A Split-Mouth Randomized Clinical Trial of Single Crowns Retained with Resin-Modified Glass-Ionomer and Zinc Phosphate Luting Cements

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Purpose: This study compared the influence of two luting cements on the clinical performance of single crowns. ***Materials and Methods:*** Twenty patients received 39 pairs of metal-ceramic and Procera crowns cemented with zinc phosphate and resin-modified glass-ionomer luting cement (Vitremer) in a split-mouth randomized pattern blinded to the recipient. The crowns were examined immediately after cementation, after 2 weeks, after 6 months, and then yearly. Clinical performance was scored according to CDA criteria, Silness and Löe criteria, patient satisfaction, and operator-appraised general clinical criteria. Three clinicians in private general practice carried out all procedures. ***Results:*** During the observation period, which varied between 80 and 104 months, seven clinical events were recorded. Two abutments fractured vertically, two underwent retrograde endodontic surgery, and one developed pulp necrosis. Two crowns were recemented. Estimated survival, defined as no negative events observed, was 89% at 102 months (85% for crowns cemented with zinc phosphate and 93% for crowns cemented with resin-modified glass-ionomer). Estimated survival, defined as no recementation or loss of pulp vitality, was 96% at 102 months (95% with zinc phosphate and 97% with resin-modified glass-ionomer). The differences between cements were not statistically significant. ***Conclusion:*** A resin-modified glass-ionomer luting cement was at least as good as zinc phosphate cement to retain single crowns over a 102-month observation period. *Int J Prosthodont 2004;17:411–416.*

For more than a century, zinc phosphate cement has been the luting cement in common use to retain crowns and fixed partial dentures.[1] Glass-ionomer–based luting cements were introduced in the mid-1980s, with a clinical performance comparable to zinc phosphate cement in terms of longevity.[2] The subsequent incorporation of a resin into the polycarboxylate matrix of the glass-ionomer cement improved compressive and diametral tensile strengths.[3,4] These and other enhanced physicomechanical properties observed in laboratory experiments suggested an expected improved clinical performance compared to traditional cement types.[5,6] A resin-modified glass-ionomer luting cement for commercial use was developed in the mid-1990s,[7] and today, several manufacturers market this type of luting cement. It is presumed that their physicomechanical properties reduce the risk of adverse clinical events and extend the longevity of fixed prostheses. However, longitudinal clinical data are sparse, and some products actually lack any data at all.

The aim of the present study was to determine whether single crowns cemented with a resin-modified glass-ionomer luting cement would demonstrate comparable clinical performance to crowns cemented with a conventional zinc phosphate cement over a minimum 5-year observation period.

Materials and Methods

The aim, study design, and procedures in the present study were described in a protocol issued to the participating clinicians that gave instructions on the selection

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of patients, abutment teeth, clinical procedures, evaluation criteria, and other technical details, as well as consent forms for patients.

The patient sample size was calculated on the basis of detecting a possible difference between the cements with regard to postcementation sensitivity with a statistical power of 80%. Johnson et al[8] report, at a 2-week recall, 34% postcementation sensitivity for zinc phosphate cement and 19% sensitivity for glass-ionomer luting cement. At the time, it was claimed by the manufacturer that the resin modification of the glass-ionomer cement would lower the sensitivity response even further, although no clinical data were presented. A moderate estimate of postcementation sensitivity for this cement was therefore set to 10%. Applying these population proportions in a two-sample power calculation algorithm with alpha = .05 in a two-tailed test, a sample size of 2 × 70 would result in a power of 94% (SamplePower, SPSS).

Seven specialists in prosthodontics who were engaged as clinical instructors at the Department of Prosthetic Dentistry, University of Oslo, and who maintained private general practices agreed to participate in the trial, each with 10 crown pairs. The clinicians were to maintain their daily clinical routines. However, it was stressed that the handling of the luting cements needed to follow the manufacturers' instructions. All patients were verbally informed by their clinician and provided with written information about the intentions of the clinical study. They consented to have crown pairs cemented with two different cement types.

The abutment preparations were designed according to general principles for crown preparation described by Karlsson et al.[9] The study included only complete crowns with occluding antagonists. Both vital and endodontically treated teeth were included. The latter were, when indicated, restored either with individually formed cast or prefabricated posts; these were in all cases cemented separately before the final impression. All abutments were provisionalized during the period between preparation and final cementation. In all cases, a zinc oxide–eugenol cement was used for retaining the provisional crown (Temp-Bond, Kerr; Nobetec, Astra; or Opotow Trial Cement, Teledyne).

The final crown was controlled and adjusted for passive fit on the abutment before cementation. The abutment was thereafter cleaned with slurry of pumice, isolated with cotton rolls, and air dried. An experimental cement (resin-modified glass-ionomer) and a control cement (zinc phosphate) were used for cementing the crown pairs. The operator selected the cement to be used for the individual abutment at random immediately prior to cementation. The two cements were DeTrey Zinc Zement Improved (liquid batch No. BJ31 83/01, powder batch No. CC35 83/05) and Vitremer Luting Cement (3M; batch No. 1994 41031). (3M/ESPE subsequently renamed the Vitremer luting cement RelyX Luting cement, although the cement composition has remained unaltered.) The dentin was not preconditioned with polyacrylic acid prior to cementation when resin-modified glass-ionomer luting cement was used. All crowns were seated using finger pressure only, and excess luting material was removed with a probe after setting had finished. Postcementation control of occlusion and articulation was determined using articulating paper.

The patient was not informed which cement had been used for which tooth to avoid biased reporting of postoperative tooth sensitivity. Before the patient was discharged, a recording was made of the crown adaptation according to modified California Dental Association (CDA) criteria[10] (Table 1) as well as the patient's general satisfaction with the crown and any postoperative sensitivity.

After intervals of 2 weeks, 6 and 12 months, and yearly thereafter, the clinician who had cemented the crowns examined the abutment teeth clinically. The examinations were carried out in the clinicians' general practices, assuming that they maintained their clinical evaluation criteria for fixed prostheses as calibrated faculty instructors. All examinations included the recording of patient-reported postoperative sensitivity and general satisfaction with the crowns as well as the crown adaptation. At the 2-week control and each subsequent assessment, an additional recording was the Gingival Index according to Silness and Löe[11] as well as response to palpation in the periapical region and pain on percussion to the crown (Table 1). At the 6-month control visit and the subsequent yearly ones, additional examination criteria included loss of retention, secondary caries, and detectable changes on periapical radiographs. Any other adverse events, such as abutment fracture and endodontic or mechanical complications, were also recorded. These criteria were recorded dichotomously.

For various reasons, four clinicians dropped successively out of the study without submitting any results to the study coordinator. The remaining three operators cemented, between March 1995 and March 1997, 39 pairs of single crowns in 20 patients (10 men and 10 women) varying in age between 34 and 72 years. Each patient received one or more pairs of single crowns on contralateral, antagonist, or neighboring teeth (Table 2). The majority of the 39 pairs were in the maxilla (22 pairs), followed by in the mandible (12 pairs), while 5 pairs were comparisons between crowns placed in opposite jaws. At the time of cementation, 55 abutments were vital (81%). Of the 13 nonvital teeth, 2 were restored with separate cast-gold posts and cores, 9 were

Table 1 Criteria Recorded at the Different Clinical Controls

Clinical examination of	Postcementation	2 wk	6 mo and later
Postoperative sensitivity*	X	X	X
General satisfaction*	X	X	X
Crown adaptation†	X	X	X
Palpation in periapical region*		X	X
Pain on percussion*		X	X
Gingival Index‡		X	X
Loss of retention*			X
Secondary caries*			X
Detectable changes on periapical radiographs*			X
Any other clinical occurrences* (abutment fractures, endodontic and mechanical complications)			X

*Dichotomous scale (yes/no).
†CDA criteria: R = excellent adaptation (probe does not catch when moved perpendicularly over crown margin); S1 = acceptable adaptation (probe catches when moved perpendicularly over crown margin); S2 = acceptable adaptation (probe catches when moved perpendicularly over crown margin); T = poor adaptation (probe penetration between crown and tooth).
‡Gingival Index[11]: G1 = mild inflammation, slight contour change, and edema, no bleeding; G2 = moderate inflammation, redness, and edema, bleeding on probing; G3 = severe inflammation, marked redness and edema, ulceration, and spontaneous bleeding.

restored with prefabricated posts made from nickel titanium (Radix-Anchor, Maillefer), and 2 were restored with no post. Twelve crowns were made completely in a ceramic material (Procera AllCeram, Nobel Biocare), while the remaining 56 were metal-ceramic crowns based on a conventionally sintered feldspar ceramic combined with a precious alloy.

The comparisons of longitudinal data were analyzed using survival statistics with the Wilcoxon (Gehan) test. Fisher's exact test was used to compare the incidence of various negative clinical events in the two cement groups at different time intervals.

Results

Postoperative sensitivity was not reported in any instances at baseline, nor at the 14-day or any subsequent clinical controls.

At baseline, all crowns displayed either excellent (n = 8) or acceptable adaptation to the preparation margin. In both cement subgroups, a majority of the crowns (44/68) were scored S1, "acceptable adaptation, although the probe catches when moved perpendicularly from the tooth over the crown margin onto the crown." The score for marginal crown adaptation was not statistically different between the two groups (Fisher's test, $P > .05$).

Throughout the observation period, there were no differences between the groups regarding Gingival Index (Fisher's test, $P > .05$). There were no recordings of secondary caries or detectable changes on periapical radiographs, nor pain on palpation in the periapical region or following percussion tests. None of the patients reported any specific negative experience with any of the crowns.

Table 2 Distribution of Intraoral Pairs of Cemented Crowns (n = 39 pairs)

Tooth type	Maxilla	Maxilla-mandible	Mandible
Incisors	10	0	4
Canines	2	0	3
Canine-premolar	2	2	0
Premolars	5	0	4
Premolar-molar	1	0	0
Molars	2	3	1

The observation period at the time of the present report varied between 6 and 8 years. During this period, seven adverse events were recorded in four patients (Table 3). Three events were possibly associated with the luting cement: Two crowns cemented with zinc phosphate loosened, and one tooth with a crown cemented with the resin-modified glass-ionomer cement became necrotic. Estimated survival, defined as no negative events observed, was 89% (standard error [SE] 4%) at 102 months (85% for crowns cemented with zinc phosphate and 93% for crowns cemented with resin-modified glass-ionomer). The survival estimates did not differ statistically significantly between the two cement types (Wilcoxon Gehan test, $P = .44$). Estimated survival, defined as no recementation or loss of pulp vitality, was 96% (SE 2%) at 102 months (95% with zinc phosphate and 97% with resin-modified glass-ionomer) (Fig 1).

Table 3 Recorded Adverse Clinical Events, Arranged Chronologically

Clinic	Gender	Age (y)	Cement	Tooth*	Vital	Post	Crown	Adaptation†	Failure (mo)	Adverse event
2	Female	54	Zinc phosphate	43	Yes	–	Procera	S1	8	Recementation
2	Female	54	Zinc phosphate	34	No	Gold	Procera	S1	40	Vertical fracture
1	Male	55	Zinc phosphate	14	Yes	–	Metal ceramic	S1	41	Recementation
2	Female	54	Glass-ionomer	44	Yes	–	Procera	S1	61	Necrosis
1	Male	55	Zinc phosphate	24	No	None	Metal ceramic	S1	68	Vertical fracture
1	Male	52	Zinc phosphate	14	No	Radix	Metal ceramic	S2	68	Retrograde amputation
1	Male	60	Glass-ionomer	24	No	Radix	Metal ceramic	S2	68	Retrograde amputation

*Fédération Dentaire Internationale tooth-numbering system.
†See Table 1 for explanation of scores.

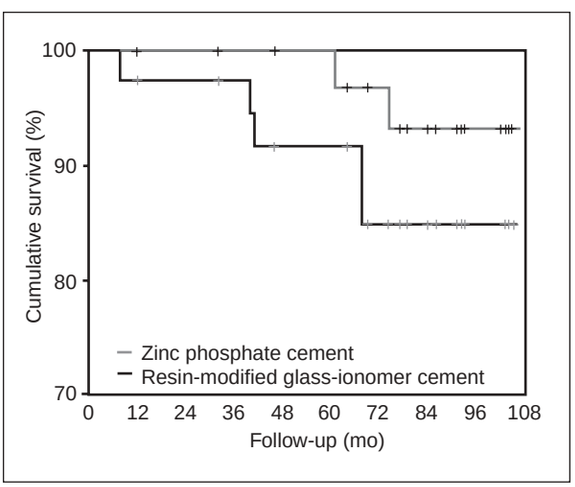

Fig 1 Survival estimates of crowns cemented with zinc phosphate cement (DeTrey) or resin-modified glass-ionomer cement (Vitremer) (n = 2 × 39). + = patient dropout/crown loss (ie, censored data).

Discussion

This trial was planned to include 70 pairs of restorations and seven clinicians working in their own practices. The fact that it instead ended up with 39 pairs made by only three clinicians weakened the reported results. This underscores a major problem with attempting to conduct trials in practice environments. There are no incentives or encouragements, either from the practitioner's patients or society, for general practitioners to carry out research. This may explain the virtual lack of such a tradition in general dental practice. In the long run, it is detrimental to our quality of patient care and is a problem that should be addressed by the dental profession. Too much research has been, and is still being, carried out in carefully controlled environments in academic settings and repeatedly extrapolated to "real world" dentistry. It can be acknowledged that the testing of materials, instruments, and procedures needs to be done first in controlled environments to address safety issues and potential efficacy. However, studies carried out in the practice environment can better reflect the expected average effectiveness of these interventions. There are many examples of initially promising trials with exciting results that show mediocre performance in the hands of the typical practitioner.

The length of the observation period also needs to be relevant for clinical expectations of dental materials. For example, a 5-year follow-up should be required for appraising glass-ionomer cement restorations,[12] and 10 years should be required for luting cements,[2] amalgams,[13] and resin composite restorations,[14] preferably carried out within the confines of general practices. Although the current situation in dentistry is that brand products seem to arrive on the market and depart at an ever faster pace, such long-term data provide important information for the educated reader and for further research strategies to improve currently available dental materials. The most relevant weaknesses and strengths of material properties become apparent in long-term clinical studies.

Perhaps the most surprising finding in this trial was the complete lack of patient reports of postoperative sensitivity. It is difficult to provide a biologic explanation for a much lower incidence of postcementation sensitivity than expected. Previous Scandinavian studies of fixed prosthodontics report few, if any, incidences of sensitivity.[15] The question of whether this is a reflection of an actual low rate of postcementation sensitivity or that this is an exaggerated problem in other clinical trials remains unanswered. Some investigators have used thermal or electric provocation tests to evaluate postoperative sensitivity, but the validity of such tests to estimate pulpal damage caused specifically by a luting cement and/or predict long-term pulpal vitality remains undetermined. As the anticipated incidence of postcementation sensitivity formed the basis for calculating statistical power and adequate

sample sizes in the present study, the statistical power remains unknown. However, given the small differences in clinical performance observed in this study, considerably larger sample sizes are needed to obtain a statistical power of 80%. Moreover, it appears that figures of postcementation sensitivity seem unreliable for calculating sample sizes in potential future studies aimed at comparing luting cements.

The adaptation of the crowns was in all cases acceptable according to the CDA criteria, although the "excellent" score was reached for comparatively few crowns. The scores would perhaps have been higher if cast crowns had been employed instead of the metal-ceramic and Procera crowns. Several studies have identified cast-gold crowns to have better general marginal fit than other crown types. On the other hand, the comparable and satisfactory marginal fit for all crowns is in accordance with laboratory experiments that demonstrate that the cements both have adequately low film thicknesses.[16]

The clinical performance of the crowns cemented with the two cements did not differ in any way. None of the crowns loosened during the observation period, which is in accordance with the excellent historic record of zinc phosphate cement. The additional higher compressive and diametral tensile strengths of the resin-modified glass-ionomer compared to zinc phosphate cement thus signify little clinical benefit, at least in situations with adequately prepared abutments and cementation procedures.

The adhesion of the resin-modified glass-ionomer cement to enamel and dentin, and their fluoride release pattern, suggests that these cements may have some cariostatic potential and resistance to marginal leakage. Both glass-ionomer and resin-modified cements are sometimes advocated, as they are claimed to reduce caries risk. As no secondary caries was observed in this trial, it is difficult to make a statement on the appropriateness of the claim. However, the notion that a cement should hinder caries in patients who cannot maintain adequate plaque control is probably flawed[17] and in all likelihood an inappropriate focus of attention. Secondary caries develops on the enamel surface, not in the microgaps between the restoration and tooth, whether a fluoride-rich environment is present or not.[18] Thus, secondary caries develops in areas that are not kept plaque free, and it is difficult to understand how a luting cement in itself can provide protection against tooth demineralization under conditions where persistent plaque is present.

A disadvantage of the resin-modified glass-ionomers is the hydrophilic nature of polyhydroxyethyl methacrylate (polyHEMA), which results in increased water sorption and subsequent plasticity and hygroscopic expansion. Although initial water sorption may compensate for polymerization shrinkage stresses, continual water sorption has deleterious effects.[19,20] The potential for dimensional change has contraindicated the use of resin-modified glass-ionomers with all-ceramic feldspar-type crowns because of the potential for expansion-induced crown fracture. At the time of the cementation, Procera had no such restrictions, as the core of this restoration consists of a highly dense aluminum oxide ceramic.

Loss of vitality occurred in only 1 of 55 vital abutments, which can be considered an excellent result.[15] Because of the relatively small sample in the present study, however, it is difficult to draw any conclusions on this aspect. Also, other failures were so few that no statistical inferences on these issues can be drawn from the present trial.

Three of the lost crowns were made in Procera, and only 12 of these had been made in total. One may therefore speculate whether these Procera crowns had poorer results than metal-ceramic crowns. However, the three crowns were all lost in one patient who had been treated for a severely worn dentition. The patient had consented to trying out the crown therapy with minimal abutment preparation on an experimental basis. It is, however, noteworthy that none of the Procera crowns had actually fractured.

One plausible explanation for the low incidence of postcementation sensitivity and otherwise excellent results regarding crown marginal fit, negligible rate of loss of tooth vitality, and high clinical scores in general is that the three clinicians who carried out the treatments were all experienced prosthodontists. In addition, they knew that their treatment outcomes would be evaluated. One may speculate whether the results would be less impressive if general practitioners had been involved in the trial.

This trial demonstrated that a resin-modified glass-ionomer luting cement was at least as good as a zinc phosphate cement over the 102-month observation period. It could even be argued that it was better, as one reason for not reaching a statistically significant difference in the present study is probably due to the relatively small sample sizes, allowing for type II errors. There is some biocompatibility concern with the resin-modified glass-ionomer cements because of the presence of free monomer in the liquid. Although rare, dimethacrylates may elicit an allergic response in certain persons, and careful handling by dental personnel is recommended during mixing.[7] However, the capsules in use today reduce the risk of adverse exposure to the liquid and unset cement. An advantage of both luting cements is that they are easily handled and do not require elaborate surface treatments. The excellent track record of zinc phosphate cements suggests that the cement film will not deteriorate with the passage of time. Further long-term observations of the resin-modified

glass-ionomer cements will show if this is also the case with this new cement type.

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Literature Abstract

Association between periodontal and peri-implant conditions: A 10-year prospective study

The purposes of this study were to compare changes in periodontal and peri-implant environments and examine the relationship between the changes in periodontal parameters and peri-implant conditions such as probing attachment level (PAL) and probing pocket depth (PPD). Eighty-nine partially edentulous patients with diverse documented periodontal disease history participated in the study. One hundred seventy-nine implants (112 hollow screw, 49 hollow cylinder, 18 angulated hollow cylinder, ITI) were placed, and the same number of remaining teeth were evaluated as a control. Periodontal disease was treated, and implants were restored with fixed prostheses. Examinations were performed at 1 and 10 years after implant surgery.
The authors found that there was statistically significant difference during the 10-year period in most aspects of clinical and radiographic data in implants and natural teeth except plaque index and recession. However, multiple linear regression analyses showed significant relationship in these changes between the implants and the matched natural teeth. Implant marginal bone level at 10 years was found to be significantly associated with smoking, implant location, general health, full-mouth PAL and variation over time in full-mouth PPD. The authors concluded that the results presented strong associations between periodontal and peri-implant conditions and the changes in these tissues over 10 years in partially edentulous patients.

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