**Special Issue** 

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## **Special Issue**

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# Editorial The Unicem 15-Year Story

Luting materials are a central component of indirect dentistry. These, essentially, fill the gap at the restoration-tooth interface and therefore must fulfil basic mechanical, biological and handling requirements.<sup>1</sup> Furthermore, the luting material<sup>2</sup>:

- Must not harm the tooth or tissues
- Must allow sufficient working time to place the restoration
- Must be fluid enough to allow complete seating of the restoration
- Must quickly form a hard mass which is strong enough to resist functional forces
- Must not dissolve or wash out, and must maintain a sealed, intact restoration.

In the beginning, there was zinc phosphate cement. Despite its shortcomings, which included solubility in the dilute organic acids found in plaque and poor tensile strength, it remains in use by some practitioners, circa 125 years after its introduction. In this regard, results of a recent survey of 500 UK-based general dental practitioners indicated that 14.6% of respondents continued to use phosphate cement for cementation of metal-ceramic single unit crowns.<sup>3</sup> Moving onwards to the 1970s, the introduction of Glass Ionomer (GI) cement facilitated the development of a luting material derived from the same technology. This proved popular, but again had suboptimal physical properties, and like phosphate cement, was soluble in dilute organic acids. The Resin Modified Glass Ionomer (RMGI) materials and their associated luting materials overcame the shortcomings of GI materials and were stated as being used by 28.2% of the respondents in the recent UK survey.<sup>3</sup>

The introduction of resin luting materials brought in a new concept in luting, because, for the first time, truly adhesive luting of crowns and inlays was possible. Why was this good? Because not all of us, all of the time, can achieve a retentive preparation and the ideal preparation geometry, especially when we are treating teeth with reduced coronal height because of wear. Three papers testify to the benefits of adhesion when resin luting materials are being utilized. Pameijer and Jefferies<sup>4</sup> tested 18 luting materials, using extracted premolars with standardised cone-shaped preparations with 33° taper, then constructing gold copings which were cemented with a tensile force being applied after 24h. The results indicated that polycarboxylate cement produced the lowest value for retention, that Ketac Cem (ESPE), a GI-based luting material, produced retention that was twice that of phosphate cement: also, that dentine bonding and resin cement produced highest values for retention. Zidan and Ferguson<sup>5</sup> made complete crowns prepared with three different tapers and luted with four different cements. Results indicated that retention of the crowns luted with the adhesive resins investigated were 20% higher at 24-degree taper than the retentive values of conventional cements at 6-degree taper, with the authors concluding "As the resin luting materials provided retention that was double the values of zinc phosphate or conventional cements, these results provide an overwhelming indication for the use of adhesive luting". Thirdly, Heintze,<sup>6</sup> in a systematic review, has also provided strong evidence with regard to resin/adhesive luting. He included 18 studies, finding that the most important factors for crown dislodgment were stump height,

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convergence angle and luting agent and that the frequency of debonding was higher for restorations luted with zinc phosphate than all other types. He advised that "In clinical situations with low mechanical retention, or situations with low stump height or high convergence angle, the adhesive properties of the luting agent are crucial for the prevention of debonding".

The dentine-bonded all ceramic crown was another example of the use of adhesive luting. In this concept,<sup>7</sup> the ceramic fit surface was etched with hydrofluoric acid (HF) in order to provide a micromechanically retentive surface, the dentine preparation was treated with a dentine bonding agent and a resin luting material employed in conjunction with a silane applied to the HF-etched crown (*Figure 1*). Results of a laboratory study showed that this adhesive concept maximised the fracture resistance of the crown<sup>8</sup> and clinical studies indicated good performance.<sup>9,10</sup> However, the clinical aspect of these restorations was technique sensitive (*Table 1*), as it was necessary to use them in conjunction with a dentine bonding agent, with particular anxieties concerning the possible pooling of the dentine adhesive which had to be cured prior to crown cementation. If that occurred, it would not be possible to fully seat the crown.

## Table 1. Steps involved in placement of a dentine-bonded crown

Try-in paste

Clean fitting surface and silanise Clean tooth with pumice, isolate Apply Dentine Bonding Agent Apply dual cure luting agent to crown Place with gentle finger pressure Remove XS luting material Light cure and finish margins Check occlusion and polish

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Resin-based luting materials have been available since 1952, although they have undergone substantial development since that time. They have excellent physical properties and are insoluble in the dilute organic acids found in plaque.<sup>1</sup> In addition, a literature review has identified these as the "go to" luting material for all-ceramic restorations.<sup>11</sup> Principal disadvantages are the reported price being 175 times that of phosphate cement<sup>2</sup> and clean-up of marginal excess more difficult than phosphate. The advantages and disadvantages of resin luting materials are presented in Table 2.

From this, it is apparent that the advantages relate mainly to the excellent physical properties of these materials, while the disadvantages relate to their technique sensitivity. The development of a resin luting material which could overcome these disadvantages would therefore have "the best of both worlds". Such a material arrived fifteen years ago, namely, the first self-adhesive resin-based luting material, RelyX Unicem (3M ESPE) (hitherto termed Unicem in this paper). Since this did not require the use of a separate bonding agent, this material substantially simplified adhesive luting when using resin luting materials.

The current self-adhesive resin cements are two-part materials: the earliest version of Unicem required capsule trituration and delivery by an auto-mixing dispenser, but newer versions have used a much simpler auto-mixing tip. These self-adhesive resin luting materials have a built in self etch primer which facilitates adhesion to dentine. According to Ferracane et al.<sup>12</sup>, one component of the material is comprised of conventional mono-, di- and/or multi-methacrylate monomers that are used in a variety of resin-based dental materials, such as Bis-GMA, urethane oligomers of BisGMA or UDMA. Also according to Ferracane et al., the acid-functionalized monomers currently utilized to achieve demineralization and bonding to the tooth surface are still predominantly (meth) acrylate monomers with either carboxylic acid groups or phosphoric acid groups. These monomers facilitate an early change upon polymerisation from hydrophilic to hydrophobic. Also, uniquely among the group of self-adhesive resin luting materials, Unicem achieves complete neutralisation after 48 hours, which was not the case for the three materials that it was tested against.13 For a complete review of the chemistry of the self-adhesive resin luting materials, readers are directed to the paper by Ferracane et al.<sup>12</sup>

Table 2. Advantages and disadvantages of early resin luting materials						
Advantages	Disadvantages					
Not soluble in oral Environment	Requires acid etch technique and separate use of a dentine bonding agent					
High compressive & tensile strengths	Moisture control is critical					
Good fracture toughness	Clean–up time is critical					
Capable of bonding to tooth structure via dentine bonding agent	All of the above make these materials technique sensitive					

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Given that the development of Unicem meant that there was no longer a need to carry out a separate dentine bonding step, it could be anticipated that clinicians considered the material to be less technique sensitive than conventional resin luting materials. This is confirmed in a couple of studies. In a "handling" evaluation by thirteen members of the UK practice-based research group, the PREP Panel, a 21-question questionnaire was designed to provide information on the handling of Unicem and to compare this material with prestudy cementation materials.<sup>14</sup> One hundred and forty-four restorations were placed in the study, and Unicem was rated higher by the evaluators for ease of use than both the pre-trial resin-based cement and "conventional" cements. Ninety-two per cent (n=12) of the evaluators considered that it was "very advantageous" for the material under evaluation not to require etching and bonding prior to cementation. In addition, none of the evaluators reported any incidence of patients with post-operative sensitivity following placement of restorations with the material. The results of the PREP Panel study are in broad agreement with those reported in the July 2003 CRA Newsletter,<sup>15</sup> in which 64% of the 28 evaluators who assessed the handling of RelyX Unicem stated that this product would replace products that they had used previously, with 96% of evaluators rating it as excellent or good and worthy of trial by colleagues.<sup>15</sup> The CRA also assessed the clinical performance of RelyX Unicem when used by 68 evaluators in the placement of 4820 restorations, with follow up from a few months to one year.<sup>16</sup> The incidence of post-operative sensitivity was reported to be "very low" and there was a very low incidence of de-bonding (0.1%).

The PREP Panel re-evaluated the restorations placed using RelyX Unicem after 2 years.<sup>17</sup> Ninety of the original 144 restorations placed using RelyX Unicem were reviewed, the mean age of the restorations being 21 months. Four restorations (4%), all in patients of one operator, had failed, but the reasons for these failures were unconnected with the use of the resin cement (root fracture, porcelain fracture, and unrelated enamel chipping) and it was concluded that restorations luted with Unicem were performing satisfactorily in UK general dental practice after 21 months.

The PREP Panel have also completed a 5-year clinical evaluation of 42 three-unit zirconia-based bridges which were luted with Unicem.<sup>18</sup> One bridge required replacement due to porcelain fracture, but examination of the margins of the bridge retainers indicated that 91% (n=31) of the bridges were scored as optimal, with no unacceptable scores being recorded, no secondary caries detected, and no post-operative sensitivity reported, each of these indicating good performance of the Unicem luting material.<sup>17</sup>

Most recently, the Dental Advisor<sup>19</sup> published a 15-year clinical performance review of a total of 2226 inlays, onlays, crowns/bridges and zirconia-based crowns and bridges luted with Unicem or Unicem 2. Good performance was noted for lack of marginal discolouration (96% and 98% no reported

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discolouration respectively for restorations luted with Unicem and Unicem 2) and less than 1% post-operative sensitivity for restorations luted with Unicem and "even lower" for restorations luted with Unicem 2, with such sensitivity typically subsiding after two weeks. These positive findings were summarised as "proven to be very reliable".

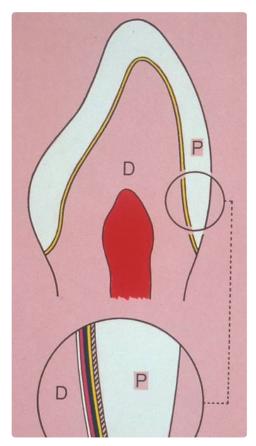
Regarding laboratory studies, Burke and colleagues<sup>20</sup> compared the laboratory fracture resistance of dentine-bonded ceramic crowns luted with Unicem with those luted with a conventional resin-based material, with the results indicating no significant difference. Ferracane *et al.*<sup>12</sup> have also reviewed the laboratory performance of Unicem, with the findings being positive, concluding that "the result of this review of the chemical and physical properties of self-adhesive resin cements would suggest that these materials may be expected to show similar clinical performance as other resin-based and non-resin based dental cements".

Given the success of Unicem, it is not a surprise that other manufacturers have developed similar materials, with a recent survey of 500 UK dentists showing that 13.1% of respondents are now using a self-adhesive resin luting material,<sup>3</sup> a substantial share of the luting material market for a material that was introduced only 15 years ago. This successful adoption to the UK market is not surprising, given the ease of use of the material, with no primer needed, its versatility in terms of indications, including the luting of fibre posts, clinical results indicating low frequency of post-operative sensitivity and low rates of marginal discolouration.

Finally, technique tips while using Unicem and its derivatives include:

- Mechanical cleaning of the tooth (for example, using a pumice and water slurry)
- Not overdrying the tooth
- Seating under gentle finger pressure
- Light curing (will improve the physical properties of the material as compared with self curing)

In summary, self-adhesive resin luting materials have become an easy to use and reliable part of the armamentarium for all indirect restorations. Is there a way to redevelop the material into a self-adhesive (no etch) restorative material? That would be the restorative dentist's dream!



**Figure 1:** The dentine-bonded crown concept, where P=porcelain and D=dentine, with the smaller illustration demonstrating the layers of the interface between the HF-etched ceramic (hatched) and the dentine bonding agent (black) on the dentine surface and the yellow layer being a silane coupling agent.

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Self-Adhesive Resin-Based Cement RelyX Unicem Clinical Experience <u>Clinical L</u>uting Procedure

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## 15 Years of Self-Adhesive Resin-Based Cements

## ABSTRACT

Self-adhesive resin-based cements have celebrated their 15th anniversary in 2017. In 2002, with 3M<sup>M</sup> RelyX<sup>M</sup> Unicem Self-Adhesive Resin Cement (3M Oral Care Solutions Division), this new class of luting materials was introduced to the dental market, and is now indispensable and popular in dental practice. Self-adhesive resin-based cements allow the practitioner a simple and time-saving handling comparable with traditional cements, which do not necessarily require a pretreatment of the tooth and restoration surface with additional adhesive components. With the success of this product, other companies entered the market with their own self-adhesive resin cement, leading to further expansion of this new luting category. Both, ingredients and dosage forms have become more and more diverse over the years. This overview is intended to describe the historical development of the self-adhesive resin-based cements in detail, to provide sound scientific results as well as tips and tricks for the practical user with the focus on RelyX Unicem Self-adhesive cement.

## INTRODUCTION

Long-term survival and success of an indirect restoration is a key factor and generally depends on the restorative material and the type of restoration, as well as the type of luting material and its specific properties.<sup>1,2</sup> There is, on the one hand, a growing demand from patients for high-quality, high esthetic tooth-colored restorations which should be as close to natural as possible. On the other hand, the practitioner and dental team are interested in a simple, esthetic, fast and reliable luting procedure with good clinical outcomes that is not technique sensitive.<sup>3,4</sup> This is accelerated by the fact that many modern restoration materials, as well as minimal invasive preparation designs, are in need of an adhesive luting procedure.<sup>5</sup> Therefore, 15 years ago, a new luting material, designed to combine these positive aspects was introduced. With RelyX Unicem Self-adhesive cement (RXU) the first self-adhesive resin-based cement (SARBC) as a new subgroup of existing conventional resin-based cements, was launched to the dental market by 3M. This material class combined the positive aspects of traditional cements (e.g., zinc oxide phosphate cement or glass ionomer cement) and conventional resin based luting materials.6 In contrast to the conventional resin-based composite matrices based on dimethacrylates, e.g. Bis-GMA (bisphenol-A-diglycidylmethacrylate), HEMA (hydroxyethylmethacrylate), TEGDMA (triethyleneglycoldimethacrylate) or UDMA (urethanedimethacrylate), SARBCs contain monomers with additional acidic groups, e.g. phosphate esters or carboxylates. These acidic monomer moieties can form a chemical bond with the calcium ions of the hydroxyapatite<sup>7</sup> and demineralize the hard tooth structure superficially.<sup>8,9</sup> This reaction enables a chemical bond of the resin network to the tooth surface.<sup>10</sup> As a consequence, clinical handling is less complex for SARBCs than for the luting of adhesive resin cements, as no primer or adhesive system on the tooth side is needed. Nevertheless, bond strength to hard tooth structures or restorative materials is lower than for conventional resin-based cements with their multistep systems.<sup>3,7</sup> Interfacial dentin bond strength increases under higher seating pressure, when RelyX Unicem Self-adhesive cement is applied.<sup>11</sup>



Due to those aspects, SARBCs are frequently used in daily dental practice today. Their dual-curing setting reaction is achieved by combining the use of photoinitiators together with self-curing initiators for the redox reaction.<sup>12</sup> As a result, the chemical setting reaction is initiated by mixing the base material with the initiator system. During setting, an additional light curing can produce higher conversion rates, which improves their mechanical properties.<sup>13-15</sup>

This overview article focuses on the analysis of published results about RXU because it was the first self-adhesive resin cement and most publications are available.

## **CLINICAL EXPERIENCE**

## RELYX UNICEM AND SARBCS: HISTORICAL DEVELOPMENT

In 2002 the first SARBC was marketed as a powder-liquid single dose capsule system (Aplicap delivery for inlays, onlays, crowns and posts and a year later Maxicap Capsule delivery for multiple unit bridges) named RelyX Unicem.<sup>6</sup> The composition of this material group is basically an organic matrix with inorganic fillers, whereas the organic matrix consists of modified dimethacrylates with additional acidic groups, e.g. phosphoric acid. The phosphorylated aspect allows self-conditioning of the tooth surface without the need for a separate conditioning or adhesive systems. For further facilitation of the luting procedure, a new dosage form was presented in 2007 in a paste-paste handmix delivery with the clicker system. This Clicker version had the same chemical composition and performance but also some additional benefits: (a) possibility to dispense variable amounts and (b) no need for RotoMix Capsule Mixing Unit (3M) or other devices.

In 2011, 3M<sup>™</sup> RelyX<sup>™</sup> Unicem 2 Self-adhesive resive cement was released. This upgrade combined an additional monomer and a new rheology modifier with an optimized processing of the filler particles in order to make the paste easily extrudable from an improved spiral delivery device: the Automix syringe. These changes lead to a formulation with increased mechanical properties and adhesion performance.<sup>16</sup> The Automix syringe ensured a consistent mixing quality and the choice of different mixtips allows for voidfree application in different indications, including luting of fiber posts in the root canal. Since the introduction of RXU, various dental companies developed further SARBC as well as improved delivery devices: for example Maxcem (Kerr) was the first SARBC to use an Automix delivery system, setting the standard for others to further innovate concerning material composition and dosage forms. Most of the currently available SARBCs are available as Automix syringes (see Table 1).

#### AREAS OF APPLICATION FOR SARBCS

SARBCs are generally dual-curing radiopaque materials accredited for the self-adhesive luting of any indirect dental restoration (except veneers) including metal- or fiber- posts in the root canal. They work with most restorative materials, such as metals, polymers or ceramics, but the adhesive strength is not equal to all materials.<sup>6</sup> In general, this luting material can be used for restoration materials with a flexural strength of more than 350 MPa: ceramics with lower strengths (under 350 MPa) need the use of an adhesive for luting.<sup>17</sup>

In this regard, if the flexural strength of the restorative material is lower, they must be luted with conventional resin-based cements. SARBCs can also be used for abutment teeth with less retention shape and have been reported to reduce postoperative sensitivities of the abutment teeth.<sup>18</sup>

In-vitro studies have already shown good long-term bond strengths of restorations and tooth surfaces. Hitherto, a large number of mechanical properties of this material class were analyzed for different materials (glass ceramics, zirconia) and tooth surfaces with good results.<sup>3,4,6,15,18,19</sup> However, the comparison of SARBCs and traditional cements is difficult, since both luting material groups exhibit different adhesion mechanisms. SARBCs are composites and possess a stable adhesive bond, whereas traditional cements obtain retention by friction. Comparisons between SARBCs and conventional resinbased cements are more reasonable. In a study comparing both luting materials, for example, a similar bond strength was observed for a SARBC and the conventional resin-based cement Panavia F (Kuraray Noritake), despite a lower surface hardness of the SARBC.<sup>20</sup> Another study found no difference in fracture resistance of all-ceramic crowns, cemented either with a conventional resin-based cement or a SARBC (RXU).18

A recent study investigated the influence of the tooth preparation and the fit of resin-based composite and lithium disilicate crowns as control group on the overall stability of the restoration. (Rosentritt *et al*). This study stated, that a retentive preparation and optimal fit of the restoration support an optimal bond.

## **CLINICAL RESULTS**

Most clinical studies evaluated just RXU / RXU2 or used it as reference or control group. Clinically relevant parameters like post-operative sensitivity, quality of marginal adaptation and discoloration resistance as well as a look at overall clinical survival rates have been evaluated and discussed.

#### **MARGINAL ADAPTATION / DISCOLORATION**

Marginal deterioration of ceramic restorations over time, in general, is attributed to degradation of the luting material due to wear and fatigue and to insufficient bonding to hard tooth tissues or restorative materials.<sup>22</sup> Therefore, the bonding of a luting material must be analyzed both, on the hard tooth substance and on the restoration side.

## **Table 1.** Overview of Self-adhesive resin based cements available on the dental market after internet searching of the authors. The authors are not liable for the completeness of this table.

SARBC	Manufacturer	Composition	Dosage Form
BeautyCem SA	Shofu Inc., Kyoto, Japan	PASTE A: UDMA, Fluoroboroaluminosilicate glass, Silicate glass, Reaction initiator and others PASTE B: UDMA, 2-HEMA, Carboxylic acid monomer, Phosphonic acid monomer, zirconium silicate, Polymerization initiator and others	Hand mixing, Automix syringe
Bifix SE	Voco, Cuxhaven, Germany	BASE: UDMA, GDMA, initiators, catalysts; CATALYST: UDMA, Bis-GMA, GDMA, Acid Adhesive Monomers, Hydroxypropyl Methacrylate, Benzoyl Peroxide, 70 wt% - 61 vol% fillers	Automix syringe (QuickMix syringe)
Breeze	Pentron Clinical, Orange, USA	Not available	Automix syringe
G-CEM Link Ace	GC, Tokyo, Japan	PASTE A: fluoroboroaluminum silicate glass, UDMA, dimetracrylates, SiO2, initiators, inhibitors and pigments PASTE B: SiO2, UDMA, dimetracrylates, phosphonic acid monomers, initiators and inhibitors	Automix syringe
iCEM Self Adhesive	Heraeus, Hanau, Germany	Acid UDMA, di-, tri- and multifunctional acrylate monomers, 49 wt% fillers	Automix syringe
MaxCem Elite Chroma	Kerr, Rastatt, Germany	Methacrylate ester monomers 19 - 40%, inert fillers, ytterbium fluoride, activators, stabilizers and dyes	Automix syringe
Panavia SA Cement Plus	Kuraray Medical Inc. Sakazu, Kurashiki, Okayama, Japan	PASTE A: MDP, bis-GMA, TEGDMA, DMA, Ba-Al fluorosilicate glass, SiO2, benzoyl peroxides, initiators; PASTE B: bis-GMA, DMA, Ba-Al fluorosilicate glass, SiO2, pigments, 66 wt% - 45 vol% fillers	Automix syringe
RelyX Unicem	3M, Seefeld, Germany	Di-methacrylates Phosphoric acid di-methacrylates Sr-Al-Fluorosilicate Glass Sodium persulfate Titanium dioxide Silanized fillers Calcium hydroxide	Capsule system
RelyX Unicem 2	3M, Seefeld, Germany	Dimethacrylates Proprietary methacrylates Phosphoric acid di-methacrylates Sr-Al-Fluorosilicat Glass Sodium persulfate Titanium dioxide Silanized SiO2-fillers Calcium hydroxide	Automix syringe Clicker Dispenser
seT/ seT PP	SDI, Köln, Germany	35 wt% methacrylate ester; 65 wt% inorganic fillers	Capsule system, Automix syringe
Calibra	Dentsply Sirona, Konstanz, Germany	UDMA, EBPADMA, urethanresine, di- and tri-functional diluents, PENTA, proprietary photoinitiator systems, self- curing initiator systems, 69 wt%, 46 vol% filler	Automix syringe
SoloCem	Coltène/Whaledent, Altstätten, Switzerland	UDMA, TEGDMA, 4-META, 2-HEMA, dibenzoyl peroxide; benzoyl peroxide	Automix syringe
SpeedCEM Plus	Ivoclar Vivadent, Schaan, Liechtenstein	DMA, ytterbium (III) fluoride, co-polymer, glass filler with 40 vol.%, SiO2, initiators, stabilizers and pigments	Automix syringe
Vita adiva F100	Vita, Bad Säckingen, Germany	Methacrylates with inorganic fillers, 50 wt.% - 45 vol.% filler	Automix syringe

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Considering adhesion quality to restorative materials, good results could be found, but were not equal for all materials.<sup>23-25</sup> Bond strengths were lower compared to conventional resinbased cements in most comparisons. Further, it is important to respect the pretreatment instructions for each restoration material for long-term success. Glass ceramic materials need to be etched with hydrofluoric acid and then treated with a silane for best bonding results, whereas other materials require sandblasting (particle size 30-50 µm, pressure 2 bar or less) followed by cleaning with alcohol and air-drying. In this respect it is therefore important to follow manufacturers' instructions.

SARBCs lead to adhesion to enamel and dentine due to their chemical bond to the tooth surface by superficial demineralization.<sup>3,7,26</sup> This is a crucial factor for a tight marginal bond. A longlasting stable marginal closure without microleakage is of great importance for the long-term success of a restoration.<sup>3,4,13,27,28</sup> Marginal discoloration is closely related to the criterion marginal adaptation. Luting materials, e.g. the SA-BRCs, are exposed and influenced by different fluids, food and temperature fluctuations especially during food intake. Clinically unacceptable marginal discolorations are one of the most frequent causes of a necessary renewal of a restoration, besides secondary caries.<sup>29-31</sup> Longitudinal studies using RXU have reported good results regarding marginal discoloration of restorations (see Table 2).

A few factors have been reported to improve marginal adaptation and seal:

- RXU/2 is thixotropic. Setting under pressure helps to reduce any voids that may have formed, increases flowability, promotes even distribution and wetting of the cement across all surfaces. Therefore, a continuous pressure should be applied during the initial curing to reduce the viscosity of the cement for better bonding results.<sup>11</sup> It helps to reduce the internal bubbles and promotes the adaptation of cement to the tooth surfaces.
- 2. It was described that selective enamel etching with phosphoric acid achieves higher adhesion values, although the difference between selective enamel etching values and non-etching values were rated to be clinically significant after 6.5 years, not before.<sup>3,22,32,33</sup> Also, selective enamel etching represents a clinically difficult procedure. In contrast to this, previous etching of the dentin surface leads to disadvantageous effects, since the collagen matrix is difficult to be fully penetrated with relatively viscous SARBCs.<sup>3</sup>
- 3. Some studies have found that light-curing after insertion of the restoration leads to higher conversion rates, which improves the polymerization process and leads again to improved mechanical properties and an improved marginal seal.<sup>3,14,27,28</sup>

#### **POSTOPERATIVE SENSITIVITY**

Long-term postoperative sensitivity has been reported for incompletely sealed dentin or detachment from luting material. In cases where the sensitivity is present after cementation, it could be attributed to the phosphoric acid etching of dentin or overdrying of exposed dentin, as well as the low pH of the SARBCs.<sup>33</sup> At the beginning of the curing phase, most SARBCs show a low pH due to the acidic groups contained in the matrix. The low pH is necessary for the self-etching properties as a pre-requisite for adhesion. During polymerization pH-levels typically increase. RXU especially shows a marked increase of the pH level, by 2-4 units during the first hour after insertion. Subsequently, this increase leads to a complete neutralization with an approximate pH of 7 after approximately 48 hours.<sup>34</sup> Compared with other SABRCs – G-Cem, Maxcem, or Smart-Cem - RXU was the only neutralized cement after 48 h.<sup>35</sup>

In vivo follow-up studies after 1, 2, 4 and 6.5 years using RXU, reported very low or nonexistent postoperative sensitivity. This low postoperative sensitivity has been attributed to the high capacity of wetting the dentin surface and providing a good dentin seal.<sup>22,27,28,32,33,36</sup>

In addition, RXU is slightly moisture tolerant, which means the tooth surface should be left slightly moist for best bonding results.<sup>33</sup> This could further reduce postoperative sensitivity resulting from overdrying the tooth in an adhesive cementation procedure.

#### LONG-TERM CLINICAL SURVIVAL RATE

The survival rate of restorations is closely related to the quality of marginal integrity as well as the occurrence rate of secondary caries. The main focus of the prospective longterm clinical studies found in the literature was to look at marginal integrity, discoloration, and secondary caries. An overview of the most essential in vivo studies of a literature search performed by the authors is provided in Table 2. Some of them are highlighted below.

#### MARGINAL INTEGRITY AND SECONDARY CARIES - A CLINICAL LITERATURE OVERVIEW

Regarding an evaluation of metal-ceramic crowns cemented with zinc oxide phosphate cement and RXU, exhibited no secondary caries after 1.8 years. Burke *et al.* presented 91% of optimal marginal adaption after 5 years for 33 zirconia-based bridges.<sup>37</sup> Four clinical studies analyzed the difference for restorations luted either with RXU alone or RXU combined with additional enamel etching. None of them showed a significant difference between both luting procedures up to 4 years, but additional enamel etching had a tendency towards slightly better results. A statistically significant difference after 6.5 years between both groups was found.<sup>22,32,33,36</sup> Baader *et al.* developed a study with students as operators, and found a survival rate of 82% for restorations with additional enamel etching in contrast to 60% survival for restorations without additional enamel etch after 6.5 years.<sup>33</sup> Other studies presented higher survival rates.<sup>22,32</sup> For ceramic **Table 2**. Overview of in vivo studies found within authors' literature research focusing on RelyX™ Unicem self-adhesive cement, listed in ascending clinical parameters investigated.

ascending clini	cai para	meters myest	igateu.							
Author	Year of publi- cation	Cement materials investigated	Number of patients	Restorations in total	Investiga- tion period (years)	Clinical parameters investigated	Results	Failures		
Marginal adap	Marginal adaptation (Secondary caries)									
Burke FJT. et al.	2013	RXU		33 bridges	5	Marginal adaptation	91% optimal marginal adaptation. No secondary caries	8 chippings, 1 bridge replacement		
Piwowarczyk A. <i>et al</i> .	2012	RXU Zinc Oxide Phosphate	20	40 metal- ceramic crowns	1.8	Marginal adaptation	No secondary caries			
Marginal adap	tation. S	urvival rate <b>v</b>	with/with	out enamel etch	ing (Seconda	ry caries)				
Schenke F. et al.	2011	RXU (with and without enamel etching)	29	58 (29 RXU+E; 29 RXU-E) partial ceramic crowns	2	Marginal adaptation with and without enamel etching	Slight deterioration of marginal adaptation in both groups. No secondary caries	RXU+E: 1.7% fractures, RXU-E: 5.1% fractures and debondings		
Azevedo CGS. e <i>t al</i> .	2012	RXU (with and without enamel etching)	25	42 (19 RXU+E; 23 RXU-E) posterior indirect composite resin restorations	1	Marginal adaptation with and without enamel etching	Little or no visible marginal changes. No secondary caries	All margins could be detected by probe showing minimal wear		
Peumans M. et al.	2013	RXU (with and without enamel etching)	31	60 (30 RXU+E; 30 RXU-E) ceramic inlays	4	Marginal adaptation with and without enamel etching	Overall Survival 95%. Clinically acceptable marginal deterioration in almost all (90%) of restorations.	RXU+E: 2 failures, 1 debonding, 1 fracture, 7% perfect margins RXU-E: 1 debonding failure 3%		
Baader K. et al.	2016	RXU (with and without enamel etching)	18	36 (18 RXU+E; 18 RXU-E) partial ceramic crowns	6.5	Marginal adaptation and survival rate with and without enamel etching Note :Student course	Marginal deterioration of all restorations, survival rate: RXU+E: 82% and RXU-E: 60%	RXU+E: 4 fractures, 1 unknown RXU-E: 3 fractures, 4 debondings , 1 caries, 1 endo treatment , 2 unknown.		
Marginal adap	tation su	urvival rate /	fracture /	retention loss /	discoloratio	n / secondary caries				
Zenthöfer A. <i>et al.</i>	2015	RXU	19	10 ceramic, 9 metal-ceramic Cantilevered FDP	3	Marginal adaptation, survival rate, fracture, retention loss, discoloration, secondary caries	100% survival rate. No secondary caries	Not available		
Marginal adapt	tation /	surface roug	hness / co	lor match / sens	itivity / prox	imal contact / radiog	raphic check			
Taschner M. et al.	2012	Variolink II, RXU	30	83 IPS Empress inlays/onlays	2	Marginal adaptation, surface roughness, color match, sensitivity, proximal contact, radiographic check	No significant differences between both materials. Variolink II showed slightly better marginal adaption	Not available		
Marcondes M. <i>et al</i> .	2016	RXU, RelyX ARC	12	24 indirect composite resin restorations	1	Marginal adaptation surface roughness, color match, sensitiv- ity, proximal contact, radiographic check	Both materials showed similar results, except color match (RXU lower)	2 endodontic treatments (RXU), 1 secondary caries by radiographic check (RXU)		

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and metal-ceramic cantilevered FDPs luted with RXU, however, a 100% survival rate after 3 years was reported.<sup>38</sup> When analyzing the difference between luting with RXU and conventional resin-based cements (RelyX ARC and Variolink II), no significant difference could be found in vivo overall. Variolink II was found to have slightly better marginal adaption after 2 years and RelyX ARC a slightly better color match at the 1-year follow-up.<sup>27,28</sup>

Several longterm studies have been performed with zirconia restorations using RelyX Unicem as the luting cement. They showed that zirconia performed well regarding adaptation and absence of secondary caries after 4 or 5 years of service. Overall they obtained satisfactory results from a clinical point of view.<sup>39-41</sup>

#### POST CEMENTATION

The use of SARBCs like RXU for placing metal or fiber posts is very convenient, because, contrary to the use of multistep adhesive resin luting materials, the pretreatment of hard tooth tissues in the root canal is not necessary. This simplifies and speeds up the post placement procedure considerably with reliable clinical results.<sup>42,43</sup>

When traditional cements are used for post cementation they withstand less simulated functional forces than adhesive approaches and may therefore not be recommended for clinical application.44 The bond strength of fiber posts adhesively luted to root canal dentin is significantly higher when SARBCs are used compared to etch-and-rinse materials and self-etch adhesives.<sup>42,45,46</sup> An evaluation of morphology and bond strength for different cements (Panavia F 2.0, Permaflo DC Variolink II, RXU, Clearfil Core) to root dentin, found RXU to be the only material that demonstrated cohesive failures inside the post. In these cases, bond strength to dentin as well as to the post was higher compared to the stability of the post itself.<sup>45,46</sup> In addition, the use of elongation tips to dispense cement into the root canal produces higher mean push-out strength values compared to microbrush use.<sup>47</sup> In general, the fracture resistance of endodontically treated teeth restored with a core build up is dependent on the degree of tooth conservation and adequate preparation. A continuous ferrule of a mimimum of 2 mm is recommended for best results.<sup>48</sup>

A clinical study followed 91 endodontically treated teeth with extensive hard tissue loss that were restored with either titanium posts (TP) or glass fiber-reinforced epoxy resin posts (GFREPs), both cemented with RXU during 84 months. The overall survival rate was 92% seven restorations failed – 3 endodontic failures (TP), 3 fractures (1 core, 1 cervical root, 1 middle root, 1 enhanced tooth mobility (GFREPs). The authors concluded that when using SARBCs to cement prefabricated posts in abutment teeth with two or less remaining cavity walls and a 2 mm ferrule, post-endodontic restorations achieve a high long-term survival rate, irrespective of the post material and it 's rigidity.<sup>42,43</sup> In general SARBCs are seen as a good clinical approach for cementing pre-fabricated fiber or metal as well as cast metal endodontic posts.<sup>49,50</sup>

## **CLINICAL PROCEDURE**

Compared to traditional cementation procedures or luting with conventional resin-based cements, SARBCs show some basic differences. When compared to traditional cements they can also be used in the esthetic zone with tooth-colored restoration materials for a natural esthetic outcome, as there is a choice of up to four different shades.

When compared to conventional resin-based cements, clinical handling is less complex for SARBCs as no primer or adhesive system is needed on the tooth side. Mechanical cleaning of the tooth preparation provides the best foundation for self-adhesive systems to work. Due to their integrated acidic groups SARBCs can directly adhere to tooth structure as already discussed. In addition, most of them are moisture tolerant to some extent, so that the tooth preparation does not have to be overdried and the risk of postoperative sensitivities is reduced. Even on the restoration side, no primers are needed in some cases.

In essence, one of the great advantages of SABRC's is the general reduction of luting steps which means less risk of errors, a reduction of treatment time and reduction in possible clinical failures. The practitioner needs to know about the necessary pretreatment steps for each material separately in advance, depending on the SARBC used. The correct handling following manufacturers' recommendations is essential for optimal bond strength and longevity of the restoration. Unfortunately – due to different chemistries used - instructions all vary slightly which leads to confusion.

#### CLINICAL CASE: LUTING OF ZIRCONIUM OXIDE (LAVA ESTHETIC, 3M) RESTORATIONS WITH RXU

A patient was restored with a new all-zirconium oxide 3M<sup>™</sup> Lava<sup>™</sup> Esthetics Fluorescent Full-Contour Zirconia bridge on teeth 22-25 and an all-zirconium oxide crown on tooth 26 in the Department of Prosthetic Dentistry of the Ludwig-Maximilians University in Munich. All teeth were first mechanically cleaned with prophylactic paste without fluoride or bicarbonate and air-dried with an oil-free air stream, leaving the tooth surface slightly moist and shiny. Only fluoride- or bicarbonate-free cleaning pastes should be used, as bicarbonate for example could penetrate the dentin and neutralize the acidic groups, leading to less bond strength. Slight moisture will help the self–adhesive bonding of the integrated acidic group site. In case of crown and bridge preparations, no additional selective enamel etching needs to be performed according to the manufacturer.

It is necessary to air-abrade the inner surface of the zirconium oxide restoration with Rocatec/Cojet (3M) or conventional aluminium oxide (particle size 30 or 50 µm, pressure >2 bar) in order to obtain a roughened surface area with free bonding sites to allow an optimal bond strength. As Lava Esthetic has less strength than conventional zirconia blocks, the Rocatec system was chosen (*Figure 1*) with a smaller particle size of 30  $\mu$ m and a lower pressure of 0,5-1 bar for airabrasion, followed by silanization with 3M<sup>TM</sup>RelyX<sup>TM</sup> Ceramic Primer for additional bonding site activation (*Figure 2*). In general, air-abrasion with conventional aluminium oxide is sufficient; the use of the Rocatec system is optional (*Figure* 1). The restorations were cleaned afterwards in an ultrasonic bath for 1 min in alcohol and air-dried with oil-free air. For cleaning after blasting, phosphoric acid should NOT be used, as the phosphoric groups can block the free binding sites of the zirconia, which are basis for further chemical bonding.



Figure 1: Air-abrasion of the restoration (Rocatec, 3M).



**Figure 2:** Application of the ceramic primer (RelyX Ceramic Primer, 3M).

After thorough cleaning and drying, the SARBC RXU was placed into the restoration as a thin layer of luting material (*Figures 3 and 4*). The restorations were seated under pressure to allow good wetting of the bonding surfaces (*Figure 5*). Short polymerization on all sides (around 2 s) was performed (*Figure 6*) and the excess cement was removed with a dental scaler (*Figure 7*). Before final light-curing for 20s from each side, the restoration margins were covered with an air barrier (Glyerin Gel, Liquid Strip, Ivoclar Vivadent) (*Figure 8*). After a recommended waiting time of 6 min in addition to light curing, all remaining excess cement and air barrier residues were removed carefully with a dental scaler and a scalpel (*Figures 9 and 10*). A waiting time of 6 min recommended by the manufacturer if sufficient light transmission through

the restoration material is not to be expected. Conventional zirconia restorations > 0.8 mm<sup>51</sup> for example absorb most of the light and therefore, the practitioner should be sure, that the whole material is fully cured. Light curing is an additional option, producing better mechanical properties of the SARBCs especially at the restoration margins. As a final step, polishing of the restoration margins with a ceramic polishing set and occlusal check was conducted, until a satisfying function and appearance was reached (*Figure 11*).

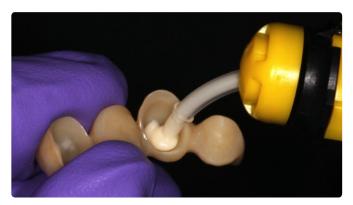


Figure 3: Application of RelyX Unicem (3M).



Figure 4: Spreading the SARBC in the restoration as thin layer.



Figure 5: Placing the restoration with pressure onto the abutment teeth.

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Figure 6: Initial light-curing for 2s.



**Figure 7:** Removing the excess self-adhesive resin cement in gel-like viscosity.



**Figure 8:** Covering the restoration margins with glycerin gel (Ivoclar Vivadent) prior to final light-curing for 20 s each side.



**Figure 9:** Final cleaning of the restoration from excess self-adhesive resin cement.



**Figure 10:** Final cleaning of the restoration from excess selfadhesive resin cement.



Figure 11: Final esthetic appearance.

## CONCLUSION

Because of their ease of use in combination with their clinical reliability for the previously mentioned indications SARBCs are today well-established in the dental practice.

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15 Years Self-Adhesive Resin-Based Cements...

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## A Case Series of Zirconia-Based Bridges Luted with a Self-Adhesive Resin Luting Material at 12 Years, in Patients in UK General Dental Practices

## ABSTRACT

Objectives: Further to the publication reporting the results at five years of fixed-fixed all-ceramic bridges, constructed in a yttria oxide stabilized tetragonal zirconium oxide polycrystal (Y-TZP) substructure, placed in adult patients in UK general dental practices, it was possible to recall 7 patients after 12 years in order to examine the performance of the luting cement, RelyX Unicem by way of assessing the restoration margins. Materials and methods: In the original study, four UK general dental practitioners recruited patients who required fixed bridgework and, after obtaining informed written consent, appropriate clinical and radiographic assessments were completed. The teeth were prepared, bridges constructed in accordance with the manufacturer's instructions and luted with the self-adhesive resin luting material 3M<sup>TM</sup> RelyX<sup>TM</sup> Unicem Self Adhesive Resin Cement (3M Oral Care Solutions Division). Of the 41 bridges originally placed, 33 bridges were examined at five-years. Eight bridges were reviewed after 12 – 13 years by the clinician who had placed the restoration, using modified USPHS criteria. Results: Of the 16 bridge retainers, no unsatisfactory margins were noted. Conclusion. The 12-year follow-up indicated satisfactory performance of the eight bridges which were evaluated, with good performance of the luting material, as assessed by examination of the restoration margins.

## INTRODUCTION

While metal ceramic restorations have been regarded as the gold standard for crowns and bridges,<sup>1</sup> demand by patients for metal-free and aesthetically excellent restorations has driven the development of high strength ceramic systems. The first crowns and bridges constructed in a yttria oxide stabilized tetragonal zirconium oxide polycrystal (Y-TZP) substructure were placed in patients in the early 2000s, and, since then, the expansion of the use of zirconia has been dramatic.<sup>2</sup> Initially, zirconia-based restorations were more expensive than traditional metal-ceramic, but factors such as the competition resulting from the expansion in zirconia systems and the rise in cost of precious metals such as gold and palladium in recent years (and the associated rise in the cost of metal-ceramic restorations) may be considered to have stabilised prices of Y-TZP substructure restorations, and improved their uptake by clinicians. In that regard, results of a recent survey of UK dentists has indicated that 57% have used, or are using, Y-TZP-based restorations.<sup>3</sup>

#### Keywords

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A practice-based multi-centre clinical observational study evaluated the five-year performance of all-ceramic fixed-fixed bridges, constructed with a Lava substructure, placed in adult patients in four UK general dental practices,<sup>4</sup>, whose dentists were members of the UK-wide practice-based research group The PREP (Product Research and Evaluation by Practitioners) Panel<sup>5</sup> (which currently comprises 31 members). These bridges were luted using a self-adhesive resin based cement (RelyX Unicem: 3M, Seefeld, Germany), with no additional surface treatment of the Y-TZP framework fitting surface, apart from sandblasting with aluminium oxide to activate the intaglio bonding surface.

The paper reporting the five-year have been published.<sup>4</sup> It was possible to recall seven patients who had been attending two of the practices continuously since the conclusion of the original evaluation and re-assess their bridges, with special interest in the restoration margins, so that the performance of the luting material could be evaluated. This short paper presents the results of these evaluations.

## **MATERIALS AND METHODS**

Ethics Committee approval was obtained prior to commencing the original study. Of the 33 bridges which were assessed for this study, two of the participating dentists agreed to assess the bridges of regularly-attending patients when they attended for their routine examination. A modified version of the criteria which were suggested by Ryge<sup>6</sup> in 1980 was used for the assessment of the restoration margins (*Table 1*). Photographs of the restorations were also taken.

#### Table 1. Criteria modified from Ryge<sup>5</sup>

Marginal adaptation (where \* indicates a filing restoration)

0 = Restoration is contiguous with existing anatomic form, sharp explorer does not catch

1 = Explorer catches, no crevice is visible into which the explorer will penetrate

2\* = Obvious crevice at margin, dentine or lute exposed

## RESULTS

Eight patients who attended for routine examination had their Lava bridges assessed as part of their examination. The distribution of the bridge pontics was as follows:

- Anterior (incisor & canine pontics) = 4
- Posterior (molar & premolar pontics) = 4

Four of the bridges were in the maxillary arch: all were between and 12 and 13 years post-placement.

The margins of six bridges were rated 0, the remaining two were rated 1.

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#### CASE 1: BRIDGE UR 4 TO UR6: MARGIN ASSESSMENT CODE 1



**Figure 1a:** April 2018, 13 years after bridge placement. This female patient is 64 years of age, with a bruxist habit which led to fracture of a previous bridge at this site. UR6 abutment, which had a very large amalgam core, required root canal treatment one year after the bridge was placed.



**Figure 1b:** Occlusal view of bridge, which required a root canal treatment in its first year following placement. Occlusal access cavity restored with resin composite.

#### CASE 2: BRIDGE UL5 TO UL7: MARGIN ASSESSMENT CODE 0



**Figure 2:** Case 2 : May 2018, Bridge at 12 years Patient is female and 50 years of age.

#### CASE 3: BRIDGE UL456: MARGIN ASSESSMENT CODE 1



**Figure 3a:** Bridge at placement Patient is female of 60 years of age and is a bruxist.

#### CASE 5: BRIDGE LL 5 TO LL7: MARGIN ASSESSMENT O



**Figure 5:** Bridge at 13 years Patient is female of 49 years of age.



Figure 3b: Bridge after 13 years

#### CASE 6: BRIDGE UL1 TO UR2 MARGIN ASSESSMENT 0



**Figure 6:** Bridge at 13 years Male patient is 60 years of age.

#### CASE 4: BRIDGE UL3 TO UL5: MARGIN ASSESSMENT 1



**Figure 4:** Bridge at 12 years Patient is male of 73 years of age.

#### CASE 7: BRIDGE UL1 TO UR2: MARGIN ASSESSMENT 1



**Figure 7:** Bridge at 12 years Patient is male and 77 years of age.

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#### CASE 8: BRIDGE UL2 TO UR1: MARGIN ASSESSMENT 0



**Figure 8:** Bridge at 13 years Patient is 60 years of age.

## DISCUSSION

This short paper has described the margins of sixteen bridge retainers (eight fixed/fixed bridges) formed with a Y-TZP framework, these having been present in patients' mouths for between 12 and 13 years. This could be considered to be a convenience sample of eight patients who were able to attend, from the 33 who were included in the original study. Ideally, the evaluation should be conducted by one or two independent assessors, but this was not possible in the present study, given that there was no funding for an independent assessment, and, furthermore, such an assessment would have required ethical approval. Hence, the patients' bridges were assessed as part of the patients' routine examinations. However, the dentists who carried out the assessments were members of the UK-based practice-based research group, the PREP (Product Research and Evaluation by Practitioners) Panel and had received training in the USPHS/Ryge criteria as part of the original study.

The results indicated satisfactory performance of the luting material which was used, RelyX Unicem Self-adhesive cement, given that no bridge retainers, after 12 to 13 years in service, had a marginal gap into which a probe would penetrate. This

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may not be considered surprising, given the low solubility of resin cements in the dilute organic acids found in plaque,<sup>7</sup> which could be responsible for the dissolution of conventional cements such as glass ionomer or zinc phosphate. The number of bridges assessed is too small to allow firm conclusions to be drawn, but could be considered to indicate that satisfactory performance of Y-TZP-based bridges is possible, as indicated by research such as that by Al-Amleh *et al.*<sup>8</sup>

### CONCLUSION

After 12 to 13 years in clinical service, the performance of Rely X Unicem resin luting material may be considered satisfactory, as evidenced by its performance at the margins of the convenience sample of eight bridges which were examined.

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