

Cementation Solutions

# RelyX™ Unicem

Self-Adhesive Universal Resin Cement

Espertise™

Clinical Studies  
2003 – 2009



**3M** ESPE



# RelyX™ Unicem

Self-Adhesive Universal Resin Cement

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Development team RelyX™ Unicem Cement

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## Introduction

The permanent cementation of an indirect restoration is a critical step in the overall treatment procedure. If the cement does not live up to its promise, in the worst case a new restoration has to be made. This is time consuming and annoying for you as a dentist as well as for your patients.

Therefore, we at 3M ESPE are proud to offer RelyX™ Unicem Self-Adhesive Universal Resin Cement which has been used by dentists worldwide over 35 million times since its introduction in the year 2002. RelyX Unicem has become one of the most-sold permanent resin cements.

With RelyX Unicem cement the 3M ESPE R&D team in Seefeld succeeded in fulfilling the market's request for a very strong but easy-to-use permanent cement. The outstanding strength and adhesion, the versatile indications as well as easy handling make RelyX Unicem an outstanding cement.

RelyX Unicem cement is an innovative product, proven *in vivo* for years, that you can trust – no matter which restoration type you choose: full ceramic, metal, PFM or composite.

This brochure combines clinical studies and an *in vivo* research on RelyX Unicem cement. You will find independent studies between 60 days and 5 years and two clinical cases using RelyX Unicem cement with RelyX Fiber Posts and Lava™ Zirconia Crowns.

We here in Seefeld are happy that with RelyX Unicem cement we came up with another product that achieves outstanding clinical results and simplifies your daily practice.

With best regards



Dr. Rainer Guggenberger  
Corporate Scientist

3M ESPE, Seefeld/St. Paul, March 2009

## Restorations after 5 years *in vivo*

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Title: 3M ESPE RelyX™ Unicem Self-Adhesive Universal Resin Cement  
5-Year Clinical Performance

Published in: THE DENTAL ADVISOR, No. 6, May 2008

**Aim of the study:** The evaluators of THE DENTAL ADVISOR used RelyX™ Unicem Cement to seat all-ceramic and PFM restorations (crowns, bridges, inlays/onlays and posts).

The characteristics RelyX Unicem cement was evaluated in included post-operative sensitivities, microleakage and debonding.

**Results:** At five years, more than 1800 restorations were available for recall, 380 of which had been *in situ* five years or more. Post-operative sensitivities only occurred in very few patients (1.8% occasional temperature sensitivity). Microleakage was comparable to that of 5<sup>th</sup> and 6<sup>th</sup> generation bondings and corresponding resin cements.

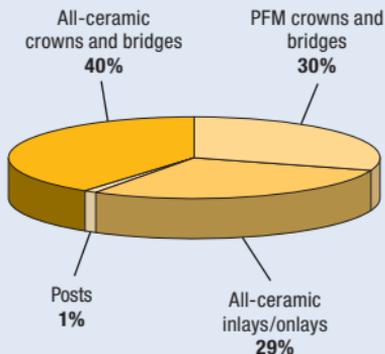
The debonding of restorations cemented with RelyX Unicem was reported to be low with 0.8%. In total, RelyX Unicem cement received a clinical rating of 99%, so that THE DENTAL ADVISOR awards its top grade of 5 plus's now the fifth year in a row.

Observation period: 5 years

Allocation of the restorations

Results (in %):

Post-operative sensitivities (n = 1820)	1.8%
Marginal discolorations (n = 1820)	5.1%
Debonding rate	0.8%



## Glass ceramic inlays and onlays after 4 years *in vivo*

Title: Single and Multi-Step Luting Agents after Four Years

Published by: S. Geraldini<sup>1</sup>, C. Stanford<sup>1</sup>, D. Dawson<sup>1</sup>, J. S. Wefel<sup>1</sup>, S. Timmons<sup>2</sup>, D. S. Cobb<sup>1</sup>, M. Hernandez<sup>1</sup>, S. Guzman-Armstrong<sup>1</sup>, T. Flynn<sup>1</sup>, C. M. Asmussen<sup>1</sup>, S. Hansen<sup>1</sup> and D. Stark<sup>1</sup>, <sup>1</sup>University of Iowa, Iowa City, IA, <sup>2</sup>University of Iowa, Coralville, IA, IADR 2009 Miami, #1639

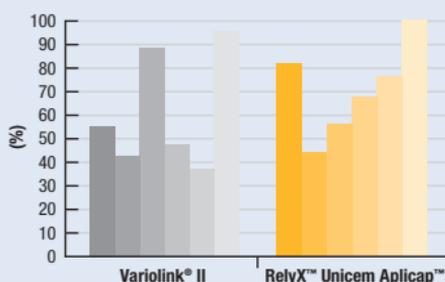
**Aim of the study:** In this clinical study 95 all-ceramic class I and II restorations (Authentic<sup>®</sup>, Microstar, Atlanta, USA) were cemented with RelyX™ Unicem Cement and a total-etch-system (Syntac<sup>®</sup>, Variolink<sup>®</sup> II, Ivoclar Vivadent). The restorations were evaluated initially and then in yearly recalls for post-operative sensitivity and according to USPHS criteria.

**Results:** At the 4-year follow-up examination RelyX Unicem Self-Adhesive Universal Resin Cement performed as well as Variolink II which was used with additional etching and bonding steps.

### Observation period: 4 years

	Syntac <sup>®</sup> / Variolink <sup>®</sup> II	RelyX™ Unicem Aplicap™
Number of restorations in the follow-up examination after 4 years	19	21

### Clinical results after 4 years



## All-ceramic inlays and onlays after 24 months *in vivo*

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Title: IPS Empress Inlays Luted with a Self-Adhesive Resin Cement After Two Years

Published by: M. Taschner, R. Frankenberger, A. Petschelt and N. Krämer, University of Erlangen, Germany.

Published in: IADR CED 2007, # 013

Complete abstract: 3M ESPE Scientific Facts, June 2008

**Aim of the study:** In this *in vivo* study RelyX™ Unicem Cement was compared with a total-etch-system (Syntac®, Variolink® II, Ivoclar Vivadent). In the split mouth design, IPS Empress® inlays and onlays were cemented with both systems and examined after 2 years *in situ*.

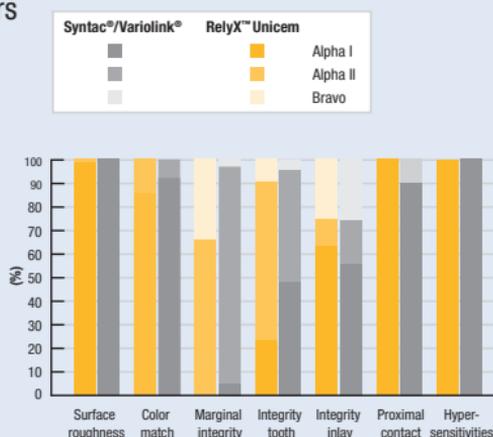
**Results:** After two years, both materials showed clinically acceptable results for all evaluation criteria. No significant differences were found between Syntac/Variolink II and RelyX Unicem cement regarding surface roughness, color match, integrity inlay and hypersensitivities.

Observation period: 12 months  
Average age of patients: 39 years

	Syntac®/ Variolink® II	RelyX™ Unicem Aplicap™
Number of cemented inlays/onlays	40	43
Number of restorations in the follow-up examination after 24 months	39*	43

\*24 loss

### Clinical results after 24 months



## All-ceramic inlays and onlays after 2 years *in vivo*

Title: 2-Year Clinical Effectiveness of a Self-Adhesive Luting Agent

M. Peumans, J. De Munck, K. Van Landuyt, A. Poitevin, P. Lambrechts, and B. Van Meerbeek, Leuven Biomat Research Cluster, Catholic University of Leuven, Belgium  
IADR PEF 2008, #331

**Aim of the study:** This controlled prospective clinical trial evaluates the clinical effectiveness of RelyX™ Unicem Self-Adhesive Universal Resin Cement for cementing all-ceramic inlays. Additionally, the influence of selective enamel etching prior to cement application was tested in a split mouth design. The restorations were evaluated according to modified USPHS criteria.

**Results:** The recall rate after 2 years was excellent. According to the authors, RelyX Unicem cement showed acceptable clinical behavior after 2 years in clinical service. Additional selective enamel etching did not yield significantly different results.

**Number of patients:** 31 (22 female/9 male)

**Mean age of patients:** 33 years

Number of restorations:	62
	54 class-II inlays
	8 onlays
No etching:	31
Selective enamel etching:	31
Recall rate at 24 months:	97 %
Survival rate:	97 %

## All-ceramic zirconia bridges after 3 years *in vivo*

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Title: Clinical Longevity of CAD/CAM Generated Y-TZP Posterior Fixed Partial Dentures

J. A. Sorensen, R. Lusch, and Yokoyama, Pacific Dental Institute, Portland, OR, USA

**Aim of the study:** This prospective longitudinal trial evaluates the clinical performance of 3- and 4-unit all-ceramic (Lava™ Zirconia) posterior fixed partial dentures (FPD) and the clinical behavior of RelyX™ Unicem Cement.

**Results:** After more than 3 years in clinical service (37–60 months) all Lava bridges available for follow-up examinations functioned well. RelyX Unicem cement showed reliable performance: marginal discolorations and debondings did not occur. Thus, RelyX Unicem cement achieves good clinical results and a good *in vivo* long-term stability. RelyX Unicem cement performed well with no signs of microleakage, no debonding of retainers, and minimal sensitivity. No discoloration of the cement and no microleakage were recorded.

Observation period:	3 years	Allocation of the bridge restorations in %*	
Lava™ Restorations available for follow-up examination:	45	3-unit bridges	73%
Debonds:	0 %	4-unit bridges	27%
		Upper jaw	56%
		Lower jaw	44%
		Premolar	31%
		Molar	69%

\* The majority of FPDs replaced the first molar

## All-ceramic zirconia based bridges after 3 years *in vivo*

Title: Five-Year Evaluation of Zirconia-Based Bridges in General Practice: Year-Three Results

R. J. Crisp and F. J. T. Burke, University of Birmingham, Birmingham, England, United Kingdom  
IADR 2009, # 3234

**Aim of the study:** In this clinical observation, Lava™ Zirconia Bridges were adhesively inserted with RelyX™ Unicem Self-Adhesive Universal Resin Cement in four UK general dental practices. The clinical performance including gingival health was monitored over 3 years.

**Results:** All restorations performed well after 3 years of clinical service. 94 % of the bridges were optimal for marginal adaptation and no change in color match from baseline was detected. No failures, secondary caries or staining were observed. No sensitivities are reported and healthy gingiva conditions were found.

Mean age of restorations: 34.1 month  
Number of patients viewed at 3 years: 17  
Number of restorations reviewed at 3 years: 19

1 = healthy gingivae 2 = mild inflammation 3 = moderate inflammation 4 = severe inflammation	Baseline	1-year	2-year	3-year
Facial	85 % 1, 15 % 2	95 % 1, 5 % 2	92 % 1, 4 % 2, 4 % 3	94 % 1, 6 % 2
Mesial	82 % 1, 18 % 2	100 % 1	100 % 1	100 % 1
Distal	85 % 1, 15 % 2	95 % 1, 5 % 2	94 % 1, 6 % 2	100 % 1

## All-ceramic, PFM and metal restorations after 2 years *in vivo*

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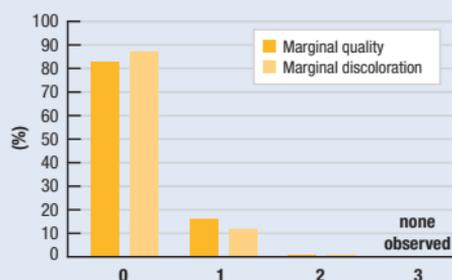
Title: Two-Year Performance of Restorations Placed with a Self-Adhesive Luting Material

Published by: R. J. Crisp, F. J. T. Burke, University of Birmingham, United Kingdom. IADR 2006, Brisbane #2098 and F. J. T. Burke, R. J. Crisp and B. Richter; Int. Dent. Journal 2006 56; 3: 142–146

**Aim of the study:** This study evaluates the clinical performance of RelyX™ Unicem Cement for luting all-ceramic, PFM and all-metal restorations in general dental practitioners' offices.

**Results:** After an average observation period of 21 months the result achieved with RelyX Unicem cement was rated very satisfactorily. No cement related failures were reported.

### Number of evaluations



### Evaluation criteria

#### Marginal quality

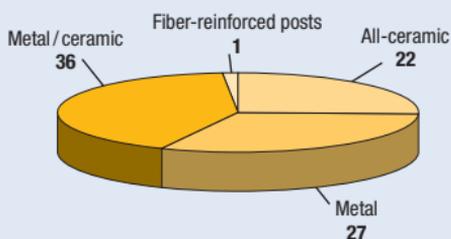
- 0 = Marginal gap cannot be detected
- 1 = Marginal gap detectable, not visible
- 2\* = Marginal gap, enamel margin exposed
- 3\* = Apparent marginal gap, dentin or cement exposed

#### Marginal discoloration

- 0 = None
- 1 = Slight discoloration, can be removed by polishing
- 2 = Significant discoloration, cannot be removed by polishing
- 3\* = Strong discoloration

\* Restorations with such a rating are unacceptable

### Evaluated restorations by type (n=86)



## Post cementations after 5 years *in vivo*

Title: Rigid vs. Flexible Endodontic Posts: 5-Year Results of a RCT

Published by: M. Naumann<sup>1</sup>, A. Franke<sup>1</sup>, T. Dietrich<sup>2</sup>, and G. Sterzenbach

<sup>1</sup>Charité-Universitätsmedizin Berlin, Germany, <sup>2</sup>The School of Dentistry, University of Birmingham, United Kingdom

Published in: IADR 2008, Toronto, #1607

**Aim of the study:** The present study examines the clinical behavior of RelyX™ Unicem Cement when cementing endodontic posts. Titanium posts (as well as glass fiber posts) were tested.

**Results:** After up to 5 years of clinical service no debonding occurred. Only one restoration was lost due to abutment tooth fracture in the fiber post group. RelyX Unicem cement proved to be well suited for the cementation of root canal posts.

### Average observation period: months (48–60)

Number of post restorations analyzed:	87
Thereof titanium posts:	46
Thereof glass fiber posts:	41
Losses total:	5
1 lost to follow-up, 2 due to change in treatment	
1 extraction for periodontal reasons	
1 tooth fracture (fiber post group)	

## Pulp compatibility after 60 days

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Title: Human Pulp Response to Resin Cements Used to Bond Inlay Restorations

Published by: C. A. de S. Costa<sup>1</sup>, J. Hebling<sup>2</sup>, R. C. Randall<sup>2</sup>

<sup>1</sup>University Sao Paulo State-UNESP, Sao Paulo, Brasil, <sup>2</sup>3M ESPE, St. Paul, USA

Published in: Journal of dental materials, No. 22, 954–962

**Aim of the study:** In this clinical study the pulp compatibility after inlay cementation with RelyX™ Unicem Cement and a total-etch-system (Syntac®, Variolink® II, Ivoclar Vivadent) has been examined.

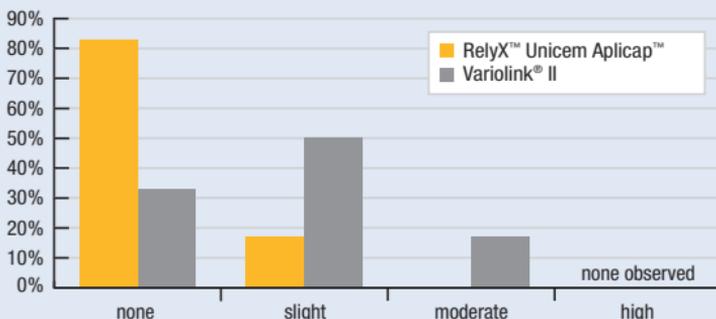
**Results:** During the histological examination 60 days after cementation with RelyX Unicem cement the area around the pulp showed a normal histology. However, with the cementation with the total-etch-system a small inflammatory reaction was discovered. This may cause a post-operative sensitivity.

Observation period: 60 days

Number of restorations: 24

Average patient age: 14 years

Frequency of inflammation reactions in the pulp area (60 days after cementation teeth/group)



Clinical results

## **Additional ongoing clinical studies with RelyX™ Unicem Self-Adhesive Universal Resin Cement:**

### **Clinical performance of fiber post restorations: 2-year results**

M. Ferrari<sup>1</sup>, M. Cagidiaco<sup>2</sup>, E. Magni<sup>1</sup>, M. Cadenaro<sup>3</sup>, L. Breschi<sup>3</sup> and C. Goracci<sup>1</sup>, <sup>1</sup>University of Siena, Siena, Italy, <sup>2</sup>Association Odontology E. Cagidiaco, Livorno, Italy, <sup>3</sup>University of Trieste, Trieste, Italy  
IADR 2009, #1015

### **Self-adhesive resin cement versus zinc phosphate luting material: a prospective clinical trial begun 2003**

M. Behr, M. Rosentritt, J. Wimmer, R. Lang, C. Kolbeck, R. Bürgers and G. Handel, Department of Prosthodontics, University Medical Center Regensburg, Regensburg, Germany  
Dental Materials 2008 Dec 17. [Epub ahead of print]

### **Prospective Study of cementing metal-ceramic crowns with two cementing agents**

A. Piwowarczyk, K. Schick and H.-C. Lauer, Johann Wolfgang Goethe University Frankfurt, Frankfurt/Main, Germany  
IADR CED 2008, #625

## Restoration of an upper premolar with RelyX™ Fiber Post and a Lava™ Zirconia Crown

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Dr. med. dent. Gunnar Reich, Munich, Germany

Initial situation: insufficient temporary glass-ionomer filling on root canal treated tooth UL5.



Root canal excavated and prepared for placing RelyX™ Fiber Post.



Application of RelyX™ Unicem Self-Adhesive Universal Resin Cement directly into the clean root canal using the RelyX™ Unicem Aplicap™ Elongation Tip.



Light curing of RelyX™ Unicem Cement around and through the light transmitting RelyX™ Fiber Post.



RelyX™ Fiber Post cemented with RelyX™ Unicem Cement.



Core build-up with Filtek™ Supreme XT Flowable Restorative.



# RelyX™ Unicem

Self-Adhesive Universal Resin Cement

Tooth prepared for Lava™ Zirconia Crown.



Precision impression with Impregum™ Penta™ Soft Quick Polyether Impression Material.



Lava™ Zirconia Crown on saw model.



Filling the crown with RelyX™ Unicem Cement (Aplicap™ Capsule) for permanent cementation.



Lava™ Crown seated in the patient's mouth.



## Front restoration with RelyX™ Fiber Post and glass ceramic crowns

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Dr. Stergios Zafiriadis, Zurich, Switzerland

Initial situation: clinically and esthetically insufficient restorations of the upper anterior region.



Excavation and preparation of the root canals for RelyX™ Fiber Posts using matching RelyX™ Fiber Post drill.



Prepared root canals.



Application of RelyX™ Unicem Cement directly into the clean root canal using the RelyX™ Unicem Aplicap™ Elongation Tip.



# RelyX™ Unicem

Self-Adhesive Universal Resin Cement

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RelyX™ Fiber Posts cemented with RelyX™ Unicem Cement after light curing.



Core build-up with Filtek™ Supreme XT Flowable Restorative.



Final restorations with CAD/CAM fabricated glass ceramic crowns (Paradigm™ C, 3M ESPE) *in situ*.



You + 3M ESPE =

*Learning that goes both ways*

**3M** ESPE

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