

Variolink® Esthetic

The esthetic luting composite

**Scientific
Documentation**



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1. Introduction and product description

1.1 Luting agents and cements

Luting agents are used in dentistry as an adhesive substance to attach fixed prosthetic restorations. Classical dental luting agents are cements that cure via an acid-base reaction. Today's modern dental luting agents are also often referred to as "cements", even though they are completely different from the original cements and feature different chemical curing mechanisms.

Today, many different types of restorative materials are used in dentistry. Dental luting agents therefore need to be capable of establishing a lasting bond to restorations made of various metals, alloys, resins and ceramics. Classical cements were only capable of generating a mechanical bond, i.e. anchoring restorations in a retentively prepared tooth. Modern "adhesive" luting agents however, adhere to the tooth structure (with minimally retentive surfaces). This is an important prerequisite for maintaining as much healthy tooth structure as possible by means of minimally invasive preparation techniques.

Luting agent	Description	Advantages	Disadvantages
Polycarboxylate cements	Acid-base reaction between metal oxides and polyacrylic acid	<ul style="list-style-type: none"> • Easy to use • Low costs 	<ul style="list-style-type: none"> • High water solubility
Phosphate cements	Acid-base reaction between phosphoric acid and basic oxides	<ul style="list-style-type: none"> • Easy to use • Clinical experience spanning more than 100 years 	<ul style="list-style-type: none"> • Low adhesion: only retentive cementation • High water solubility • Very brittle
Glass ionomer cements	Acid-base reaction between polyacrylic acid and calcium fluoroaluminium silicate glass	<ul style="list-style-type: none"> • Release of fluoride • Clinical experience spanning more than 20 years 	<ul style="list-style-type: none"> • Weak bond to tooth structure
Resin-reinforced glass ionomer cements	Hybrid cements: glass ionomer cements with additional light-curing components	<ul style="list-style-type: none"> • Combination of inorganic network and light-induced polymer network 	<ul style="list-style-type: none"> • Mostly low adhesion to tooth structure
Self-adhesive composite cements	Organic monomers and inorganic filler particles; setting is based on light activated or chemically activated polymerization and cross linking	<ul style="list-style-type: none"> • Wear resistant • Resistant to oral conditions • Application without adhesive 	<ul style="list-style-type: none"> • Some technique sensitivity • Low bond strength on tooth • Retentive preparation
Adhesive luting composites	Organic monomers and inorganic filler particles; setting is based on light activated or chemically activated polymerization and cross linking	<ul style="list-style-type: none"> • Wear resistant • Resistant to oral conditions • Good adhesion to the tooth structure • Highly esthetic due to comprehensive shade range 	<ul style="list-style-type: none"> • Some technique sensitivity • Adhesive required • Complex application

Table 1: Summary of dental luting agents

Phosphate cements, polycarboxylate cements and glass ionomer cements are considered classic cements and belong to the group of "dental water-based cements", the properties of which are specified by ISO 9917. Luting composites, except for self-adhesive luting composites, are classified as "polymer-based restorative materials" and therefore fall under ISO 4049, which also applies to the entire range of composite restorative materials.

1.2 Luting composites

Luting composites can be subdivided into two groups: *Adhesive* Luting composites and self-adhesive composite cements. In order to obtain a strong bond between the tooth structure and the restoration, adhesive luting composites are used in combination with dentin adhesives. The adhesive is able to penetrate into the dentin tubules and bind the collagen fibres of the dentin to form a hybrid layer. The effect of the adhesive can be further enhanced if the dental hard tissue is etched - to remove the existing smear layer (so-called "total-etch" technique). As a result, the dentin tubules and the collagen fibres of the dentin are exposed. Luting agents in turn form a chemical bond with the adhesive and therefore generate a particularly strong bond to the tooth structure. Adhesive luting permits bonding in situations where no large retentive surfaces are prepared. An adhesive bond increases the fracture resistance and thus the survival rate of restorations fabricated using non-high-strength ceramics. Minimally invasive restorative techniques, such as adhesive bridges, would be unthinkable without adhesive luting composites. Self-adhesive, or rather, "semi-adhesive" composite cements contain monomers that can react with the smear layer of a prepared tooth and generate a bond without application of a dental adhesive. This bond is far weaker than the bond achieved by using an adhesive luting composite in combination with a dental adhesive. Semi-adhesive composite cements should only be used when the tooth preparation provides sufficient mechanical retention.

Variolink Esthetic is an adhesive luting composite which is applied in combination with a dental adhesive. The adhesive system and etching technique can be selected by the dentist according to the clinical situation and personal preferences. The bond to restorative surfaces is accomplished by a restorative primer e.g. Monobond Plus.

1.3 Polymerization of adhesive luting composites

Adhesive luting composites can be light-curing (LC), self-curing (SC) or combine self-curing and light-curing initiators to be dual-curing (DC). Each system has its own advantages and indications.

	Advantage	Disadvantage
SC	<ul style="list-style-type: none">• no light necessary• suitable when light does not reach composite	<ul style="list-style-type: none">• working time is limited• most chemical initiators tend to discolour
LC	<ul style="list-style-type: none">• dentist decides when curing starts, more time for inserting restoration (working time)• no chemical initiators with tendency to discolour• excess removal can be triggered by short light impulse	<ul style="list-style-type: none">• light must reach composite• not suitable for opaque and thick restorations
DC	<ul style="list-style-type: none">• sufficient polymerization where light does not reach completely• excess removal can be triggered by short light impulse	<ul style="list-style-type: none">• light should reach the composite• chemical initiator might have tendency to discolour

Table 2: Properties of different polymerization modes

The latest high-performance ceramics are available in various shades and levels of translucency. Opaque ceramics as well as translucent yellowish ceramics hamper the passage of polymerization light quite considerably (Figure 2). Therefore the translucency and thickness of the restoration must be considered when selecting the suitable luting material and light exposure time.

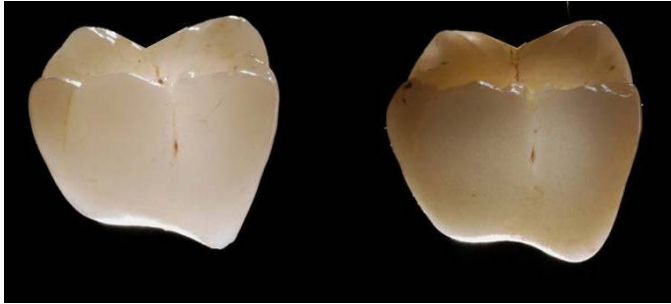


Figure 1: Translucency of lithium disilicate (LS₂) and zirconium oxide (Y-TZP) ceramic in transmitted light

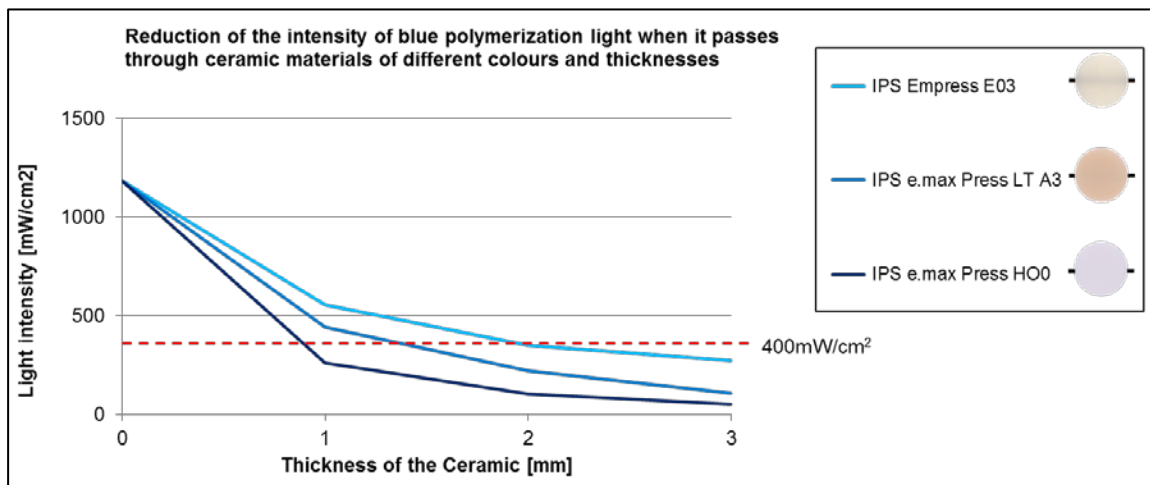


Figure 2: Reduction of the intensity of blue polymerization light when it passes through ceramic materials of different colours and thicknesses, R&D Ivoclar Vivadent AG, Schaan, 2009

1.4 Variolink Esthetic

Today's large variety of restorative materials with many different characteristics demands modern, universal cementation systems with well-balanced properties.

Variolink Esthetic is a colour-stable, adhesive luting system for the permanent cementation of glass-ceramic, lithium disilicate glass-ceramic, composite and oxide ceramic restorations (inlays, onlays and veneers). Variolink Esthetic is offered in two versions: Variolink Esthetic LC, which is purely light-curing and Variolink Esthetic DC which is dual-curing. The table below summarizes the indications for Variolink Esthetic DC and LC. Variolink Esthetic DC can be used with opaque restorations, whereas the LC variant should only be used for thin restorations with a thickness less than 2mm plus sufficient translucency (e.g. restorations made of IPS e.max Press HT or IPS e.max CAD HT).

	Variolink Esthetic LC light-curing	Variolink Esthetic DC dual-curing
Glass-ceramic, e.g. IPS Empress® Veneers	✓	✓
Inlays / onlays / partial crowns	(✓)	✓
Crowns	–	✓
Lithium disilicate (LS₂) glass ceramic, e.g. IPS e.max® CAD Occlusal veneers	✓	✓
Thin veneers / veneers	✓	✓
Inlays / onlays / partial crowns	(✓)	✓
Crowns	–	✓
3-unit bridges	–	✓
Indirect composite, e.g. SR Nexco® Inlays / onlays	(✓)	✓
Crowns	–	✓

Table 3: Indications for Variolink Esthetic DC and LC

✓ Recommended product combination – not recommended
 (✓) only for restorations with a low thickness (<2mm) and sufficient translucency (e.g. restorations made of IPS e.max CAD HT)

In cases where Variolink Esthetic DC is used purely self-curing, e.g. when luting highly opaque or very thick restorations, it is mandatory that the adhesive has to be light cured prior to seating the restoration.

Selected product properties at a glance:

<ul style="list-style-type: none"> - high esthetics - new colour concept with 5 shades; same shades for DC and LC - excellent colour stability (amine free) - easy removal of excess cement - combination of flowable and form stable consistency - optimal bonding with Adhese Universal - reliable bonding to restoration with Monobond Plus - natural tooth-like fluorescence - excellent X-ray visibility for all shades - practical Automix double-push syringe with mixing tip - high mechanical strength - storage at room temperature

1.5 New colour concept for LC and DC

Reducing the number of available shades and providing the same colours for the DC and LC variants makes it easier for dentists to choose the suitable shade for each individual clinical situation. Variolink Esthetic therefore, has a new colour concept with 5 shades which cover all the clinical needs covered by the existing Variolink II and Variolink Veneer shades. The shades are named according to their effect on the finished restoration. The new shades of Variolink Esthetic are compared with Variolink II and Variolink Veneer in Table 4 below.






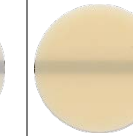
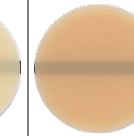










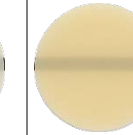
Variolink® Veneer							
Shade	High Value +3	High Value +2	High Value +1	Medium Value 0	Low Value -1	Low Value -2	Low Value -3
Variolink® Esthetic							
Shade	Light+	Light	Neutral	Warm	Warm+		
Translucency	approx. 5%	approx. 10%	> 17%	approx. 12%		approx. 8.5%	
Variolink® II							
Shade	White opaque	Bleach XL-010	Transparent	White 110/A1	Yellow 210/A3	Brown 340/A4	

Table 4: Comparison of shades of Variolink II, Variolink Veneer and Variolink Esthetic.

Similar to the Variolink Veneer colour system, Variolink Esthetic shades are named according to their effect on the finished restoration rather than on the colour of the composite paste. Warm shades darken the restoration; light shades lighten the restoration as indicated in the table below.

Shade	Effect	Indications	
		Veneers	Inlays / Onlays
Light +	considerably lightens	✓	--*
Light	slightly lightens	✓	✓
Neutral	no shade effect	✓	✓
Warm	slightly darkens/more yellowish	✓	✓
Warm +	considerably darkens/more yellowish	✓	--*

* The use of the shades Light+ and Warm+ may lead to visible restoration margins when cementing inlays/onlays.

Table 5: Effects of Variolink Esthetic shades on the restoration.

When providing patients with highly aesthetic translucent restorations (e.g. IPS e.max CAD HT), the restoration may assume the shade of the adjacent teeth in what is known as the chameleon effect. A transparent cement is the prerequisite for this effect to develop. The translucency of Variolink Esthetic neutral has been elevated compared to VL II transparent, to further improve the chameleon effect.

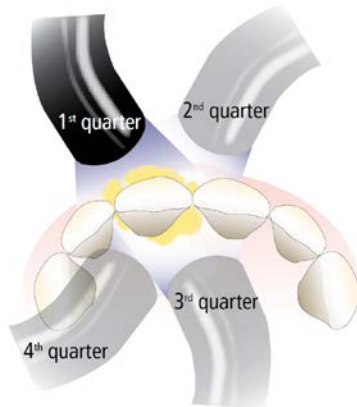
The Try-in pastes allow the shade of the restoration to be simulated and checked. These pastes correspond exactly to the shades of *cured* Variolink Esthetic. The shades of *uncured* composites are slightly different from cured composites; therefore the shades of Try-in pastes differ from the shades of *uncured* composite. The glycerol based Try-in pastes are water-soluble and therefore easy to remove from the restoration and the tooth structure.

1.6 Easy removal of excess cement

Handling of luting composites was considered rather complex mainly due to laborious excess removal. Excess removal is facilitated with Variolink Esthetic; via short initial light-activation - the excess material then reaches an ideal consistency for easy removal in a few sections e.g. with a scaler. After excess removal, Variolink Esthetic is light activated for a second time to reach final strength. This could be achieved via combining the highly reactive photoinitiator Ivocerin with a light controller - allowing partial initial polymerization plus efficient final polymerisation.

Depending on the type of restoration and version of Variolink Esthetic used, two different methods of initial light activation of excess material are proposed: the “quarter technique” or the “circular technique”. These are described below:

“Quarter technique” for Variolink Esthetic DC

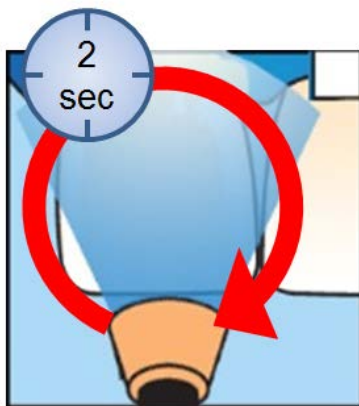


Light-cure excess material with the polymerization light (e.g. Bluephase Style) for 2 s per quarter surface (mesio-oral, disto-oral, mesio-buccal, disto-buccal) at a distance of max. 10 mm.

Thereafter, excess cement is easy to remove with a scaler. Make sure to remove excess material in time, especially in areas that are difficult to reach (proximal areas, gingival margins, pontics).

Figure 3: “Quarter technique” for excess removal

“Circular technique” for Variolink LC (veneers / inlays / onlays)



Light-cure excess material with a polymerization light (e.g. Bluephase Style) for 2 s at a distance of 10-15 mm by running the light probe along the entire cement line.

For laminate veneers, choose a start and end point in the incisal area and light-cure the cement line by moving the polymerization light in a circle in clockwise direction.

For inlays / onlays, choose a start and end point in the mesial or distal region and light-cure the cement line by performing a circular movement with the polymerization light.

After that, excess cement is easy to remove with a scaler. Make sure to remove excess material in time, especially in areas that are difficult to reach (proximal or gingival margins).

Figure 4: “Circular technique” for excess removal

1.7 Colour Stability

Especially when highly esthetic translucent restorations (e.g. IPS e.max) are placed in the anterior region, long-term colour stability is a prerequisite for lasting high-quality esthetics. The main cause of discoloration is the presence of amines as coinitiators in luting materials. With the new, patented, reactive photoinitiator Ivocerin®, it was possible to eliminate any amine from the formulation. As a result, Variolink Esthetic is highly colour-stable as proven by discoloration tests carried out according to the international standard ISO 4049. Even after prolonged illumination, Variolink Esthetic did not discolour to a visible degree. Additionally, water storage for 8 weeks did also not change the colour of Variolink Esthetic.

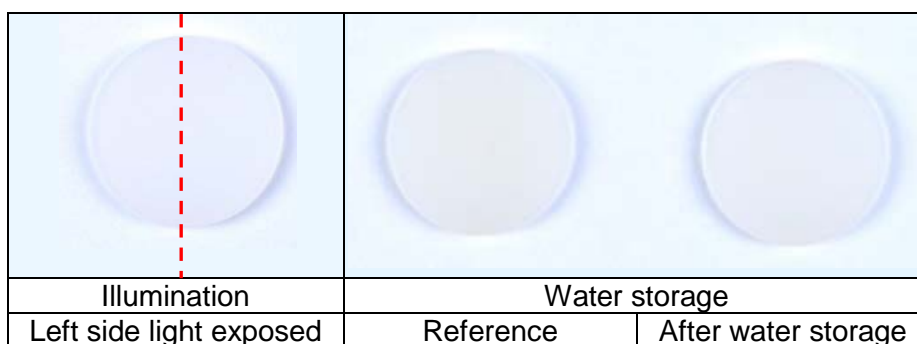


Figure 5: Colour stability of Variolink Esthetic DC. R&D Ivoclar Vivadent AG, Schaan, 2013-2014

1.8 Flexible, situational consistency

For convenient handling, luting composites should be easy to extrude from the syringe and adapt to the restorative surface and tooth structure; excess material should flow from the cement gap with little force on the restoration. Therefore a luting composite should be flowable.

On the other hand, once applied, the composite should remain in position; especially excess material should remain in place for convenient removal. Therefore, the material needs form stability.

Variolink Esthetic combines flowability with form stability, an effect called “thixotropy”: thixotropic material is fluid when a force is applied and form stable when no force is applied.

The ideal thixotropy of Variolink Esthetic is achieved by a special filler composition which functions as viscosity controller. It is easy to extrude from the syringe, excess material smoothly flows from the cement gap while it remains stable at the cementation joint so that it can be readily removed.



Figure 6: Consistency of Variolink Esthetic when applied from the syringe (left) and in a clinical situation when the restoration is placed (right).

1.9 Optimal bonding with Adhese Universal

The dental adhesive Adhese® Universal provides the ideal partner for achieving highly esthetic restorations with Variolink Esthetic. Adhese Universal is supplied in the unique VivaPen and can be applied directly onto the prepared tooth structure. It is compatible with all etching techniques (self-etch, selective-enamel-etch and total-etch), allowing the clinician to choose the tooth preparation depending on the clinical situation and preferences.

The technique- and fault-tolerant Adhese Universal ensures consistently high bond strengths and minimizes the risk of postoperative sensitivities. Naturally, Variolink Esthetic can also be used in combination with the established adhesives Syntac® and ExciTE® F.



Figure 7: Adhese Universal in VivaPen

1.10 Reliable bonding of the restoration after conditioning with Monobond Plus

Before restorative materials can be placed with adhesive cements, their contact surfaces have to be treated to render them chemically compatible with the luting composite.

Consequently, the surfaces have to be roughened in order to obtain a micro-retentive pattern. This can be accomplished either by etching with hydrofluoric acid (glass-ceramics) or by sandblasting (zirconium oxide/aluminium oxide ceramics, metal, composite resins). Furthermore, the materials must be chemically modified in order to establish a bond to the composite. Monobond Plus is a universal primer which is designed to establish an adhesive bond between luting composites (from the Variolink and Multilink product ranges in particular) and **all** indirect restorative materials (glass and oxide ceramics, metal, composite resins, fibre-reinforced composites). The application protocol is the same in each case.

All restorative materials can therefore be prepared for cementation with Variolink Esthetic using just one primer, i.e. Monobond Plus.

Important:

Oxide ceramics (e.g. zirconium oxide ceramics) must not be cleaned with phosphoric acid (e.g. Total Etch) prior to cementation. Phosphoric acid causes an irreversible reaction on the surface. A zirconium-phosphate coating forms on the surface, which inhibits the coupling mechanism of the phosphoric acid methacrylate in Monobond Plus and therefore renders the primer ineffective.

1.11 Radiopacity

The radiopacity of dental materials allows the tooth-coloured restorative material to be distinguished from the natural teeth or caries on X-rays. The radiopacity of a material is determined according to ISO 4049 in relation to the radiopacity of aluminium. The special filler composition gives Variolink Esthetic a very high radiopacity that is clearly above that of enamel and dentin. Consequently, Variolink Esthetic is easy to distinguish from the natural tooth structure on X-rays.

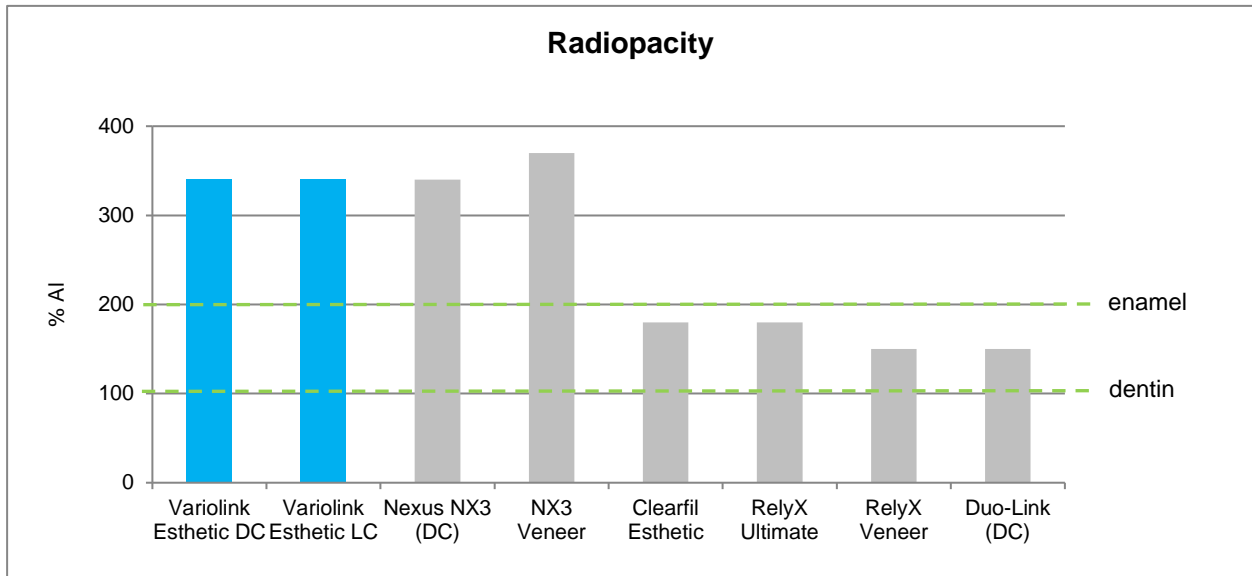


Figure 8: Radiopacity measured according to ISO 4049; R&D Ivoclar Vivadent AG, Schaan, 2013

1.12 Fluorescence

When natural teeth are illuminated with shortwave light, they appear blue-fluorescent. In order to achieve a true-to-life appearance, restorative materials must also demonstrate tooth-like fluorescence.

As shown in the figure below, cured Variolink Esthetic has a tooth-like fluorescence when illuminated with shortwave light.



Figure 9: Fluorescence of Variolink Esthetic (shade neutral) in comparison to a natural tooth; R&D Ivoclar Vivadent AG, Schaan, 2014

1.13 Variolink Esthetic and Multilink Automix

Variolink Esthetic is optimized for situations where the luting composite is essential for the esthetic outcome of the restoration. Variolink Esthetic can be combined with an adhesive of the dentists' choice and the etching mode can be chosen according to the dentists' preferences and the clinical indication. If Variolink Esthetic is used in the self-curing mode (e.g. when luting highly opaque or thick restorations) previous light curing of the adhesive is mandatory.

Multilink Automix ideally complements the indications for Variolink Esthetic; it is a luting system with a self-etching, self-curing primer. Multilink Automix cannot be combined with other adhesives as the performance of the luting material depends on specific interactions with the primer. A self-curing primer is especially required in situations where light cannot reach the adhesive e.g. for root canal post cementation - The combination of Variolink Esthetic and Adhese Universal is not indicated in such situations.

1.14 Materials and compositions

The characteristics of Variolink Esthetic have been achieved by a well-balanced new mixture of monomers, fillers and initiators. Variolink Esthetic contains low viscosity monomers and therefore allows a high filler content. By using exclusively spherical fillers of small size Variolink Esthetic shows high thixotropy, combining form stability and flowability. Additionally, the small particle size results in good polishability, superior surface gloss and high transparency. By the use of ytterbium trifluoride Variolink Esthetic reaches high radiopacity in all shades.

Variolink Esthetic employs the new, patented light initiator Ivocerin; no tertiary amines as initiators or co-initiators are required, thus eliminating the risk of discolourations by amines.

1.15 Interactions

Potential interactions with other products used in the treatment should be excluded, in order to ensure that the selected restoration can be placed safely and durably.

Phenolic substances (e.g. eugenol, wintergreen oil) inhibit polymerization. Consequently, the application of products containing these components, e.g. mouth rinses and temporary cements, must be avoided. Disinfectants with an oxidative effect (e.g. hydrogen peroxide) may interact with the initiator system, which in turn may impair the curing process. The preparation and syringe should therefore not be disinfected using oxidative agents. Alkaline jet mediums applied on dentin (e.g. Airflow) may also compromise the effect of self-etching adhesives.

2. Technical data

2.1 Composition

The monomer matrix of Variolink Esthetic is composed of urethane dimethacrylate and further methacrylate monomers. The inorganic fillers are ytterbium trifluoride and spheroid mixed oxide. Initiators, stabilizers and pigments are additional ingredients. The particle size is 0.04 – 0.2 µm. The mean particle size is 0.1 µm. The total volume of inorganic fillers is approximately 38%.

2.2 Physical Properties

Characteristics	Unit	Specification	
		Variolink Esthetic LC	Variolink Esthetic DC
Film thickness	µm	≤ 50	≤ 50
Curing depth	mm	Light, Neutral, Warm ≥ 1.5 Light+, Warm+ ≥ 0.5	Not applicable
Sensitivity to ambient light	s	≥ 60	Not applicable
Working time (23 °C)	s	Not applicable	≥ 60
Setting time (37 °C, ≥ 95% RH)	s	Not applicable	≤ 600
Flexural strength	MPa	≥ 50	≥ 50
Water sorption (7 days)	µg/mm ³	≤ 40	≤ 40
Solubility (7 days)	µg/mm ³	≤ 7.5	≤ 7.5
Radiopacity (Relative equivalence to ≥ 1mm Al)	%	> 300	> 300
Wave length for light-curing (blue light)	nm	400 - 500	400 - 500

Table 6: Physical properties of Variolink Esthetic

The product meets the relevant performance criteria defined in EN ISO 4049:2009 Dentistry – Polymer-based restorative materials

3. Materials science and physical investigations

Numerous *in vitro* investigations are carried out during the development phase of a dental medical device. Though not capable of predicting clinical success directly, they are useful indicators – notably in predicting the compatibility to other restorative materials or the tolerance to handling influences. Variolink Esthetic was tested in numerous *in vitro* tests and a selection of the results is presented in the following chapter.

3.1 Adhesion to restorative surfaces

Adhesive luting materials are normally applied in combination with dental adhesives and restoration primers (e.g. Monobond Plus) to achieve a good bond towards the very different materials. In the development of dental luting materials, the adhesive strengths towards dental tissue and restorative materials are of central importance.

Adhesive strength can be measured in various test setups which can be categorized in shear bond strength (SBS) and tensile bond strength (TBS) tests. In shear bond strength tests, the force is applied parallel to the bonding surface, whereas in tensile tests, the force is applied at a right angle to the bonding surface.

Since the results are highly dependent on the test setup and the test procedure (e.g. the diameter of the specimens), the results of different test series can only be compared to a limited extent (Scherrer 2010; Heintze and Rousson 2011).

The figure below shows a typical setup of a shear bond strength test specimen for luting materials.

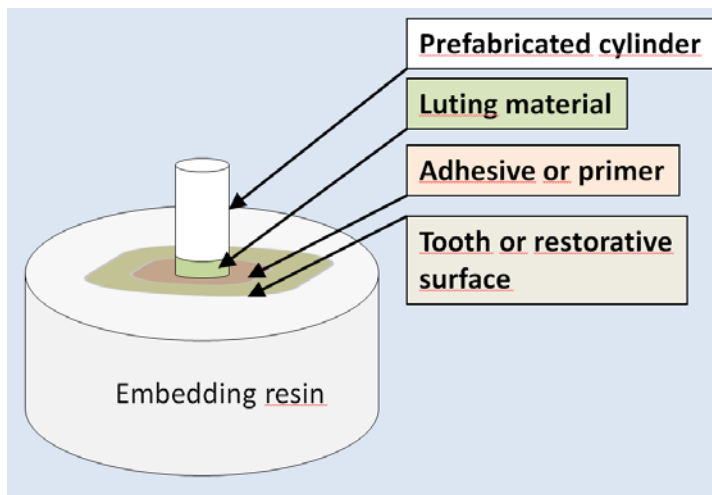


Figure 10: Schematic representation of shear bond strength test specimen for luting materials.

3.1.1 Adhesion to different restorative surfaces

The restorative materials were prepared and conditioned with Monobond Plus according to the instructions for use. The restorative materials were pre-treated as follows: lithium disilicate (LS2) and leucite-reinforced (silicate) glass ceramic specimens were etched for 20 s using Ceramic Etching Gel, the composite block was ground with 120 grit sandpaper, the aluminum and zirconium oxide ceramic specimens were sandblasted with 110 μ m Al₂O₃ at 2.0 bar. All specimens were rinsed with water followed by an application of Monobond Plus for 60 s. A Tetric EvoCeram cylinder was then luted onto the restorative material using Variolink Esthetic DC in a mold with a diameter of 4 mm. These results cannot be directly compared with those obtained with the Ultradent method as it uses a different sample diameter. Shear bond strength was measured using a universal testing machine at 0.8 mm/min crosshead speed.

Results:

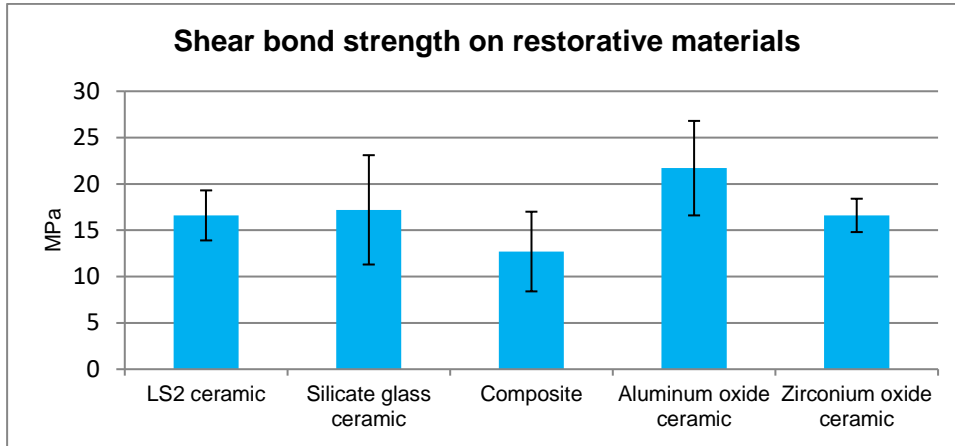


Figure 11: Shear bond strength on different restorative materials; R&D Ivoclar Vivadent AG, Schaan, 2013

In combination with Monobond Plus, Variolink Esthetic reached strong bonds to a range of dental restorative materials.

3.1.2 Tensile strength on lithium disilicate glass-ceramic (IPS e.max CAD)

As an alternative to the shear bond strength, the tensile strength can be determined in order to quantify the adhesion of a luting material. Tensile strength measurements should demonstrate less scattering than shear bond strength measurements, as they are less dependent on the surface structure of the material. For the micro-tensile bond strength (mTBS) measurements, the luting material is applied onto a prepared, flat, retention-free substrate block (enamel, dentin or restorative material) according to manufacturer instructions. Subsequently, another block of a previously defined size, is adhesively bonded to the block. The specimens are then cut perpendicular to the adhesive surface, using a diamond saw. The tensile stress is then determined using a suitable universal testing machine.

The ceramic surface was etched with hydrofluoric acid and conditioned with the primers or adhesives according to the respective instructions for use. The samples were immersed in water for 24 h at 37 °C and aging of the restorations was simulated with 10,000 thermal cycles between 5 and 55°C.

Results:

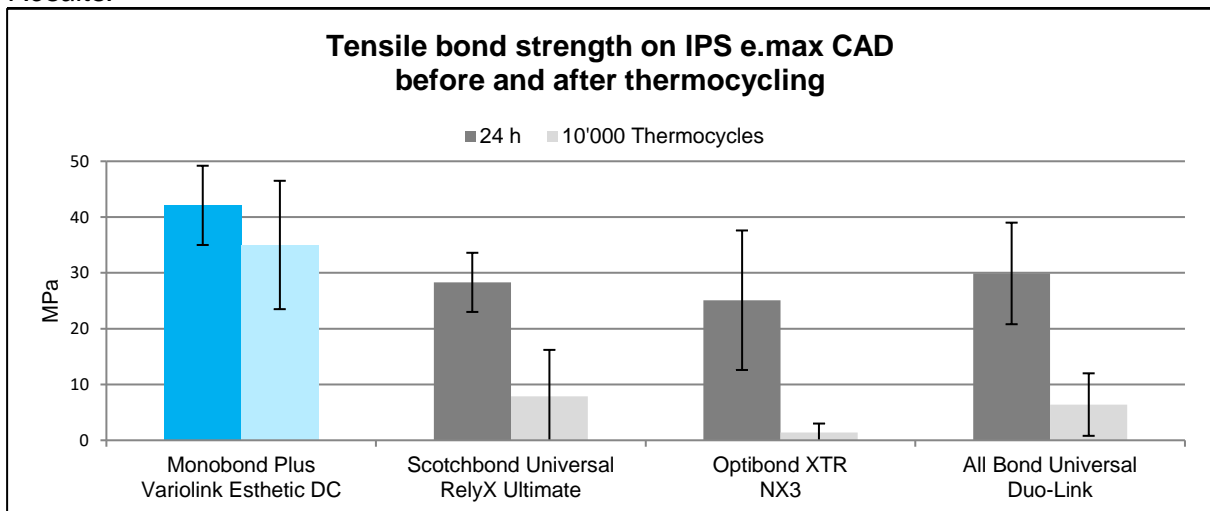


Figure 12: Tensile bond strength on IPS e.max CAD lithium disilicate glass-ceramic before and after thermocycling; R&D Ivoclar Vivadent AG, Schaan, 2014

Variolink Esthetic DC demonstrated high adhesion values and only a minimal decrease in the bonding performance after simulated aging.

When universal adhesives were used instead of a specialized primer or silane, the bond strengths were dramatically reduced after thermocycling. These results are in line with results of an investigation by Kern and Lehmann at the University Clinic Schleswig-Holstein, Germany, that evaluated the adhesive bond achieved with “universal” adhesives to lithium disilicate ceramic - compared to a system using a dedicated primer (Kern and Lehmann 2013 and unpublished data).

3.2 Adhesion to dentin and enamel

A luting composite must be capable of establishing a strong and long-lasting bond between the tooth structure and the restorative material, which are very different types of substrates.

3.2.1 Shear bond strength on dentine and enamel

a. Shear bond strength on dentin and enamel before and after thermocycling (TC)

The adhesives were applied to the bovine tooth substrate using the self-etch technique followed by the application of the luting material. All materials were applied according to their instructions for use. Sample preparation and measurements were conducted according to the Ultradent method. The shear bond strengths were measured before and after 10'000 thermocycles between 5 and 55°C.

Results:

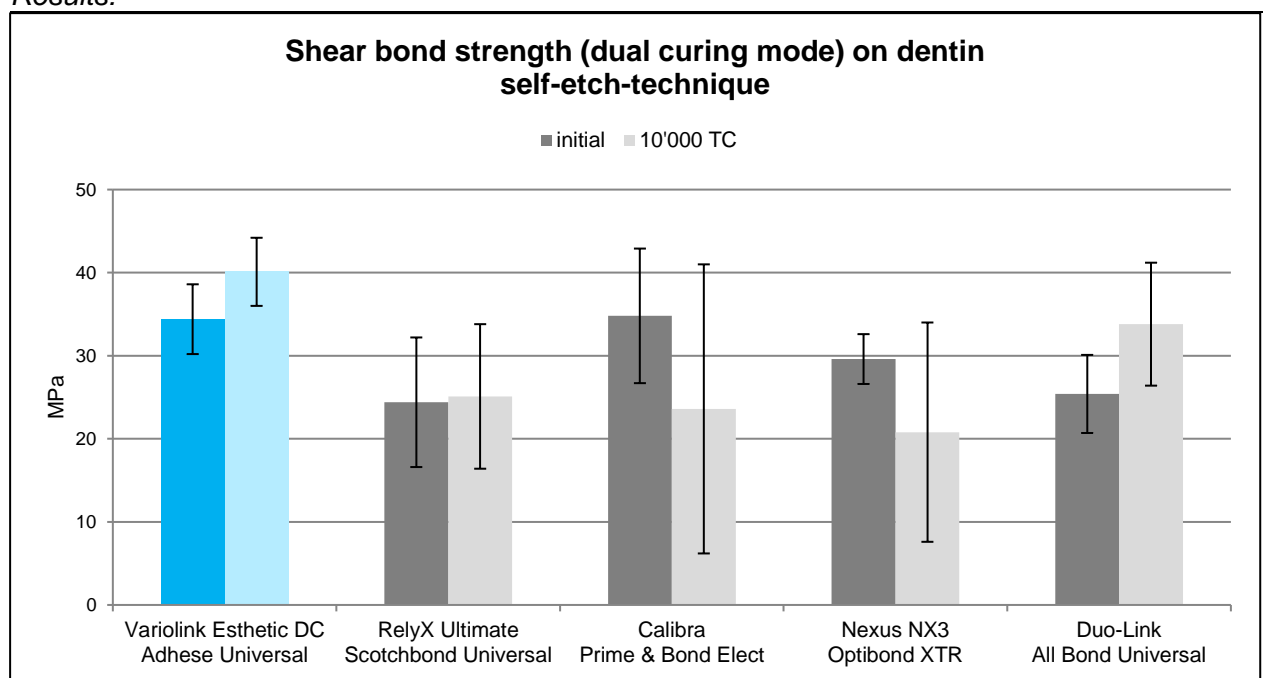


Figure 13: Shear Bond Strength (dual curing mode) on bovine dentin before and after thermocycling; R&D Ivoclar Vivadent AG, Schaan, 2014

Spontaneous debonding during thermocycling was valued as 0 MPa. This explains the high standard deviations for some competitor materials.

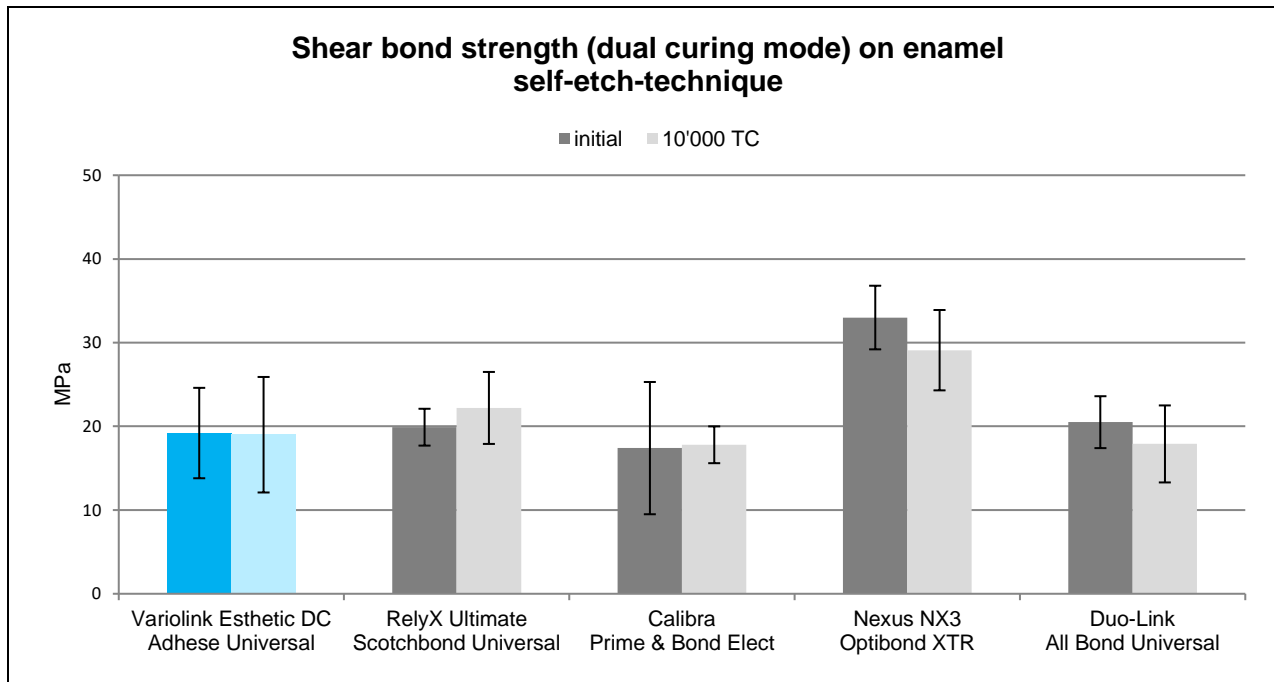


Figure 14: Shear Bond Strength (dual curing mode) on bovine enamel before and after thermocycling; R&D Ivoclar Vivadent AG, Schaan, 2014

On both tooth substrates, Variolink Esthetic showed high and consistent bond strengths before and after thermocycling.

b. External measurements

The adhesion of Variolink Esthetic plus Adhese Universal to tooth substrates was also tested by Prof. M. Irie at Okayama University. The shear bond strength on 3.6-mm test specimens was determined according to ISO TR 11405: 2003 as described in (Munksgaard 1985; Irie 2010). Consequently, the results cannot be directly compared with other shear bond strength values obtained with other methods.

The adhesives were applied on the tooth substrate, bovine dentin or enamel, either after phosphoric acid etching (total-etch, TE) or without phosphoric acid etching (self-etch, SE). Then, cylinders of polymerized Tetric EvoCeram were luted to the specimens. All luting composites were dual-cured. The shear bond strength was measured after 24-h immersion in water at 37°C.

Results:

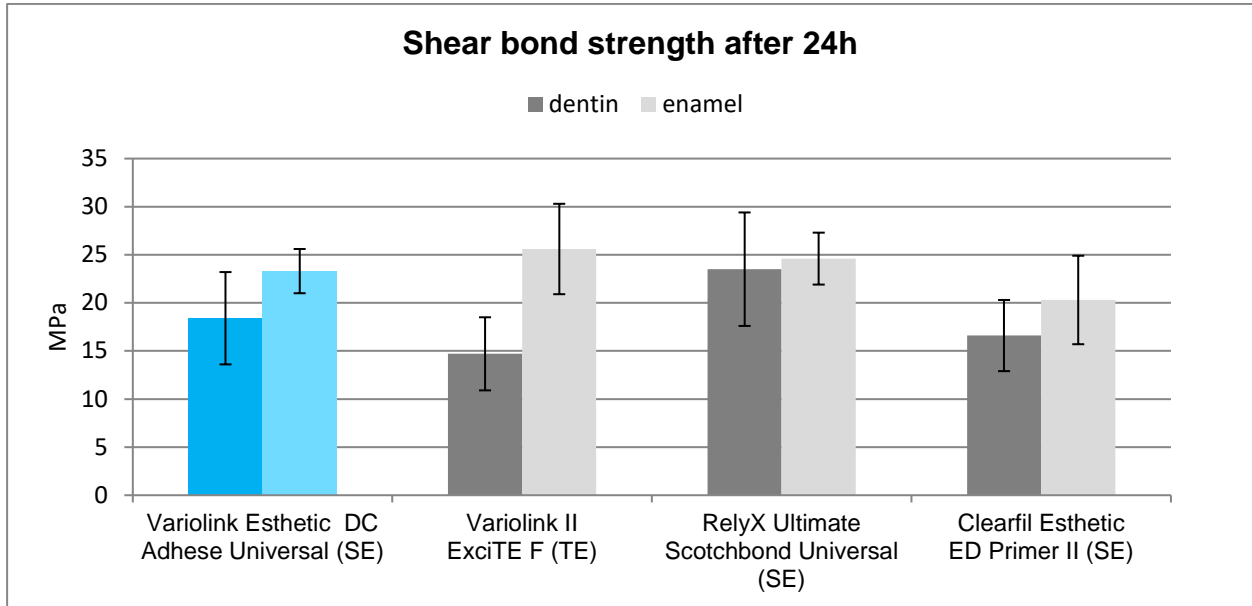


Figure 15: Shear bond strength on dentin and enamel, 24h after application; M. Irie, Okayama University, Japan, 2014.

3.3 Polymerization through ceramic

The properties of luting composites depend on the extent to which they are cured. In this test, all shades of Variolink Esthetic LC were light-cured through 1 and 2 mm thick ceramic specimens. IPS e.max press (in shades A3 and C4) was used as the ceramic, and light curing was performed for 10s per mm ceramic using a Bluephase G2 in high power mode (1100mW/cm²). The degree of polymerization of all shades of Variolink Esthetic LC was evaluated using Vickers hardness measurements.

Results:

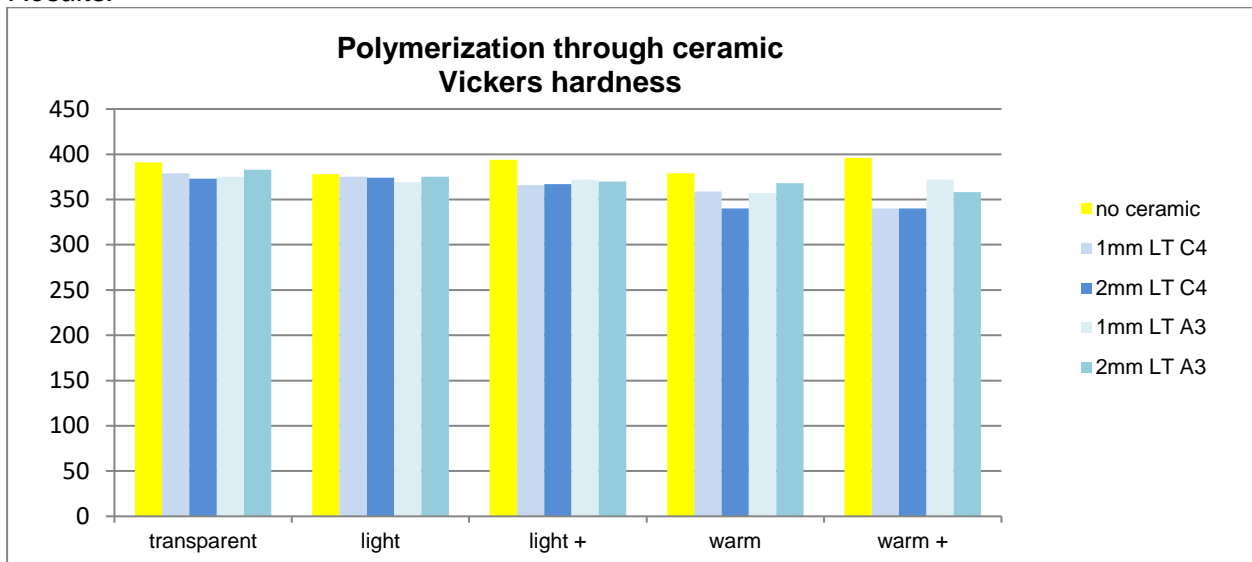


Figure 16: Vickers hardness after light curing without ceramic or through ceramics; R&D Ivoclar Vivadent AG, Schaan, 2013

Variolink Esthetic reached more than 85% of the hardness measured without ceramic in all conditions. Polymerizing Variolink Esthetic through ceramic is therefore considered sufficient when light curing is performed according to the instructions for use.

3.4 Water absorption and water solubility

In order to ensure adequate wetting of the hydrophilic dental material, the luting composite must also exhibit hydrophilic properties. The higher the hydrophilicity of a composite, the higher is its tendency to absorb water and to swell.

The increase in volume due to swelling may damage the restoration. As a result, water absorption must be kept to a minimum. Therefore, ISO 4049 limits the maximum acceptable water absorption to $40 \mu\text{g}/\text{mm}^3$. Examinations conducted according to this standard show that Variolink Esthetic absorbs a minimal amount of water. Water absorption remains clearly below the specified ISO limit.

Furthermore, the water solubility of a luting composite should be as low as possible, so that the material remains stable in the oral cavity. In ISO 4049 the limit for water solubility is defined at $7.5 \mu\text{g}/\text{mm}^3$. Variolink Esthetic also complies with this standard; its water solubility is hardly measurable in standardized tests.

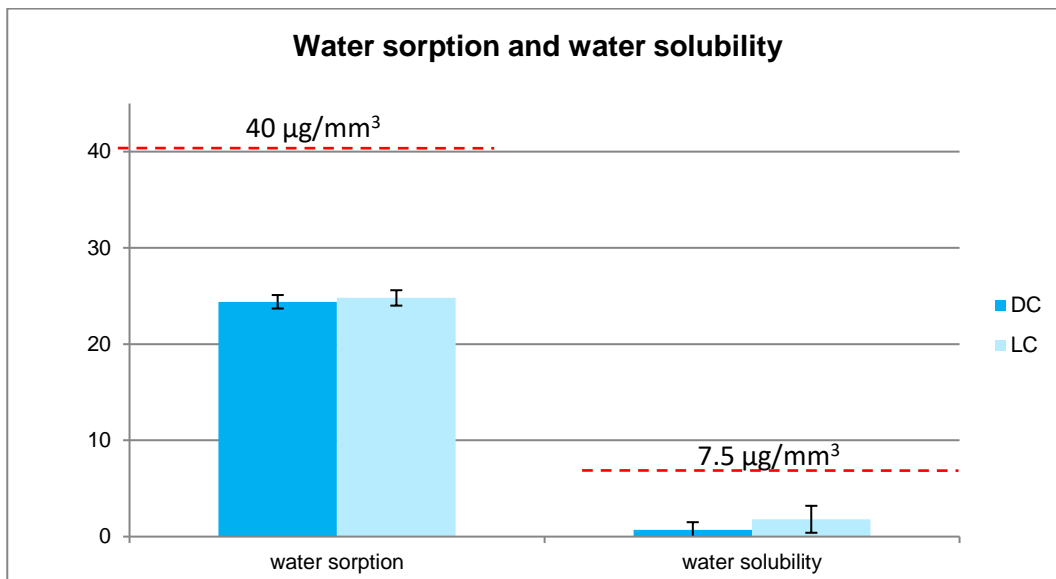


Figure 17: Water absorption and water solubility of Variolink Esthetic DC and LC. Limits of ISO 4049 are indicated; R&D Ivoclar Vivadent AG, Schaan, 2012

3.5 Flexural strength

Flexural strength is the resistance of a material to flexural stress at the breaking point. In addition to compressive strength and tensile strength, flexural strength is a significant parameter describing the mechanical strength of a material. The flexural strength of composites is essentially influenced by their chemical composition.

In the flexural resistance test, the luting composites were light cured and subsequently immersed in water for 24 h at $37 \text{ }^\circ\text{C}$ (test conducted according to ISO 4049).

Results:

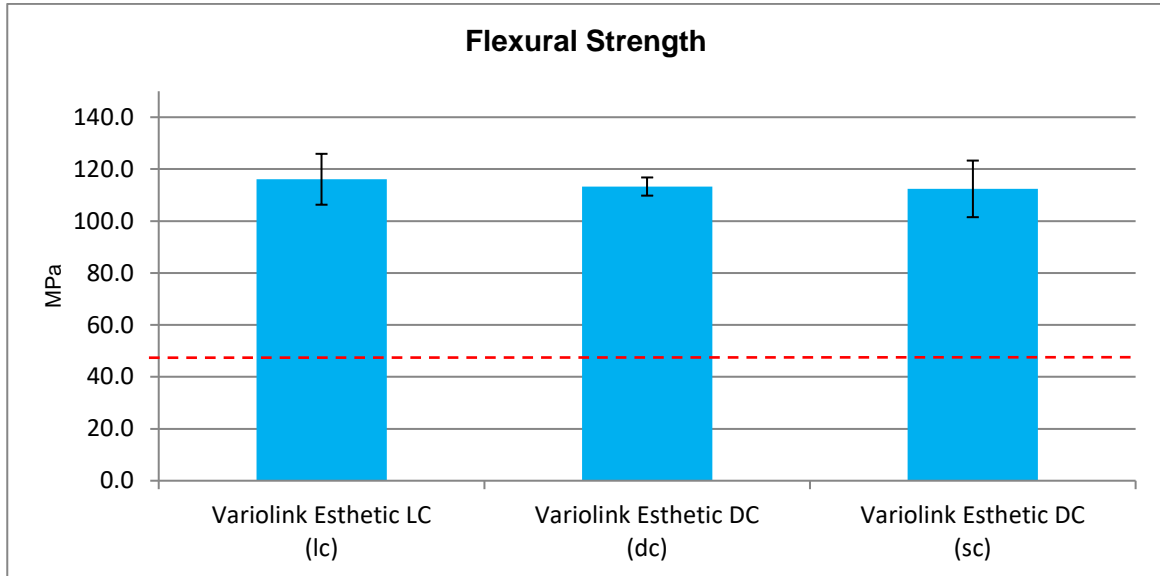


Figure 18: Flexural strength of Variolink Esthetic LC and DC. The curing mode is indicated in small letters (lc = light-cure, dc = dual-cure, sc = self-cure). The red dotted line indicates the minimal flexural strength defined in ISO 4049 (50 MPa); R&D Ivoclar Vivadent AG, Schaan, 2013-2014

Irrespective of whether the material is light-cured (lc), dual-cured (dc) or self-cured (sc), the flexural strength is clearly above that of the 50 MPa stipulated by ISO 4049.

The high flexural strength of Variolink Esthetic was confirmed by external measurements by Prof. Irie in Japan. In this study, one part of the samples was measured immediately after sample preparation and the other part after 24h storage in water.

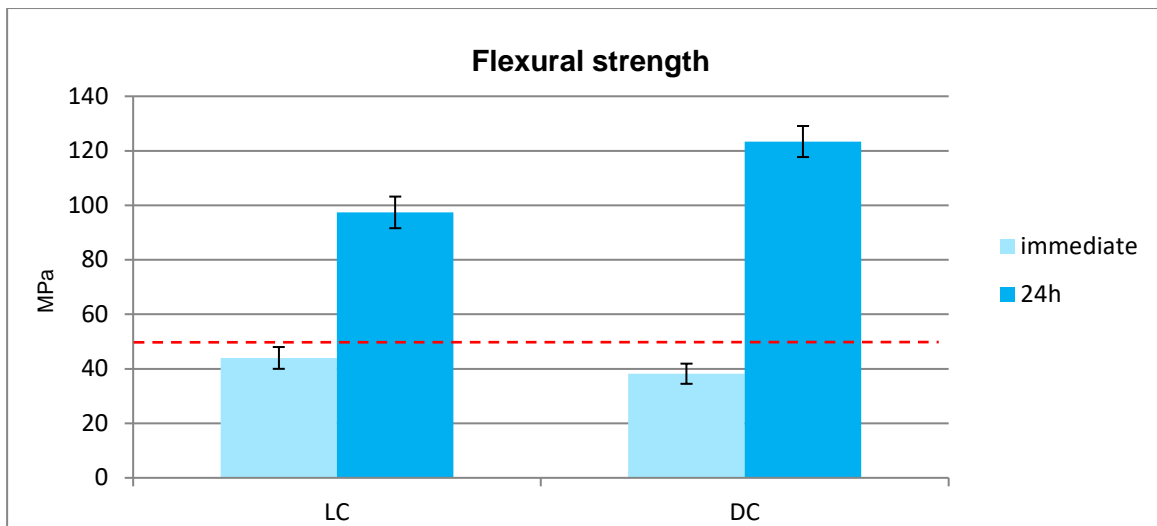


Figure 19: Flexural strength of Variolink Esthetic LC and DC. Comparison of immediate and 24h- values. The red dotted line indicates the minimal flexural strength that is defined in ISO 4049 (50 MPa after 24h). M. Irie, Okayama University, Japan, 2014

To allow convenient excess removal, the initial curing speed of Variolink Esthetic has been reduced. That is why immediate values are lower than the values measured after 24 h. ISO defines a flexural strength of 50 MPa after 24 h as a limit. This limit is almost reached immediately after application.

4. Clinical studies

4.1 *Prospective clinical observation*

on a single-component adhesive (Adhese Universal) and luting composite (Variolink Esthetic LC) for the cementation of veneers and onlays made of lithium disilicate ceramic (IPS e.max Press) – summary of intermediate report

by Prof Dr D. Edelhoff, Hospital of the Ludwig-Maximilians -University (LMU) Munich, Germany

Objective

In this study, Adhese Universal and Variolink Esthetic LC are assessed.

Method and scope

A total of 199 restorations (79 veneers and 120 onlays) made of IPS e.max Press (some Multi) were seated in 15 patients (11 women, 4 men) using Adhese Universal (VivaPen) and Variolink Esthetic LC according to the study guidelines. Outside the framework of this study, the same patients received 8 sintered veneers and 10 full crowns (IPS e.max Press Multi). The restorations were seated with Adhese Universal and Variolink Esthetic LC (Veneers) and Variolink Esthetic DC (crowns) following an adhesive cementation protocol. In addition of postoperative sensitivity and gingiva behaviour (rubber dam or non-impregnated retraction cord (UltraPak 000), excess removal and marginal quality were assessed. Up until today, four 12-month recalls and two 24-month recalls were performed.

Results

No biting or relief pain has occurred thus far. As a result of the adhesive cementation measures, isolated cases of temporary, moderate temperature sensitivity occurred, which abated completely after a few days. Thus far, none of the patients described any sensitivity to chemical stimuli (sweet/sour). Moreover, no anomalies in the area of the marginal gingiva were observed. This can be attributed to a major part to the supra- or equigingival preparation margins, which hardly permit any contact points with the gingiva. In very few cases, slight interdental irritation of the papilla occurred as a result of insufficient removal of Variolink Esthetic LC excess. However, the irritation abated in a few days after careful excess removal. Variolink Esthetic LC excess (cured for 2 seconds) was easy to remove in most cases. In certain cases, however, the excess was difficult to access, which required longer post-processing times (moderately difficult). In a few cases, a slight deficiency formation was observed, which, however, did not have any clinical relevance. Furthermore, no inherent discolouration has occurred to date.

Summary

The clinical performance has been very satisfactory until now. Only isolated cases of temporary temperature sensitivity have occurred. Also, slight irritation of the papilla as a result of insufficient removal of excess occurred only sporadically and abated after a short time. Post-processing was only necessary if excess was difficult to access. However, this did not have any clinical relevance.

4.2 *Clinical Evaluation of Variolink Esthetic & Adhese Universal for Posterior Ceramic Restoration Cementation – summary of intermediate report*

by John A. Sorensen, University of Washington.

Objective

The purpose of this study was to assess the clinical performance of a new dual-curing composite resin cement in combination with a light-cured single-component dental adhesive for cementation of posterior ceramic CAD/CAM restorations.

The focus of the study was on measuring the cementation factors of post-operative sensitivity, marginal integrity, microleakage, marginal discoloration, retention, caries and gingivitis. A

secondary aim was to evaluate the clinical behavior of the restoration ceramic surface and opposing natural tooth structure.

Method

27 onlays and 24 crowns (IPS e.max CAD) are adhesively luted using Variolink Esthetic DC and Adhese Universal in the Total-Etch technique. Sensitivity is evaluated after air and ice stimulation preoperatively, at baseline and at the recalls at 6, 12 and 24 months. The restorations are evaluated according to USPHS criteria.

Results

37 restorations were placed on vital teeth, 14 on non-vital teeth. So far, 31 patients had the baseline recall evaluation, 16 patients the 6-months recall and one patient the 1-year recall. One crown completely dislodged in one piece with the crown- composite core- fiber post. As the crown was replacing a defective crown it was not possible to recognize that the tooth had no ferrule extension. This crown was recemented but will not remain in the study. One crown showed an elevation after seating due to improper air-thinning of the adhesive before curing. In one restoration, the patient experienced moderate post-cementation sensitivity (VAS level 5) measured at the baseline appointment.

No staining, no discoloration, no increase in roughness and no debonding of restorations remaining in the study has been observed. No increase in surface roughness and no fracture of the ceramic has been observed. One margin was USPHS rated as a Beta. All others have been rated as Alpha.

Summary

So far, the clinical performance of the investigated materials is very satisfactory. The only debonding that occurred was on a tooth that should have been excluded from the study.

4.3 Variolink Esthetic – 18-month clinical performance

Dental Advisor, Michigan, USA

Method

A total of 216 restorations were placed with Variolink Esthetic between January 2016 and May 2017. As of February 2018, 26 restorations had been placed less than 6 months at recall, 64 from 6 months to less than 1 year prior to recall, 73 between 1 year and less than 18 months previously, and 53 at least 18 months prior.

Restorations were placed on 56 molars, 40 bicuspid and 120 anterior teeth. The restorations included 26 upper and 30 lower molar crowns, 19 upper and 19 lower bicuspid crowns, 86 upper anterior and 15 lower anterior crowns; 1 upper bicuspid, 15 upper anterior, and 1 lower anterior veneers; 3 upper anterior bridges; and 1 upper bicuspid onlay. Sixteen restorations were placed with Variolink Esthetic LC and 200 with Variolink Esthetic DC.

Results at 18 months

Recalled restorations were evaluated in the following areas: esthetics, lack of sensitivity, resistance to marginal discoloration, and resistance to fracture/chipping. Restorations were evaluated on a rating scale from 1 = poor to 5 = excellent.

Three teeth were extracted at recall for reasons unrelated to the restorations.

Esthetics

Two hundred and thirteen restorations (99%) placed with Variolink Esthetic (16 with LC cement and 197 with DC cement) received an excellent rating of five for esthetics. Clinicians commented on the excellent esthetics.

Lack of Sensitivity

Two hundred and fourteen of the 216 restorations placed with Variolink Esthetic received an excellent rating of 5, with no reports of sensitivity. Resistance to Marginal Discoloration. All recalled restorations (100%) placed with Variolink Esthetic received an excellent rating of five. No microleakage was observed.

Resistance to Fracture/Chipping

At recall, 214 restorations placed with Variolink Esthetic were intact and received an excellent rating of five. Two restorations fractured but these failures were deemed not related to the cement.

Conclusion

Over the 18-month recall period, the clinical performance of recalled restorations placed with Variolink Esthetic was exceptional. Esthetics was excellent, as were the lack of sensitivity, resistance to marginal discoloration, and resistance to fracture/chipping. The restorations will continue to be monitored over time.

At 18 months, Variolink Esthetic received a clinical performance rating of 99%.

4.4 Clinical case

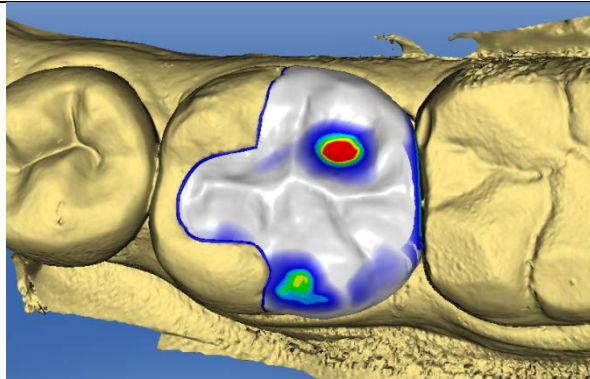
Variolink Esthetic is in clinical use since June 2014 in our internal R&D clinic and with selected customers. Figure 20 below shows the documentation of a clinical case in the internal R&D clinic.



A) Initial situation: tooth 36 with insufficient composite filling



B) Preparation



C) CAD image of e.max CAD-restoration



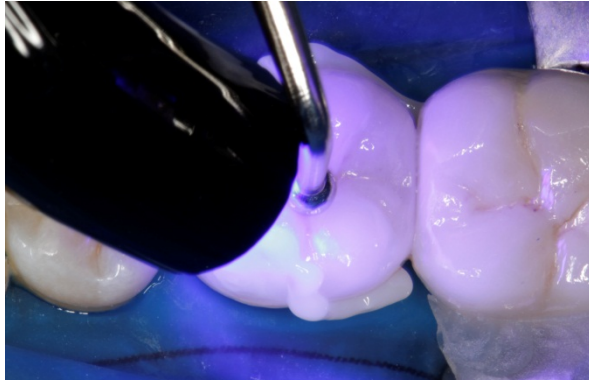
D) Try-in of crystallized and characterized restoration using Variolink Esthetic Try-In paste (neutral)



E) Etching of prepared dental surface with 37% phosphoric acid (Total Etch)



F) Application of Adhese Universal using the VivaPen



G) Pre-polymerization of excess material using quarter technique (distance max. 10mm, 2 sec. per quarter, Bluephase Style)



H) Convenient removal of excess material with a scaler



I) Application of glycerin gel (Liquid Strip) followed by final light curing in segments



J) Final restoration after one week

Figure 20: Variolink Esthetic in a clinical case. R&D clinic, Ivoclar Vivadent AG, Schaan, 2014

5. Biocompatibility

5.1 Introduction

Medical devices are subject to very strict requirements, which are designed to protect patients and operators from any potential biological risks. ISO 10993 "Biological evaluation of medical devices" defines how the biological safety of a medical device is to be evaluated. Furthermore, dental medical devices are subject to ISO 7405 "Preclinical evaluation of biocompatibility of medical devices used in dentistry".

The biocompatibility of Variolink Esthetic has been examined according to these standards.

5.1.1 Cytotoxicity

Cytotoxicity refers to the destructive action of a substance or mixture of substances on cells. The XTT assay is used to examine whether or not a substance causes cell death or inhibits cell proliferation in a cell culture. The XTT₅₀ value refers to the concentration of a substance which reduces the cell number by half. The lower the XTT₅₀ concentration of a substance, the more cytotoxic it is.

Extracts of *cured* Variolink Esthetic did not show any cytotoxic effects (1). *Uncured* Variolink Esthetic exhibits a moderate cytotoxicity that is inherent to monomers used in luting composites; the calculated XTT₅₀ value was approx. 230µg/mL (2), (3).

When Variolink Esthetic is polymerized, the cytotoxic compounds (monomers) react and are immobilized; i.e. the cytotoxic effect of the uncured composite is limited in time.

Most dental composites in clinical use, exhibit a similar initial cytotoxic potential, however negative long-term effects have not been observed. When used according to the instructions for use, the risk for patients or users is negligible when compared to the overall benefit of the product.

5.1.2 Sensitization

Like all dental composite materials, Variolink Esthetic contains methacrylates and acrylate derivatives. Such materials may cause sensitization, which can lead to allergic contact dermatitis. Allergic reactions are extremely rare in patients but are increasingly observed in dental personnel, who handle uncured composite material on a daily basis (Kallus and Mjor 1991; Kiec-Swiercynska 1996; Munksgaard 1996; Geurtsen 2000; Geukens and Goosens 2001; Aalto-Korte 2007; Sasseville 2012). These reactions can be minimized by clean working conditions and avoiding contact of the unpolymerized material with the skin (Munksgaard 1996; Geurtsen 2000). Commonly employed gloves, made of latex or vinyl, do not provide effective protection against sensitization to such compounds.

The use of Variolink Esthetic is contraindicated in patients with a known allergy to methacrylates.

5.1.3 Genotoxicity

Genotoxicity refers to the capability of a substance or a mixture of substances to damage genetic material. There are several assays to evaluate the mutagenic potential of a substance, and Variolink Esthetic has been examined regarding its potential gene changing properties in a set of mutagenicity tests.

Cured Variolink Esthetic and the uncured pastes did not show any genotoxic or mutagenic potential in mammalian cell culture and in vivo. Therefore Variolink Esthetic is considered non-genotoxic in humans (4-7).

5.1.4 Conclusion

After testing the toxicity and mutagenicity of Variolink Esthetic, the following conclusions can be drawn:

- Uncured Variolink Esthetic is cytotoxic due to its monomer composition. After polymerization, the monomers are immobilized within the polymer network, thus the cytotoxic effect is minimized shortly after application.
- Variolink Esthetic, particularly in the uncured state may cause sensitization to methacrylates. This is typical for all resin-based dental materials.
- According to the data available Variolink Esthetic is not genotoxic.

In summary, on the basis of the toxicological evaluation of the product and the longstanding worldwide clinical use of similar materials, it can be concluded that the benefits provided by the final product will exceed any potential risks produced by device materials.

5.1.5 Toxicological data:

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- (2) Heppenheimer, A. (2012) Cytotoxicity assay in vitro: Evaluation of test items in the XTT-Test with Variolink 4 Base (uncured), p 18, harlan.
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6. List of products

The following materials mentioned in this scientific documentation are not registered trademarks of Ivoclar Vivadent AG:

Product name	Manufacturer
RelyX Veneer	3M ESPE
RelyX Ulimite	3M ESPE
Scotchbond Universal	3M ESPE
All Bond Universal	Bisco
Duo-Link	Bisco
Calibra	Dentsply
Prime & Bond Elect	Dentsply
Nexus NX3	Kerr
NX3 Veneer	Kerr
Optibond XTR	Kerr
Panavia F2.0	Kuraray
Clearfil Esthetic	Kuraray
Clearfil Ceramic Primer	Kuraray
ED-Primer II	Kuraray

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Contents: Dr. Erik Braziulis
Edition: September 2014
Update: August 2018