RelyX™ Unicem
Self-Adhesive Universal Resin Cement

Clinical Studies
2003 – 2009

3M ESPE
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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*

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 5th and 6th generation bondings and correspondig 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

#### Results (in %):

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<table>
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<tr>
<td>Post-operative sensitivities (n = 1820)</td>
<td>1.8%</td>
</tr>
<tr>
<td>Marginal discolorations (n = 1820)</td>
<td>5.1%</td>
</tr>
<tr>
<td>Debonding rate</td>
<td>0.8%</td>
</tr>
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</table>

### Allocation of the restorations

- All-ceramic crowns and bridges: 40%
- PFM crowns and bridges: 30%
- Posts: 1%
- All-ceramic inlays/onlays: 29%
Glass ceramic inlays and onlays after 4 years in vivo

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

Published by: S. Geraldeli¹, C. Stanford¹, D. Dawson¹, J. S. Wefel¹, S. Timmons², D. S. Cobb¹, M. Hernandez¹, S. Guzman-Armstrong¹, T. Flynn¹, C. M. Asmussen¹, S. Hansen¹ and D. Stark¹, ¹University of Iowa, Iowa City, IA, ²University 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®, Microstar, Atlanta, USA) were cemented with RelyX™ Unicem Cement and a total-etch-system (Syntac®, Variolink® 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.
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

<table>
<thead>
<tr>
<th></th>
<th>Syntac®/Variolink® II</th>
<th>RelyX™ Unicem Aplicap®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of cemented inlays/onlays</td>
<td>40</td>
<td>43</td>
</tr>
<tr>
<td>Number of restorations in the follow-up examination after 24 months</td>
<td>39*</td>
<td>43</td>
</tr>
</tbody>
</table>

*24 loss

### Clinical results after 24 months

- Surface roughness
- Color match
- Marginal integrity
- Integrity tooth
- Integrity inlay
- Proximal contact
- Hypersensitivities

<table>
<thead>
<tr>
<th></th>
<th>Syntac®/Variolink® II</th>
<th>RelyX™ Unicem</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alpha I</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alpha II</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bravo</td>
<td></td>
<td></td>
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</tbody>
</table>

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

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


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 %
**Clinical results**

**All-ceramic zirconia bridges after 3 years **

*in vivo*

**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.

<table>
<thead>
<tr>
<th>Allocation of the bridge restorations in %*</th>
<th>3 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lava™ Restorations available for follow-up examination: 45</td>
<td>Debonds: 0 %</td>
</tr>
<tr>
<td>3-unit bridges</td>
<td>73 %</td>
</tr>
<tr>
<td>4-unit bridges</td>
<td>27 %</td>
</tr>
<tr>
<td>Upper jaw</td>
<td>56 %</td>
</tr>
<tr>
<td>Lower jaw</td>
<td>44 %</td>
</tr>
<tr>
<td>Premolar</td>
<td>31 %</td>
</tr>
<tr>
<td>Molar</td>
<td>69 %</td>
</tr>
</tbody>
</table>

* 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

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>1-year</th>
<th>2-year</th>
<th>3-year</th>
</tr>
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<tbody>
<tr>
<td>Facial</td>
<td>85 % 1, 15 % 2</td>
<td>95 % 1, 5 % 2</td>
<td>92 % 1, 4 % 2, 4 % 3</td>
<td>94 % 1, 6 % 2</td>
</tr>
<tr>
<td>Mesial</td>
<td>82 % 1, 18 % 2</td>
<td>100 % 1</td>
<td>100 % 1</td>
<td>100 % 1</td>
</tr>
<tr>
<td>Distal</td>
<td>85 % 1, 15 % 2</td>
<td>95 % 1, 5 % 2</td>
<td>94 % 1, 6 % 2</td>
<td>100 % 1</td>
</tr>
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</table>
Title: Two-Year Performance of Restorations Placed with a Self-Adhesive Luting Material


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.

Clinical results

<table>
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<tr>
<th>Evaluation criteria</th>
<th>Marginal quality</th>
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<tbody>
<tr>
<td>0</td>
<td>Marginal gap cannot be detected</td>
</tr>
<tr>
<td>1</td>
<td>Marginal gap detectable, not visible</td>
</tr>
<tr>
<td>2*</td>
<td>Marginal gap, enamel margin exposed</td>
</tr>
<tr>
<td>3*</td>
<td>Apparent marginal gap, dentin or cement exposed</td>
</tr>
</tbody>
</table>

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

Published by: M. Naumann¹, A. Franke¹, T. Dietrich², and G. Sterzenbach ¹Charité-Universitätsmedizin Berlin, Germany, ²The 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

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

Published by: C. A. de S. Costa¹, J. Hebling², R. C. Randall²
¹University Sao Paulo State-UNESP, Sao Paulo, Brasil, ²3M 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. Ferrari¹, M. Cagidiaco², E. Magni³, M. Cadenaro³, L. Breschi³ and C. Goracci¹, ¹University of Siena, Siena, Italy, ²Association Odontology E. Cagidiaco, Livorno, Italy, ³University 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
RelyX™ Unicem
Self-Adhesive Universal Resin Cement

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

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.

Clinical results
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

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™ 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.
The graphs in this brochure were reproduced by 3M ESPE according to the data mentioned in the respective sources. Based on this data, 3M ESPE has also prepared “Aim of the Study” and “Results” summaries.

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