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TRULY FAST

MULTILINK® SPEED

Scientific Documentation

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1. Introduction

1.1 Dental cements

Dental cements or luting agents are based on foundations laid as early as in the 19th century. In those days, magnesium chloride-based cement was used to bond tooth restorations to natural tooth structure. Hand in hand with the technological advances in restorative dentistry, new cements were developed. Most cements set by means of an ionic reaction that occurs in an aqueous environment. In most cases, this reaction is an acid-base reaction (= neutralization reaction). These luting materials are called conventional cements. Due to the lack of adhesion, they rely on mechanical retention to hold the restoration in place. However, in the past few decades an increasing trend towards preparation procedures that minimize or avoid the loss of healthy tooth structure has been noticeable. An adhesive bond is needed where retentive features cannot be created. Simultaneously with the further development of conventional luting materials, adhesive techniques for the incorporation of direct composite restorations were developed. As a result, composite-based luting materials which are capable of establishing a chemical bond to the dental hard tissues are available today. These adhesive composite-based luting systems form the basis for the success of esthetic all-ceramic restorations (IPS Empress).

1.2 Conventional cements

The different types of conventional cements are named after their composition. Today, the most frequently used are:

- Zinc phosphate cements
- carboxylate cements
- glass-ionomer cements

Most of them consist of a powder and liquid component, which are manually mixed. Some are available in mixing capsules, which are less complicated to use but slightly more expensive. The chemical setting process starts immediately after mixing and does not involve additional initiation. No special pre-treatment of the prepared tooth is needed in conjunction with these materials. Usually, the restoration is simply placed as delivered by the dental laboratory. Complete isolation of the prepared tooth is not required. However, a retentive preparation design needs to be ensured, which often entails a considerable loss of healthy tooth structure. Conventional cements usually have a grey-opaque appearance and the cement joint is, as a consequence, clearly visible. In unfavourable situations, loss of material and discoloration may occur in the area of the cement joint.

A further development of glass-ionomer cements are the so-called hybrid cements. Apart from glass-ionomer components, they contain monomers, so that both a cement setting reaction and polymer cross-linking ensure a complete cure. These luting materials feature better mechanical properties than genuine cements. However, they also lack the ability to establish an adhesive bond to the tooth structure.

1.3 Adhesive, composite-based luting materials

This category of materials enables dental professionals to establish a sound chemical bond with the dental hard tissues. Enamel and dentin are pre-treated as prescribed by the adhesive luting protocol. Composite luting materials themselves are composite resins that are composed of monomers and inorganic fillers. They are classified into self-curing, dual-curing and light-curing materials. By carefully selecting the pigments and colour additives, tooth-coloured luting composites, which cannot be distinguished from the natural tooth structure, are achieved, so that the cement joint becomes virtually invisible. As they exhibit comparatively favourable mechanical properties, they are able to compensate for relatively wide cement joints.

Moreover, the adhesion to the restorative material is improved by the establishment of chemical bonds. Glass-ceramic materials can be etched with hydrofluoric acid and treated with a silane coupling agent. Metal and zirconium oxide can also be conditioned with suitable primers. The clinical success of glass-ceramic restorations would have been unthinkable without composite luting materials.

	Conventional cements	Adhesive composite luting materials
Advantages	- Easy handling - Easy removal of excess - Unproblematic removal of the restoration	- Minimally invasive preparation techniques can be used - Excellent adhesion to the tooth structure - Stability - Low solubility in the oral environment - Low wear - Reduced occurrence of postoperative sensitivity - Esthetics
Disadvantages	- Retentive preparation - Solubility - Limited adhesion to tooth structure - Increased wear - Unsatisfactory esthetics	- Difficult removal of excess - Restoration can only be removed with difficulty

Table 1: The advantages and disadvantages of conventional cements contrasted with those of adhesive luting materials

1.4 New requirements: Simplicity and versatility

One would think that all the indications and demands in the field of luting materials have already been covered, so that dental professionals can simply use the technique they prefer. However, a product that combines the advantages of conventional and adhesive luting materials is still missing.

<u>Simplicity:</u> Even though composite-based materials offer overriding benefits, their application often involves a great deal of effort and is error-prone. It is therefore desirable that composites show self-adhesive properties and are capable of bonding to dentin, as this reduces the number of working steps involved in their application and eliminates potential sources of error.

<u>Versatility:</u> Depending on the indication, economic considerations and esthetic requirements, dental professionals may choose from a multitude of restorative materials. Would it not be advantageous to use one single luting material for the majority of these restoratives?

1.5 Multilink Speed

Multilink Speed was developed to meet the demand among dentists for luting materials that offer easy, quick and universal application. No conditioners or bonding agents need to be applied to the dental hard tissues when Multilink Speed is used. Details on the bonding values and mechanical properties of this material can be found on the technical data sheet. These values are comparable to those of similar products available on the market and surpass the bonding and strength values of conventional cements. Multilink Speed is available in the most used shade transparent. To facilitate its use, Multilink Speed is offered

as a paste-paste system in a convenient double syringe with exchangeable mixing tips. Multilink Speed can be used in a self-cure or dual-cure mode.
Multilink Speed is based on the successful self-adhesive resin cement SpeedCEM. Flexural strength and radiopacity are slightly lower due to an adaption of the filler composition.. The bond strength to dentin and enamel is in the same range.

Advantages of the automix-syringe delivery form
Compared with cements that require manual mixing or cements that are mixed in a capsule, cements that are offered in a automix-syringe delivery form offer a number of considerable advantages.

...advantages over manual mixing	**...advantages over mixing capsules**
consistent, ideal 1:1 mixing ratio each time	more rapid application
significantly more rapid application	no working accessories required
no working accessories (e.g. mixing pad, spatula) required	material can be dispensed in individual quantities
no residual cement on mixing pad	no residual cement on mixing pad
no air entrapments	no air entrapments

Table. 2: Advantages of automix-syringe

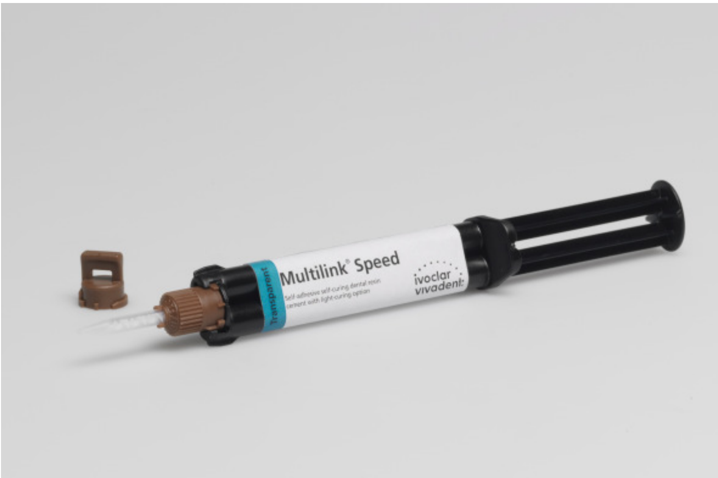

Fig. 1: Automix-syringe delivery form of Multilink Speed

1.6 Self-adhesive mechanism

Multilink Speed contains an adhesive monomer which has been specifically formulated to endow the cement with self-adhesive properties. This monomer consists of a long-chain methacrylate with a phosphoric acid group (see Fig.). The phosphoric acid group enables a stable chemical bond to zirconium oxide and many metals. Consequently, using an additional bonding agent or primer is not required for final bonding to these restoration substrates. In addition, phosphoric acid reacts with the calcium ions of the dental hard tissues and, in the process, produces a bond with the tooth structure. The need for a separate adhesive is eliminated. As the bonding mechanism is not established by integration of a hybrid layer, the bond strength values measured on the dentin are lower than those obtained with genuine adhesive composites (e.g. Multilink Automix).

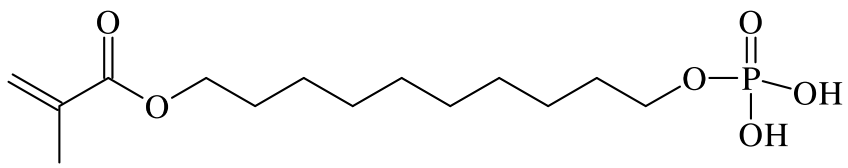

Fig. 2: Methacrylate monomer with phosphoric acid group

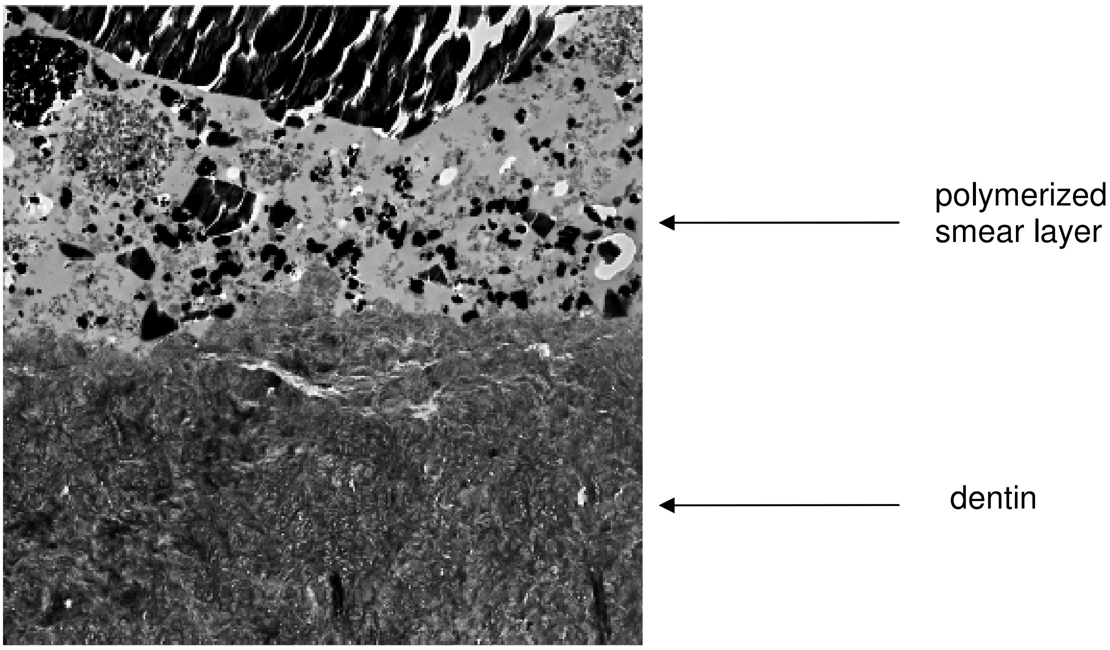

Fig. 3: TEM image of the interface between self-adhesive luting agent and dentin (Van Meerbeek, Leuven, 2009)

The self-adhesive luting agent (e.g. Multilink Speed) penetrates the smear layer, which becomes incorporated into the polymer network as the cement cures to its final state. The polymerized smear layer seals the dentin surface.

1.7 Interactions

It is important to be aware of the fact that interactions with certain other materials may adversely affect the bonding mechanism of resin cements. The following materials should not be used together with Multilink Speed:

- Eugenol-containing temporary cements
  Eugenol inhibits free radical polymerization of resin cements and prevents or hampers the setting reaction.
- Alkaline abrasive media, e.g. AirFlow
  Alkaline residues neutralize the active acidic component of the resin cement and prevent it from reacting with the dentin.
- Hydrogen peroxide
  Hydrogen peroxide oxidizes the initiator system and thereby destroys it.
- Phosphoric acid for cleaning zirconium oxide and metal surfaces
  Phosphoric acid reacts with metal surfaces and causes them to be inert to reacting with Multilink Speed.

2. Technical Data Sheet

<u>Standard composition</u> (in wt%)

	Base	Catalyst
Dimethacrylates	23.3	26.0
Ytterbium trifluoride	-	45.2
Co-polymer	-	22.6
Glass filler (base only), silicon dioxide	75.0	2.2
Adhesive monomer	-	3.1
Initiators, stabilizers and pigments	1.7	0.9

<u>Physical properties</u>

According to: ISO 4049:2000 – Polymer-based filling, restorative and luting materials
Mixing ratio base:catalyst (1:1)

	Self-curing	Dual-curing	
Working time (37 °C)	100 - 140	100 - 140	sec
Setting time (37 °C)	150 - 220	150 - 220	sec
Film thickness	< 50	< 50	µm
Radiopacity	> 300	> 300	% Al
Linear expansion in water	0.8	0.8	%
Flexural strength	60 ± 10	80 ± 10	MPa
Modulus of elasticity	4500 ± 600	6000 ± 600	MPa
Compressive strength	190 ± 20	190 ± 20	MPa
Translucency: transparent	9 ± 1.5	9 ± 1.5	%
Translucency: yellow	7.5 ± 1	7.5 ± 1	%
Translucency: opaque	2 ± 0.3	2 ± 0.3	%
Shear bond strength:(dentin)	8 ± 2	11 ± 2	MPa

3. *In vitro* Investigations

3.1 Adhesion to dentin and enamel

The task of a luting material is to create a bond between the dental hard tissues and the restorative material. Generally, cements show very low adhesion to dentin. In conjunction with composites, adhesive techniques are employed which involve enamel etching and dentin conditioning to obtain what we call a hybrid layer with demineralized collagen. In self-etch adhesives these two steps are conducted with one product. With the self-adhesive Multilink Speed, measurable adhesion to dentin and prepared enamel, which clearly exceeds that of conventional cements, is achieved.

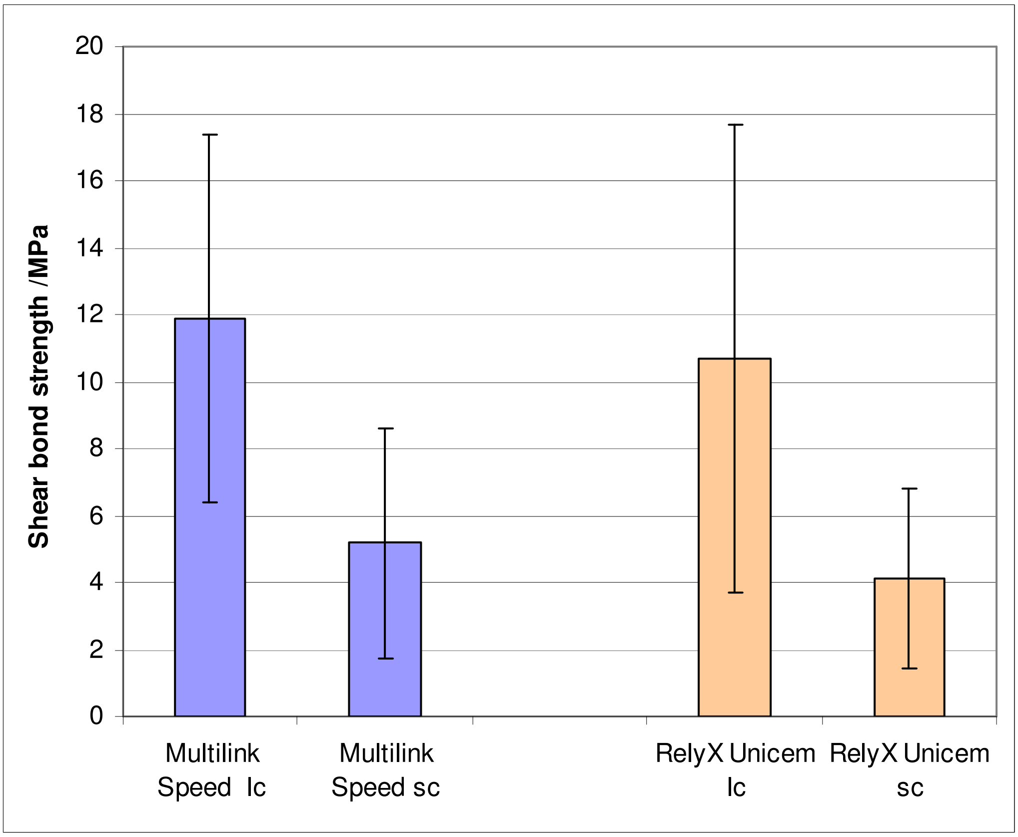

Fig. 4: Shear bond strength of Multilink Speed on human dentin after self-curing and light-curing in comparison with RelyX Unicem [trademark of 3M ESPE] (Watts, Manchester, 2009)

Cylindrical samples, which consisted of polymerized Tetric EvoCeram and measured 2.3 mm in diameter, were bonded to flat surfaces of freshly prepared human dentin. The light-cured samples were stored in water at 37 °C for 24 hours. The self-cured samples were first stored at 37 °C for 1 hour and then immersed in water for 24 hours. Subsequently, the samples were subjected to shear bond testing. A significantly higher shear bond strength was measured in the light-cured samples.

Shear bond strength measurements depend on many factors. The individual learning curve of the investigator should not be neglected when evaluating the results of a study. For this reason, it is essential that several experts conduct comparative measurements independently of each other. In addition to the data obtained by D. Watts from the University of Manchester, Ms A. Rzanny from the University of Jena also performed shear bond strength measurements. The results achieved in the process generally confirmed the findings of previous tests. In comparison, the adhesive luting composite Multilink Automix produces clearly higher bond strength values.

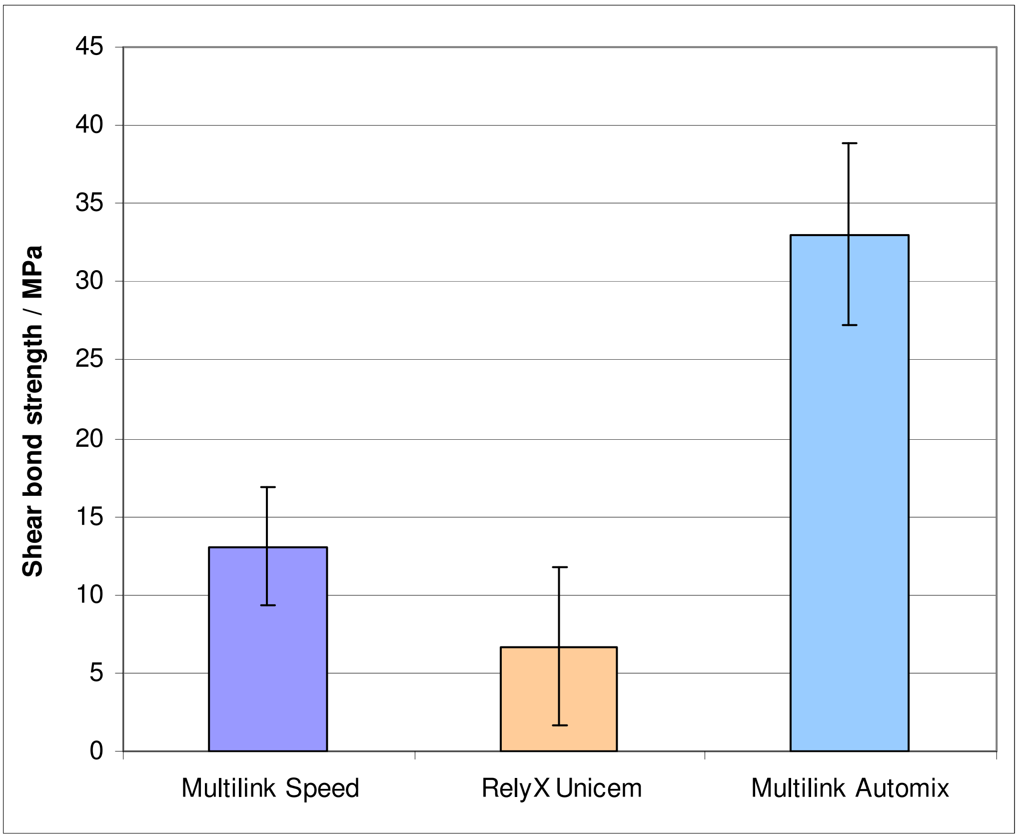

Fig. 5: Shear bond strength of Multilink Speed to dentin after light-curing (Rzanny, Jena, 2008)

The shear bond strength to dentin was measured on human dentin using the above-mentioned method.

In addition to shear bond strength evaluations, tensile strength measurements may also be employed to assess dentin adhesion. For this purpose, what is known as micro-tensile strength testing is often performed. Blocks made of IPS Empress CAD were bonded to flat dentin discs made of human dentin. The dentin surfaces were roughened either with a diamond-coated bur or with 600-grit sanding paper to simulate a dentin smear layer. The ceramic surface was etched and silanized before bonding. After the samples had been stored in water at 37 °C for 7 days, small right-angled rods with a bonding surface of 1mm x 1mm were cut from these samples using a diamond saw. If the bond failed already at this stage, the samples were allocated the value of '0 MPa' in the measuring series.

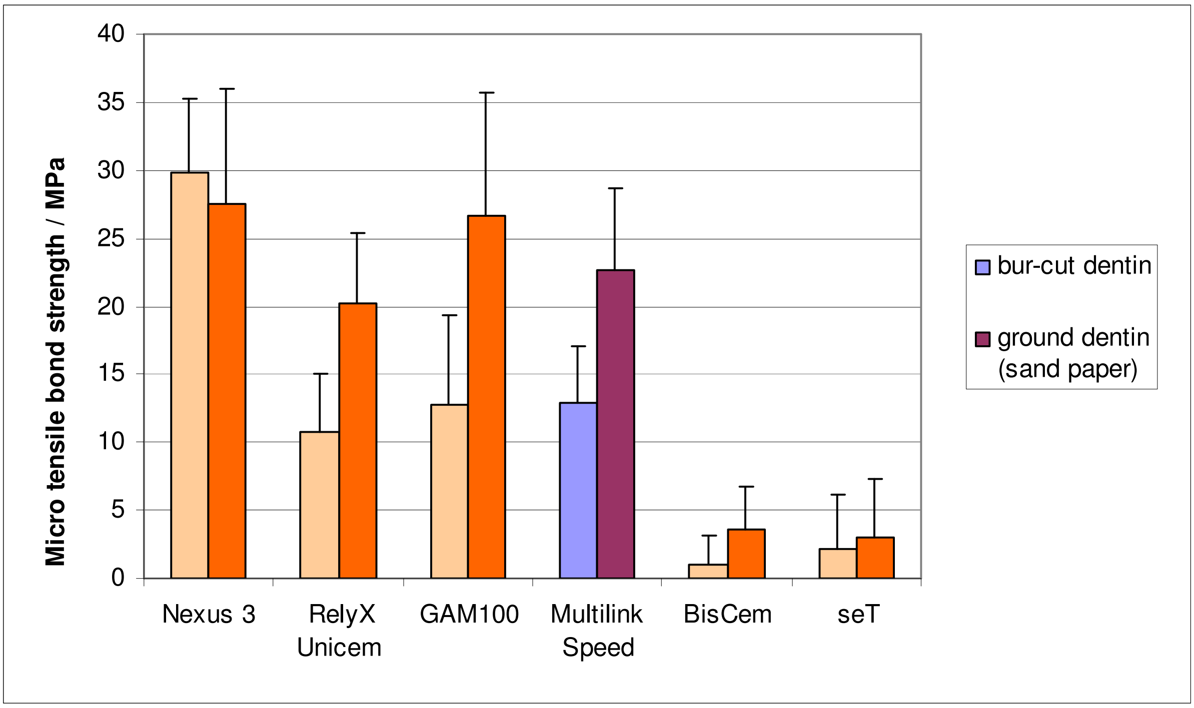

Fig. 6: Micro tensile bond strength of various luting materials on ground and polished dentin (van Meerbeek, Leuven, 2009) [Nexus 3 is trademark of Kerr, GAM100 of GC, BisCem of Bisco and seT of SDI]

The self-adhesive luting materials RelyX Unicem, GAM100 and Multilink Speed reacted with the smear layer and created adhesion to the dentin through this reaction. Therefore, the preparation method has, amongst other parameters, an effect on the bonding behaviour of this category of materials. When Nexus 3 was used, the smear layer was etched off; consequently, no dependence on surface treatment could be observed with this material.

Prof. Munoz (State University of New York at Buffalo) examined the shear bond strength of various dentin-bonded substrates at two points: 10 minutes after the samples had been light cured and after 24 hours of water storage. This examination showed that the final bonding strength is reached after a short time.

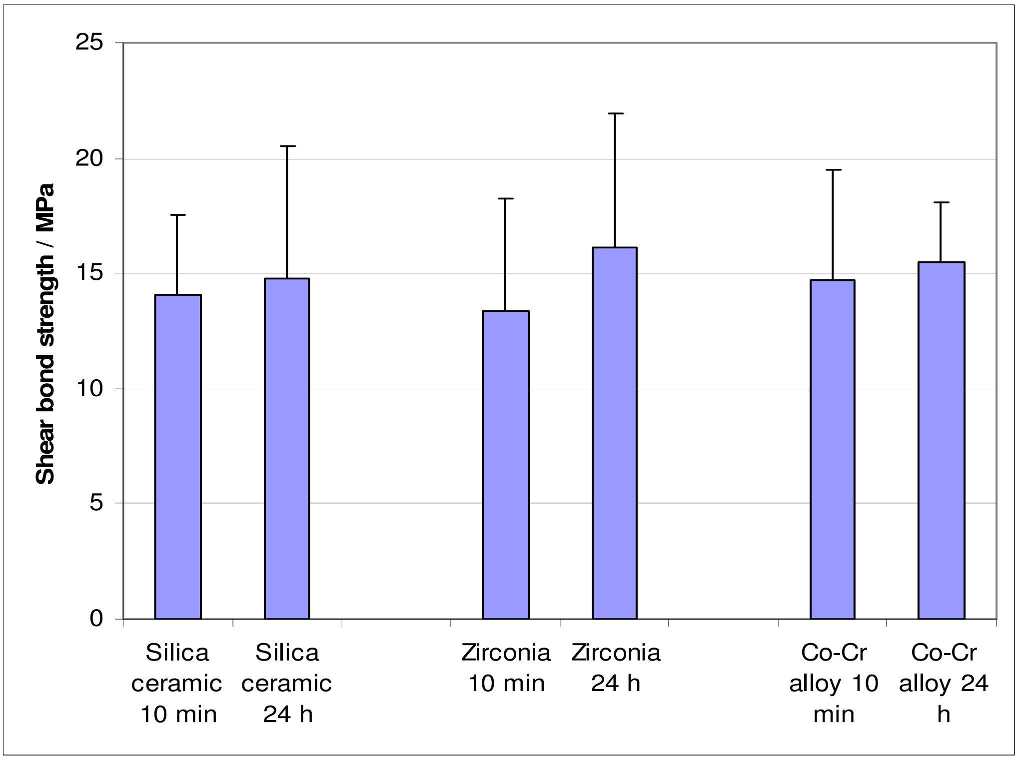

Fig. 7: Shear bond strength of various dentin-bonded substrates after 10 min and 24 hrs (Munoz, Buffalo, 2009)

A drawback of adhesive composite-based luting materials is the fact that they require a completely dry treatment field. It is often difficult to achieve a completely dry bonding site on the prepared tooth, for instance if subgingival preparation margins are present. Self-adhesive resin cements such as Multilink Speed are less reliant on a completely dry treatment field to work properly.

A series of tests examined the effect of moisture on the shear bond strength. For this purpose, the dentin bonding surfaces were treated in a variety of manners to create various degrees of moisture:

- dry: complete drying with an strong stream of air
- moist: careful dabbing with paper towel
- wet: visible water film left on dentin surface

In a fourth test series, the shear bond strength was measured after the dentin surfaces had been contaminated with saliva.

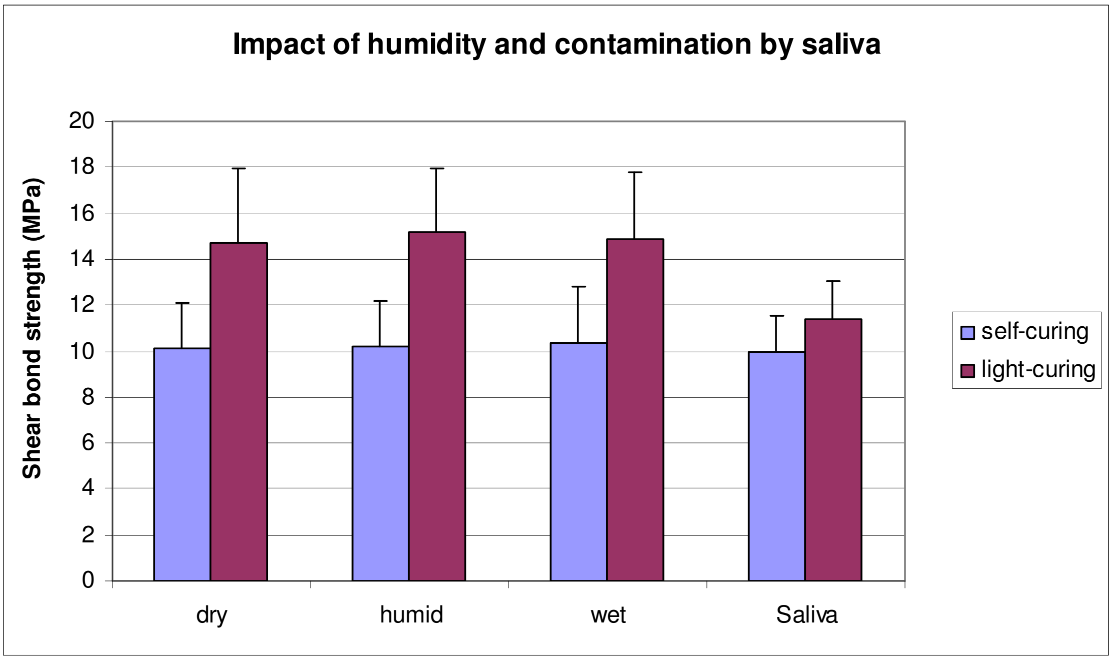

Fig. 8: Shear bond strength in conjunction with various levels of moisture on dentin (Ivoclar Vivadent AG, Schaan, 2009)

Multilink Speed has shown to be fairly tolerant of moisture. However, users should make sure that the surfaces are not contaminated with blood or residues of other dental treatment materials, which may have an adverse effect on adhesion.

3.2 Adhesion to enamel

Multilink Speed shows reasonable bond strength values on freshly prepared enamel.

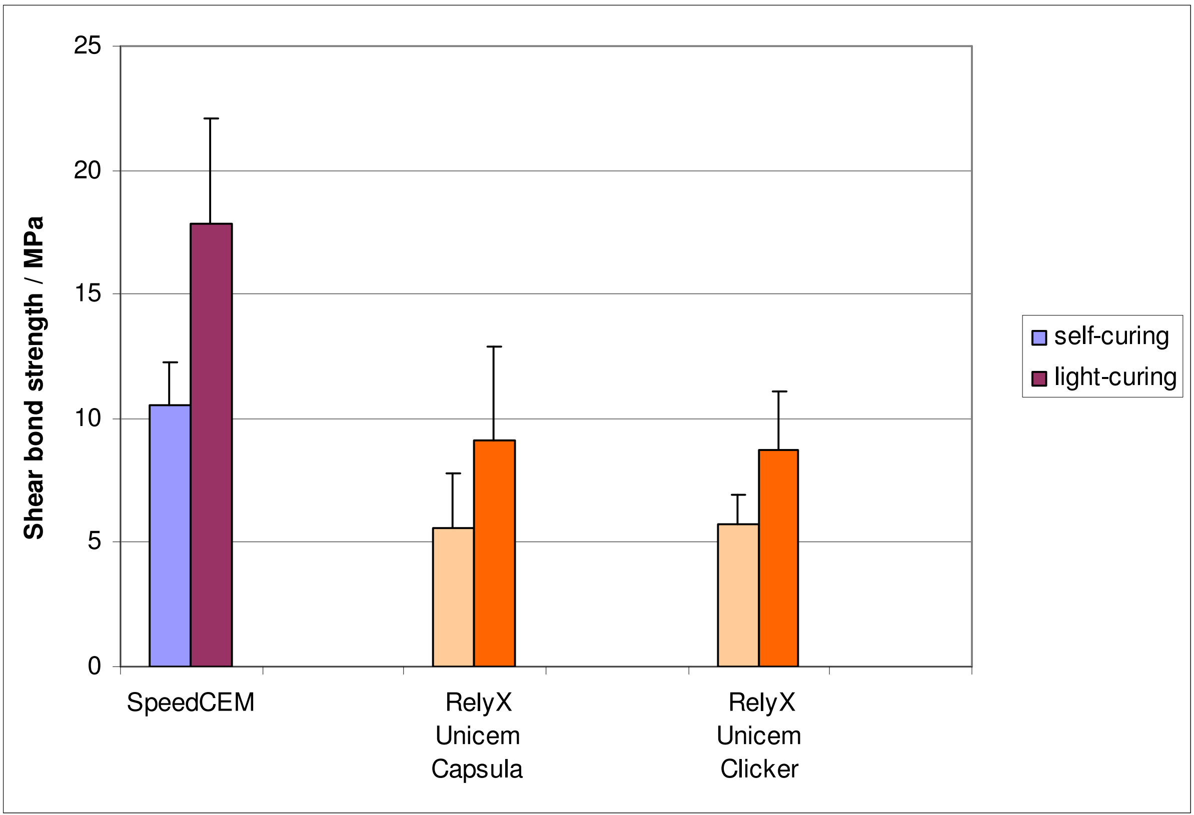

Fig. 9: Bond strength on freshly prepared bovine enamel (Ivoclar Vivadent AG, Schaan, 2009)

Self-adhesive resin cements do not act as an etchant. Separate enamel etching with phosphoric acid may be performed to ensure that enamel surfaces provide sufficient microretention.

3.3 Adhesion to different substrates

Self-adhesive resin cements eliminate the need for an additional bonding agent or primer because they exhibit self-adhesion to dentin, which is an advantage. As they comprise a phosphoric acid monomer, bonding to zirconium oxide and base-metal surfaces can be achieved without having to condition these substrates with a bonding agent.

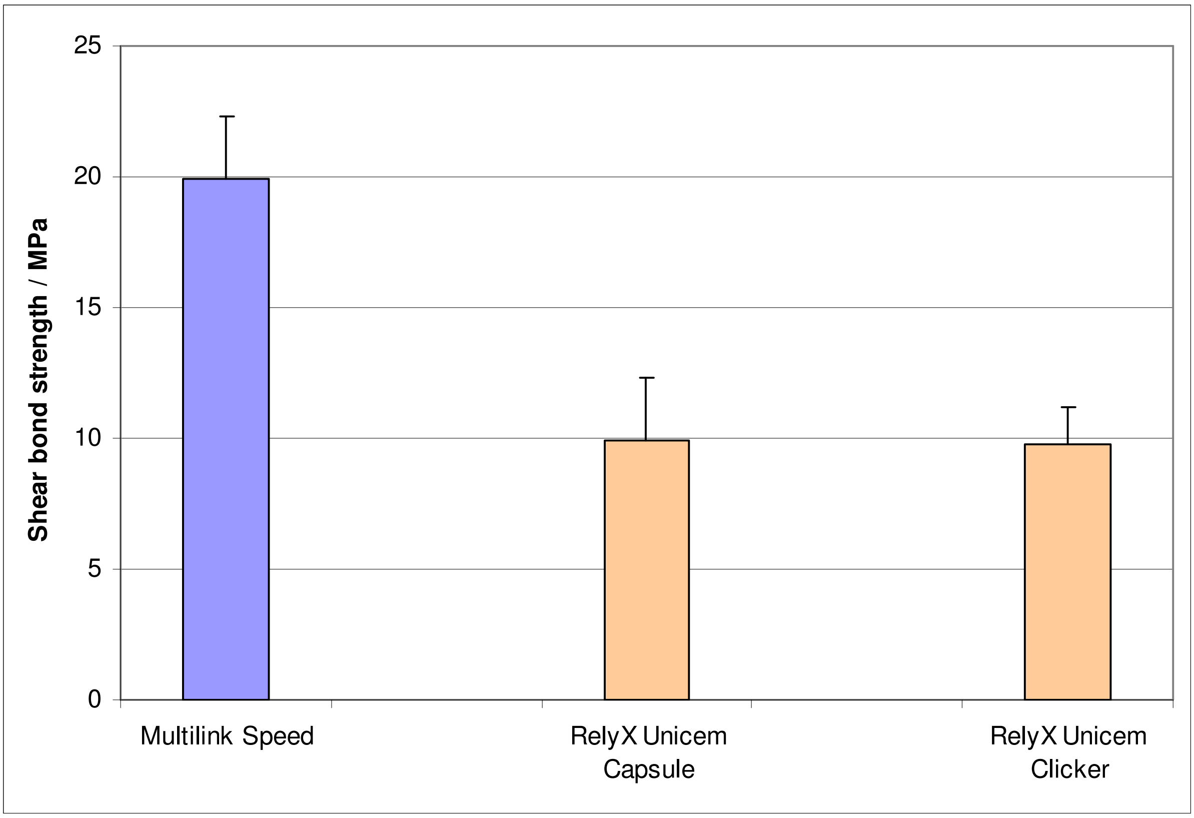

Fig. 10: Shear bond strength of different self-adhesive resin cements to zirconium oxide (IPS e.max ZirCAD) after self-curing (Ivoclar Vivadent AG, Schaan, 2009)

Bonding to zirconium oxide can be achieved without applying a separate primer. In the above test, the shear bond strength was only measured in conjunction with the self-cure mode, as zirconium oxide is very opaque and only allows a limited amount of light to pass through it.

Lithium disilicate glass-ceramics, such as IPS e.max Press or IPS e.max CAD, are etched and silanized before they are cemented in place with Multilink Speed. Monobond-S may be used as a silanizing agent.

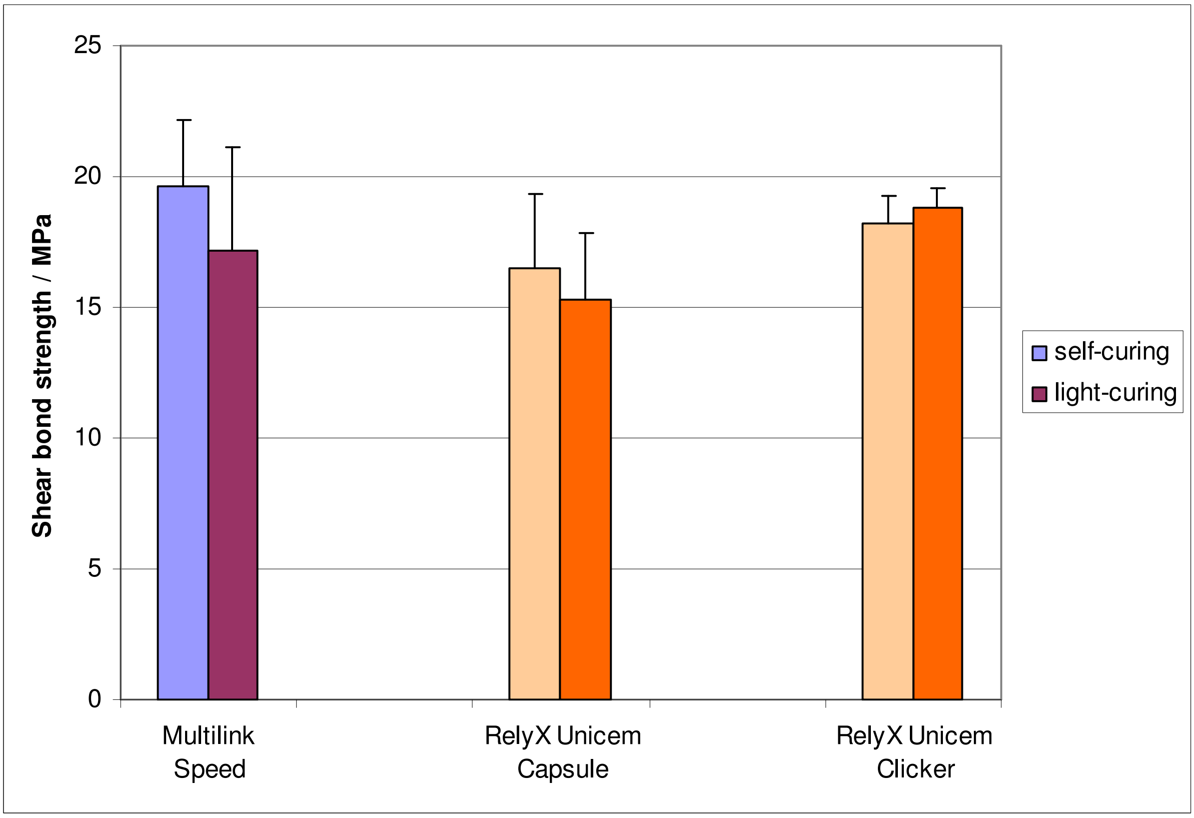

Fig. 11: Shear bond strength of different self-adhesive resin cements to lithium disilicate glass-ceramic (IPS e.max Press) (Ivoclar Vivadent AG, Schaan, 2009)

All the materials tested produced similar shear bond strength values to glass-ceramic. In other words, the adhesive effect is created by the silanization agent (e.g. Monobond-S) in this case. The lithium disilicate glass-ceramic is sufficiently translucent up to a maximum thickness of 3 mm to allow light to pass through it for light-activation. Consequently, the bond strength was measured after self-curing and after initial light-activation.

3.4 Evaluation of the marginal seal

Poor sealing of the dentin surface may lead to post-operative sensitivity and secondary decay. Dye penetration tests are a suitable method to assess the seal at the interface between luting composite and dentin.

Another method is to prepare standardized cavities in bovine dentin, into which ceramic inserts are cemented (see Figure). The ceramic (IPS Empress) is etched and silanized. After cementation, the specimens are immersed in water for 24 hours at 37 °C prior to removing the material excess. After subjecting them to thermocycling involving 2000 cycles at 5 °C and 55 °C, replicas are fabricated. These replicas are analysed under the scanning electron microscope using a special analysis program. A detailed description of the test set-up can be found in S. D. Heintze et al.; J. Adhes. Dent. (2005).

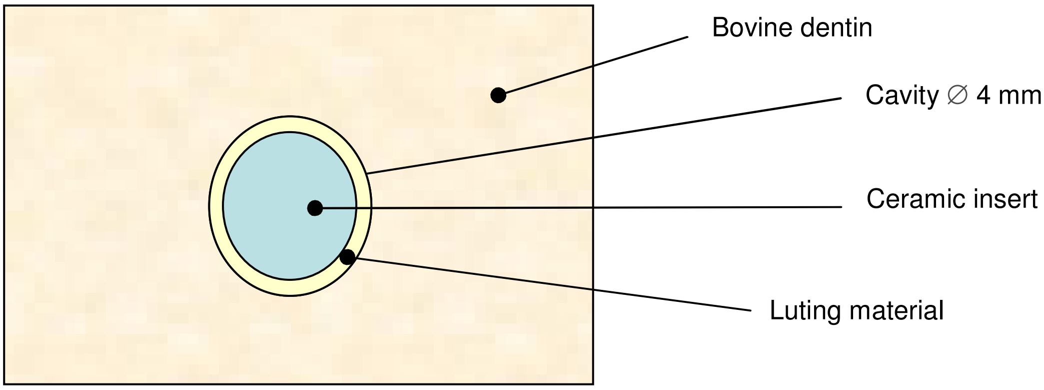

Fig. 12: Schematic representation of the test set-up for the measurement of the marginal seal of ceramic inserts in dentin

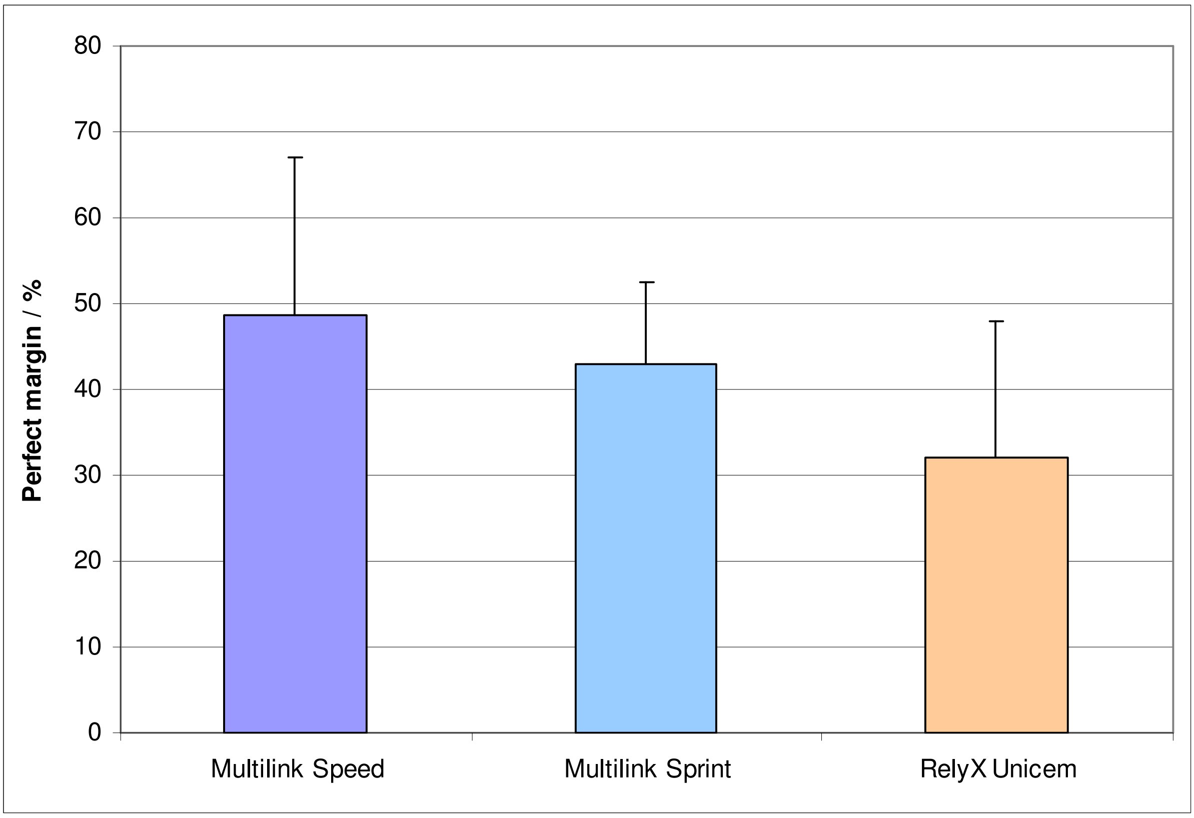

Fig. 13: Assessment of the percentage of perfect margin in bovine dentin using ceramic inserts (Heintze, Ivoclar Vivadent, Schaan, 2008)

Compared with other self-adhesive resin cements, Multilink Speed shows the highest percentage of perfect margin.

3.5 Water solubility

Conventional cements tend to be hydrophilic and continue to contain water soluble components after they are completely set. By contrast, luting composites are not soluble in water. Self-adhesive resin cements are based on organic monomers, similar to dental restorative composites. However, they have to be sufficiently hydrophilic to be able to wet the dentin appropriately. There is therefore a risk that water may cause the material to partially dissolve or to expand.

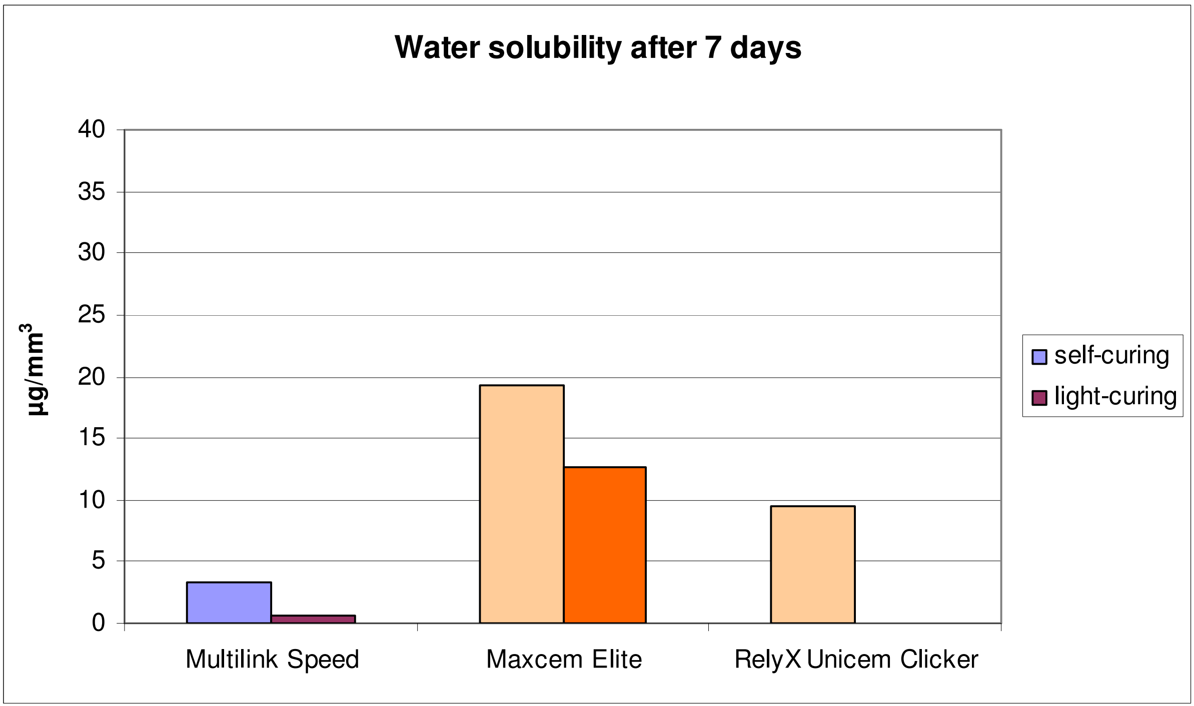

Fig. 14: Water solubility of different self-adhesive resin cements after 7 days of water storage (Ivoclar Vivadent AG, Schaan, 2009)

Water solubility was measured after 7 days. After light-curing, the monomer conversion and, consequently, network density of the material are increased. As a result, the availability of substances that can be eluted is reduced.

3.6 Water absorption

Cross-linked composites do not dissolve, as they form a three-dimensional stable network. However, solvents, such as water, may penetrate the network and cause the composite to expand. Linear expansion can be determined according to normative standards. Linear expansion is expressed in percentage of vertical change in dimension after complete expansion. This state is reached when the weight of the material stops increasing. It may take several weeks until a material has expanded to its maximum.

In the study below, water absorption was measured after 7 days.

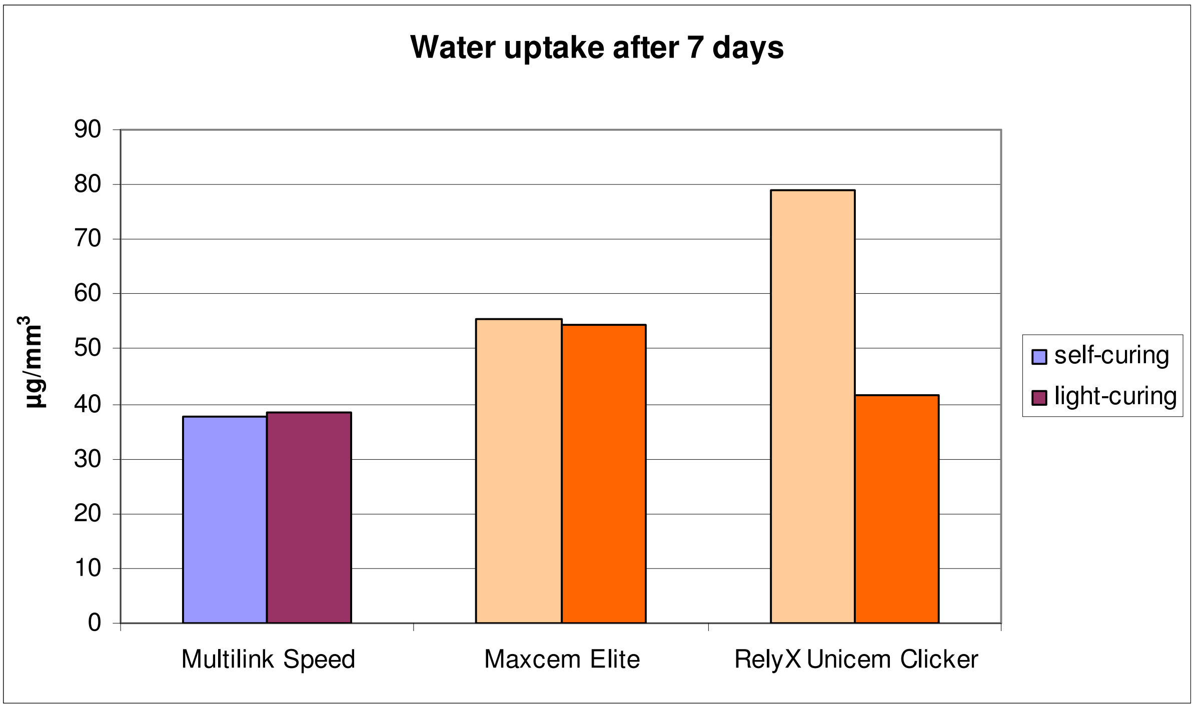

Fig. 15: Water absorption of cured resin cements after 7 days of water storage (Ivoclar Vivadent AG, Schaan, 2009)

Water absorption in composite materials results in volumetric change. In worst cases, this expansion may destroy the restoration or damage the tooth structure. Furthermore, water acts like a softening agent and may undermine the strength of the composite. The water absorption of Multilink Speed is comparatively low.

3.7 Summary

The physical data and bond strength values obtained in these studies demonstrate that Multilink Speed produces similar or better values than well-established self-adhesive resin cements. Its bonding properties are comparable to the successful SpeedCEM.

4. Clinical Studies

SpeedCEM has been used as luting material in various clinical studies. Due to its comparable composition and luting properties these studies can be referred to Multilink Speed.

R. Watzke, Schaan, Liechtenstein
Cementation of lithium disilicate and zirconium oxide restorations

F. Beuer, Munich, Germany
20 bridges made of IPS e.max ZirCAD

D. Fasbinder, Ann Arbor, USA
30 crowns made of IPS e.max CAD

C. Stanford, Iowa City, USA
30 crowns made of IPS e.max Press

The clinical outcome of these trials after more than 12 months is excellent. No or only sporadic debondings are reported. There is no evidence of marginal discoloration.

The self-adhesive resin cement Multilink Sprint, which is related to Multilink Speed, has also been tested in a number of clinical studies. The results over a longer period of observation are available for this material.

M. Ferrari; Livorno, Italy
Prospective study of clinical behavior of FRC Postec Plus fiber posts in combination with an experimental cement
In 75 patients with decayed premolars, FRC Postec Plus root posts were inserted after endodontic treatment. This was followed by a composite core build-up and the placement of IPS Empress 2 crowns. Four failures were reported over a period of observation of three years.

C. Munoz, Buffalo, USA
Clinical evaluation of a self-adhesive resin cement on all-ceramic crowns
Forty crowns made of IPS e.max ZirCAD were cemented with Multilink Sprint. A single incidence of an initial debonding was reported after a period of three years.

J. Setz, Halle-Wittenberg, Germany
Klinischer Vergleich von Komposit- und Keramik-verblendeten metallunterstützten Kronen
Thirty posterior crowns each made of a high-gold alloy were veneered with SR Adoro (composite) and IPS Inline (ceramic) and permanently incorporated using Multilink Sprint. No debonding was reported after three years.

S. Reich, Leipzig, Germany
Klinische Studie zur Bewertung einer neuartigen CAD/CAM bearbeitbaren Keramik (Blue Ceramic) zur chair-side Herstellung von Einzelzahnrestaurationen im Seitenzahnbereich
Forty molar crowns made of IPS e.max CAD were milled using the Cerec CAD/CAM unit and permanently seated with Multilink Sprint. A single incidence of debonding was reported after three years.

F. Beuer, Munich, Germany
Klinische Studie zu vollkeramischen Brücken aus CAD/CAM bearbeitbarer Lithiumdisilikatkeramik

Thirty-six crowns and 2 three-unit bridges were made using IPS e.max CAD for Everest and incorporated using Multilink Sprint. No incidence of debonding was reported after 3 years.

D. Fasbinder, Ann Arbor, USA
Clinical evaluation of a glass ceramic material for CAD/CAM crowns
Sixty-two crowns were milled from IPS e.max CAD blocks using the Cerec 3D system and permanently placed using Multilink Sprint. Two decementation were noted after two years.

Both SpeedCEM and the former brand Multilink Sprint have shown excellent performance in all clinical studies to date. The convenient handling and the easy removal of excess in particular, were very positively rated by all the study directors. Virtually no post-operative sensitivity occurred. Based on the data available today, to which we can refer, we expect Multilink Speed to stand the clinical test with regard to the range of indications described in the Instructions for Use.

5. Biocompatibility

The individual components of Multilink Speed are already used in other clinically proven dental materials and have therefore already been tested accordingly.

Test specimens of the experimental, self-adhesive luting paste were investigated with regard to cytotoxicity, mutagenicity and irritation by an independent testing body (Harlan CCR, Rossdorf, Germany).

The cytotoxic potential of the test specimens was determined by means of XTT tests (Harlan CCR #1250803; 20 March 2009). In the process, extractions in a buffering solution were brought into contact with the connective tissue cells of mice. The results of the test showed that cell viability was not reduced. No cytotoxic potential was found.

With regard to mutagenicity, the results of an Ames test (Harlan CCR; #1250806; 2 June 2009) are available. Under these test conditions, no gene mutation was triggered. This means that the risk of a mutagenic effect can also be excluded.

Furthermore, an in vitro skin irritation test was performed. The cured test samples did not cause any irritating reaction of the skin.

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