Multilink®

Scientific Documentation

ivoclar vivadent

Table of contents

1. Introduction and product description ... 3
1.1 Luting agents and cements ... 3
1.2 Adhesive resin cements ... 4
1.3 Self-curing adhesive resin cements ... 5
1.4 Multilink ... 5
1.5 Material and composition ... 6
2. Technical data ... 7
3. Materials science and physical investigations ... 8
3.1 Flexural strength ... 8
3.2 Radiopacity ... 9
3.3 Water sorption and solubility in water ... 9
3.4 Adhesion on dentin and enamel ... 10
3.4.1 Shear bond strength ... 10
3.4.2 Microtensile strength ... 11
3.5 Push-out test in conjunction with various substrates ... 12
3.6 Adhesion of the luting composite to metal and metal alloy ... 13
3.7 Marginal integrity ... 14
3.8 Micrographs of the tooth adhesive interface ... 15
3.9 Additional studies with Multilink ... 16
4. Clinical studies ... 16
5. Toxicological data ... 18
5.1 Multilink ... 18
5.2 Multilink Primer ... 18
6. Literature ... 19

1. Introduction and product description

1.1 Luting agents and cements

Dental luting agents are used in dentistry as a bonding medium to cement fixed dental restorations to the tooth structure. The entire group of dental luting agents is often erroneously called cements.

Like the cements employed in the building industry, oral "cements" are exposed to various environmental conditions. It goes without saying that the cements used in the building industry would not be able to match the stringent conditions that oral cements have to fulfil, for instance regarding hygiene and toxicology. Dental luting agents and composites are used to cement a broad variety of substrates. They must be capable of providing a permanent bond between the tooth structure and restorations made of various materials, such as metal, metal alloy, resin or ceramic. Since the first formulation for a magnesium chloride cement, dental luting agents have been continuously further developed from phosphate cements, glass ionomer cements, resin-reinforced glass ionomer cements to adhesive resin cements. Current luting materials offer a high degree of bonding strength and advanced aesthetic properties. Adhesive resin cements enable the clinician to cement a restoration in place even if retention is very limited. This has also allowed dentistry to come closer to minimally invasive dentistry, which is based on the principle of conserving as much healthy tooth structure as practically possible.

Luting materials have traditionally been classified into the following categories:

- phosphate cements
- polycarboxylate cements
- glass ionomer cements
- resin-modified glass ionomer cements
- compomers
- luting composites

<u>Phosphate cements</u> were and still are very popular in spite of their clear disadvantages in terms of solubility and bonding strength. Phosphate-based cements principally consist of water, phosphoric acid and metal oxides, mainly zinc oxide. The setting reaction is based on an acid/base reaction between phosphoric acid and basic oxides. Phosphate cements stand for a category of very brittle materials. They have been used for clinical applications for more than a hundred years.

<u>Polycarboxylate cements</u> are composed of metal oxides and polyacrylic acid. The dry powder mixture is usually dissolved with water. The setting reaction is based on a complex reaction between the metal oxides and polyacrylic acid. A major drawback of this type of cement is their comparatively high solubility.

<u>Glass ionomer cements</u> are also very popular. They offer the advantage of fluoride release. The setting reaction of these cements is also based on an acid/base reaction. Here, the reaction takes place between polyacrylic acid and a calcium fluoro-alumino-silicate glass. Glass ionomer cements possess a record of clinical acceptability of over 20 years.

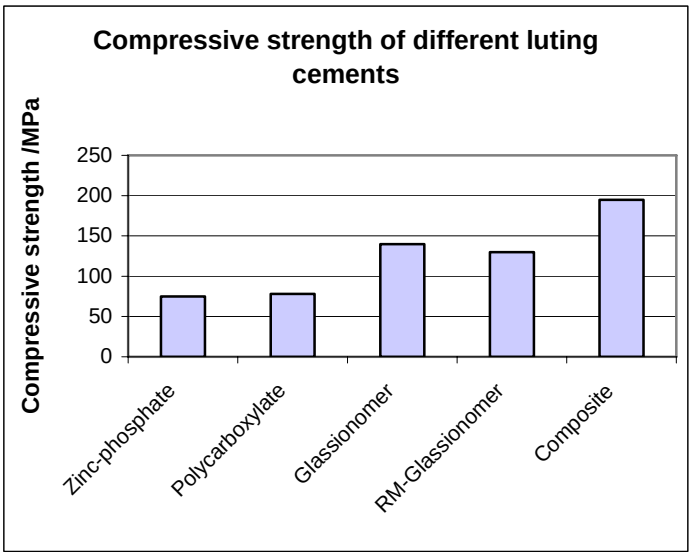
<u>Resin-modified glass ionomer cements</u> rely on light-activated compounds in addition to the above setting reaction. In response to light activation, a polymer matrix forms besides the inorganic structure. A large number of what is known as hybrid cements fall into this category of luting agents. The physical and clinical properties of these cements vary considerably, depending on the composition of the individual compounds. Their adhesion to the tooth structure is usually weak.

Compomers are also hybrid cements. However, they are mainly composed of resins. They comprise ingredients such as carbon acid containing monomers, which react with glass ionomer fillers. Compomers may be applied in conjunction with the total etch technique and consequently provide enhanced adhesion to the tooth structure. As they contain highly hydrophilic monomers, they are highly sensitive to moisture and susceptible to expansion.

Resin cements have been developed entirely from dental filling composites. They consist of monomers and inorganic filler particles. The curing reaction of these cements is based on the light-activated or chemically activated formation of polymer chains. Luting composites provide increased wear resistance, chemical durability in the oral environment and impeccable aesthetics thanks to a wide selection of shades.

Phosphate cements, polycarboxylate cements and glass ionomer cements fall into the category of dental water-based cements, whose specifications are set down by ISO Standard 9917. Resin cements come into the domain of ISO Standard 4049 – a standard that encompasses the entire range of composite filling materials.

The compressive strength of the different types of luting agents is used to provide an example of the properties of these materials as follows:



Average value derived from various relevant sources (RM glass ionomer = resin-modified glass ionomer cement)

1.2 Adhesive resin cements

Adhesive resin cements are used in conjunction with a dentin adhesive system. Consequently, this cementation method is capable of providing an adhesive bond to the tooth structure and therefore can be used to place restorations even if large retentive surfaces are not present. The adhesive bonding technique improves the fracture resistance of restorations and thus increases the survival rate of restorations made of non-high-stability ceramic materials. Minimally invasive restorative treatments, such as those involving adhesive bridges, would not be feasible without adhesive resin cements.

1.3 Self-curing adhesive resin cements

Most adhesive resin cements are light-curing or dual-curing. Consequently, the light of the curing unit must (light-curing) or should (dual-curing) penetrate to the resin cement to ensure fast and complete curing. However, restorations made of metal, metal alloy or opaque ceramics such as zirconium dioxide are not translucent, i.e. light cannot travel through these materials. Consequently, conventional phosphate cements and glass ionomer cements are typically used to cement such restorations in place. However, the drawback of these cements is that they necessitate extensively prepared retentive surfaces to provide a durable bond and therefore often entail considerable reduction of tooth structure.

1.4 Multilink

Multilink has been designed to provide a fully self-curing version of the proven Variolink II cementation technique.

Multilink covers the following range of indications:

Cementation of
- crowns
- bridges
- inlays
- onlays
- root canal posts

made of
- metal (gold, titanium, …)
- metal ceramic
- all ceramic (silicate, zirconium oxide, aluminium oxide,…)
- resin, composite (including fibre reinforced materials)

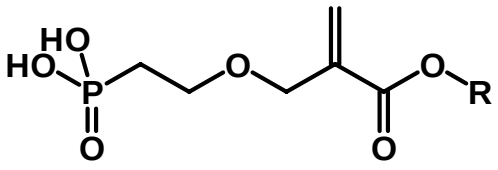
Multilink is a composite material that is applied in conjunction with Multilink Primer. Multilink Primer is a self-etch adhesive system that is supplied in two bottles, containing acidic monomers and an initiator respectively. These two compounds are mixed in a 1:1 ratio. The resulting mixture is applied to the dentin for 15 seconds and to the enamel for 30 seconds. Immediately after the primer has been allowed to react, the restoration in question is seated using Multilink resin cement. Within a few minutes of the application of the luting agent, a strong bond develops, ensuring an excellent marginal seal and preventing postoperative sensitivity.

Overview of a few selected features:

- Multilink is a self-curing, self-etch luting composite system, which can be used for nearly all typical clinical cementation applications (⇒ "multi" use).
- Multilink is available as a paste-paste system in a creamy, stable consistency and is provided in convenient double push syringes.
- The material ensures fast and reliable curing when used as Multilink / Multilink Primer system; excess material can be easily removed.
- When used in conjunction with Multilink Primer, Multilink resin cement provides high bonding values within a short time of having been applied. Moreover, studies on marginal integrity have shown that Multilink produces excellent marginal results.
- None or minimal postoperative sensitivities were reported for Multilink in clinical studies.
- Multilink is characterized by high mechanical strength values.
- Multilink incorporates hybrid filler technology and, as far as the composition of the paste compound is concerned, is akin to the proven Variolink II material.

1.5 Material and composition

The innovative ingredients incorporated into the self-etch primer represent a further development of the phosphoric acid acrylate contained in the two adhesives Excite and AdheSE – an adhesive monomer that is characterized by hydrolytic stability.



The end sequence R is either an ethyl group or a large bulky group, which does not split up in the presence of water, even if the medium is highly acidic. Ivoclar Vivadent has patented this type of compound. The toxicological properties of the corresponding derivatives have been scrupulously examined.

The formulation of Multilink was adapted to match the primer. It was necessary to adjust the surface properties of the monomer paste to the aqueous formulation of the primer in order to prevent phase separation from occurring between the composite and primer. If the phases separate because the individual compounds are not compatible with each other, the bonding strength of the adhesive system decreases and the resulting porosity could lead to postoperative sensitivity. The hydrophilic properties of the composite have been slightly increased by incorporating an appropriate selection of monomers, enabling the material to optimally wet most dental restoratives.

2. Technical data

Standard composition (in wt %)

Multilink base and catalyst	Base	Catalyst
Dimethacrylate and HEMA	31.6	31.2
Barium glass filler and silicon dioxide filler	44.5	44.5
Ytterbium trifluoride	23.0	23.0
Catalysts and stabilizers	0.9	1.3
Pigments	< 0.01	< 0.01

Multilink Primer A	
Water	85.7
Initiators	14.3

Multilink Primer B	
Phosphonic acid acrylate	48.1
Hydroxyethyl methacrylate	48.1
Methacrylate mod. polyacrylic acid	3.8
Stabilizers	< 0.02

Metal/Zirconia Primer:

Solvent	88.0
Phosphonic acid acrylate	5.0
Ethoxylated Bis-EMA	5.0
Initiators and stabilizers	2.0

Physical properties:

In compliance with ISO 4049 – polymer-based filling, restorative and luting materials
Mixing ratio of base and catalyst (1:1)

Working time (37 °C)	3-4	Minutes
Setting time	7-9	Minutes
Film thickness	< 20	µm
Water absorption (7 days)	< 25.0	µg/mm³
Solubility in water (7 days)	< 3.0	µg/mm³
Radiopacity	350	% Al

Additional values:

Flexural strength		90 ± 10	MPa
Flexural modulus		5000 ± 1000	MPa
Compressive strength		240 ± 20	MPa
Translucency	Base 110 and Cat	12 ± 1.5	%
	210 and Cat	10 ± 1.5	%
	110 opaque and Cat	2 ± 0.5	%
Vickers hardness (HV 0.5/30)		370 ± 30	MPa
Shear bond strength	dentin / 24h	21 ± 2	MPa
	enamel / 24h	23 ± 4	MPa

Working and setting time of the composite when applied in conjunction with Multilink Primer:

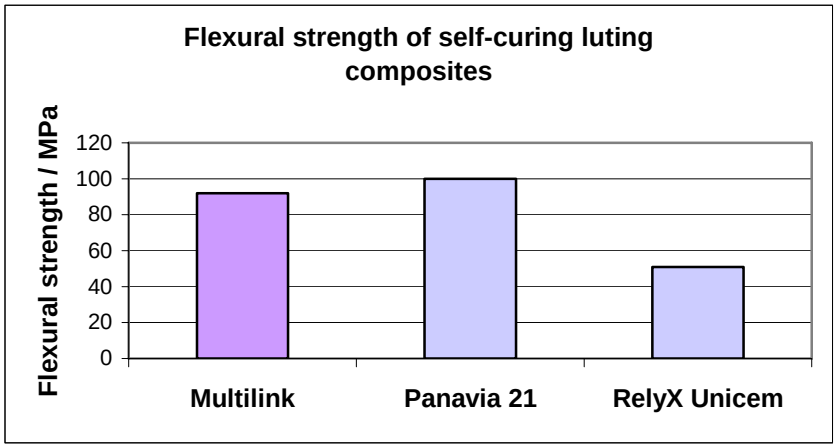
	room temperature 23°C +/- 1°C	intraoral 37°C +/- 1°C
Working time (without mixing time)	180 +/- 30 s	120 +/- 30 s
Curing time (without working time)	300 +/- 30 s	180 +/- 30 s

3. Materials science and physical investigations

The most important physical properties of Multilink were tested before the material was utilized in clinical applications.

3.1 Flexural strength

The flexural strength of a material is its ability to resist deformation under bending load. The load at fracture is reported as the flexural strength. Together with compressive and tensile strength, flexural strength is a significant benchmark value, characterizing the mechanical strength of a material. The flexural strength of a composite generally relies on its chemical composition.



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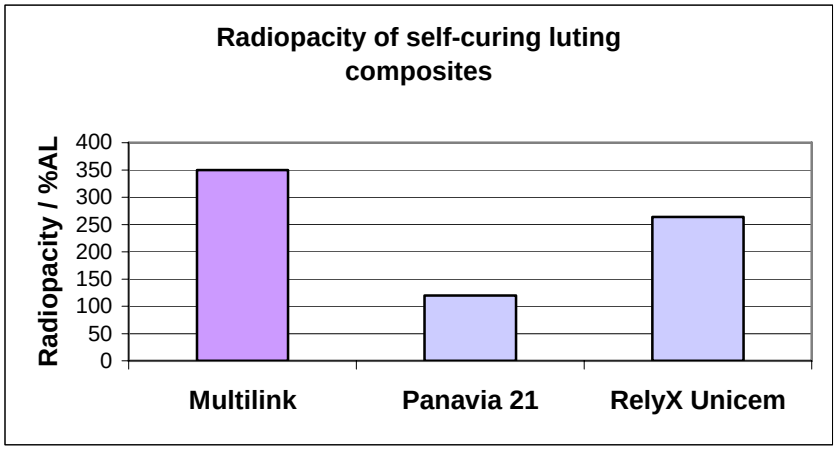
The cements were cured for 1 hour at 37 °C and subsequently immersed in water for 24 h at 37°C.

3.2 Radiopacity

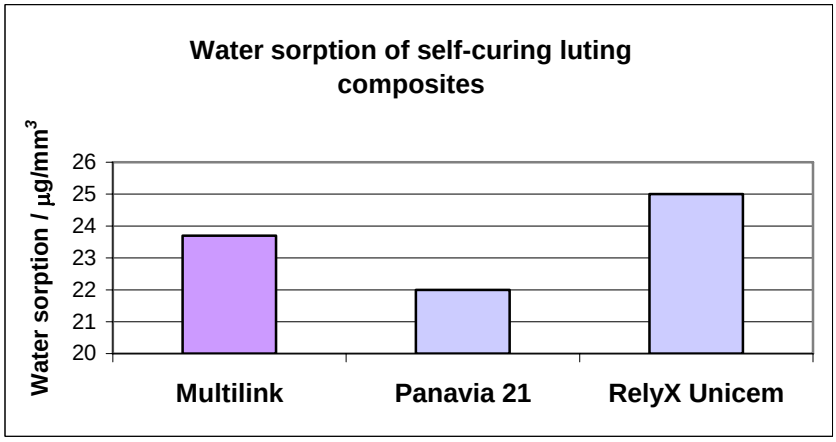
On X-rays, tooth-coloured restorative materials can be differentiated from the surrounding tooth structure or carious lesions because of their radiopaque characteristics. The radiopacity of dental materials is determined in comparison with aluminium.



Ivoclar Vivadent, R&D

3.3 Water sorption and solubility in water

Water sorption may result in a volumetric increase or expansion and may consequently have a detrimental effect on the restoration. The more hydrophilic a composite is, the more susceptible it is to absorbing water and expanding. At the same time, luting composites have to provide an interface that is compatible with the hydrophilic properties of dental material to ensure an appropriate level of wetting.



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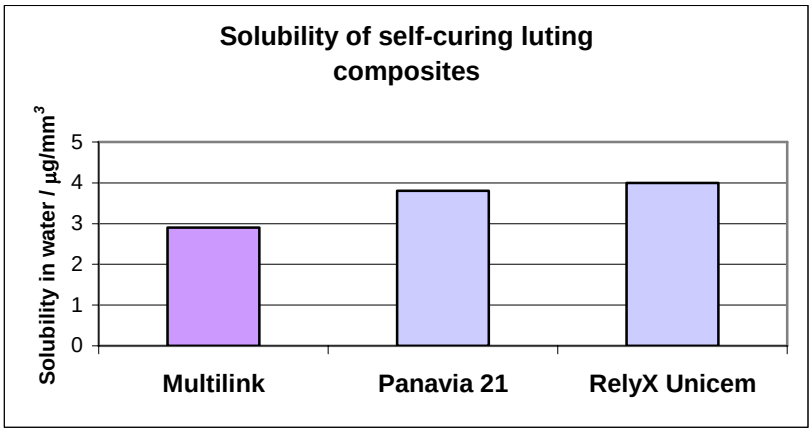
Water sorption after immersion in water for 7 days, determined according to ISO 4049.

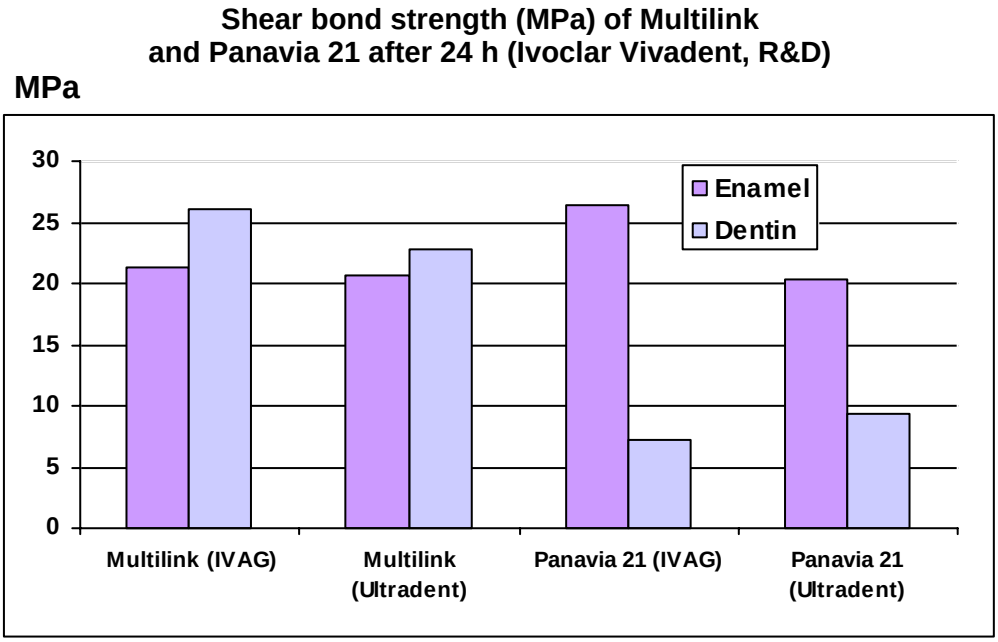


Ivoclar Vivadent, R&D

The solubility in water was measured according to ISO 4049.

3.4 Adhesion on dentin and enamel

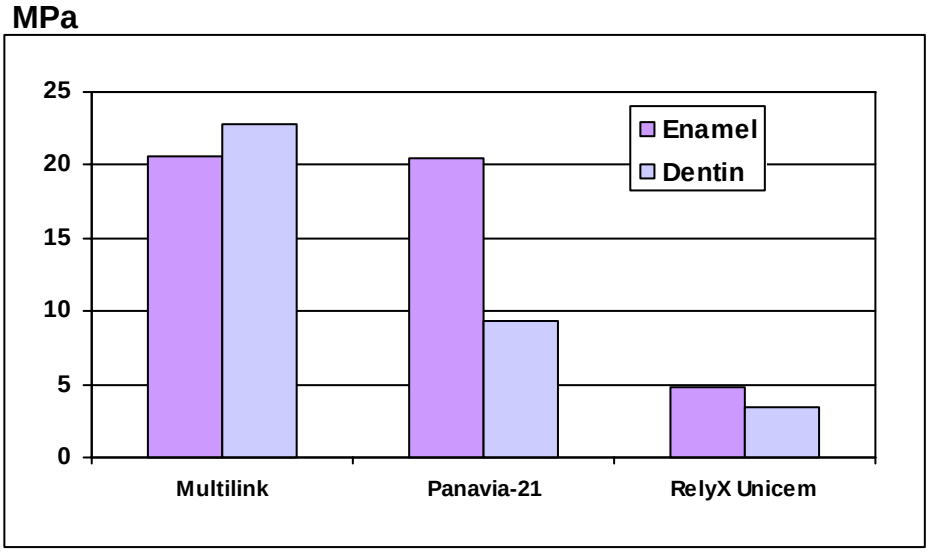
3.4.1 Shear bond strength



Ivoclar Vivadent, R&D

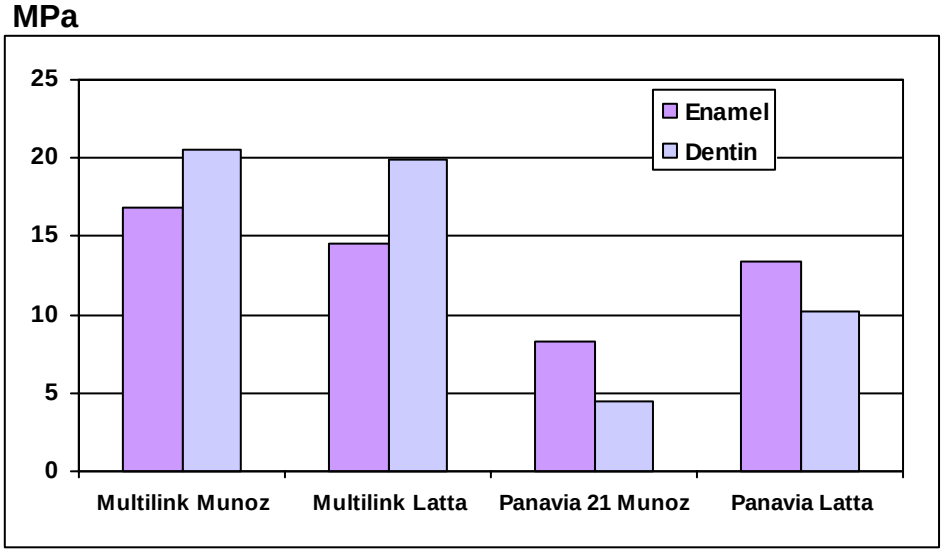
The shear bond strength values were determined using two different methods: IVAG uses bovine teeth to determine the shear bond strength values according to ISO TS 11405, while the enamel and dentin of human teeth are employed to measure the shear bond strength in what is known as the Ultradent method.

Shear bond strength (MPa) of Multilink, Panavia 21, RelyX Unicem Ultradent-Method, after 24 h (Ivoclar Vivadent, R&D)



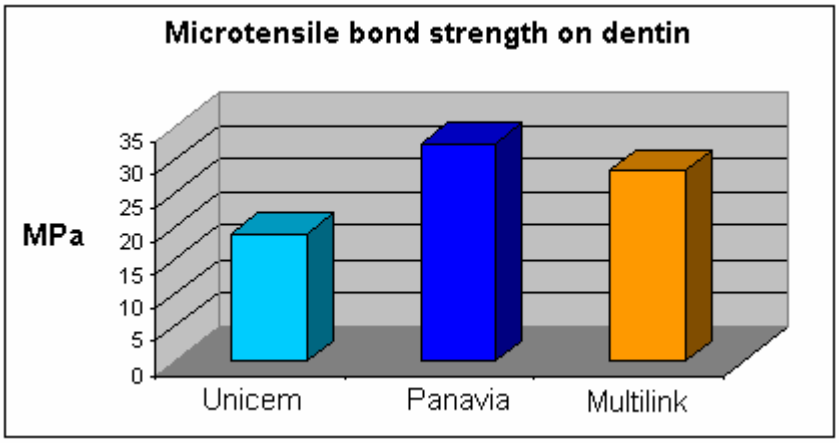
Shear bond strengths of Multilink on human Dentin and Enamel were compared to Panavia 21 and self-curing RelyX Unicem. Also in this test Multilink showed very high bond strengths both on enamel and dentin.

Initial bond strengths (MPa), 10 minutes after application, determined by Latta / Omaha and Munoz / Loma Linda



3.4.2 Microtensile strength

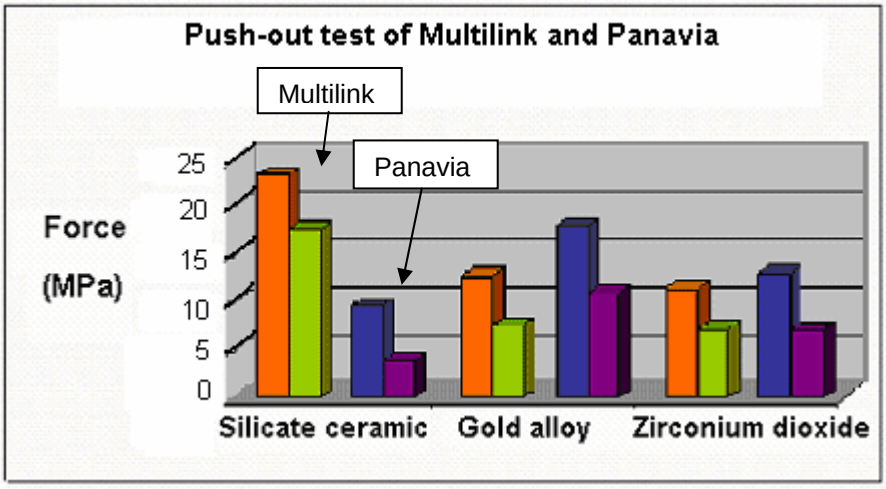
Measuring the shear bond strength is associated with a drawback: the results obtained demonstrate a wide range of scattering. The methods used to measure the microtensile strength are expected to narrow the range of scattering. In this method, the adhesive to be tested is applied to a prepared, flat, retention-free dentin or enamel block according to the relevant instructions. Subsequently, a composite block of a previously defined size is seated on the thus treated surface. The tooth structure and composite block are cut into bars perpendicular to the adhesive surface, using a diamond saw. Next, the tensile strength of the samples is determined with the help of a universal testing machine.



M. Ferrari, Livorno

3.5 Push-out test in conjunction with various substrates

While Multilink Primer is responsible for creating a bond to the tooth structure, the task of the resin cement is to promote the adhesion to the substrate, or the restoration to be seated. The hydrophilic components impart Multilink with optimal wetting capabilities. The study below provides a rough picture whether the substrate needs to be specially conditioned before being placed to ensure an optimal adhesion.



First bar: storage at RT; 1 week in tap water
Second bar: 5000 thermocycles (5° / 55°C) in tap water

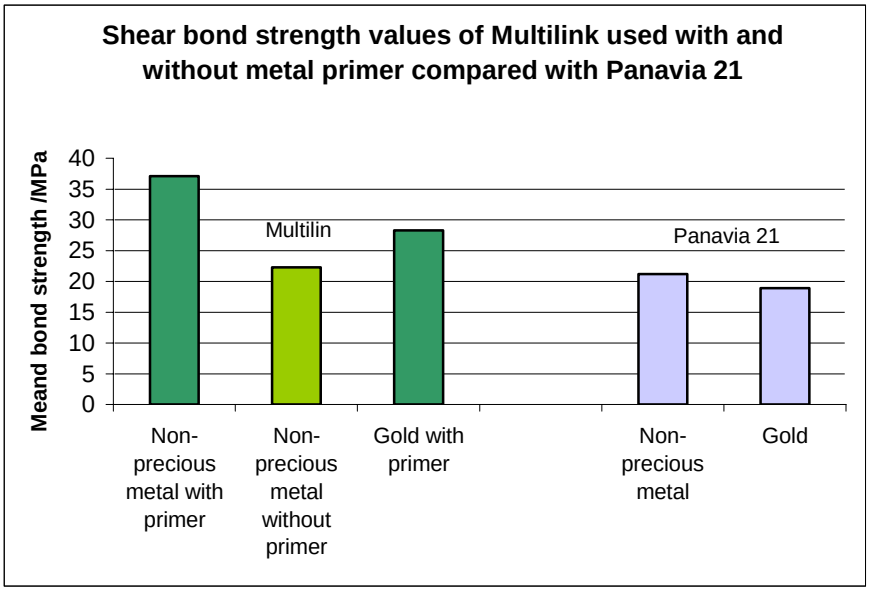
A Dagostin, University of Chicago

Panavia 21 was used in compliance with the conditions specified in the manufacturer's instructions, while the samples placed with Multilink were conditioned as follows:

- Silicateceramic: a) Etching with etching gel; b) Silanizing with Monobond S
- Gold alloy: Sandblasting
- Zirconium dioxide: Sandblasting

In view of the above results, a special metal primer was developed to promote the adhesion to metal. The bond to zirconium dioxide can be further increased either by using the metal primer (see studies of Prof. Kern on comparable products) or by silicoating.

3.6 Adhesion of the luting composite to metal and metal alloy

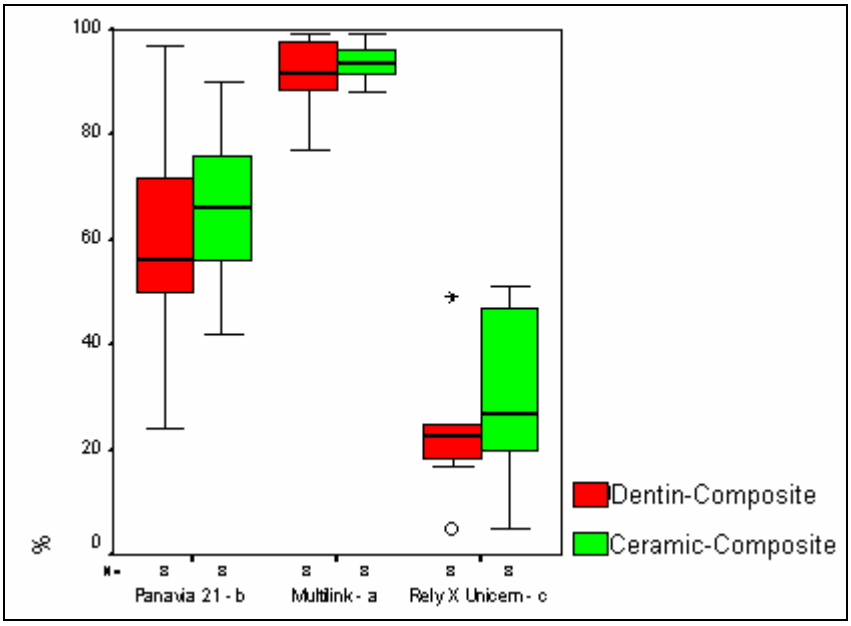


Prof. Latta, University of Nebraska

The shear bond strength values of Multilink were determined by means of two applications: one in conjunction with the metal primer (dark green) and the other without metal primer (light green), while Panavia was applied using an air block, as stipulated in the manufacturer's instructions. The results show that the shear bond strength values of Multilink can be improved by using the metal primer.

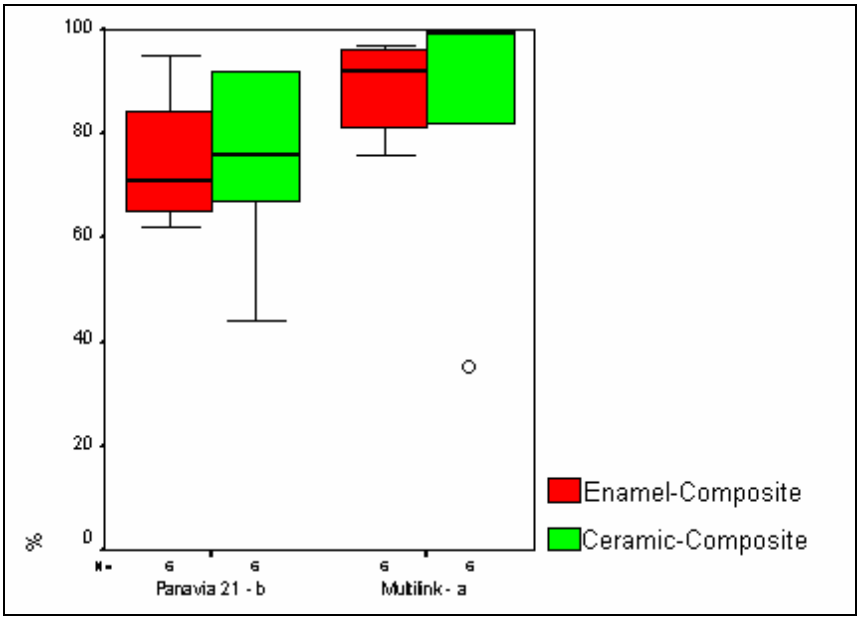
3.7 Marginal integrity

The marginal quality was determined by cementing ceramic inserts on standardized preparations in bovine dentin (diameter = 4 mm). The chart below indicates the proportion (in percent) of continuous margin after 2000 thermocycles.



Ivoclar Vivadent, R&D

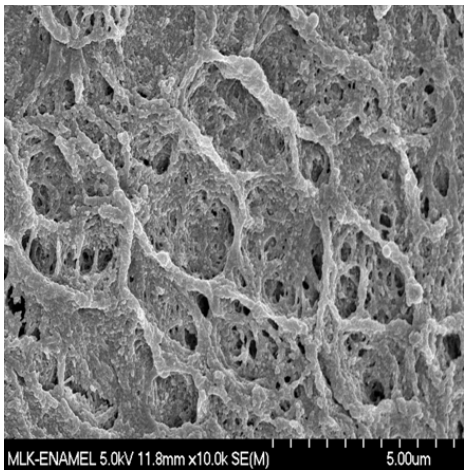
The same procedure was used to determine the marginal quality in enamel, ie ceramic inserts were placed on standardized preparations in bovine enamel and subjected to 2000 thermocycles.



Ivoclar Vivadent, R&D

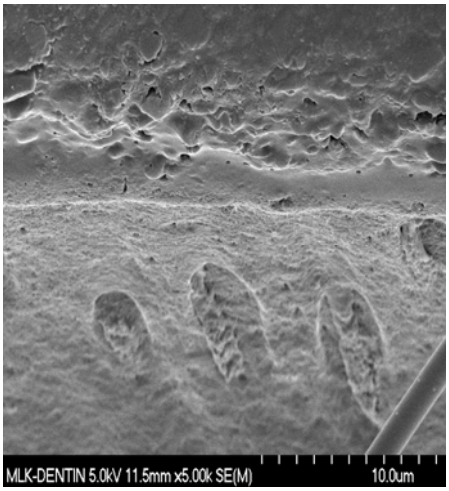
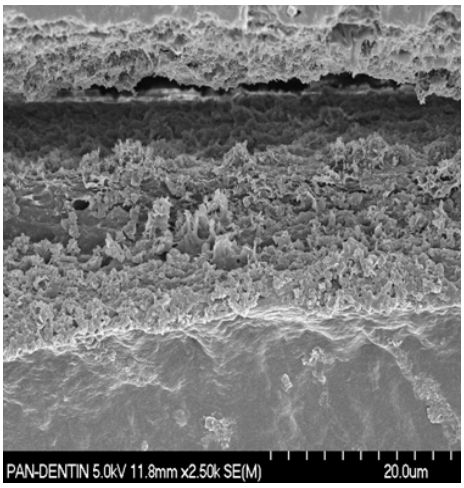
3.8 Micrographs of the tooth adhesive interface

Images of the enamel etching pattern following the application of Multilink Primer and Panavia ED Primer according to the manufacturer's instructions (as reported by G Perdigao, University of Minnesota)

	
Multilink Primer: Brush for 15 s (SEM: magnification x10,000)	Panavia ED Primer: Allow to react for 60 s (SEM: magnification x10,000)

After application of Multilink Primer, a typical etching pattern, which significantly increases retention, can be observed.

Hybrid layer after Multilink Primer and Panavia ED Primer have been applied to the dentin using reaction times (as reported by G Perdigao, University of Minnesota)

	
Multilink Primer: brush for 15 s (SEM: magnification x5,000)	Panavia ED Primer: allow to react for 60 s (SEM: magnification x2,500)

Both adhesive systems produced a hybrid layer at the transition between dentin and composite after they had been applied according to the manufacturer's instructions.

3.9 Additional studies with Multilink

Durability of adhesive bond of Multilink resin cement and a new phosphate primer to various restorative materials in comparison with established phosphate monomer containing adhesives
Prof Kern, Universitätsklinikum Kiel, Germany

In vitro stability tests of inlay bridges made of lithium disilicate ceramic
Prof Ludwig, Universitätsklinikum Kiel, Germany

Adhesion de postes de fibra de vidrio a distintos niveles del canal radicular
Prof. Gonzalez, Universidad de Granada, Spain

Sealing ability of Empress II porcelain inlays luted with Excite self-curing and Multilink self-curing resin cement
Prof Ferrari, Cagidiaco Emilio Studio Associato, Livorno, Italy

4. Clinical studies

To date, Multilink has been used for the placement of restorations in several clinical studies and its performance has been documented accordingly.

Clinical trial of fibre-reinforced posts luted with self-curing Excite in combination with an experimental resin cement

Head of study: M Ferrari, Livorno, Italy

Objective: Assess the performance of Multilink after the placement of 40 fibre-reinforced composite posts

Experimental: Place 40 fibre-reinforced composite root canal posts using Multilink as the luting agent

Results: No retention problems have been reported twelve months after the insertion of the root canal posts

Clinical trial of Empress II porcelain inlays luted to vital abutments with self-curing Excite and Multilink resin cement

Head of study: M Ferrari, Livorno, Italy

Objective: Determine the bonding characteristics of Multilink/ceramic inlays under clinical conditions

Experimental: 36 inlay preparations to be re-examined after 24 months

Results: All 36 inlays have been in situ 24 months after having been placed. Slight discoloration was observed at two margins (5.6%)

While Excite DSC was used as the adhesive in the above two studies, Multilink Primer, which was developed by us, was used as self-curing and self-etch adhesive in the following studies:

In vivo marginal gap examination of Multilink: Empress 2 all-ceramic crowns versus conventional porcelain veneer crowns

Head of study: Prof Dr Gerwin Arnetzl; University of Graz, Austria

Objective: 48-month long-term clinical study on porcelain veneered restorations and Empress 2 all-ceramic restorations cemented in conjunction with Multilink

Experimental: 54 crowns (of which 27 were made of Empress 2 and 27 of d.SIGN via Porta Geo Ti) plus an additional 6 inlays, 5 onlays, 6 adhesive bridges and 3 post-core build-ups

Results: Postoperative sensitivities were reported for only 2 restorations (2.7 %) out of 74 (inlay with cavity preparation close to the pulp; onlay with postoperative sensitivity to pressure). In both cases, the postoperative sensitivities did not last for longer than 36 hours

Desquamation of epithelial tissue, which tends to occur with other self-etch primers, was not observed

Gingival tissue reaction, such as redness, bleeding, edema or whitish surface burn, did not occur

Pilot clinical trial on modified lithium disilicate ceramic crowns

Head of study: Dr John A Sorenson; Pacific Dental Institute, Lake Oswego, OR, USA

Objective: Place 15 all-ceramic crowns made of a modified lithium disilicate ceramic

Experimental: 15 molar and premolar crowns

Results: Preparation of 14 crowns after 6 months (7 of them on vital teeth). No postoperative sensitivities have been reported

Clinical evaluation of Multilink in conjunction with inlay/onlay restorations

Head of study: Dr Arnd Peschke; Ivoclar Vivadent, Schaan, FL

Objective: Examine the handling characteristics and clinical performance of Multilink in relation to inlay and onlay restorations

Experimental: 21 vital teeth

Results: All preparations exhibited a large contact surface between dentin and luting agent. Nonetheless, no postoperative sensitivity has been reported

A 60-month prospective study to assess the long-term success rate of teeth restored with IPS Eris/Empress all-ceramic restorative material
Dr David Felton, UNC School of Dentistry, Chapel Hill, NC, USA

In vitro evaluation of Postec fibre-reinforced post system
Dr Nathanson, Boston University, Boston, MA, USA

5. Toxicological data

The cytotoxicity, genotoxicity and carcinogenicity of Multilink and Multilink Primer were tested according to ISO 10993 as follows:

5.1 Multilink

1.) XTT test (cytotoxicity assay in vitro: Evaluation of materials for medical devices) RCC-CCR Report 670501; 05. 09. 2000

2.) Ames test (salmonella typhimurium reverse mutation assay) RCC CCR Report 670502; 04.07.2000

Both the cytotoxicity test and mutagenicity test did not reveal any toxicological risk. These results do not come as a surprise as the composite is composed of components that are comparable to those of most proven dental composites.

5.2 Multilink Primer

1.) XTT test (cytotoxicity assay in vitro: Evaluation of materials for medical devices) RCC-CCR Report 758703; 13. 11. 2002

The primer has a XTT value of 1693 mg/l. Its level of toxicity is therefore significantly lower than that of many other monomers used in the dental industry.

2.) Ames test (cytotoxicity assay in vitro: Evaluation of materials for medical devices) RCC-CCR Report 758702; 28. 01. 2003

3.) Comet Assay (in vitro single cell gel electrophoresis in Chinese hamster V79 Cells) RCC-CCR Report 760 700; 18. 10. 2002

4.) In vivo mutagenicity test (Micronucleus assay in bone marrow cells of the mouse) RCC-CCR Report 776201; 19. 05. 2003

The results of these investigations and examinations show that the adhesive formulation of Multilink Primer does not pose any mutagenic risk.

6. Literature

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Ivoclar Vivadent AG
Research and Development
Scientific Service
Bendererstrasse 2
FL - 9494 Schaan
Liechtenstein

Compiled by: Dr Thomas Völkel
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