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ORIGINAL ARTICLE

Metal–ceramic crowns cemented with two luting agents: short-term results of a prospective clinical study

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Abstract A prospective, randomized, controlled, split-mouth trial was performed to evaluate the cementation modes for metal–ceramic crowns. A total of 40 fully veneered metal–ceramic crowns were delivered in the posterior jaw segments of 20 patients using either a self-adhesive resin cement (RelyX Unicem Aplicap, 3M ESPE; n=20) or a zinc oxide phosphate cement (Hoffmann's Cement, Hoffmann; n=20). Thirteen parameters related to the abutment teeth and their periodontal status were evaluated. A visual analog scale was used to assess the sensitivity of the abutment teeth by patient-based outcomes. Data were statistically analyzed by a single-classification ANOVA (α=0.05) and logistic regression analysis. The results presented were obtained after a mean observation period of 1.8 years. The dropout rate was 0%. None of the abutment teeth exhibited secondary caries at the restoration margins. No significant differences were demonstrated between the luting agents based on visual analog scale (p>0.05), hypersensitivity (OR=1.31), abutment mobility (p>0.05), or probing depths (p>0.05). Based on the sulcus fluid flow rates, a significantly greater mean difference was obtained with zinc oxide phosphate cement than with self-adhesive resin cement (9.2 units; p=0.0006). Significant differences between the baseline examination and the follow-up examinations for sulcus bleeding index (p=0.0013) and plaque index (p<0.0001) were observed regardless of the luting agent used. The two cement types showed scarcely any differences between the parameters investigated. The outcomes of cementing fully veneered metal–ceramic crowns were equally good with self-adhesive resin cement as with the clinically proven zinc oxide phosphate cement.

Keywords Self-adhesive cement · Zinc oxide phosphate cement · Randomized controlled trial · Prospective clinical study · Split-mouth design

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Introduction

Luting agents of different classes are available for the final delivery of indirect restorations [1]. Zinc oxide phosphate cements have been used to deliver metal-based restorations for over a century [2]. These materials do not form a chemical bond with the hard tissue of the tooth structure [1]. A self-adhesive resin cement was first presented under the trade name RelyX™ Unicem Aplicap™ (3M ESPE; Seefeld, Germany) in 2002. Manufacturers claim that this class of materials combines the advantages of traditional cements (such as ease of handling) with those of adhesive luting agents (such as good mechanical and adhesive properties). They do not require etching, priming, or bonding. A bond with dental hard tissues is created without the preparatory steps involved in the use of adhesive technology [3].

Numerous in vitro studies have examined the mechanical properties of self-adhesive materials [4–9]. Self-adhesive resin cements have been shown to offer better compressive and flexural strength than traditional luting cements [4]. Good results have also been demonstrated regarding their adhesion to enamel/dentine [8, 10, 11] and regarding microleakage [12, 13].

However, the results of in vitro investigations cannot be readily transferred to the clinical situation. Controlled

clinical trials are indispensable when comparing self-adhesive luting agents with traditional cements. Behr et al. [14] have published the only study of this type so far, evaluating the outcomes of 49 metal-based anterior and posterior restorations delivered to 49 patients with either a self-adhesive composite or a zinc oxide phosphate cement.

These considerations prompted us to devise a prospective, randomized, controlled split-mouth trial that compared a self-adhesive resin cement (RelyX Unicem) with a conventional zinc oxide phosphate cement (Hoffmann's Cement) for fully veneered metal–ceramic crowns. A total of 13 parameters were evaluated, pertaining to the abutment teeth, periodontal conditions, and patient-based outcome measures, based on the null hypothesis that no difference in performance existed between both luting agents.

Materials and methods

A total of 40 fully veneered metal–ceramic crowns were placed in 20 patients (mean age, 53.6 years) at our institution (Department of Prosthodontics, Johann Wolfgang Goethe University, Frankfurt, Germany). All abutment teeth were vital at baseline. No clinical or radiographic abnormalities were noted. Institutional approval for the study was obtained from the relevant ethics commission at Johann Wolfgang Goethe University (reference number 147/04).

Each patient received two crowns in non-antagonistic contralateral quadrants. According to the randomization protocol, one of both crowns was cemented with a zinc oxide phosphate cement (Hoffmann's Cement; Hoffmann, Berlin, Germany), the other one with a self-adhesive resin cement (RelyX Unicem, 3M ESPE). Randomization was performed following tooth preparation and temporization to avoid investigator bias. A blinded design was used, with the patients unaware of which agent was being applied at which site.

Dental treatment and laboratory steps

Pretreatment of the abutment teeth involved the application of a liner (Kerr Life; Kerr, Orange, CA, USA) to the parapulpal area if deep caries was present. The core restoration was placed with a dual-curing composite (Luxa Core; DMG, Hamburg, Germany) in combination with a dentine adhesive (OptiBond FL; Kerr, Orange, CA, USA). The abutment teeth were prepared according to the guidelines defined by Shillingburg et al. [15]. Preparation margins were created as circular chamfers, placed at a supragingival level in non-visible areas and at a subgingival level (0.5–0.8 mm below the gingiva) in visible areas to meet esthetic requirements, unless preexisting factors such as caries, restorations, or preparation margins (in previously prepared teeth) dictated otherwise. Occlusal surfaces were reduced to around 1.5 mm and axial surfaces to 1.0–1.2 mm. High-precision impressions were taken using a polyether material (Impregum™ Penta; 3M ESPE). The temporary crowns were made of Protemp™ 3 Garant (3M ESPE) and delivered with a non-eugenol temporary cement (RelyX Temp NE; 3M ESPE).

The fully veneered metal–ceramic crowns were fabricated by two technicians at the central laboratory of the Department of Prosthodontics (School of Dentistry, Frankfurt, Germany). The frameworks were cast in a high-gold ceramic alloy (BiOcclus HT; DeguDent, Hanau, Germany) and were veneered with Duceram Kiss (DeguDent).

When the self-adhesive universal resin cement RelyX Unicem Aplicap was used, the capsule was activated and mechanically triturated with a mixing device (CapMix; 3M ESPE) for the time recommended by the manufacturer (15 s). The powder-to-liquid ratio of zinc oxide phosphate cement was determined by weight as per the manufacturer's instructions, using an analytical balance (±1 mg). Mixing was performed on a cool slab, over a wide area, to incorporate small increments of powder into the liquid for approximately 90 s. Prior to the definitive insertion, the prepared residual tooth structures were thoroughly cleaned. Cotton rolls were inserted to obtain a dry working field. The restorations were covered with a thin layer of luting agent, then seated and cemented by finger pressure. Excess zinc oxide phosphate cement was removed after setting using scalers and dental floss. Excess self-adhesive universal resin cement was removed after setting the restoration.

Parameters examined

All examinations were performed by an independent dentist at various points of time: preoperatively at baseline, at delivery of the metal–ceramic crowns, and at 6 months, 1 year, 2 years, and 3 years. The parameters evaluated at follow-up included loss of retention, decementation, secondary caries, inadequate proximal contacts, and veneer fracture. Any fractures were categorized by location (occlusal–cervical–proximal) and depth (metal involvement–ceramic only).

Hard tissue defects of the abutment teeth following caries excavation were assessed for the degree of destruction (one, two, three, multiple surfaces) and depth of destruction (grade 1, defect within the enamel; grade 2, defect extending beyond the cementoenamel junction; grade 3, defect extending to the parapulpal area). Table 1 presents the distribution of hard tissue defects and intraoral locations of the abutment teeth. Margins were placed 0.5–1.5 mm subgingivally on the proximal and buccal surfaces and 0.5 mm supragingivally on the palatal/lingual surfaces.

Table 1 Hard tissue defects, caries depth, and intraoral positions of the abutment teeth at baseline

	Abutment teeth										
	Hard tissue defect				Caries depth			Intraoral position			
	One surface	Two surfaces	Three surfaces	Multiple surfaces	Grade 1	Grade 2	Grade 3	Maxillary premolar	Maxillary molar	Mandibular premolar	Mandibular molar
Number (*n*)	4	7	18	9	5	35	18	5	11	7	17

An intraoral examination was performed that covered vitality and percussion, probing depths, and mobility as abutment-related parameters. Vitality testing was performed using a cold spray (Pluradent 200ML DS; Pluradent, Offenbach, Germany) and an electronic pulp tester (Digitest D6260; Parkell Electronics Division, Farmingdale, NY, USA). Abutment tooth sensitivity or pain was explored by vertical and horizontal percussion. Probing pocket depths were measured at two locations per tooth (mesiobucally and distobuccally) with a periodontal probe (PCPUNC15; Hu-Friedy Inc., Chicago, IL, USA). Prior to launching the study, the measurements had been performed in duplicate on ten patients to ensure their reproducibility. A Periotest device (Periotest S; Medizintechnik Gulden, Modautal, Germany) was used to check the abutment teeth for mobility [16].

A visual analog scale was used to evaluate the abutment teeth for hypersensitivity at the above-mentioned times, with additional time points added as follows: 3–10 days after core buildup, before framework try-in, 3–10 days after crown delivery, 4 weeks after crown delivery. On these occasions, patients were asked to answer three questions related to how sensitively their teeth (old or new crowns) reacted to (1) chewing, (2) air streams or cold temperatures, and (3) hot temperatures. The patients were asked to rate each parameter by marking the perceived sensitivity on a line 10 mm in length, offering increments ranging from 0 (not sensitive) to 10 (extremely sensitive). Hypersensitivity of the abutment teeth was also checked by prompting for yes/no replies following the application of air for 5 s and cold water for another 5 s.

Sulcus fluid flow rates were determined using a Periotron 8000 system (Oraflow Inc., NY, USA) in conjunction with the supplied PerioPaper strips. Measurements were taken at two locations per tooth (mesioproximally and buccally). The values obtained were categorized as defined by the manufacturer (http://www.oraflow.com/FAQ4.html, accessed 22 Nov 2010).

Using the modified sulcus bleeding index, each tooth was tested for inflammatory reactions mesially and distally. This was accomplished by documenting the presence or absence (yes/no) of bleeding 10–30 s after using a periodontal probe (Parodontometer Colorvue UNC 12; Hu-Friedy Inc.) [17].

A periodontal probe was also used to determine the plaque index after relative isolation of the abutment teeth to obtain a dry working field. Depending on the extent and thickness of plaque accumulation, one of four values was assigned [18].

Statistical analysis

For descriptive statistical comparison, the usual measures of location (mean and median values) and dispersion (standard deviations, interquartile ranges, and minimum/maximum values) were computed for each luting agent. For qualitative variables, the corresponding absolute and relative frequencies were obtained. Luting agents were compared statistically using a single-classification ANOVA (level of significance, α=0.05) and logistic regression analysis. All calculations were performed using statistics software (SAS version 8.0.2; SAS Institute Inc., Cary, NC, USA).

Results

Based on the mean observation period of 1.8 years (median, 1.7; range, 0.9–2.8) after cementation, none of the metal–ceramic crowns exhibited loss of retention, decementation, secondary caries, or fracture of the veneering porcelain. The proximal contacts remained unchanged.

One abutment (mandibular molar) exhibited vitality loss 13 months after the final delivery of a crown with zinc oxide phosphate cement. The same abutment exhibited a three surface defect with grade 3 depth and required endodontic treatment due to an apical lesion. No sensitivity to percussion was observed for any of the restored abutment teeth.

Based on all examinations, the two cement types did not significantly differ in terms of probing depths (p>0.05). The mean differences between the two cement types were 0.0 (95% CI, −0.26; 0.26), preoperatively; 0.2 (95% CI, −0.07; 0.37), 6 months after delivery; 0.0 (95% CI, −0.18; 0.18), 1 year after delivery; and −0.2 (95% CI, −0.40; 0.07), 3 years after delivery. Probing pocket depths for the two cement types revealed no significant

differences between the follow-up and baseline examinations ($p>0.05$). Comparing the measurements of the two locations per tooth, only self-adhesive resin cement showed significant higher values mesiobuccally ($p=0.019$). Table 2 illustrates the means and standard deviations of the distobuccal measurements.

Mobility of the abutment teeth, based on individual examination times, did not significantly differ depending on which of the two cement types was used for delivery ($p>0.05$; Table 2). The three patient-based questions surveyed by a visual analog scale (cold, heat, mastication) were pooled for statistical analysis (Table 2). No significant differences were observed with respect to any of these examinations between the two cement types ($p>0.05$).

However, the scores obtained from the visual analog scale differed significantly within both groups over the observation period ($p<0.0001$). The following significant differences ($p<0.05$) were noted at follow-up examinations compared to the baseline: Sites where zinc oxide phosphate cement was used revealed the mean differences of 0.8 (95% CI, 0.10; 1.50), 1.3 (95% CI, 0.57; 1.97) at framework try-in, and −0.8 (95% CI, −1.47; −0.05) at 1 year following cementation. Sites where self-adhesive resin cement was used revealed a mean difference of 1.1 (95% CI, 0.48; 1.71) at the framework try-in.

No difference between the luting agents was noted concerning the risk of developing hypersensitivity (logistic regression analysis, $OR_{RelyX\ Unicem}=1.32$).

The sulcus fluid flow rates were significantly higher in the presence of zinc oxide phosphate cement than self-adhesive resin cement ($p=0.0006$), regardless of the examination times (Table 2). The mean difference between the two cement types was 9.2 units (95% CI, 4.02; 14.45). Significant differences between the luting agents in terms of sulcus fluid flow rates were obtained at baseline, 6 months, and 1 year after delivery ($p<0.05$). No significant differences were observed 2 and 3 years after delivery ($p>0.05$). The mean differences between mesioproximal and buccally measurements for the zinc oxide phosphate cement were 4.25 (95% CI, −4.79; 13.29) ($p>0.05$). Significantly higher mesioproximal values, 8.4 (95% CI, 3.30; 13.57) ($p=0.0014$), were obtained with the self-adhesive resin cement. Both the sulcus bleeding index and plaque index differed significantly ($p=0.0013$ and $p<0.0001$) between all follow-up examinations on one hand and the baseline values on the other (Table 3).

Discussion

Few reports are available on the effect of two different luting agents for the intraoral delivery of indirect restorations [14, 19, 20]. Due to variations in the study designs, as well as the different materials and observation periods involved, these studies offer a limited basis for direct comparison.

Jokstad [19] conducted a randomized split-mouth study with 80–104 months of follow-up, demonstrating that the clinical success of a zinc oxide phosphate cement was comparable to that of a resin-modified glass ionomer luting cement. That study included 20 patients with 39 pairs of metal–ceramic or all-ceramic (Procera AllCeram) crowns inserted in the anterior and/or posterior jaw segments by three clinicians in three dental offices.

Table 2 Mean values (SD) for zinc oxide phosphate cement and self-adhesive resin cement based on probing depth (distobuccal), mobility of abutment tooth, visual analog scale (summary of three questions), and sulcus fluid flow rate (mesioproximal) at each examination

Time of examination	Probing depth (distobuccal) [mean (SD)]		Mobility of abutment tooth [mean (SD)]		Visual analog scale [mean (SD)]		Sulcus fluid flow rate (mesioproximal) [mean (SD)]	
	Zinc oxide phosphate cement	Self-adhesive resin cement	Zinc oxide phosphate cement	Self-adhesive resin cement	Zinc oxide phosphate cement	Self-adhesive resin cement	Zinc oxide phosphate cement	Self-adhesive resin cement
Before treatment	3.2 (0.8)	3.0 (0.6)	−0.2 (1.6)	−0.1 (1.4)	0.8 (1.9)	0.7 (1.6)	62.4 (46.8)	38.3 (28.8)
3–10 days after placing the core buildup	–	–	–	–	1.6 (2.9)	1.3 (2.4)	–	–
Before framework try-in	–	–	–	–	2.1 (3.0)	1.8 (2.8)	–	–
Before insertion	3.1 (0.6)	3.0 (0.5)	–	–	1.4 (2.3)	1.2 (2.1)	–	–
3–10 days after insertion	–	–	–	–	1.3 (2.1)	1.0 (1.9)	–	–
4 weeks after insertion	–	–	–	–	0.6 (1.5)	0.5 (1.1)	–	–
6 months after insertion	3.1 (0.4)	2.9 (0.6)	−0.3 (1.7)	−0.8 (2.0)	0.2 (0.8)	0.1 (0.4)	29.3 (13.7)	30.4 (18.1)
1 year after insertion	2.9 (0.4)	2.8 (0.4)	−0.7 (0.9)	−0.70 (1.1)	0.04 (0.3)	0.1 (0.3)	21.6 (9.4)	19.4 (12.7)
2 years after insertion	2.9 (0.3)	2.9 (0.3)	−0.7 (1.0)	−0.8 (1.4)	0.1 (0.4)	0.3 (0.7)	18.0 (9.0)	16.4 (8.0)
3 years after insertion	2.8 (0.4)	3.0 (0.0)	−1.0 (1.1)	1.2 (2.0)	0.1 (0.2)	0.1 (0.2)	16.2 (5.4)	12.0 (3.4)

Table 3 Mean values (SD) independent of the luting cement based on sulcus bleeding index and plaque index at each examination

Time of examination	Sulcus bleeding index [mean (SD)]	Plaque index [mean (SD)]
Before treatment	18.0 (8.4)	35.1 (19.3)
6 months after insertion	11.8 (8.3)	26.5 (22.1)
1 year after insertion	10.4 (7.5)	22.9 (18.3)
2 years after insertion	7.4 (6.5)	21.6 (23.4)
3 years after insertion	5.8 (6.1)	23.0 (24.7)

There were 55 vital and 13 non-vital abutment teeth at the time of delivery. The crowns examined differed in terms of restorative design, intraoral location, and vitality. The present study, by contrast, was based on a clearly structured treatment protocol. A single clinician performed all the dental treatments and inserted the 40 crowns, all metal–ceramic crowns delivered in posterior segments. Furthermore, our study design implied that two crowns were placed on the vital abutment teeth and that the sequence of the luting agents (zinc oxide phosphate cement versus self-adhesive resin cement) was randomly selected in each patient. To rule out any spillover effects and to ensure valid results for each luting agent, the two crown restorations per patient were inserted in non-antagonistic, contralateral quadrants. In addition, the teeth adjacent to the treated sites could not show any signs and symptoms of pulpitis, periodontitis, or periapical inflammation. Also, a blinded approach was used where patients remained unaware of which luting agent was used at which site, minimizing any bias in the form of preconceived notions when answering questions about abutment sensitivity [21].

Kern et al. [20] used a split-mouth design to evaluate postoperative sensitivity following the cementation of 120 partial- and full-coverage restorations in 60 patients using a zinc oxide phosphate cement or a glass ionomer cement. Following a mean observation period of 17.3 months, no significant differences were seen between both luting agents in terms of decementation and postoperative sensitivity. These results were confirmed by our own study, which revealed no differences between the two cement types with regard to these parameters after a mean observation period of 1.8 years.

Behr et al. [14] have contributed the only prospective clinical study available on the subject thus far. They compared a zinc oxide phosphate cement and a self-adhesive resin cement (RelyX Unicem) in 49 patients treated with 49 metal-based restorations, including 5 anterior crowns, 42 posterior crowns, and 2 onlays. Consequently, a parallel study design was used for two-treatment comparisons, rather than a split-mouth design as in the present study. After a mean follow-up of 3.16± 0.6 years, no significant differences between the luting agents were demonstrated in that study with regard to plaque formation and bleeding [14]. Our own investigation did not reveal any differences for almost any of the parameters evaluated. Only the sulcus fluid flow rates showed significantly higher mean values at sites with zinc oxide phosphate cement than at sites with self-adhesive resin cement. This finding was consistent regardless of the examination times, allowing the conclusion that restorations cemented with self-adhesive resin cement RelyX Unicem are associated with less inflammation in the periodontal pockets and the gingiva, possibly due to the good cross-linking and the resultant lower solubility in water [22]. There is no doubt that the position of the restorative margin will influence the periodontal parameters [23]. Both groups of crowns investigated in the present study were located at comparable levels relative to the gingival margin, such that the findings obtained in all these cases could be readily compared.

Behr et al. [14] reported one case of vitality loss after 1.9 years, affecting one abutment tooth with a deep carious lesion treated with self-adhesive resin cement. Our own study involved one case of vitality loss after 13 months, affecting one abutment tooth under a crown cemented with zinc oxide phosphate cement. This case involved a hard tissue defect extending to the parapulpal area. Consequently, an association between the luting agent and vitality loss cannot be established at present. It is, however, essential to consider the specific history (including the depth and degree of destruction) of any abutment teeth with vitality loss.

The results of the study did not falsify the working hypothesis. Although no differences between the two luting agents were observed for most parameters, the RelyX Unicem self-adhesive resin cement did involve lower sulcus fluid flow rates than the Hoffmann's zinc oxide phosphate cement.

Conclusion

1. The clinical performance of both luting agents (RelyX Unicem self-adhesive resin cement and Hoffmann's zinc oxide phosphate cement) scarcely differed with regard to the investigated parameters.
2. The self-adhesive luting cement was associated with a lower sulcus fluid flow rate than the zinc oxide phosphate cement.

Conflicts of interest The authors declare that they have no conflicts of interest.

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