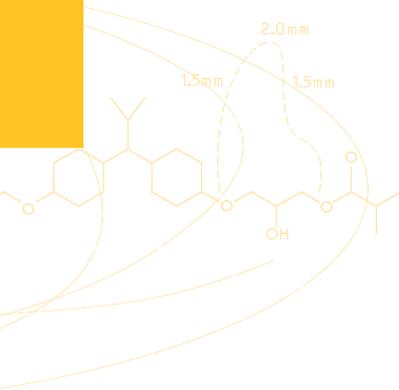


# RelyX™ Unicem – Self-Adhesive Universal Resin Cement in the Clicker™ Dispenser

## Technical Data Sheet

### Product Description

RelyX™ Unicem cement is a dual-curing, self-adhesive universal resin luting cement for adhesive cementation of indirect ceramic, composite or metal restorations. When using RelyX Unicem cement, bonding and conditioning of the tooth are no longer necessary. The cement is characterized by a higher moisture tolerance, as compared to multi-step composite cements. RelyX Unicem cement releases fluoride ions and is available in various shades. Among others, its essential characteristics are high dimensional stability and a high degree of adhesion to the tooth structure. RelyX Unicem cement is now also available in the 3M ESPE Clicker™ Dispenser. Each Clicker Dispenser contains 11g RelyX Unicem cement which can be dispensed in approximately 80 individual doses (approx. 40 crown applications).



### RelyX™ Unicem benefits

Cement properties	Clicker™ Dispenser
Eliminates the need for etching, priming and bonding steps	No waste of cement through mixing tips
Strong, adhesive, esthetic and moisture-tolerant	Consistent mixing ratio for dispensed pastes
Easy to use for virtually all indications (except veneers and maryland bridges)	Exact dosage through easy clicks
Low risk of postoperative sensitivities	Consumption level indicator for better material management

### Composition

- The resin matrix of RelyX Unicem cement consists of specially designed multifunctional, phosphoric acid modified methacrylate monomers. On the one hand these monomers form a highly cross-linked cement matrix during radical polymerization. As a consequence, RelyX Unicem cement features high mechanical and dimensional stability. On the other hand the phosphoric acid groups of the methacrylate monomers interact with the tooth surface and facilitate self-adhesion.
- The amount of inorganic fillers contained in RelyX Unicem cement approximates 70 percent by weight, the grain particle size ( $d[90]=90\%$  of the fillers) is  $<12.5\mu\text{m}$ . In addition, the fillers account for the cement's radiopacity in all available shades. A portion of the fillers is silanated to chemically bond to the methacrylate monomers; another portion is alkaline (basic) and neutralize the remaining phosphoric acid groups of the methacrylate monomers. Thus, adhesion to dentin and enamel, an increase of the pH value to a neutral level, and the fluoride release are achieved in the course of the cement setting reaction.

## Indications

RelyX™ Unicem – self-adhesive universal resin cement in the Clicker™ dispenser is indicated for the definite cementation of inlays, onlays, crowns, bridges, posts, pins, and screws made of ceramics, composite or metals.

## Shades

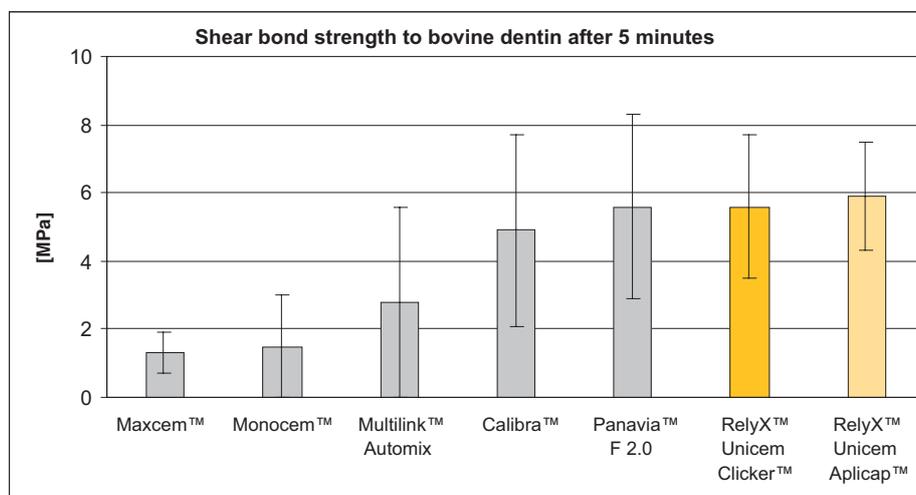
RelyX Unicem cement is available in A2 Universal, A3 Opaque, and Translucent shades. All shades are radiopaque.

## Material Properties

Properties	RelyX™ Unicem in the Clicker™ Dispenser	Panavia™ F 2.0 (Kuraray)	Maxcem™ (Kerr)
Film thickness [ $\mu\text{m}$ ] <sup>1</sup>	17	26	21
Linear expansion after 1 month [%] <sup>1</sup> (self / light cure)	0.45/0.44	0.36/0.4	1.1/1.1
Water absorption [ $\mu\text{g}/\text{mm}^3$ ] <sup>1</sup> (self / light cure)	42/25	24/25	75/75
Solubility [ $\mu\text{g}/\text{mm}^3$ ] <sup>1</sup> (self / light cure)	4/-2	2/1	18/20
Radiopacity [mm Al] <sup>1</sup>	1.79	1.45	2.06
Flexural strength [MPa] <sup>1</sup> (self / light cure)	60/71	92/89	54/56
Compressive strength [MPa] <sup>1</sup> (self / light cure)	216/244	203/228	260/283

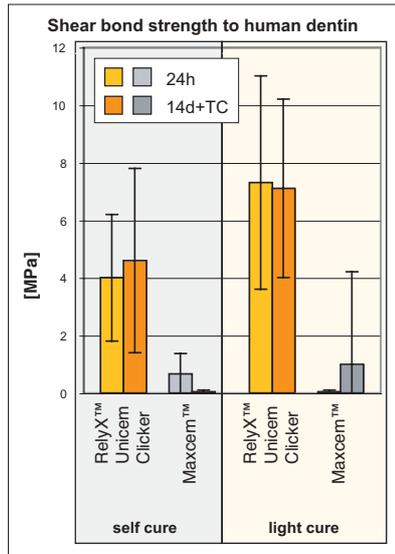
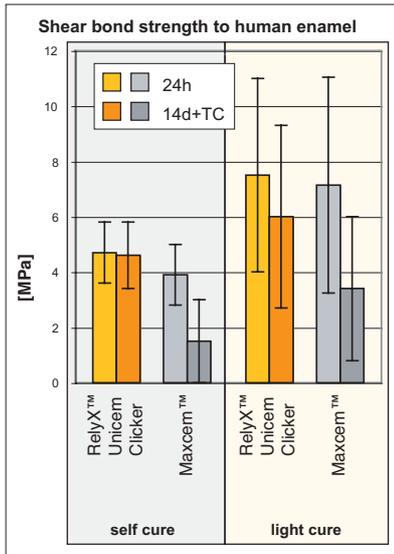
## Clinically Relevant Material Properties

All the data displayed in the following provides an overview of the RelyX Unicem cement bond strength to tooth substance and various restorative materials. Although the results are shown as “shear bond strength” one should remember that they derive from different experimental set ups (e.g. wire-loop test vs. shear bond tests using wedges). Therefore absolute numbers should only be compared within the particular experiments.



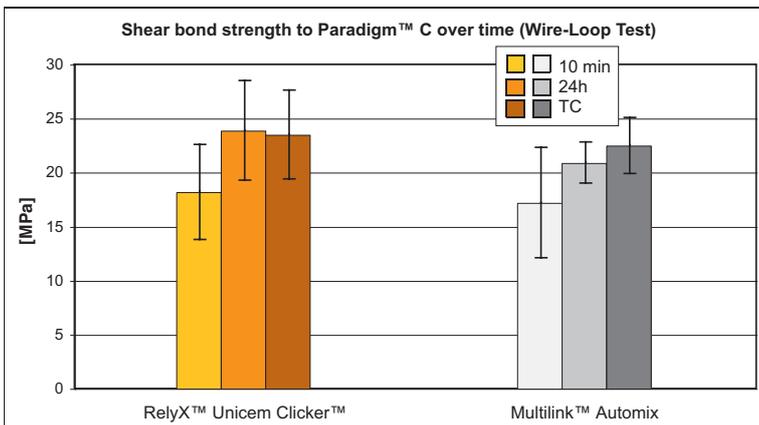
### Bond Strength on Bovine Dentin<sup>1</sup>

The shear bond strength of RelyX Unicem cement (light cure) on bovine dentin was measured 5 minutes after cementation.



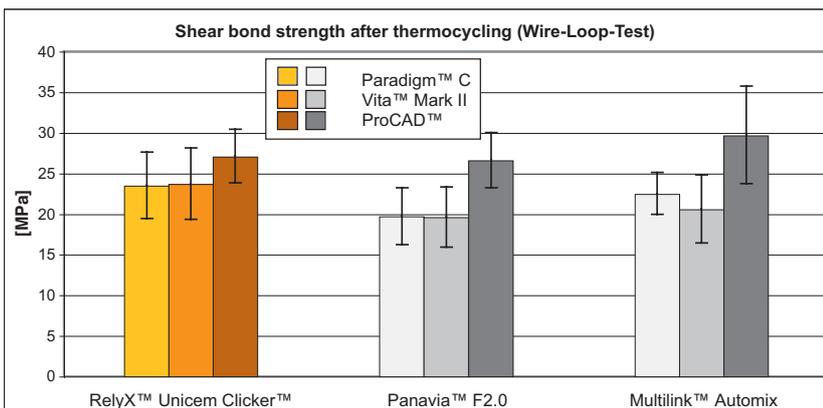
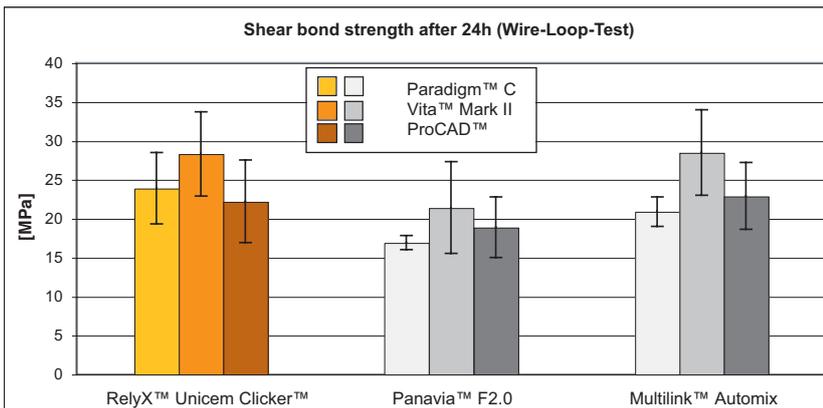
## Bond Strength on Human Enamel and Dentin<sup>2</sup>

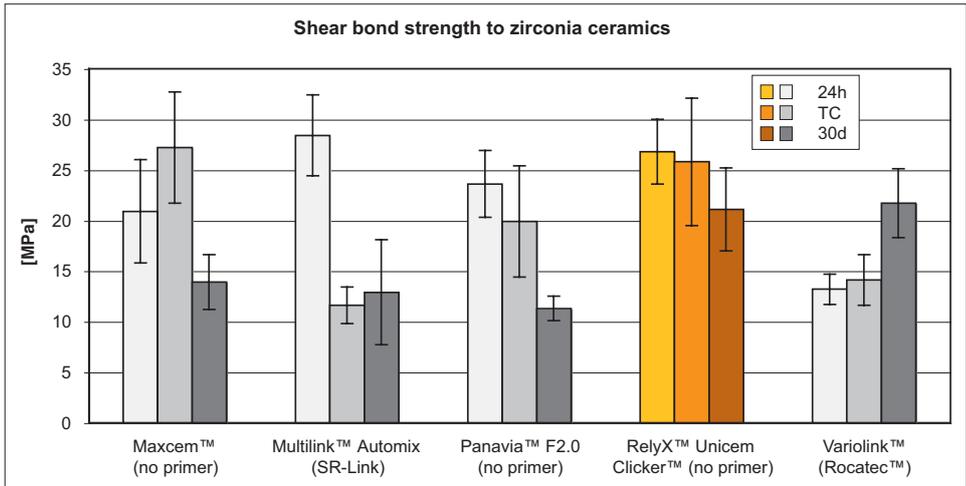
The shear bond strength of RelyX™ Unicem cement (self and light cure) on human enamel and dentin was determined 24 hours after cementation and after 14 days of water storage followed by thermocycling (TC) (1,000 cycles; 5°/55°C).



## Bond Strength on Glass Ceramics<sup>1</sup>

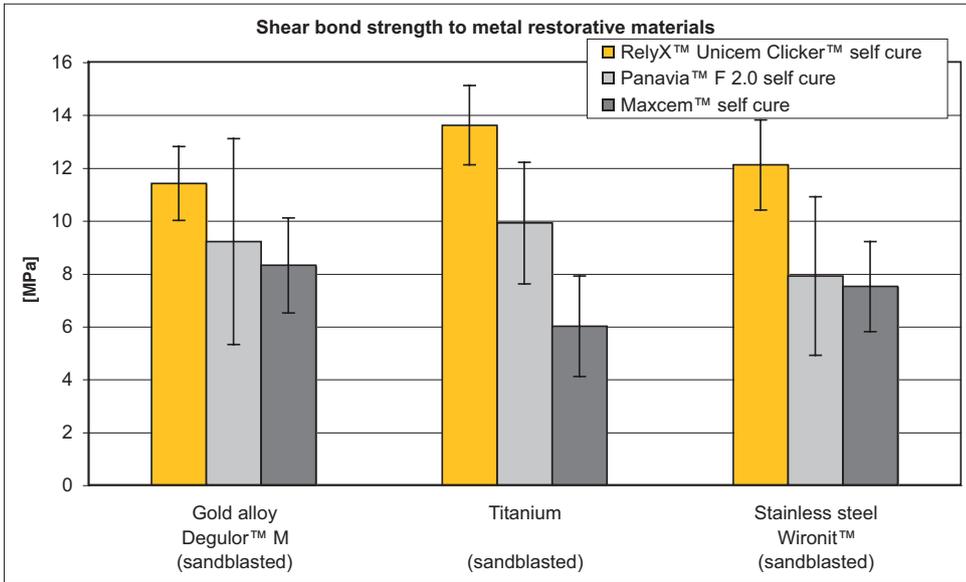
The shear bond strength of RelyX Unicem cement (light cure) on different glass ceramics was determined using the wire-loop test after 10 minutes, 24 hours of water storage, and after thermocycling (TC) (5,000 cycles; 5°/55°C).





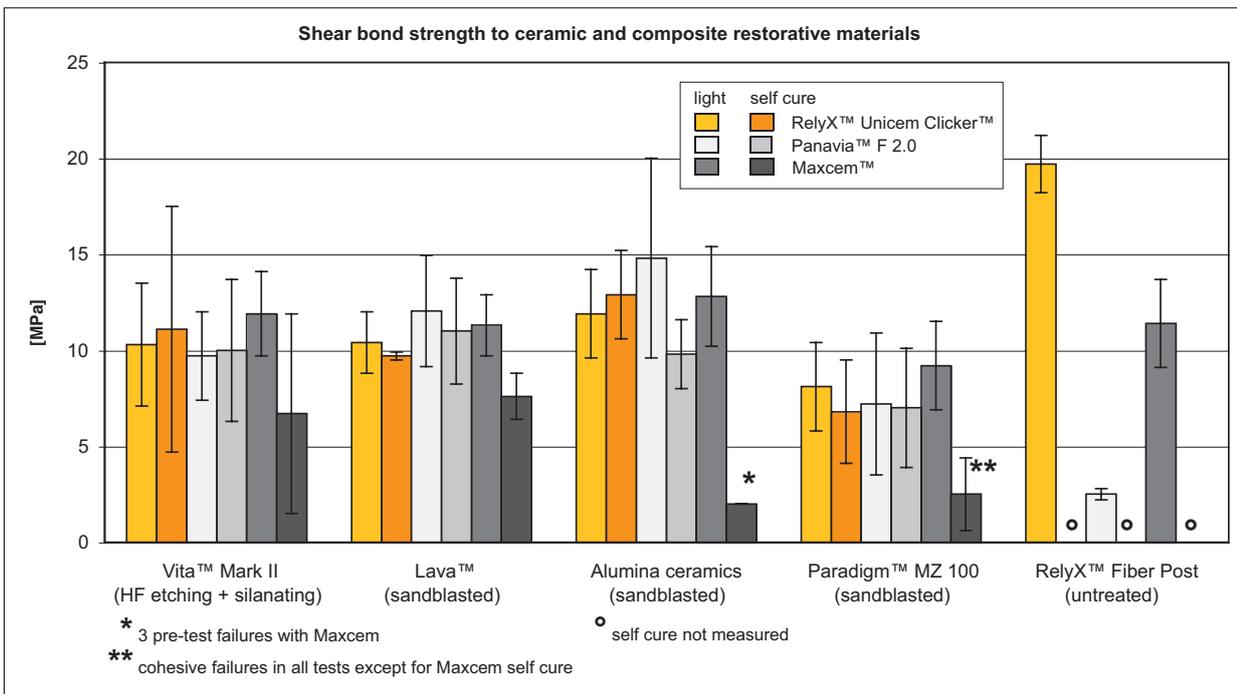
**Bond Strength on Zirconia Ceramics<sup>3</sup>**

The shear bond strength of RelyX™ Unicem cement (self cure) on high strength ceramic (Cercon, DeguDent) was measured after 24 hours, 30 days of water storage, and after thermocycling (12,000 cycles; 5°/55°C).



**Bond Strength on Various Restorative Materials<sup>1</sup>**

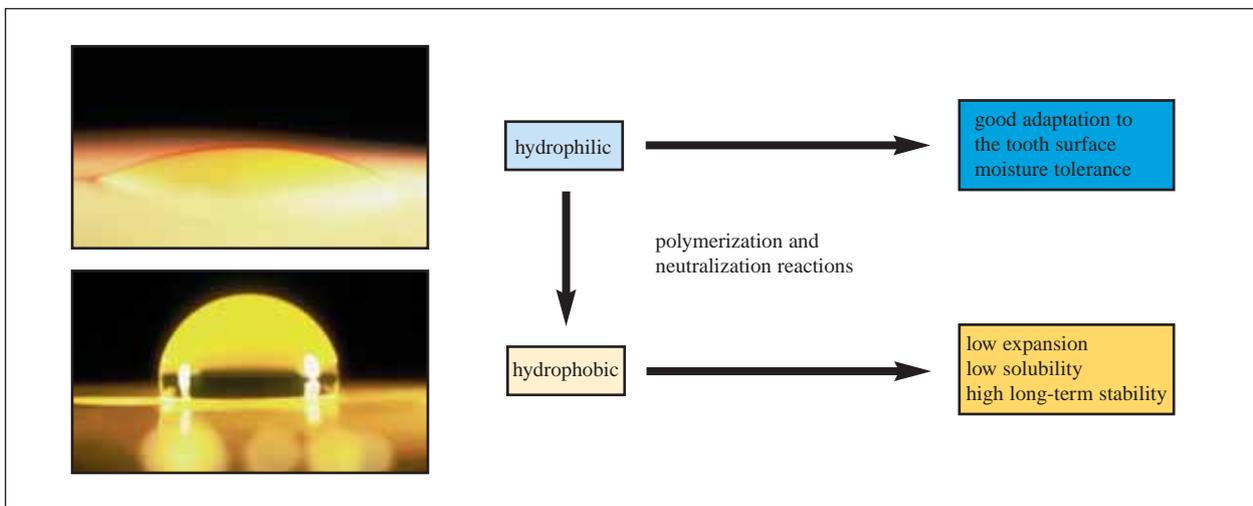
The shear bond strength of RelyX Unicem cement (self and light cure) on various metal, ceramic and composite restoration materials was determined after 20 hours of water storage.



## Active Transformation

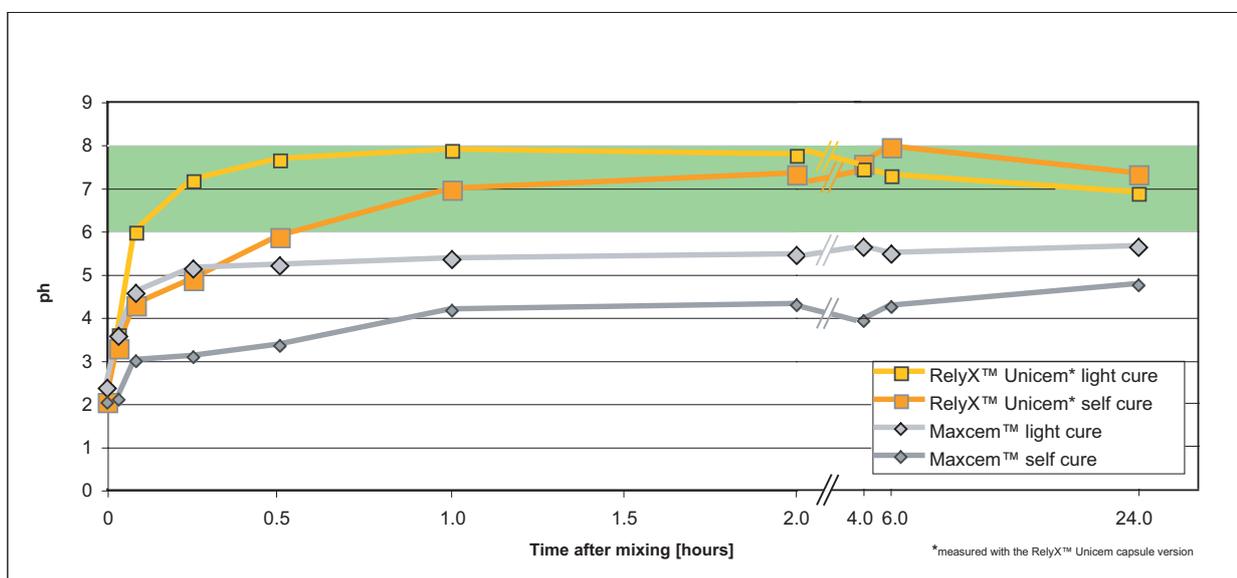
### Hydrophilic – Hydrophobic

Immediately after mixing RelyX™ Unicem, the cement paste is very acidic and has hydrophilic properties. Therefore it shows a higher moisture tolerance than multi-step composite cements. This together with the good adaptation to the hydrophilic tooth surface is the immediate advantage for the dentist during the very first steps of the clinical cementation procedure. The resulting high bond strength is one prerequisite for a long-lasting success of the restoration. During setting of RelyX Unicem cement a strongly cross-linked cement matrix with hydrophobic properties develops through the proceeding radical polymerization and the subordinate neutralization reactions. A low linear expansion and low solubility are the results and lead to the clinically proven, long-term stability which plays a central role especially for all-ceramic restorations. Thus, RelyX Unicem cement automatically changes its properties from hydrophilic to hydrophobic during setting.



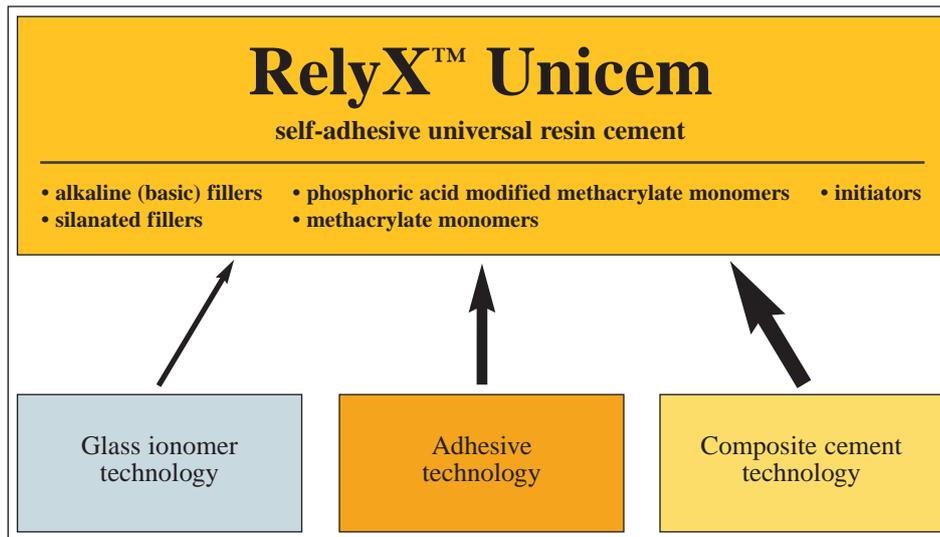
### Acidic – Neutral<sup>4</sup>

Parallel to the change from a hydrophilic to a hydrophobic state the pH-value increases during the setting of RelyX Unicem cement. Immediately after mixing RelyX Unicem the cement paste is very acidic. Within a few minutes the pH-value reaches about pH 5. After approximately 24 hours it is neutralized and has a pH of 7. After application to the tooth, the low pH-value of RelyX Unicem cement is pivotal for the self-adhesive mechanism, whereas the pH increase as well as the hydrophobic condition are essential prerequisites for the long-term hydrolytic stability of the cement.



## History and Innovation

The overall objective when developing RelyX™ Unicem cement was to combine the easy handling of conventional cements with the excellent mechanical properties, good adhesion and esthetics of composite cements. One goal within this development process was to achieve the adhesion to the tooth without any pre-treatment step whatsoever, i.e. without etching, priming, and bonding. A universal “all-purpose” cement, i.e. for cementing composite, metal and ceramic restorations, was created and introduced into the market as a powder/liquid system in the Aplicap/Maxicap capsule (RelyX Unicem cement). Since then the continually positive clinical performance proves that the researchers have been able to implement these requirements without compromising long-term or dimensional stability. Although this new self-adhesive cement technology is based on existing knowledge its ideal combination of easy handling known from conventional cements with a bond



strength comparable to that of adhesive resin systems demanded new monomers, fillers, and initiators. Now, based on the same reliable and proven chemistry, the formulation of the capsule system was transformed into a paste/paste system for the Clicker™ Dispenser application.

## New Monomers

Dental cements have to excel in the following areas: adhesion, mechanical properties, long-term stability, esthetics and biocompatibility. In order to provide RelyX Unicem cement with optimal properties and self-adhesion, the monomers which impart adhesion were optimized with regard to their basic structure as well as to the number and kind of their functional chemical groups. Several phosphoric acid groups and carbon double bonds per molecule are characteristic for the acidic methacrylate monomers in RelyX Unicem cement. Whereas the phosphoric acid groups contribute to self-adhesion, the carbon double bonds cause a high reactivity of the methacrylate monomers with each other. Thus after setting of RelyX Unicem, the cement matrix shows a high degree of cross-linking between the particular monomers. In this way good mechanical properties (e.g. high compressive and flexural strength) and adhesive bonding without pre-treatment can be achieved. Furthermore, a high degree of cross-linking is one essential requirement for the long-term stability of the cement which is met by RelyX Unicem.

## New Fillers

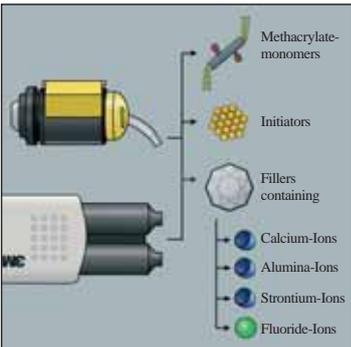
Fillers have also an important impact on the cement's properties. One fraction of the fillers in RelyX Unicem cement is silanated and, thus, is chemically embedded into the cement matrix during setting. Another fraction is able to react with the phosphoric acid groups of the methacrylate monomers in a neutralization reaction. Therefore, during setting the pH value increases and lifts the initially acidic RelyX Unicem cement paste to a neutral level. This avoids hydrolysis processes in the cement in the long run and is therefore another important prerequisite for the long-term stability of any initially acidic cement. Additionally, during the neutralization reaction fluoride ions are released from the fillers. RelyX Unicem cement provides these ions to the tooth substance without containing soluble fluoride salts in the cement matrix.

## New Initiator Systems

In dental technology most initiator systems for self curing (= chemical/dark curing) are based on alkaline (basic) amines. However, these are deactivated in an acidic environment which would inhibit self curing. For this reason, a completely new dual-curing initiator system was developed to function in the initially acidic RelyX™ Unicem cement paste. It is characterized by moisture tolerance and the ability to effectively initiate the polymerization reaction in a broad pH range. This ensures that the first step on the way to a highly cross-linked cement matrix proceeds most effectively. Thus, in addition to innovative monomers and fillers, the initiator system, too, contributes to a permanently strong bond strength and stability of RelyX Unicem cement.

## Setting Reactions

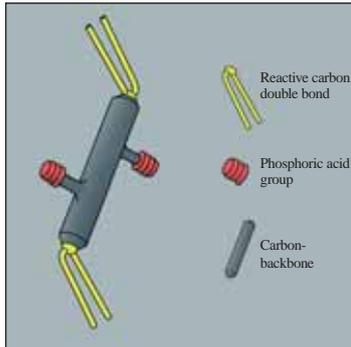
The setting of RelyX Unicem cement is started either by a curing light or by the chemical reaction of the initiator system. The main setting reaction is a radical polymerization reaction by which the single monomer molecules are chemically cross-linked to form a three-dimensional polymer network. Simultaneously, but to a minor extent, neutralization reactions take place, which are nonetheless quite important for the properties of the set RelyX Unicem cement. The following figures illustrate in a simplified way the reactions that proceed simultaneously during the setting of RelyX Unicem cement.



The main components of RelyX™ Unicem cement are:

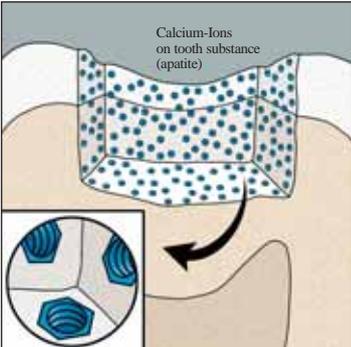
- **methacrylate monomers**, partially containing phosphoric acid groups
- **fillers**, one part releasing ions, another part is silanated
- **chemical initiator system**
- **light initiator system**

1



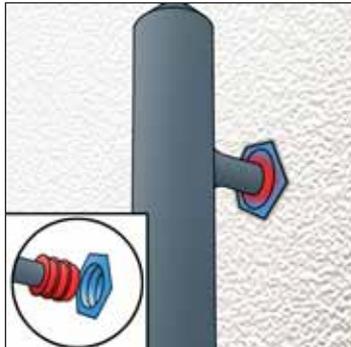
Acidic methacrylate monomers contain **phosphoric acid groups** and **reactive carbon double bonds** which are connected with each other via a carbon backbone.

2



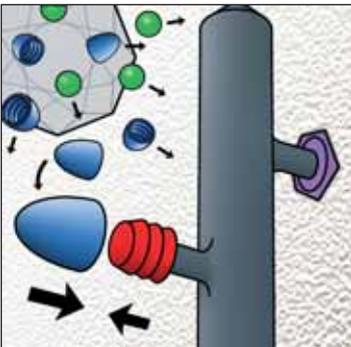
Next to the restoration material enamel and dentin are the substrates to which dental cement has to show safe and reliable adhesion. The tooth substance (enamel and dentin) consists of inorganic **apatite-crystals** containing calcium and organic **collagen fibers**. Additionally, the tooth structure contains **water**.

3



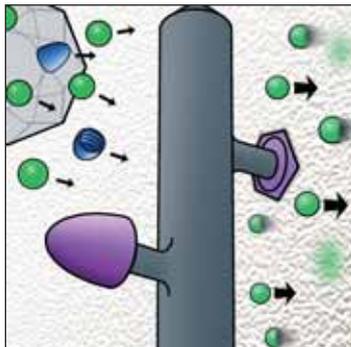
After mixing, RelyX™ Unicem cement is very acidic (**low pH-value**) and **hydrophilic** (water binding). Upon contact with the **tooth surface** the negatively charged phosphoric acid groups of the methacrylate monomers bond to **Ca<sup>2+</sup>-ions** in the tooth substance. Thus, the phosphoric acid groups are **neutralized** (i.e. pH rises) and anchored at the tooth surface.

4



The remaining phosphoric acid groups of the methacrylate monomers are **neutralized** by ions, which are released from the **fillers** during the setting reactions.

5



The released fluoride ions are **absorbed by the tooth substance**.

6

Simultaneously, setting of the cement takes place through the **radical polymerization reaction** of the methacrylate monomers.

The initiator system generates the necessary starter radicals through **light-induced or chemical activation**.

7

The methacrylate monomers are chemically cross-linked with each other through the interaction of **reactive carbon double bonds**.

8

**RelyX™ Unicem cement is cured** by the radical polymerization reaction. Thus, successively a highly cross-linked **three-dimensional network** is formed consisting of methacrylate molecules and fillers. During this process the cement matrix changes from an initially hydrophilic to a **hydrophobic** condition.

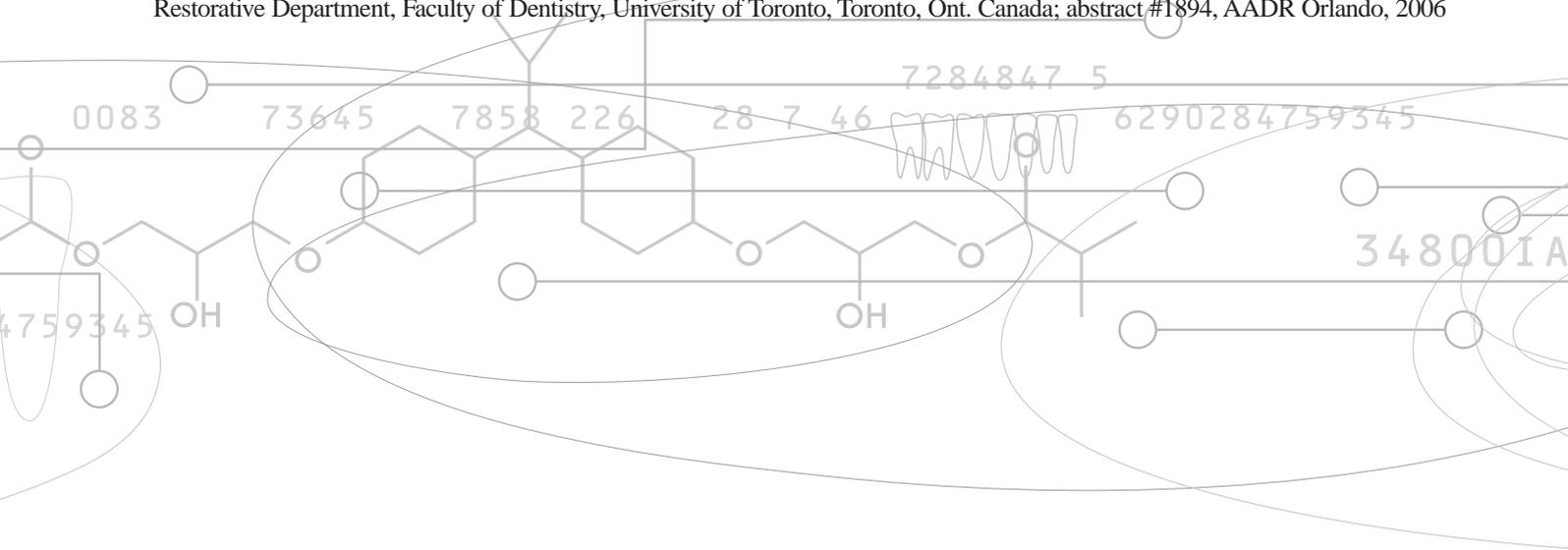
9

The methacrylate monomers and fillers are firmly linked and permanently embedded in the three-dimensional network of the cement matrix.

10

**Source:**

- <sup>1</sup> 3M ESPE internal data, 2006
- <sup>2</sup> PD Dr. A. Piwowarczyk, University of Frankfurt/Main, Germany, data submitted for publication, 2006
- <sup>3</sup> Prof. Dr. M. Behr, University of Regensburg, data submitted for publication, 2006
- <sup>4</sup> Physical Characteristics of New Universal Self-etching Resin Luting Cements, E. Sakalauskaite, L. Tam, and D. McComb; Restorative Department, Faculty of Dentistry, University of Toronto, Toronto, Ont. Canada; abstract #1894, AADR Orlando, 2006



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