

# RelyX™ Unicem 2 Automix

Self-Adhesive Resin Cement



## Technical Data Sheet

**3M** ESPE

# 1 Introduction

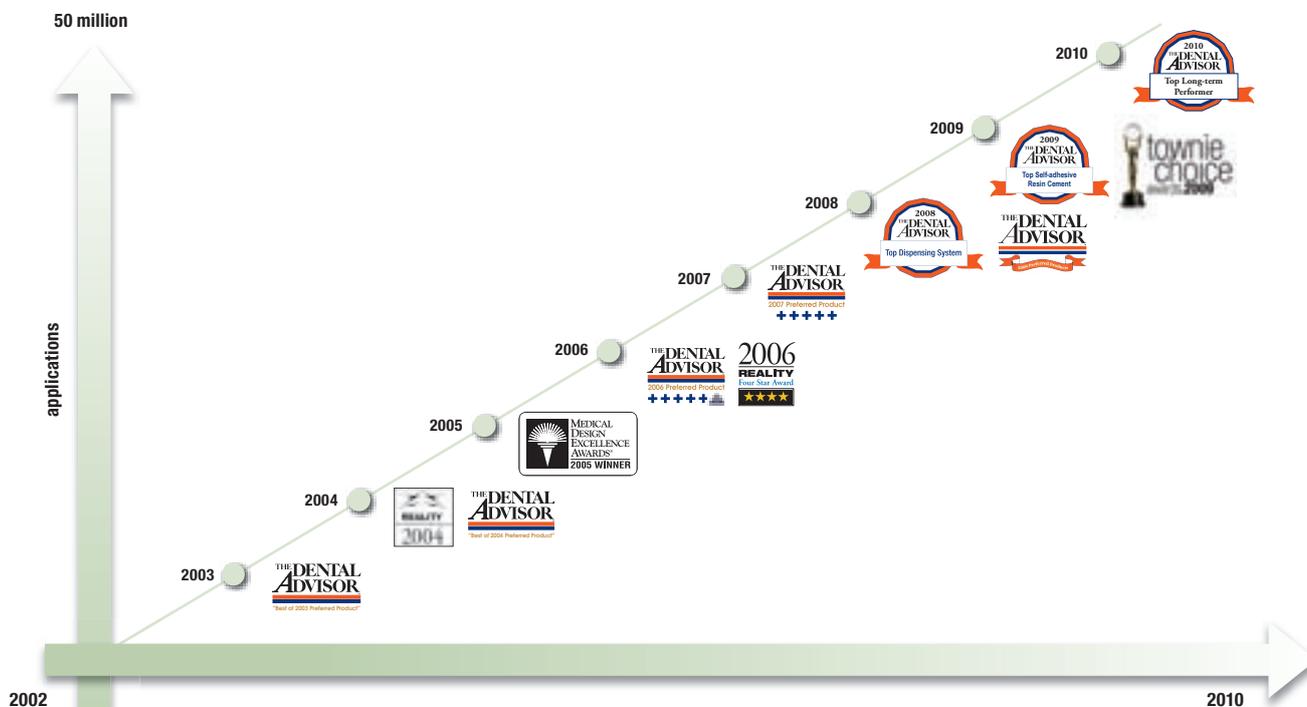
RelyX™ Unicem 2 Automix represents the next generation of self-adhesive resin cements.

This newcomer is based on the same chemistry as RelyX™ Unicem, the most clinically proven self-adhesive resin cement worldwide. This year it received the “2010 Top Long-term Performer” award by THE DENTAL ADVISOR\*, which is only one of many awards the cement has won.

\*www.dentaladvisor.com



The improved formulation remains closely related to its predecessor, while offering even more convenience due to its automix delivery system. The syringe dispenses the ready-mixed cement using mixing tips offered in three different sizes: Mixing tips for standard applications, endo tips ensuring a safe and void-free procedure when working in the root canal and for the cementation of inlays and onlays, special intra-oral tips are available as well.



As with the 1<sup>st</sup> generation, the need for any pre-treatment of the tooth, such as etching, priming and bonding, is eliminated. The combination of proven technology with innovative features makes RelyX Unicem 2 Automix cement a convenient and powerful, high performing product.

## Product benefits at a glance:

### Simplicity

- Ease of use delivery system
- Self-adhesive
- Dual-cure
- Moisture-tolerant
- Very easy removal of excess

### Performance

- Very high bond strength on all substrates
- Low post-operative sensitivity
- Excellent mechanical properties
- Excellent color stability
- Long-term stability

## 2 Indications

RelyX™ Unicem 2 Automix cement is indicated for the permanent cementation of

- All-ceramic, composite, or metal inlays, onlays, crowns and bridges
- Posts and screws
- All-ceramic, composite, or metal restorations to implant abutments
- 2- or 3-unit Maryland bridges and 3-unit inlay/onlay bridges\*

\*The high adhesive bond strength of RelyX Unicem 2 Automix cement allows for reliable and comfortable cementation of Maryland and inlay/onlay bridges. For these indications an additional enamel etching step is required to increase the available surface area for bonding.

## 3 Description of self-adhesive resin cements

Based on their chemical composition, two of today's most commonly used dental cements are resin cements.

These cements can be classified into two groups – adhesive and self-adhesive resin cements. Various pretreatment steps (etching, priming, bonding) and the absolute exclusion of moisture (rubber dam) are necessary to successfully use adhesive resin cements. Therefore, adhesive cementation is much more technique sensitive than conventional cementation and the clinical success may be compromised by the technical challenges it imposes on the dentist. These drawbacks were resolved with the introduction of the first self-adhesive universal resin cement RelyX™ Unicem in 2002.

The next generation RelyX Unicem 2 Automix raises the high standard even higher: very easy and convenient usage combined with outstanding bond strength and very good mechanical properties.

### 3.1 What's unique for RelyX Unicem 2 Automix?

RelyX™ Unicem 2 Automix is based on the same proven and patented chemistry as RelyX™ Unicem Aplicap™/Maxicap™ Capsules and Clicker™ Dispenser. The RelyX™ Unicem adhesion monomer (a phosphoric acid methacrylate), the patented initiator system and the special filler technology providing the unique neutralization behaviour remained unchanged.

Several modifications to that system were made to further enhance material properties and to achieve reliable material quality when automatically mixed in the mixing tip. An additional monomer and a new rheology modifier were added to the mixture and we optimized the processing of our filler particles. All that leads to a formulation optimized for the new syringe delivery and displaying increased mechanical properties and excellent overall adhesion performance.

### 3.2 Chemical composition

Base paste	Catalyst paste
Methacrylate monomers containing phosphoric acid groups	Methacrylate monomers
Methacrylate monomers	Alkaline (basic) fillers
Silanated fillers	Silanated fillers
Initiator components	Initiator components
Stabilizers	Stabilizers
Rheological additives	Pigments
	Rheological additives

## Setting reaction

The setting of RelyX™ Unicem 2 Automix cement is the same as for RelyX™ Unicem. The reaction is started by light and/or by a chemical reaction of the initiator system (dual cure). The setting reaction is a radical polymerization during which the single monomer molecules are chemically cross-linked to form a three-dimensional polymer network. Simultaneously, neutralization reactions take place, which are important for the long-term stability of the set RelyX Unicem 2 Automix cement.

# 4 Application

RelyX Unicem 2 Automix combines the simple handling of the Automix syringe with the performance and convenience known of RelyX Unicem.

The system includes three shades (translucent, A2 universal and A3 opaque) offered in a 8.5 g automix syringe. Mixing tips for standard application, angulated intra-oral tips, and endo tips are available.

### Convenient and easy to use:

- Comfortable handling
- Optimal consistency for dispensing and seating
- Flexible dosing
- Time-saving
- Universal – a versatile choice of tips allows always easy application for different indications
- Low risk of air bubbles and voids
- Easy excess removal

## 4.1 The delivery system is highly accepted by dentists

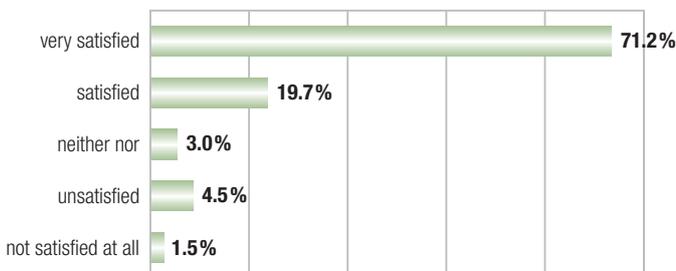


Fig. 1: Satisfaction level regarding delivery system. Source: Field Test Jan. 2010, n = 68

## 4.2 The rheology of the cement is optimized for the delivery system and also for the clinical handling

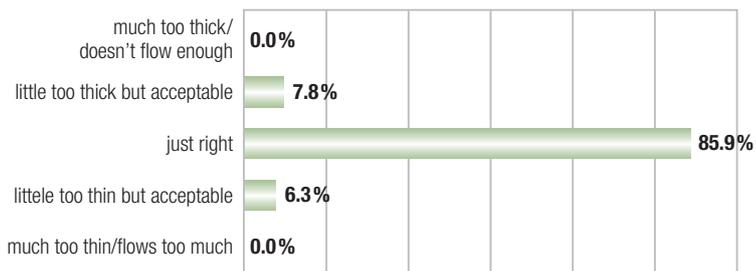


Fig. 2: Evaluation of the consistency of the cement when applying into or onto the restoration. Source: Field Test Jan. 2010, n = 68

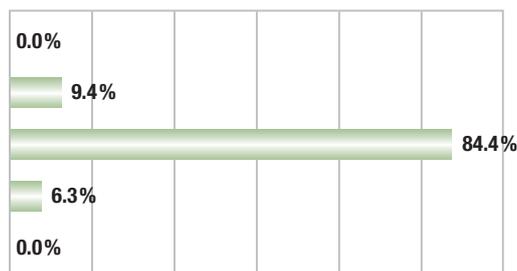


Fig. 3: Evaluation of the consistency of the cement when placing the restoration in the mouth.

### 4.3 Excess removal

Excess cement is best removed after brief – approximately two seconds – light exposure or alternatively during self-curing in the gel/wax-like state. Excess material of larger volume is easier to remove. The simplicity and easy excess removal is confirmed by 84 % of dentists in a field test.

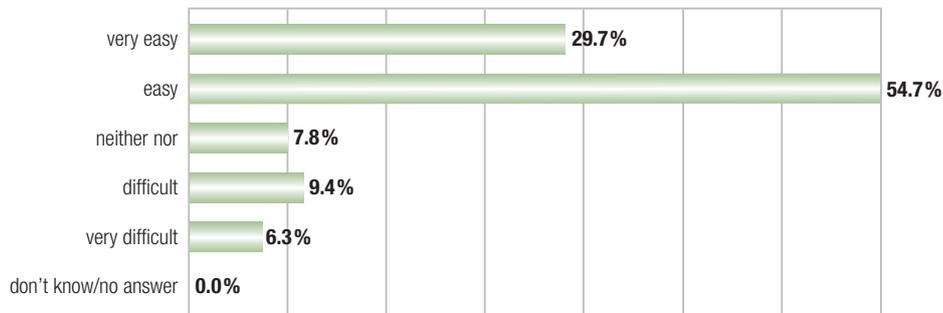


Fig. 4: Rating for excess removal. Source: Field Test Jan. 2010, n = 68

### 4.4 The perfect system: RelyX™ Unicem 2 Automix and RelyX™ Fiber Post

The endo tips facilitate easy access to the root canal, so you can apply cement in the canal from bottom to top. Compared to the traditional method of coating the post with cement before insertion, the risk of entrapping air bubbles and voids is much lower. This leads to outstandingly strong and virtually void-free post cementations.

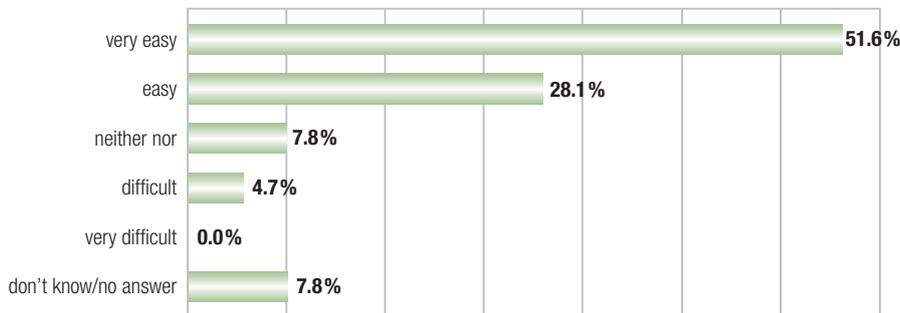


Fig. 5: Rating for usage of endo tips for post cementation. Source: Field Test Jan. 2010, n = 68

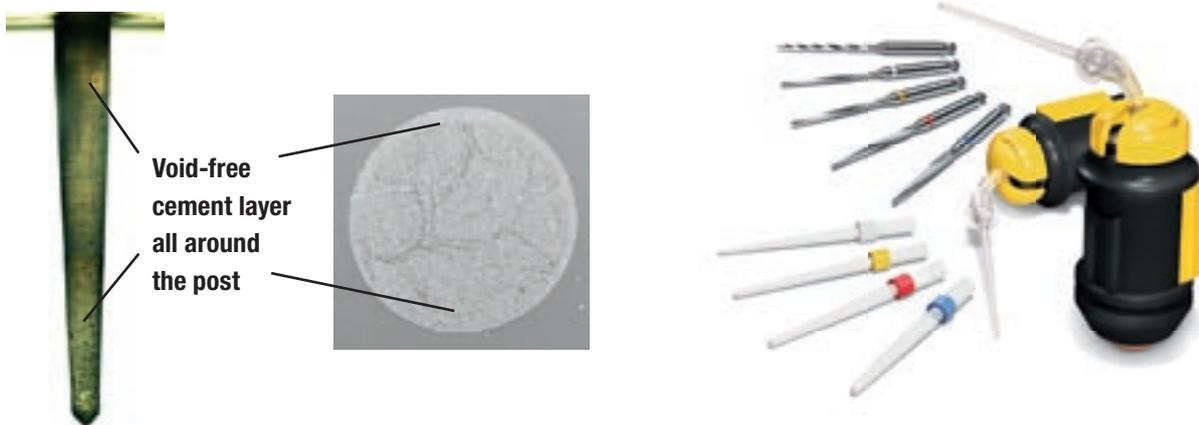


Fig. 6: The method of cement application determines the number of voids. Light microscopy and SEM images (cross section) of a simulated root canal filling in an acrylic glass test device. Source: Watzke R., Frankenberger R., Naumann M.; Probability of interface imperfections within SEM cross-sections of adhesively luted GFP. DentMater. 2009 Oct; 25(10): 1256-63

# 5 Material Properties

In summary, strong performance needs to be balanced over many clinical relevant criteria to help the restoration to become a clinical success. Those criteria go well beyond bond strength to tooth or to restorative material and consider longevity, esthetics and marginal quality.

When several self-adhesive resin cements were compared, RelyX Unicem 2 Automix shows very good values for all important parameters.

**The strength of RelyX Unicem 2 Automix is the lack of a weakness – and that makes it reliable and successful.**

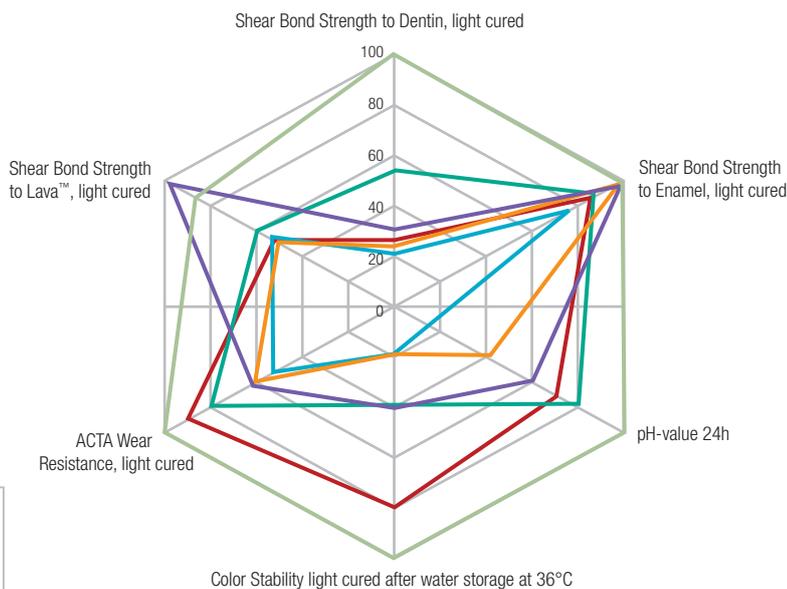
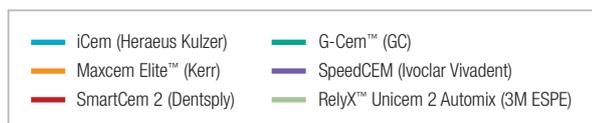


Fig. 7: Several self-adhesive resin cements were compared in different material properties. The best result achieved in each test was set to 100, the results of the other materials in the same test series were calculated in percent relative to the best. Source: 3M ESPE internal data

## 5.1 Bond strength

In independent research, RelyX Unicem 2 Automix shows the highest bond strength to dentin (Fig. 8), etchable ceramics and zirconia (Fig. 10), compared to other self-adhesive resin cements.

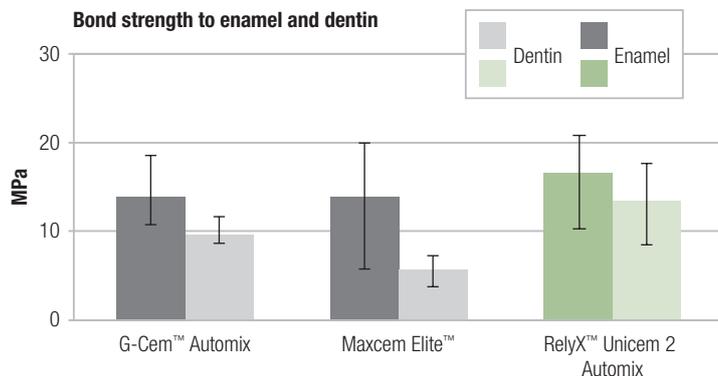


Fig. 8: Shear bond strength (light cured) after 24h and thermocycling (6–60°C/15 s dwell time/1000 cycles). Source: S Singhal, J Burgess, D Cakir et al. Birmingham, AL, USA. IADR 2010 # 139456

In this clinical relevant test design, Zirconia (Lava™) crowns are cemented onto slightly conical (10°) tooth preparations and pulled off. RelyX Unicem 2 Automix shows excellent retentive strength compared to other cements.

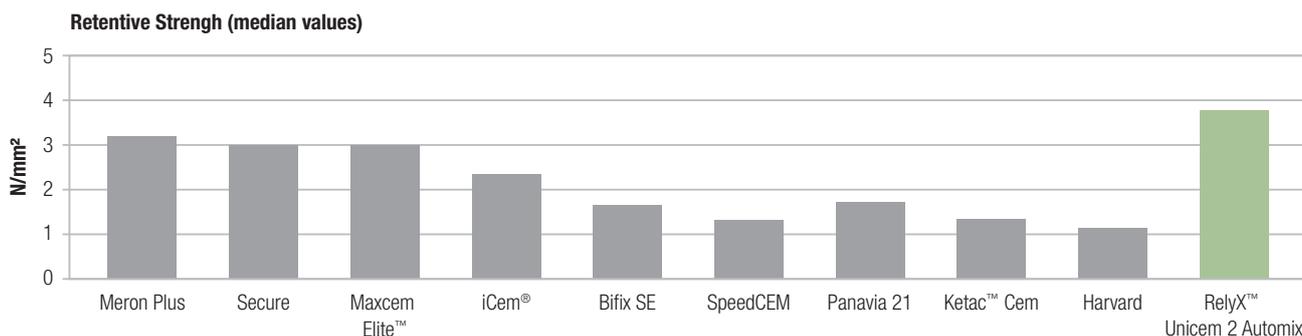


Fig. 9: Retention of zirconia crowns. Source: CP Ernst et al. Mainz, Germany. IADR 2010 # 394

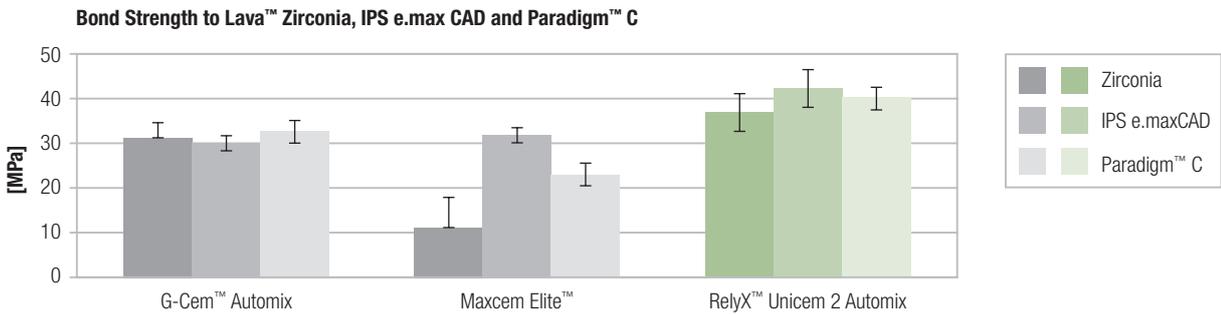


Fig. 10: RelyX™ Unicem 2 Automix showed significantly higher bond strength to Lava™ zirconia, e.max, and Paradigm™ C than all other cements (p<0.05). Source: S Singhal, J Burgess, D Cakir et al. Birmingham, AL, USA. IADR 2010 # 395

RelyX Unicem 2 Automix performs at a high level on all substrates. The interface to tooth structure as well as to restoration materials is reliably bonded.

## 5.2 With RelyX Unicem 2 Automix cement, the retention rate for RelyX Fiber Posts is significantly greater than with other self-adhesive resin cements

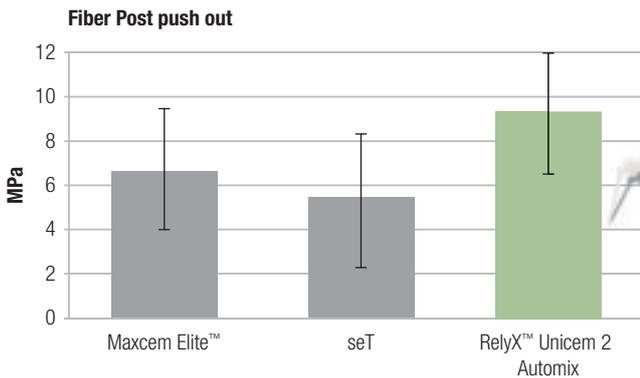


Fig. 11: RelyX™ Unicem 2 Automix exhibited a significantly greater retentive ability and provided a better marginal seal in the root canal than the other self-adhesive resin cements. Source: Interfacial strength and morphology of new self-adhesive resin cements. A. CANTORO, C. GORACCI, A. MAZZONI, L. BRESCHI, and M. FERRARI; IADR 2010 #621

## 5.3 Marginal sealing

The reliable marginal sealing is crucial for a long lasting restoration. Debonding to tooth structure would enhance the risk of secondary caries. RelyX Unicem 2 shows impressive marginal sealing after artificial aging resulting in least dye penetration. The SEM analysis confirms the dye penetration results. The integrity of bonding surfaces to tooth structure as well as to restoration is obvious.

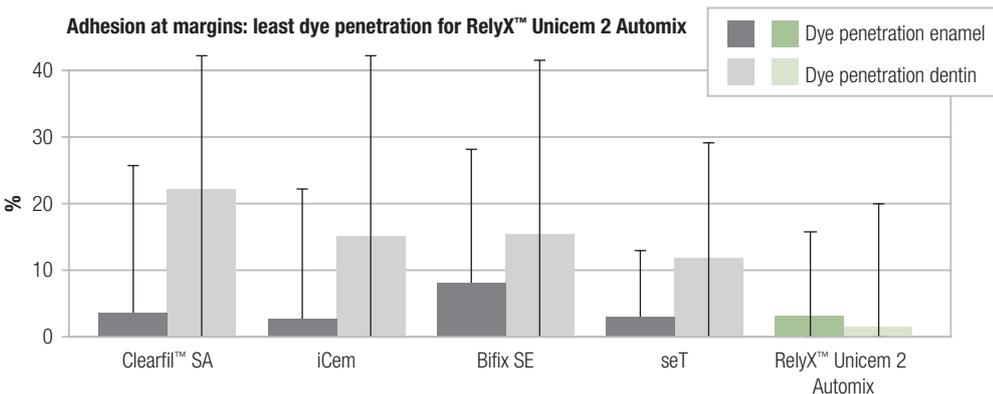


Fig. 12: Dye penetration for MOD inlays after simulation of 5 years clinical wear (1c, thermocycling and mastication 1.2×106×50N, 6000×5°/55°C, 1.6HZ). Source: M. Rosentritt, C. Aschenbrenner, M. Behr et al. Regensburg, Germany. IADR 2010 # 3976

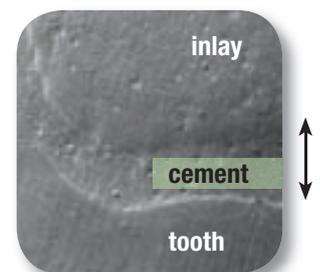


Fig. 13: Outstanding marginal sealing of RelyX™ Unicem 2 Automix. Source: M. Rosentritt, C. Aschenbrenner, M. Behr et al. Regensburg, Germany. IADR 2010 #3976

## 5.4 Abrasion resistance

Due to the optimal balance of mechanical properties the wear resistance of RelyX™ Unicem 2 Automix is superior. This will help to keep the initial marginal sealing over the life time of restoration and prevents marginal discoloration due to marginal gaps.

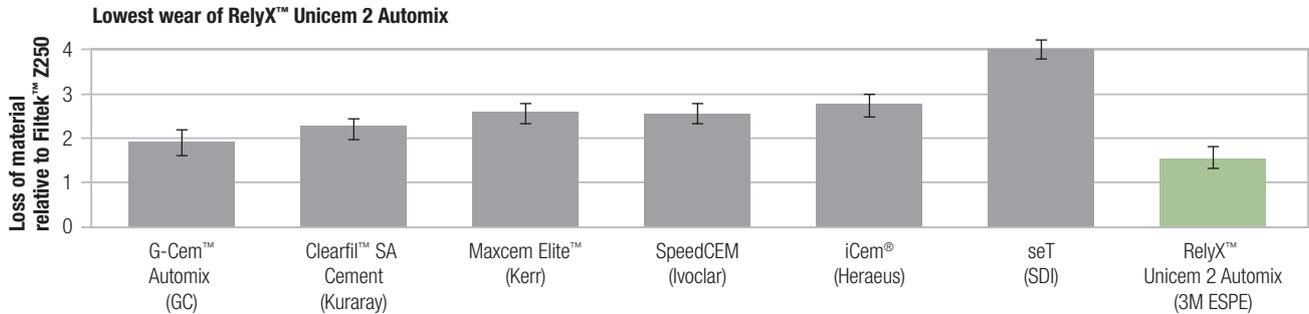


Fig. 14: ACTA-Abrasion test. Cements light cured. Source: 3M ESPE internal data

## 5.5 Consistency

The mixing quality is very important for final material performance. To achieve best mixing results in a static mixing tip, the catalyst and base pastes need to flow into each other readily. So they are well adapted in their rheology. The similar rheology leads to a homogeneously mixed material which can perform reliably in the clinical application.

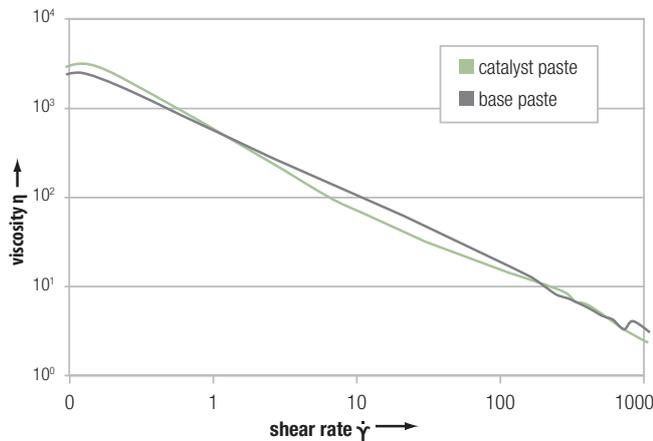


Fig. 15: The catalyst and the base paste show similar behaviour in viscosity when shearing. Source: 3M ESPE internal data

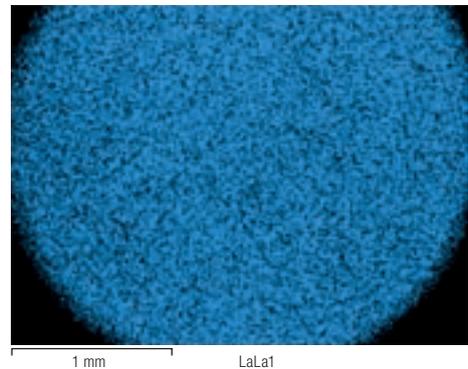


Fig. 16: Element (lanthanum) mapping of a RelyX™ Unicem 2 sample shows homogeneous distribution over the cement disc surface. Source: 3M ESPE internal data

## 5.6 Long term stability (pH progression)

The pH-value increases during the setting of RelyX Unicem 2 Automix cement. Immediately after mixing RelyX Unicem 2 Automix, the cement paste is very acidic. Within a few minutes the pH-value starts to increase and within 24 hours reaches a neutral level. After application to the tooth, the low pH-value of RelyX Unicem 2 Automix cement is crucial for the self-adhesive mechanism, whereas the pH increase is essential prerequisite for the long-term stability of the cement.

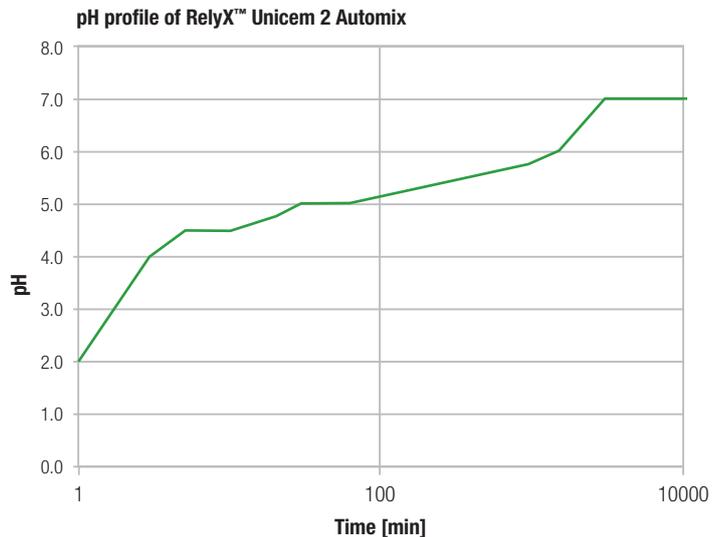


Fig. 17: pH-values were measured using a pH indicator paper at different times after mixing the cement. Source: 3M ESPE internal data

The unique chemical formulation of RelyX™ Unicem 2 Automix raises its pH to a neutral level after application. This contributes to the material becoming hydrophobic, meaning it is better able to resist water uptake, staining and cracking



Fig. 18: Results of stress test on self-adhesive resin cements. All samples were self-cured and thermocycled 10,000 times. Source: 3M ESPE internal data

## 5.7 Esthetics – Color stability

Compared to other leading products, RelyX Unicem 2 Automix clearly shows the lowest discoloration after incubation in a coffee solution. The pictures show cement samples after storage in standardized coffee solution for 3 days at 36 °C.



	before	after
RelyX™ Unicem 2 Automix		
Maxcem Elite™		
SmartCem® 2		
G-Cem™		

Fig. 19: Storage of cement specimen (light cured) in standardized coffee solution for 3 days. Source: 3M ESPE internal data

## 5.8 Mechanical Properties overview

Properties	RelyX™ Unicem 2 Automix (lc)
Flexural strength [MPa]	99
Compressive strength [MPa]	291
Modulus of elasticity [GPa]	6.6
Surface hardness [MPa]	190
Film thickness [µm]	13
Water sorption [µg/mm <sub>3</sub> ]	28
Solubility [µg/mm <sub>3</sub> ]	0
Expansion after 1 month [%]	0.63

Source: 3M ESPE internal data



# 6 Clinical Performance

## 6.1 Results from field test

1593 restorations were cemented by 68 dentists within the European application test. RelyX Unicem 2 Automix was used for the indications displayed in Fig. 20.

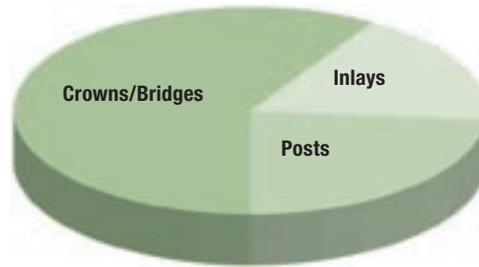


Fig. 20: Indications.

### Overall satisfaction

97 % of respondents were very satisfied or satisfied with RelyX Unicem 2 Automix Cement.

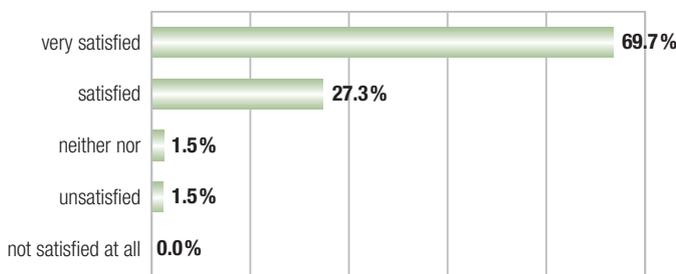


Fig. 21: Overall satisfaction with RelyX™ Unicem 2 Automix. Source: Field Test Jan. 2010, n = 68

### Post-operative sensitivities

Only 0.25 % (4) sensitivities were reported for the 1593 restorations placed with RelyX™ Unicem 2 Automix (Fig. 22).

Source: Field Test Jan. 2010, n = 68

#### Post-operative sensitivities

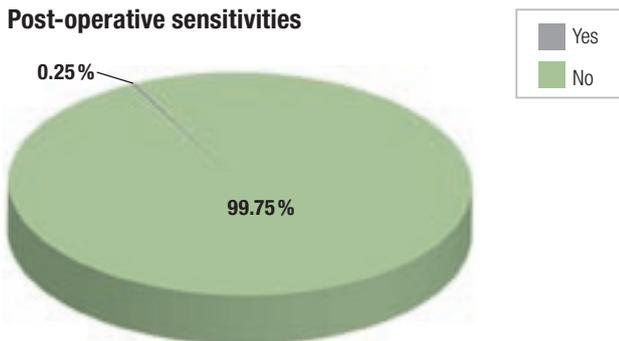


Fig. 22: 0.25% post-operative sensitivities reported. Source: Baseline report, May 2010, Dr. Dr. A. Syrek

The low post-operative sensitivity rate was also confirmed in a controlled clinical trial for RelyX™ Unicem 2 Automix. Zero cement related hypersensitivities were reported.



## 6.2 Clinical cases

### Restoration of the anterior region with a 6-unit Lava™ Zirconia bridge

Dr. med. dent. Jakob Zafran, Zurich, Switzerland

Initial situation.



Prepared abutment teeth and recovering gingiva after covering of the pontic area with a connective tissue graft.



Esthetic and functional try-in of 6-unit Lava™ bridge before final glaze firing.



Filling of the bridge abutments with RelyX™ Unicem 2 Automix cement out of the automix syringe.



Restoration seated in the patient's mouth. Excess cement will be removed in the gel phase after initial curing.



Final light curing of RelyX™ Unicem 2 Automix cement.



6-unit Lava™ Zirconia bridge *in situ* after light curing and removal of excess cement. Also note improved pink esthetics.



### All Ceramic Restoration on Root Treated Second Upper Premolar

Dr. Barbara Cerny, Munich, Germany

Initial situation.



Preparation of the root canal using RelyX™ Fiber Post drills (3M ESPE).



Fit check of the RelyX™ Fiber Post (3M ESPE).



Extra-oral trimming of the RelyX™ Fiber Post.



Attaching mixing tip with endo tip on RelyX™ Unicem 2 Automix syringe (3M ESPE).



Application of RelyX™ Unicem 2 Automix cement directly into the root cavity.



Insertion of the RelyX™ Fiber Post.



Light curing using Elipar™ S10 Curing Light from 3M ESPE.



Preparation for Lava™ Crown (3M ESPE).



Lava™ Crown after final cementation.



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