Scientific Documentation

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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 (dentin and enamel). Classical dental luting agents are cements that cure via an acid-base reaction. Today's modern dental luting agents are also often referred to as "cements", even though they are completely different from the original cements and feature different chemical curing mechanisms.

Today, many different types of restorative materials are used in dentistry. Dental luting agents therefore need to be capable of establishing a lasting bond to restorations made of various metals, alloys, resins and ceramics. Classical cements were only capable of generating a mechanical bond, i.e., anchoring restorations in a retentively prepared tooth cavity. Modern "adhesive" luting agents, however, adhere to the tooth structure (with minimally retentive surfaces). This is an important prerequisite for maintaining as much healthy tooth structure as possible by means of minimally invasive preparation techniques.

Luting agent	Description	Advantages	Disadvantages
Polycarboxylate cements	Acid-base reaction between metal oxides and polyacrylic acid	• Easy to use • Low costs	• High water solubility
Phosphate cements	Acid-base reaction between phosphoric acid and basic oxides	• Easy to use • Clinical experience spanning more than 100 years	• Low adhesion: only retentive cementation • High water solubility • Very brittle
Glass ionomer cements	Acid-base reaction between polyacrylic acid and calcium fluoraluminium silicate glass	• Release of fluoride • Clinical experience spanning more than 20 years	• Weak bond to tooth structure
Resin-reinforced glass ionomer cements	Hybrid cements: glass ionomer cements with additional light-curing components	• Combination of inorganic network and light-induced polymer network	• Mostly low adhesion to tooth structure
Luting composites	Organic monomers and inorganic filler particles; setting is based on light activated or chemically activated polymerization and cross linking	• Wear resistant • Good adhesion to the tooth structure • Resistant to oral conditions • Highly esthetic due to comprehensive shade range	• Some technique sensitivity • Complicated application

Table 1: Summary of dental luting agents

Phosphate cements, polycarboxylate cements and glass ionomer cements are considered to be classic cements and belong to the group of "dental water-based cements", the properties of which are specified by ISO 9917. Luting composites are classified as “polymer-based restorative materials” and therefore fall under 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 below:

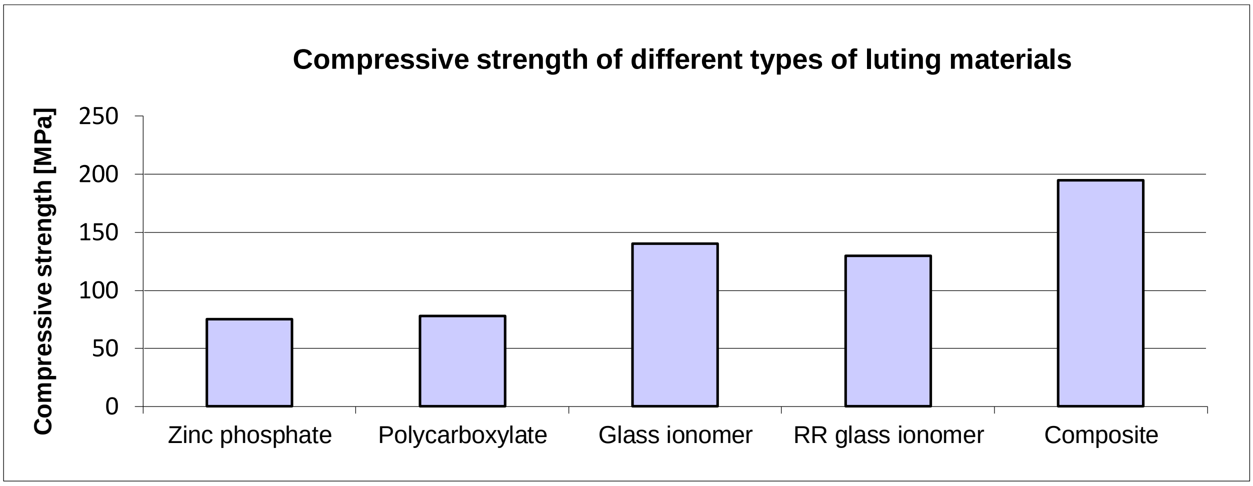


Figure 1: Average values from various literature sources (RR glass ionomer = resin-reinforced glass ionomer cement)

1.2 Luting composites

In order to obtain a strong bond between the tooth structure and the restoration, conventional luting composites are used in combination with dentin adhesives. The adhesive is able to penetrate into the dentin tubules and bind the collagen fibres of the dentin to form a hybrid layer. The effect of the adhesive is further enhanced if the dental hard tissue is etched to remove the existing smear layer. As a result, the dentin tubules and the collagen fibres of the dentin are exposed. Luting agents in turn form a chemical bond with the adhesive and therefore generate a particularly strong bond to the tooth structure. Adhesive luting permits bonding in situations 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 using non-high-strength ceramics. Minimally invasive restorative techniques, such as adhesive bridges, would be unthinkable without adhesive luting composites.

So-called self-adhesive luting composites were introduced a number of years ago. These materials no longer require a dentin adhesive. Since the conditioning step is eliminated, the treatment is shortened. Furthermore, the susceptibility to error is reduced. However, the bonding values are considerably lower than in cases where an adhesive luting system is used (see Section 3.4).

Self-adhesive, or rather, “semi-adhesive” composites use a different bonding mechanism than self-conditioning adhesives. In this case, the smear layer is not removed. Instead, it is penetrated by the reactive composite and bonded to the dentin. If good wetting is ensured, even dentin tubules are penetrated. This is visible in the form of resin tags on scanning electron micrographs (SEM). Without a hybrid layer, bonding values that meet the requirements of adhesive cementation materials cannot be achieved.

	Semi-adhesive	Adhesive
Examples	SpeedCEM (Ivoclar Vivadent) RelyX Unicem 2 Automix (3M ESPE) Maxcem Elite (Kerr)	Multilink Automix Relyx Ultimate (3M ESPE) Nexus 3 (Kerr) Duolink (Bisco) Panavia F2.0 (Kuraray)
Preparation	Retentive	Non-retentive preparation is possible
Bonding mechanism	Curing of the smear layer	Formation of a hybrid layer
Primer / Adhesive	-	Yes
Typical shear bond strength on dentin	SC 1-6 MPa DC 3- 14 MPa	Up to 30 MPa (cohesive fracture)

Table 2: Comparison of various characteristic parameters of adhesive and semi-adhesive luting composites

1.3 Polymerisation of adhesive luting composites

Most adhesive luting composites are light-curing or dual-curing. In order to achieve quick and thorough polymerization, the light of the curing device must (light-curing) or should (dual-curing) reach the composite unimpeded. However, restorations made of metals, metal alloys and opaque ceramics (e.g. zirconium oxide), are impervious to light. Such restorations are often luted using conventional phosphate cements or glass ionomer cements. These materials, however, require well-prepared retentive surfaces to establish a durable bond, which very often entails a substantial loss of tooth structure.

The latest high-performance ceramics are available in various shades and levels of translucency. Opaque ceramics as well as translucent yellowish ceramics hamper the passage of polymerization light quite considerably (Figure 3). Therefore luting materials must be able to establish a strong bond to the restoration not only via light-curing but also via self-curing alone.

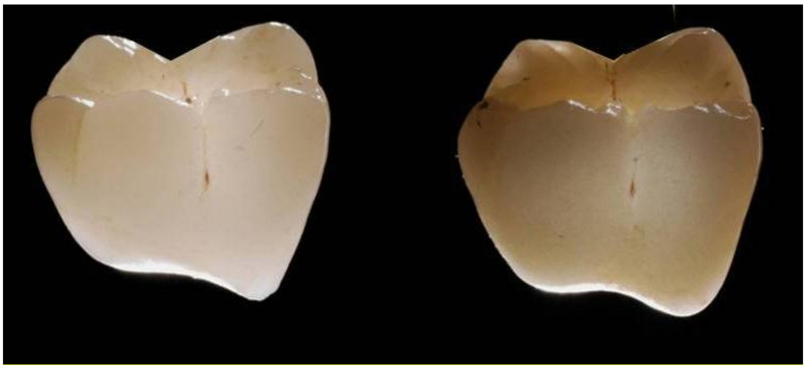


Figure 2: Translucency of lithium disilicate (LS2) and zirconium oxide (ZrO2) ceramic in transmitted light

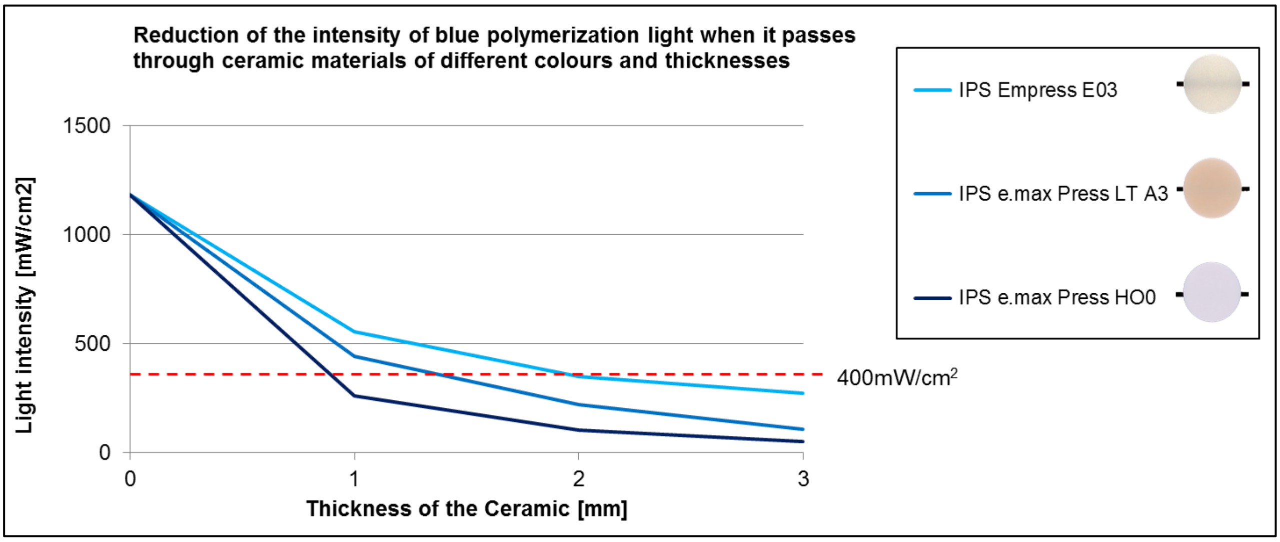


Figure 3: Reduction of the intensity of blue polymerization light when it passes through ceramic materials of different colours and thicknesses, R&D Ivoclar Viavadent AG, Schaan, 2009

1.4 Multilink Automix

Today's large variety of restorative materials with many different characteristics demands modern, universal cementation systems with well-balanced properties.

Multilink Automix is a self-curing luting composite which can be light-cured if required. It is indicated for the adhesive cementation of indirect restorations made of metal, metal-ceramic, all-ceramic and composite.
Multilink Automix is used in combination with the self-etching and self-curing Multilink Primer. This primer is responsible for establishing a strong adhesive bond to the tooth structure. The initiator contained in the primer permits chemically initiated polymerization (self-curing), which is accelerated when the composite comes into contact with the primer. Furthermore, the presence of a photo-initiator enables final polymerization with light.
In order to ensure a sound bond to precious metal and base metal alloys and to all-ceramics, such as zirconium oxide, aluminium oxide and silicate ceramics, the coupling agent Monobond Plus is recommended.

In combination with these coordinated components, Multilink Automix is suitable for a large variety of materials and indications:

Indications for Multilink Automix		Material		
		Metal (gold, titanium, etc.)	All-ceramics (silicate, zirconium oxide, aluminium oxide, etc.)	Resins, composites (also fibre-reinforced)
Restoration	Crown	+	+	+
	Bridge	+	+	+
	Inlay	+	+	+
	Onlay	+	+	+
	Root post	+	+	+

Table 3: Indications for Multilink Automix

The system composed of Multilink Automix, Multilink Primer and Monobond Plus achieves strong bond strength values in a just a few minutes. These values are responsible for good marginal integrity and avoiding post-operative sensitivity.

Selected product properties at a glance:

- Self-curing, self-etching luting composite system (composed of dentin/enamel primer, composite resin and Monobond Plus bonding agent)
- Light-curing option
- Suitable for nearly all the typical clinical cementation applications
- Practical Automix double-push syringe with mixing tip
- Paste-paste system with convenient creamy and firm consistency
- Fast and reliable setting; high bond values are achieved rapidly
- Easy removal of excess cement
- Outstanding results in investigations on marginal quality
- High mechanical strength values
- Hybrid filler technology
- Paste composition based on that of the proven Variolink II
- (New) storage possible at room temperature
- (New) four shades and additional white version
- (New) color-coordinated try-in pastes

1.5 Easy removal of excess

Optional light polymerization facilitates the removal of excess cement after the placement of the restoration. The excess cement is exposed to short intervals of light using the "quarter technique". In the process, the composite resin assumes a gel-like consistency, which enables the material to be removed in a few sections. Final light curing takes place once the excess cement has been removed.

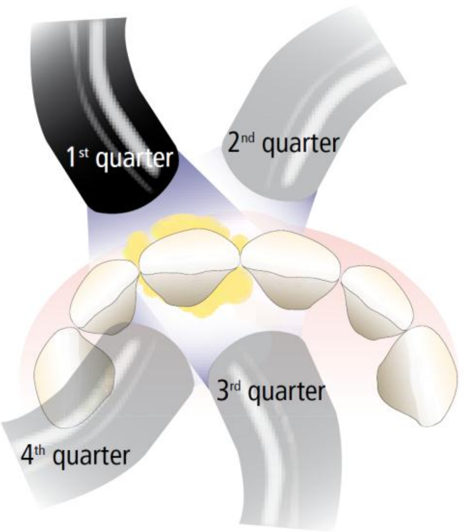
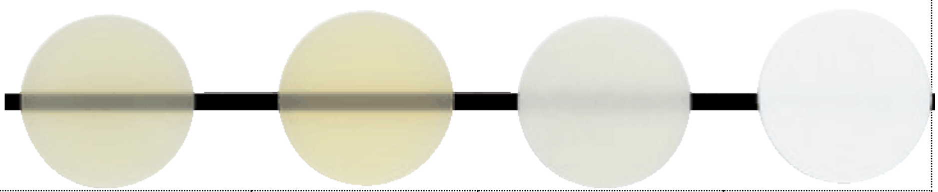


Figure 4: Removal of excess by means of the "quarter technique".
Excess can be light-activated in 1 to 3 seconds per quarter surface (mesio-oral, disto-oral, mesio-buccal, disto-buccal). Within this time, the material acquires a gel-like consistency, which makes it easy to remove with a scaler.

1.6 Four shades and try-in pastes

Multilink Automix is supplied in four shades featuring different levels of translucency.
In situations where translucent glass-ceramic crowns are used to replace both enamel and sections of dentin, the restoration may appear greyish if a translucent luting cement is used. A new “white” version has therefore been developed specifically for these cases.



Shade	Transparent	Yellow	White	Opaque
Translucency	13 %	10 %	5%	2 %

Figure 5: Translucency of Multilink Automix, R&D Ivoclar Vivadent AG, Schaan, 2012

Try-in pastes are now available, which allow the shade of the restoration to be simulated and checked. These pastes exactly correspond to the shades of Multilink Automix. The glycerine-based try-in pastes are water soluble and therefore easy to remove from the restoration and the tooth structure.

1.7 Conditioning of the restoration with Monobond Plus

Before restorative materials can be placed with adhesive cements, their contact surfaces have to be treated to render them chemically compatible with the luting composite.
Consequently, the surfaces have to be roughened in order to obtain a micro-retentive pattern. This can be accomplished either by etching with hydrofluoric acid (glass-ceramics) or by sandblasting (zirconium oxide/aluminium oxide ceramics, metal, composite resins). Furthermore, the materials must be chemically modified in order to establish a bond to the composite. Monobond Plus is a universal primer which is designed to establish an adhesive bond between luting composites (from the Variolink and Multilink product ranges in particular) and **all** indirect restorative materials (glass and oxide ceramics, metal, composite resins, fibre-reinforced composites). The application protocol is the same in each case.
Therefore, all restorative materials can be prepared for cementation with Multilink Automix with just one primer, that is, Monobond Plus.

Important:
Oxide ceramics (zirconium and aluminium oxide ceramics) must not be cleaned with phosphoric acid (e.g. Total Etch) prior to cementation. Phosphoric acid causes an irreversible reaction on the metal oxide surface. A metal-phosphate coating forms on the surface, which inhibits the coupling mechanism of the phosphonic acid methacrylate in Monobond Plus and therefore renders the primer ineffective.

1.8 Materials and compositions

Multilink Primer contains an advanced hydrolytically stable phosphonic acid acrylate, which is also used in the proven adhesives ExciTE and AdheSE.

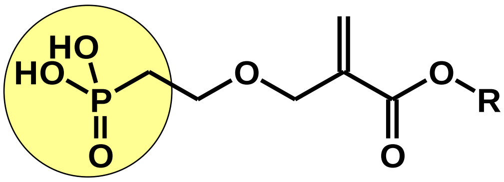


Figure 6: Phosphonic acid methacrylate. The phosphonic acid group is highlighted in yellow.

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 is protected by an Ivoclar Vivadent patent. The toxicological properties of these derivatives have been thoroughly investigated.

Multilink Automix and Multilink Primer are perfectly matched and constitute an integrated system. It is necessary to harmonize the surface properties of the composite with the hydrophilic primer formulation in order to prevent phase separation between the composite and the 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 particular monomers used in the formulation, also permits optimum wetting of most restorative materials.

1.9 Caution: Interactions

Potential interactions with other products used in the treatment should also be excluded, in order to ensure that the selected restoration can be placed safely 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. Therefore, the cavity must not be treated with alkaline agents (e.g. Airflow, which contains sodium hydrogen carbonate).

In addition, oxidizing components (e.g. oxidizing disinfectants) are known to influence the initiator systems used for chemical curing. Hydrogen peroxide and sodium hypochlorite are classic examples of this type of disinfectant. If these agents are not entirely rinsed from the tooth, adequate bonding cannot be achieved with self-curing composites.

If alcohol is used for disinfection purposes, the fact that alcohol may dry out the collagen layer should be taken into account. Excessive drying of the dentin causes the collagen layer to collapse. In this case, no hybrid layer can be obtained.

2. Technical data

2.1 *Standard – Composition (in weight %)*

Multilink Automix	Base	Catalyst
Dimethacrylates and HEMA	33.1	32.4
Barium glass filler, Ba-Al-Fluoro-Silicate glass	37.4	37.4
Ytterbium trifluoride	23.0	23.0
Highly dispersed silica	5.4	5.4
Catalysts and Stabiliser	1.0	1.8
Pigments	< 0.03	-

Multilink Primer A	
Water	85.7
Initiators	14.3

Multilink Primer B	
Phosphonic acid acrylate	48.1
Hydroxyethyl methacrylate, Methacrylate mod. Polyacrylic acid	51.9
Stabiliser	< 0.02

2.2 *Physical Properties*

EN ISO 4049:2009 Dentistry – Polymer-based restorative materials (ISO 4049:2009)
Mixing Ratio: Base:Catalyst (1:1)

		Specification	Example value Self-curing	Example value Dual-curing
Film thickness	µm	≤ 50	14	14
Flexural strength	MPa	≥ 50	98	114
Working time (23 °C)	s	≥ 60	164	Not relevant
Setting time (37 °C)	s	≤ 600	273	Not relevant
Water sorption (7 Tage)	µg/mm³	≤ 40	28	28
Water solubility (7 Tage)	µg/mm³	≤ 7.5	0	0
Radiopacity	% Al	> 100	356	356

Other physical properties

			Example value Self-curing	Example value Dual-curing
Flexural modulus	MPa	≥ 3000	4510	6195
Transparency: (Base and Catalyst)				
Transparent	%	10.5 to 13.5	13	13
Yellow	%	8.5 to 11.5	11	11
Opaque	%	1.5 to 2.5	2	2

3. Materials science and physical investigations

Before Multilink Automix was released for clinical use, the most important properties were determined.

3.1 Flexural strength

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

In the flexural resistance test, the luting composites were cured for 1 h at 37 °C and subsequently immersed in water for 24 h at 37 °C (test conducted according to ISO 4049).

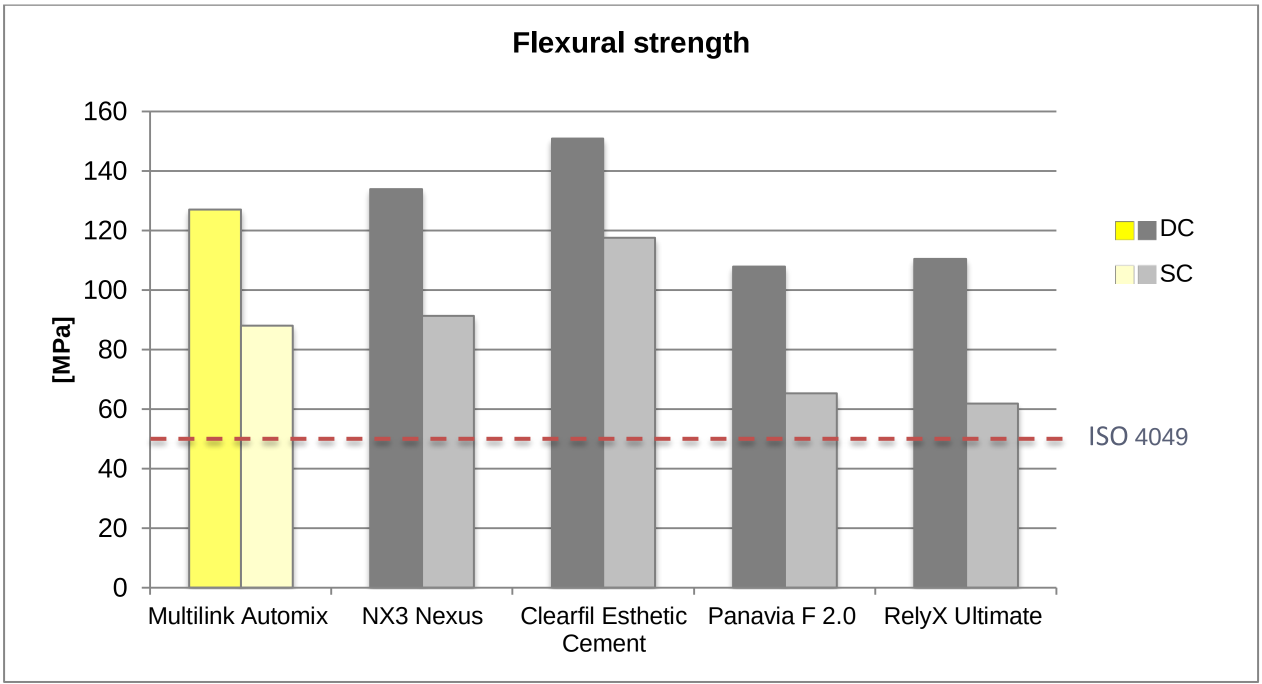


Figure 7: Flexural strength, R&D Ivoclar Vivadent AG, Schaan, 2011-2012.

Irrespective of whether the material is self-cured (SC) or dual-cured (DC), the flexural strength is clearly above that of the 50 MPa stipulated by ISO 4049.

Additional investigations compared flexural strength and modulus at 1 hour and 24 hours after curing. Multilink attains its high strength, very quickly even if it is simply self-cured. This aspect is particularly important in areas where light cannot penetrate.

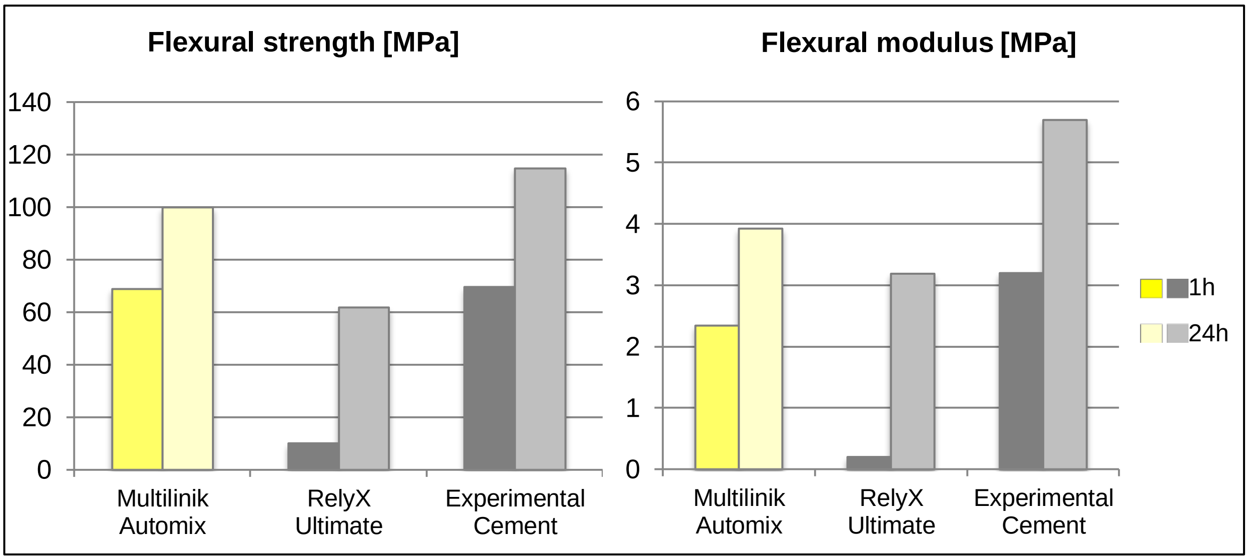


Figure 8: Flexural strength and flexural modulus after self-curing after 1 h and 24 h (Gianasmidis 2012)

An external investigation conducted by the Dental Advisor confirmed the high flexural strength of Multilink Automix under different light-curing conditions.

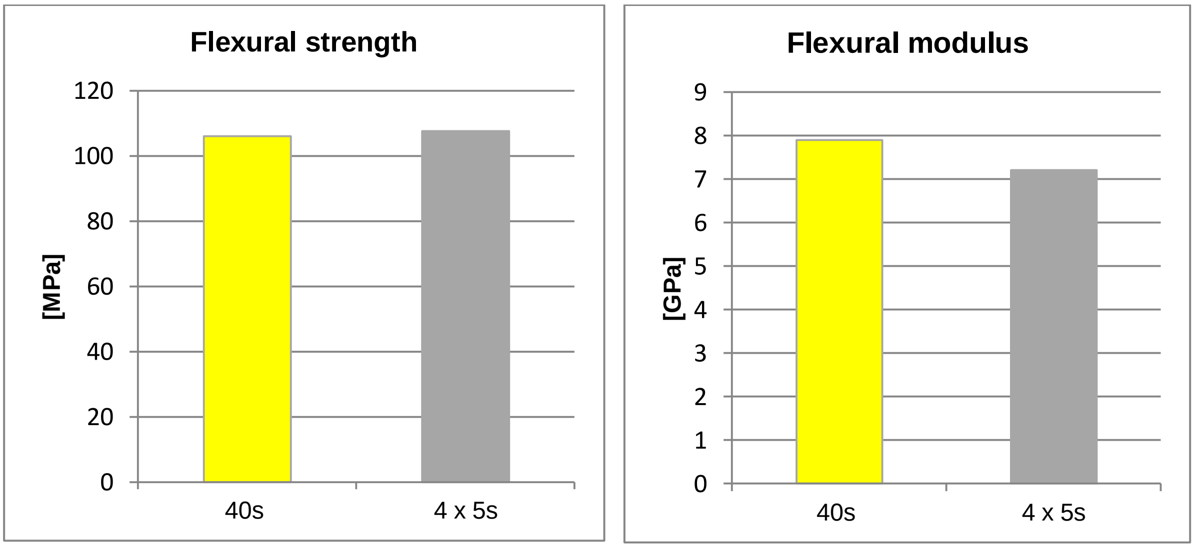


Figure 9: Flexural strength and flexural modulus; Dental Advisor 2010. (Yapp 2010) Light curing for 40 seconds from above or 4x 5 seconds from the sides.

The flexural strength measurements show that Multilink attains its high strength quickly and irrespective of the light-curing mode.

3.2 Radiopacity

The radiopacity of dental materials allows the tooth-coloured restorative material to be distinguished from the natural teeth or caries on X-rays. The radiopacity of a material is determined (in comparison with aluminium) according to ISO 4049. The radiopacity of Multilink Automix is clearly much higher than that of enamel and dentin. Consequently, Multilink Automix is easy to distinguish from the natural tooth structure on X-rays.

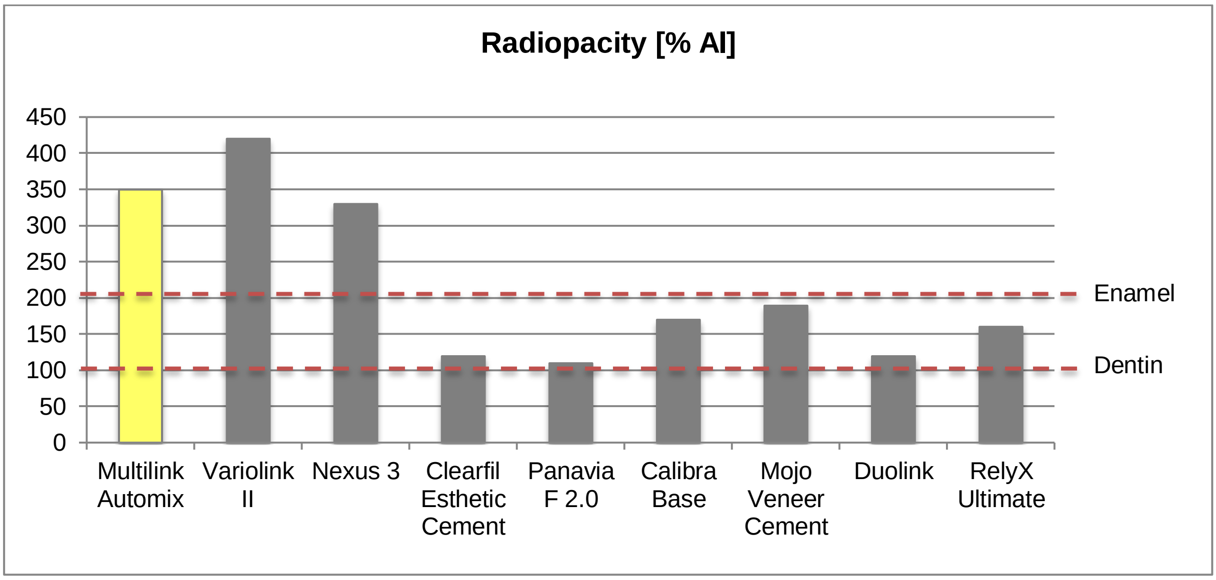


Figure 10: Radiopacity (according to ISO 4049), R&D Ivoclar Vivadent AG, Schaan, 2011-2012

3.3 Water absorption and water solubility

In order to ensure adequate wetting of the hydrophilic dental material, the luting composite must also exhibit hydyrophilic properties. The higher the hydrophilicity of a composite, the higher is its tendency to absorb water and to swell.

The increase in volume due to swelling may damage the restoration. As a result, water absorption must be kept to a minimum. Therefore, ISO 4049 limits the maximum acceptable water absorption to 40 µg/mm³. Examinations conducted according to this standard show that Multilink Automix (either self-cured or dual-cured) absorbs a minimal amount of water. Water absorption remains clearly below the specified ISO limit. Furthermore, the water solubility of a luting composite should be as low as possible, so that the material remains stable in the oral cavity. In ISO 4049 the limit for water absorption is defined at 7.5 µg/mm³. Multilink Automix also complies with this standard, irrespective of the curing mode used, and it does not show any measurable water solubility in standardized tests.

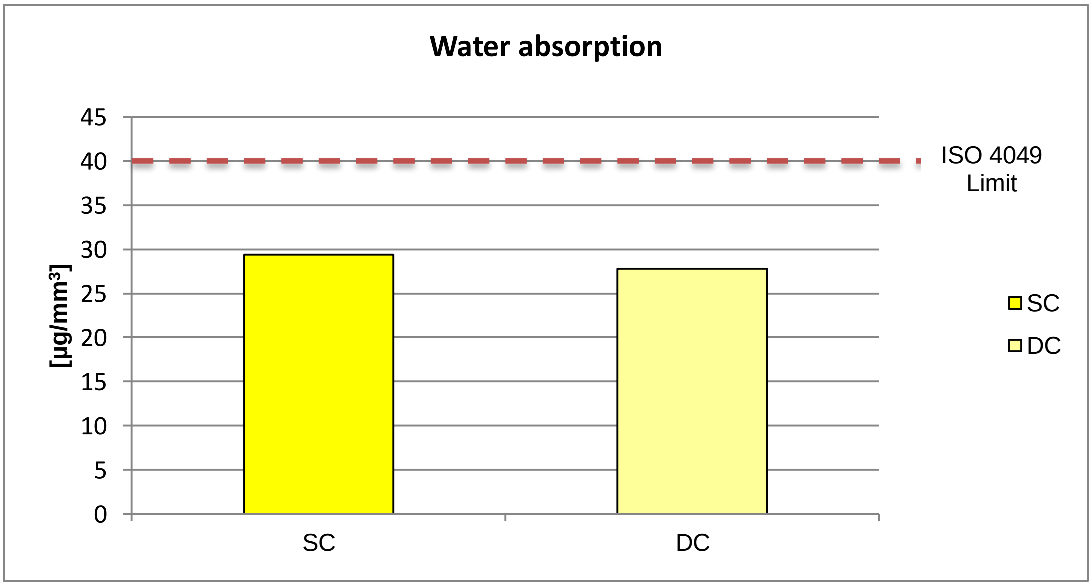


Figure 11: Water absorption of Multilink Automix, R&D Ivoclar Vivadent AG, Schaan, 2012

Whether Multilink Automix is self-cured (SC) or dual-cured (DC), water absorption is far below the ISO 4049 limit of 40 µg/mm3.

3.4 *Adhesion to dentin and enamel*

A luting composite must be capable of establishing a strong and long-lasting bond between the tooth structure and the restorative material, which are very different types of substrates.
The bonding performance of luting composites to dental hard tissue and restorative materials can be examined by determining the shear bond strength (SBS) or the tensile bond strength (TBS). Since the results are highly dependent on the test setup and the test procedure (e.g. the diameter of the specimens), the results of different test series can only be compared to a limited extent (Scherrer 2010; Heintze and Rousson 2011).

3.4.1 Shear bond strength

Multilink Automix shows well-balanced adhesion values on enamel and dentin, irrespective of the curing mode used: self-cure (SC) or dual-cure (DC). Thus, the amount of curing light available does not play a substantial role regarding final adhesion.

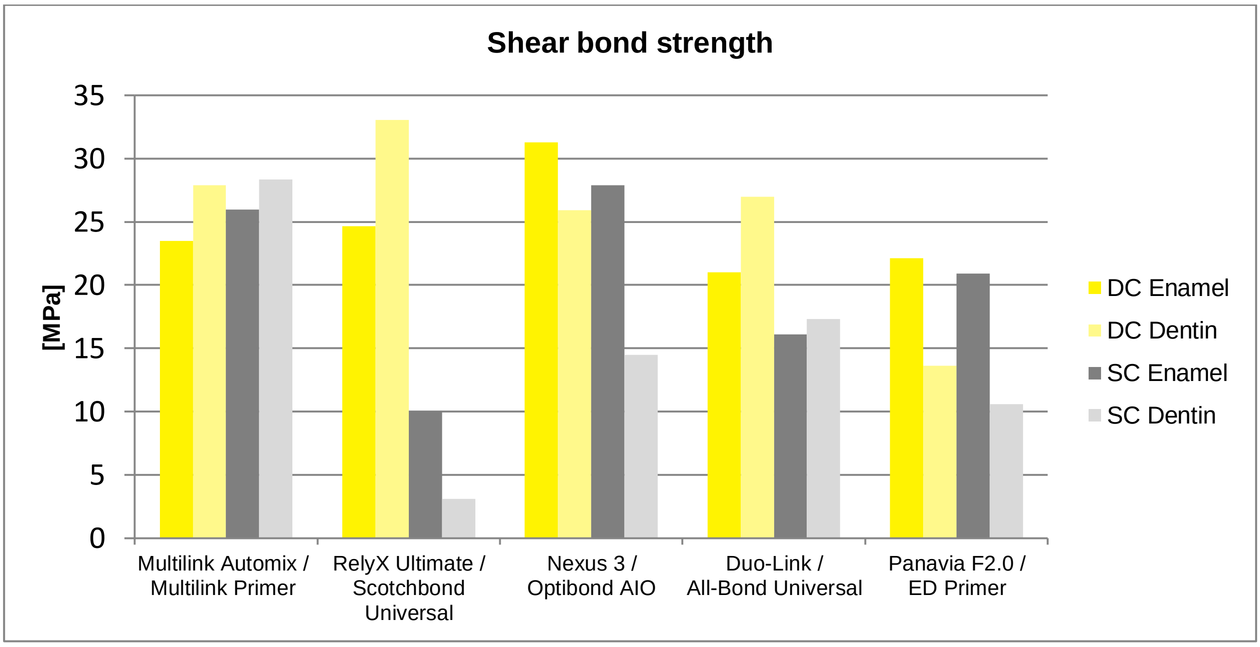


Figure 12: R&D Ivoclar Vivadent AG, Schaan, 2012, application according to Instructions for Use.

Cylinders of polymerized Tetric EvoCeram were cemented to specimens made of bovine dentin or enamel. The cement was either self-cured or dual-cured. The shear bond strength was measured after 24-h immersion in water at 37 °C.

In a shear bond strength investigation by the Dental Advisor in 2010, using the Ultradent method, Multilink Automix also showed well-balanced adhesion on human enamel and dentin under various light-curing conditions.

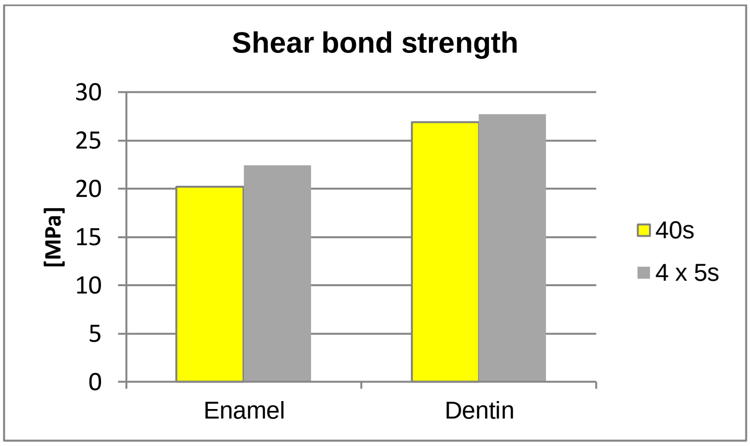


Figure 13: Shear bond strength (Ultradent) on enamel and dentin, Dental Advisor 2010 (Yapp 2010). Light curing for 40 seconds from above or 4x 5 seconds from the sides.

3.4.2 Tensile strength

As an alternative to the shear bond strength, the tensile strength can be determined in order to quantify the adhesion of a luting material. Tensile strength measurements should demonstrate less scattering than shear bond strength measurements, as they are less dependent on the surface structure of the material. For the micro-tensile bond strength (mTBS) measurements, the cementation material is applied onto a prepared, flat, retention-free substrate block (enamel, dentin or restorative material) according to manufacturer instructions. Subsequently, another block of a previously defined size is adhesively bonded to the block. The tooth structure and composite block are then cut into rectangular specimens, perpendicular to the adhesive surface, using a diamond saw. The tensile stress is then determined using a suitable universal testing machine.

In a study by Hangzhou University (China) and the University of Kiel (Germany) published in 2010, the tensile strength of various luting composites was measured on human dentin. Since the pressure of the fluid in the dentin tubules (pulpal pressure, pp) can influence the bond strength, the pulpal pressure was simulated in this study. The influence of aging on the specimens after 1 day of immersion in water at 37°C and after 30 days and 5,000 thermal cycles (TC) and after 90 days and 15,000 thermal cycles was measured.

The tensile strength of Multilink Automix remained almost unchanged during the application of simulated pulpal pressure. The tensile strength of Multilink Automix decreased only minimally as a result of accelerated aging by thermocycling.

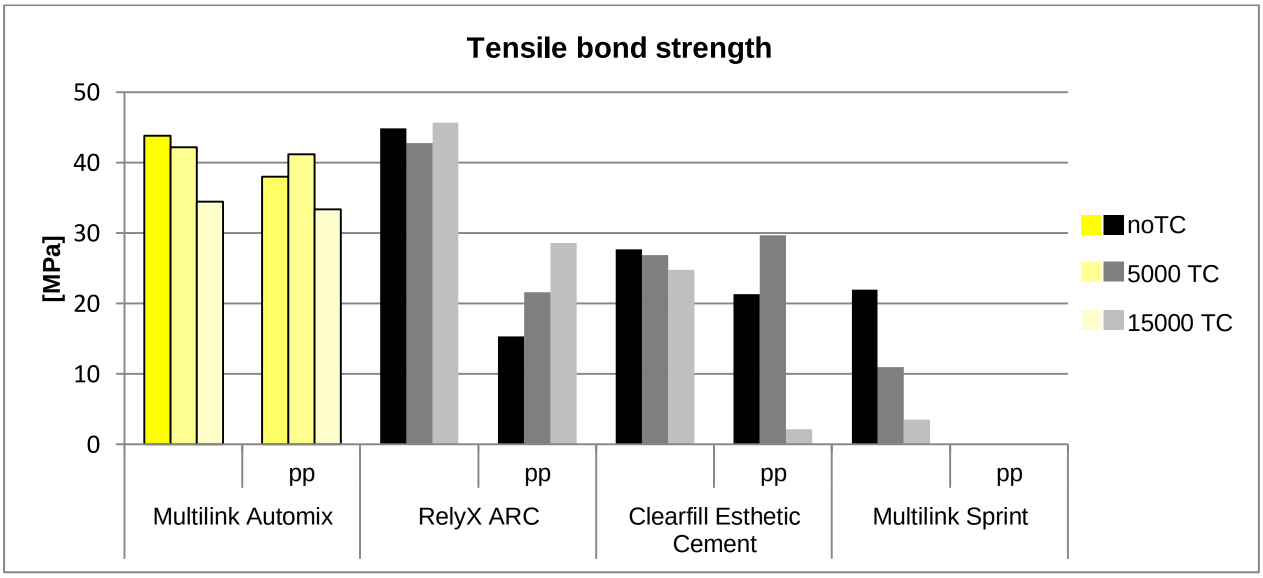


Figure 14: Tensile strength (mTBS) on dentin during the application of simulated pulp pressure (pp) and after thermocycling (TC) (Lin 2010)

3.5 Adhesion of Multilink Automix on various substrates

Multilink Automix is a multi-use luting composite. Therefore, it must be capable of bonding to a wide range of dental materials. Apart from its ability to bond with different types of ceramics, such as glass-ceramics and oxide ceramics, the material's ability to adhere to metal was also examined.

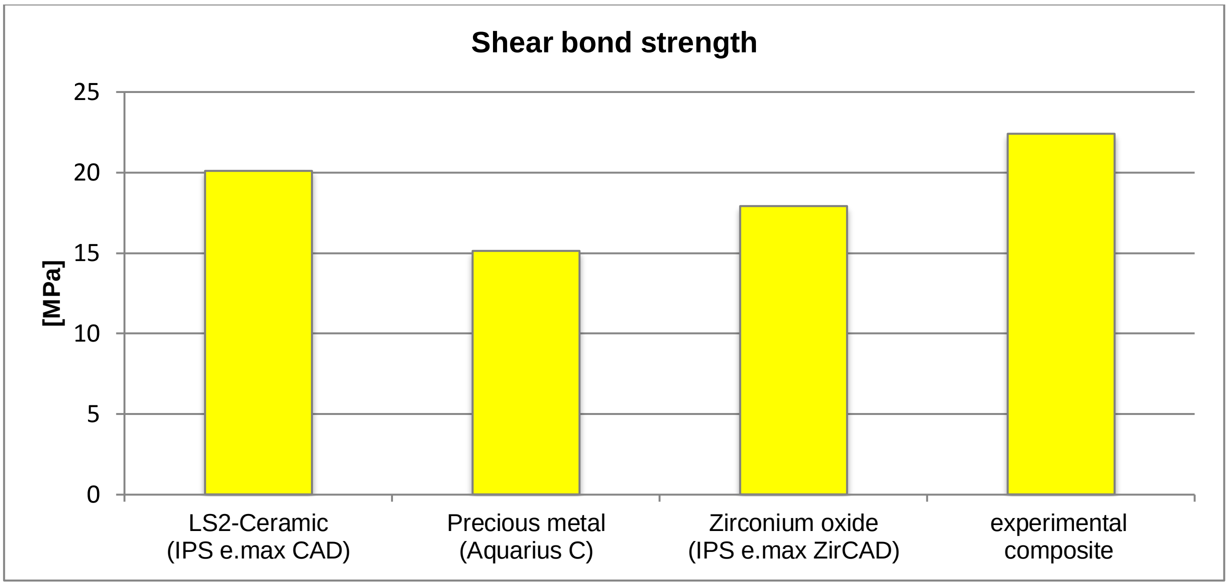


Figure 15: Shear bond strength of Multilink Automix on ceramics, metal and composites. R&D Ivoclar Vivadent AG, Schaan, 2012

The restorative materials were conditioned with Monobond Plus according to the Instructions for Use. Specimens measuring 4 mm in diameter were used. Therefore, the results cannot be directly compared with those obtained with the Ultradent method.

In the external study headed by Prof. Kern of the University of Kiel, the tensile bond strength of Multilink Automix on various restorative materials was examined in combination with Monobond Plus. The test specimens were measured after 3 days of immersion in water and after 160 days of immersion in water plus 75,000 thermal cycles (simulated aging).

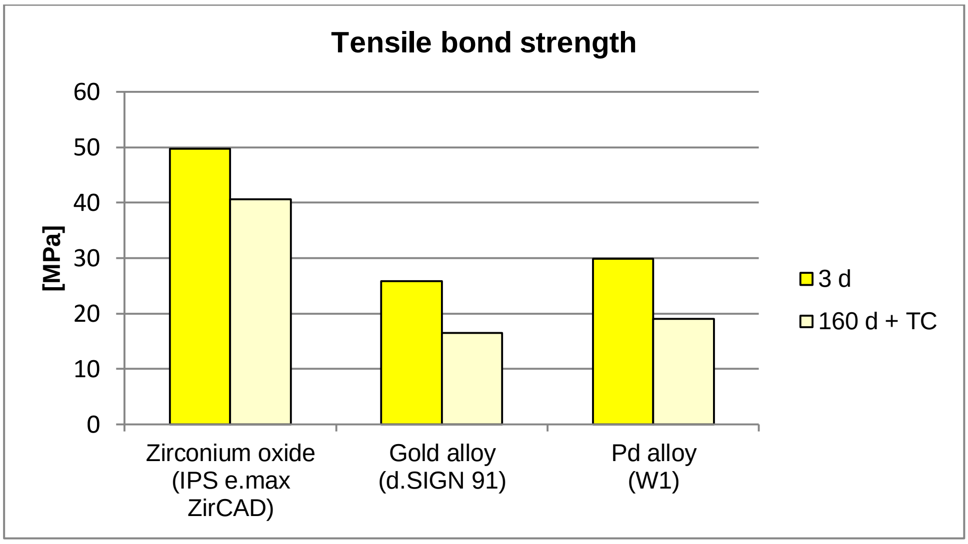
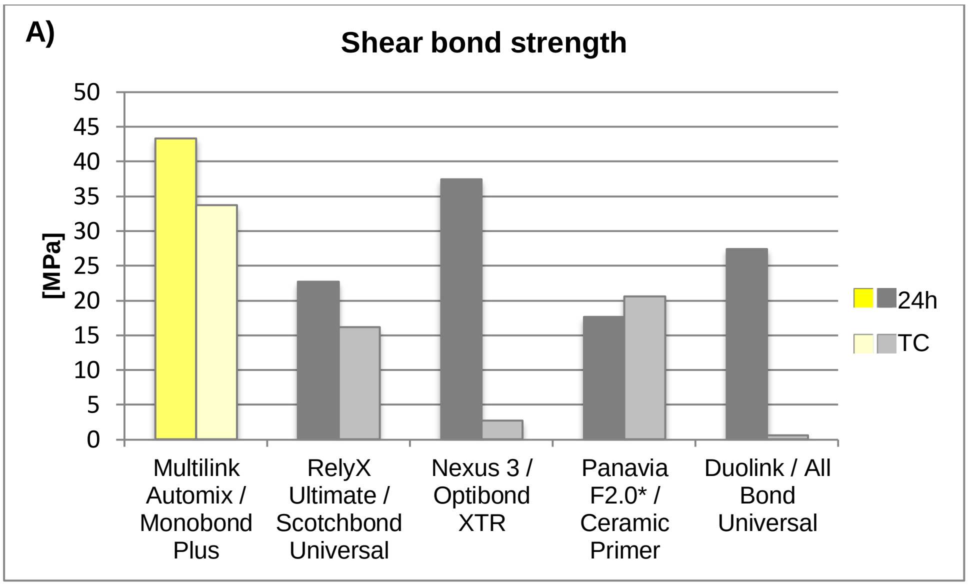


Figure 16: Tensile bond strength after 3 days and after 160 days and 75,000 thermal cycles, Prof. Kern, University of Kiel, 2008

The highest bond strength values were measured on IPS e.max ZirCAD zirconium oxide ceramics. Lower values were measured on the alloys d.SIGN 91 (gold alloy) and W1 (Pd alloy).

3.5.1 Adhesion to lithium disilicate glass-ceramic (IPS e.max CAD)

The adhesion of different luting composites on IPS e.max lithium disilicate glass-ceramic was investigated using shear bond strength and tensile strength tests. The lithium disilicate surface was etched with hydrofluoric acid and conditioned with the dedicated ceramic primers. The samples were immersed in water for 24 h at 37 °C. As a comparison, aging of the restorations was simulated with 10,000 thermal cycles.
In both of the tests, Multilink Automix demonstrated high adhesion values and only a minimal decrease in the bonding performance after simulated aging.



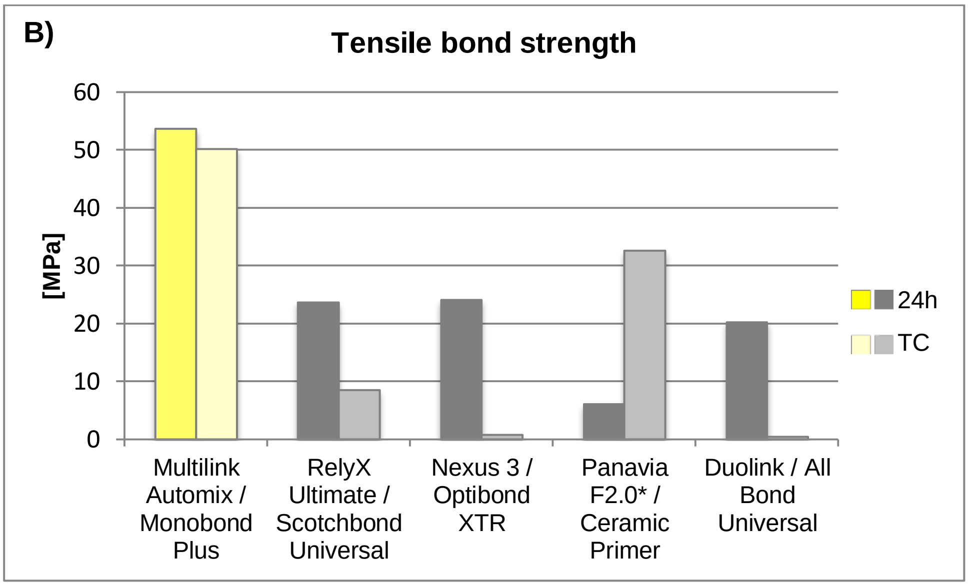


Figure 17: A) Shear bond strength (SBS, Ultradent) and B) tensile bond strength (TBS) on IPS e.max lithium disilicate glass-ceramic; R&D Ivoclar Vivadent AG, Schaan, 2012, application according to the Instructions for Use.
*) Post-curing increases the adhesion of Panavia F2.0

The strong adhesion of Multilink Automix to lithium disilicate glass-ceramic has also been confirmed in axial tensile tests by Prof. Kern, University of Kiel. IPS e.max CAD test specimens (diameter of approx. 6 mm, thickness of min. 3.4 mm) were etched with hydrofluoric acid and subsequently treated with the corresponding ceramic primer according to the Instructions for Use.

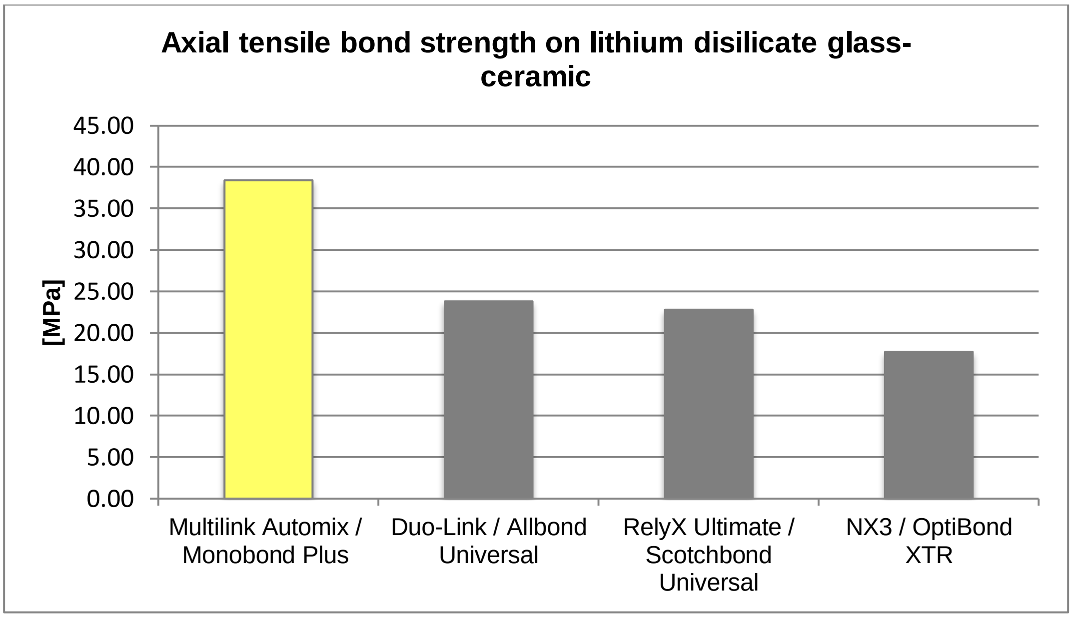


Figure 18: Axial tensile bond strength (TBS), (Kern and Lehmann 2012)

Compared with the other tested luting composites, Multilink Automix achieved the highest axial tensile bond strength results on IPS e.max CAD test specimens in combination with Monobond Plus.

3.5.2 *Shear bond strength on zirconium oxide ceramics*

In a study headed by Prof. Irie, Okayama University, the shear bond strength of various luting composites on zirconium oxide ceramic (Lava™ Zirconia, 3M ESPE) was compared. The shear bond strength on 3.6-mm test specimens was determined according to ISO TR 11405: 2003. Consequently, the results cannot be directly compared with other shear bond strength values.

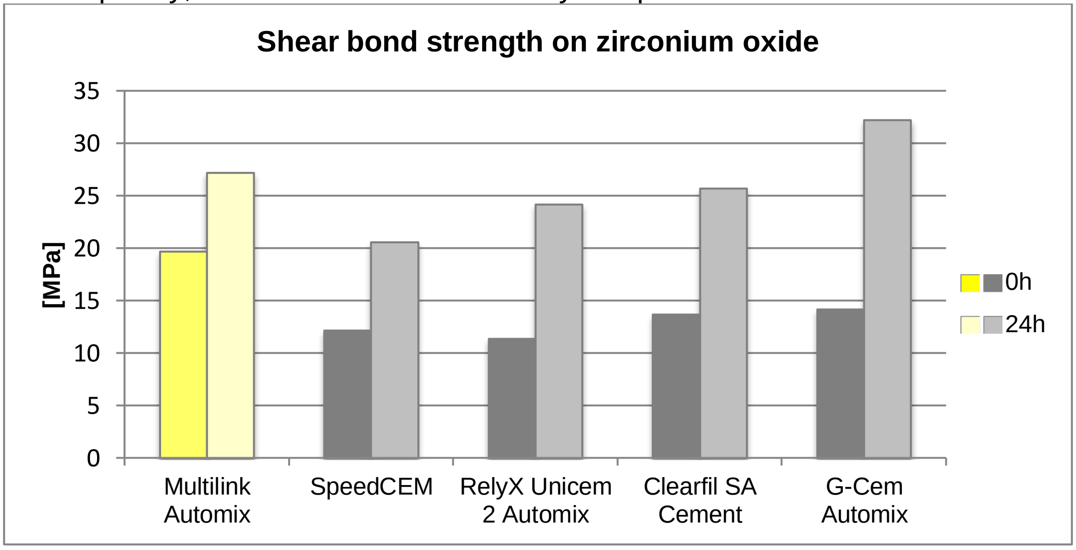


Figure 19: Shear bond strength on zirconium oxide ceramic (Lava™ Zirconia, 3M ESPE), Prof. M. Irie, Okayama, Japan (2010) after 24-h storage.

In comparison with the other luting composites examined, Multilink Automix showed the highest initial bond strength on zirconium oxide ceramics.

3.6 Degree of polymerization

The properties of luting composites depend on the extent to which they are cured. In a study conducted at the University of Brescia, Italy, the degree of polymerization of four luting composites was determined using spectrometry. The materials were light-cured through 2-mm, 3-mm, and 4-mm thick onlays made of Signum composite A2 (Heraeus) using two different curing lights (Bluephase C8, Bluephase G2). As a result of the decreasing light intensity, the degree of polymerization decreased as the onlay thickness increased. Nevertheless, Multilink Automix achieved a very high degree of polymerization of more than 70% under all conditions.

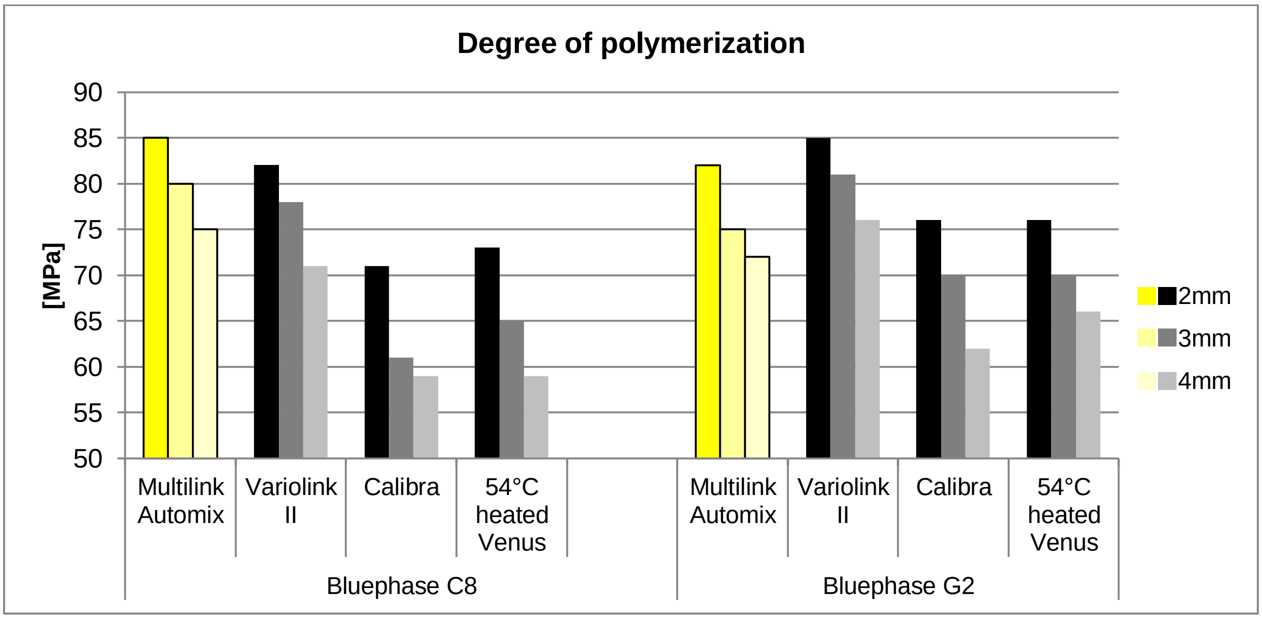


Figure 20: Degree of polymerization (Grigolato 2009)

3.7 Materials durability

Even when Multilink Automix is only self-cured it achieves a high flexural strength very rapidly (see Figure 8). As a result, the material is more resistant to the development of stress cracks during thermal loading than less stable luting composites.
After the specimens had been cured for one hour, they were subjected to 10,000 thermal cycles. The Multilink Automix specimens did not develop any stress cracks. However, pronounced cracks occurred in the RelyX Ultimate specimens.

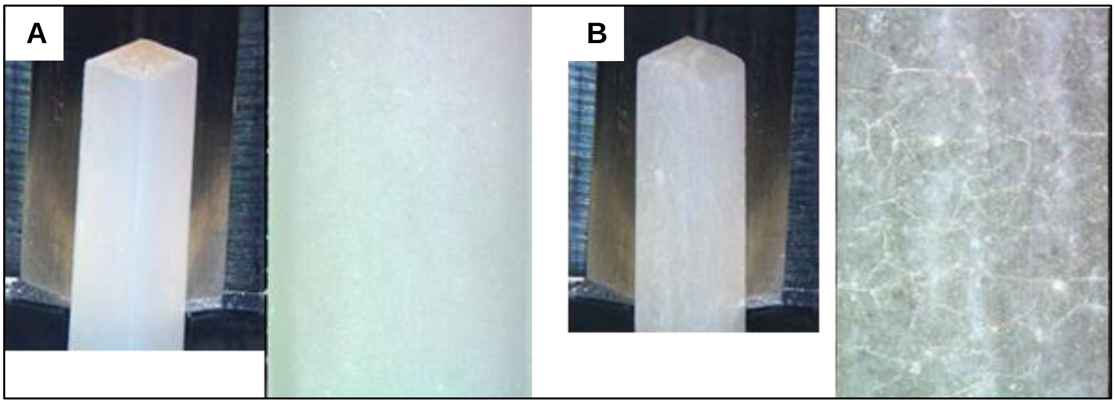


Figure 21: Stress cracks after Thermocycling. R&D Ivoclar Vivadent AG, Schaan, 2012. Multilink Automix specimen (A) did not develop any stress cracks, while RelyX Ultimate (B) showed pronounced stress cracks.

3.8 Fluorescence

When natural teeth are illuminated with short wave light, they appear blue-fluorescent. In order to achieve a true-to-life appearance, restorative materials must also demonstrate tooth-like fluorescence. All four versions of Multilink Automix exhibit balanced tooth-like fluorescence when they are illuminated with short wave light (figure 22A), while other luting composites show significantly less fluorescence (figure 22B).

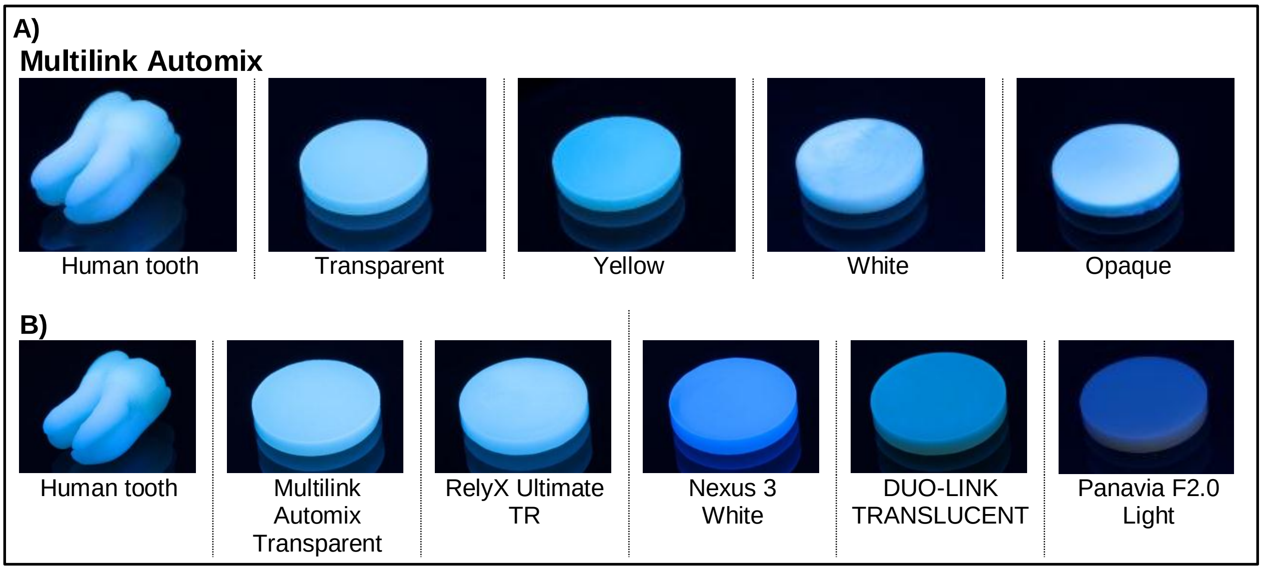


Figure 22: Fluorescence of luting composites compared with that of natural tooth structure. A) All the Multilink Automix materials show the same level of fluorescence. B) Comparison of the fluorescence of different luting materials. Ivoclar Vivadent AG, Schaan, 2012.

3.9 Margin quality

IPS e.max Press crowns were luted to 10 extracted human molars with either Multilink Automix (5) or RelyX Unicem (5). After 24-h immersion in a water bath at 37 °C, the prepared teeth were subjected to 5,000 thermal cycles. The root tips were subsequently sealed and the prepared teeth were immersed in basic fuchsin solution for 24 h. After embedding, the teeth were cut lengthwise in order to evaluate four surfaces. Three people examined four surfaces of each tooth for dye penetration into the enamel and dentin at 12.5-fold magnification.

The crowns cemented with Multilink Automix showed hardly any staining at the margins after 5,000 thermal cycles, which is a sign of excellent margin quality. In comparison, crowns cemented with RelyX Unicem showed significantly more dye penetration into the enamel. Concerning dye penetration into dentin, the difference between Multilink Automix and RelyX Unicem was statistically not significant.

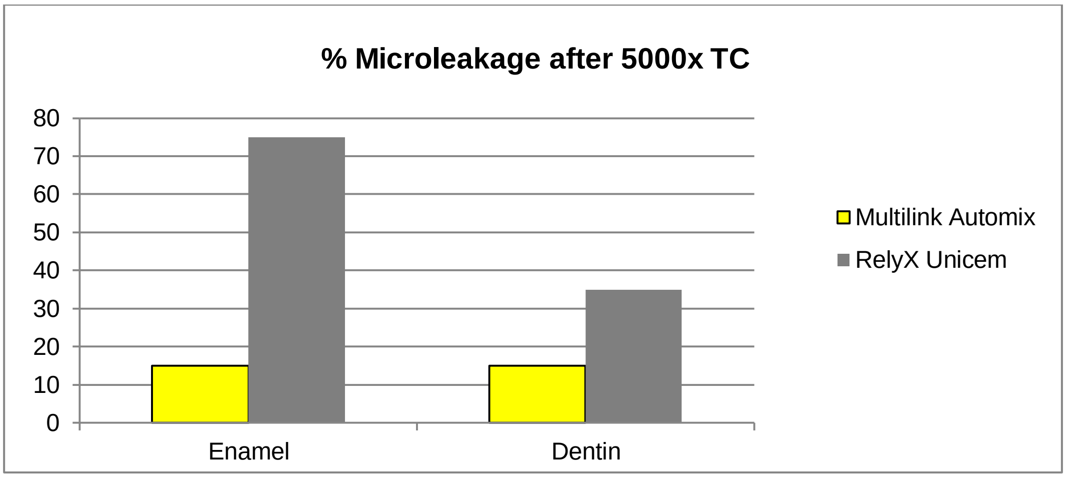


Figure 23: Microleakage. Staining after 5,000 thermal cycles. (Antonson 2011)

4. Clinical studies

So far, Multilink has been used for the cementation of restorations in several clinical studies, the results of which have been documented. These studies attest to the outstanding clinical performance of Multilink Automix in various areas of application.

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

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

Objective:
Clinical long-term study over a period of 48 months, which compared the performance of metal-ceramic restorations to that of Empress 2 all-ceramic restorations, both cemented with Multilink

Method:
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 post&core build-ups were adhesively cemented using Multilink.

Results:
In only 2 (2.7%) of 74 restorations, were postoperative sensitivities noted (one inlay with the cavity area near the pulp and one onlay with postoperative sensitivity to pressure). Both sensitivity episodes did not last longer than 36 hours.

- In contrast to other self-etching primers, no desquamation of the epithelial tissue was noted.
- No tissue reaction of the gingiva in the form of reddening, bleeding, oedema, or whitish surface burns occurred.
- No loss of retention was noted after 48 months.

(Salz and Arnetzl 2007)

4.2 Report on the clinical suitability of crowns and bridges made of lithium disilicate – Results after 4 years

Head of study:
Dr. F. Beuer, Ludwig Maximilian University, Munich, Germany

Objective:
Assessment of the clinical suitability of crowns and bridges made of lithium disilicate.

Method:
Prospective clinical study involving 15 full-contour or partly reduced IPS e.max CAD restorations which were adhesively luted using Multilink Automix

Results:
After an observation period of 4 years, the survival rate was 100%. In addition, there were no instances of hypersensitivity and no incidents of debonding.

(Richter 2009; Beuer 2011)

4.3 Clinical evaluation of chairside lithium disilicate CAD/CAM crowns

Head of study:
Prof. Dr J. Fasbinder, University of Michigan, Ann Arbor, MI, USA

Objective:
Clinical evaluation of lithium disilicate crowns, fabricated chairside

Method:
Twenty-three IPS e.max lithium dicilicate crowns (premolars and molars) were fabricated chairside with a CEREC 3D-milling unit and adhesively cemented using Multilink Automix.

Results:
One week postoperatively, the participants described 13.0% (3/23) of the crowns as slightly sensitive. However, 3 weeks after treatment all participants were symptom-free. No patient required treatment for sensitivity.

Twenty-two of 23 cases could be evaluated at the 36-month recall, 21 at the 48-month recall. One crown debonded after 36 months and was rebonded using Multilink Automix.

(Fasbinder 2010)

4.4 Prospective clinical evaluation of all-ceramic crowns at 36 months

Head of study:
Prof. Dr D. A. Felton, University of North Carolina, Chapel Hill, NC, USA

Objective:
Evaluation of the long-term performance of all-ceramic posterior crowns cemented with Multilink

Method:
Twenty-three patients received 33 posterior all-ceramic lithium disilicate single unit crowns (Eris / Empress 2, Ivoclar Vivadent), bonded within 3 weeks of tooth preparation with Multilink.

Results:
Twenty-nine of 33 teeth (87.8%) exhibited no symptoms or radiographic evidence of pulpal pathology, one tooth required root canal treatment (RCT) prior to crown delivery, three required RCT after crown cementation. No other experimental or control teeth exhibited any postoperative sensitivity, nor evidence of peri-apical pathology at the 12-month interval. There was a loss of proximal contact on 5% of the crowns.

(Felton 2010)

4.5 Randomized clinical trial on single retainer, all-ceramic resin-bonded fixed partial dentures: Influence of the bonding system after up to 55 months

Head of study:
Prof. Dr M. Kern, University of Kiel, Germany

Objective:
Clinical evaluation of anterior zirconia-based adhesive bridges cemented with Multilink Automix

Method:
Fourteen anterior zirconia cantilever adhesive bridges were placed using Multilink Automix with Metal/Zirconia primer.

Results:
After 20.8 months, one debonding occurred due to traumatic impact. The restoration could be successfully re-bonded with the original bonding system. If these debonding incidents are considered (partial) technical failures, the overall three-year survival rate calculated with SPSS software according to Kaplan-Meier is 92.9%. If only the final loss of a bridge is considered a failure i.e. rebonded bridges are considered successful, the three-year survival rate increases to 100%.

(Sasse 2012)

4.6 Clinical performance and fit of a milled ceramic crown system

Head of study:
Prof. Dr D. Nathanson, Boston University, MA, USA

Objective:
Evaluation of the marginal quality and clinical behaviour of a new lithium disilicate all-ceramic crown system

Method:
Thirty-one IPS e.max CAD LS_2 crowns (23 anterior crowns, 8 posterior crowns) were placed in 14 patients. They were veneered with IPS e.max Ceram and adhesively cemented using Multilink or Multilink Automix. Marginal quality and clinical performance were assessed.

Results:
Mean in-vitro marginal fit was 67.92 (+/-25.2) µm. Clinical fit was ranked Alpha for all restorations. Three anterior single crowns required re-fabrication for improved colour. Seventeen (55% of all) were evaluated at 2-3 years. One (posterior) restoration fractured after requiring RCT through the crown after 12 months.

(Nathanson 2008)

4.7 Clinical behaviour of all-ceramic single-unit restorations cemented with Multilink Automix at two years

Head of study:
R. Watzke; Ivoclar Vivadent, Schaan, Principality of Liechtenstein

Objective:
Evaluation of all-ceramic single-unit restorations (IPS e.max) cemented with Multilink Automix after 2 years of clinical observation

Method:
Fifty-five single-unit restorations (IPS e.max) were adhesively luted with Multilink Automix. After two years of clinical service, all the restorations were evaluated based on the FDI criteria for the evaluation of indirect restorations (Hickel et al. 2007). The FDI criteria include the evaluation of esthetics (A) as well as functional (B) and biological (C) properties. Criteria concerning the restorations' marginal quality were semi-quantitatively evaluated as a percentage of the total margin length (SQACE). For statistical analysis, SPSS 19.00 was used.

Results:
After two years, all the restorations adhesively luted with Multilink Automix were ranked Alpha with regard to their clinical performance. No loss of retention and no postoperative hypersensitivity were reported.

(Watzke and Peschke 2012)

4.8 Conclusion

Clinical studies on Multilink have been conducted for more than 10 years. They confirm the excellent clinical performance of Multilink when used for the cementation of ceramic crowns, bridges and inlays as well as metal-ceramic restorations. Moreover, the results of previous studies show that Multilink Automix is excellently suitable for the cementation of root posts (Ferrari 2001; Grandini 2002; Monticelli 2003).

5. Biocompatibility

5.1 Introduction

Medical devices are subject to very strict requirements, which are designed to protect patients and operators from any potential biological risks. ISO 10993 "Biological evaluation of medical devices“ defines how the biological safety of a medical device is to be evaluated. Furthermore, dental medical devices are subject to ISO 7405 “Preclinical evaluation of biocompatibility of medical devices used in dentistry”.
The biocompatibility of Multilink Automix and Multilink Primer has been examined according to these standards.

5.1.1 Cytotoxicity

Cytotoxicity refers to the destructive action of a substance or mixture of substances on cells. The XTT assay is used to examine whether or not a substance causes cell death or inhibits cell proliferation in a cell culture. The XTT_{50} value refers to the concentration of a substance which reduces the cell number by half. The lower the XTT_{50} concentration of a substance, the more cytotoxic it is..

Multilink Automix:
Mixed Multilink Automix that is dispensed from the double push syringe with mixing tip polymerizes within a few minutes. Therefore, the XTT assay was carried out with extracts of fully polymerized Multilink Automix. These extracts did not show any cytotoxicity in the XTT assay (1).

Multilink Primer:
Primer A mainly consists of water with low concentrations of initiators. These initiators have been used in dental products for many years and are not critical in these concentrations.
As is to be expected on the basis of its composition Primer B has cytotoxic potential, which has been confirmed by XTT assay (2-4). Nevertheless, the XTT_{50} concentration is clearly below that of many types of monomers used in the dental industry. As the primer cures within a few minutes after the components A and B have been mixed, the cytotoxic effect of Primer B is uncritical.

5.1.2 Genotoxicity

Genotoxicity refers to the capability of a substance or a mixture of substances to damage genetic material. Multilink Automix and Multilink Primer have been examined regarding their potential gene changing properties in a number of mutagenicity tests. Multilink Automix (5) and Multilink Primer (6-11) did not show any mutagenic potential in these tests.

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Contents:	Dr. Erik Braziulis
Edition:	November 2013
Replaces Version:	December 2012