



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 essentially rely on mechanical retention to hold the restoration in place. However, in the past few decades an increasing trend towards tooth preparation procedures that minimize or avoid the loss of healthy tooth structure has been noticeable. An adhesive bond is needed where the mechanical retention is not sufficient. 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 an adhesive 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 (e.g. IPS e.max CAD).

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 a 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, as a consequence, are clearly visible if the cement joint is exposed. In unfavourable situations, loss of material and discolouration may occur in the area of the cement joint.

Glass-ionomer cements have been further developed to produce a new group of materials known as hybrid cements. In addition to glass-ionomer components, hybrid cements 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 luting composites*

This category of materials establishes 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 are achieved. These tooth-coloured materials are not visible if the cement joint is exposed. 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. The new Monobond Etch & Prime enables dental professionals to etch and silanate glass-ceramic surfaces in one easy step. 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 | <ul style="list-style-type: none"> - Easy handling - Easy removal of excess - Unproblematic removal of the restoration | <ul style="list-style-type: none"> - Minimally invasive preparation techniques can be used - Excellent adhesion to the tooth structure - Stability - Low solubility in the oral environment - Low wear - Esthetics |
| Dis-advantages | <ul style="list-style-type: none"> - Retentive preparation - Solubility - Limited or no adhesion to tooth structure - Increased wear - Unsatisfactory esthetics | <ul style="list-style-type: none"> - Excess removal can be difficult in some cases - 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 efficiency

Self-adhesive luting composites meet the demand for a material that combines the advantages of conventional and adhesive luting materials in a single product.

Simplicity: Even though composite-based luting materials offer overriding benefits, their application involves a great deal of effort (isolation, application of additional steps and products such as dentin adhesives and primers). It is therefore desirable that composites show self-adhesive properties and are capable of bonding to both the tooth structure and the restorative material, as this reduces the number of steps involved in their application and eliminates potential sources of error.

SpeedCEM Plus is a self-adhesive resin cement that bonds to dentin and certain restorative materials and enables dentists to seat e.g. zirconium oxide restorations or restorations on zirconium oxide or titanium implant abutments using an efficient cementation protocol. SpeedCEM Plus is suitable for metal, metal-supported, zirconium oxide and lithium disilicate-based restorations, such as crowns and bridges.

SpeedCEM Plus is a self-adhesive resin cement, which can be used in both a self-cure and dual-cure mode.

1.5 SpeedCEM Plus

SpeedCEM Plus was developed to meet the demand among dentists for luting materials that offer an easier and faster application. It eliminates the need for using a dentin adhesive and primers for zirconium oxide and base metal restorations. The bonding values and mechanical properties are comparable to those of similar products available on the market and clearly surpass the bonding and strength values of conventional cements. SpeedCEM Plus is available in the shades transparent, yellow and white opaque. To facilitate its use, SpeedCEM Plus is offered as a paste-paste system in a convenient double-push syringe with an exchangeable mixing tip. SpeedCEM Plus can be used in a self-cure and light-cure mode (dual-cure application).

Advantages of the double-push syringe delivery form

Compared with cements that require manual mixing or cements that are mixed in a capsule, cements offered in a double-push syringe delivery form offer several advantages.

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

Table 2: Advantages of the double-push syringe delivery form



Fig. 1: SpeedCEM Plus double-push syringes

1.6 Self-adhesive mechanism

SpeedCEM Plus 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. 2). 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 permanent 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 on the dentin are lower than those obtained with adhesive luting composites used in combination with a genuine adhesive (e.g. Multilink Automix / Multilink Primer).

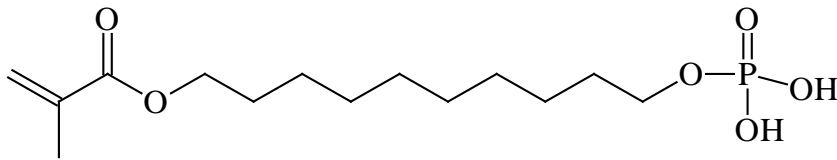


Fig. 2: Methacrylate monomer with phosphoric acid group (MDP)

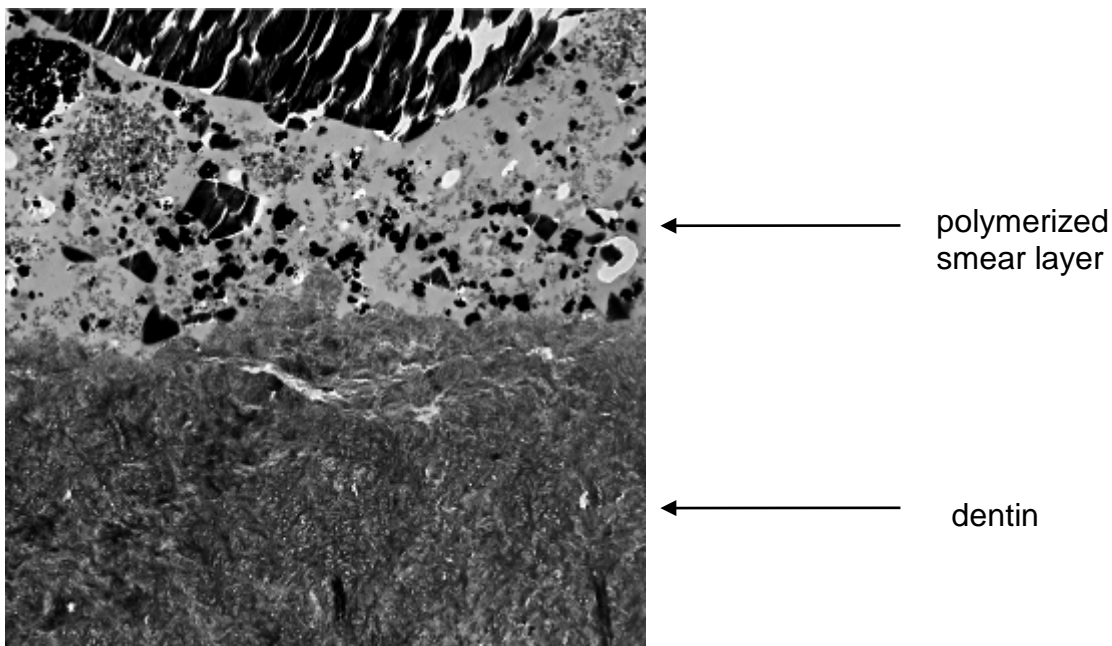


Fig. 3: TEM image of the interface between SpeedCEM and dentin (van Meerbeek, Leuven, 2009)

SpeedCEM Plus 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 self-adhesive resin cements.

Phenolic substances (e.g. eugenol, oil of wintergreen) inhibit polymerization. Therefore, products containing these components, e.g. mouth rinses or temporary cements, should not be used.

Disinfectants with an oxidative effect (e.g. hydrogen peroxide) may interact with the initiator system, which in turn may hamper the curing process. Neither the prepared tooth nor the syringe may be disinfected with an oxidative disinfectant. The syringe can be wiped with e.g. customary disinfecting wipes.

The residues of alkaline abrasive media, e.g. AirFlow, neutralize the active acidic component of SpeedCEM Plus and prevent it from reacting with the dentin. The performance of SpeedCEM Plus may be compromised.

Phosphoric acid should not be used for cleaning zirconium oxide and metal surfaces. Phosphoric acid reacts with these surfaces and causes them to be inert to reacting with SpeedCEM Plus.

2. Technical data

| | |
|----------------------|---|
| | Product category: |
| SpeedCEM Plus | Self-adhesive, self-curing resin cement with optional light-curing |

| Mechanical and physical properties | Note | Specification | Unit |
|---|-------------|-------------------------|---------------------------|
| Flexural strength | 1 | ≥ 60 | MPa |
| Shear bond strength | 2 | ≥ 6 | MPa |
| Working time | at 23°C : | $120 \leq t_w \leq 180$ | s |
| | at 37°C : | $80 \leq t_w \leq 140$ | |
| Setting time | at 23°C : | $180 \leq t_s \leq 300$ | s |
| | at 37°C : | $120 \leq t_s \leq 200$ | |
| Solubility (7 days) | 1 | ≤ 7.5 | $\mu\text{g}/\text{mm}^3$ |
| Water absorption (7 days) | 1 | ≤ 40 | $\mu\text{g}/\text{mm}^3$ |

The product meets the requirements as prescribed by EN 1641:2009 – Dentistry – Medical devices for dentistry – Materials

¹ Quantification method: ISO 4049:2009

² Quantification method: ISO 29022 (Ultradent)

3. *In vitro* investigations

Numerous *in vitro* tests are carried out in the course of developing a dental product. Although these investigations can never fully predict the clinical performance of a material, they nonetheless can give valuable information with regard to its adhesion to the dental hard tissues, technique sensitivity and compatibility with other restorative materials. SpeedCEM Plus was tested in several *in vitro* studies and the results of these studies are presented in the following chapters.

3.1 Adhesion

Achieving a sufficiently strong bond between the dental hard tissues and the restorative materials plays a central role in the development of self-adhesive luting materials.

Adhesion is assessed using various test set-ups; often the shear bond strength (SBS) and tensile bond strength (TSB) are measured. In shear bond strength tests, the loading force is directed parallel to the bonding interface, whereas in tensile bond strength tests, the loading force is applied in a perpendicular direction to the bonding interface. The load required to destroy the test sample is recorded in Mega Pascal units (MPa).

The different methods of bond strength testing investigate the adhesive properties from different perspectives and are best used in combination to maximize the significance of the data obtained in the tests. Since the values measured largely depend on the test set-up and test method used (e.g. diameter of the test specimens), the results of different test series are comparable with each other only to a limited extent [1; 2].

The Figure below shows the typical set-up of a shear bond strength test for luting materials.

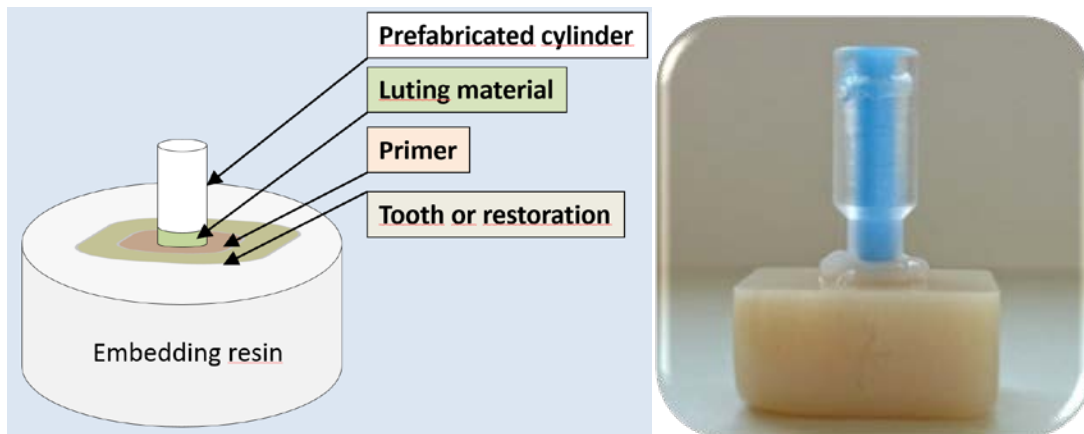


Fig. 4: Schematic depiction and example of a test specimen used in shear bond testing of luting materials.

3.1.1 Adhesion to dentin

The task of a luting material is to create adhesion between the dental hard tissues and the restorative material. Generally, conventional cements show very low adhesion to dentin. Composite-based luting materials are applied in conjunction with adhesives to obtain strong adhesion to dentin and enamel. Self-adhesive luting materials should establish adequate adhesion to dentin without the use of an additional adhesive.

3.1.1.1 Comparison of the dentin bond strength of different luting materials

All luting materials were processed and applied according to their instructions for use. The test specimens were prepared and the measurements conducted on bovine dentin according to ISO 29022 (Ultradent method). The samples were cured, protected from light, in a drying cabinet for 15 minutes at 37°C, followed by 24 hours of immersion in water at 37°C. Some test specimens were subjected to 10,000 temperature cycles between 5 and 55°C (10K TC) to simulate aging.

The shear bond strength was determined at a feed rate of 1mm/min.

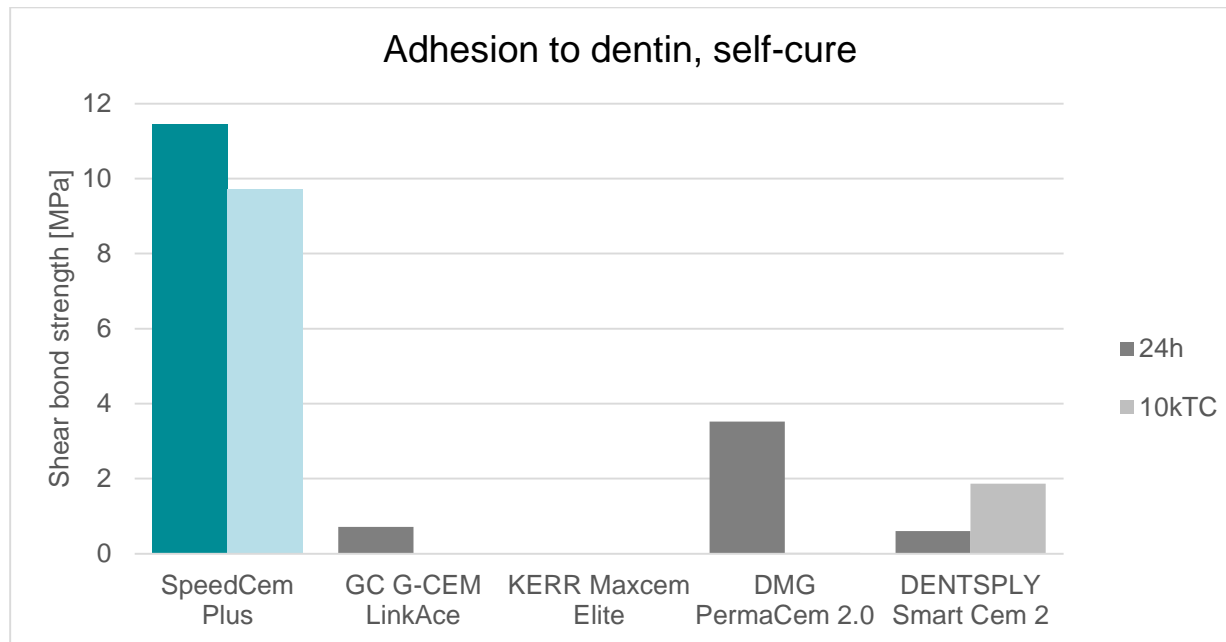


Fig. 5: Shear bond to dentin before and after 10,000 temperature cycles (10kTC). The materials were not illuminated (self-cure). R&D, Ivoclar Vivadent, FL, 2014-2015

SpeedCEM Plus produced high bond strength values to dentin in contrast to the other test materials shown. The bonding values for SpeedCEM Plus remained high after thermocycling, while other materials only showed a quantifiable adhesion to dentin at the initial measurement.

3.1.1.2 Adhesion to dentin at baseline and after storage

An external study determined the shear bond strength to human dentin after approx. 10 min after illumination (initial) and after 24 h of storage at 37 °C.

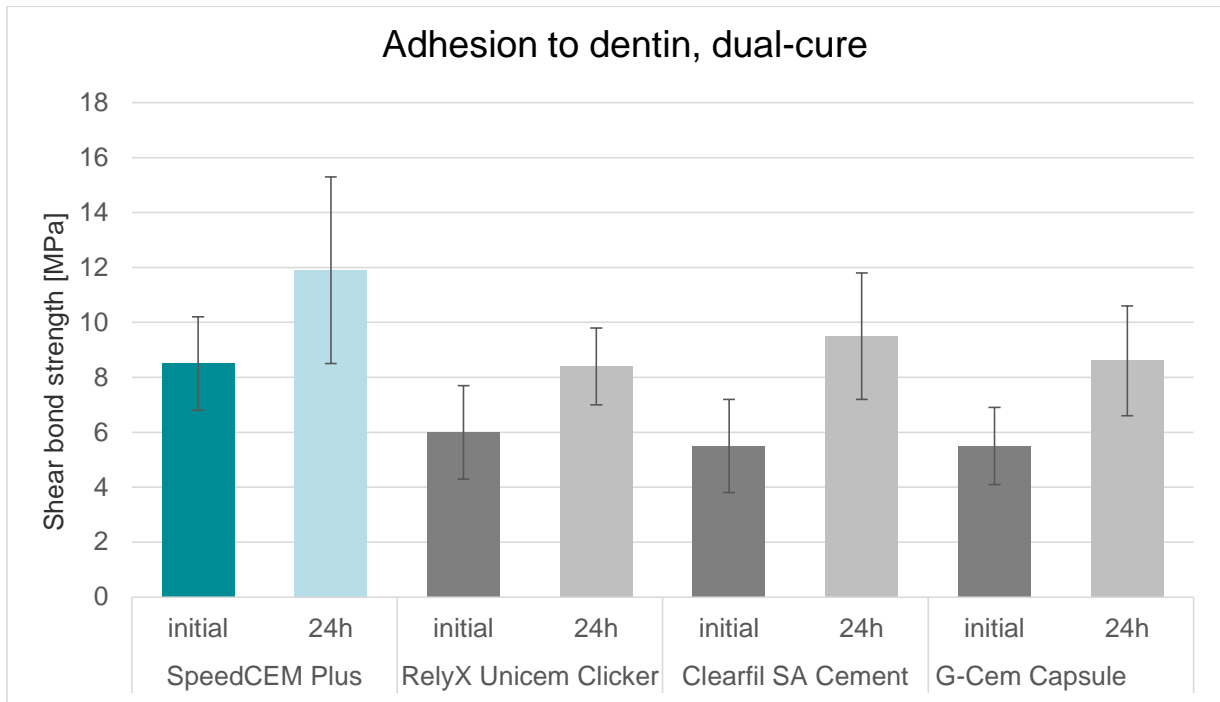


Fig. 6: Shear bond strength to dentin: comparison of initial adhesion and after 24 hours of storage. All materials were light-cured (dual-cure). M. Irie, Okayama University, Japan, 2014 – 2015

Among all the materials shown, SpeedCEM Plus achieved the highest shear bond strength values to dentin both at baseline and after 24 hours.

3.1.1.3 Adhesion of zirconium oxide cylinders to dentin

A study at Creighton University, Omaha, Nebraska, investigated the shear bond strength of three self-adhesive luting materials to dentin after self-curing and light-curing.

Cylindrical zirconium oxide samples were sandblasted (50 μ m AIO) and then cleaned in an ultrasonic bath. The dentin of human teeth was sanded down to a level surface and the sanded surfaces were finished using 600-grit paper. Prior to bonding, the dentin was blotted dry. The bonding procedure was performed according to the instructions for use of the individual materials. The test specimens of the light-cured group were illuminated 3 x 15 seconds at 600 mW/cm²; the specimens of the self-cured group were protected from light.

Prior to measuring the shear bond strength, the specimens were stored in water at 37°C for 24 hours.

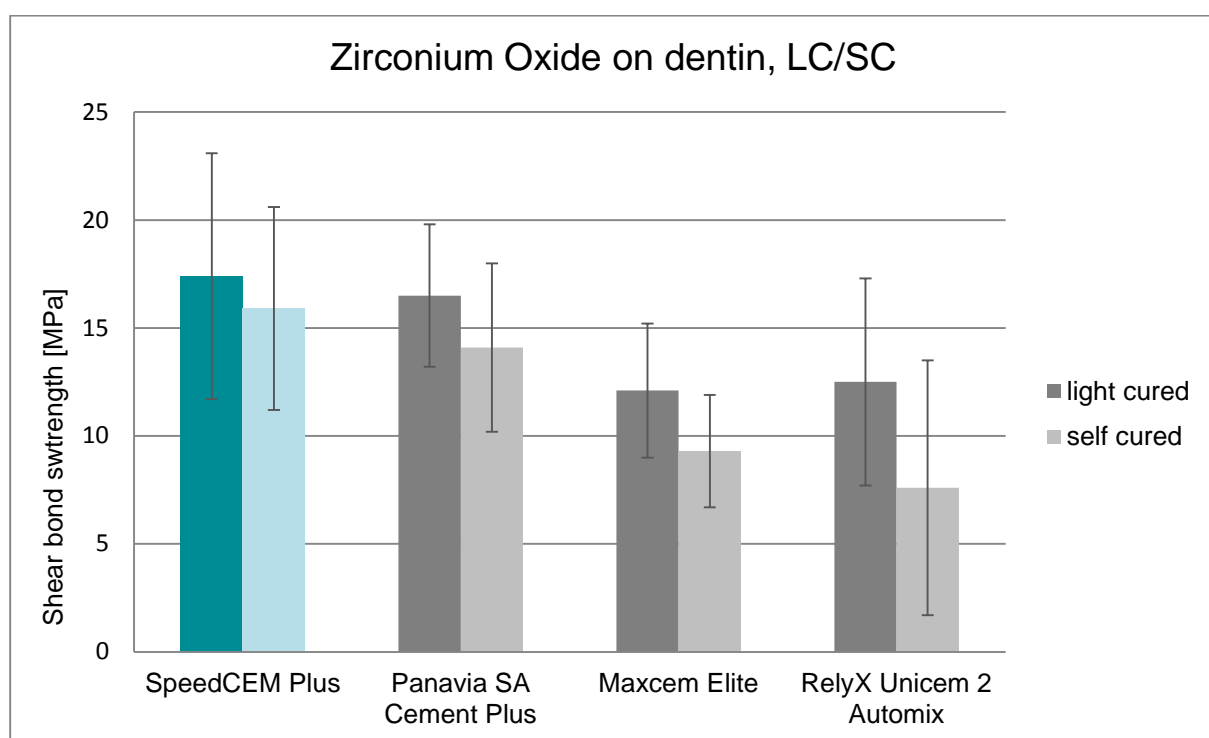


Fig. 7: Shear bond strength in conjunction with zirconium oxide on human dentin. Comparison between light-cured (LC) and self-cured (SC) resin cements. M. Latta, Creighton University, Nebraska, USA, 2015

Conclusion: SpeedCEM Plus produces a strong bond between zirconium oxide and dentin in both the self-cure and light-cure mode.

3.1.1.4 Adhesion to desiccated dentin

When using a (self-)adhesive luting technique, the question often arises as to how well the prepared tooth should be dried to facilitate an adequate bond. If the dentin becomes desiccated, the collagen fibres collapse and the bond to the luting material becomes less effective.

To investigate the effect of dentin desiccation on adhesion, the dentin bonding surfaces were treated in a variety of manners after they had been prepared and rinsed:

- blot dry (moist): blotting dry with tissue paper
- 5s dry: drying the surface using an intensive stream of air for 5 seconds
- 10s dry (over-drying): drying the surface using an intensive stream of air for 10 seconds

The luting materials were applied according to their instructions for use. The test specimens were stored at 37 °C for 24 h prior to measuring the bond strength values.

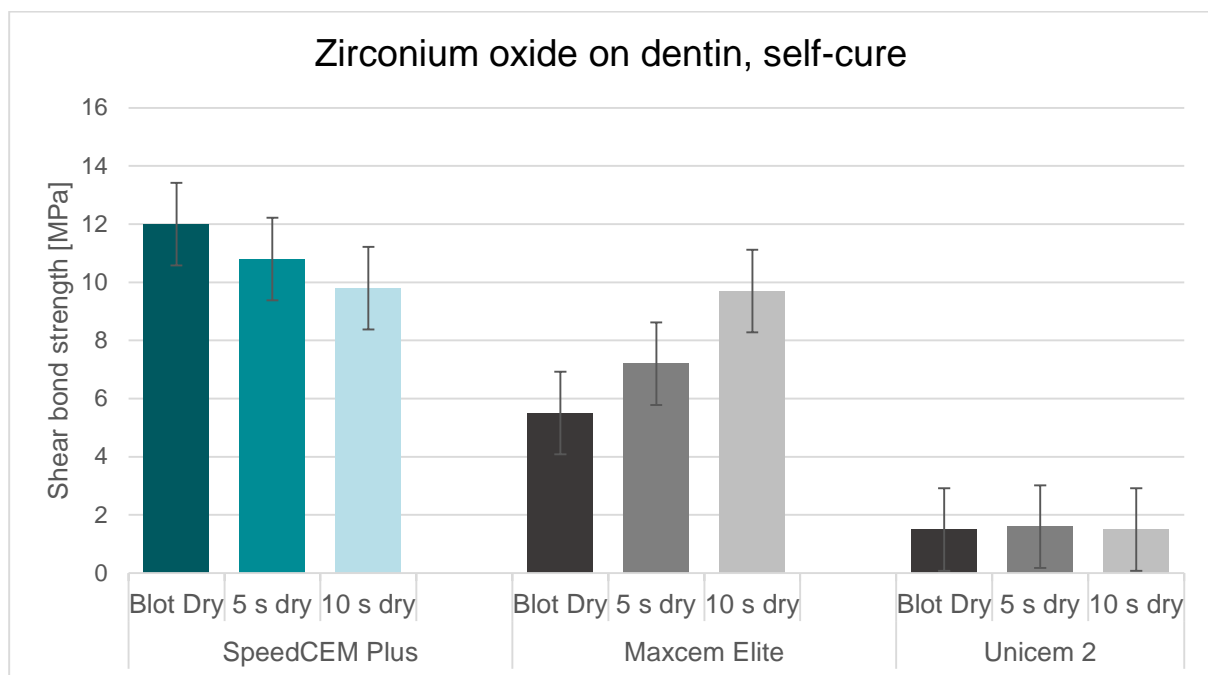


Fig. 8: Shear bond strength on dentin. The materials were not light cured (self-cure), measurements were performed after 24 h. Comparison between different drying procedures. Ivoclar Vivadent, Amherst, USA, 2015

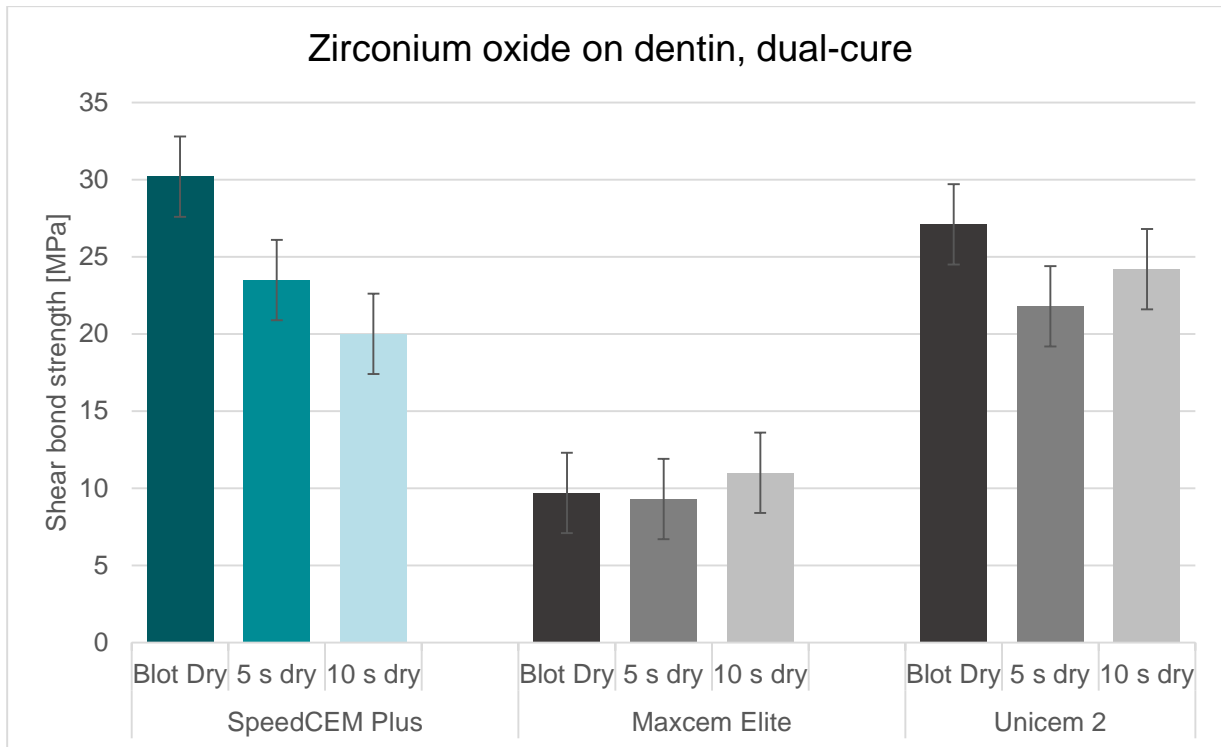


Fig. 9: Shear bond strength on dentin. The materials were light cured (dual-cure), measurements were performed after 24 h. Comparison between different drying processes. Ivoclar Vivadent, Amherst, USA, 2015

SpeedCEM Plus achieves high bond strength values even on excessively dry dentin in conjunction with both the self-cure and light-cure mode.

3.1.1.5 Adhesion to moist dentin

The necessity for complete isolation is a drawback of composite-based adhesive luting materials. Often the situation on the prepared tooth is such that a completely dry bonding site cannot be ensured, for instance if subgingival preparation margins are involved. To investigate the tolerance to moisture, the dentin was dried in the usual manner and afterwards moistened with water.

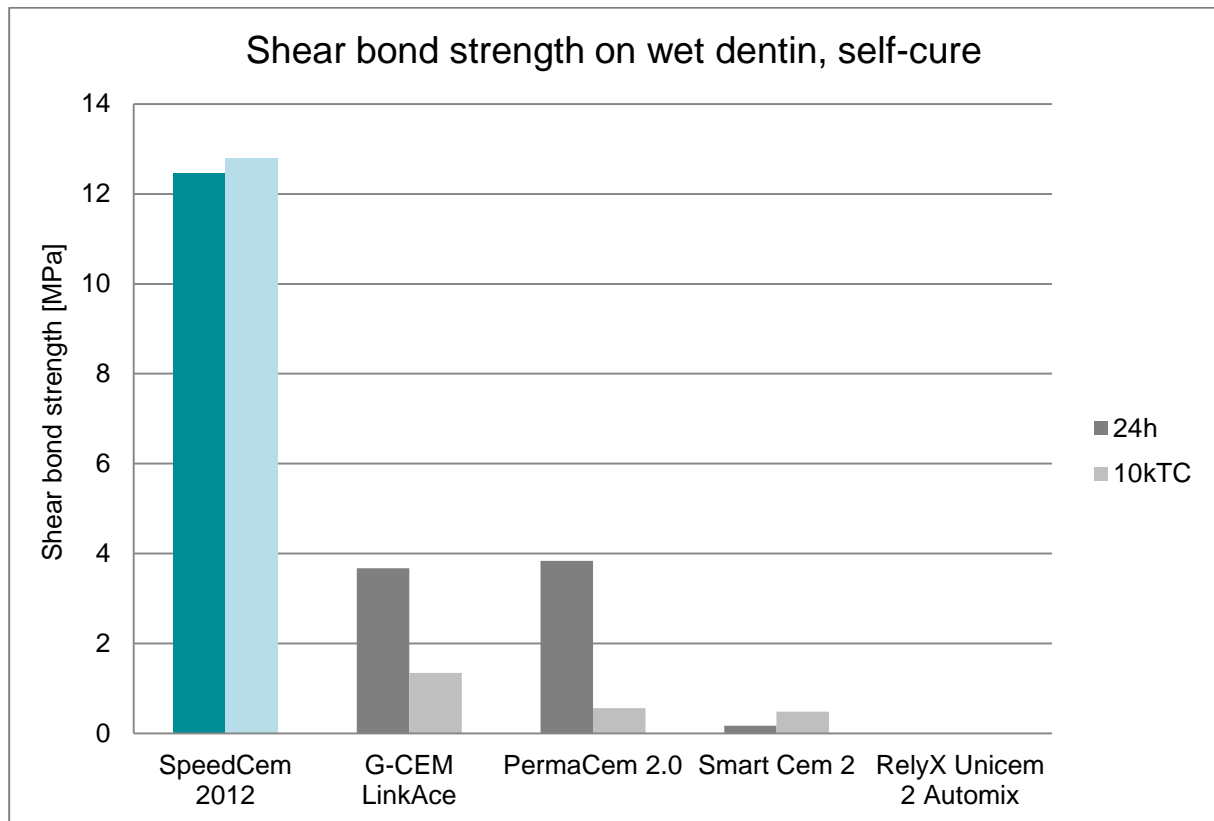


Fig. 10. Shear bond strength on wet dentin before and after 10,000 temperature cycles (10K TC)
The materials were not illuminated (self-cure). R&D, Ivoclar Vivadent, FL, 2014-2015

SpeedCEM Plus achieves adequate adhesion even on wet dentin.

Conclusion: Compared with other self-adhesive luting materials, SpeedCEM Plus showed high and consistent shear bond strength values on dentin in conjunction with all levels of moisture investigated.

3.1.2 Adhesion to enamel

Self-adhesive resin cements do not have an etching effect and, consequently, they do not create a micro-retentive pattern. Separate enamel etching with phosphoric acid may be performed to provide micro-retention.

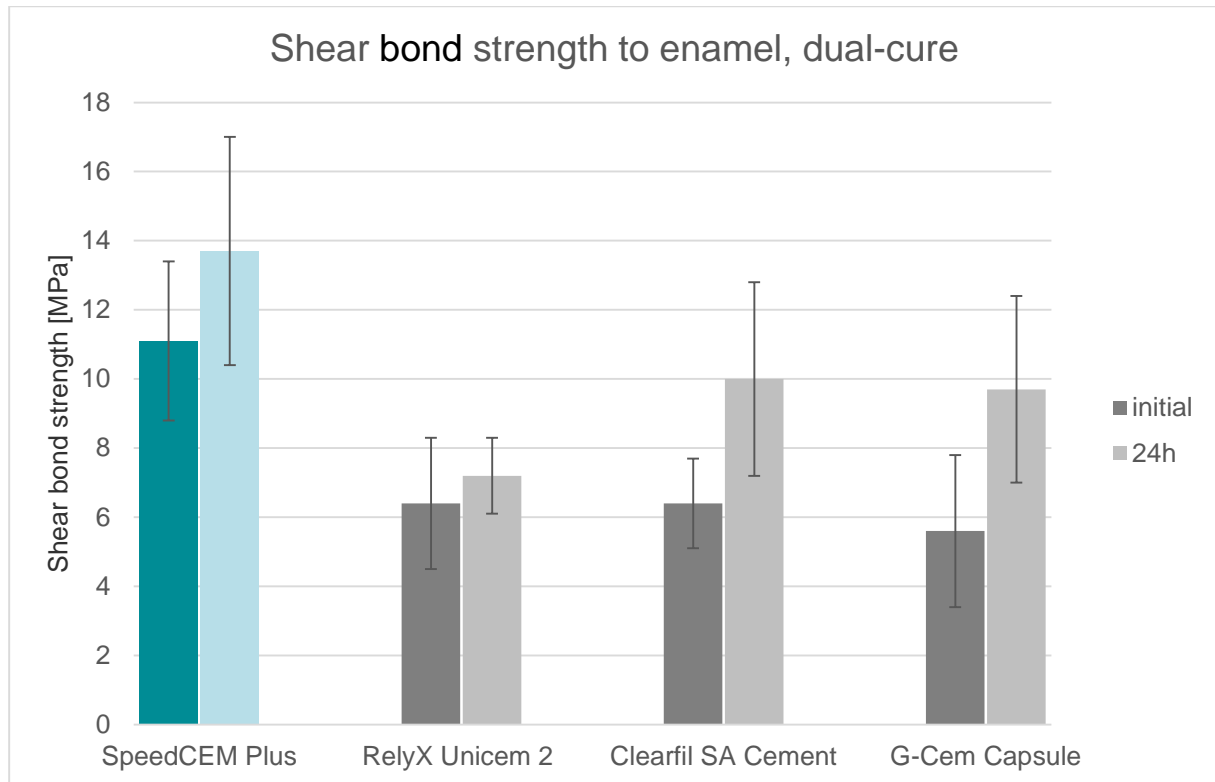


Fig. 11: Shear bond strength to freshly prepared enamel without phosphoric acid etching. Comparison of adhesion at baseline and after 24 h water storage. All materials were illuminated (dual-cure). M. Irie, Japan, 2014 – 2015

SpeedCEM Plus also shows reliable shear bond strength on freshly prepared, unetched enamel.

3.1.3 Adhesion to zirconium oxide ceramic and metal

SpeedCEM Plus comprises a phosphoric acid monomer (MDP), which forms a chemical bond with zirconium oxide and base metals. Bonding to restorations made of these materials can be achieved without applying a separate primer.

3.1.3.1 Adhesion without light exposure, before and after thermocycling

To determine the shear bond strength to zirconium oxide, test specimens (Zenostar T, Wieland Dental) were ground to a level surface and luted to composite cylinders using a self-adhesive luting cement. The resin luting cements were not illuminated. The shear bond strength was determined after 24 hours of water storage and after 10,000 temperature cycles between 5 and 55°C.

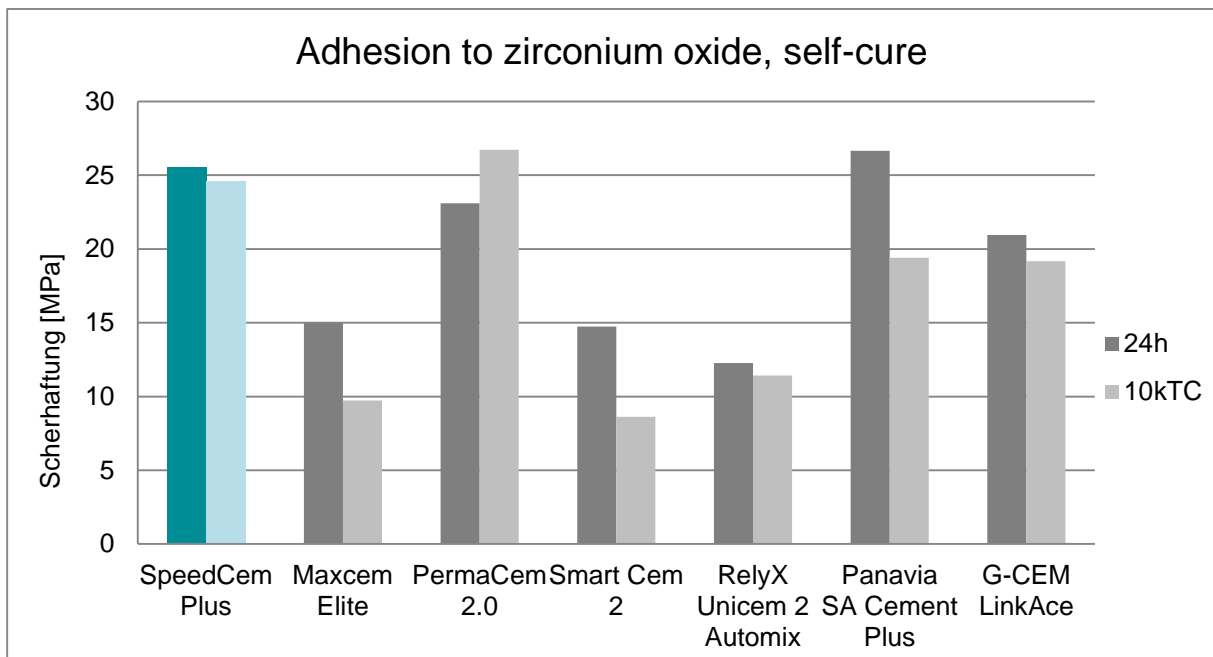


Fig. 12: Shear bond strength of different self-adhesive resin cements to zirconium oxide (IPS e.max ZirCAD) after self-curing. R&D Ivoclar Vivadent AG, FL, 2014-2015

SpeedCEM Plus achieves high and consistent bond strength values without an additional primer. Reliable bond strength values are particularly important in the self-cure mode when highly opaque restoration materials such as zirconium oxide are used.

3.1.3.2 Adhesion to zirconium oxide after illumination

In a similar study, the shear bond strength of resin cements to zirconium oxide was measured after the test specimens were illuminated (dual-cure mode) (Ghumann, 2015).

The zirconium oxide test specimens were first ground to a level surface and then sandblasted (1 bar Al₂O₃, 50 μm) and finally cleaned in an ultrasonic bath. Subsequently, cylindrical composite bodies were attached to the test specimens using three different luting materials with or without Monobond Plus. The luting materials were illuminated as prescribed in their instructions for use and stored at 37°C for 24 hours.

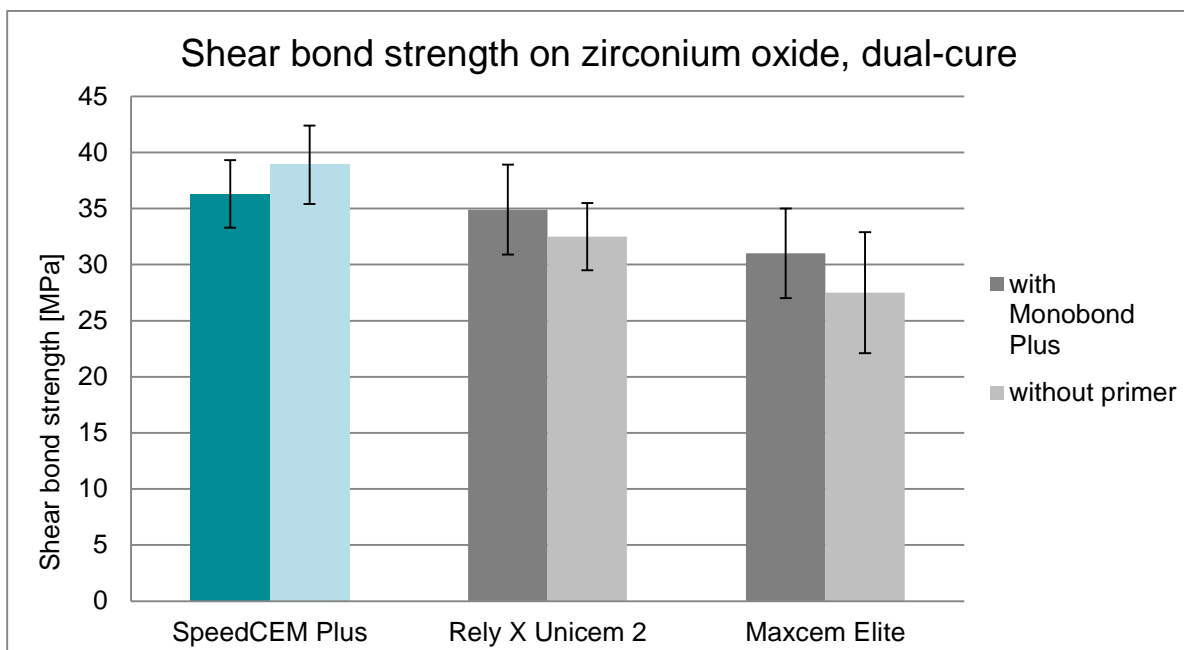


Fig. 13: Shear bond strength of self-adhesive resin cements after illumination (dual-cure) to zirconium oxide with and without Monobond Plus. T. Ghuman, University of North Carolina at Chapel Hill, USA [3]

SpeedCEM Plus also achieves high and consistent bond strength values even in applications without an additional primer.

3.1.3.3 Adhesion of metal and zirconium oxide to dentin

In a further study, cylindrical bodies made of zirconium oxide (IPS e.max ZirCAD) and base metal (d.sign 30) were bonded to human dentin [4]. The cylindrical bodies were air-blasted ($\text{Al}_2\text{O}_3/50 \mu\text{m}/15 \text{psi}$) and subsequently bonded to ground dentin using a self-adhesive luting cement. A primer was not used. Shear bond strength values were determined after 24 hours of self-curing at 37°C .

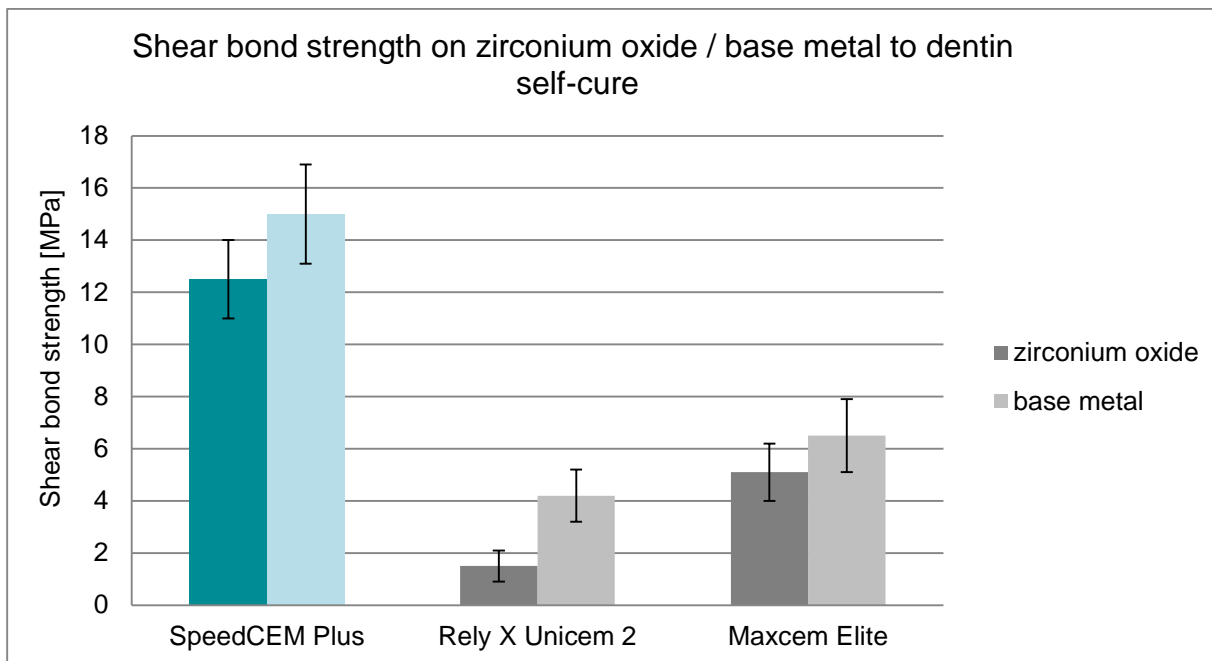


Fig. 14: Shear bond strength after cementation of cylindrical zirconium oxide and base metal bodies to dentin using the self-cure (SC) mode. S. Singhal, University Buffalo, USA, 2015 [4]

SpeedCEM Plus produces high bond strength values in conjunction with both restorative materials.

3.1.3.4 Adhesion to different restoration substrates

In a similar study, cylindrical samples made of Tetric EvoCeram were luted to different substrates using SpeedCEM Plus. The bonding values achieved on zirconium oxide and titanium without using a primer were similarly high as the values achieved on lithium disilicate with Monobond Plus.

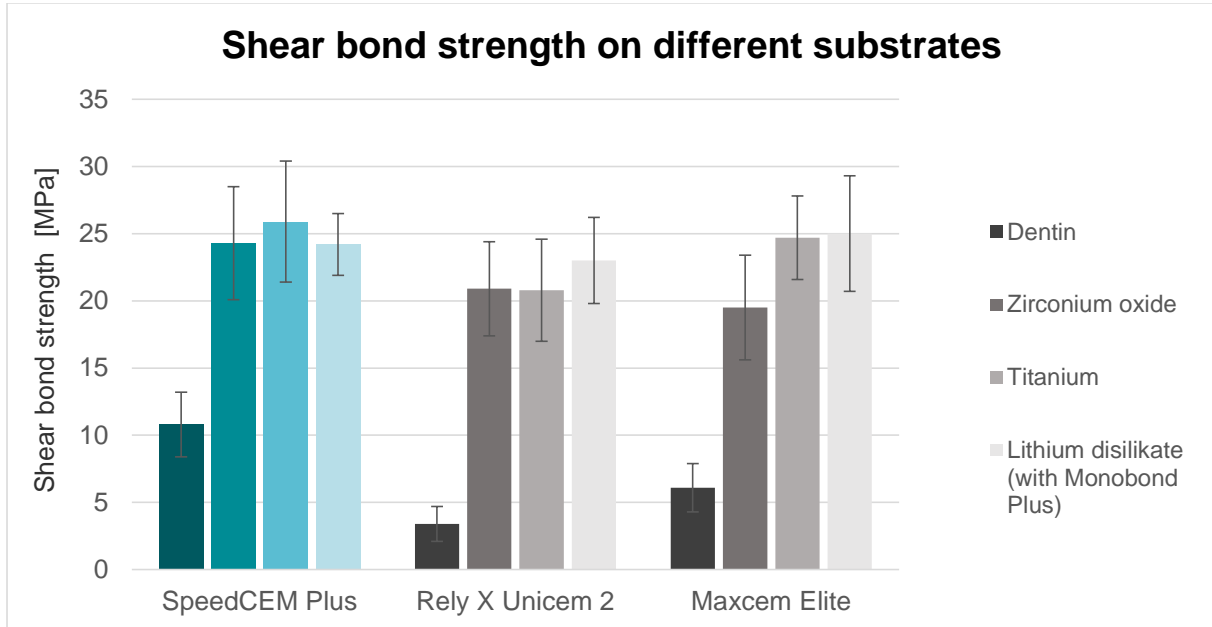


Fig. 15: Shear bond strength of SpeedCEM Plus to different restorative materials and dentin. S. Singhal, Universität Buffalo, USA, 2015 [5]

Conclusion:

In all the studies shown SpeedCEM Plus achieved high bond strength values to zirconium oxide and base metal substrates in both the dual-cure and single-cure mode - without necessitating the use of an additional primer.

3.1.4 Adhesion to lithium disilicate ceramic materials

Lithium disilicate glass-ceramic materials, such as IPS e.max Press or IPS e.max CAD, are etched and silanized before they are cemented in place using SpeedCEM Plus. Monobond Etch & Prime or Monobond Plus may be used as silanizing agents.

3.1.4.1 Comparison of self-cure and light-cure

Lithium disilicate test specimens (IPS e.max CAD) were conditioned with Ceramic Etching Gel and then primed with Monobond Plus according to the instructions for use. Subsequently, composite cylinders were luted to the test specimens using the luting materials being examined. The shear bond strength values were determined after 24 hours of water storage and/or after an additional 10,000 temperature cycles between 5 and 55°C.

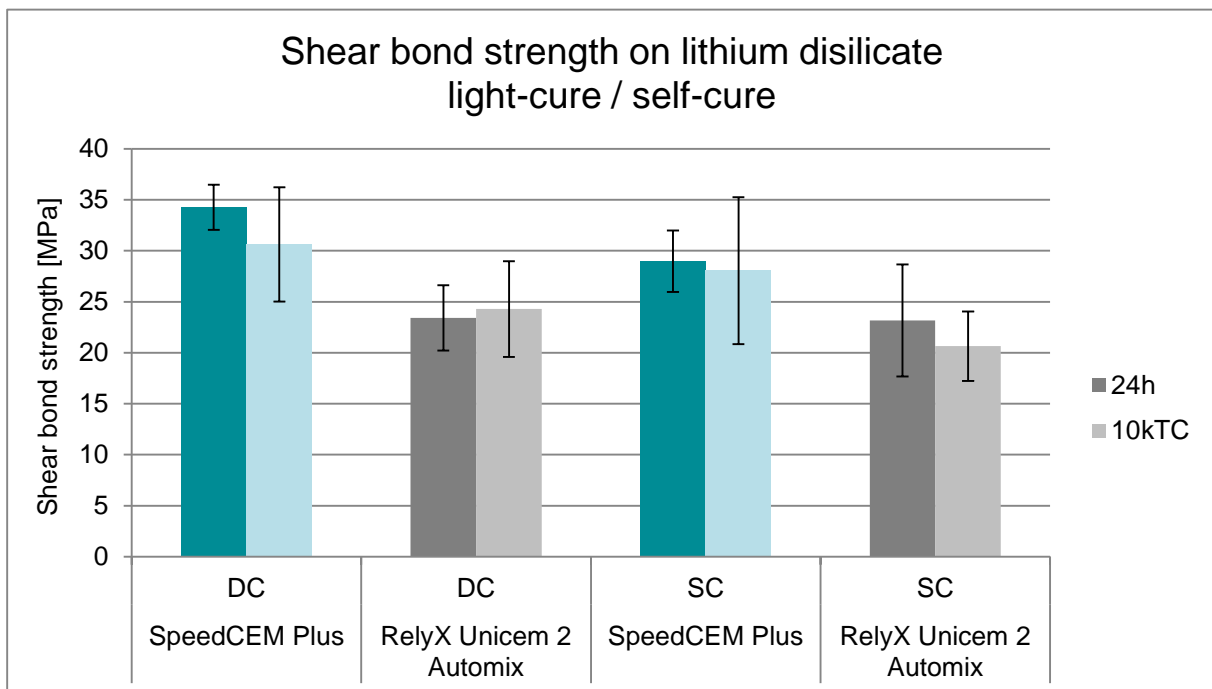


Fig. 16: Shear bond strength of different self-adhesive resin cements to lithium disilicate glass-ceramic (IPS e.max Press). R&D Ivoclar Vivadent AG, FL, 2014-2015.

All the systems tested produced similar bonding values to the glass-ceramic. In other words, the adhesive effect is created by Monobond Plus in this case. The lithium disilicate glass-ceramic is sufficiently translucent up to a maximum of 3 mm to allow light to pass through it for light-activation. Therefore it was possible to measure the bond strength after self-curing and after initial light-activation.

3.1.4.2 Adhesion to lithium disilicate and zirconium oxide ceramic

The adhesion of SpeedCEM Plus to zirconium oxide ceramic and to lithium disilicate glass-ceramic (IPS e.max CAD) was investigated at University Okayama, Japan. The IPS e.max CAD surfaces were silanized with Monobond Plus.

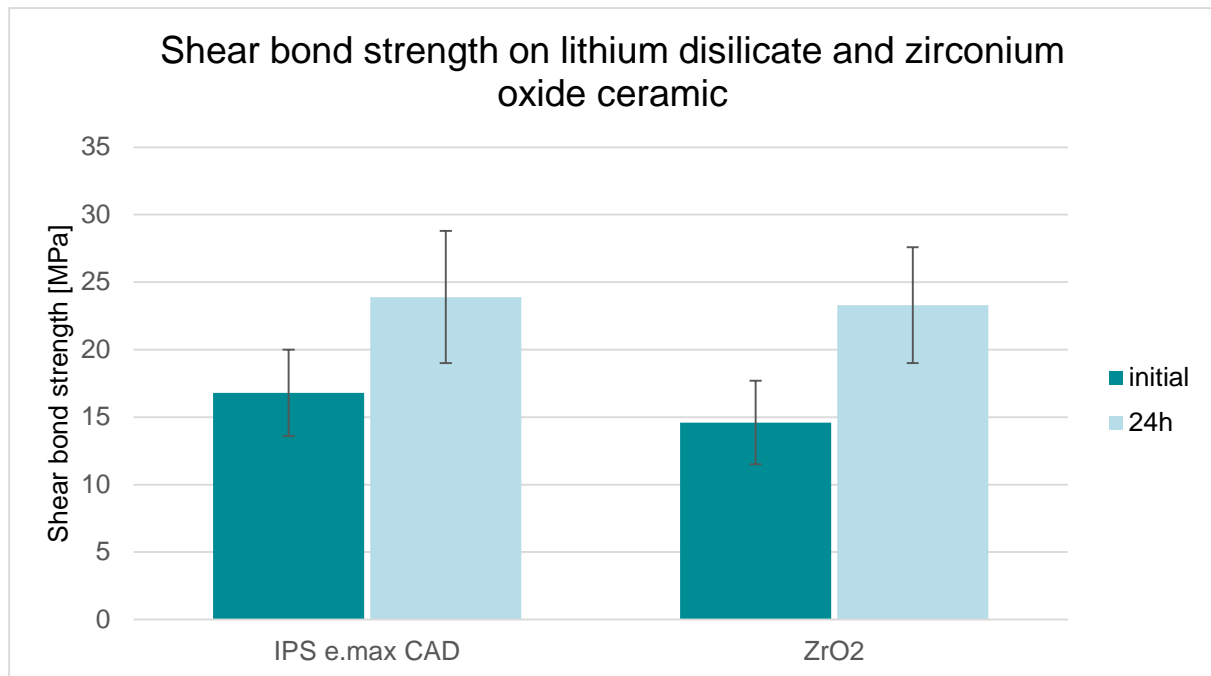


Fig. 17: Shear bond strength to glass-ceramic (IPS e.max CAD, in combination with Monobond Plus) and to zirconium oxide. M. Irie, Japan, 2016

SpeedCEM Plus achieved high bond strength values to both zirconium oxide and lithium disilicate after silanizing.

3.2 Flexural strength

Cured resin cements show a significantly higher strength than inorganic cements. As a result, they improve the stability and durability of the restoration. Flexural strength is a measure of strength. The flexural strength of composites is dependent on their composition and the degree of cross-linking.

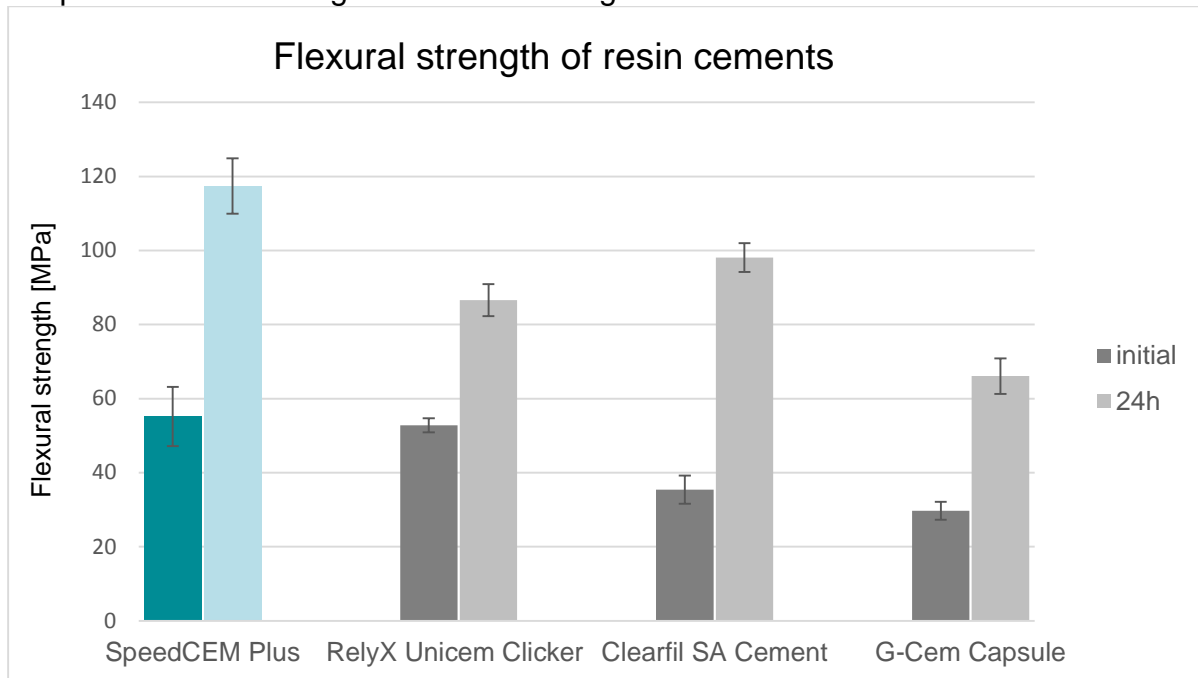


Fig. 18: Flexural strength values of dual-cured luting materials measured immediately after application and one day after immersion in water at 37 °C. M. Irie, Japan, 2014-2015

SpeedCEM Plus achieves an initial flexural strength of more than 50 MPa already a few minutes after application. Storage in water at 37 °C for 24 hours leads to a further increase in the flexural strength.

3.3 Water absorption and 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.

Water absorption in composite materials results in an increase in volume. In worst cases, this expansion may destroy the restoration or damage the tooth structure. Furthermore, water absorption may undermine the strength of the composite.

Water absorption and water solubility were measured over 7 days according to ISO 4049.

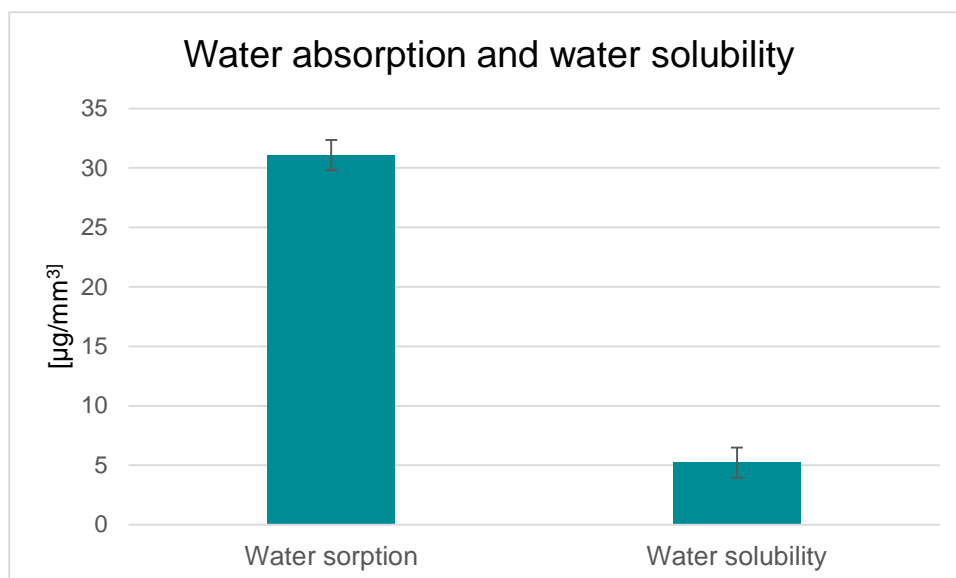


Fig. 19: Water absorption and water solubility of SpeedCEM Plus after 7 days of water storage. R&D Ivoclar Vivadent AG, FL, 2014

As a self-adhesive resin cement, SpeedCEM Plus does not fall within the scope of ISO 4049. Nonetheless, its water absorption is below the limit value of $50\mu\text{g}/\text{mm}^3$ for water absorption and below $7.5\mu\text{g}/\text{mm}^3$ for water solubility specified by this standard.

3.4 Radiopacity

The radiopacity of dental materials enables the clinician to distinguish tooth-coloured restorations from the natural tooth structure or caries on X-ray images. The radiopacity of a material is determined against the radiopacity of aluminium according to ISO 4049. Given its special filler composition, the radiopacity of SpeedCEM Plus is significantly higher than that of dentin (approx. 100%) and enamel (approx. 210%) [6]. Consequently, SpeedCEM Plus can be easily distinguished from the natural tooth structure on radiographs.

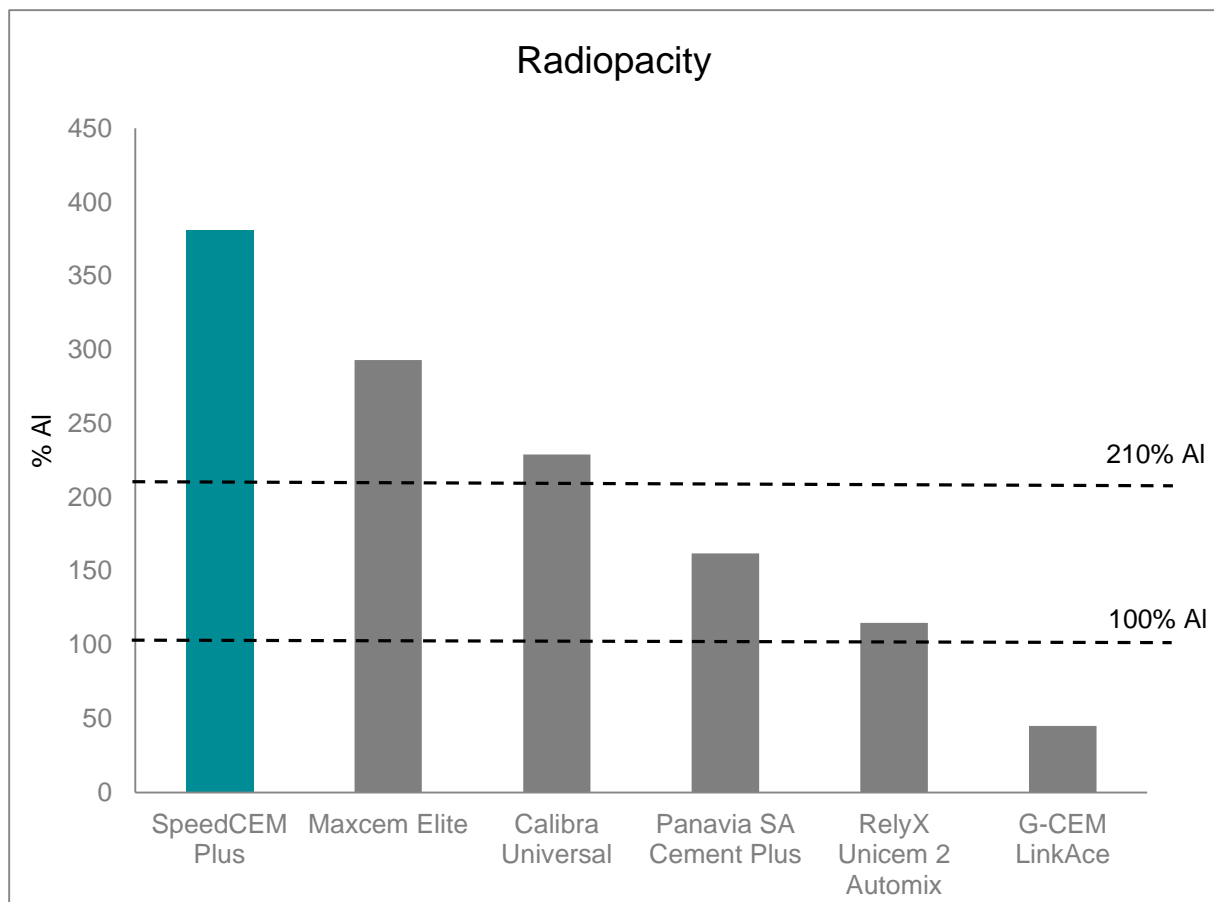


Fig. 20: Radiopacity of luting materials. F&E Ivoclar Vivadent AG, FL, 2015

3.5 Summary

The physical properties and the bond strength values measured in the above studies show that SpeedCEM Plus provides comparable and at times superior values to those of self-adhesive resin cements currently established on the market.

4. Clinical studies

4.1.1 *Clinical study of SpeedCEM Plus with zirconium oxide and lithium disilicate restorations: One-year results*

In a study carried out by The Dental Advisor, 117 restorations (101 crowns, 16 bridges) made of zirconium oxide (73) or lithium disilicate ceramic (44) were placed on molars and premolars in 93 patients using SpeedCEM Plus. The zirconium oxide restorations were conditioned by sandblasting, the lithium disilicate restorations were conditioned by hydrofluoric acid (5%) etching. All restorations were cleaned with Ivoclean and pre-treated with Monobond Plus. When the restorations were seated, excess material was tack cured with light before excess was removed. Once the excess was removed, the restorations were light-cured using the quarter technique.

One year after the insertion, all 117 restorations were assessed with regard to retention, postoperative sensitivity, esthetics and marginal discolouration.

Results:

In the "esthetics" category, SpeedCEM was rated "excellent"; the esthetic properties of the restorations were not adversely affected by the cement. The transparent SpeedCEM Plus material was invisible in translucent IPS e.max CAD restorations.

None of the restorations showed any marginal discolouration during the twelve-month observation period.

Eight out of the 93 patients developed postoperative sensitivities. In two of these patients, the symptoms were mild and subsided without necessitating further treatment. Three patients reported moderate complaints lasting for longer than four weeks. In one case, the complaints were alleviated with the help of occlusal adjustments. Three patients experienced severe sensitivity. Two teeth, where the complaints were not caused by the luting material, required endodontic treatment. In one severe case, the crown debonded.

Conclusion / Summary:

SpeedCEM Plus is easy to use in clinical applications and was given excellent ratings for esthetics, colour stability and lack of marginal discolouration. SpeedCEM Plus was given a 98% clinical performance rating.

5. Biocompatibility

Medical devices are subject to very strict requirements which are designed to protect patients and operators from potential biological risks. The International Standard ISO 10993 "Biological evaluation of medical devices" defines how the biological safety of a medical device is to be evaluated. Furthermore, medical dental devices must comply with the requirements of ISO 7405 "Evaluation of biocompatibility of medical products used in dentistry".

The biocompatibility of SpeedCEM Plus has been tested in accordance with these standards. Some investigations were carried out on SpeedCEM, whose composition is equivalent to that of SpeedCEM Plus; the results of these studies consequently also apply to SpeedCEM Plus.

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 XTT₅₀ value refers to the concentration of a substance which reduces the cell number by half. The lower the XTT₅₀ concentration of a substance, the more cytotoxic it is.

SpeedCEM Plus is polymerized shortly after application. In the process, potentially cytotoxic monomers react and are immobilized. Extracts of polymerized SpeedCEM showed no cytotoxic effect (1).

5.1.2 Sensitization

Like all resin-based dental materials, SpeedCEM Plus contains methacrylate and acrylate derivatives. Such materials may cause sensitization that can lead to allergic contact dermatitis. Allergic reactions are extremely rare in patients, but are increasingly observed in dental personnel who handle uncured composite material on a daily basis [3-9]. These reactions can be minimized by clean working conditions and by avoiding contact of unpolymerized material with the skin [3; 4]. Commonly employed gloves made of latex or vinyl do not provide effective protection against sensitization to such compounds.

SpeedCEM Plus should not be used in patients with a known allergy to methacrylates.

5.1.3 Genotoxicity

Genotoxicity refers to the capability of a substance or a mixture of substances to damage genetic material. The mutagenic potential of a substance can be determined on the basis of a number of tests. Cured SpeedCEM showed no genotoxic or mutagenic potential in the Ames test (Salmonella typhimurium and Escherichia coli reverse mutation assay). On the basis of the data obtained in these tests, SpeedCEM is not considered genotoxic (2).

5.1.4 Skin irritation

To investigate the potential of SpeedCEM to irritate the epithelial cells, extracts of polymerized SpeedCEM were applied in vitro to an EpiSkin human epidermis model. The extracts did not show any irritating effect on the skin (3); one can therefore assume that SpeedCEM Plus also has no irritating effect.

5.1.5 Summary

The results of the biocompatibility tests can be summarized as follows:

- After polymerization, the monomers are immobilized within the polymer network of SpeedCEM Plus; extracts showed no cytotoxicity.
- Particularly in the uncured state, SpeedCEM Plus may cause a sensitization to methacrylates. This is typical for all methacrylate-based dental materials.
- According to the data available, SpeedCEM Plus is not genotoxic.
- According to the data available, extracts of SpeedCEM have no irritating effect.

On the basis of the toxicological evaluation and the long years of clinical use of similar materials all over the world, it can be concluded that the benefits provided by the final product exceed any possible risks.

5.1.6 Biocompatibility references

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