhesive is moisture tolerant and forms a strong bond in self-etch or total-etch mode at various moisture levels, which gives confidence in situations where complete isolation from saliva or moisture is difficult.



Adhesion and hybrid layer formation on dentin

Bonding to enamel is pretty straightforward – either mechanical interlocking with an etch pattern created by an acid or chemical bonding to hydroxyapatite by reaction with an acidic monomer, e.g. MDP.

Bonding to dentin with its higher organic content (predominantly collagen) and porosity, on the other hand, is more complex. A great step towards achieving high, durable bond strength to dentin was the concept of the hybrid layer - the resin infiltrated part of the dentin immediately beneath the adhesive layer - introduced by Nakabayashi in 1982 (N. Nakabayashi, K. Kojima, E. Masuhara: The promotion of adhesion by the infiltration of monomers into tooth substrates, J Biomed Mater Res 1982, 16, 265-273). The action of acid on the dentin (either a separate phosphoric acid etchant or the acidic monomers of a self-etch adhesive) will demineralize the surface of the dentin. Infiltration of the residual collagen with adhesive resin will then form the hybrid layer. In order to achieve a strong and durable bond, it is necessary to create a continuous hybrid layer without gaps or voids.

The etching protocol used defines the thickness of the hybrid layer. Mild self-etch adhesives with a pH >2 produce a hybrid layer with a thickness of one micrometer or less. With a phosphoric acid etch of the dentin, demineralization of the substrate and consequently the hybrid layer thickness reaches several micrometers. However, hybrid layer thickness does not correlate with bond strength or durability. In fact, a more aggressive etch will lead to a deeper demineralization, which will be more challenging for the adhesive to properly infiltrate.

There is more and more evidence that etching the dentin can create problems like incomplete infiltration of the etched dentin, leakage, post-operative sensitivity, activation of enzymes that can degrade collagen (e.g. MMPs), and ultimately loss of dentin bond strength. For these reasons, a selective enamel etch with a mild self-etch adhesive (without etching the dentin with phosphoric acid) seems to be the etching protocol of choice (e.g. B. Van Meerbeek, M. Peumans, A. Poitevin, A. Mine, A. Van Ende, A. Neves, J. De Munck: Relationship between bond-strength tests and clinical outcomes, Dent Mater 2010, 26, e100-e121).

The interface of 3M[™] Scotchbond[™] Universal Plus Adhesive (= ADH-XTE experimental name) to etched and unetched

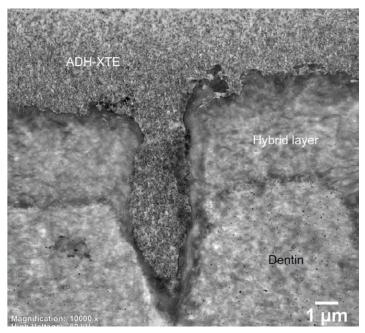


Fig. 10: Transmission electron micrograph of the hybrid layer of 3M[™] Scotchbond[™] Universal Plus Adhesive on etched dentin (demineralized, stained). Note the hybrid layer thickness of about 5 µm (as consequence of phosphoric acid etch), and formation of a resin tag in a dentin tubule. (M. Ahmed, C. Yao, Y. Ozaki, B. Van Meerbeek: 3M ADH-XTE Universal Adhesive – ultra-structural characterization of adhesive-dentin interface, Report to 3M, 2019)

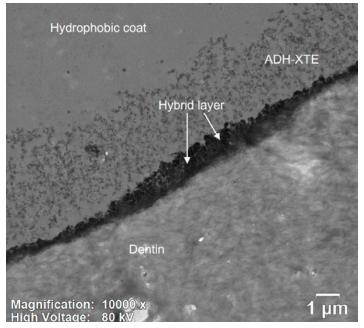


Fig. 11: Transmission electron micrograph of the hybrid layer of 3M[™] Scotchbond[™] Universal Plus Adhesive on unetched dentin (demineralized, stained). Note the hybrid layer thickness of 0.5 – 1µm (as consequence of self-etch application). (M. Ahmed, C. Yao, Y. Ozaki, B. Van Meerbeek: 3M ADH-XTE Universal Adhesive – ultra-structural characterization of adhesive-dentin interface, Report to 3M, 2019)

dentin was investigated in a transmission electron microscopy (TEM) study (M. Ahmed, C. Yao, Y. Ozaki, B. Van Meerbeek: 3M ADH-XTE Universal Adhesive – ultra-structural characterization of adhesive-dentin interface, Report to 3M, 2019).

In both etching modes, there was a well-defined hybrid layer without voids or gaps. Its thickness depended on the etching mode.

Further observations demonstrated that the adhesive layer was relatively thin (between $3-6\,\mu$ m). There were no voids in the adhesive layer. During specimen preparation and imaging, no interface debonding occurred, which indicates a tight bond to bur-cut dentin.

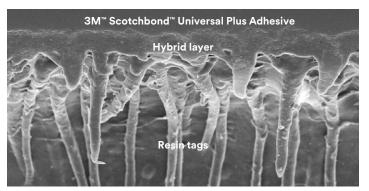
Hybrid layer formation and moisture tolerance

Bonding to etched dentin can be challenging because of its moisture sensitivity. If the etched dentin dries, the exposed collagen can collapse and form a compact substrate which can be difficult to infiltrate to form a hybrid layer depending on the adhesive used.

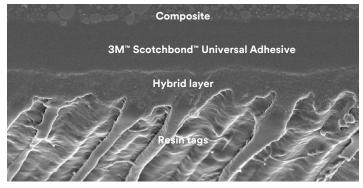
3M[™] Scotchbond[™] Universal Adhesive has been shown to form a distinct, void-free hybrid layer even on dry, etched dentin (J. Perdigao, A. Sezinando, PC. Monteiro: Laboratory bonding ability of a multi-purpose dentin adhesive, Am J Dent 2012, 25, 153-158), and the authors concluded that the performance of Scotchbond Universal Adhesive was not affected by the adhesion strategy or by the degree of dentin moisture. In order to assess the ability of Scotchbond Universal Plus Adhesive to form a hybrid layer on etched dentin at varying degrees of moisture, it was compared with its predecessor in a SEM study (J. Perdigao: Ultra-morphological evaluation of the interaction of an experimental universal adhesive with dentin, Report to 3M, 2019).

Both adhesives were applied to moist and dry, etched middle dentin of extracted human molars. After application, the adhesives were covered with a 1-mm thick layer of a composite resin. Then the specimens were immediately processed for scanning electron microscopy.

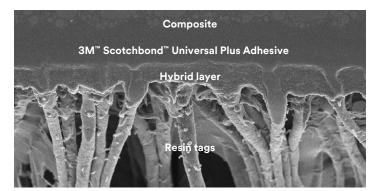
A fully formed hybrid layer, which was measured on the intertubular area to avoid the hybridization around the tubules, was observed for all four groups, without discernible differences among groups. Well-defined lateral peritubular triangular hybridization and resin tag hybridization were also observed.



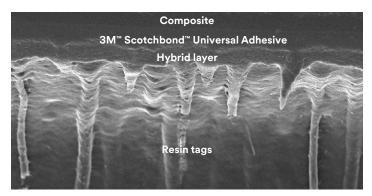
3M[™] Scotchbond[™] Universal Plus Adhesive on moist, etched dentin



3M[™] Scotchbond[™] Universal Adhesive on moist, etched dentin



3M[™] Scotchbond[™] Universal Plus Adhesive on dry, etched dentin



3M™ Scotchbond™ Universal Adhesive on dry, etched dentin

Fig. 12: SEM study of hybrid layer formation on etched dentin J. Perdigao, University of Minnesota, USA, report to 3M, 2019. (J. Perdigao: Ultra-morphological evaluation of the interaction of an experimental universal adhesive with dentin, Report to 3M, 2019) In spite of the NaOCI deproteinizing challenge, the hybrid layer was intact without signs of exposed collagen fibers. Collagen fibers in the hybrid layer were apparently fully enveloped by polymerized adhesive resin.

The thickness of the hybrid layer is shown in the SEM legends in the images. Air-drying dentin for 5 sec after rinsing off the etchant did not influence the morphology of the hybrid layer regardless of the adhesive used.

Both adhesives were able to infiltrate dentinal tubules and secondary anastomoses, forming prominent resin tags.

No gaps were observed between the adhesive and the flowable composite resin or between the adhesive and the hybrid layer.

Like its predecessor, 3M[™] Scotchbond[™] Universal Plus Adhesive forms a well-defined hybrid layer without exposed collagen. In other words, it's able to infiltrate even the collapsed collagen on dried, etched dentin. This explains the high bond strength of Scotchbond Universal Plus Adhesive to dentin of varying moisture levels shown above – which in turn means less technique sensitivity. It is important to fully envelop the collagen with polymerized resin in order to protect the collagen from enzymatic and hydrolytic attack, thereby ensuring the long-term stability of the bond.

In combination with the occlusion of dentin tubules by resin tag formation, full resin impregnation of the collagen will help prevent liquid movement under a restoration – an important source of post-operative sensitivity according to Brännström's hydrodynamic theory (M Brännström: Sensitivity of dentine, Endodontics 1966, 21, 517-526).

Additionally, hybrid layer formation was investigated by confocal Raman microscopy analysis (3M internal data, Dentin Interface Characterization of Universal Adhesives by Raman Microscopy, B. Anich, B. Dippel, G. Mishra, H. Loll, A. Lopez, C. Thalacker, J Dent Res 98 (Spec Iss B): No. 443 (CED-IADR), 2019). Bovine incisors were ground to expose dentin and treated with 3M[™] Scotchbond[™] Universal Adhesive or Scotchbond Universal Plus Adhesive in total-etch or self-etch modes according to manufacturers' instructions. A 1mm thick layer of composite (3M[™] Filtek[™] Z250 Universal Restorative) was placed on the adhesive and cured. The samples were ground perpendicular to the bonded surface to expose the interface for confocal Raman microscopy to determine the chemical nature and thickness of the hybrid layer and adhesive layer.

As shown in the TEM study by B. van Meerbeek et al. the hybrid layer on etched dentin has a thickness of several micrometers, whereas on unetched dentin, it is about 1µm. Scotchbond Universal Plus Adhesive and its predecessor Scotchbond Universal Adhesive form similarly thick hybrid layers on dentin, which explains the observed high bond strength to dentin. A well-defined hybrid layer without voids is a prerequisite for a high, long lasting bond to dentin, while the observed adhesive layer thickness of about 10µm (resulting layer thickness when applied according to manufacturer's instruction) is thin enough to make sure there will not be any fitting issues when seating indirect restorations.

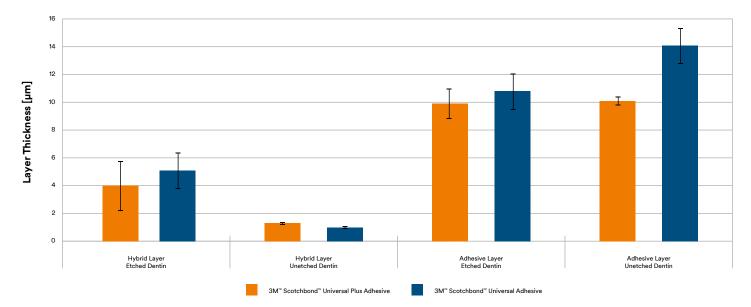


Fig. 13: Hybrid layer and adhesive layer thickness of 3M[™] Scotchbond[™] Universal Plus Adhesive and 3M[™] Scotchbond[™] Universal Adhesive on enamel and dentin (3M internal data, Dentin interface characterization of universal adhesives by raman microscopy, B. Anich, B. Dippel, G. Mishra, H. Loll, A. Lopez, C. Thalacker, J Dent Res 98 (Spec Iss B): No. 443 (CED-IADR), 2019)

Degree of monomer conversion

Confocal Raman microscopy was used to measure the degree of monomer conversion at the adhesive layer on etched and unetched bovine dentin. 3M[™] Scotchbond[™] Universal Plus Adhesive showed a 92% conversion, indicating a very high percentage of reacted double bonds that matches the level of its predecessor 3M[™] Scotchbond[™] Universal Adhesive.

The high degree of conversion enables a switch from an initially hydrophilic formulation in the uncured state to a

hydrophobic formulation in the cured state. This is beneficial because first, the adhesive needs to wet a hydrophilic substrate (the tooth). After curing, the adhesive needs to be hydrophobic for high and long-lasting bonding performance, low staining, low water uptake, and low hydrolysis.

The low contact angle for uncured Scotchbond Universal Plus Adhesive indicates a hydrophilic character while the high contact angle for cured Scotchbond Universal Plus Adhesive indicates hydrophobic character (see Fig 15).

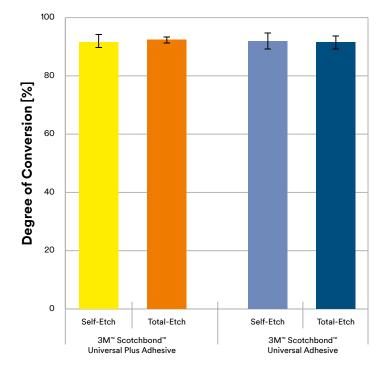


Fig. 14: Degree of monomer conversion measured by confocal Raman microscopy of 3M[™] Scotchbond[™] Universal Plus Adhesive in comparison to 3M[™] Scotchbond[™] Universal Adhesive (3M Corporate Research Analytical Laboratory Neuss, Germany, unpublished)

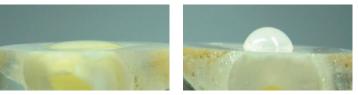


Fig. 15: Water droplet on 3M[™] Scotchbond[™] Universal Plus Adhesive. Left: uncured, air dried (low contact angle) / Right: cured, oxygen inhibited layer removed (high contact angle). Substrate: bovine dentin. (3M internal data, unpublished)

Marginal integrity

One further aspect of bonding is the ability to bridge polymerization forces between composite and tooth tissue, thus providing a continuous intact interface. In an *in vitro* study from Charité Berlin, Germany the marginal integrity of 3M[™] Scotchbond[™] Universal Plus Adhesive was examined.

Class V cavities were prepared in extracted teeth. The cavities were gently dried before the application of the universal adhesive according to manufacturers' instructions either in etch & rinse mode or in self-etch mode.

After the composite resin was applied it was light-cured for 40 seconds. After finishing and polishing, the teeth were

stored in water for 21 days and then thermocycled. Before and after the thermocycling procedure, impressions were taken for replicas. The restoration margins at the dentin and enamel composite interface were examined and quantified with a scanning electron microscope (SEM) to assess marginal qualities.

Scotchbond Universal Plus Adhesive achieves a high marginal adaptation, resulting in a 97–99% continuous margin between dentin and enamel. The marginal adaptation in the tested groups showed extremely good results.

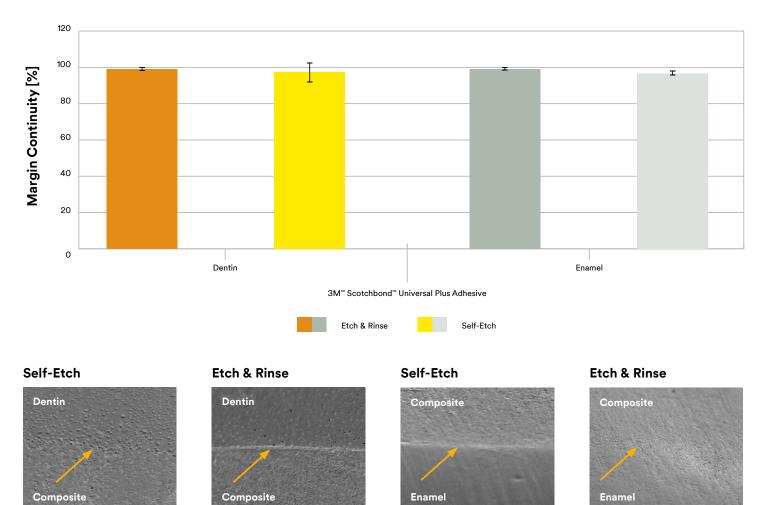


Fig. 16: Quantitative margin analysis at Class V restorations of 3M" Scotchbond" Universal Plus Adhesive (Dr. U. Blunck, Charité Berlin, report to 3M, 2019)

Bond strength to core build-up materials

Dual-cure composite materials like core build-up materials and luting cements have both a light- and self-cure initiator system in order to ensure a full cure in situations where it is not possible to use a photopolymerization light. These self (or dark) cure initiator systems are often based on peroxide/amine chemistry, which is incompatible with acidic adhesives. An acidic adhesive may protonate the amine, rendering it unable to react with the peroxide and initiate the curing reaction. As a consequence, the dual-cure (or self-cure) material would not harden in proximity to the adhesive, which may lead to failure of the restoration.

In order to overcome this issue, a dual-cure activator (DCA) was developed for use with the original 3M[™] Scotchbond[™] Universal Adhesive. The sulfinate salt in the DCA reacts with the peroxide in an acidic environment and overcomes the incompatibility mentioned above. In Scotchbond Universal Plus Adhesive, this separate DCA component is replaced by a dual-cure accelerator (a transition metal salt) which is part of the adhesive, making the separate activator bottle obsolete (see Chemical Composition section).

The following study compared the bond strength of dual-cure core build-up composites in self-cure mode with Scotchbond Universal Plus Adhesive and its predecessor Scotchbond Universal Adhesive with the 3M[™] Scotchbond[™] Universal Dual Cure Activator.

To assess shear bond strength with core build-up materials, a loop of orthodontic wire was used to shear a cylindrical button (4.7 mm diameter) off bovine enamel or dentin. This study uses a larger composite button than ISO 29022:2013 to make it easier to prepare the specimen with self- or dual-cure materials, where two pastes have to be mixed together prior to filling the mold.

Bond strength achieved with Scotchbond Universal Plus Adhesive was higher or similar to that obtained with the mixture of Scotchbond Universal Adhesive and Scotchbond Universal Dual Cure Activator, showing that the simplification of the adhesive system does not come at the expense of performance.

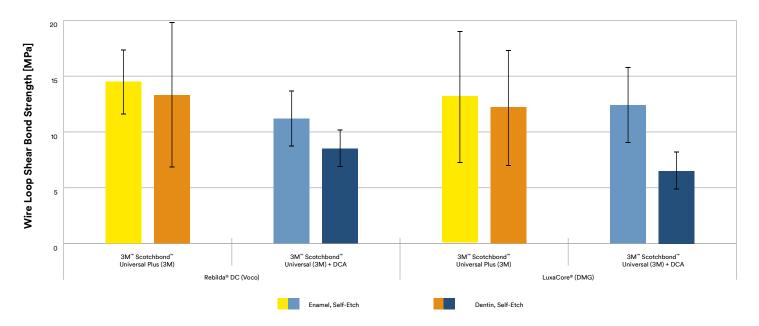


Fig. 17: Shear bond strength of 3M[™] Scotchbond[™] Universal Plus Adhesive (light-cured) with different core build-up materials (self-cure mode) (3M internal data 2020)

Bond strength to dental materials

Basics of adhesion to dental materials

Today, a wide variety of restoration materials are available to serve different needs in terms of esthetics, strength, and ease of use. 3M[™] Scotchbond[™] Universal Plus Adhesive uses several different mechanisms to bond to these materials due to their individual surface chemistries:

- The phosphate group of acidic monomers like **MDP** bond **to non-etchable ceramics (zirconia, alumina)** and the oxide layer on nonprecious metals. Therefore, these materials must not be cleaned with phosphoric acid because this will block the reactive surface sites! On precious metals, sandblasting embeds corundum particles in the metal. MDP can then bond to the embedded corundum particles.
- The silanes bond to etchable glass ceramics (feldspathic, leucite reinforced, lithium disilicate) and to silicate-based fillers in resin-based materials.
- Double bonds of the monomers in Scotchbond Universal Plus Adhesive can react with residual double bonds in resin-based materials.

Generally, all of these materials need to be cleaned and the surface needs to be roughened in order to increase mechanical retention.

The following table provides an overview of how to pretreat different restorative materials for optimal bonding with Scotchbond Universal Plus Adhesive:

Restoration Material	Pretreatment
Etchable glass ceramics – feldspathic, leucite reinforced and lithium disilicate (e.g. Vitablocs® Mark II, VITA; IPS e.max® CAD, Ivoclar Vivadent)	Etching with hydrofluoric acid (HF) according to ceramic manufacturers' instructions for optimal results Where it is not possible to use HF (e.g. intraoral repair or for safety reasons), sandblasting with 3M [™] CoJet [™] or corundum (< 50 µm, < 2 bar) may be used instead
Non-etchable zirconia and alumina ceramics (e.g. 3M™ Lava™, 3M; Cercon®, Dentsply Sirona; Procera® AllCeram, Nobel Biocare)	Sandblasting (< 50 µm, < 2 bar) Do not use phosphoric acid on sandblasted surface – this will lower bond strength!
Resin nanoceramic (3M™ Lava™ Ultimate, 3M)	Sandblasting (< 50 µm, < 2 bar)
Composite (e.g. 3M [™] Paradigm [™] MZ100, 3M; composite core build-up materials; composite restoration repairs)	Sandblasting (<50 µm, <2 bar)
Metal (precious and nonprecious)	Sandblasting (< 50 µm, < 2 bar)
Fiber reinforced composite posts	No pretreatment

Table 2: Pretreatment of different restoration materials

Bond strength to glass ceramics (lithium disilicate)

Bond strength to lithium disilicate (IPS e.max[®] CAD, Ivoclar Vivadent) was assessed in a study by the Catholic University of Leuven, Belgium (C. Yao, M. Ahmed, B. Mercelis, B. Van Meerbeek: Shear-bond strength of a new 3M Universal Adhesive to Glass-Ceramic, Report to 3M, 2020).

The following materials were applied and cured on lithium disilicate with different pretreatments:

- 3M[™] Scotchbond[™] Universal Plus Adhesive (containing silane)
- 3M[™] Scotchbond[™] Universal Adhesive (containing silane)
- 3M[™] RelyX[™] Ceramic Primer + 3M[™] Adper[™] Scotchbond[™] 1XT Adhesive (clinically proven classic silane + separate adhesive)
- 4. RelyX Ceramic Primer + Scotchbond Universal Plus Adhesive (to assess influence of additional silane)
- 5. RelyX Ceramic Primer + Scotchbond Universal Adhesive (to assess influence of additional silane)

According to ISO 29022:2013, a composite button (3M[™] Filtek[™] Z250 Universal Restorative, 3M) was cured on the treated specimen surface using a mold. Notched edge shear bond strength was measured immediately and after aging. When the ceramic surface was pre-treated with 3M[™] CoJet[™] or HF, no significant difference in shear bond strength (SBS) was recorded between the group in which only Scotchbond Universal Plus Adhesive was applied, and the control group, in which the ceramic primer was applied prior to Adper Scotchbond 1XT Adhesive.

Scotchbond Universal Plus Adhesive achieved higher "immediate" and "aged" SBS than Scotchbond Universal Adhesive when the pretreated (CoJet or HF-streated) ceramic surface did not receive the additional ceramic primer.

Upon aging, significant reduction in SBS was recorded for both Scotchbond Universal Plus Adhesive and Scotchbond Universal Adhesive when bonded to the CoJet-pretreated ceramic surfaces.

Scotchbond Universal Plus Adhesive performed better than Scotchbond Universal Adhesive for glass-ceramic (IPS e.max CAD) bonding. After the glass-ceramic was etched with HF acid, a favorable "immediate" and "aged" SBS were recorded for Scotchbond Universal Plus Adhesive.

This study shows that on HF etched lithium disilicate, Scotchbond Universal Plus Adhesive affords statistically the same bond strength as a classic separate silane (RelyX Ceramic Primer) immediately and after aging.

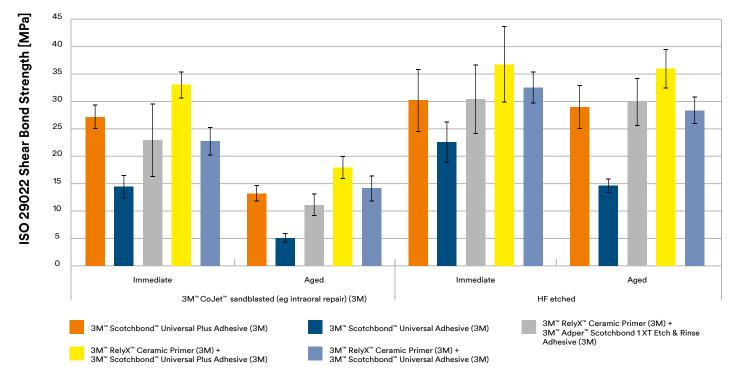


Fig. 18: Bond to lithium disilicate glass ceramic (C. Yao, M. Ahmed, B. Mercelis, B. Van Meerbeek, KU Leuven, Belgium, Report to 3M, 2020)

Bond strength to glass ceramic (feldspathic glass ceramic)

Shear bond strength (SBS) was tested using the notchededge method according to ISO 29022:2013. Feldspathic glass ceramic blocks (Vitablocs® Mark II, Vita) were etched with hydrofluoric acid (HF), rinsed with water and treated with 3M[™] Scotchbond[™] Universal Plus Adhesive (SBU+), 3M[™] Scotchbond[™] Universal Adhesive (SBU), and the combination of 3M[™] Adper[™] Scotchbond[™] 1 XT Etch & Rinse Adhesive with a conventional silane primer (SB 1 XT) according to manufacturers' instructions. As an experimental alternative to HF treatment, blocks were sandblasted with 3M[™] CoJet[™] sand (3M) and treated with Scotchbond Universal Plus Adhesive. A cylindrical button of composite resin was cured on the samples, which were stored in water at 37°C for 24h.

With both pretreatments Scotchbond Universal Plus Adhesive achieved similar bond strength as the controls.

This study on feldspathic glass ceramic nicely complements the data shown above for lithium disilicate. Scotchbond Universal Plus Adhesive affords statistically the same bond strength as a classic separate silane (3M[™] RelyX[™] Ceramic Primer).

Tensile bond strength to different substrates including lithium disilicate and feldspathic glass ceramic

The test consisted of two adhesive systems containing silane as an ingredient (3M[™] Scotchbond[™] Universal Plus Adhesive and 3M[™] Scotchbond[™] Universal Adhesive) and two adhesive systems that required application of a separate silane coupling agent (CLEARFIL[™] Universal Bond Quick with CLEARFIL Ceramic Primer PLUS (UBQ, Kuraray-Noritake Dental) and G-Premio BOND[™] with Ceramic Primer II (GPB, GC)). Resin composite, lithium-disilicate glass ceramic, feldspathic ceramic, sound enamel, and dentin were selected as bonded substrates. Each bonded substrate was treated with each system according to manufacturers' instructions and the tensile bond strength (TBS) was measured.

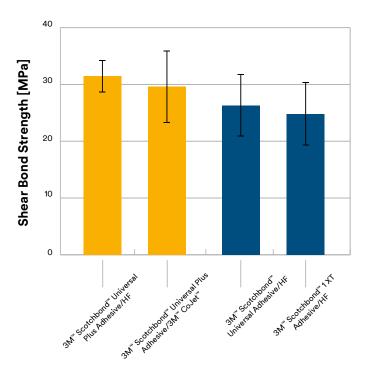


Fig. 19: Adhesion to feldspathic glass ceramic (Vitablocs Mark II, VITA); (3M internal data: Adhesion of an experimental universal adhesive to feldspathic glass ceramic, C. Thalacker, M. Schuckar, K. Dede, H. Loll, B. Anich, A. Andrés, J Dent Res 98 (Spec Iss B): No. 196 (CED-IADR), 2019)

The bonding characteristic of recent adhesive systems did vary with bonded substrates.

The mean bond strength, bonding reliability and durability of Scotchbond Universal Plus Adhesive to five types of substrate were similar or superior to those of other systems. Scotchbond Universal Plus Adhesive without a separate silane afforded similar bond strength to glass ceramic as competitive universal adhesives together with a separate silane application.

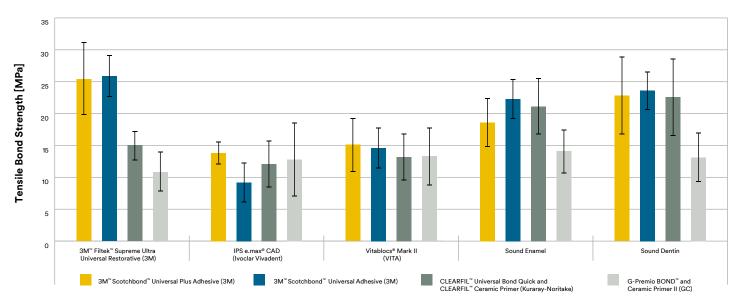


Fig. 20: Tensile bond strength of 3M[™] Scotchbond[™] Universal Plus Adhesive on different substrates in comparison to other universal adhesives (Bonding characteristic of recent adhesive systems used for repair restoration, M. Maeno, T. Kawai, T. Murata, M. Okada, S. Nagai, Y. Nara, J Dent Res 98 (Spec Iss A): No. 1324, 2019)

Bond strength to dental materials

Substrate surfaces of all samples were ground with P400 silicon-carbide paper and the adhesive was applied following the manufacturers' instructions. Composite resin was placed over the adhesive and light-cured for 40 seconds. Specimens were placed in tap water, stored in an incubator at 37°C for 24 hours and shear bond strength was measured according to ISO 29022:2013.

When bonding to a wide range of materials 3M[™] Scotchbond[™] Universal Plus Adhesive consistently showed a shear bond strength of over 10 MPa, but the bond strength was different depending on the substrates. The results of this study suggest that Scotchbond Universal Plus Adhesive has a consistently high bond strength to a wide range of restorative materials. (For comparison, samples were ground with sandpaper in a similar manner. This is contrary to manufacturers' instructions for lithium disilicate where the surface should be etched with HF, and for zirconia, where the surface should be sandblasted).

A high bond strength to enamel, dentin, and restorative materials was also found in combination with 3M[™] RelyX[™] Universal Resin Cement, where Scotchbond Universal Plus Adhesive was used as adhesive to the tooth and restoration primer (see section RelyX Universal Resin Cement).

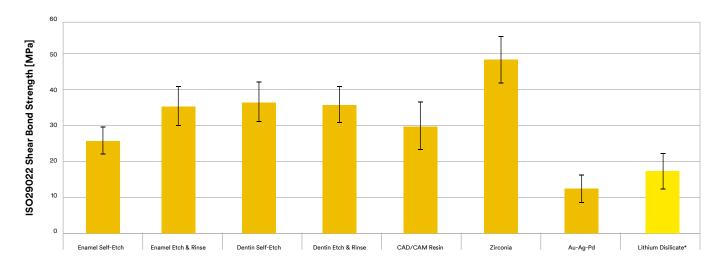


Fig. 21: Bonding performance of 3M^{TC} Scotchbond^{TC} Universal Plus Adhesive to different dental substrates; (*ground surface, for countries were HF etching is not allowed). (Bonding performance of experimental universal adhesives to different substrates, A. Tsujimoto, W.W. Barkmeier, Y. Nagura, Y. Shimatni, T. Takamizawa, M.A. Latta, M. Miyazaki, J Dent Res 98 (Spec Iss A): 1917, 2019)

Bond strength to caries-affected dentin

Over time, opinions on when to stop excavating have changed considerably. Over 100 years ago, G. V. Black recommended "extension for prevention." Now, in the era of minimally invasive (or minimum intervention) dentistry (MID), the philosophy is "prevention of extension" (F. J. T. Burke, From Extension for Prevention to Prevention of Extension: Minimal Intervention Dentistry Dent. Update 2003, 30, 492-502).

Minimally invasive preparation guidelines recommend excavating to caries-affected (discolored, but firm, preservable) dentin at the center of the cavity. In deep cavities where there is a risk of opening the pulp, selective removal to affected (soft) dentin should be performed pulpally (F. Schwendicke, J. E. Frencken, L. Bjorndal, M. Maltz, D. J. Manton, D. Ricketts, K. Van Landuyt, A. Banerjee, G. Campus, S. Doméjean, M. Fontana, S. Leal, E. Lo, V. Machiulskiene, A. Schulte, C. Splieth, A. F. Zandona, N. P. T. Innes: Managing Carious Lesions: Consensus Recommendations on Carious Tissue Removal, Adv Dent Res 2016, 28, 58-67; A Banerjee: Minimal intervention dentistry: part 7. Minimally invasive operative caries management: rationale and techniques, Brit Dent J 2013, 214, 108-111).

This is preferred because complete removal of bacteria by excavation is impossible and not necessary. Instead, sealing in the remaining bacteria and blocking them from nutrients has been shown to stop caries progression (e.g. EAM Kidd: Clinical Threshold for Carious Tissue Removal, Dent Clin N Am 2010, 54, 541-549).

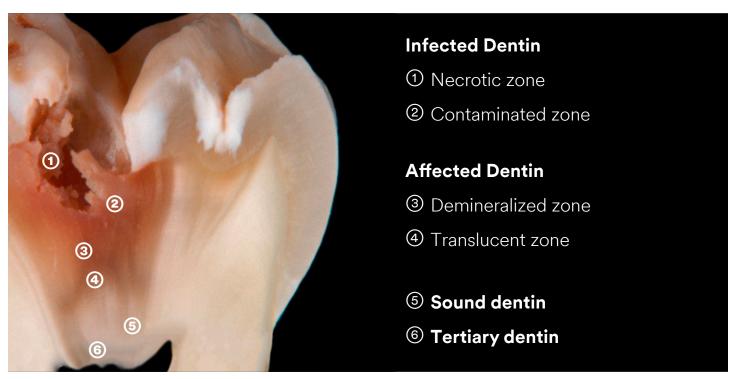


Fig. 22: Sections of a carious lesion (Image courtesy of Prof. L. Hilgert and Prof. S. Leal, University of Brasilia, Brazil)

The bond strength of 3M[™] Scotchbond[™] Universal Plus Adhesive was assessed by a study where carious human molars were prepared with a polymer bur to expose caries-affected dentin. According to ISO 29022:2013, Scotchbond Universal Plus Adhesives shear bond strength to caries-affected dentin and sound human dentin were measured in both self-etch and total-etch modes. 3M[™] Scotchbond[™] Universal Adhesive on sound dentin was used as a control.

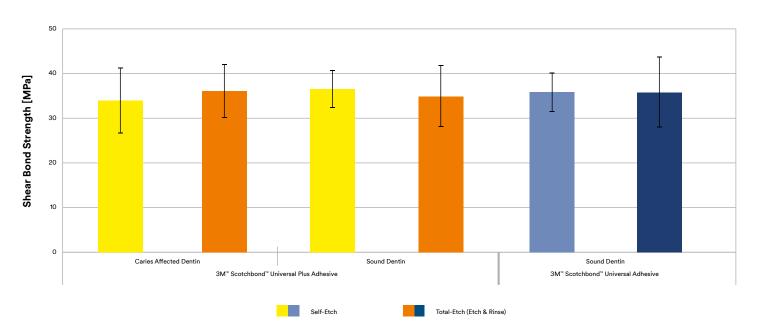


Fig. 23: Bond strength to caries-affected dentin of 3M[®] Scotchbond[®] Universal Plus Adhesive (3M internal data: Interaction of an experimental universal adhesive with caries-affected dentin, C. Thalacker, H. Loll, B. Anich, K. Dede, J. Madden, A.S. Abuelyaman, B. Craig, J Dent Res 99 (Spec Iss A): No. 191, 2020)

In both etching modes, 3M[™] Scotchbond[™] Universal Plus Adhesive achieved similar shear bond strength to caries-affected dentin and sound dentin as the control 3M[™] Scotchbond[™] Universal Plus Adhesive on sound dentin. Universal Plus Adhesive forms a distinct, well defined, void-free hybrid layer on caries-affected dentin. Therefore, it seals caries-affected dentin against further damage and is ideally suited for minimally invasive procedures.

Hybrid layer formation on caries-affected dentin was studied by scanning electron microscopy (SEM). Scotchbond

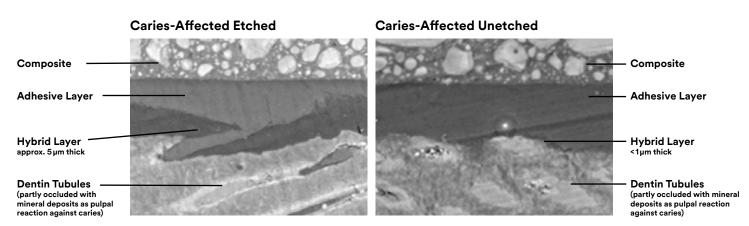


Fig. 24: Hybrid layer formation of 3M[™] Scotchbond[™] Universal Plus Adhesive on etched and unetched caries-affected dentin (3M internal data: Interaction of an experimental universal adhesive with caries-affected dentin, C. Thalacker, H. Loll, B. Anich, K. Dede, J. Madden, A.S. Abuelyaman, B. Craig, J Dent Res 99 (Spec Iss A): No. 191, 2020)

Radiopacity

On average, every day doctors see at least one hard to interpret X-ray with radiolucency under an existing restoration. It can be difficult to determine whether this radiolucency is caused by caries, marginal gaps or voids, or a thick layer (pooling) of a non-radiopaque adhesive. Thick layers of radiolucent adhesives under a restoration can therefore increase the risk of misdiagnosis and unnecessary overtreatment (The Thickness of the Adhesive Layer Increases the Misdiagnosing of the Radiolucent Zones and Restoration Replacement Indication. T. T. Fröhlich et al. J Esthet Restor Dent 29:193-200, 2017).

3M[™] Scotchbond[™] Universal Plus Adhesive now contains a novel, crosslinking, BisGMA monomer-free resin that gives the adhesive a dentin-like radiopacity to help reduce the risk of misdiagnosis and overtreatment.

Scotchbond Universal Plus Adhesives achieves its dentin-like radiopacity while maintaining low viscosity and without the need for shaking before use. Traditionally, radiopacity has been achieved in dental materials by adding inorganic fillers. However, the amount of fillers needed to achieve high radiopacity leads to a pasty composite-like consistency and undesirable handling for an adhesive application. These bottles must also be shaken before each application because the radiopaque fillers separate and settle when added to liquid adhesives.

To analyze the radiopacity of different adhesives the solvent was evaporated from the adhesives. The remaining residue was cured to 1mm thick disks. Radiopacity was determined according to ISO 13116:2014.

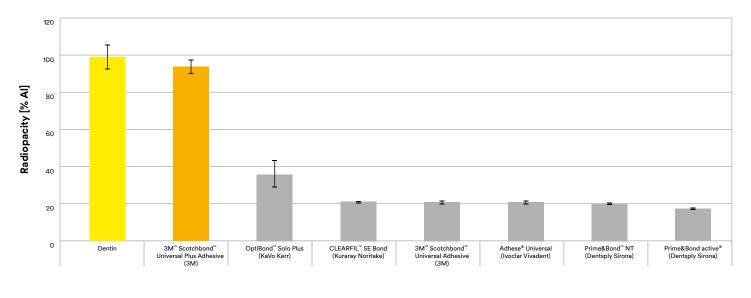




Fig. 25: Radiographs of 1 mm thick samples of mid-coronal dentin (surrounded with a thin enamel layer) and adhesives / radiopacity (ISO 13116:2014, % Al) (3M internal data: Radiopacity of an experimental universal adhesive, H. Loll, O. Brinkmann, B. Anich, K. Dede, B. Craig, A.S. Abuelyaman, C. Thalacker, J Dent Res 99 (Spec Iss A): No. 757, 2020)

3M[™] Scotchbond[™] Universal Plus Adhesive has radiopacity similar to dentin – minimizing the risk of misdiagnosis of a thicker adhesive layer (pooling) as secondary caries, marginal gaps or voids.

To assess the clinical significance of the radiopacity, Class I cavities were prepared in extracted human molars.

Adhesives were applied using a fully saturated disposable applicator and gently air dried to create a thick adhesive layer (pooling) at the bottom of the cavity. Cavities were restored with a resin composite and radiographs were taken and examined for radiolucent areas underneath the fillings.

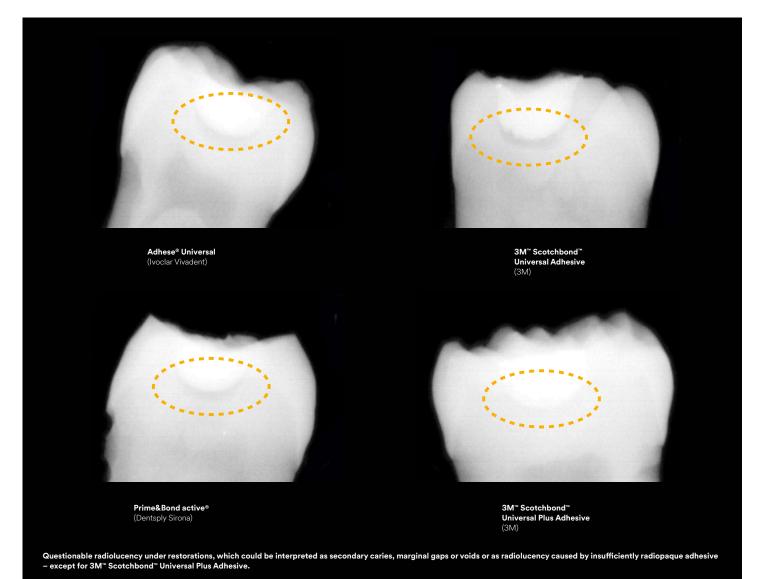


Fig. 26: Adhesive pooling – x-rays of Class I restorations in human molars, filling material 3M[™] Filtek[™] One Bulk Fill Restorative (3M internal data: Radiopacity of an experimental universal

adhesive, H. Loll, O. Brinkmann, B. Anich, K. Dede, B. Craig, A.S. Abuelyaman, C. Thalacker, J Dent Res 99 (Spec Iss A): No. 757, 2020)

6. Customer Feedback

An *in vivo* evaluation was conducted with 309 dentists from 10 different countries (WE = Germany, Austria, Switzerland, Spain, Italy, France, UK, Denmark, Poland; US = United States of America). During an evaluation period of 6-12 weeks dentists were asked to use the new adhesive as often as possible for all indications following the instructions for use, resulting in over 20,000 restorations. After this period participants were asked to rate the features of the new adhesives via an online questionnaire.

Satisfaction rate – overall performance

- 94.5% of all evaluators were satisfied or very satisfied
- 99% of evaluators using the predecessor
 3M[™] Scotchbond[™] Universal Adhesive (SBU) and
 91% of evaluators not using SBU were satisfied or very satisfied

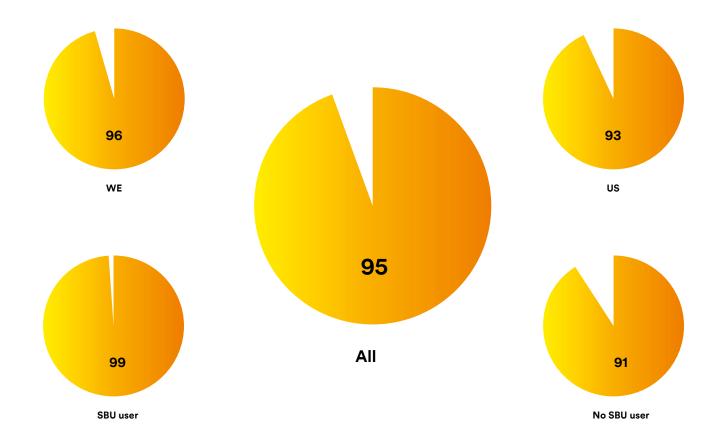


Fig. 27: Satisfaction rating after in vivo testing of the overall performance of 3M[™] Scotchbond[™] Universal Plus Adhesive divided in different groups

Handling

Nearly all handling features of 3M[™] Scotchbond[™] Universal Plus Adhesive received over 80% satisfied and very satisfied rating.

Wettability of tooth surface, overall handling and homogeneity of the film were the best rated features.

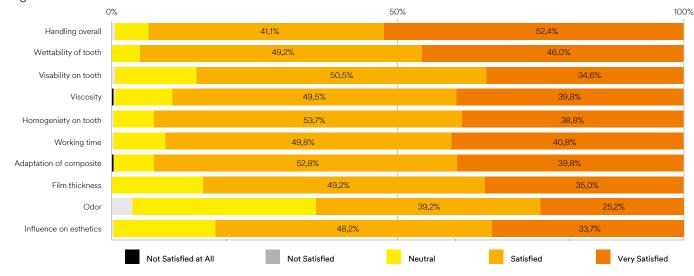
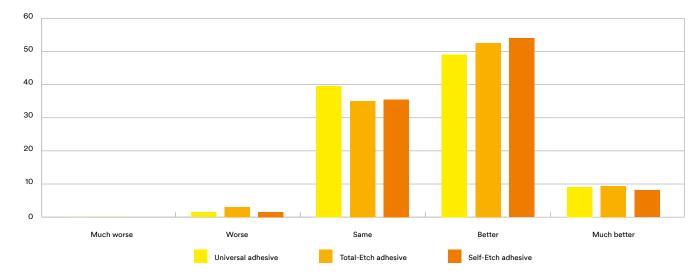


Fig. 28: Rating of handling features of 3M™ Scotchbond™ Universal Plus Adhesive in a first in vivo test

Comparison to preferred adhesive

When asked to rate Scotchbond Universal Plus Adhesive against their preferred adhesive more than 95% of evaluators rated it the same or better. Nearly 60% even

rated Scotchbond Universal Plus Adhesive better or much better than their preferred adhesive.



How do you rate Scotchbond Universal Plus overall compared to your preferred adhesive?

Fig. 29: Rating of 3M[™] Scotchbond[™] Universal Plus Adhesive in comparison to currently preferred adhesive

Post-operative sensitivity

When asked "How many post-operative sensitivities have you observed with 3M[™] Scotchbond[™] Universal Plus Adhesive compared to your preferred adhesive?" 99% of the 309 evaluators stated that Scotchbond Universal Plus Adhesive had the same or lower incidence of post-operative sensitivity than their preferred adhesive. 99% of current 3M[™] Scotchbond[™] Universal Adhesive users reported the same or lower incidence of post-operative sensitivity with the new adhesive.

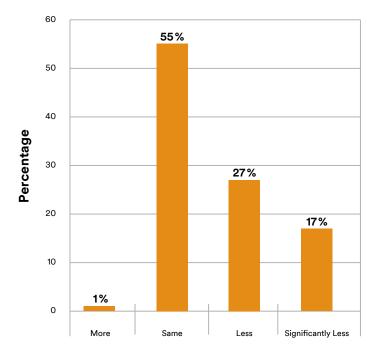


Fig. 30: Incidence of post-op sensitivity when using 3M[™] Scotchbond[™] Universal Plus Adhesive in comparison to currently used adhesive (3M[™] Scotchbond[™] Universal Adhesive)

Selected comments from evaluators after testing

66

Simple, reliable, one bottle system, gold standard, sealing, for all surfaces and materials."

66

3M[™] Scotchbond[™] Universal Plus Adhesive can be used very well for composite repairs. It is also very easy to use for the application on primary teeth."

66

The product slips easily into the portfolio of materials we use and works predictably. The ease of use and broad spectrum of applications makes this product the go-to adhesive bonding system." 66

What I particularly like about 3M[™] Scotchbond[™] Universal Plus Adhesive is that I don't have to adjust [...]. Scotchbond Universal Plus Adhesive is the universal adhesive for really all cases."

I like it because of its clinical results (none of the patients had postoperative sensitivity) and the fact that it can be used with all types of composite. A very useful thing is that I can see the radiopacity of the adhesive after treatment. This is a good characteristic for differential diagnostic of decay or secondary decay."

7. 3M[™] RelyX[™] Universal Resin Cement

While 3M[™] Scotchbond[™] Universal Plus Adhesive is compatible with all dual- and self-cure composite materials like resin cements and core build-ups, it reaches its full potential in combination with 3M[™] RelyX[™] Universal Resin Cement. The two products form a co-developed, optimized, fully aligned system that features high bond strength in all curing modes and with all etching techniques. When combined with RelyX Universal Resin Cement, Scotchbond Universal Plus Adhesive does not need to be light-cured before application of the cement.

RelyX Universal Resin Cement is a truly universal cement because it can be used in either self-adhesive mode or in adhesive mode together with Scotchbond Universal Plus Adhesive. In addition to great bond strength in all application and curing modes, RelyX Universal Resin Cement has excellent handling, easy excess removal, and comes in a novel automix syringe with improved ergonomics and minimized waste. Knife-edge shear bond strength to unetched enamel and dentin was measured for RelyX Universal Resin Cement with Scotchbond Universal Plus Adhesive as tooth primer, Multilink® (Ivoclar Vivadent) with its Primer A + B, and Variolink® Esthetic (Ivoclar Vivadent) with Adhese® Universal (Ivoclar Vivadent). All cements were light-cured; Scotchbond Universal Plus Adhesive and the mixture of Primer A+B were not light-cured, while Adhese Universal was light-cured before cement application according to the instructions.

RelyX Universal Resin Cement demonstrated similar shear bond strength as the controls while using fewer application steps and / or components.



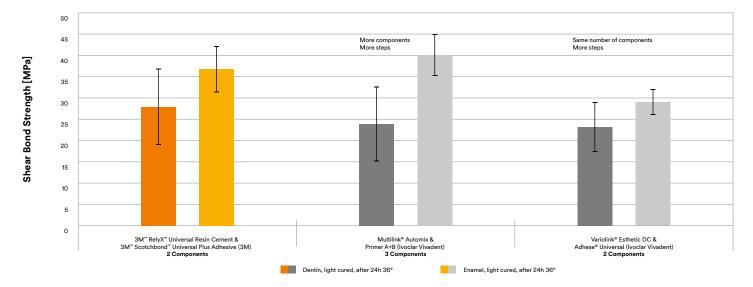
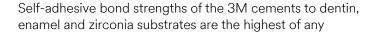


Fig. 31: Shear bond strength of 3M[™] Scotchbond[™] Universal Plus Adhesive in combination with 3M[™] RelyX[™] Universal Resin Cement compared to different resin cements (3M internal data, adapted from shear bond strength and ease of use of adhesive resin cements, K. Claussen, M. Ludsteck, S. Hader, R. Hecht, J Dent Res 99 (Spec Iss A): No. 2785, 2020)

In a study by The Dental Advisor[™], the shear bond strength of 3M[™] RelyX[™] Universal Resin Cement in self-adhesive and adhesive modes was measured and compared to that of competitive cements.

self-adhesive cements tested with this method. Adhesive bond strength to dentin and enamel was excellent, and in particular, the zirconia bond strength is the highest among the universal adhesives tested (Report to 3M, 2020).



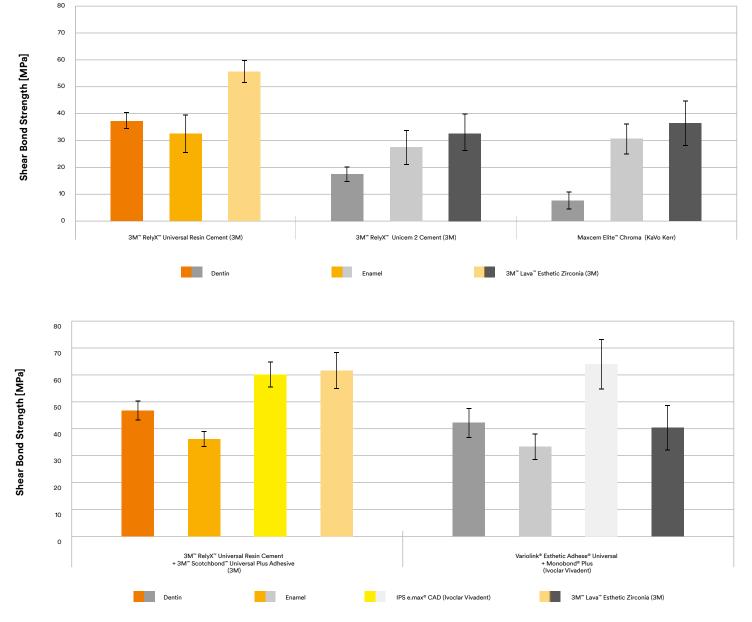


Fig. 32: Shear bond strength of 3M[™] RelyX[™] Universal Resin Cement w / o or with 3M[™] Scotchbond[™] Universal Plus Adhesive compared to different adhesive or self-adhesive resin cements (Report to 3M, 2020)

8. Clinical Case

3M[™] Scotchbond[™] Universal Plus Adhesive and 3M[™] Filtek[™] Universal Restorative were used to restore the upper central incisors.



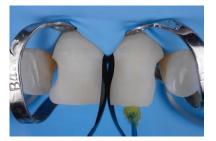
Initial situation



After isolation with rubber dam



Selective enamel etch – etchant gel was applied for 15 seconds, rinsed and lightly dried



Application of the adhesive on dentin, rubbing in for 20 seconds, air-drying for 5 seconds



Light-curing for 10 seconds



After placement of the composite material 3M[™] Filtek[™] Universal Restorative, Shade A2, on the mesial side of both central upper incisive



Using a rounded diamond flame bur for shaping



Placement of composite material



Polishing with fine grit rubber abrasive 3M[™] Sof-Lex[™] Spiral. Afterwards an ultra fine spiral (pink) was applied for high gloss.



Adhesive layer after light-curing



Finishing the restorations using a coarse or medium-coarse 3M[™] Sof-Lex[™] disc



Final restoration

9. Frequently Asked Questions

Application and properties

How do I need to apply 3M[™] Scotchbond[™] Universal Plus Adhesive and what are the curing times?



Fig. 34: Schematic illustration of application of 3M[™] Scotchbond[™] Universal Plus Adhesive

Is the viscosity different and if so, how?

 3M[™] Scotchbond[™] Universal Plus Adhesive has a slightly lower viscosity than 3M[™] Scotchbond[™] Universal Adhesive. However, most participants in an 8-week clinical field evaluation with over 120 dentists from Europe and the US did not notice the change in viscosity.

Does the yellowish color of the adhesive completely disappear after curing?

• Yes. The yellow color comes from the camphorquinone photoinitiator. It provides good visibility on the tooth during application. Upon air drying and light-curing, the yellow color fully disappears and does not come back.

Why do I need to rub in Scotchbond Universal Plus Adhesive for 20 seconds?

• Rubbing for 20 seconds is required in order to ensure optimum performance. Active application or rubbing has been shown to increase bond strength for a variety of universal adhesives (P. Saikaew et al.: Does shortened application time affect long-term bond strength of

universal adhesives to dentin?, Oper Dent. 2018 43, 549-558).

• Since functional monomers like MDP need time to react with the tooth, a shortened application time can reduce bond strength (AD Loguercio et al.: Does active application of universal adhesives to enamel in self-etch mode improve their performance?, J. Dent 2015, 43, 1060-1070).

What properties contribute to achieving virtually no post-op sensitivity in total-etch mode?

- Like its predecessor, Scotchbond Universal Plus Adhesive has been optimized for high moisture tolerance (high bond strength at varying moisture levels). It forms a continuous, well-defined hybrid layer without gaps or voids, which means the dentin is well sealed and open tubules are closed. 3M's proprietary 3M[™] Vitrebond[™] Copolymer has been shown to contribute to high bond strength to even dry, etched dentin (3M internal data: Influence of Vitrebond[™] Copolymer on Bonding to Dry Etched Dentin,
 - C. Thalacker, R. Guggenberger, A. Syrek, H. Loll, D. Krueger, J Dent Res 89 (Spec Iss B): No. 2937, 2010).

Can I use it for porcelain repair?

• Yes, it bonds to all dental surfaces without the need for an additional primer.

Is it effective in both total- and self-etch techniques?

• Like its predecessor, Scotchbond Universal Plus Adhesive has been developed as a universal adhesive, optimizing bond strength on etched and unetched enamel and dentin.

Can I use the self-etch method when bonding a veneer?

• Yes. However, since veneers are predominantly bonded to enamel and can be subject to high forces when biting into hard food, we recommend etching in order to maximize enamel bond strength. Also, etching the enamel minimizes the chance for marginal discoloration (T. Burke et al.: What's New in Dentine Bonding? Universal Adhesives, Dent. Update. 2017, 328-337).

Do I have to use 3M[™] Scotchbond[™] Universal Etchant Etching Gel with this adhesive?

• No. Any common phosphoric acid etching gel (about 30–40%) can be used.

Why is it indicated to use without etching on uncut enamel with a sealant, but not in other restorations?

• The bond strength needed for a sealant is not as high as for a composite filling, as sealants are located in fissures outside the reach of occlusal forces (and are worn quickly anyway if they are on an occlusal surface). Fillings can be subject to occlusal forces – therefore it is advisable to maximize bond strength by etching if the filling extends over uncut enamel.

Does it bond to amalgam?

 Bond strength of amalgam to a cured methacrylate based formulation is very low – that is why amalgam fillings still have to be placed in a retentive cavity preparation, regardless if the cavity has been treated with an adhesive or not. Scotchbond Universal Plus Adhesive is not indicated for bonding amalgam, however it is indicated for sealing the cavity prior to placing amalgam to prevent post-operative sensitivity. On the other hand, Scotchbond Universal Plus Adhesive has high bond strength to cured amalgam (e.g. if part of a core preparation).

Delivery system

What is different about the delivery system (vial)?

- Streamlined vial with smooth surface and edges
- Tamper seal for added safety
- Reduces the environmental footprint by more than 18% compared to 3M[™] Scotchbond[™] Universal Adhesive because of:
 - No more rubber gasket in cap
 - No need for additional bottle of activator to accomplish self-cure
 - Less plastic needed compared to predecessor bottle
- Also available in unit dose (L-Pop) for efficient hygiene management

How many applications are there in each delivery system?

- Vial: 5 ml ~ 200 drops
- Unit dose: 0.11 ml ~ 0.12 g

Do I need to shake the 3M[™] Scotchbond[™] Universal Plus Adhesive vial before use?

• No shaking is needed. The radiopacity in Scotchbond Universal Plus Adhesive is achieved via a novel radiopaque resin, not by conventional radiopaque filler particles, which might settle from the liquid.

Storage

How should I store 3M[™] Scotchbond[™] Universal Plus Adhesive between uses?

• The vial lid should be closed immediately after dispensing and between uses to minimize the risk of cross-contamination and to help protect the shelf life of the material.

What is the shelf life and recommended storage condition?

- 36 months at 2–25°C/36–77°F.
 - Do not use after the expiration date.
 - Vial cap should be closed between uses.

Is refrigeration during storage required?

• Refrigeration is not required if room temperature does not exceed 25°C/77°F.

Is it stable over time and will all components remain reactive at the pH of the solution?

• Yes. It can be stored for 36 months at room temperature.

Is the silane in Scotchbond Universal Plus Adhesive stable?

• Yes. Scotchbond Universal Plus Adhesive contains an optimized proprietary combination of silanes for high bond strength to all dental materials including glass ceramics throughout its shelf life.

Use for indirect restorations

Can I use Scotchbond Universal Plus Adhesive with my composite or cement (non 3M product)?

• Yes, it is compatible with light-, dual-, and self-cure composite filling materials, cements and core build-ups.

When using Scotchbond Universal Plus Adhesive with a cement other than 3M[™] RelyX[™] Universal Resin Cement, do you need to light-cure Scotchbond Universal Plus Adhesive before applying the cement?

• Yes. Only RelyX Universal Resin Cement has been co-developed with Scotchbond Universal Plus Adhesive to ensure high bond strength without light-curing of the adhesive.

What are the system benefits of Scotchbond Universal Plus Adhesive with RelyX Universal Resin Cement?

- The fully aligned, two component system covers virtually all adhesive and self-adhesive dual-cure resin cement indications.
- A simplified resin cement workflow with fewer steps makes it easier to train office staff and reduces potential for errors.
- RelyX Universal Resin Cement initiates and cures Scotchbond Universal Plus Adhesive saving an additional light-cure step.
- Scotchbond Universal Plus Adhesive can further enhance the already high bond strength of RelyX Universal Resin Cement.
- The system shows higher bond strength values to zirconia than competitors.
- RelyX Universal Resin Cement and Scotchbond Universal Plus Adhesive have virtually no post-operative sensititvity.
- Product formulations enable a completely BPA derivative-free procedure when used together.
- Minimized cement waste and excellent handling due to novel automix syringe.

10. Summary

3M[™] Scotchbond[™] Universal Plus Adhesive maintains all the benefits of the original 3M[™] Scotchbond[™] Universal Adhesive, the first truly universal adhesive, while adding several unique features for even greater control and predictability.

- First radiopaque universal adhesive, reducing the risk of misdiagnosis and overtreatment
- Bonds and seals caries-affected dentin to support minimally invasive preparations
- Advanced bonding to dental and restorative substrates, including glass ceramics
- Full dual- and self-cure compatibility without the need for an additional dual-cure activator bottle
- BPA free formulation (free of BPA derivatives like BisGMA) to enable a completely BPA derivative-free procedure when combined with 3M[™] Filtek Universal Restorative, 3M[™] Filtek[™] One Bulk Fill Restorative, and / or 3M[™] RelyX[™] Universal Resin Cement
- Fully aligned system with 3M[™] RelyX[™] Universal Resin Cement, offering excellent bond strength for virtually all dual-cure resin cement indications.
 Simplified workflows – adhesive cured by RelyX Universal Resin Cement.

Numerous *in vitro* and initial *in vivo* data show that Scotchbond Universal Plus Adhesive performs similarly to or better than its award-winning predecessor Scotchbond Universal Adhesive.

Additional *in vitro* and *in vivo* studies will be conducted to deepen insights on various performance features and demonstrate clinical procedures and outcome.



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