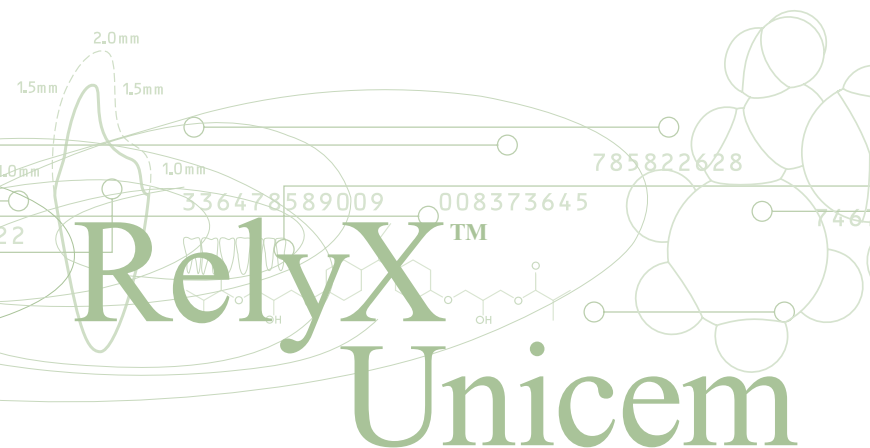


3M ESPE

Summary of
in-vivo studies



Self-Adhesive Universal Resin Cement

Clinical studies
2003 – 2006

RelyX™ Unicem

Self-Adhesive Universal Resin Cement

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RelyX™ Unicem

Self-Adhesive Universal Resin Cement

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 25 million times since its introduction in the year 2002. RelyX Unicem cement became one of the most-sold permanent resin cements in many countries, including the United States, Canada, Germany and UK.

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 cement 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 overview of the situation of the in-vivo research about RelyX Unicem Self-Adhesive Universal Resin Cement. You will find independent studies between 60 days and 3 years as well as a clinical case where a Lava™ Zirconia Crown was cemented with RelyX Unicem cement.



Development team RelyX™ Unicem Cement

We here in Seefeld are happy that with RelyX Unicem cement we produced another product which does not only achieve outstanding clinical results but also simplifies your daily practice.

With best regards

Dr. Rainer Guggenberger
Manager R&D
3M ESPE

Seefeld/St. Paul, January 2007

RelyX™ Unicem

Self-Adhesive Universal Resin Cement

Clinical results

Restorations after 4 years *in-vivo*

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

Published in: THE DENTAL ADVISOR, Vol. 24, No. 4, May 2007

Aim of the study: The evaluators of THE DENTAL ADVISOR used RelyX™ Unicem cement for cementing restorations made of full ceramic, metal, PFM and composites (crowns, bridges, inlays/onlays, posts). RelyX Unicem cement was evaluated in the categories postoperative sensitivities, microleakage and debonding.

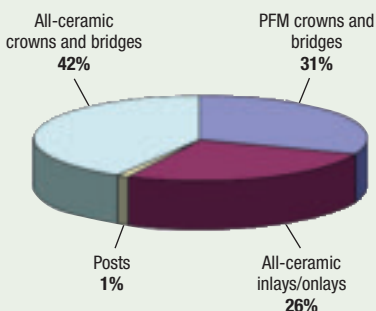
Results: Post-operative sensitivities only occurred with few patients after cementation with RelyX Unicem. The number of microleakage for cementations is comparable to that of multi-step resin cements with 5th generation bondings. The loss rate of restorations cemented with RelyX Unicem is only 0.6%. In total, RelyX Unicem cement received a clinical rating of 98%, so that THE DENTAL ADVISOR awards its top grade of 5 stars also after 4 years.

Observation period: 4 years

Allocation of the restorations

Results (in %):

Postoperative sensitivities (n = 1560)	1.8%
Marginal discolorations (n = 1560)	4.2%
“Debonding” rate (n = 4400)	0.7%



RelyX™ Unicem

Self-Adhesive Universal Resin Cement

Clinical results

Full ceramic inlays and onlays after 12 months *in-vivo*

Title: Ceramic inlays luted with a self-adhesive cement after one year.

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

Published in: AADR 2006, Florida #1361

Complete Abstract: 3M ESPE Scientific Facts, March 2006.

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 clinically examined after a wearing time of 12 months.

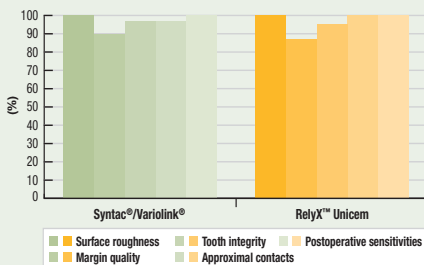
Results: After one year of service time the one-step cement RelyX Unicem cement proves just as good as the total-etch-system Syntac/Variolink II. Postoperative sensitivities did not occur.

Observation period: 12 months

Clinical results after 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 12 months	39*	43



* 1 loss

RelyX™ Unicem

Self-Adhesive Universal Resin Cement

Clinical results

Glass ceramic inlays and onlays after 36 months *in-vivo*

Title: Clinical Comparison of RelyX Unicem and Variolink II used to lute Ceramic Inlays.

Published by: C. Stanford et al.; University Iowa, USA

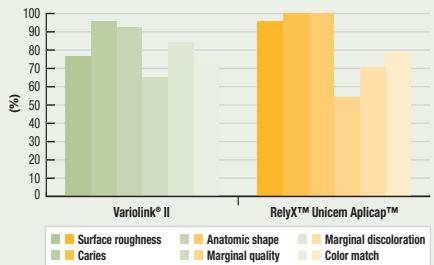
Aim of the study: In this clinical long-term study 95 inlays and onlays made of glass ceramic (Authentic, Microstar, Atlanta, USA) were cemented with RelyX™ Unicem cement and a total-etch-system (Syntac®, Variolink® II, Ivoclar Vivadent) and clinically evaluated after 36 months.

Results: When comparing the two adhesive cements for ceramic inlays/onlays at vital posterior teeth, no differences were observed in the clinical result after 3 years.

Observation period: 36 months

Clinical results after 36 months

	Syntac®/ Variolink® II	RelyX™ Unicem Aplicap
Number of restorations in the follow-up examination after 36 months	26	24



RelyX™ Unicem

Self-Adhesive Universal Resin Cement

Clinical results

Restorations from full ceramic, veneer metal ceramic and metal after 2 years *in-vivo*

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.

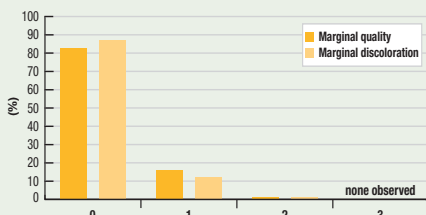
Published in: IADR 2006, Brisbane #2098

Complete Abstract: 3M ESPE Scientific Facts, June 2006.

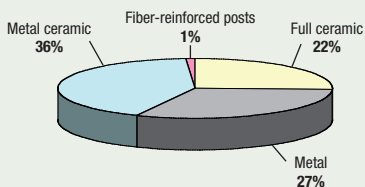
Aim of the study: This *in-vivo* study evaluates the clinical results when carrying out cementations of full ceramics, PFM and full metal restorations with RelyX Unicem cement.

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

Number of evaluations



Number of restorations according to material



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

RelyX™ Unicem

Self-Adhesive Universal Resin Cement

Clinical results

Full ceramic bridges after 18 months *in-vivo*

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

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

Published in: AADR 2006, Florida #0270

Complete Abstract: 3M ESPE Scientific Facts, March 2006

Aim of the study: In the present study the clinical success rate of RelyX™ Unicem cement with three- and four-unit bridges made of Lava™ zirconium oxide has been examined.

Results: After a mean service time of 18 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.

Observation period: 18 months

Lava™ restorations available for follow-up examination: 52

Debondings: 0%

Allocation of the bridge restorations in %*

Three-unit bridges 73%

Four-unit bridges 27%

Upper jaw 54%

Lower jaw 46%

* The majority of FPDs replaced the first molar

RelyX™ Unicem

Self-Adhesive Universal Resin Cement

Clinical results

Post cementations after 36 months *in-vivo*

Title: FRC vs. Titanium Posts – Preliminary Results of a RCT

Published by: M. Naumann¹, G. Sterzenbach² and K.-P. Lange²

¹ Humboldt-University, Charite Berlin, Germany, ² Humboldt-University, Berlin, Germany

Published in: IADR 2006, Brisbane #0077

Complete Abstract: 3M ESPE Scientific Facts, June 2006

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 an observation period of 12 to 36 months no post restorations were lost with both, the glass fiber as well as the titanium posts. Thus, RelyX Unicem cement is very suitable for the cementation of endodontic posts.

Average observation period:	20 months
Number of post restorations:	91
Thereof titanium posts:	51%
Thereof glass-fiber posts:	49%
Losses total:	0%

RelyX™ Unicem

Self-Adhesive Universal Resin Cement

Clinical results

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

¹ University Sao Paulo State-UNESP, Sao Paulo, Brasil, ² 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.

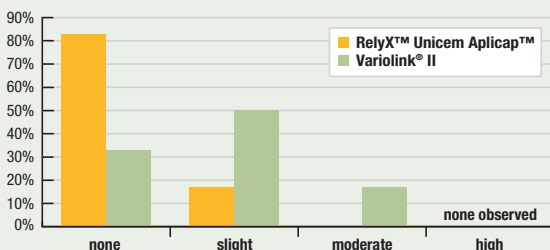
Results: During the histological examination 60 days after cementation with RelyX Unicem cement the area around the pulp showed a normal histology. However, with the cementation with the total-etch-system a small inflammatory reaction was discovered. This may cause a post-operative sensitivity.

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)



RelyX™ Unicem

Self-Adhesive Universal Resin Cement

Clinical case

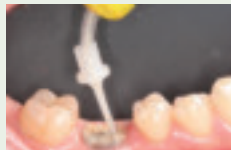
Replacement of an insufficient PFM crown by a Lava™ Zirconia Crown

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

Initial situation: Two-year old, insufficient PFM crown at tooth 36 with large carious lesion lingual.



Application of RelyX™ Unicem cement in root canal with the RelyX™ Unicem Aplicap™ Elongation Tip.



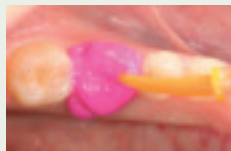
Tooth 36 reinforced with two RelyX™ Fiber Posts.



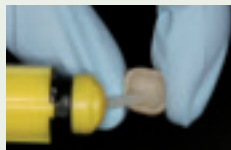
Core build-up with Filtek™ Z250 composite and circular chamfer preparation for Lava™ Zirconia Crown.



Precision impression with light-bodied impression material Express™ 2 Light Body *Standard* Quick, using the one-step technique.

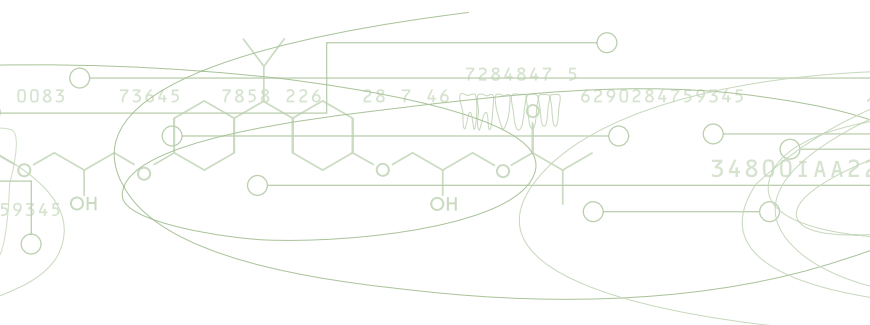


Application of the cement into the prepared Lava™ Zirconia Crown.



Lava™ Zirconia Crown permanently cemented with RelyX™ Unicem cement.





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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 of the Study" summaries.

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