# Variolink® II
# Variolink® Veneer

## Scientific Documentation

ivoclar vivadent

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# 1. Introduction

Variolink is a product family consisting of Variolink II, Variolink Ultra, and Variolink Veneer.

Variolink II is a radiopaque, dual-curing composite for the adhesive cementation of indirect all-ceramic and composite restorations. The Variolink II cementation system is particularly recommended for the incorporation of glass ceramic restorations (IPS Empress, ProCAD, IPS Empress 2, IPS e.max Press and IPS e.max CAD), as it forms a uniquely integrated, comprehensive system for aesthetic single-tooth restorations, bridges, inlays and onlays, particularly in conjunction with these products.

The composite cement consists of the following two components:

*Catalyst* two shades (transparent and yellow) and two consistencies (high and low viscosity),

*Base* one consistency and six shades (bleach XL, transparent, white, yellow, brown, and white opaque).

Variolink II is available in three different consistencies:

**Variolink II**, low viscosity **Variolink II**, high viscosity **Variolink II Ultra**, extra-high viscosity

Variolink II is clinically approved since more than 10 years. Over ten million restaurations have been luted with Variolink II worldwide.

Variolink Ultra is a dual- and light-curing adhesive luting composite for the ultrasonic application. In contrast to Variolink II it has a higher filler ratio.

Furthermore, a light-curing version of Variolink has been especially developed for the adhesive cementation of aesthetic anterior restorations: Variolink Veneer. This material is available in 7 shades, or degrees of translucency, ranging from the *High Value +3* (HV+3) opaque white bleach shade to the highly translucent *Medium Value 0* (MV0) and the *Low Value -3* (LV-3) shade, the latter of which shows a warm yellow-reddish tinge. The amine content of the composite paste has been strongly reduced to ensure a long-term constant colour stability.

Appropriate adhesives to dentin and enamel are:

- Syntac (multi-component adhesive)
- Excite DSC (one-component adhesive in combination with Variolink II and Variolink Ultra)
- Excite (one-component adhesive in combination with the light-curing Variolink Veneer)

## *1.1 Advantages of Variolink II / Variolink Veneer*

### *1.1.1 Selection of shade and translucency*

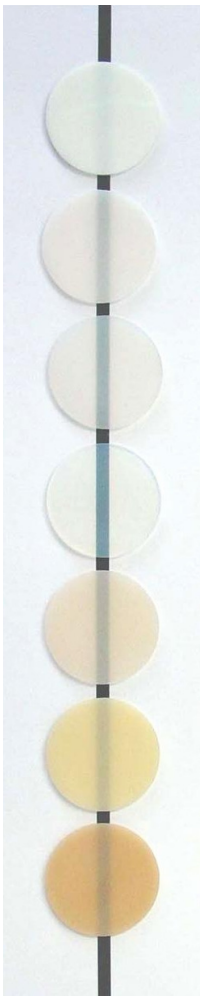
When providing patients with highly aesthetic, relatively translucent restorations (e.g. IPS Empress or ProCAD), the restoration may assume the shade of the adjacent teeth in what is known as the chameleon effect. A transparent cement is the prerequisite for the chameleon effect to develop. For conventional restorations, a cement in various shades is required to ensure uniform shading of tooth, cement, and restoration. The shade of the cement is particularly important if the cement joint is wide. A cement in a highly opaque shade is necessary to block out and mask discoloration.

Especially, the luting of veneers in the anterior region requires materials which ensure a long-term colour stability for high-quality esthetics. This requirement could be fulfilled with an amine-reduced formulation, which was exclusively developed for the light-curing Variolink Veneer.

Variolink II is available in **six shades** and **three degrees of translucency**.


Extended Variolink II shade range comprising 6 shades

Variolink Veneer is characterized by a special shade mapping (Shade Value), which covers different opacities and colours.



High Value +3

High Value +2

High Value +1

Medium Value 0

Low Value -1

Low Value -2

Low Value -3

The Shade Value enables the dentist to choose the right shade and translucency step by step: step-wise lucency (High Value) and step-wise shade increase.

### *1.1.2 Sensitivity to light*

Basically, two methods can be employed to polymerize composites, which are a combination of fillers and monomers:

- **Self-curing** : redox-initiated polymerization (two-component system)
- **Light-curing**: photochemical polymerization (single-component system)

Variolink II uses both types of polymerization. For its light-curing composite materials (Tetric Ceram, Tetric Flow and Variolink II), Ivoclar Vivadent has developed a new type of catalyst system (initiator and stabilizer), which demonstrates a comparatively low sensitivity to ambient light, without compromising the other properties, such as long-term stability and curing depth. At the beginning of the polymerization process, Variolink II enters a deliberate inhibition phase and, subsequently, polymerizes as quickly as other tried-and-tested composites. While the inhibition phase is prolonged under the influence of ambient light, it is much shorter under exposure to a polymerization light (approx. 0.5 s).

Variolink Veneer is a purely light-curing material.

### *1.1.3 Polishability*

Rather than the mean particle size, the maximum particle size of the filler is decisive for the surface roughness. In Variolink II, the mean particle size of the barium glass filler has been reduced to 1.0 µm, while the maximum particle size is 3 µm. As a result, the polishability of Variolink II has been substantially improved compared to that of its predecessor, Variolink.

### *1.1.4 Radiopacity*

Barium silicate glass is one of the fillers used in Variolink II. This glass distinguishes itself from the strontium silicate glass contained in other composite cements by its high radiopacity. Furthermore, the additional use of $YbF_3$ has resulted in both an increase in the fluoride release and unmatched radiopacity. The high level of radiopacity facilitates the identification of excess material, air bubbles, or secondary caries on X-rays.

### *1.2 Classification of dental luting materials*

In general the luting materials are divided into two categories: the conventional cements and the luting composites. Conventional cements require a retentive tooth preparation to ensure sufficient retention. Their advantage is their easy and quick application. It is not always necessary to work with a rubberdam. Luting composites are mainly used in combination with adhesives. With their higher shear bond strengths composites can be applied when adhesive bonding is mandatory. Colours and translucencies of composites can be varied: Therefore, luting composites provide esthetic solutions, when the margin is visible. In addition adhesive luting composites stabilize high-end glass ceramics, like IPS Empress or ProCAD.

Between the conventional cements and the luting composites is the group of hybrid cements, which can be cured by a glass ionomer reaction and by a light-induced polymerization. They show a higher mechanical stability than glass ionomer cements and unify the disadvantages of conventional cements and composites.

| Classification | Conventional Cements | Hybrid Ionomers | Composite Cements |
|---|---|---|---|
| Curing mechanism | neutralization reaction | | free-radical polymerization, initiated by light or chemically |
| Advantages | • easy processing<br>• excess material can be easily removed<br>• restoration can be easily removed | - | • non-invasive, adhesive preparation technique possible<br>• excellent bond with the tooth<br>• high stability<br>• limited solubility<br>• high wear resistance<br>• reduced postoperative sensitivity<br>• outstanding aesthetics |
| Disadvantages | • retentive preparation required<br>• solubility<br>• limited bond with the tooth<br>• low wear resistance<br>• risk of postoperative sensitivity | ⇔ | • excess material is difficult to remove after polymerization<br>• restorations are difficult to remove |
| Product examples | glass ionomer cements: Vivaglass CEM, Ketac CEM<br>phosphate cements: PhosphaCEM, Harvard | | Variolink II, DualCement, Multilink Automix, Panavia 21, Rely X Unicem, Calibra, Nexus II |

### *1.3 Adhesive cementation*

Adhesive cementation presents the following advantages:

- Aesthetics (translucency, surface lustre, no marginal discoloration)
- Reduction of postoperative sensitivity
- Additional reinforcement of ceramic and composite restorations
- Non-invasive preparation technique due to high bonding values and high stability

### *1.4 Indication*

Variolink II is a light- and dual-cruing composite cement designed for the adhesive cementation of:

- inlays, onlays, veneers
- crowns
- metal-free adhesive bridges
- glass-fibre reinforced composite root canal posts

Variolink II is recommended for the cementation of glass-ceramic restorations.

Variolink Veneer is suitable for the cementation of aesthetic anterior restorations.

Variolink Ultra is recommended for ultrasonic application.

The Variolink II Try-In pastes are water-soluble glycerine pastes coordinated with Variolink II. They are used for shade simulation during try-in.

# 2. Technical data

## Variolink II

**Standard – Composition** (in weight %)

| | Base | Catalyst high | Catalyst low |
|---|---|---|---|
| Dimethacrylates | 26.3 | 22.0 | 27.9 |
| Inorganic fillers (silica, barium glass, Ytterbium trifluoride | 73.4 | 77.2 | 71.2 |
| Catalysts and Stabilizers | 0.3 | 0.8 | 0.9 |
| Pigments | < 0.1 | < 0.1 | < 0.1 |

**Physical properties**

In accordance with ISO 4049 – Polymer-based filling, restorative and luting materials

| | | | |
|---|---|---|---|
| Flexural strength | light curing Base<br>light curing Base and Catalyst<br>self curing Base and Catalyst | 115<br>110<br>85 | MPa<br>MPa<br>MPa |
| Flexural modulus | light curing Base<br>light curing Base and Katalyst<br>self curing Base and Katalyst | 8300<br>8300<br>6000 | MPa<br>MPa<br>MPa |
| Compressive strength | | 240 | MPa |
| Depth of cure | Base opaque / white /yellow / brown / transparent | 1.0 / 3.0 / 2.8 / 2.2 / 3.0 | mm<br>mm |
| Film thickness | | 15 | µm |
| Radiopacity | | 450 | % Al |
| Shear bond strength | on ceramic with Monobond-S | cohesive | fracture |
| Transparency | Base transparent<br>white, yellow, brown<br>opaque | 15.0 ± 1.5<br>12.0 ± 1.5<br>1.5 ± 0.5 | %<br>%<br>% |
| Working time (37 °C) | | 3.5 ± 0.5 | min |
| Vickers hardness (HV 0.5/30) | | 500 | MPa |
| Water absorption (7 days) | | 25.0 | µg/mm³ |
| Water solubility | | 1.0 | µg/mm³ |

## Variolink Veneer

**Standard – Composition** (in weight %)

| | medium value 0 | high value +1 | high value +2<br>low value -1 | low value -2<br>low value -3<br>high value +3 |
|---|---|---|---|---|
| Dimethacrylates | 33.7 | 34.5 | 32.7 | 32.7 |
| Inorganic Fillers | 65.9 | 60.1 | 56.9 | 46.9 |
| Ytterbium Trifluoride | - | 5.0 | 10.0 | 20.0 |
| Catalysts and Stabilizers | 0.4 | 0.4 | 0.4 | 0.4 |
| Pigments | - | < 0.1 | < 0.1 | < 0.1 |

**Physical Properties**

In accordance with ISO 4049 - Polymer-based filling, restorative and luting materials

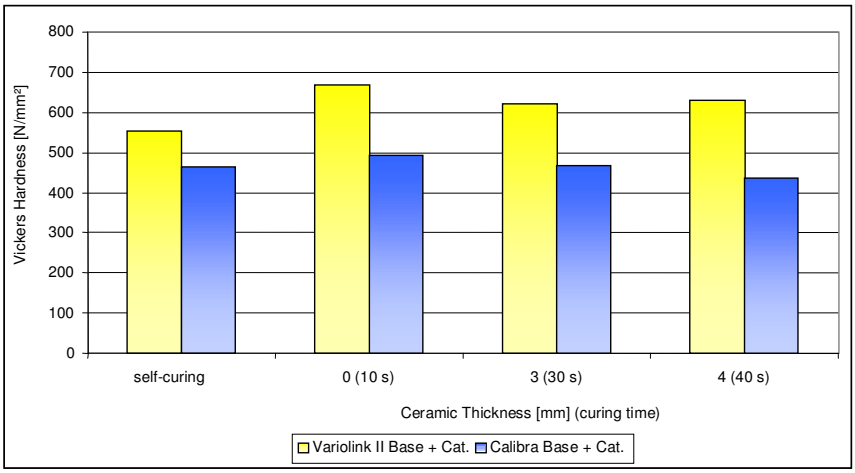
| | | |
|---|---|---|
| Translucency | 8-50 | % |
| Flexural strength (2x3 min Spectramat ) | 107 | MPa |
| Flexural modulus (2x3 min Spectramat) | 4500 | MPa |
| Vickers hardness (2x3 min Spectramat 24h dry) | 450 | MPa |
| Compressive strength (2x3 min Spectramat) | 400 | MPa |
| Water absorption after 7d | 18.5 | µg/mm³ |
| Water solubility after 7d | 0.0 | µg/mm³ |
| Film thickness | 9 | µm |
| Consistency | 21 | mm |
| Radiopacity | 50-200 | % Al |

# 3. In vitro investigations

In this section, the properties of Variolink II and Variolink Veneer are compared with those of other luting materials available on the market.

## *3.1 Polymerization*

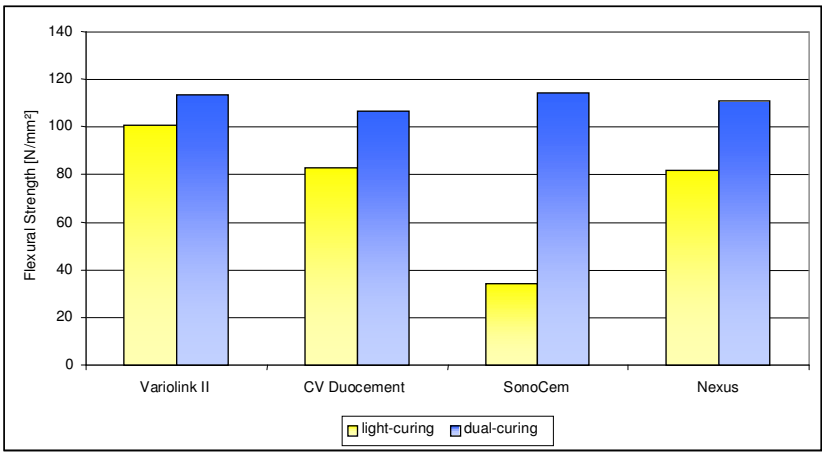
The polymerization behaviour of Variolink II and Calibra when cured through Empress 2 ceramic discs (shade 210) of different thicknesses using Astralis 10 was examined by determining the Vickers hardness. The composites were polymerized in a dual-cure mode by related exposure times through Empress 2 disks up to 4 mm.




R&D Ivoclar Vivadent AG, Schaan, Liechtenstein

### *3.2 Flexural strength*

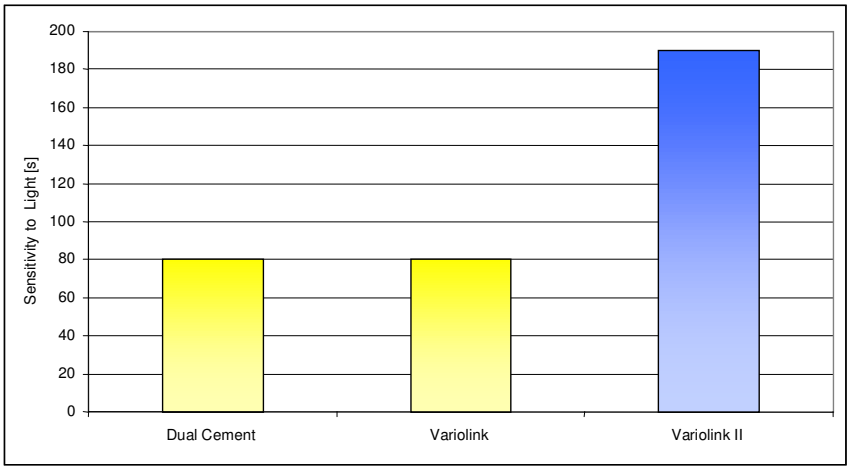
The flexural strength of Variolink II and competitive materials was investigated at the University of Würzburg (Germany) using light-curing and dual-curing polymerization methods. For this purpose, the cements were cured through IPS Empress ceramic discs of 2.5 mm thickness using a polymerization light. While the flexural strength values of the cements investigated were comparable when the light- and self-curing mode was used, Variolink II demonstrated the best curing characteristics when light-curing alone was used.




University Clinic Würzburg

### *3.3 Sensitivity to ambient light*

In the investigations carried out by Ivoclar Vivadent according to the standard for composite restorative materials (ISO 4049), the uncured restoratives are exposed to the light of 8,000 lux on a slide. Subsequently, the samples are pressed against a second slide to form a thin layer. The restoratives are then visually checked for inhomogeneity.

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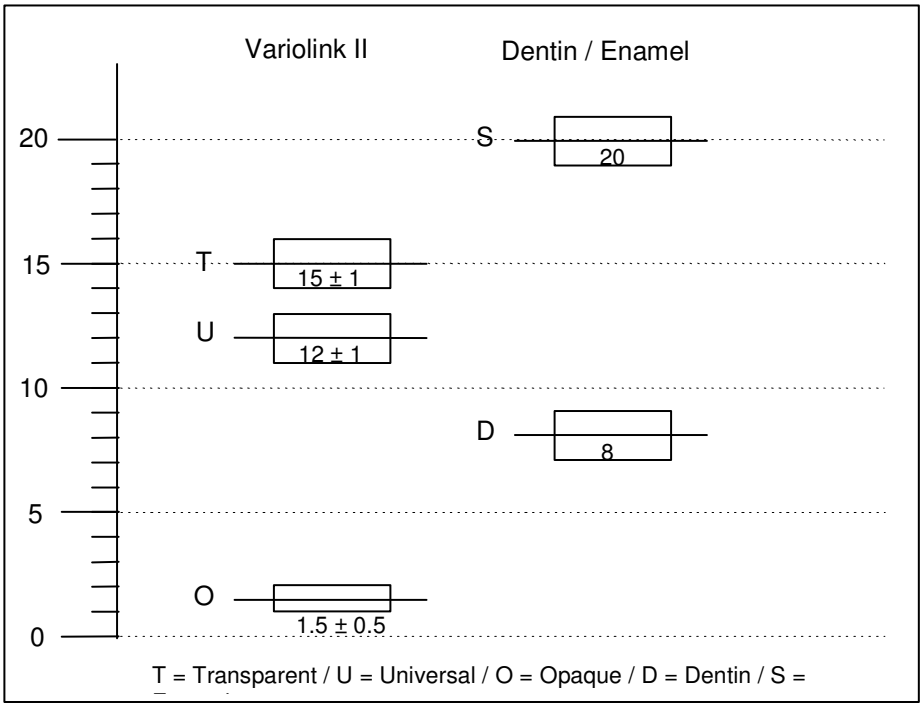
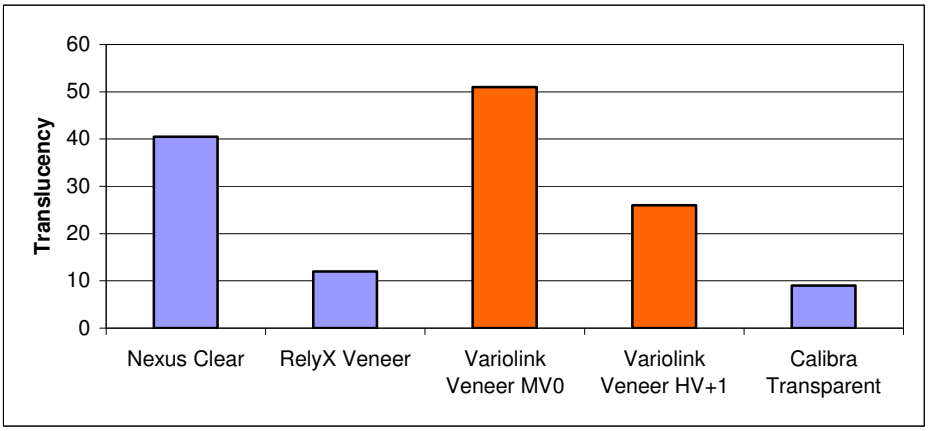
If the material has started to polymerize, cracks and bubbles will form when the material is pressed to a thin layer. The graph shows the times at which the different restorative materials started to polymerize. Variolink II demonstrates a considerably longer working time than Variolink and Dual Cement at ambient light. Hence, dentists have ample time to place a restoration accurately and to remove excess material before polymerization.

### *3.4 Translucency*

The graph below shows the translucency of Variolink II compared with that of natural enamel and dentin.

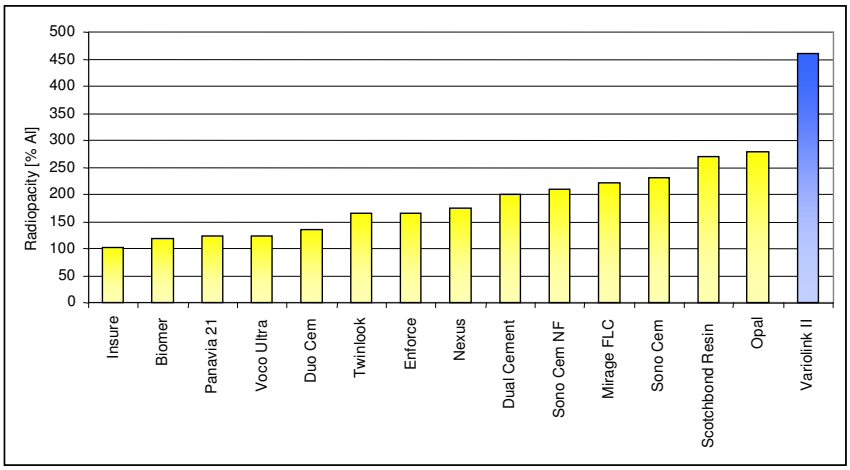



The translucency of two versions of Variolink Veneer was examined and compared with competitive materials. In this investigation, the highly translucent *Medium Value 0* shade showed the highest degree of translucency.




R&D, Ivoclar Vivadent AG, Schaan

### *3.5 Radiopacity*

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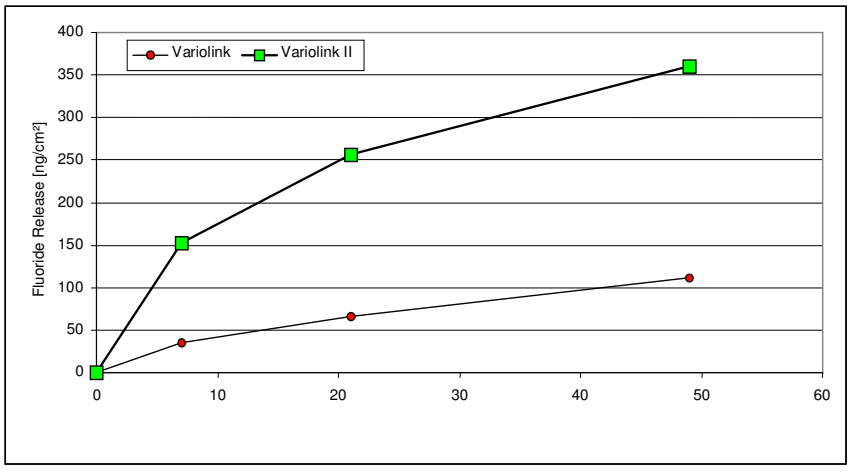
The radiopacity of dental materials is determined in relation to the radiopacity of aluminium. Variolink II features a very high level of radiopacity, enabling the operator to clearly distinguish between restoration, cement, and caries on X-rays. Even the smallest amounts of proximal excess can be detected.

Variolink Veneer Medium Value 0, High Value +1 and High Value +2 are not radiopaque because of their high degree of translucency.

### *3.6 Fluoride release*

Test samples (Ø=50mm, h=0.5mm, surface=40.1cm²) were fabricated and subsequently polymerized in the Spectramat twice for 5 minutes. The samples were placed in individual polypropylene vials, covered with 200 ml of water (0.02 % sodium azide) and stored at 37 °C for 7 days. To prepare the test samples for the individual measurements, they were removed from the storage liquid and blotted dry.

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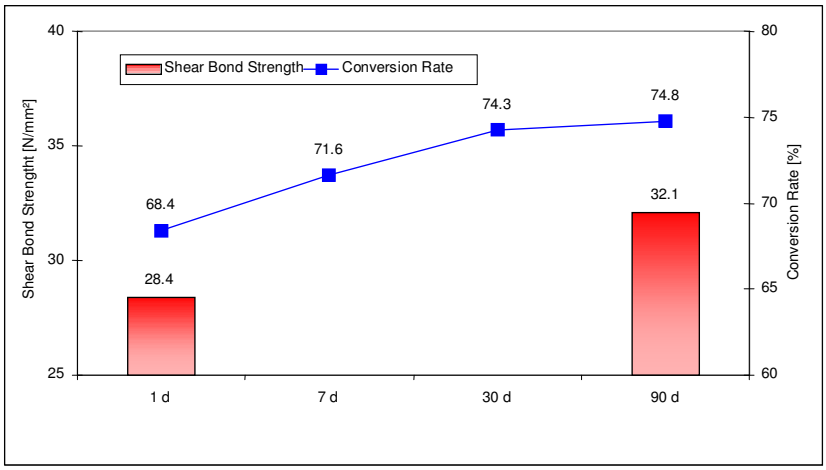
Subsequently, the samples were placed in fresh storage liquid for the next measuring period (14, 28, 56, 112 days). To determine the fluoride content in the storage liquid, the fluoride-sensitive ORION 96-09 probe in combination with the ORION 920A ionometer were used. Variolink II clearly releases more fluoride than Variolink.

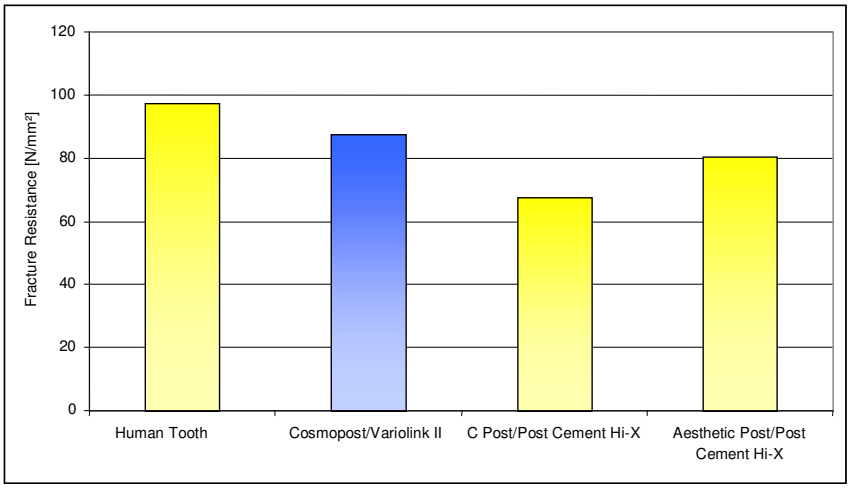
### *3.7 Conversion rate and shear bond strength*




Gahse S, Lohbauer U, Frankenberger R, Krämer N; Conversion rate and bond strength of a dual-curing luting composite; J Dent Res 80 (2001) 62

At the University of Erlangen-Nuremberg (Germany), the effect of the storage time on the polymerization and shear bond strength of Variolink II low and Vita InCeram was investigated. After a three-month storage period in water at 37 °C, a significant increase in the conversion rate and the bond strength was observed.

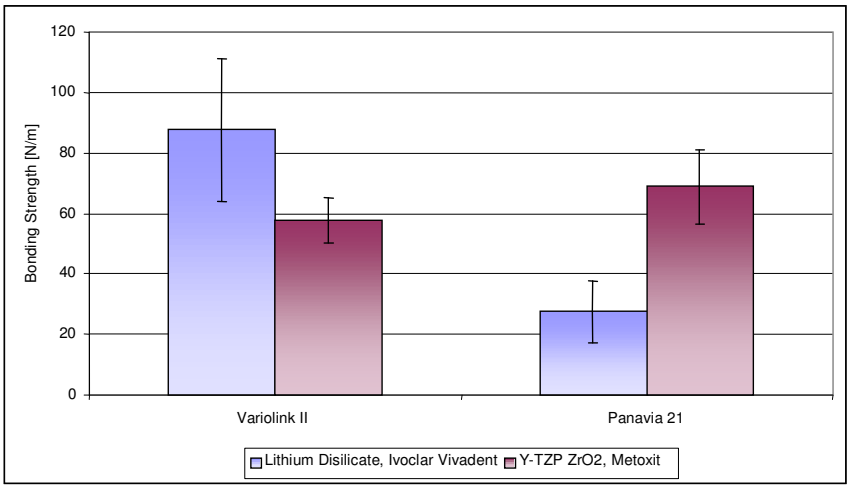
### *3.8 Fracture resistance of root canal post-retained restorations*




Cardoso PC, Burmann PA, Silveira B, Albers A, Soares LF; Fracture strength of bovine pulpless teeth restored by post systems; J Dent Res 80 (2001) 64

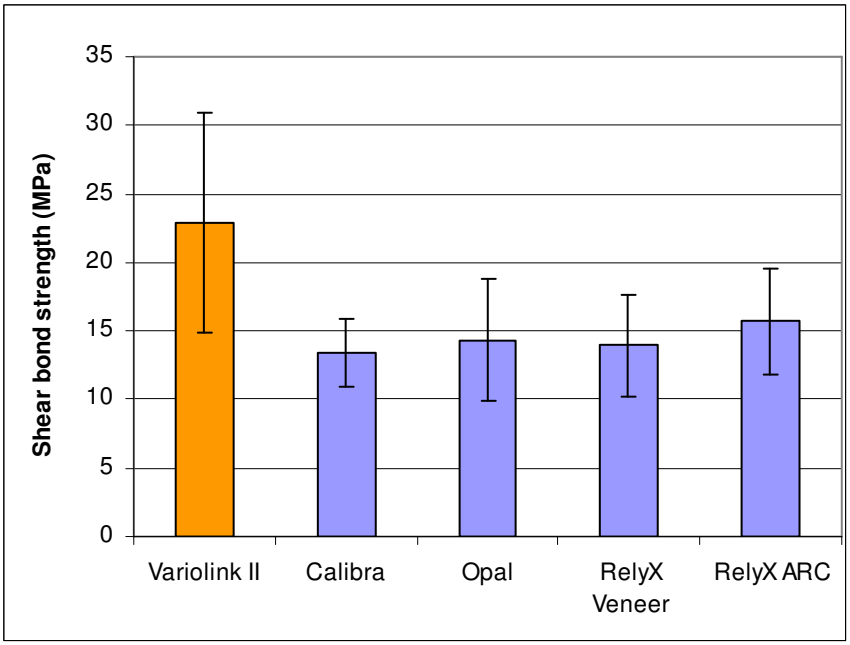
The fracture resistance of root canal post/composite build-ups compared to that of natural teeth was investigated by Cardoso et al. For the root canal post/cement combinations shown in the graph on the left, the Cosmopost bonded in place with Variolink II achieved the highest fracture resistance values for root canal post-retained restorations in this study. The fracture resistance of this combination was closest to the one of natural teeth.

### *3.9 Bond strength*




Edelhoff D, Marx R, Abuzayeba m, Yildirim M, Spiekermann H, Sorensen JA; Adhesive bond strength between resin cements and high-strength ceramics; J Dent Res 79 (2000) 618

Edelhoff et al. investigated the influence of surface conditioning of highly stable ceramic materials on the bonding strength in conjunction with composite cements. After blasting with $Al_2O_3$ (110 µm) and silanating, both the lithium disilicate glass ceramic (Empress 2) and the zirconium oxide (Metoxid AG) used in combination with Variolink II showed very high bonding values.

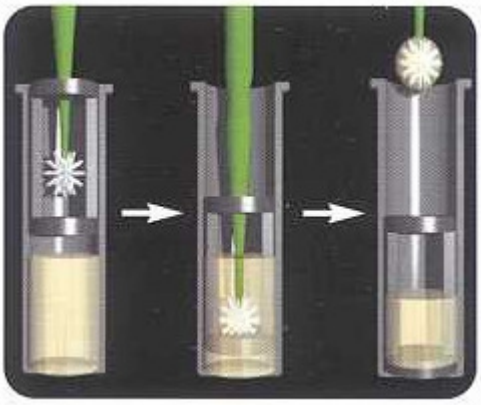



Shear bond strength of different luting materials in conjunction with IPS Empress 2
(V. Bookhan et al. SADJ 60, 103 (2005)

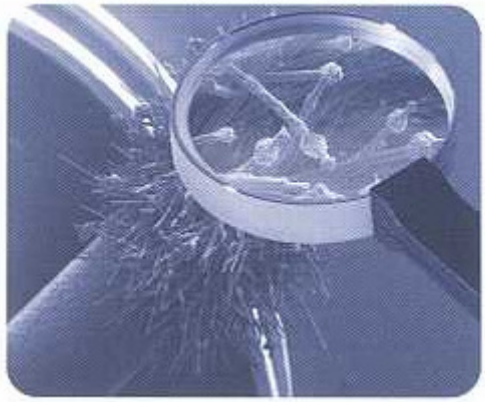
Bookhan et al measured the shear bond strength of different luting materials on a lithium disilicate ceramic; IPS Empress 2 was used in the present case. The ceramic materials were prepared according to the relevant instructions for use. The bonded samples were stored for 24 hours and then thermocycled for 300 times at alternating temperatures of 5º and 55 ºC.

### *3.10 Variolink II in combination with Excite DSC*

The *Variolink II Esthetic Cementation System* contains Excite DSC, the dual-curing single-component adhesive, which is supplied in the new single-dose vessel with an integrated application brush. The brush is coated with the initiators necessary for the dual-curing feature.



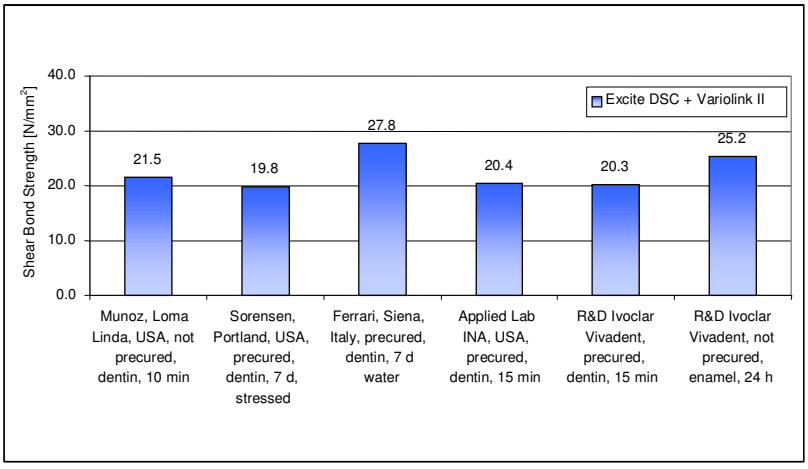
Excite DSC single-dose vessel



Microbrush coated with initiators

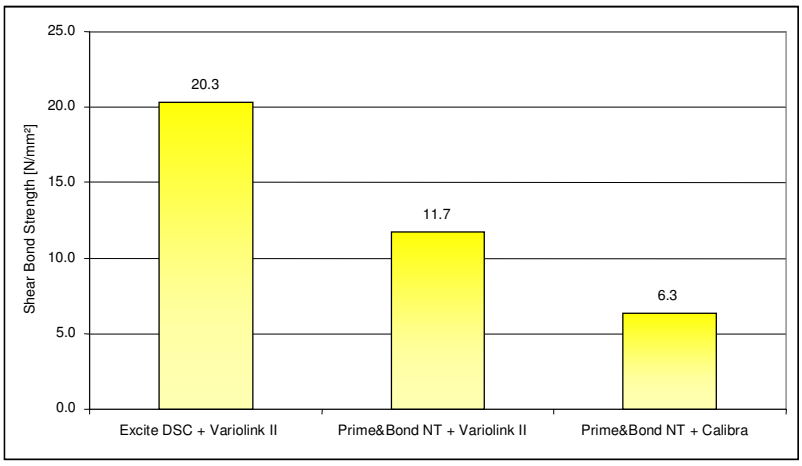
When activating the single-dose vessel, the initiators mix with the adhesive solution. Subsequently, Excite DSC is quickly and easily applied in a single layer. The restoration may be directly incorporated using Variolink II without having to light-cure the single-component adhesive.

#### *3.10.1 Shear bond strength*




Various test centers

The shear bond strength of the combined bonding/ cementation system Excite DSC/Variolink II was determined by various test centers. Several users measured high shear bond strength values without exception under various general conditions. These values indicate the high compatibility of the two systems.

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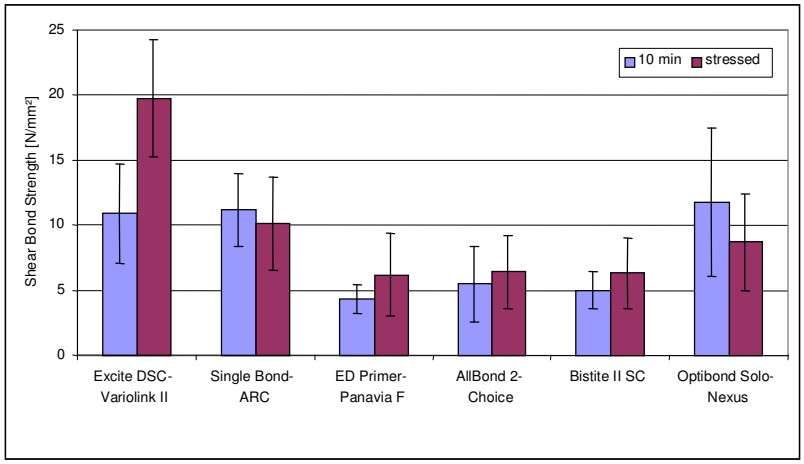
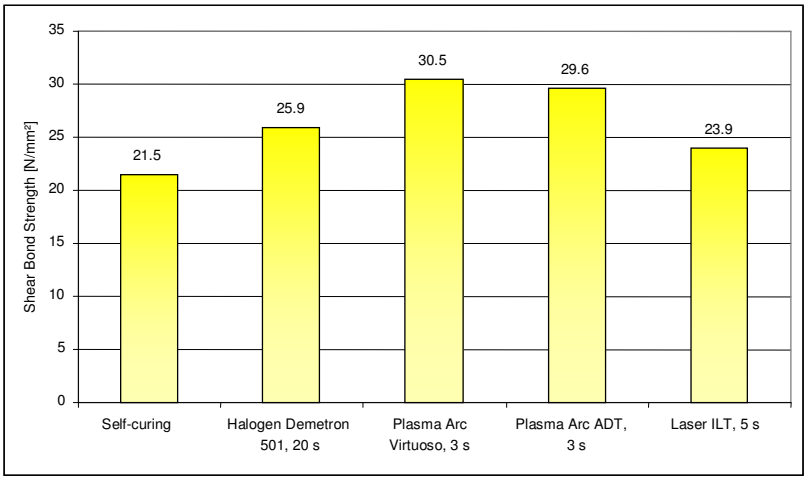
The shear bond strength values of the Excite DSC/Variolink II bonding/cement combination compared with Prime & Bond NT/Variolink II and Prime & Bond NT/Calibra are shown in the graph on the left. The combination of Excite DSC and Variolink II demonstrates the best performance of the three material combinations.




Sorensen JA, Hedayat L, White MD; Ceramic inlay microleakage and shear bond strength of new dentin adhesives; J Dent Res 80 (2001) 102

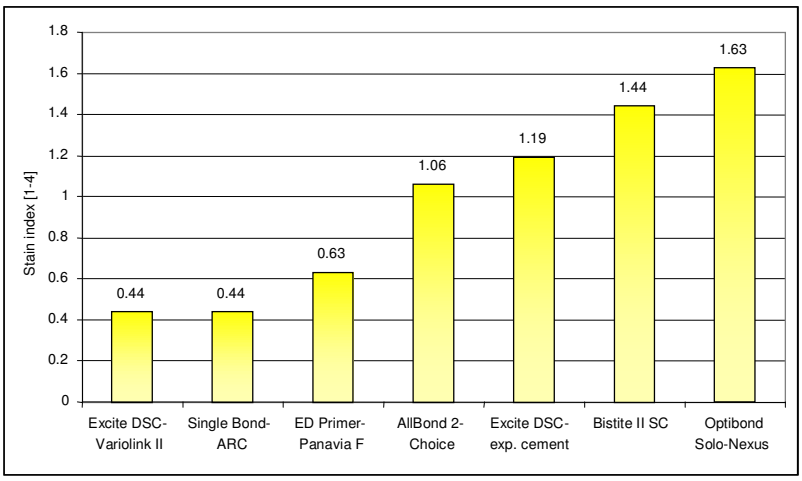
Sorensen et al. investigated the influence of modern dental bonding agents on the shear bond strength of adhesively cemented ceramic inlays. For that purpose, the bonding values were determined after 10 min. and 7 days immersion in water and thermocycling (1000 cycles). The ceramic inlays cemented using Excite DSC and Variolink II demonstrated the highest bonding values after immersion in water and thermocycling.




Dr. Munoz, University of Loma Linda, USA

The influence of various curing lights on the shear bond strength of Excite DSC/Variolink II was determined at the University of Loma Linda, USA. Very good bonding values were achieved with various curing lights.

*3.10.2 Microleakage*

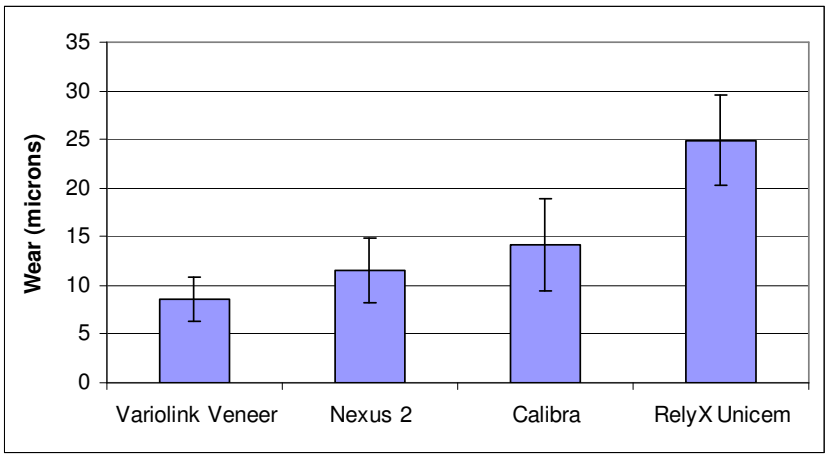



Sorensen JA, Hedayat L, White MD; Ceramic inlay microleakage and shear bond strength of new dentin adhesives; J Dent Res 80 (2001) 102

In order to evaluate whether the use of modern dentin adhesives influences the adhesive cementation of ceramic inlays, Sorensen et. al. investigated the marginal integrity of various adhesive/cement systems after a seven-day immersion in water (37 °C) and thermocycling. The graph on the left shows the stain index of the systems examined. In view of the limited penetration depth of the dye, the marginal integrity of the ceramic inlays cemented with Variolink II and Excite DSC can be considered excellent.

### *3.10.3 Wear of Variolink Veneer*

The subject of this investigation was the behaviour of composites in the presence of an abrasive medium, since dental materials are frequently exposed to abrasives in the oral cavity. As the composite abrades, its surfaces become rougher and, as a result, are more susceptible to discoloration. High wear may result in aesthetic disadvantages. This is particularly true for anterior materials such as Variolink Veneer. In a comparative study, the wear properties of Variolink Veneer and several other commercial luting composites were examined in a three-body wear test. A water-based suspension of spherical poly(methylmethacrylate) particles was used as the abrasive medium. The test samples, which had flat polished surfaces, were subjected to 400,000 chewing cycles in the course of 90 hours. The loss of substance was measured on replicas of the samples using a profilometer.




*In vitro* wear of composite cements (S. Suzuki, Alabama School of Dentistry)

The results show that Variolink Veneer shows low wear compared with other composite cements.

# 4. Clinical investigations

## *4.1 Clinical investigations*

### *4.1.1 "Clinical trial of Empress 2 inlays luted to vital abutments with Excite and Variolink II"*

*Research Center for Dentistry, Livorno, Italy, Dr. M. Ferrari*

The objective of this study was to assess the marginal quality of Excite/Variolink II/Empress 2 restorations under clinical conditions over a period of 18 months. For this purpose, 40 patients were provided with Class II Empress 2 inlays.

| **Examination** | **Status upon completion of the study** |
|---|---|
| ▪ Postoperative sensitivity | 0 % |
| ▪ Marginal tightness | 88.3 % perfect interface |
| | 11.7 % slight discoloration |
| ▪ | |
| ▪ Marginal integrity | 88.3 % perfect integrity |
| | 11.7 % slight depression |
| ▪ | |
| ▪ Retention | 100 % |
| ▪ Mikrorissbildung | 0 % |

The Excite/Variolink II/Empress 2 combination showed an excellent performance under the clinical conditions mentioned above.

### *4.1.2 "Clinical investigation of a highly stable ceramic (Empress 2) used as a C&B material"*

*University Clinic of Freiburg (Germany); Prof. Strub*

A total of 59 IPS Empress 2 restorations were incorporated in 44 patients (Syntac Classic/Variolink II). Recall examinations were conducted after a mean wear period of 2 years.

| **Examination criteria** | **Status upon completion of study** |
|---|---|
| ▪ Changes in marginal quality | 0 % |
| ▪ Marginal discoloration | 0 % |
| ▪ Secondary caries | 0 % |
| ▪ Loss of retention | 0 % |

Adhesive cementation of the IPS Empress 2 crowns and bridges using the Variolink II system has proved its suitability under the conditions of this study.

*4.1.3 "Short term clinical evaluation of inlay and onlay restorations made with a ceromer (Targis)"*

*University of Bologna, Italy, Dr. C. Monaco; Int. J. of Prosthodontics, 14 (1), 2001*

For this study, 25 Targis inlay and onlay restorations were cemented using Variolink II and Syntac Classic. The examination period was 18 months.

| **Examination criteria** | **Status upon completion of study** |
|---|---|
| | |
| ▪ Marginal discoloration | 5 % |
| ▪ Secondary caries | 0 % |
| ▪ Marginal integrity | 95 % |
| ▪ Postoperative sensitivity | 0 % |

The original postoperative sensitivity was no longer observed after 12 months. The Targis ceromer material, used in conjunction with the adhesive technology, presents a viable alternative in restorative dentistry.

*4.1.4 "Porcelain laminate veneers: 6 to 12-year clinical evaluation – a retrospective study"*

*M. Fradeani, M. Redemagni, M. Corrado; Int. J. of Periodontics Restorative Dent., 25, 9 (2005)*

182 ceramic veneers were evaluated retrospectively. The mean observation period was 5.7 years. The veneers were incorporated using Variolink II, DualCement and, at the beginning of the study, using the original Variolink. The survival rate was 94.4 %. These successful statistical results are attributed to the fact that a correct and durable adhesive technique was applied using, *inter alia*, Variolink II.

*4.1.5 "Clinical applicationof all-ceramic fixed partial dentures and crowns"*

*S. Toksavul, M. Ulusoy, M. Toman; Quintessence Int. 35, 185 (2004)*

In this study, the aesthetic interplay between translucent glass ceramic and Variolink II composite material is explained on the basis of clinical cases involving bridges made of IPS Empress 2.

# 5. Toxicological data

## *5.1 Introduction*

ISO 10993 "Biological testing of materials for medical devices" [1] describes a procedure for the biological evaluation of medical devices. In addition to the 10993 series, ISO/DIS 7405 [2] has to be observed for the biological testing of materials in dentistry.

Variolink II is used as composite cement for the incorporation of inlays, onlays and crowns (ceramic/resin). Direct contact with the oral cavity occurs only to a limited extent (cement margin). The use of an adhesive is required to cover the dentin. The composition of Variolink II is based on Variolink and Tetric/Tetric Ceram. Basically, the same ingredients are used in slightly different concentrations. Very positive clinical results have been obtained for more than four years with the original Variolink.

## *5.2 Toxicological evaluation*

### *5.2.1 Cytotoxicity*

Cytolysis, impaired cellular proliferation, and other effects caused by medical products are determined by means of cell culture tests. These tests provide the initial assessment regarding the biocompatibility of the material. An Agar overlay [6] has proved that the material in question demonstrates no cytotoxic potential. A further test with Variolink [3] has confirmed that this material is not harmful to cells.

### *5.2.2 Sensitization and irritation*

When using suitable models, this test permits an estimation of a medical product's potential to cause contact sensitization. A maximization test with guinea pigs [4] has shown that Variolink II does not have a sensitizing effect.

Since the removal of cement excess is sometimes difficult in subgingival preparations, mechanical irritation caused by excess material cannot always be completely excluded.

### *5.2.3 Genotoxicity*

In these cell culture tests, gene mutation, possible mutation in the chromosomal structure, or gene damage are evaluated. The screening test is always the Ames test. In several reverse mutation tests [5,7,8], Tetric Ceram did not show any mutagenic alterations. Given the similarity of the two materials, these data also apply for Variolink II.

### *5.2.4 Subchronical toxicity*

Subchronical toxicity deals with effects that may result from multiple or sustained contact with medical products. The contact of Variolink II in the oral cavity is restricted to the restoration margins. With 1 µg/mm$^3$, the water solubility of Variolink is very low (the limiting value according to ISO 4049 for resin restorative materials is 7.5 µg/mm$^3$) and is thus comparable to that of competitive products. The materials used in Variolink II have been known for years, they feature an extremely low water solubility, their chemico-physical properties have been extensively examined and they have achieved excellent results in the tests described. In view of these facts, the investigations regarding subchronical toxicity are not necessary.

**Conclusion:** Based on the known data of the tests conducted and the current standard knowledge [9], Variolink II shows no signs of increased or unacceptable risks for patients.

### *5.2.5 Additional toxicological evaluation for dental professionals*

Like most light-curing dental materials, Variolink II contains dimethacrylates. According to our investigations and experiences, these products are not irritating, even when uncured. Allergic reactions to dimethacrylates have been reported in the literature [10]. The materials may have an irritating effect on predisposed persons and may cause an allergic reaction or sensitization to dimethacrylates. These reactions can be prevented by clean working conditions and by avoiding contact of the unpolymerized material with the skin. The Instructions for Use contain corresponding recommendations to minimize the above risks.

## ***5.3 Literature on toxicology***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Ivoclar Vivadent AG
Research & Development
Scientific Service
Bendererstrasse 2
FL – 9494 Schaan
Liechtenstein

Contents: Dr. Thomas Völkel
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