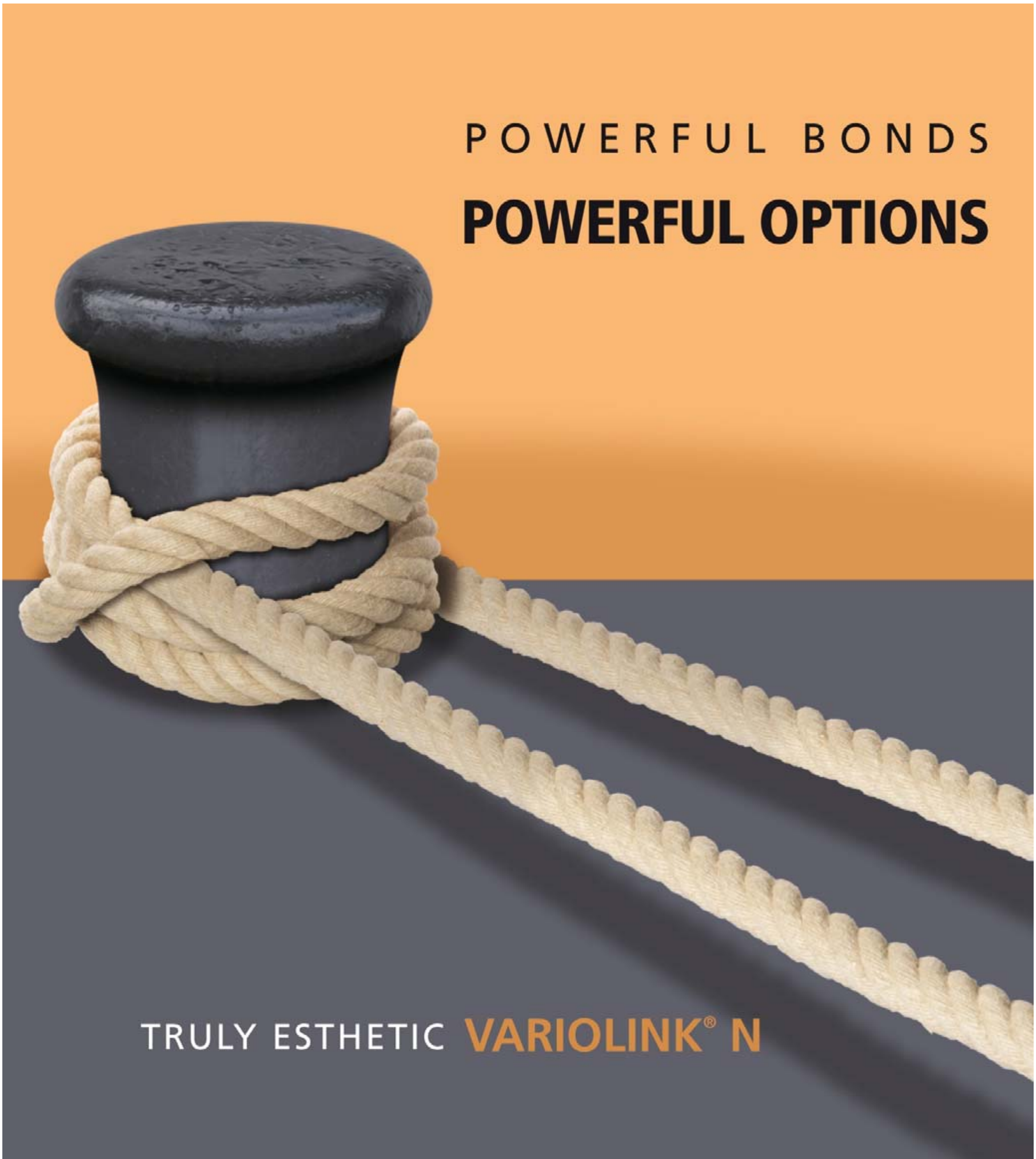

Scientific Documentation

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1. Introduction

Variolink N is a radiopaque, dual-curing composite for the adhesive cementation of indirect all-ceramic and composite restorations. The Variolink N luting system is especially recommended for the incorporation of glass-ceramic restorations (IPS Empress System, IPS e.max lithium disilicate), as it forms a uniquely integrated comprehensive system for esthetic single restorations, bridges, as well as inlays and onlays, particularly in conjunction with these products.

The composite cement consists of the following components:

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

Base available in one consistency and five shades (bleach XL, transparent, white, yellow, clear).

Variolink N is available in two different consistencies:

Variolink® N high viscosity

Variolink® N low viscosity

Variolink II has been successfully used for ten years in more than twenty million restorations. Variolink N has been developed on the basis of Variolink II and most material data coincide with those of its predecessor. Unlike Variolink II, Variolink N does not release fluoride.

A suitable adhesive for dentin and enamel bonding in conjunction with Variolink N is:

- Syntac (multi-component adhesive)

1.1 Advantages of Variolink N

1.1.1 Selection of shade and translucency

When highly esthetic, relatively translucent restorations (e.g. IPS Empress System and IPS e.max lithium disilicate) are incorporated, 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 a uniform shading across all structures, i.e. tooth, cement and restoration. The shade of the cement is particularly important if supragingival cement margins are present. 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 long-term colour stability to achieve high-quality esthetics. Variolink N Clear Veneer, which is applied only in the light-curing technique is ideal for this indication.

1.1.2 Sensitivity to light

At room temperature, two basic mechanisms are available for the polymerization reaction of the luting composite consisting of fillers and monomers:

- **Self-curing**: Redox-initiated polymerization (two-component system)
- **Light-curing**: Photochemical polymerization (single-component system)

Both types of polymerization are utilized in Variolink N. Ivoclar Vivadent has developed a new catalyst system (initiator and stabilizer) for Variolink N. This system 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 N 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 the exposure of light from a polymerization unit (approx. 0.5 sec).

Variolink N Clear 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 N, 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 N has been substantially improved.

1.1.4 Radiopacity

Barium silicate glass is one of the fillers utilized in Variolink N. This glass distinguishes itself from the strontium silicate glass contained in other luting composites by its high radiopacity. In addition, the material comprises ytterbium fluoride as an additional radiopaque filler.

1.2 Classification of dental luting materials

In general, luting materials are divided into two categories: conventional cements and luting composites. Conventional cements require a retentive tooth preparation to ensure sufficient retention. Their advantage is their easy and quick application. Complete isolation with a rubber dam is not always necessary. Luting composites are mainly used in combination with adhesives. With their high shear bond strengths, composites can be applied when adhesive bonding is mandatory. The shades and translucencies of composites can be adjusted more accurately. Consequently, luting composites provide esthetic solutions in restorations where the cement margins are visible. In addition, adhesive luting composites have a stabilizing effect on highly esthetic ceramics, e.g. IPS Empress or IPS e.max lithium disilicate.

Hybrid cements form a category between conventional cements and luting composites. These cements are cured by both a glass-ionomer reaction and light-induced polymerization. They show a higher mechanical strength than glass-ionomer cements. On the downside, they unify the disadvantages of conventional cements and composites.

Classification	Conventional cements	Composites
Curing mechanism	Neutralization reaction	Free-radical polymerization initiated by light or chemically
Advantages	• Easy processing • Easy removal of surplus material • Easy removal of restorations	• Minimally invasive, adhesive preparation technique possible • Excellent bond with the tooth • High stability • Low solubility • High wear resistance • Reduced postoperative sensitivity • Outstanding esthetics
Disadvantages	• Retentive preparation necessary • Solubility • Limited bond with the tooth • Low resistance to wear • Risk of postoperative sensitivity	• Excess material is difficult to remove after polymerization • Restorations are difficult to remove

1.3 Adhesive cementation

Adhesive cementation with composites presents the following advantages:

- Esthetics (translucency, surface lustre, no marginal discolouration)
- 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 Indications

Variolink N is a light- and dual-curing luting composite designed for the adhesive cementation of:

- Inlays, onlays, veneers
- Crowns
- Metal-free adhesive bridges
- Glass-fibre reinforced composite root canal posts

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

Variolink N Clear Veneer is suitable for the cementation of esthetic anterior restorations.

Variolink N Try-In are water-soluble glycerol pastes coordinated with Variolink N. They are used for shade simulation during try-in.

2. Technical Data

Variolink N and Variolink N Clear Veneer

Standard - Composition (in weight %)

	Base	Clear Veneer	Catalyst high	Catalyst low
Barium glass filler, mixed oxide	48.4	-	52.2	46.2
Dimethacrylates	26.3	34.5	22.0	27.9
High dispersed silica	-	60.1	-	-
Ytterbiumtrifluoride	25.0	5.0	25.0	25.0
Initiators and stabilizers	0.3	0.4	0.8	0.9
Pigments	< 0.1	< 0.1	< 0.1	< 0.1

Physical properties

In accordance with ISO 4049:2009 - Polymer-based restorative materials

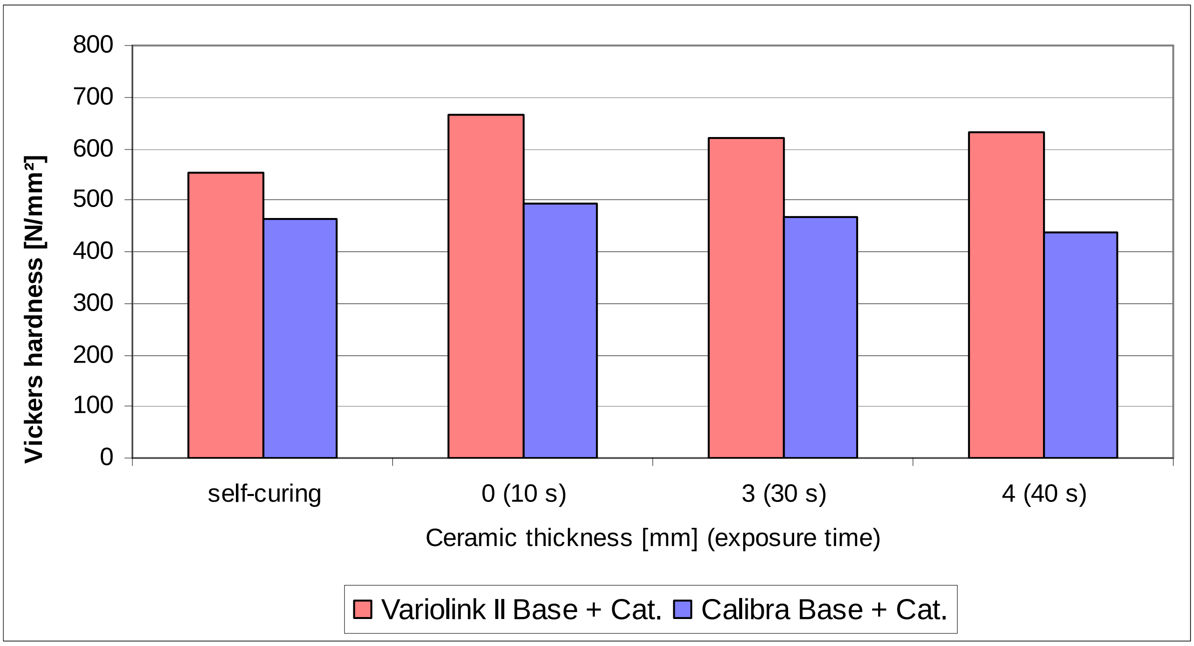
			Clear Veneer	
Flexural strength	light curing Base	115	107	MPa
	light curing Base and Catalyst	110	-	MPa
	self curing Base and Catalyst	85	-	MPa
Flexural modulus	light curing Base	8300	4500	MPa
	light curing Base and Catalyst	8300	-	MPa
	self curing Base and Catalyst	6000	-	MPa
Compressive strength		240	400	MPa
Depth of cure	Base white / yellow /	3.0 / 2.8	3.0	mm
	bleach XL / transparent	2.4 / 3.0	-	mm
Film thickness		15	9	µm
Radiopacity		450	80	% Al
Shear bond strength	on IPS Empress with Monobond-S	cohesive fracture	cohesive	fracture
Transparency	Base transparent	15.0 ± 1.5	24 ± 3	%
	white, yellow	12.0 ± 1.5	-	%
	bleach XL	6	-	%
Working time (37 °C)		3.5 ± 0.5	-	min
Vickers hardness (HV 0.5/30)		500	450	MPa
Water absorption (7 days)		25.0	18.5	µg/mm³
Water solubility		1.0	0.0	µg/mm³

3. *In vitro* Investigations

Most physical and material properties of Variolink N coincide with those of the Variolink II luting composite. Reference to the corresponding studies on Variolink II are made for those areas where the properties are identical.

3.1 Polymerization

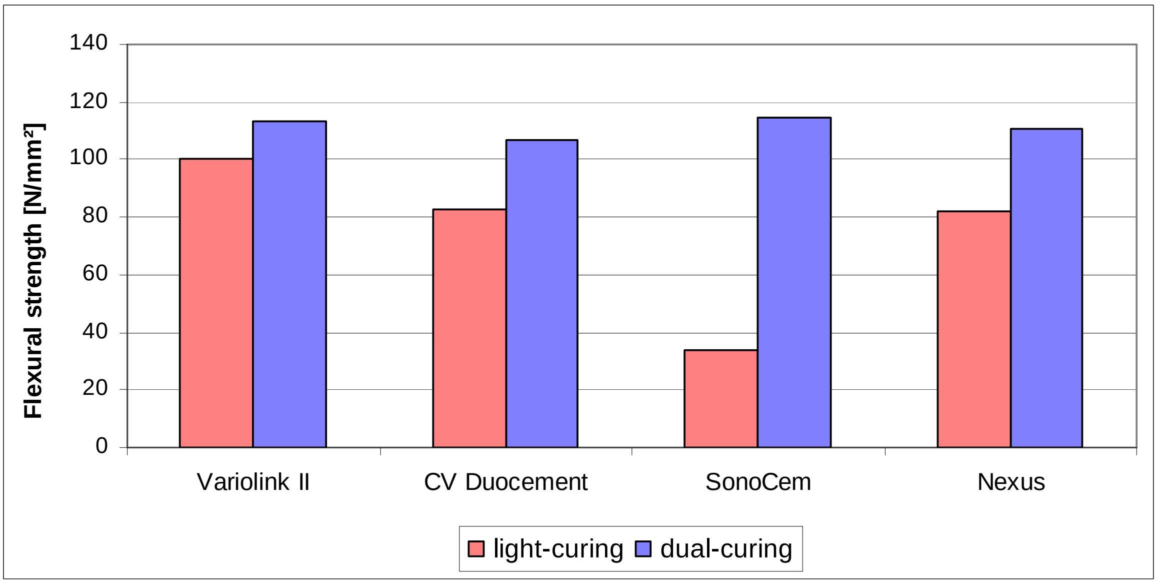
The polymerization behaviour of Variolink and Calibra, when cured through ceramic discs of different thicknesses using a bluephase curing light (1200 mW/cm^2), was examined by determining the Vickers hardness. The composites were cured in a dual-cure mode through lithium disilicate glass-ceramic discs of up to 4 mm thickness (shade A2) using corresponding exposure times.



R&D Ivoclar Vivadent AG, Schaan, Liechtenstein

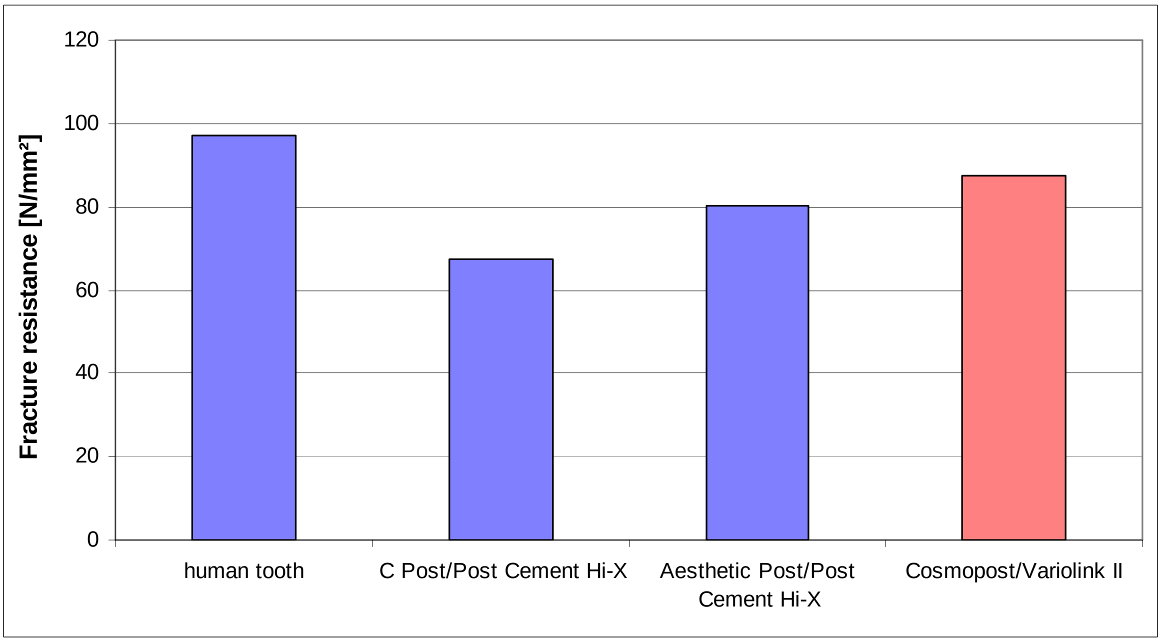
3.2 Flexural strength

The flexural strength of Variolink II and competitive materials was investigated at the University of Würzburg in Germany. For this purpose, the composites 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.



Hofmann N, University Clinic Würzburg

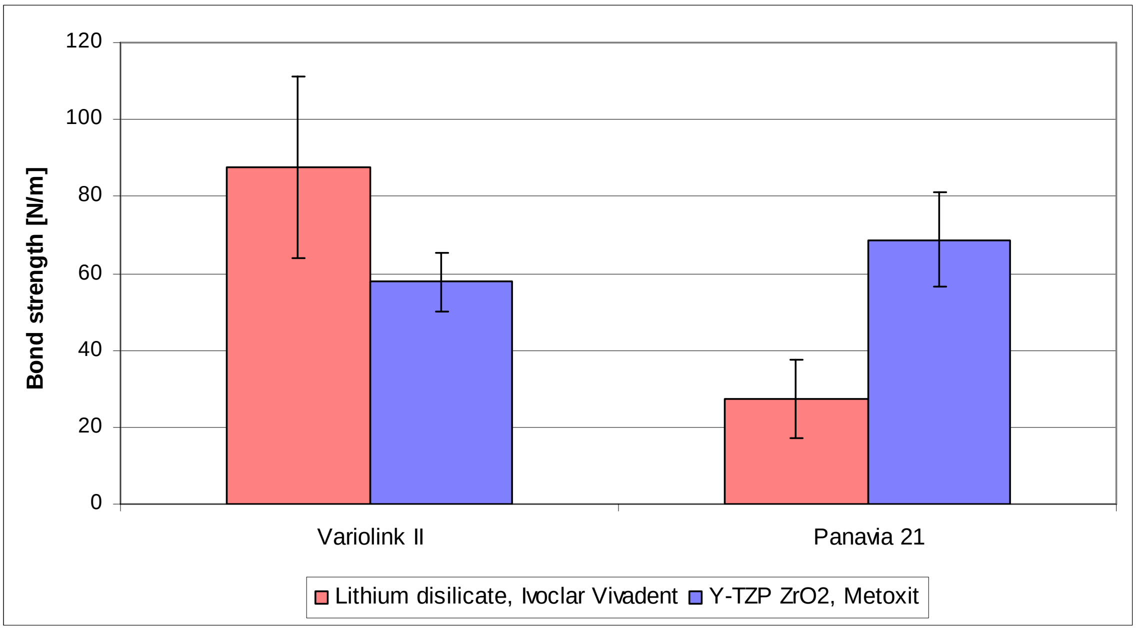
3.3 Fracture resistance of root canal post-retained restorations



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

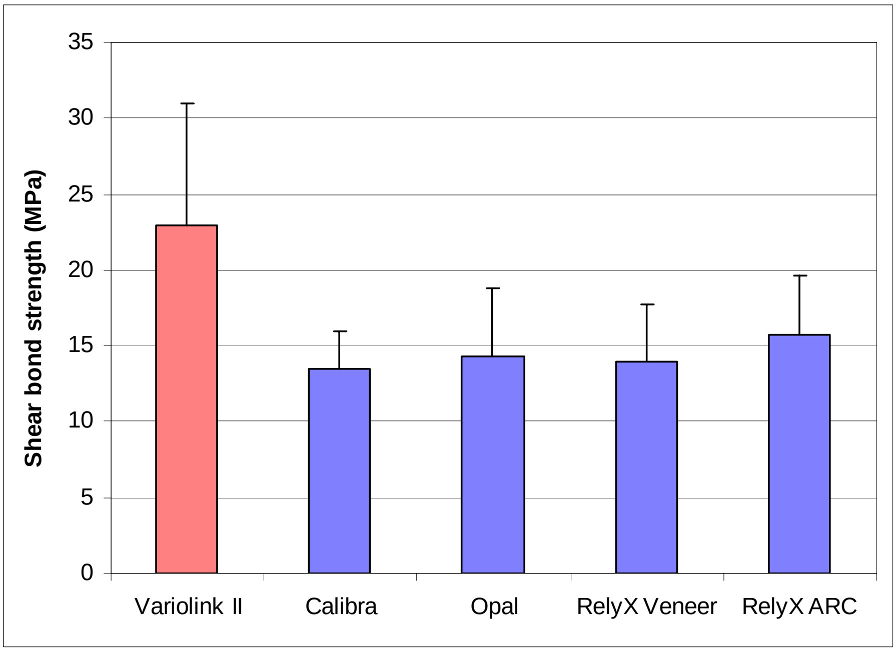
The fracture resistance of root canal post/composite build-ups compared to that of natural teeth was investigated by Cardoso et al. For the root canal post/cement combinations shown in the graph above, CosmoPost bonded in place with Variolink II achieved the highest fracture resistance values for root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

3.4 Adhesive 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 luting materials. After abrasive blasting with Al_2O_3 (110 µm) and silanating, both the lithium disilicate glass-ceramic and the zirconium oxide used in combination with Variolink II showed very high bonding values.

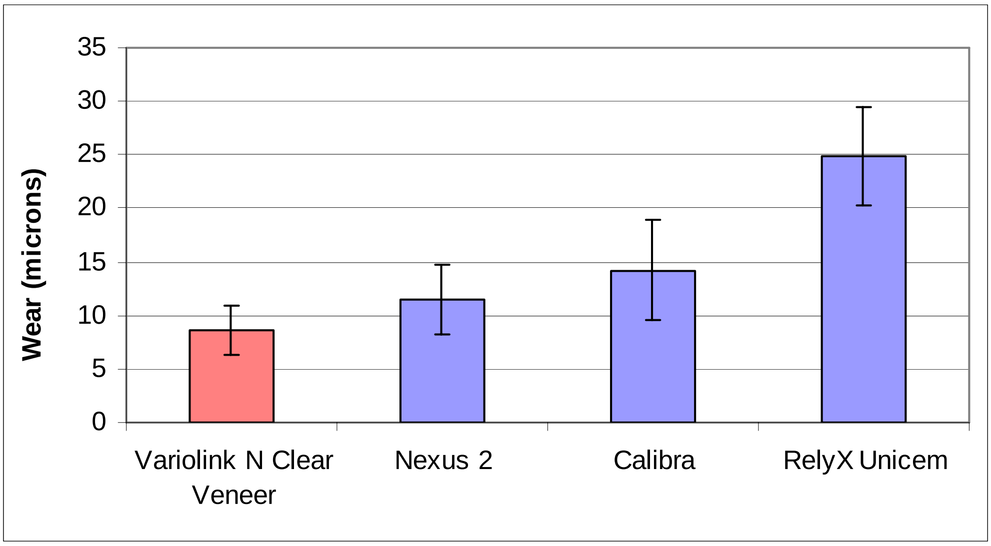


Shear bond strength of different luting materials in conjunction with IPS Empress 2
(V. Bookhan et al. SADJ 60, 103 (2005)

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 in water and then thermocycled for 300 times at alternating temperatures of 5° and 55°C.

3.4.1 Wear of Variolink N Clear 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, consequently, are more susceptible to discoloration. High wear may result in esthetic disadvantages, which is particularly true for materials such as Variolink N Clear Veneer. In a comparative study, the wear properties of Variolink N Clear 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 the wear of Variolink N Clear Veneer is lower than that of other luting composites.

4. Clinical Investigations

Variolink N is based on Variolink II and most of its physical properties coincide with those of Variolink II. Therefore, it is allowable to refer to the clinical data achieved with Variolink II.

4.1 “Clinical application of all-ceramic fixed partial dentures and crowns”

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

In this study, the esthetic 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.

4.2 “Ceramic inlays bonded with two adhesives after 4 years”

N. Krämer, J. Ebert, A. Petschelt, R. Frankenberger; Dent. Mater. 22, 13 (2008)

Ninety-four IPS Empress inlays were incorporated using Variolink II and EBS Multi/Compolute. After four years, a significant difference between the two luting system was not detected, whilst the actual failure rate was clearly lower among the inlays inserted with Variolink II.

4.3 “Four-Year Clinical Performance of a Lithia Disilicate-Based Core Ceramic for Posterior Fixed Partial Dentures”

J. F. Esquivel-Upshaw, H. Young, J. Jones, A. Yang, J. Anusavice; Int. J. Prosthodont. 21, 155 (2008)

Thirty posterior bridges made of IPS e.max Press were placed either using a hybrid cement or Variolink II. Debonding did not occur in any of the cases.

4.4 “Midterm results of a 5-year prospective clinical investigation of extended ceramic veneers”

P. C. Guess, C. F. J. Stappert; Dent. Mater. 24, 804 (2008)

Sixty-six veneers made of IPS e.max Press were adhesively cemented in place using Variolink II. During the period of observation, one restoration debonded and this restoration was re-cemented using Variolink II.

4.5 Clinical 5-year results for posterior bridges with a zirconium dioxide framework, fabricated with a prototype CAM method

I. Sailer, A. Fehér, F. Filser, L. J. Gauckler, H. Lüthy, C. H. F. Hämmerle; Quintessenz Zahntech. 34, 86 (2008)

In total, 57 three- to five-unit zirconium oxide bridges were incorporated. The restorations were cemented in place using either Panavia 21 or Variolink II. The failures (secondary caries, loss of retention, chipping of veneering ceramic) included three bridges placed with Variolink II and nine bridges seated with Panavia 21.

4.6 Conclusion

Variolink II has proven very successful as dual-curing luting composite in the marketplace. In controlled studies, this material has also shown excellent results in combination with the established adhesives Syntac Classic and ExciTE / ExciTE DSC. It can be concluded from these results that Variolink N, whose chemical structure is comparable to that of Variolink II, is bound to perform equally well in clinical applications, if it is used according to the Instructions for Use.

5. Toxicological Data

5.1 Introduction

The directive ISO 10993-1 "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 N is used as composite luting material 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 mandatory to cover the dentin. The composition of Variolink N 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 ten 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, these tests permit an estimation of a medical product's potential to cause contact sensitization. A maximization test in guinea pigs [4] has shown that Variolink N 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 N.

5.2.4 Subchronical toxicity

Subchronical toxicity deals with effects that may result from multiple or sustained contact with medical products. The direct contact of Variolink N in the oral cavity is restricted to the restoration margins. With 1 µg/mm^3, the water solubility of Variolink N 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 N have been known for years, they feature very 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 of knowledge [9], Variolink N shows no manifestations of an increased or unacceptable risk to patients.

5.2.5 Additional toxicological evaluation for dental professionals

Like most light-curing dental materials, Variolink N 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 habits and by avoiding contact of the unpolymerized material with the skin. The Instructions for Use contain corresponding recommendations to minimize these risks.

5.3 Literature on toxicology

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