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Technical Data Sheet

RelyX™ Unicem – Self-Adhesive Universal Resin Cement

Product Description

RelyX Unicem Aplicap is a dual-curing, self-adhesive universal resin luting cement in a capsule delivery system for adhesive cementation of indirect ceramic, composite or metal restorations. RelyX Unicem was developed for universal cementation, i.e. for usage with all-ceramic **as well as** metal restorations. When using RelyX Unicem Aplicap, bonding and conditioning of the dentin or enamel are no longer necessary. This provides for simplified resin cement procedure with a significant reduction in sensitivity potential. The cement is characterized by having good esthetics, high strengths, moisture tolerance, low linear expansion, high dimensional stability, high adhesion to tooth structure, availability in multiple shades and limited fluoride release.

Composition

The organic matrix of RelyX Unicem consists of recently developed novel multifunctional, phosphoric acid modified methacrylates. The phophorylated aspect allows for self-conditioning of the tooth surface and thus self-adhesion without a separate conditioner or adhesive. The unique dual-curing initiator system insures efficient polymerization in both the light-cured and self-cured mode thus resulting in high mechanical properties and dimensional stability.

The inorganic filler content of RelyX Unicem is approximately 72 % by weight, with an average particle size of less than 9.5µm. In addition, the fillers account for the cement's radiopacity in all available shades. One of the fillers has a characteristic basic property, allowing a cement reaction with the acidic functionality of the monomers. By this mechanism, adhesion to tooth structure is enhanced, the pH value increases to a neutral level in the course of the setting reaction, and there is fluoride release.

[1] A. Piwowarczyk, B. Windmüller, A. Mahler, H.-Ch. Lauer, IADR Meeting, San Diego, 2002, Abstract # 3342.
[2] 3M ESPE internal data, 2002.
[3] M. Irie, K. Suzuki, B. Windmüller, IADR Meeting, San Diego, 2002, Abstract # 3365.
[4] J. Powers, industrial report, 2002.
[5] A. Piwowarczyk, H.X. Berge, H.-Ch. Lauer, J.A. Sorensen, IADR Meeting, San Diego, 2002, Abstract # 3241.
[6] M. Rosentritt, M. Behr, R. Lang, G. Handel, IADR Meeting, San Diego, 2002, Abstract # 53.

Material Properties

Characteristics	Rely X Unicem	Panavia F	Variolink II
Physical material properties			
Film thickness [µm][1]	16 ± 2	21 ± 3	22 ±2
Depth of cure [mm][1]	2.5	0.7	3.1
Water sorption (dark curing) [µg/mm³][1]	25	26	20
Solubility (light curing) [µg/mm³][1]	-4	2	-3
Radiopacity [mm][1]	2.0	0.9	7.9
Flexural strength (light curing) [MPa][1]	63 ± 7	86 ± 17	105 ± 18
Compressive strength (light curing) [MPa][1]	241 ±9	244 ± 26	303 ± 32
Linear expansion after 1 month [%][2]	0.4	n/a	0.3
Shear bond strength on human dentin			
Dark curing[3] [MPa]	16.2 ± 1.9	13.4 ± 3,0	N/a
Light curing[4] [MPa]	19.5 ± 5.1	n/a	19.4 ± 5.2
Shear bond strength on indirect materials			
Empress 2 / HF etched (light curing) after 14 days of thermocycling[5]	18.42 ± 2.17	10.35 ± 1.86	18.82 ± 5.86
Lava / sand blasted (light curing) after 14 days of thermocycling[5]	12.66 ± 2.29	8.33 ± 2.42	2.78 ± 0.94

Marginal analysis of ceramic inlays(simulated mastication test)			
Perfect margin [%] Enamel before and after thermal and mechanical cycling[6]	98.1 / 98.5	97.3 / 100.0	100.0 / 97.0
Perfect margin [%] Dentin before and after thermal and mechanical cycling[6]	100.0 / 99.5	98.5 / 97.3	100.0 / 93.5

Indications

Final cementation of ceramic, composite or metal inlays, onlays, crowns, bridges, and endodontic pins and posts.

Shades

RelyX Unicem is available in the shades A1, A2 Universal, A3 Opaque, White-opaque and Translucent. All shades are radiopaque.

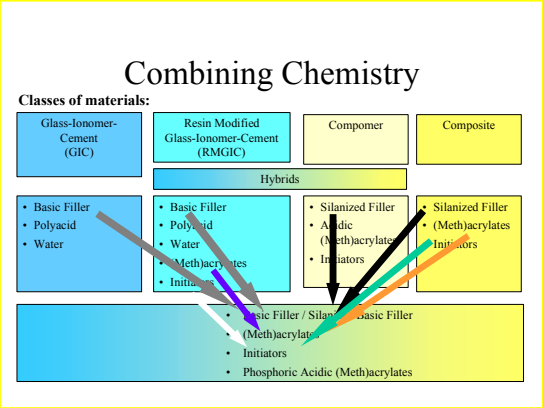
Discussion

The goal when developing RelyX Unicem was to combine the easy handling of conventional cements with the excellent mechanical properties, good adhesion and aesthetics of composites. One objective within this goal was to obtain adhesion to the tooth without any pre-treatment steps. A universal "all-purpose" cement, i.e. for cementing metal and ceramic restorations, was created. This was achieved without compromising long-term dimensional stability or low linear expansion.

Advantages of Conventional Cement Types	Advantages of Resin Cements
☺ Easy handling	☺ Good mechanical properties
☺ Moisture tolerance	☺ Good adhesion after respective pre-treatment
☺ No pre-treatment steps	☺ Good aesthetics / translucency
☺ Main indication: metal-based restorations	☺ Main indication: ceramic restorations

The combination of the advantages of conventional and resin cements was realized by optimally combining advantageous components from all material classes.

If we observe the revolutionary product profile more closely it becomes clear that the development of the self-adhesive universal resin cement RelyX Unicem could not be achieved by efforts to improve existing products. Its monomer, filler and initiator technologies required a completely new and novel development effort to achieve the desired results.



New Monomers

In principle, self-adhesion can be generated by using phosphorylated methacrylates. But it is only by complex optimization of the monomer system and the use of multifunctional monomers that essential requirements such as high aesthetics, low expansion (a basic prerequisite for the use with dental ceramics) and good mechanical values can be guaranteed.

Filler Technology

In order to guarantee the long-term stability of an initially acidic system, an increase of the pH-value to neutral level has to be reached during setting. Otherwise, hydrolysis processes would be an immediate consequence. This happens in a similar manner as with glass ionomer technology. The desired increase of the pH takes place by a reaction of the acidic functionality with the basic fillers as well as having some fluoride release without adding any soluble fluoride salts.

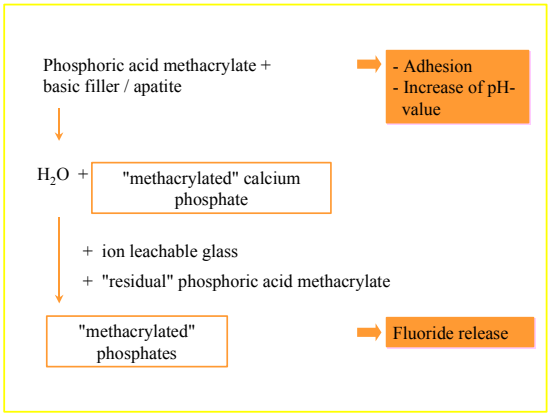
Initiator system

Most self-cure initiator systems used in dental materials are based on the use of amines. They are, however, incompatible with acidic systems. This has been understood for some time in connection with the newer self-etching adhesive systems. For the development of a self-adhesive, dual-curing cement it was imperative and essential to develop a completely new initiator system. This system is designed to work under conditions of light-curing as well as dark-curing. Tolerance towards humidity is as important as the functional ability within a wide range of pH-values. Moreover, it has to tolerate a high degree of networking of the monomer matrix in order to allow long-term stability and reliable adhesion. This was a very complex task that was realized for the first time with the new RelyX Unicem cement.

Setting Reaction

The predominant setting reaction which hardens the material and which is responsible for the high mechanical dimensional stability properties, actually is a radical polymerization reaction. It can be initiated by light activation or via a redox system and happens in a way analogous to the reactions used for composite materials. By utilizing the special monomers mentioned before, a high degree of networking and a high molecular weight of the polymers are generated. As a result, low solubility, low swelling and high biocompatibility are achieved.

However, for really understanding how RelyX Unicem works, further reactions have to be taken into account. These are indicated in the following chart.



In addition to the radical polymerization reaction, the acid modified monomers are also involved in an acid-base reaction with the basic fillers.The monomers used are not only subject to the described polymerization reaction. By functional groups in the same molecule which are modified by phosphoric acid, a reaction with basic salt occurs on the one hand. Additionally, there is a reaction with the tooth structure's apatite. During this neutralization reaction, water is released. This step makes a contribution to hydrophilicity and therefore to a good adaptation of the cement to the dentin but also to its tolerance towards moisture, which in everyday practice should be reflected by fewer problems when used subgingivally. The generated water is used up as it reacts with the acidic monomer and the ion-releasing basic filler. Two advantages result from this reaction: An intelligent switch to a hydrophobic matrix and the verifiable fluoride release.

How to explain the difference towards known hybrid systems (RMGI's and Compomers)?

Resin-modified glass ionomers utilize hydrophilic monomers and have water present after setting resulting in a hydrophilic system and a higher degree of swelling. Additionally, monofunctional monomers are used with this material class, leading to a limited cross-linked network.

Though compomer systems reach a higher degree of cross-linking, the reaction of polyacid with glass fillers is remarkably reduced. This is the cause for an uncompleted neutralization of this system. In the long run, this results in a certain susceptibility to hydrolysis processes. These shortfalls can be avoided with the novel chemistry of RelyX Unicem.