ACP AMERICAN COLLEGE OF PROSTHODONTISTS
Your smile. Our specialty.

Prospective Observation of a New Bioactive Luting Cement: 2-Year Follow-Up

Steven R. Jefferies, DDS, PhD, FAGD, FACD, FADI,[1] Cornelis H. Pameijer, DMD, DSc, PhD, FADM, FADI,[2] David C. Appleby, DMD, MScD, FACP,[3] Daniel Boston, DMD, FACD, FICD,[4] Colin Galbraith, BS,[5] Jesper Lööf, PhD,[6] & Per-Olof Glantz, BDS, Odont.Dr., Dr.odonthc, FCM, FDSRCS, FADM[7]

[1] Professor, Department of Restorative Dentistry and Director of Clinical Research, Kornberg School of Dentistry, Temple University, Philadelphia, PA
[2] Professor Emeritus, University of Connecticut, Farmington, CT
[3] Professor Emeritus and Clinic Director, Removable Prosthodontics (and formerly Director, Graduate Prosthodontics), Department of Restorative Dentistry, Kornberg School of Dentistry, Temple University, Philadelphia, PA
[4] Associate Dean of Clinical Affairs, Kornberg School of Dentistry, Temple University, Philadelphia, PA
[5] Fourth-Year Dental Student, Kornberg School of Dentistry, Temple University, Philadelphia, PA
[6] Director of Research, Doxa Dental AB, Uppsala, Sweden
[7] Professor Emeritus, Department of Prosthetic Dentistry, Faculty of Odontology, Malmo, Sweden

Keywords
Dental cement; cementation; luting cement; bioactive; crowns; bridges; fixed partial dentures; gold; PFM.

Correspondence
Steven R. Jefferies, Kornberg School of Dentistry, Temple University-Restorative Dentistry, 3223 N. Broad St., Philadelphia, PA 19140. E-mail: sjefferies@dental.temple.edu

This study was supported by Doxa Dental AB, Axel Johanssons gata 4–6, SE 754 51, Uppsala, Sweden.

Accepted March 10, 2011

doi: 10.1111/j.1532-849X.2011.00790.x

Abstract

Purpose: A pilot study was conducted to determine the 2-year clinical performance of a new bioactive dental cement (Ceramir C&B, formerly XeraCem) for permanent cementation.

Materials and Methods: The cement used in this study is a new formulation class, a hybrid material comprising calcium aluminate and glass ionomer. Thirty-eight crowns and fixed partial denture (FPD) abutments were cemented in 17 patients. Thirty-one of the abutment teeth were vital, 7 nonvital. Six reconstructions were FPDs comprising 14 abutment teeth (12 vital/2 nonvital). A two-unit fixed splint was also included. Preparation parameters and cement characteristics (dispensing, working time, seating characteristics, ease of cement removal) were recorded. Baseline and postcementation data were recorded for marginal integrity, marginal discoloration, secondary caries, retention, and gingival inflammation. Tooth sensitivity was assessed at pre- and postcementation time points using categorical and visual analogue scale (VAS) assessment measures.

Results: Mixing of the cement was reported as "easy." Clinical working time for this cement was deemed acceptable. Assessment of seating characteristics indicated all restorations were seated completely after cementation. Cement removal was determined to be "easy." Fifteen of 17 subjects were available for 1-year recall examination; 13 patients were available for the 2-year recall examination. Restorations at 2-year recall examination included 17 single-unit, full-coverage crown restorations, four 3-unit FPDs comprising 8 abutments, and one 2-unit splint. No retentive failures or sensitivity were recorded at 2-year recall. Marginal integrities of all restorations/abutments at 2 years were rated in the "alpha" category. Average VAS score for tooth sensitivity decreased from 7.63 mm at baseline to 0.44 mm at 6-month recall, 0.20 mm at 1-year recall, and 0.00 mm at 2-year recall. The average gingival index score for gingival inflammation decreased from 0.56 at baseline to 0.11 at 6-month recall, then 0.16 at 1-year recall, and 0.21 at 2-year recall.

Conclusions: Two-year recall data yielded no loss of retention, no secondary caries, no marginal discolorations, and no subjective sensitivity. All restorations rated "alpha" for marginal integrity at the 2-year recall. After periodic recalls up to 2 years, the new bioactive cement tested thus far has performed favorably as a luting agent for permanent cementation.

Long-term success of fixed restorations depends on a range of factors,[1] including the quality of the luting agent used,[2] biocompatibility, insolubility, and resistance against degradation; all of which help maintain the seal at the restoration margins, thus preventing ingress of bacteria leading to leakage, sensitivity, and secondary decay.[3] The progression of luting agents has evolved with a succession of chemistries over the past century or more, including zinc phosphate, polycarboxylate, glass ionomer, resin, resin-modified glass ionomer (RMGI), and self-adhesive resin cements. These cement compositions are now succeeded by a new hybrid calcium aluminate/glass ionomer cement: Ceramir C&B (CM), originally named XeraCem (Doxa Dental AB, Uppsala, Sweden), a luting agent intended for permanent cementation of crowns and fixed partial dentures (FPDs), gold inlays and onlays, prefabricated metal and cast dowel and cores, and all-zirconia or all-alumina crowns. The cement is a water-based composition comprising calcium aluminate and glass ionomer components, and has been demonstrated to be bioactive.[4] The term "bioactivity" refers to a property of this new cement to form hydroxyapatite (HA) when immersed in vitro in a physiological phosphate-buffered saline solution.[4] The introduction of any new cement chemistry necessitates assessment of its laboratory and clinical performance. The laboratory performance of this new cement has been assessed with respect to a number of performance criteria. Assessment of compressive strength, film thickness, and setting time all conformed favorability to the International Standard Organization (ISO) standard for water-based luting cements.[5] Comparative in vitro microleakage performance of this new bioactive cement has also been assessed by two methodologies. Dye leakage analysis in cemented crowns concluded that CM demonstrated significantly less leakage than a conventional glass ionomer cement, Ketac-Cem (KC).[6] An in vitro, bacterial leakage model comparison of CM to a conventional glass ionomer luting cement, KC, and an RMGI cement (Rely X Luting Plus, RX) demonstrated that the groups cemented with CM and RX showed no significant difference in microleakage patterns ($p > 0.05$), while both recorded significantly lower microleakage scores ($p < 0.05$) than the group cemented with KC.[7,8]

Biocompatibility ranks as one of the most important properties of a final luting cement, and as such, a number of in vitro and in vivo tests (as recommended by ANSI/ADA Spec. 41 and ISO 10993) were conducted prior to the clinical investigation to evaluate the biocompatibility of Ceramir C&B cement.[9] Results for the Ames test for mutagenicity indicated that this new cement formulation did not induce gene mutations. In vitro cytotoxicity testing indicated cell responses ranging from none to mildly cytotoxic, an acceptable response. The skin sensitization test (in guinea pigs) indicated that this cement is not a skin sensitizer, while testing for mucous membrane irritation (hamster pouch test) indicated that it produced no local irritation.[9] Pulpal testing in *Rhesus macaques*, according to ANSI/ADA Spec. 41, indicated a virtual absence of pulpal inflammation, at both 30- and 85-day evaluation periods, after CM was used to cement composite resin inlays in a Class V preparation.[9]

Retention is perhaps the most critical factor in the performance of a final luting cement. A comparative, in vitro crown retention study was conducted (also prior to the clinical evaluation) to assess the retentive properties of this new cement.[10] Results of this test indicated that it demonstrated retentive values equivalent (no statistically significant difference) to a self-adhesive resin cement, Rely X Unicem, but were significantly higher than a conventional glass ionomer (KC) and zinc phosphate cement.

This cement is currently approved to be marketed in the United States in its powder-liquid, hand-mixed version, and most recently in a capsule delivery system. The aim of this pilot clinical study (a prospective, consecutive case series clinical study) was to assess the clinical performance of a new bioactive cement as a luting cement for cast high-gold alloy and noble metal porcelain-fused-to-metal (PFM) restorations.

Materials and methods

A total of 38 crowns and FPDs were cemented in 17 patients (8 men, 9 women, age 25 to 79 years) of which 31 were on vital and 7 on nonvital teeth. Inclusion and exclusion criteria for the clinical investigation are listed in Table 1. The patients were informed about the purpose of the study, the clinical procedures involved, the materials to be used, and the risks and benefits of the study. The study protocol (IRB Protocol No. 11411) and informed consent form were approved by the Institutional Review Board at Temple University, Kornberg School of Dentistry, Philadelphia, PA. All participating patients signed an informed consent form prior to participating in this study.

The cement handling parameters evaluated in the clinical study were dispensing, mixing, working time, seating characteristics, and ease of cement removal (Table 2). Clinical measurement data are also detailed in Table 2 and consisted of pre- and postcementation sensitivity according both to categorical and Visual Analogue Scale (VAS)-based measurements, marginal integrity, marginal discoloration, and secondary caries according to the Modified Ryge (USPHS) Criteria.[11] Gingival response was evaluated pre- and postcementation by means of the Loe and Silness gingival index (GI)[12] (Tables 2 and 3). Retention was assessed by the criteria described in Table 3. The procedure for categorical tooth sensitivity data was simply to ask the patient to characterize any pain or discomfort (or lack thereof) for the treated tooth/teeth in question based on four possible choices: none, slight, moderate, severe. The response was recorded. For the VAS assessment of tooth-restoration sensitivity, the patient physically marked a point on a line of 100 mm (10 cm) with one end (left) of the line indicating "no sensitivity or pain" and the other (right) end of the line indicating "maximum sensitivity or pain." The point marked by the patient was measured to the nearest millimeter and recorded at each designated time point.

One investigator performed all cementation procedures. Additionally, only one investigator (a board-certified prosthodontist, with over 20 years clinical experience) performed the recording of all clinical data at baseline and all subsequent recall periods. During the try-in appointment, the units were assessed clinically to determine if the restoration(s) was/were acceptable. The manufacturer (Doxa Dental AB) provided the cement in a powder-liquid format, with the powder supplied in predosed vials, and the liquid supplied in a dropper bottle. The powder and liquid components were dispensed and mixed

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
1. Must have given written consent to participate in study. 2. Patients must be at least 18 years of age. 3. Patients must require and be treatment planned for at least one unit of fixed restorative dentistry. 4. Must be available for required recalls as outlined in the protocol. 5. The patients selected for this study will have a low-to-moderate caries rate, stable periodontal status with good home care and not involving extensive alveolar bone loss, and/or gingival recession with tooth mobility. 6. Teeth treated should be assessed clinically as vital (in selected situations, root-canal-treated, nonvital teeth may be included in the study) without evidence of pulpal or surrounding periodontal soft-tissue pathology. 7. Must be in generally good health, with no medical contraindication to dental treatment.	1. Does not meet all inclusion criteria. 2. Has untreated periodontal disease. 3. Has any pathologies or systemic problems that would not allow the dental procedures in this study to take place. 4. Has rampant caries. 5. Severe bruxing or clenching of teeth. 6. Teeth that are nonvital, exhibit pulpal pathologies, or with expected pulp exposures; (exception when inclusion of a root-canal-treated, nonvital tooth is deemed warranted due to clinical circumstances or in the judgment of the investigators). 7. The subject is pregnant.

according to the manufacturer's instructions. Mixing time was accomplished within 1 minute to ensure complete incorporation of all powder into the liquid. After mixing, the cement was applied uniformly to the internal intaglio surfaces of the restoration. The restoration was seated with constant digital pressure, and the cement was allowed to achieve initial set before removal.

The crown was again evaluated for marginal adaption (designated as baseline score) using the same Modified Ryge Criteria after cementation. Marginal discoloration was also assessed using the Modified Ryge Criteria.

Clinical study parameters in terms of specific patient and restoration data are provided in Table 4. The clinical investigation consisted of 6 FPDs with 13 abutment teeth (12 vital/1 nonvital). One fixed splint comprising two abutment teeth, both of which were treated endodontically, was also included in the study. Twenty-three were single units (i.e., crowns); 19 on vital and 4 on nonvital teeth. Five 3-unit FPDs replaced a single missing tooth. One 5-unit FPD replaced two missing teeth. Twenty-three of the cemented crown and FPD units involved anterior teeth (cuspid to cuspid); 15 were on posterior teeth.

A 1-week post-op telephone call recorded the patient's subjective comfort level shortly after cementation using the categorical measurement scale for pre- and postcementation sensitivity. Full recall examinations were carried out after 30 days, 6, 12, and 24 months. Marginal adaptation, marginal discoloration, and secondary caries were measured clinically using the Modified Ryge (USPHS) Criteria[11] (Table 3). Gingival response was evaluated pre- and postcementation by means of the Loe and Silness GI[12] (Table 3).

To determine retention at subsequent recall periods, the restoration was clinically examined digitally to assess mobility of the crown/abutment on the prepared tooth. Additionally, the patient was asked if the restoration felt loose, resulting in a "yes" or "no" answer.

Data for VAS and gingival inflammation were analyzed statistically for within-treatment cement-influenced effects by comparing changes from baseline to the 1- and 2-year recall points using the Student's *t*-test for paired data (significance $p < 0.05$). Data for VAS were based on patient-level data, that is, the 17 patients who participated in the study. In the case of GI (for any given evaluation time), the patient-level score

Table 2 Measurement parameters for clinical study

Cement measurement data	Clinical measurement data
Dispensing (easy/difficult)	Sensitivity (alpha-none/beta-slight/charlie-moderate/delta-severe)
Working time (OK/too short/too long)	Retention (restoration in place: yes-alpha; no-delta)
Mixing (easy/difficult)	Marginal integrity (Table 3)
Seating characteristics (restoration completely seated after cementation: yes/no)	Marginal discoloration (Table 3)
Ease of cement removal (easy/normal/difficult)	Caries (Table 3)
	VAS-sensitivity: (measurement by patient in mm on continuous line between "no" and "extreme" pain or discomfort)
	Gingival inflammation index (GI): (0–1–2–3 scoring as per Loe & Silness,[12] Table 3)

Table 3 Evaluation criteria for clinical evaluation (including criteria adopted from modified Ryge criteria* and gingival inflammation index of Loe & Silness**)

	Rating			
Characteristic	Alpha	Bravo	Charlie	Delta
Marginal adaptation*	No visible evidence of a crevice along the margin explorer will penetrate	Visible evidence of a crevice along the margin that the explorer will penetrate	Explorer penetrates crevice, reaching dentin or base/core material	Restoration is mobile or missing
Marginal discoloration*	No discoloration evident along visible marginal areas between the restoration and tooth structure	Discoloration present, but superficial (has not penetrated along the margin in a pulpal direction	Discoloration present and has penetrated along the margin in a pulpal direction	N/A
Secondary caries*	No caries as evidenced by softness, opacity, or evidence of demineralization at the margin of the restoration	Evidence of caries at margin of the restoration	N/A	N/A
Pre- and postoperative sensitivity	No sensitivity	Slight sensitivity	Moderate sensitivity	Severe sensitivity
Retention	Restoration still in place	N/A	N/A	Restoration not in place
Gingival Inflammation (GI**)	0: Absence of inflammation	1: Mild inflammation—slight change in gingival color and little change in texture	2: Moderate inflammation—moderate glazing, redness, edema, and hypertrophy. Bleeding or pressure at entrance to sulcus	3: Severe inflammation—marked redness and hypertrophy. Tendency to spontaneous bleeding or ulceration

represented the highest (greatest level) inflammation score for the restoration under evaluation. Gingival inflammation scores (pairwise comparison of baseline versus 2-year data) were also analyzed statistically using the Mann-Whitney-Wilcoxon nonparametric statistical test (significance $p < 0.05$).

A restoration was deemed to have failed in this clinical investigation, at any recall point, if it had:

1) Recurrent decay;
2) Loss of retention;
3) Persistent tooth sensitivity categorized as "moderate" or "severe";
4) Requirement for postinsertion endodontic treatment.

Table 4 Baseline clinical study parameters

No. of patients	17
No. of restorations	38
Demographics	8 Men 9 Women Ages 25 to 79 Years
No. of single-unit crowns	23
No. of FPDs/fixed splints	6 FPDs (13 abutments) 1 Splint (2 units)
Vital/nonvital prepared teeth	31 Vital/7 RCT-treated

Failure rates and survival statistics were assessed at 6, 12, and 24 months using Kaplan-Meier survival analysis.[13] The lower and upper limits of the 95% confidence intervals were calculated according to the efficient-score method (corrected for continuity) described by Newcombe,[14] based on the procedure outlined by Wilson.[15]

Clinical photographs were made of selected restorations immediately following placement of the crown(s) or FPD(s), and at 1-, 6-, 12-, and 24-month recall appointments. The photographs consisted of digital color (2 × 2) photographs taken at a magnification of approximately 1:1.

Results

Baseline data

Handling characteristics of this luting cement have been reported elsewhere, but will be reviewed here to provide information regarding the baseline cementation characteristics of the cement in this clinical investigation.[16] After some initial difficulties in dispensing the powder component from the glass vials, subsequently, in every instance during the clinical investigation, mixing of the cement, cement working time, and viscosity of the cement during placement and seating were deemed to be favorable. The ease of mixing and acceptable working time were noted in the clinical placement of restorations. Clinically, it was determined that the working time for the

Table 5 Clinical data for retention, subjective postoperative sensitivity

	Baseline (at cementation)	1 Month	6 Months	1 Year	2 Years
No. of patients	17	17	17	15	13
No. of restoration/abutments	38	38	38	31	27
% Alpha—retention	100%	100%	100%	100%	100%
% Alpha—categorical, subjective precementation sensitivity	58.8%	88.2%*	100%	100%	100%

*Recorded incidences of sensitivity (11.8%) were mild and not cement-related.

cement was acceptable ("OK" ratings for all units). In all cases, try-in of restorations prior to and visual/tactile inspection after cementation indicated complete seating of the casting with respect to fit and marginal adaptation. The favorable consistency and viscosity of the cement appeared to ensure complete seating of all castings at cementation. Removal of excess set cement from the marginal areas was also noted to be "easy" for all subjects and restorations. No patients noted any taste, adverse or otherwise, and no patients experienced any immediate postcementation hypersensitivity. In 16 of 17 patients, there was no immediate tissue response to the cement or the cementation procedure. In one patient, slight bleeding occurred after cementation, probably due to a remaining superficial inflammation caused by the temporary restoration. Assessments conducted immediately after cementation indicated excellent (alpha) readings for postcementation marginal integrity, as well as for marginal discoloration (no evidence of marginal discolorations).

Baseline data on the key clinical performance characteristics are summarized in Tables 5 and 6. With respect to categorical, patient-based assessment of tooth sensitivity, only 7 of 17 subjects indicated some degree of precementation sensitivity. With respect to precementation gingival inflammation (as measured by GI scores), 16 out of 17 patients presented with GI scores of 0–1, indicating a low degree of gingival inflammation. Nine of these 17 patients scored baseline gingival inflammation values of 0, while seven patients scored GI values of 1. Only one patient registered a GI score of 2. Despite the presence in all patients of temporary acrylic restorations cemented with temporary cements, the recorded baseline gingival inflammation levels were low. No caries lesions were recorded in any participating subjects. The mean precementation VAS score was 7.63 ± 1.63 mm (range 0–32 mm), but only 7 of 17 patients registered a VAS score above 0. In all seven of these patients, the positive VAS score correlated to a subjective, categorical rating for some degree of tooth/tissue sensitivity above "none."

Table 6 Clinical data for modified Ryge criteria, GI, VAS scores

	Baseline	1 Month	6 Months	1 Year	2 Years
No. of patients recalled	17	17	17	15	13
No. of restoration/abutments	38	38	38	31	27
% Alpha—absence of caries	100%	100%	100%	100%	100%
% Alpha—marginal integrity	100%	100%	100%	100%	100%
% Alpha—marginal discoloration	100%	100%	100%	100%	100%
Average VAS score	7.6 mm	3.1 mm	0.4 mm	0.2 mm	0.0 mm
Average GI	0.56	0.10	0.11	0.16	0.21

Immediate postoperative response

The phone contact at 7 to 10 days after cementation showed that 14 of 17 patients contacted had experienced no postcementation sensitivity. Three patients indicated some degree of slight postcementation sensitivity, which, as noted in an earlier report,[16] disappeared spontaneously after an occlusal adjustment or without intervention by the 1-month recall.

One- and 6-month recall data

The detailed 1- and 6-month recall data are reported elsewhere.[16] In summary, at both the 1- and 6-month recall evaluations, the clinical performance of this new luting cement appeared clinically acceptable. There were no retentive failures.

Twelve-month recall data

The detailed 12-month recall data have been reported elsewhere,[17] but will be reviewed below. After 12 months, 15 patients (88%) and 31 of 38 restorations/abutments (82%) were available for clinical recall documentation. One of the two patients unavailable for recall had relocated more than 500 miles from the study site and did not respond to a certified-return receipt letter. The other patient was contacted by telephone, but was unable to attend a formal recall examination due to a serious illness. This patient was able, however, to indicate a complete absence of tooth sensitivity, no problems of any kind, and the awareness that all cemented restorations were in place and in normal occlusion. Nevertheless, this patient's responses have not been included in calculations for retention and subjective postoperative sensitivity in this 2-year report.

The 12-month recall data for key clinical performance characteristics are summarized in Tables 5 and 6. None of the 15 patients available for recall reported any tooth-tissue sensitivity. Marginal integrity and discoloration for all restorations received "excellent (alpha)" scores, indicating optimal marginal integrity and no evidence of marginal discolorations. Caries was absent in all examined restorations. Thirteen of 15 patients had GI scores of 0, suggesting very low levels or an absence of gingival inflammation. One of 15 patients scored a GI of 2, and another one of 0.5. It was thus observed that the gingival response had improved from baseline to 12 months. As was reported for the previous postcementation GI scores, good

soft tissue compatibility continued. Descriptive statistics for the 12-month GI inflammation score was an average of 0.16 ± 0.51, which can be compared directly to the baseline, precementation average value of 0.56 ± 0.62. Statistical analysis (Student's *t*-test for paired data) of GI scores, comparing baseline to the 12-month mean values (in a restoration-subject, pairwise fashion) for the 15 recall patients, showed a statistically significant difference between precementation and 12-month data ($p = 0.049$, significance $p < 0.05$).

Descriptive statistics for the 12-month, postcementation VAS scores was an average of 0.2 ± 0.78, with a range of 0 to 3 mm. This is greater than one order of magnitude less than the value of the corresponding precementation VAS average score, and at or below the numerical score registered at 6-month recall. Also, of significance is the fact that statistical analysis using Student's *t*-test for paired data indicated a statistically significant difference between the precementation and 12-month postcementation values ($p = 0.036$). Statistical analysis using the Student's *t*-test for paired data comparing baseline versus 12-month values also indicated a statistically significant difference in the reduction of VAS scores at these two time periods ($p = 0.031$, $p \leq 0.05$). Additionally, 14 of 15 patients (at 1-year recall) registered a VAS score of 0 at the 12-month recall. Furthermore, in the examiner-determined, subjective, and categorical rating for the degree of tooth/tissue sensitivity, none of the 15 patients were assessed as having any degree of tooth/tissue sensitivity.

Twenty-four-month recall data

After 24 months, 13 patients (78%) and 27 out of 38 restorations/abutments (71%) were available for clinical recall documentation. Four patients were not available for recall at the 24-month interval: one patient had died between the 12- and 24-month recall periods, and another was unavailable for recall after relocating more than 500 miles from the study site and not responding to a certified-return receipt letter. Another patient was contacted by telephone, but was unable to attend in person at the formal 24-month recall examination due to a serious illness, which had rendered the patient nonambulatory and requiring periodic hospital in-patient treatment. This patient was able, however, to indicate a complete absence of tooth sensitivity, no problems of any kind, and the awareness that all cemented restorations were in place and in normal occlusion. Nevertheless, despite this verbal contact, this patient's responses were not included in 24-month calculations for retention and subjective postoperative sensitivity. Finally, a subject with a single ceramometal crown on a maxillary molar did not respond to either phone or mail contact to arrange a recall appointment.

The 24-month recall data for key clinical performance characteristics are summarized in Tables 5 and 6. None of the 13 patients available for the 2-year recall reported any tooth-tissue sensitivity. Marginal integrity and discoloration for all restorations received "excellent (alpha)" scores, indicating optimal marginal integrity and no evidence of marginal discolorations. Caries was absent in all examined restorations. Nine out of 13 patients had GI scores of 0, suggestive of very low levels or an absence of gingival inflammation. One of 13 patients scored a localized GI score of 2, and three additional

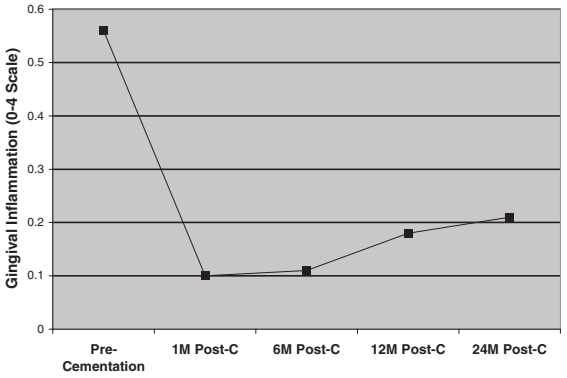

Figure 1 Change in average GI scores over course of 2-year clinical evaluation for the experimental cement.

patients displayed GI scores of 1.0. Subjectively and numerically, as was reported previously concerning the clinical performance of this new cement, postcementation GI scores indicating good soft tissue compatibility continued at the 2-year recall.[16,17] Descriptive statistics for the 24-month GI score was an average of 0.21 ± 0.38, which can be compared directly to the baseline, precementation average value of 0.56 ± 0.62. This represents approximately a 63% reduction in gingival inflammation. While the gingival response had reduced numerically from baseline to 24 months, statistical analysis (Student's *t*-test for paired data) of GI scores, comparing baseline to the 24-month values (in a restoration-patient, pairwise fashion) for the 13 recall patients, failed to show a statistically significant difference between precementation and 24-month data ($p = 0.086$). Nevertheless, an additional analysis of this data using the Mann-Whitney-Wilcoxon nonparametric statistical test revealed a statistically significant difference between the baseline mean GI as compared to the mean GI score at 24-month recall ($p = 0.02$). Figure 1 depicts the change in GI scores over the baseline to 2-year recall period.

Descriptive statistics for the 24-month, postcementation VAS scores was an average of 0.0 ± 0.00, with all scores at 0 mm; all 13 patients (at 2-year recall) registered a VAS score of 0 at the 24-month recall. This VAS score represented a continued reduction over values obtained at 1-year recall (0.20 mm). Figure 2 depicts the change in VAS scores over the baseline to the 2-year recall period. Of significance is also the fact that statistical analysis using Student's *t*-test for paired data indicated a statistically significant difference between the precementation and 24-month, postcementation values ($p = 0.03$). Furthermore, in the examiner-determined, subjective, and categorical rating for the degree of tooth/tissue sensitivity, none of 13 patients were assessed as having any degree of tooth/tissue sensitivity. At the 24-month recall, none of the single-unit restorations or FPD/split abutments displayed any loss of retention (100% alpha for retention). Additionally, it should be noted that up to the 2-year recall period, none of the restorations or abutments required any endodontic intervention (Fig 2). Failure rates after 6, 12, and 24 months were all 0% for both single-unit FPDs (Kaplan-Meier survival analysis).[13] Table 7 provides

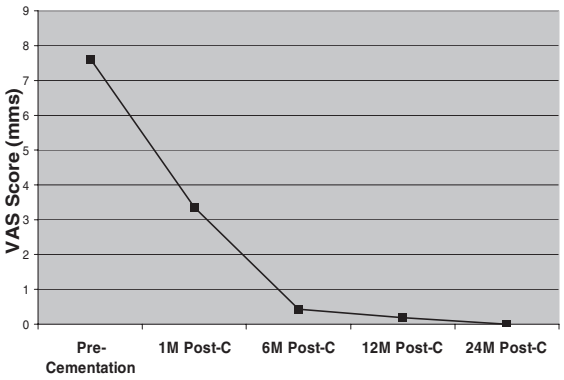

Figure 2 Change in average VAS score over course of 2-year clinical evaluation for the experimental cement.

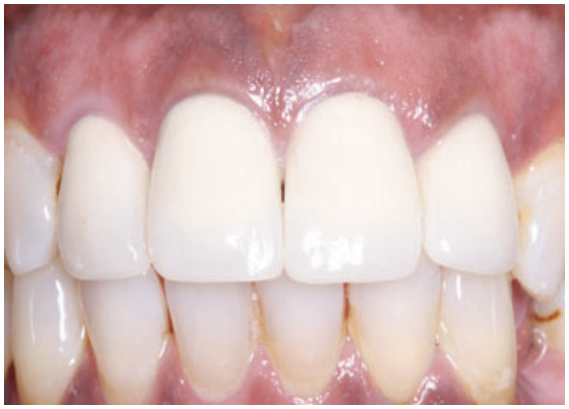

Figure 3 Clinical digital photograph of maxillary anterior, ceramometal restorations (right and left lateral and central incisors) cemented with the experimental cement at 2-year clinical evaluation.

the specific parameters and results for the Kaplan-Meier survival analysis.[14,15] The Kaplan-Meier cumulative success rate of the bioactive cement with respect to success/failure criteria at the 24-month recall was 100% (95% confidence interval 89% to 100%).

Figure 3 depicts an intraoral photograph of four anterior PFM restorations at the 2-year recall visit and is provided for the interest of the reader. Note the healthy gingival margins and soft tissue contours.

Discussion

The objective of this study was to provide initial data regarding the clinical performance of a new cement intended for permanent cementation of high noble, all-metal, and PFM restorations. Systematic evaluation included assessment of specific clinical performance criteria starting at precementation baseline levels compared directly to postcementation data. Based on the available literature, this report is the first to document the clinical performance of a "bioactive" cement as a luting agent for permanent dental restorations over a prolonged clinical use period (2 years). The tested water-based cement comprises calcium aluminate and glass ionomer components.[4] The dispensing, mixing, handling, and working-time properties of the cement were considered, along with its clinical performance up to 24 months.

Clean-up for the cement was also rated as "easy," and cement removal was found to be somewhat similar to that of RMGIs (i.e., a distinct gel consistency formed within a few minutes, permitting easy removal). In contrast to RMGI and self-adhesive resin cements, the new cement does not, however, form an oxygen-inhibited layer on its surface, making clean-up less complicated. Furthermore, there was no need to rush the removal, as can be the case with resin-based luting cements, which can snap-set to a hard consistency, making early removal mandatory.[18]

Gingival soft tissue response improved from pre- to postcementation, based on statistical analysis of GI scores. Mean GI scores reduced to statistically significant levels below the mean baseline level for all three postcementation observation periods (1, 6, and 12 months) and remained at relatively lower levels through the 24-month recall. While pairwise statistical analysis comparing the mean baseline and 24-month GI values using the paired Student's *t*-test calculated a *p*-value not quite at, but approaching, a statistically significant difference ($p = 0.08$), a further analysis of this data using a nonparametric method (Mann-Whitney-Wilcoxon statistical test) indicates a statistically significant difference in these mean GI values ($p < 0.022$). Soft-tissue response to this new cement chemistry appeared to be good and certainly within clinically acceptable levels through the 2-year observation period. One can conclude that gingival health around the studied restorations improved over the course of observation after cementation (Fig 1).

Postoperative sensitivity is a fairly common early complication in fixed prosthodontics.[19] This factor was measured both qualitatively and quantitatively and demonstrated that the situation improved from baseline levels up to the 2-year recall evaluation. Those isolated incidents of postcementation tooth sensitivity were subjectively characterized as "slight," and not

Table 7 CeraMir™ Kaplan-Meier analysis

Time period	At risk	Became unavailable (censored)	Succeeded/ (failed)	Survival probability estimate	0.95 confidence interval	
					Lower limit	Upper limit
6 month	38	0	(0)	1	0.88566	1
12 month	38	7	(0)	1	0.88566	1
24 month	31	4	(0)	1	0.88566	1

directly associated with the cement. Rather, the noted postcementation occurrences of sensitivity were found either to be due to occlusal prematurities in the final restorations or to an incident of exposed, sensitive root dentin gingival to the marginal finish line of the cemented final restoration. All of the incidences related to occlusal factors responded to minor occlusal adjustments. The one instance of dentinal root sensitivity diminished with the passing of time after treatment. By the 1- and 2-year recall periods (Table 5), all patients recalled indicated an absence of categorical, subjective postoperative pain associated with any of the restorations cemented with the experimental cement. With respect to the correlation between subjective, patient-elicited sensitivity and VAS scores at the 2-year evaluation, none of the patients gave a VAS score greater than 0, while at the same time providing a response indicating an absence of subjective sensitivity concerning the experimental cement. Anecdotally, one patient, with CM-cemented PFMs on the right maxillary cuspid, right lateral incisor, right central incisor, and left maxillary first premolar, also had a PFM on the left central maxillary incisor cemented with an RMGI cement. Upon questioning, the patient mentioned this localized, study-unrelated area at the 1-year recall. This patient localized "sensitivity when touched" to the left central maxillary incisor cemented with the RGMI. In view of these findings and representative of the VAS scores represented in Figure 2, it is reasonable to state that over the 24-month observation period, the tested cement appeared to perform in a clinically acceptable fashion with respect to tooth sensitivity, and indirectly to clinical pulpal biocompatibility.

There were no retentive failures of any units examined through the 2-year recall. As the degree of taper of all prepared teeth was subjectively noted and recorded for each patient, it should be noted that the majority of preparations were described as having normal, nonexcessive taper. Although a small number of preparations were described as having a greater-than-preferred preparation taper, none of these teeth have failed thus far. In an analogous fashion, surveyed and prepared crowns and abutments for acceptance of removable partial dentures (RPDs) were not excluded from this study. As such, none of the crowns that served as a retainer for an RPD have experienced any untoward retentive effects. While this study did not intend to compare the performance of this new cement with that of any other currently available cement, it is interesting to note that one subject lost retention for a contralateral PFM cemented with an RMGI cement during the course of study, approximately 1 month after cementation.

This investigation was limited to a clinical evaluation of a new cement used to lute full-coverage restorations, which were restricted to either all-metal or PFM-fixed restorations. While two metals (gold alloy or palladium) were used for fabrication of the restorations, all intaglio surfaces were metal. Thus, all restorations possessed a "generic" metal substructure. Additionally, since there were no failures observed in this study, it appears that the cement was successful, regardless of whether the cemented restoration was a bridge abutment or crown.

While the apparent longevity and stability of zinc phosphate cement is still viewed as a "gold" standard in its use as a dental luting cement,[18,20–22] dental cements for luting and retention of fixed dental restorations have undergone significant compositional changes over the last 50 years. Long-term success after cementation of indirect restorations depends on retention as well as maintenance of the integrity of the marginal seal. A marginal seal can be established through bonding/adhesive techniques or other mechanisms. The introduction of chemical adhesion (as in polycarboxylate and glass ionomer cements) has been one approach to improving the performance of dental luting cements. Similarly, the inherent presence or intentional inclusion of fluoride into many of these cement formulas may provide some degree of protection in the event of material breakdown or disintegration of the cement. Yet only limited data exists to support such a protective mechanism in glass ionomer cement.[23] As such, the pursuit of alternative mechanisms to protect the cemented marginal areas of fixed restorations is worthy of consideration. The new bioactive cement tested here introduces another possible functionality to the capabilities of dental cements, namely, bioactivity. When this new cement is immersed in vitro in a physiological phosphate-buffered saline solution, HA is formed.[4] The formation of HA, which appeared after 7 days, demonstrates that the cement tested here quite possibly possesses dynamic self-sealing properties, while it is speculated that actual remineralization at the margins may take place. Such a protective mechanism could provide a more durable seal of the tooth/cement/restoration interface. Furthermore, areas of marginal breakdown over time may potentially be able to be addressed through bioactivity and a resealing via deposition of HA. While no bioactivity at the tooth interface has yet been established with this specific calcium aluminate-glass ionomer formulation, interfacial bioactivity of a calcium aluminate-based filling material in teeth in vivo has been analyzed and reported.[24] The earlier material is different from the luting material used in the current investigation, in that it only contains calcium aluminate and is not a hybrid calcium aluminate/glass ionomer material. Nevertheless, the earlier report demonstrated the ability of a calcium aluminate-based cement to bond to apatite. It also suggested that "at the interface it is probable that the apatite forms directly on the tooth, as also suggested by the line scan results for Ca, P, and Al." With respect to bonding mechanisms to enamel and dentin for this new class of dental cements, possible mechanisms may include:

1) The precipitation of the nanocrystals from a water-based solution that wets the tooth surface forming mechanical interlocking and surface energy-based attachment of the calcium aluminate hydrate nanocrystals with the tooth structure;
2) Formation of nanocrystals that can nucleate and start to grow on the tooth surface indicates that there may be bonding at the molecular level, but this mechanism has not been conclusively established; and
3) The glass ionomer component in this luting cement may well establish a chemical bond of the poly salt to the calcium component of tooth structure.

Additional research will be necessary to conclusively demonstrate the ability to integrate to adjacent tooth structure via apatite formation/bonding or some other interfacial mechanism.

To summarize, in up to 2 years of periodic clinical evaluation, the clinical performance of Ceramir C&B appears acceptable. Thus far, there have been no retentive failures reported or

presented during recall examination. From a subjective clinical assessment, the cement appeared to be easy to use and handle. Postoperative gingival inflammation measured both qualitatively and quantitatively, improved statistically from baseline levels up to the 1-year recall, and remained at a lower level compared to baseline values at the 2-year recall. Postoperative sensitivity, measured both qualitatively and quantitatively, improved from baseline levels up to the 2-year observation point as well. As a quantitative measure of tooth sensitivity, VAS scores were significantly reduced at the 6-month, 1-, and 2-year recall points, while demonstrating a continual decrease in values from 1 month through 2 years of measurement. All restorations also scored "excellent" for marginal integrity. Caries or recurrent caries were not an issue at any time during the study. All patients tolerated the cement well, and there was an absence of any cement-related adverse events. While further clinical assessment of this cement is indicated; thus far, the clinical performance of this new cement has been, and continues to be, quite acceptable and warrants continued investigation, particularly as its potential bioactive properties offer promising advantages.

Conclusions

Ceramir C&B, after 2 years of clinical observation, performed well and in a clinically acceptable fashion as a luting agent for permanent cementation of all-metal (high noble metal) and ceramic-fused-to metal (noble metal) crowns and FPDs. Tooth sensitivity, as measured by subject-scored average VAS scores, based on statistical analysis and clinical observation, reduced significantly from the baseline precementation value to the values obtained at 6 months and 1 and 2 years after cementation. Gingival inflammation, based on statistical analysis, significantly reduced from the baseline average value to the 1- and 6-month and 1-year average values. GI levels at 2 years were 63% lower than baseline and approached a statistically significant difference between baseline and 2-year values. Retentive properties of this cement, up to the two 2-year recall period, appear to be excellent, as no retentive failures have been reported. Mixing, handling, working time, and clinical removal/clean-up properties of this cement were excellent. None of the patients treated and examined at recall has required endodontic intervention in any teeth serving as preparations for crowns or abutments cemented with this bioactive cement. Given the potential of this bioactive cement formulation to dynamically maintain marginal seal and integrity and successful performance up to this 2-year recall period, further clinical evaluation of this cement is warranted.

References

1. Drago C: Clinical and laboratory parameters in fixed prosthodontic treatment. J Prosthet Dent 1996;76:233-238
2. Black SM, Charlton G: Survival of crowns and bridges related to luting cements. Restorative Dent 1990;6:26-30
3. White SN, Furuichi R, Kyomen SM: Microleakage through dentin after crown cementation. J Endod 1995;21:9-12
4. Lööf J, Svahn F, Jarmar T, et al: A comparative study of the bioactivity of three materials for dental applications. Dent Mater 2008;24:653-659
5. Jefferies SR, Lööf J, Pameijer CH, et al: Physical properties of XeraCem®. J Dent Res 2008;87(B):3100
6. Pameijer CH, Jefferies S, Lööf J, et al: Microleakage evaluation of XeraCem® in cemented crowns. J Dent Res 2008;87(B):3098
7. Pameijer CH, Zmener O, Garcia-Godoy F, et al: Sealing of XeraCem®, and controls using a bacterial leakage model. J Dent Res 2009;88(A):3145
8. Pameijer CH, Zmener O, Alvarez Serrano S, et al: Sealing properties of a calcium aluminate luting agent. Am J Dent 2010;23:121-124
9. Pameijer CH, Jefferies SR, Lööf J, et al: In vitro and in vivo biocompatibility tests of XeraCem®. J Dent Res 2008;87(B): 3097
10. Pameijer CH, Jefferies SR, Lööf J, et al: A comparative crown retention test using XeraCem®. J Dent Res 2008;87(B): 3099
11. Cvar JF, Ryge G: Criteria for the Clinical Evaluation of Dental Restorative Materials. San Francisco, Government Printing Office, US Public Health Services Publication No. 790-244, 1971
12. Loe H, Silness J: Periodontal disease in pregnancy. I. Prevalence and severity. Acta Odontol Scanda 1963;21:533-551
13. Kaplan EL, Meier P: Nonparametric estimation from incomplete observations. J Am Statistic Assoc 1958;53:457-481
14. Newcombe RG: Two-sided confidence intervals for the single proportion: comparison of seven methods. Statistics Med 1998;17;857-872
15. Wilson EB: Probable inference, the law of succession, and statistical inference. J Am Statistic Assoc 1927;22: 209-212
16. Jefferies SR, Appleby D, Boston D, et al: Clinical performance of a bioactive dental luting cement- a prospective clinical pilot study. J Clin Dent 2009;20:231-237
17. Jefferies SR, Pameijer CH, Appleby D, et al: One year clinical performance and post-operative sensitivity of a bioactive dental luting cement – a prospective clinical study. Swed Dent J 2009;33:193-199
18. Pameijer CH, Nilner K: Long term clinical evaluation of three luting materials. Swed Dent J 1994;18:59-67
19. Kern M, Kleimeier B, Schaller HG, et al: Clinical comparison of postoperative sensitivity for a glass ionomer and a zinc phosphate luting cement. J Prosthet Dent 1996;75:159-162
20. Jokstad A, Mjor IA: Ten years' clinical evaluation of three luting cements. J Dent 1996;24:309-315
21. Jokstad A: A split-mouth randomized clinical trial of single crowns retained with resin-modified glass ionomer and zinc phosphate luting cements. Int J Prosthodont 2004;17: 411-416
22. Behr M, Rosentritt M, Wimmer J, et al: Self-adhesive resin cement versus zinc phosphate luting material: a prospective clinical trial begun 2003. Dent Mater 2009;25:601-604
23. Muzynski BL, Greener E, Jameson L, et al: Fluoride release from glass ionomers used as luting agent. J Prosthet Dent 1988;60:41–44
24. Engqvist H, Schultz-Walz JE, Loof J, et al: Chemical and biological integration of a mouldable bioactive ceramic material capable of forming apatite in vivo in teeth. Biomaterials 2004;25:2781-2787