Variolink® II
Variolink® Veneer

Scientific Documentation
Table of Contents

1. Introduction.................................................................................................................. 3
   1.1 Advantages of Variolink II / Variolink Veneer ......................................................... 4
   1.2 Classification of dental luting materials .................................................................. 7
   1.3 Adhesive cementation ............................................................................................... 8
   1.4 Indication ..................................................................................................................... 8

2. Technical data.............................................................................................................. 9

3. In vitro investigations ................................................................................................. 10
   3.1 Polymerization ......................................................................................................... 10
   3.2 Flexural strength ...................................................................................................... 11
   3.3 Sensitivity to ambient light ..................................................................................... 11
   3.4 Translucency ............................................................................................................ 12
   3.5 Radiopacity ................................................................................................................. 13
   3.6 Fluoride release ....................................................................................................... 13
   3.7 Conversion rate and shear bond strength ................................................................. 14
   3.8 Fracture resistance of root canal post-retained restorations .................................... 14
   3.9 Bond strength ........................................................................................................... 15
   3.10 Variolink II in combination with Excite DSC ........................................................ 16

4. Clinical investigations ............................................................................................... 20
   4.1 Clinical investigations .............................................................................................. 20

5. Toxicological data .................................................................................................... 22
   5.1 Introduction .............................................................................................................. 22
   5.2 Toxicological evaluation .......................................................................................... 22
   5.3 Literature on toxicology .......................................................................................... 23

6. Literature .................................................................................................................. 24
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 restorations 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 color 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.
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.

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

<table>
<thead>
<tr>
<th></th>
<th>Base</th>
<th>Catalyst high</th>
<th>Catalyst low</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimethacrylates</td>
<td>26.3</td>
<td>22.0</td>
<td>27.9</td>
</tr>
<tr>
<td>Inorganic fillers (silica, barium glass, Ytterbium trifluoride)</td>
<td>73.4</td>
<td>77.2</td>
<td>71.2</td>
</tr>
<tr>
<td>Catalysts and Stabilizers</td>
<td>0.3</td>
<td>0.8</td>
<td>0.9</td>
</tr>
<tr>
<td>Pigments</td>
<td>&lt; 0.1</td>
<td>&lt; 0.1</td>
<td>&lt; 0.1</td>
</tr>
</tbody>
</table>

**Physical properties**

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

<table>
<thead>
<tr>
<th></th>
<th>light curing Base</th>
<th>light curing Base and Catalyst</th>
<th>light curing Base and Catalyst</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexural strength</td>
<td>115 MPa</td>
<td>110 MPa</td>
<td>85 MPa</td>
</tr>
<tr>
<td>Flexural modulus</td>
<td>8300 MPa</td>
<td>8300 MPa</td>
<td>6000 MPa</td>
</tr>
<tr>
<td>Compressive strength</td>
<td>240 MPa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depth of cure</td>
<td>1.0 / 3.0 / 2.8 /</td>
<td>2.2 / 3.0 /</td>
<td>mm</td>
</tr>
<tr>
<td>Film thickness</td>
<td></td>
<td>1.0 µm</td>
<td></td>
</tr>
<tr>
<td>Radiopacity</td>
<td></td>
<td>450 % Al</td>
<td></td>
</tr>
<tr>
<td>Shear bond strength</td>
<td>on ceramic with</td>
<td>cohesive fracture</td>
<td></td>
</tr>
<tr>
<td>Transparency</td>
<td>Monobond-S</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working time (37 °C)</td>
<td>3.5 ± 0.5 min</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vickers hardness (HV 0.5/30)</td>
<td>500 MPa</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water absorption (7 days)</td>
<td>25.0 µg/mm³</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>1.0 µg/mm³</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Variolink Veneer**

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

<table>
<thead>
<tr>
<th></th>
<th>medium value 0</th>
<th>high value +1</th>
<th>high value +2</th>
<th>low value -2</th>
<th>low value -3</th>
<th>high value +3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimethacrylates</td>
<td>33.7</td>
<td>34.5</td>
<td>32.7</td>
<td>32.7</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inorganic Fillers</td>
<td>65.9</td>
<td>60.1</td>
<td>56.9</td>
<td>46.9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ytterbium Trifluoride</td>
<td>-</td>
<td>5.0</td>
<td>10.0</td>
<td>20.0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Catalysts and Stabilizers</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td>0.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pigments</td>
<td>-</td>
<td>&lt; 0.1</td>
<td>&lt; 0.1</td>
<td>&lt; 0.1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Physical Properties**

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

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

**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.

![Graph](image.png)

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.

![Flexural strength graph](image)

#### 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.

![Sensitivity to light graph](image)

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

R&D Ivoclar Vivadent AG, Schaan, Liechtenstein

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

R&D Ivoclar Vivadent AG, Schaan, Liechtenstein

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**

![Graph showing shear bond strength and conversion rate over time.](image)


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**

![Graph showing fracture resistance of different post/cement combinations.](image)

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 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$_2$O$_3$ (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.

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

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.
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.
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

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.

Dr. Munoz, University of Loma Linda, USA
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.

\[ \text{In vitro wear of composite cements (S. Suzuki, Alabama School of Dentistry)} \]

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.

<table>
<thead>
<tr>
<th>Examination</th>
<th>Status upon completion of the study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Postoperative sensitivity</td>
<td>0 %</td>
</tr>
<tr>
<td>Marginal tightness</td>
<td>88.3 % perfect interface</td>
</tr>
<tr>
<td></td>
<td>11.7 % slight discoloration</td>
</tr>
<tr>
<td>Marginal integrity</td>
<td>88.3 % perfect integrity</td>
</tr>
<tr>
<td></td>
<td>11.7 % slight depression</td>
</tr>
<tr>
<td>Retention</td>
<td>100 %</td>
</tr>
<tr>
<td>Mikrorissbildung</td>
<td>0 %</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Examination criteria</th>
<th>Status upon completion of study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Changes in marginal quality</td>
<td>0 %</td>
</tr>
<tr>
<td>Marginal discoloration</td>
<td>0 %</td>
</tr>
<tr>
<td>Secondary caries</td>
<td>0 %</td>
</tr>
<tr>
<td>Loss of retention</td>
<td>0 %</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Examination criteria</th>
<th>Status upon completion of study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marginal discoloration</td>
<td>5 %</td>
</tr>
<tr>
<td>Secondary caries</td>
<td>0 %</td>
</tr>
<tr>
<td>Marginal integrity</td>
<td>95 %</td>
</tr>
<tr>
<td>Postoperative sensitivity</td>
<td>0 %</td>
</tr>
</tbody>
</table>

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"


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 application of all-ceramic fixed partial dentures and crowns"


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


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/mm³, the water solubility of Variolink is very low (the limiting value according to ISO 4049 for resin restorative materials is 7.5 µg/mm³) 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**


[4] Contact Hypersensitivity to Variolink II in Albino Guinea Pigs (Maximization Test) RCC Project 391454

[5] Salmonella Typhimurium Reverse Mutation Assay with Tetric Ceram (Ames Test) CCR Project 563300

[6] Cytotoxicity Test in vitro: Agar Diffusion Test with Variolink® II RCC Projekt 391465


6. Literature

Derand T
Stress analysis of loaded porcelain inlays after cementation or resin bonded

Jensen ME, Redford DA, Williams BT, Gardner F
Posterior etched porcelain restorations - an in vitro study
Compend Contin Educ Dent 8 (1987) 615-622

Ludwig K, Joseph K
Untersuchungen zur Bruchfestigkeit von IPS-Empress-Kronen in Abhängigkeit von den Zementierungsmodalitäten
Quintessenz Zahntech 20 (1994) 247-256

Pelka M, Dettenhofer G, Reinelt C, Krämer N, Petschelt A
Validität und Reliabilität klinischer Kriterien für adhäsive Inlaysysteme
Dtsch Zahnärztl Z 49 (1994) 921-925

Malament KA, Grossmann DG
Bonded vs. non-bonded DICOR crowns: four-year report

Morin DL, Douglas DH, Cross M, DeLong R
Biophysical stress analysis of restored teeth: experimental strain measurement

Moll KH, Haller B, Hofmann N, Klaiber B
Phosphoric acid etching and enamel bond of composite/glass ionomer hybrids

Resin ionomer luting cements
Reality Now, March 1996
Resin ionomer luting cements
Reality Now, May 1996

Publications on Variolink II

Sorensen JA, Hedayat L, White MD
Ceramic inlay microleakage and shear bond strength of new dentin adhesives

Fay RM, Konings MS, Powers JM
Color stability of resin cements after aging and water storage

Gahse S, Lohbauer U, Frankenberger R, Krämer N
Conversion rate and bond strength of a dual-curing luting composite

Rasetto FH, Driscoll CF, von Fraunhofer JA
Curing efficiency of resin polymerized through veneers with various lights

Banasr F, Nathanson D
Curing mode effect on physical properties of new resin cements

Frankenberger R, Oberschachtsiek H, Soganci M, Krämer N, Petschelt A
Effect of a desensitizing agent on dentin bond strengths of different materials

Lang H, Schüller N, Nolden R, Raab WHM
Excess of luting composite resin formed at different resin-bonded restorations

Behr M, Rosentritt M, Ledwinsky E, Lang R, Handel G
Fracture strength of conventionally and adhesively cemented FRC-FPDs

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

Braga RR, Ballester RY, Daronch M
Influence of time and adhesive system on porcelain/bovine dentin bond strength

Pfretzschner M, Siepmann S, Frankenberger R, Lohbauer U
Margin analysis of CAD/CAM inlays using different luting systems

Manhart J, Schmidt M, Chen HY, Hickel R
Microleakage of tooth-colored restorations in class II cavities after artificial aging

El-Gendy TA, Zidan OA
The effect of different resin cements on the bonding strength of fiber-reinforced composites

Nathanson D, Banasr F
The effect of resin cement thickness on retention

Fasbindrner DJ, Lampe K, Dennison JB, Peters MC, Nematollahi K
Three year clinical performance of CAD/CAM generated ceramic onlays

Monaco C, Baldissara P, Scotti R
Clinical evaluation of ceromer inlay and onlay posterior restorations

Yılmaz D, Gemälmez D
Clinical evaluation of class II Targis inlays: 6-month results

Jung H, Friedl KH, Hiller KA, Haller A, Schmalz G
Curing efficiency of different polymerization methods through ceramic restorations

Dumfahrt H
Entwicklung und klinische Anwendung von Keramikveneers - 12-jährige Erfahrungen
Quintessenz 51 (2000) 357-367

Esthetic resin cements
The Dental Advisor 17 (2000) 2-4

Aristidis GA
Etched porcelain veneer restoration of a primary tooth: A clinical report
J Prostheth Dent 83 (2000) 504-507

Frankenberger R, Schmidt G, Radakovic T, Lohbauer U, Krämer N
Fatigue bond strength of a luting composite to composite inlays

Vichi A, Ferrari M, Davidson CL
Influence of ceramic and cement thickness on the masking of various types of opaque posts

Braga RR, Baliester RY, Daronch M
Influence of time and adhesive system on the extrusion shear strength between feldspathic porcelain and bovine dentin
Dent Mater 16 (2000) 303-310

Light-cured / Dual cure resin cements

Farag JH, Antinson SA, Anusavice KJ
Marginal integrity of different veneer systems

Rinn B, Roth K, Wöstmann B, Ferger P
Marginal microleakage of Empress inlays luted with resin-based cements

Manhart J, Schmidt M, Chen HY, Kunzelmann KH, Hickel R
Marginal quality of a new resin cement after artificial aging

The influence of dental alloys on three-body wear of human dentin an enamel

Park SH, Lee CK
The microhardness of restorative composite and dual-cured composite cement under precured composite overlay

Agarwala V, Dorosti Y, Dubos J, Seghi R
The relative wear of enamel opposing low fusing ceramic restorative materials

Örtengren U, Elgh U, Spasenoska V, Milleding P, Haasum J, Karlsson S
Water sorption and flexural properties of a composite resin cement
J Prosthodont 13 (2000) 141-147

Ritter RG, Culp Lee
A fluorapatite ceramic for restoring a fractured dentition
Contemp Esthet Rest Prac 0 (1999) 40-48

Krejci I, Boretti R, Lutz F, Giewendunganner P
Adhesive crowns and fixed partial dentures of optimized composite resin with glass fiber-bonded framework
QDT 1 (1999) 107-127

Kunzelmann KH, Chen HY, Manhart J, Hickel R
Bruchfestigkeit und Ermüdungsverhalten von Cerec-Keramikkronen
Dtsch Zahnärztl Z 54 (1999) 681-687

Gross JM, Haak R, Noack MJ
Can proximal overhangs be avoided when luting tooth-colored inlays?
J Dent Res 78 (1999) 228

Yu XY, Glace D
Coefficient of thermal expansion of six composite resin materials

Hunt J, Ripps AH, Burgess JO
Color measurements of two resin cements

Ferrari M, Mannocci F, Mason PN, Kugel G
In vitro leakage of resin-bonded all-porcelain crowns

Ivoclar North America
Restorative dentistry technique. Full coverage crowns on 6 upper anteriors using the Variolink II cementation system by Vivadent
Dental Products Report 0 (1999) 158-159

Salz U, Rumphorst A, Gianasmidis A, Rheinberger V
Comparative linear expansion study of various cements after water storage
Watts DC, Al-Hindi A, Ibrahim A
Hygroscopic-stress-development of resin-based luting and restorative materials

Ario PD
Immediate shear bond strengths of a new 3M resin cement

Ferrari M, Mason PN, Fabianelli A, Kugel G, Davidson CL
Influence of different margin substrates on leakage of Class II indirect restorations

Przygocki DA, Fasbinder DJ, Dennison JB
Shear bond strength of alternative luting agents to porcelain for CAD/CAM generated restorations

Issa MH, Watts DC
Shear bond strengths of adhesive luting systems to dental tissues

Noaman KM, Powers JM, Zaki AH
Surface treatments affect bond strength of resin cement to ceramic

Cements 1997
CRA Newsletter 21 (1997) 1-2

Variolink II
Reality Now 94 (1997) 2-3

Rosentritt M, Behr M, Lang R, Handel G
Influence of cement type on the marginal adaptation of all-ceramic MOD inlays

Reich SM, Wichmann M, Rinne H, Shortall A
Clinical performance of large, all-ceramic CAD/CAM-generated restorations after three years

Bookhan V, Essop RMN, Du Preez IC
The bonding effectiveness of five luting resin cements to the IPS Empress 2 all ceramic system
SADJ 60 (2005) 103-107

This documentation contains a survey of internal and external scientific data (“Information”). The documentation and Information have been prepared exclusively for use in-house by Vivadent and for external Vivadent partners. They are not intended to be used for any other purpose. While we believe the Information is current, we have not reviewed all of the Information, and we cannot and do not guarantee its accuracy, truthfulness, or reliability. We will not be liable for use of or reliance on any of the Information, even if we have been advised to the contrary. In particular, use of the information is at your sole risk. It is provided "as-is", "as available" and without any warranty express or implied, including (without limitation) of merchantability or fitness for a particular purpose.

The Information has been provided without cost to you and in no event will we or anyone associated with us be liable to you or any other person for any incidental, direct, indirect, consequential, special, or punitive damages (including, but not limited to, damages for lost data, loss of use, or any cost to procure substitute information) arising out of your or another’s use of or inability to use the Information even if we or our agents know of the possibility of such damages.

Ivoclar Vivadent AG
Research & Development
Scientific Service
Bendererstrasse 2
FL – 9494 Schaan
Liechtenstein

Contents: Dr. Thomas Völkel
Issued: August 2005