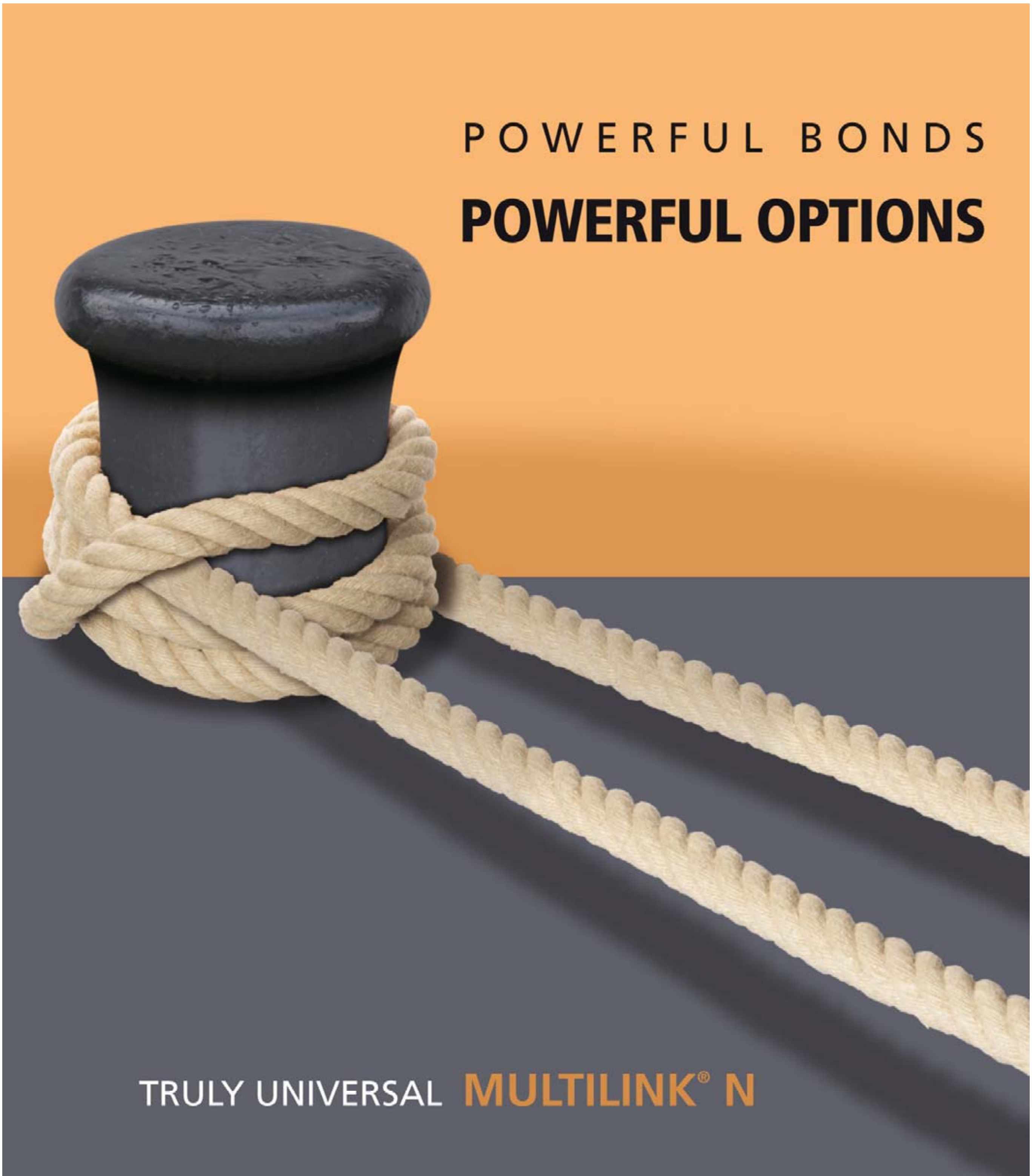


Scientific Documentation

ivoclar vivadent
passion vision innovation

Table of Contents

1. Introduction and Product Description

1.1 Luting agents and cements

Luting agents are used in dentistry as an adhesive substance to attach fixed prosthetic restorations to the tooth structure. The entire group is often erroneously called "cements".

Same as in the construction industry, "cements" are exposed to various environmental influences in the oral cavity. However, the cements used in construction would not be suitable to meet the very special conditions in the oral cavity alone for reasons of hygiene and toxicity. The substrates that have to be luted in dentistry cover a wide range. Dental cements and composites have to establish a durable bond between the tooth structure and restorations made of various metals and metal alloys, resins, and different ceramics. Since the advent of the first magnesium cements, these materials have been continuously further developed to produce phosphate cements, glass ionomer cements, resin-reinforced glass ionomer cements up to adhesive composite materials. The adhesion and esthetic appearance have reached a very high level in the meantime. With the help of adhesive luting composites, it is now also possible to cement restorations with small retentive surfaces. This is also a further step toward minimally invasive tooth preparation with dentists trying to preserve as much of the healthy tooth structure as possible.

To date, the following luting agents are available:

- Phosphate cements
- Polycarboxylate cements
- Glass ionomer cements
- Resin-reinforced glass ionomer cements
- Luting composites

Despite their obvious drawbacks regarding solubility and adhesion, phosphate cements were, and still are, very popular. They consist of an aqueous phosphoric acid solution and metal oxides, mainly zinc oxide. The setting reaction is based on an acid-base reaction between the phosphoric acid and the basic oxides. They represent a category of very brittle materials. Up until today, the clinical experiences with phosphate cements stretch over more than a 100 years.

Polycarboxylate cements consist of metal oxides and polyacrylic acid. The dry mixture is mostly used as a powder, which is mixed with water for processing. The complicated setting reaction takes place by the reaction of metal oxides with the polyacrylic acid. The comparatively high solubility of the cement is a substantial disadvantage.

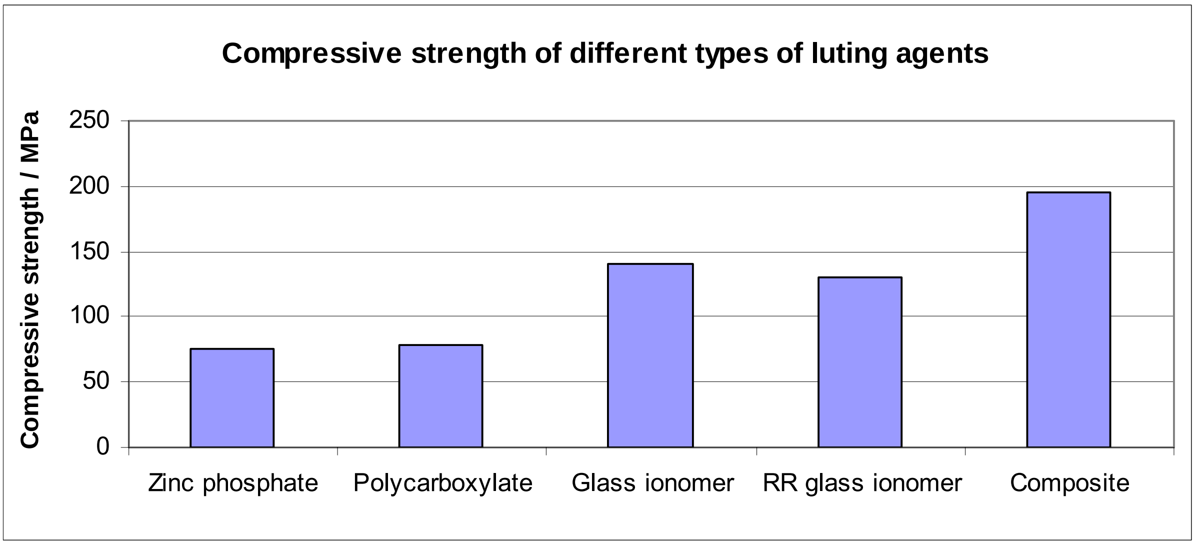
Glass ionomer cements also enjoy great popularity. They demonstrate the advantage of being able to release fluoride ions. Setting also takes place with the help of an acid-base reaction. In this case, the polyacrylic acid reacts with a calcium fluoroaluminosilicate glass. Clinical experiences with glass ionomer cements have been gathered for more than 20 years.

Besides the above described cement setting reaction, resin-reinforced glass ionomer cements include, above all, light-curing organic cross-linking agents. Consequently, polymer networks are formed upon exposure to polymerization light. This group of luting agents includes a number of hybrid cements, whose physical and clinical properties strongly vary depending on the composition of the individual components. Their adhesion to the tooth structure is often weak.

Luting composites are completely based on dental restorative composite technology. They consist of monomers and inorganic filler particles. Their setting is based on a cross-linking of the polymer chains, which is initiated chemically or by light. Composites are more wear resistant, demonstrate resistance to the oral environment, and offer outstanding esthetics provided by the choice of several shades.

Phosphate cements, polycarboxylate cements, and glass ionomer cements belong to the group of "dental water-based cements", whose properties are specified by ISO 9917. Composite "cements" are covered by ISO 4049, which also applies to the entire range of composite restorative materials.

Using the example of compressive strength, the properties of the different types of luting agents are compared with each other.



Average values from different sources in the literature (RR glass ionomer = resin-reinforced glass ionomer cement).

1.2 Adhesive luting composites

Luting composites are used in combination with a dental adhesive system. This means that this type of cementation establishes an adhesive bond with the tooth structure. Adhesive cementation also permits a bond where no large retentive surfaces were or could be prepared. An adhesive bond increases the fracture resistance and thus the survival rate of restorations fabricated of non-high-strength ceramics. Minimally invasive restorative techniques, such as adhesive bridges, would be unthinkable without adhesive luting composites.

1.3 Self-curing adhesive luting composites

Most adhesive luting cements are light- and / or dual-curing. In other words, the curing light must (light-curing) or should (dual-curing) reach the composite unimpeded to achieve quick and thorough polymerization. However, restorations made of metals, metal alloys, and opaque ceramics, e.g. zirconium oxide, are impervious to light. To date, such restorations have usually been incorporated using conventional phosphate cements and glass ionomer cements. These cements, however, require well-prepared retention to establish a durable bond, which, very often, entails a substantial loss of tooth structure.

1.4 Multilink N

Multilink N consists of a composite and Multilink N Primer A and B. The corresponding initiator system permits chemical curing (self-curing), which is accelerated by the contact of the composite with the primer. Furthermore, the presence of a photoinitiator provides the possibility of final polymerization with light.

The indications for Multilink N are as follows:

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

made of
- metal (gold, titanium, …)
- metal-ceramics
- all-ceramics (silicate, zirconium oxide, aluminium oxide, …)
- resins, composites (also fibre-reinforced)

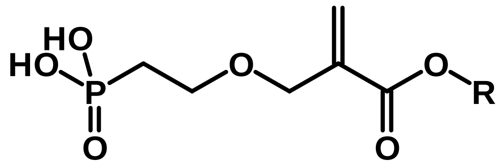
Multilink N is a composite and is used in conjunction with Multilink N Primer A & B. Multilink N Primer is a self-etching adhesive system, which is offered in two bottles. One contains the acidic monomers and the other the initiator solution. These two components are mixed in a 1:1 ratio and applied on the dentin for 15 seconds and on the enamel for 30 seconds. The indirect restoration can be seated using Multilink N immediately afterwards. The high adhesive values are reached after only a few minutes. They are also responsible for an excellent marginal seal and the prevention of postoperative sensitivity.

A few selected product properties at a glance:

- Multilink N is a self-curing, self-etching luting composite system which can be used for nearly all the typical clinical cementation applications (⇒ "multi"-use). Moreover, it also offers the possibility of final light-curing.
- As a paste-paste system, Multilink N demonstrates a pleasant creamy and stable consistency and is supplied in the convenient double-push syringe with a mixing tip.
- In the Multilink N / Multilink N Primer system, the material sets quickly and reliably.
- Together with the Multilink N Primer, very high bond strength values are achieved after only a short time. In investigations on the marginal quality, Multilink N also showed outstanding results.
- In clinical investigations, Multilink N showed none or minimum postoperative sensitivity.
- Multilink N offers high mechanical strength values.

1.5 Materials and compositions

A phosphonic acid monomer is responsible for the adhesive and self-etching effect of Multilink N Primer:



The rest R is either an ethyl rest or a large bulky rest, which, in the presence of water, is no longer split off, even in a very acidic medium. This compound class has been protected with a patent by Ivoclar Vivadent. The toxicological properties of these derivates have been thoroughly investigated.

The composition of Multilink N has been adjusted to this primer. It is necessary to harmonize the surface properties of the monomer paste with the aqueous primer formulation in order to prevent phase separation between the composite and primer. Phase separation caused by incompatibility would reduce the strength of the bonding system and the resulting porosities could lead to postoperative sensitivity. The slightly increased hydrophilicity of the composite, which is achieved by the selection of the monomers used in the formulation, also permits optimized wetting of most restorative materials.

1.6 Note on interactions

Possible interactions with other materials used in the course of the treatment should be ruled out to ensure that the selected restoration can be inserted reliably and durably.

The active component in the adhesive (Primer B) is a phosphonic acid group. Its acidic effect demineralizes the tooth surface and irreversibly bonds to calcium ions. Alkaline components can neutralize the phosphonic acid and thus eliminate its activity. This is the case when the cavity is treated with an *Airflow* system before the adhesive cementation. The solid component of devices such as *Airflow* is sodium hydrogen carbonate, which has a strong alkaline effect. Furthermore, it is known that oxidizing components which can be used to disinfect the cavity affect the initiator systems of the self-curing mechanism. A typical example is the use of *hydrogen peroxide*. If it has not been thoroughly rinsed from the tooth, adequate bonding cannot be achieved with self-curing composites. If *alcohol* is used for disinfection, it has to be considered that alcohol is hygroscopic and may lead to overdrying and therefore to a collapse of the collagen layer. In this case, a hybrid layer cannot be achieved.

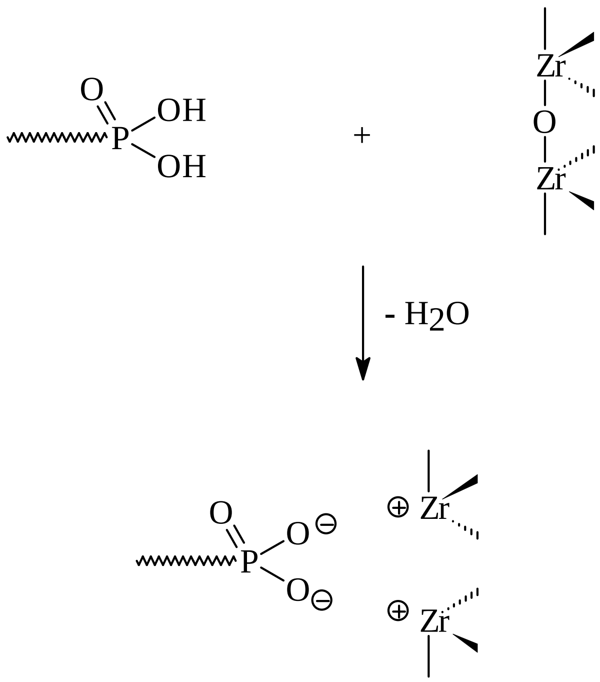
1.7 Conditioning of glass-ceramic materials

For the adhesive cementation of glass-ceramic restorations, a combination of etching and silanizing has proved most effective. Hydrofluoric acid gels, such as the Ceramic Etching Gel, can create a micro-retention pattern on the ceramic surface by dissolving silicate components. Silanization forms a chemical link to the glass-ceramic surface and changes the hydrophilic properties, so that improved wetting with the luting composite is possible.

An appropriate and well-proven silane agent is Monobond-S, which is applied for 60 s on the surface. In contrast to competitor products Monobond-S is available as one bottle component with a proven stability at room temperatur up to the expiry date.

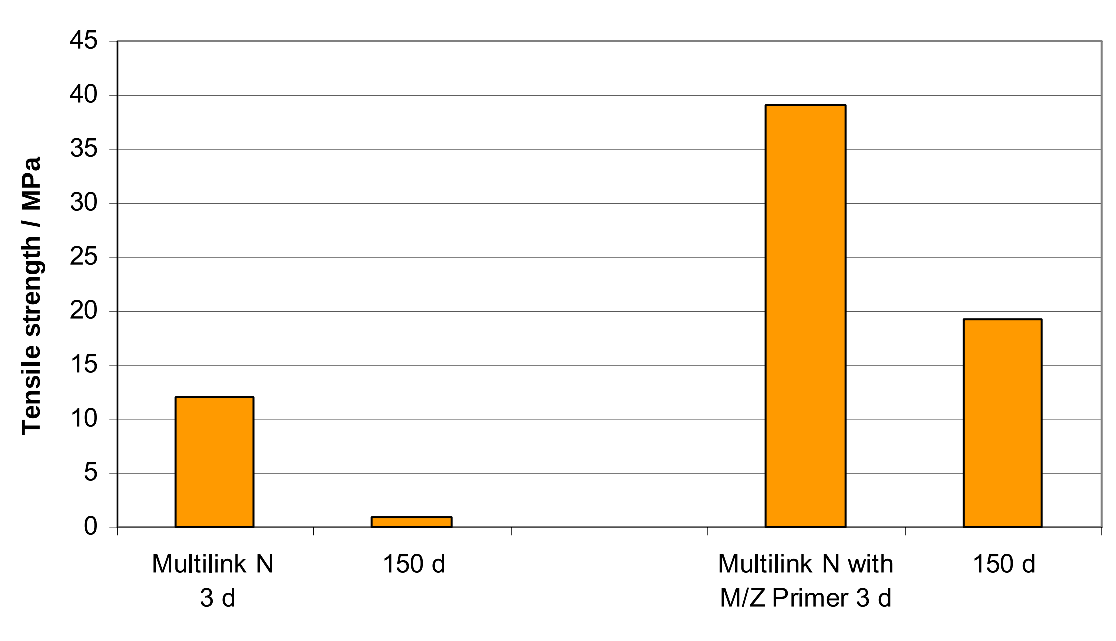
1.8 Conditioning of metals and oxide ceramics – Metal/Zirconia Primer

Zirconium oxide and most metals cannot be etched with a hydrofluoric acid gel. Here, the retention can be increased, for instance, by abrasive blasting with aluminium oxide (< 1 bar). In this case, it is recommended to use a phosphoric / phosphonic acid reagent. Zirconium and many metals form low-soluble, stable phosphates / phosphonates in the presence of phosphoric acid / phosphonic acid.



Assumed surface reaction of phosphoric / phosphonic acid with zirconium oxide

The Metal/Zirconia Primer utilizes the high affinity between these two components. The active reagent of the primer is a methacrylate monomer which has a phosphonic acid group. Similarly to silane on silicate ceramic, chemical bonding is made possible and the zirconium oxide / metal surface can be wetted with the luting composite. This conditioning is stable enough to withstand the stress of thermocycling.



Kern, University of Kiel, Germany

Tensile strength measurement after 3 days and after 150 days plus thermocycling of Multilink N and zirconium oxide with and without Metal/Zirconia Primer

Important:
Zirconium oxide surfaces must not be cleaned with phosphoric acid (e.g. Total Etch) prior to cementation. Phosphoric acid undergoes an irreversible reaction with the zirconium oxide surface, similar to phosphonic acid methacrylate. In the process, a zirconium phosphate layer forms and this layer prevents the Metal/Zirconia Primer to couple with the zirconium oxide substrate and, as a consequence, the primer becomes ineffective.

1.9 Excess removal

Due to different curing modes, there are different strategies for an easy and complete excess removal.

Self-curing:

Seat the restoration in place and fix it with a slight pressure. Remove the excess material immediately meticulousely with a microbrush, brush, pellet, dental floss or a scaler. Make sure to remove the excess material in time, especially in sites, which are different to access.

Self-curing with additional light-curing:

Seat the restoration in place and fix it with a slight pressure. Cure excess material briefly with light (1-2 s.), which enables a smooth removal by using a scaler. Make sure to remove the excess material in time, especially in sites, which are different to access. Subsequently light-cure all cementation joints for 20 s (see the instructions for use of the applied curing unit).

2. Technical Data

Standard composition (in % by weight)

Multilink N	Base	Catalyst
Dimethacrylate and HEMA	30.5	30.2
Barium glass filler and silicon dioxide filler	45.5	45.5
Ytterbiumtrifluoride	23.0	23.0
Catalysts and stabilizers	1.0	1.3
Pigments	< 0.01	-

Multilink N Primer A	
Water	85.7
Initiators	14.3

Multilink N 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

Monobond-S	
3-Methacryloxypropyltrimethoxysilane	1.0
Aethyl alcohol	52.0
Distilled water	47.0

Physical properties

In compliance with ISO 4049:2000 – Polymer-based filling, restorative and luting materials
Mixing ratio of base and catalyst (1:1)

	Self-curing	Dual-curing	
Working time (37 °C)	3 - 4		min
Setting time	7 - 9		min
Film thickness	< 20	< 20	µm
Water absorption (7 days)	< 25	< 25	µg/mm³
Water solubility (7 days)	< 3.0	< 3.0	µg/mm³
Radiopacity	350	350	% Al

Additional values:

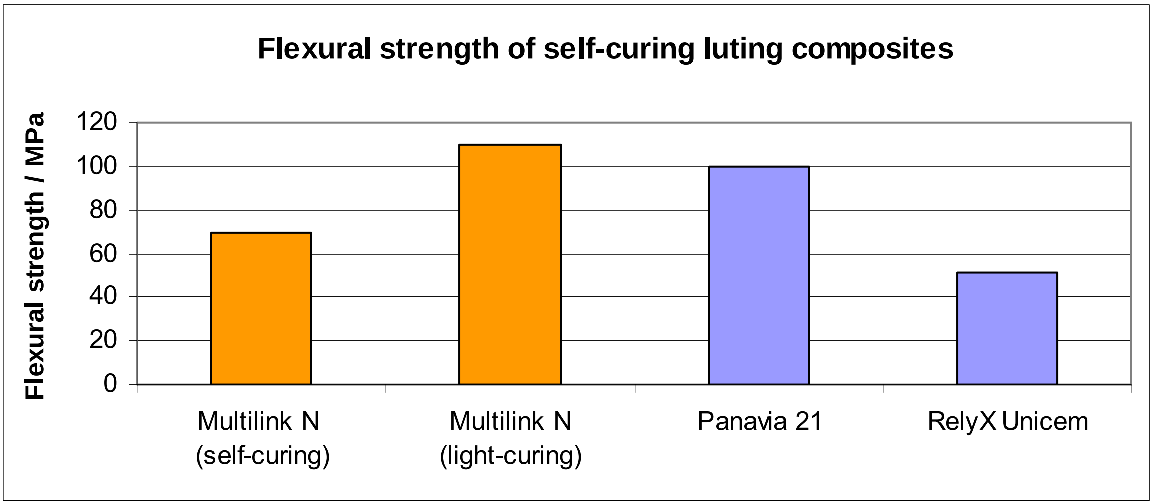
			Self-curing	Dual-curing	
Flexural strength			70 ± 20	110 ± 10	MPa
Modulus of elasticity			3250 ± 400	7000 ± 400	MPa
Compressive strength			240 ± 20	280 ± 20	MPa
Transparency	Base	transp. and cat.	12 ± 1.5	12 ± 1.5	%
		yellow and cat.	10 ± 1.5	10 ± 1.5	%
		opaque and cat.	2 ± 0.5	2 ± 0.5	%
Vickers hardness (HV 0.5/30)			370 ± 30	440 ± 30	MPa
Shear bond strength	Dentin / 24h		17 ± 5	21 ± 2	MPa
	Enamel / 24h		18 ± 3	23 ± 4	MPa

3. Materials Science and Physical Investigations

Many properties of Multilink N are comparable to those of the tried-and-tested Multilink. Multilink N offers the possibility of optional light-curing, which accelerates the curing time.

3.1 Flexural strength

The flexural strength is the resistance of a test sample against flexural stress at the point of breaking. In addition to the compressive strength and tensile strength, it is a significant parameter describing the mechanical strength of a material. The flexural strength of composites is essentially affected by the chemical composition.

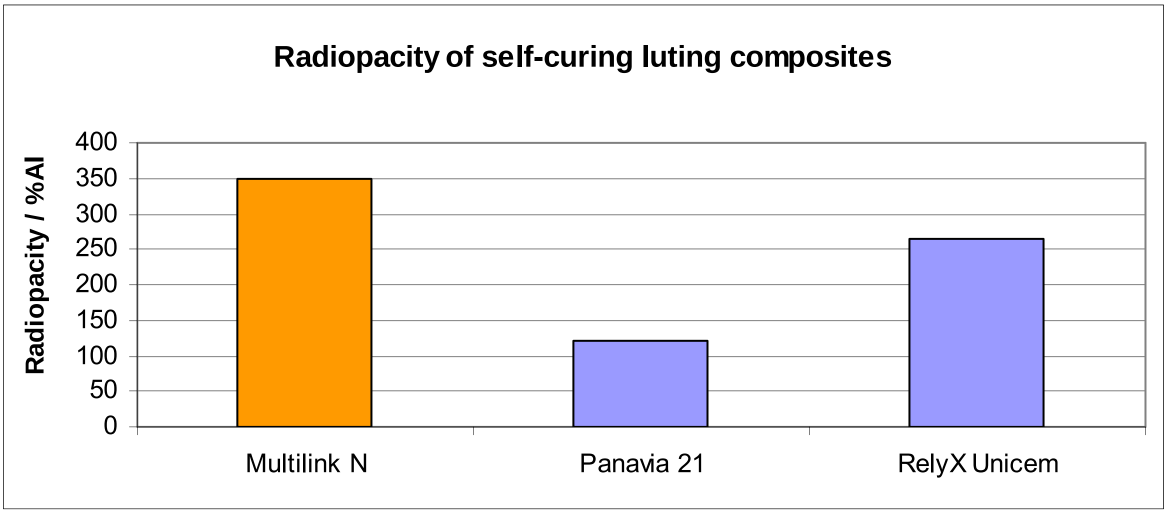


Ivoclar Vivadent, R&D

The luting composites were cured for 1 h at 37 °C and stored in water for 24 h at 37 °C.

3.2 Radiopacity

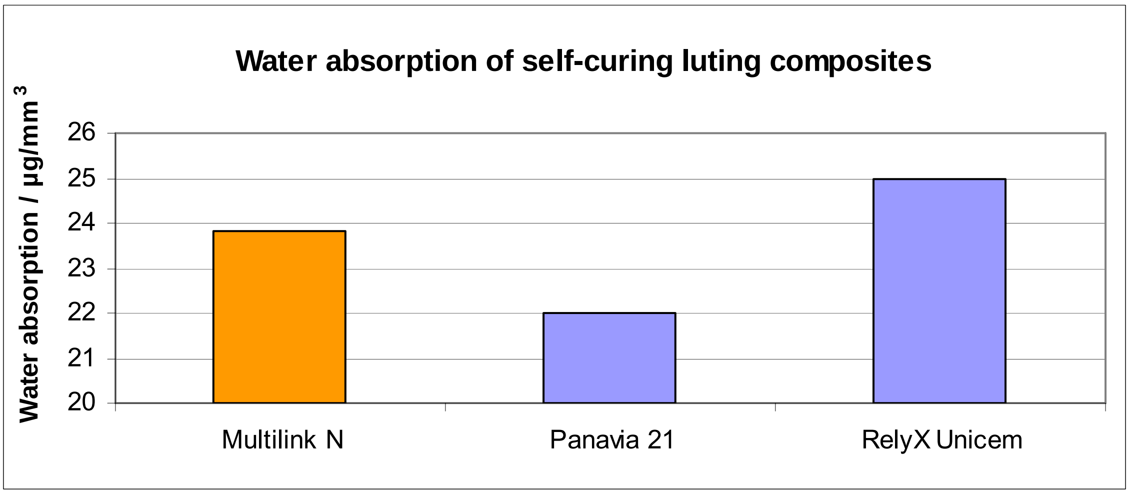
The radiopacity of dental materials permits the differentiation of tooth-coloured restorative materials from the natural tooth or caries on X-rays. The radiopacity is determined in comparison to aluminium.



Ivoclar Vivadent, R&D

3.3 Water absorption and water solubility

The absorption of water may result in an increase in volume (expansion) and, as a consequence, damage to the restoration. The higher the hydrophilicity of the composite is, the higher is its tendency to absorb water and to swell. On the other hand, the luting composite must have a surface that is compatible with the hydrophilic dental material to ensure sufficient wetting.

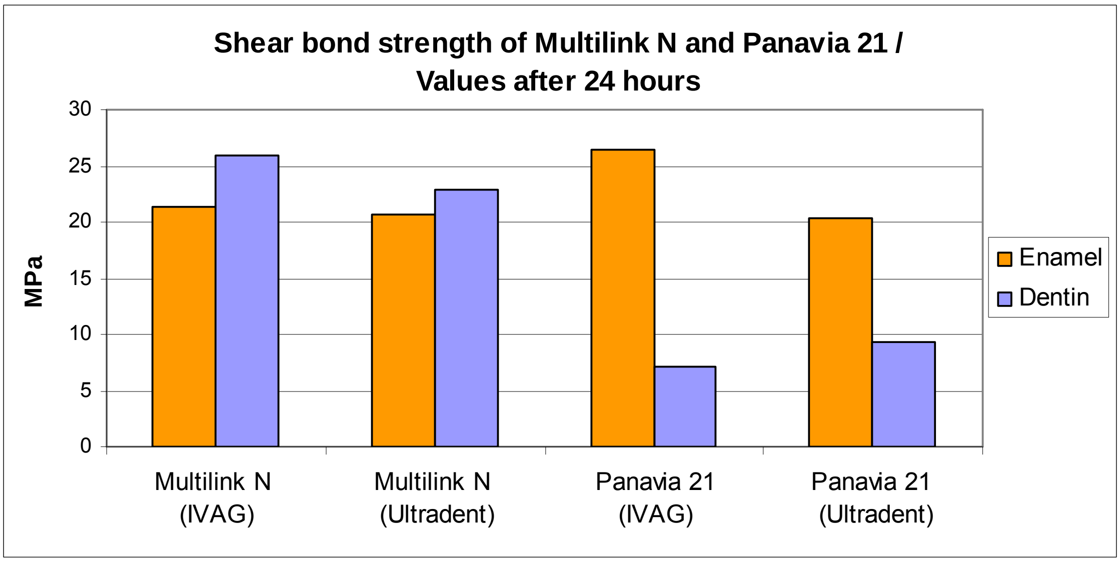


Ivoclar Vivadent, R&D

Water absorption was determined after 7 days of water storage according to ISO 4049.

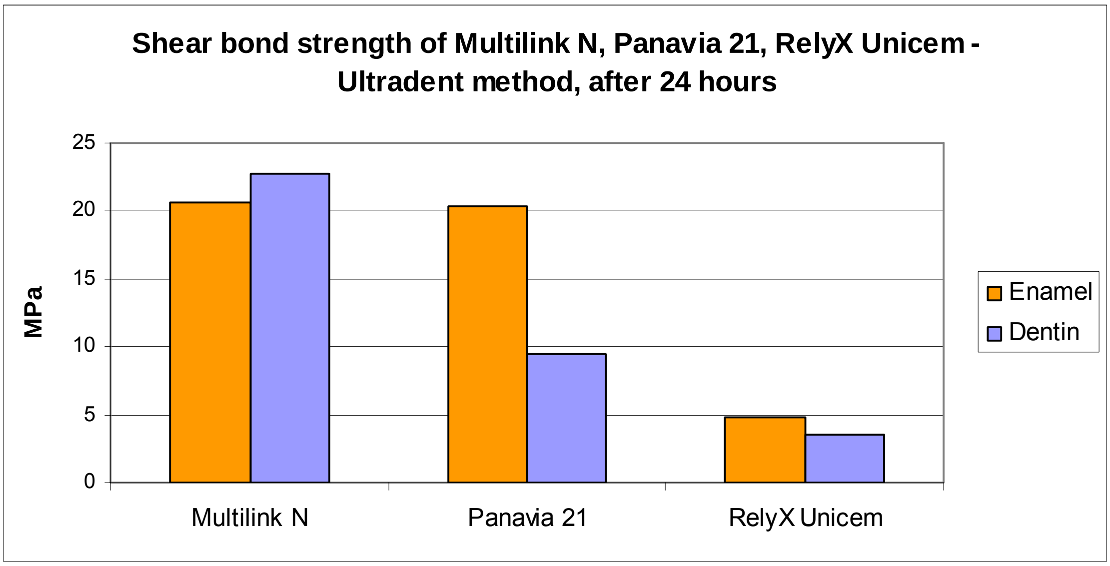
3.4 Bonding to dentin and enamel

3.4.1 Shear bond strength



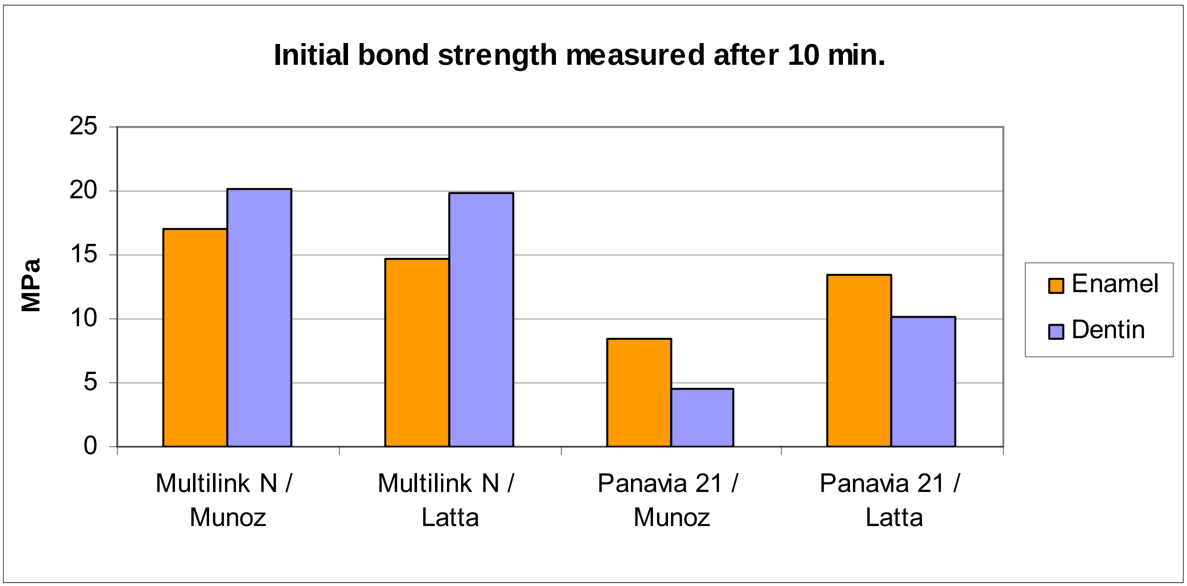
Ivoclar Vivadent, R&D

The shear bond strength values were obtained using two different methods: IVAG means that the shear bond strength was determined according to ISO TS 11405 on bovine teeth. In what is known as the Ultradent method, the dentin and enamel of human teeth were used.



Ivoclar Vivadent, R&D

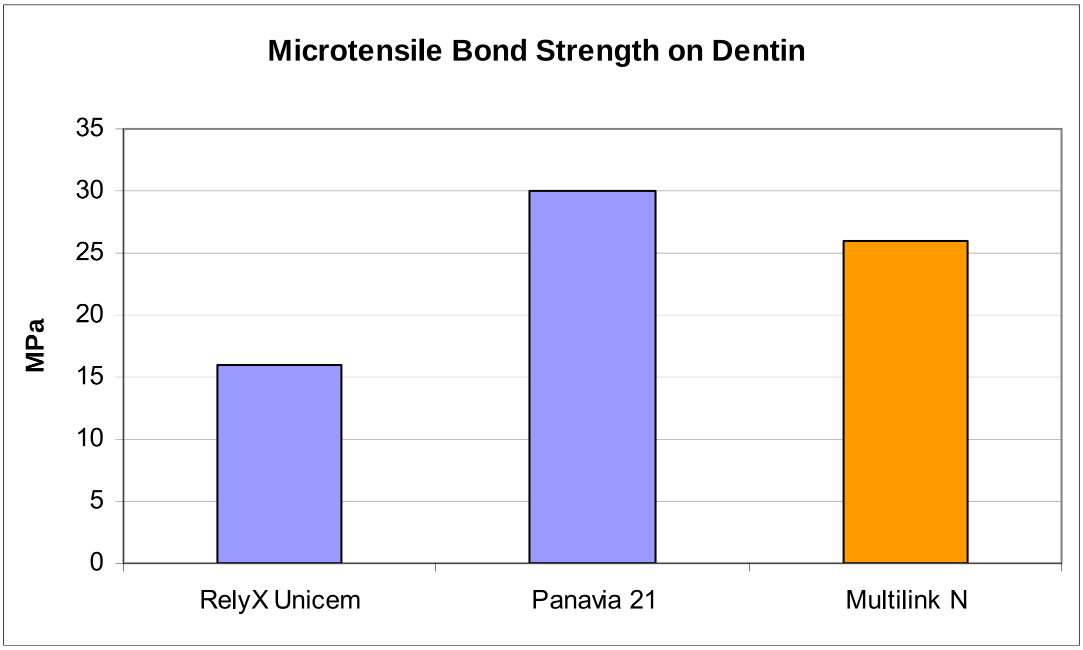
The shear bond strength of Multilink N was measured on human dentin and enamel and compared to that of Panavia 21 and the self-curing RelyX Unicem. Multilink N showed very high bonding capabilities on both enamel and dentin in this test as well.



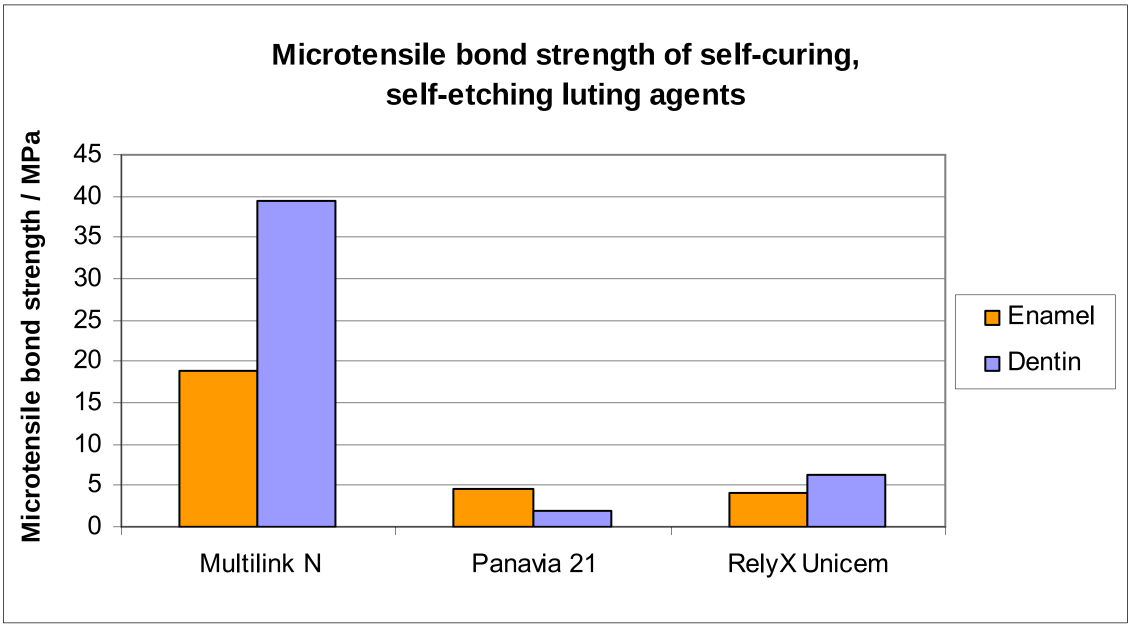
Latta, Omaha and Munoz, Loma Linda

3.4.2 Microtensile bond strength

Measurements of the shear bond strength involve a problem: Their results show considerable scattering. The methods of microtensile strength measurement have been developed in an attempt to reduce this scattering. For this purpose, the adhesive is applied on a prepared, even, retention-free dentin or enamel block according to the instructions. Subsequently, another block of a previously defined size is adhesively bonded to the block. The tooth structure and composite blocks are then cut into rectangular blocks perpendicular to the adhesive surface using a diamond saw. The tensile stress is determined using an appropriate universal testing machine.



Ferrari, Siena



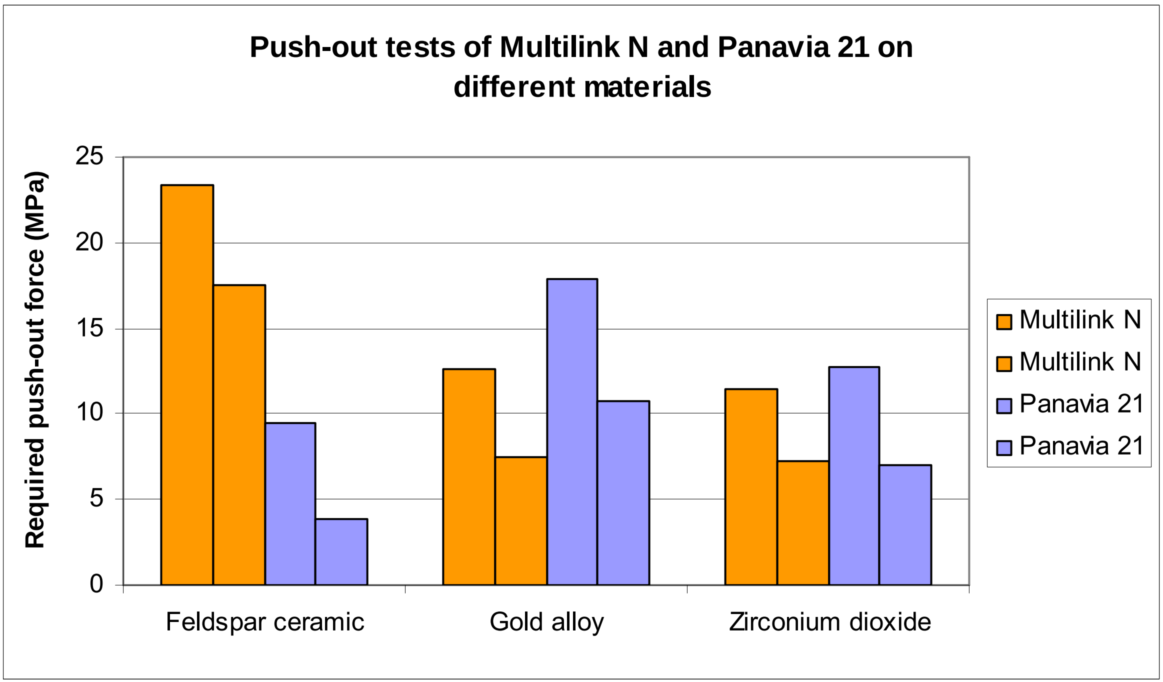
Perdigao, Minneapolis (Abstract# 3179; IADR 2004, Honolulu)

The tensile stress tests were conducted on human dentin and roughened enamel. The luting systems were applied according to the manufacturer's instructions for use. Cylindrical composite blocks (8 mm in diameter and 5 mm in height) made of Tetric Ceram HB were cemented in place after they had been submitted to abrasive blasting.

In sum, Multilink N demonstrates excellent bonding capabilities on dentin and enamel.

3.5 *Push-out tests on various substrates*

While the Multilink N Primer ensures the adhesion to the tooth structure, the composite must provide a bond with the substrate of the restorations to be seated. The hydrophilic components in Multilink N are responsible for achieving an optimal level of wetting. The present study was also supposed to provide a rough idea as to whether or not the substrate requires special conditioning to ensure an optimal bond.



Dagustin, Chicago

The first bar of each pair represents the bonding values after storage at room temperature and storage in tap water for one week.

The second bars show the values after 5,000 thermocycles (5° / 55°C) in tap water.

The conditions stipulated in the manufacturer's directions were used for Panavia 21. In conjunction with Multilink N, the test samples were pre-treated as follows:

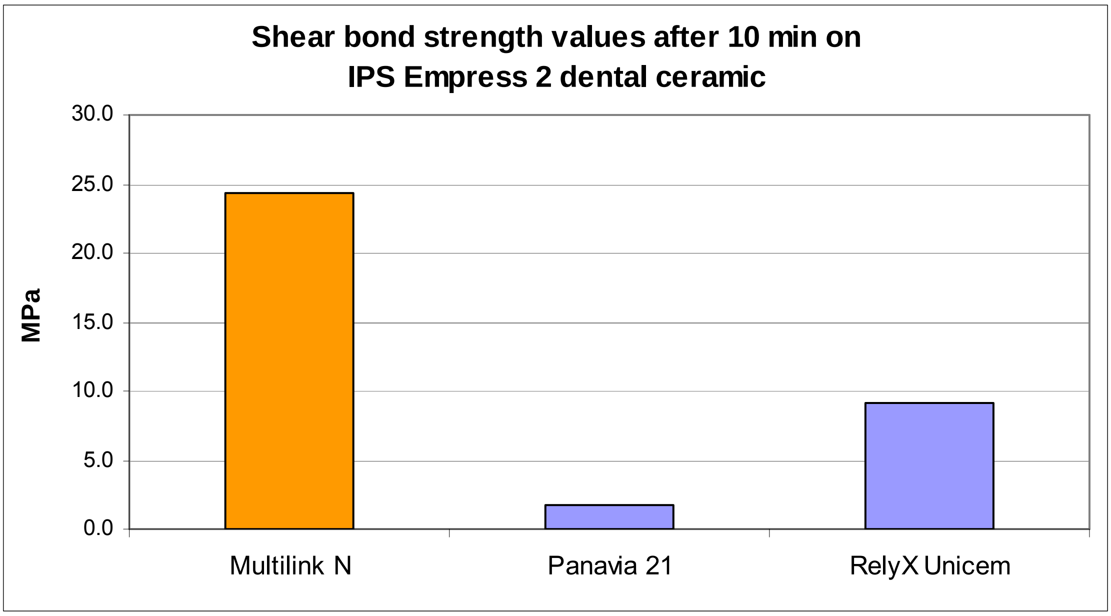
- Feldspar ceramic: a) etching with etching gel, b) silanizing with Monobond-S
- Gold alloys: abrasive blasting
- Zirconium oxide: abrasive blasting

In view of the above results, a special Metal/Zirconia Primer has been developed for the bonding to metal and zirconium oxide materials. The bond to zirconium oxide can be further increased by abrasive blasting and applying an appropriate bonding agent or by silica coating.

3.6 Bonding strength of Multilink N on different substrates

As a multi-purpose luting composite, Multilink N has to adhere to a variety of different materials. In addition to the adhesion to various ceramic materials, such as glass-ceramic and oxide ceramic, the adhesion to metals was also investigated.

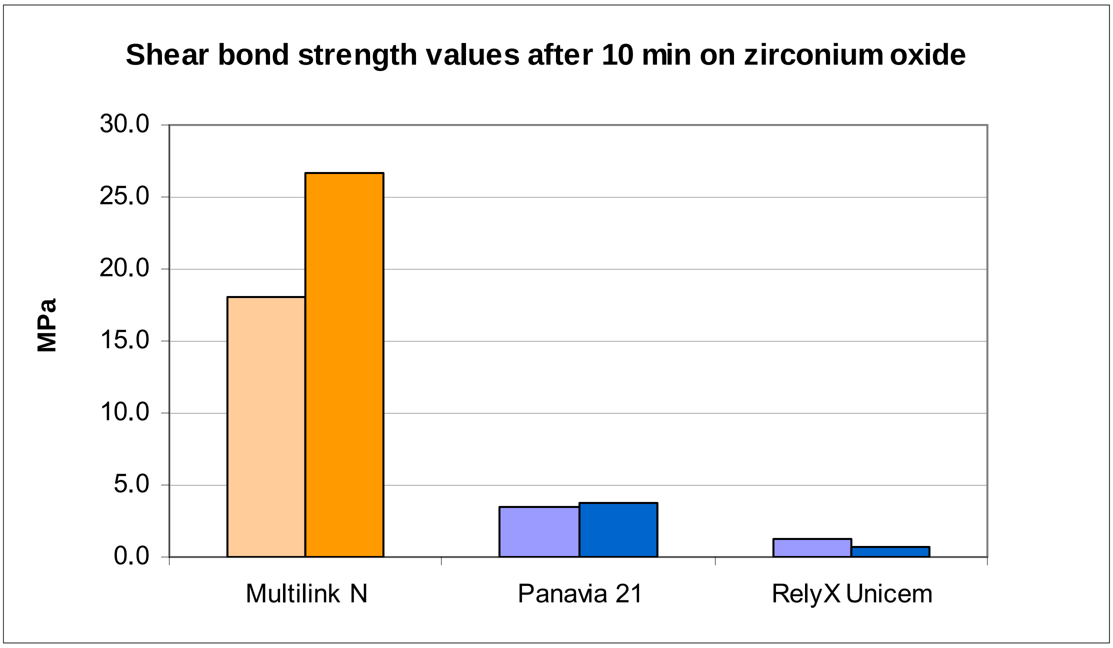
3.6.1 Shear bond strength after 10 min on IPS Empress 2 dental ceramic



Munoz, Loma Linda

Test samples made of the lithium disilicate ceramic (diameter: 2.4 mm; thickness 2 - 4 mm) were blasted with abrasive according to the instructions for use, etched with hydrofluoric acid for 20 s, rinsed, and conditioned with Monobond-S for 60 s. Subsequently, the samples were bonded to a human dentin surface according to the corresponding instructions fur use. After the samples had been stored in an incubator at 37 °C for 10 min, the shear bond strength values were determined using an Instron machine.

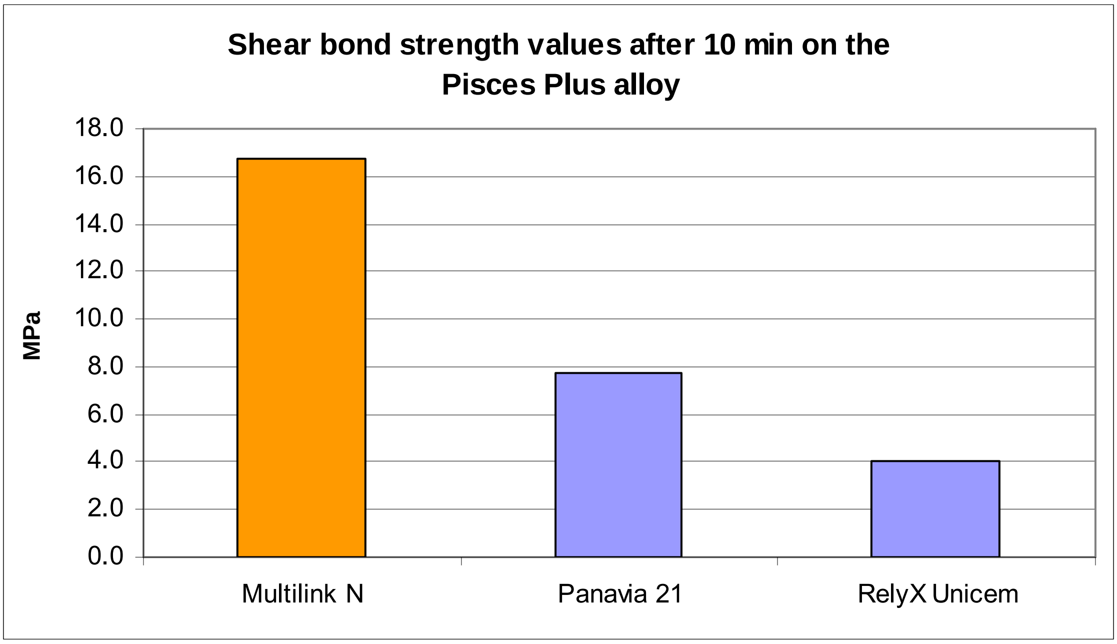
3.6.2 Shear bond strength values after 10 min on zirconium oxide



Munoz, Loma Linda

Test specimens made of zirconium oxide (diameter: 2.4 mm; thickness: 2 - 4 mm) were blasted using 50 µm aluminium oxide and cleaned with steam. The lighter bar (left) indicates the bonding values without further conditioning, while the darker bar (right) represents the results for the ZrO_2 samples, whose surfaces had been silanated with Monobond-S for 60 seconds. Subsequently, the samples were bonded to a human dentin surface according to the corresponding instructions for use. After the samples had been stored in an incubator at 37 °C for 10 min, the shear bond strength values were determined using an Instron machine.

3.6.3 Shear bond strength values after 10 min on the Pisces Plus alloy

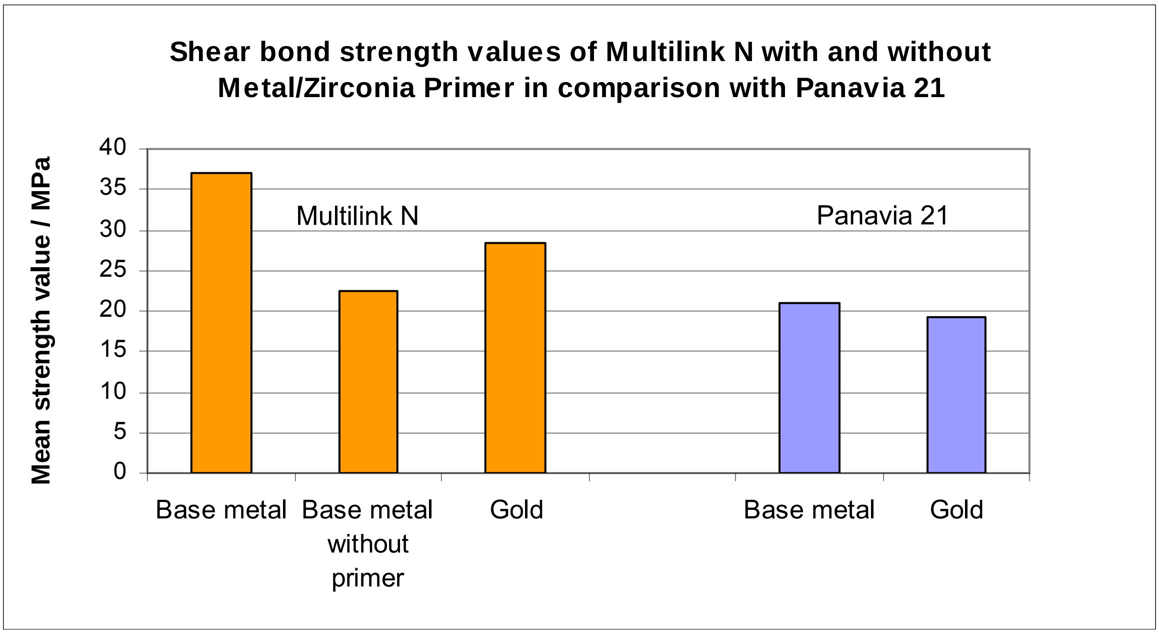


Munoz, Loma Linda

Test specimens made of the Pisces Plus base metal alloy (diameter: 2.4 mm; thickness: 2–4 mm) were blasted with 50 µm aluminium oxide and cleaned with steam. Subsequently, the samples were adhesively bonded to a human dentin surface according to the corresponding instructions for use. After the samples had been stored in an incubator at 37 °C for 10 min, the shear bond strength values were determined using an Instron machine.

The results confirm that, in comparison with Panavia 21 and RelyX Unicem, Multilink N produces very high bond strength values on different substrates after only a short period of time.

3.6.4 Shear bond strength values of Multilink N on various metals

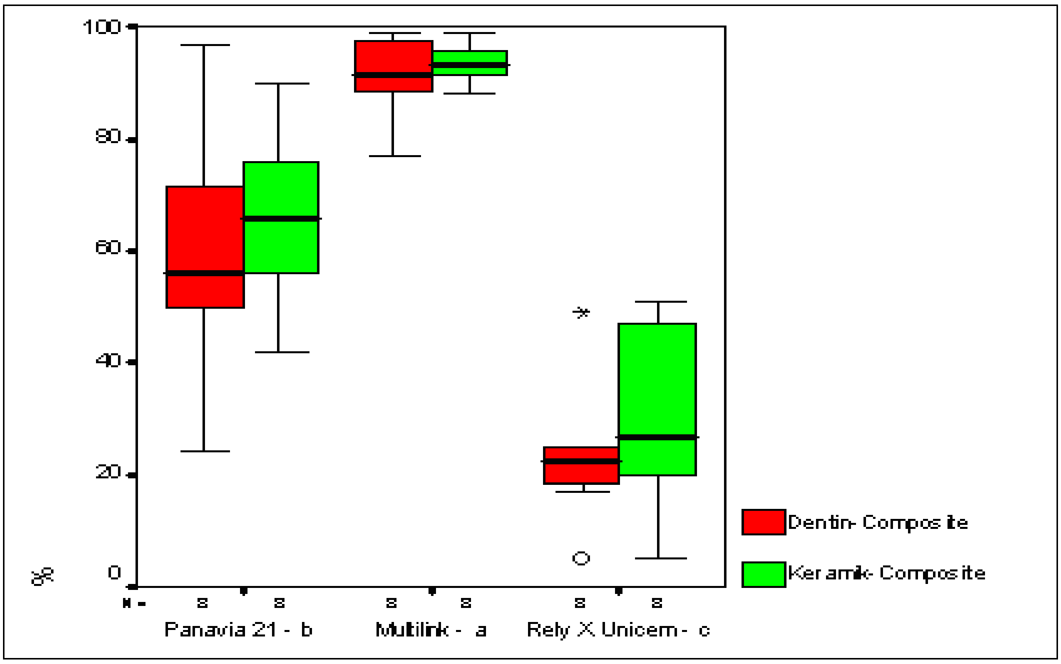


Latta, Omaha

The shear bond strength values of Multilink N were determined in conjunction with and without the Primer. Panavia 21 was used in conjunction with an “Airblock” system, as suggested in the manufacturer’s directions. The results show that the shear bond strength values of Multilink N can be increased by using the Metal/Zirconia Primer.

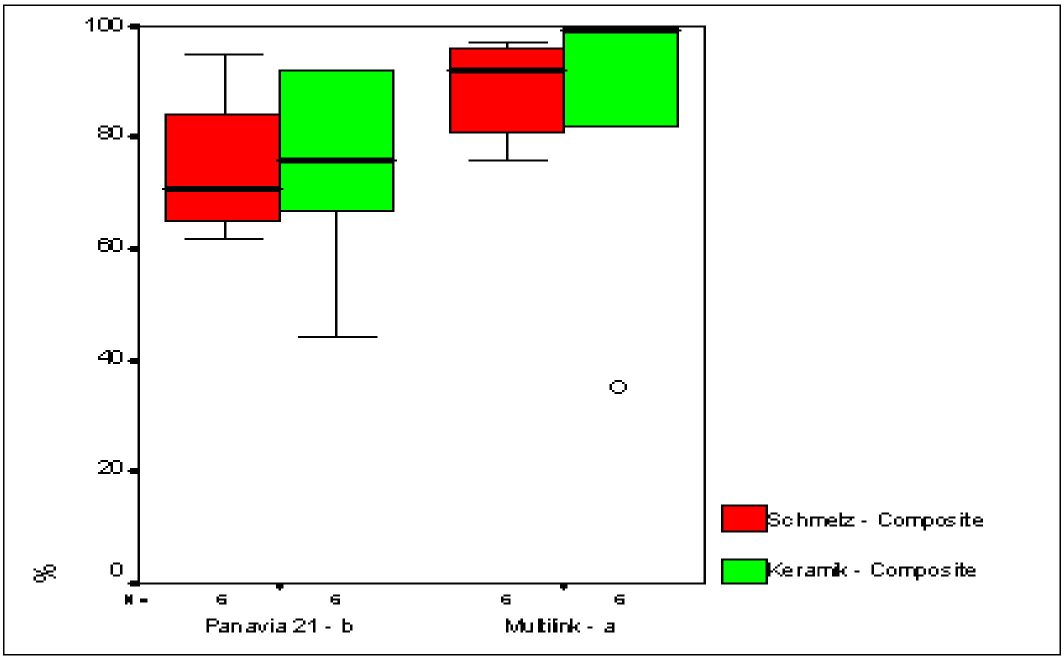
3.7 *Marginal quality*

The marginal quality was determined wit the help of ceramic inserts in standardized drill holes in bovine dentin (diameter = 4 mm). The graph below shows the percentage of continuous margin after 2,000 thermocycles.



Ivoclar Vivadent, R&D

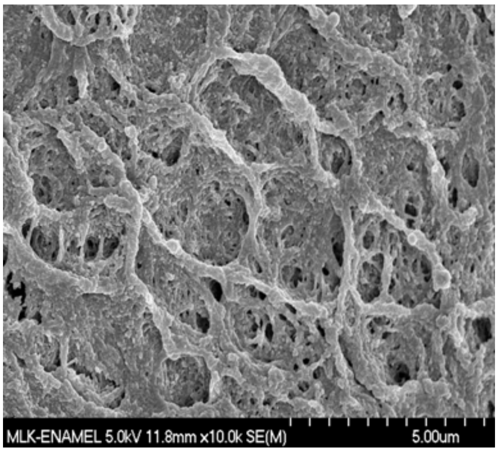
In line with the tests to evaluate the dentin margins, ceramic inserts were also inserted into standardized drill holes in bovine enamel and submitted to 2,000 thermocycles.



Ivoclar Vivadent, R&D

3.8 SEM images of the tooth-adhesive interface

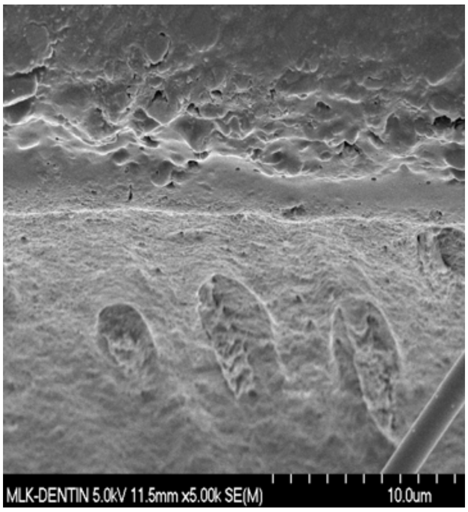
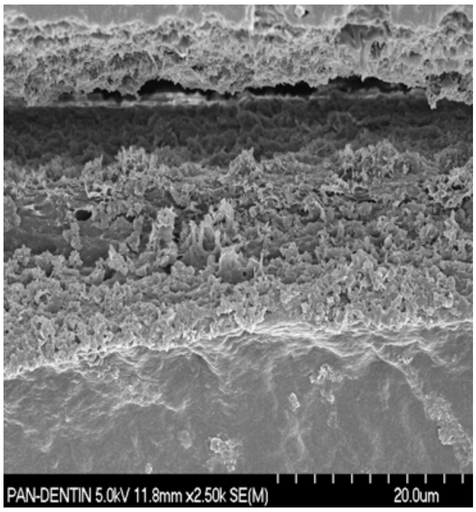
Enamel etching pattern after the application of Multilink N Primer (A&B) and Panavia ED Primer according to the manufacturer's directions

	
Multilink N Primer A & B: 15 s agitation (SEM: 10,000x enlargement)	Panavia ED Primer: 60 s reaction time (SEM: 10,000x enlargement)

Perdigao, University of Minnesota

After Multilink N Primer (A & B) has been brushed into the tooth structure, the enamel shows a typical etching pattern with a clearly increased retention.

Hybrid layer after different reaction times of Multilink N Primer (A&B) and Panavia ED Primer on dentin

	
Multilink N Primer (A & B): 15 s agitation (SEM: 5,000x enlargement)	Panavia ED Primer: 60 s reaction time (SEM: 2,500x enlargement)

Perdigao, University of Minnesota

After the application of both adhesives according to the instructions for use, the dentin-composite interface shows a hybrid layer.

4. Clinical Studies

Multilink and Multilink Automix have performed very well in clinical studies and five years of excellent clinical performance on the market attest to the efficacy of these materials. These studies can also be used as a reference for Multilink N.

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

Head of study: M. Ferrari, Livorno, Italy

Objective: Establish the performance of Multilink in the incorporation of 40 fibre-reinforced composite root canal posts

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

Clinical trial of Empress 2 porcelain inlays luted to vital abutments with self-curing ExciTE and Multilink resin cement

Head of study: M. Ferrari, Livorno, Italy

Objective: Determine the adhesive properties of Multilink for ceramic inlays under clinical conditions

Experimental: 40 inlays made of Empress 2

***In-vivo* marginal seal of Multilink: Empress 2 all-ceramic crowns vs conventional porcelain veneered crowns**

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

Objective: Clinical long-term investigation over a period of 48 months on metal-ceramic restorations vs Empress 2 all-ceramic restorations adhesively cemented using Multilink.

Experimental: Fifty-four crowns (27 made of Empress 2 and 27 made of d.SIGN on Porta Geo Ti), as well as 6 inlays, 5 onlays, 6 adhesive bridges, 3 root canal post build-ups

Pilot Clinical Trial on Modified Lithium Disilicate Ceramic Crowns

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

Objective: Incorporation of 16 all-ceramic crowns made of a modified lithium disilicate ceramic

Experimental: Sixteen molar and premolar crowns

Clinical evaluation of Multilink used for inlay and onlay restorations

Head of study: Dr Arnd Peschke, Ivoclar Vivadent, Schaan, Liechtenstein

Objective: Investigation of the handling properties and clinical performance level of Multilink used for the incorporation of inlays and onlays.

Experimental: Twenty-one vital teeth

Clinical Evaluation of an Experimental Dental Ceramic Material for Anterior and Posterior Crowns

Head of study: Dr Nathanson, Boston University, Boston, MA, USA

Objective: Incorporation of 40 crowns made of a millable lithium disilicate ceramic using Multilink

Experimental: Forty crowns in the anterior and posterior region

Summary

The clinical experiences with Multilink stretch over more than five years. Multilink has proved its excellent clinical performance for the cementation of crowns, bridges and inlays made of ceramic and metal alloy. The cementation of root canal posts was also successfully tested. The rare occurrence of postoperative sensitivities is especially noteworthy. These outstanding properties can be transferred to Multilink N, which is comparable to Multilink. The rapid curing time in conjunction with Multilink N Primer A+B in particular deserves to be highlighted.

5. Toxicological Data

The cytotoxicity, genotoxicity and carcinogenicity of Multilink and Multilink Primer (A & B) were tested according to ISO 10993:

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 the mutagenicity test did not show any toxicological risk. Given the composition of the composite, which contains components comparable to those used for most of the established dental composites, nothing else has to be expected.

5.2 Multilink Primer A & B

1.) XTT Test (Cytotoxicity Assay in vitro: Evaluation of Materials for Medical Devices) RCC-CCR Report 758703; 13. 11. 2002

The Primer shows an XTT value of 1693 mg/l. This means that it demonstrates a cytotoxicity level that is clearly lower than that of many 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 evaluations and investigations have shown that the adhesive composition of Multilink N Primer does not demonstrate any mutagenic risks.

Due to the similar chemical composition and the indicated applications, the test results can also be applied to Multilink N and Multilink N Primer A and B. Therefore, it can be stated that Multilink N is safe, when used according to the Instructions.

6. Literature

G. Oilo: Luting cements: a review and comparison. Int. Dent. J. 41, 81 (1991)

S. F. Rosenstiel, M. F. Land, B. J. Crispin: Dental luting agents: a review of current literature. J. Prosthet. Dent. 80, 280 (1998)

M. Ferrari, A. Vichi, S. Grandini, C. Goracci: Efficacy of a self-curing adhesive – resin cement system on luting glass-fiber posts into root canals: an SEM investigation. Int. J. Prosthodont. 14, 543 (2001)

S. Grandini, M. Ferrari, P. Balleri, A. Vichi: Clinical trial of fiber posts luted with self-curing ExciTE in combination with an experimental resin cement. J. Dent. Res. 81 (Spec. Iss. A) # 198 (2002)

A. Dagostin, M. Sierraalta, A. Macedo, M.E. Razzoog: Bonding properties of an experimental self-curing resin cement. J. Dent. Res. 82 (Spec. Iss. B) # 2615 (2003)

F. Monticelli, C. Goracci, P. Balleri, S. Grandini, M. Ferrari: Clinical behaviour of translucent fibre posts and luting and restorative materials: a 2-year report. Vortrag bei ConsEuro 2003 in München (Abstract-Band S. 46)

F. Monticelli, S. Grandini, C. Goracci, M. Ferrari: Clinical behaviour of translucent fibre posts and luting and restorative materials: a 2-year prospective study. Int. J. Prosthodont. 16, 593 (2003)

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