

One year clinical performance and post-operative sensitivity of a bioactive dental luting cement

– A prospective clinical study

S R JEFFERIES¹, C H PAMEIJER², D APPLEBY¹, D BOSTON¹, J LÖÖF³, P-O GLANTZ⁴

Abstract

© A one-year clinical study was performed on the efficacy of a bioactive dental cement (Ceramik C&B) with calcium aluminate and glass ionomer components. The study was performed on 38 crown and bridge abutments in 17 patients. Preparation parameters were recorded, as well as working-times, setting-times, and other handling characteristics. Baseline data were also recorded for gingival inflammation (GI) and pre-cementation sensitivity. Post-cementation parameters included sensitivity, gingival tissue reactions, marginal integrity and discolorations.

All patients were seen for recall examinations at 30 days, and 6 months. For sixteen patients one-year recall data were collected on retention and subjective sensitivity. Fifteen subjects were available for one year clinical examinations.

Three independent examiners found the working and setting time of the cement to be well within expected limits and that cement removal was easy.

Four patients reported low-grades of immediate post-cementation sensitivity, however, this disappeared after an occlusal adjustment or without intervention within one month.

At 12 months no retentive failures were recorded and no subjective sensitivity reported. All crowns were rated in the "Excellent" quality category for marginal integrity. Both GI-scores and scores for tooth sensitivity decreased during the course of the study. One year recall data yielded no incidence of secondary caries and no visible marginal discoloration. The new cement was thus found to perform favorably as a luting agent for permanent cementation.

Key words

Dental cement, cementation, luting cement, bioactive, crowns, bridges, gold, PFM

¹Kornberg School of Dentistry, Temple University, Philadelphia, USA

²University of Connecticut, Farmington, USA

³Doxa AB, Uppsala, Sweden

⁴Faculty of Odontology, Malmö, Sweden

En 1-års studie av de kliniska resultaten vid användning av ett bioaktivt fastsättningscement – En prospektiv klinisk studie

S R JEFFERIES, C H PAMEIJER, D APPLEBY, D BOSTON, J LÖÖF, P-O GLANTZ

Sammanfattning

⊙ En 1-årig klinisk studie av ett nytt fastsättningscement (Ceramir C&B) för metalliska och keramiska konstruktioner har genomförts på 17 patienter och totalt 38 gjutna kronor. Stödtändernas preparationsgeometri noterades liksom hanterings-egenskaper för det testade cementet, som huvudsakligen består av en vattenbaserad blandning av kalciumaluminat och s.k. glassjonomer. Vid cementeringstillfället gjordes även bedömningar av status hos det marginala parodontiet kring stödtänderna (GI-index) och förekomst av eventuell ökad grad av känslighet hos de preparerade tänderna.

Samtliga patienter genomgick klinisk undersökning efter en och sex månader och 15 patienter även efter ett år. I samband med dessa undersökningar bedömdes det marginala parodontiets status liksom kantanslutningen och eventuella missfärgningar kring rekonstruktionerna. Eventuell ökad känslighet hos stödtänderna noterades även.

Det testade cementet var mycket lätt att hantera enligt tre oberoende bedömare, som också påpekade lättheten att blanda cementet och att applicera cementfyllda kronor på de preparerade tänderna.

Fyra patienter rapporterade viss ökad känslighet i stödtänder efter cementeringen. Detta försvann emellertid antingen direkt efter justering av ocklusala kontakter eller spontant under den första månaden efter cementeringen.

Varken lossnanden, stödtänder med karies eller ökad känslighet kunde noteras vid ett-årskontrollen efter kronornas cementering. Alla kronor bedömdes dessutom ha perfekt kantanpassning utan missfärgningar. Slutligen noterades ett kontinuerligt förbättrat status (GI-index) hos det marginala parodontiet kring kronorna. Det testade cementet (Ceramir C&B) ansågs mot denna bakgrund ha stor potential som permanent fastsättningscement för metalliska och keramiska konstruktioner.

Introduction

Long-term success of fixed restorations depends on a range of factors (5) including the quality of the luting agent (2). Biocompatibility, insolubility and resistance against degradation, are for example requirements to maintain the seal at the margins of the restorations thus preventing ingress of bacteria, leakage, sensitivity and secondary decay (18).

Historically the progression of luting agents include in succession, zinc phosphate, polycarboxylate, glass ionomer, resin, and resin modified glass ionomer cements. These cements are now followed by a hybrid calcium aluminate glass ionomer cement (Ceramic C&B, Doxa Dental AB, Uppsala, Sweden) intended for permanent cementation of cast restorations and all-zirconia or all-alumina crowns.

The aim of this study was to assess the clinical performance of Ceramic C&B as a luting cement for cast high-gold alloy and noble metal porcelain-fused-to-metal (PFM) restorations.

Material and Methods

Thirty eight (38) crown and bridge abutments were cemented in 17 patients (8 males and 9 females, aged 25 to 79 years). Thirty-one of the selected teeth were vital and 7 non-vital. The study included 6 bridges with a total of 13 abutment teeth (12 vital/1 non-vital). One fixed splint comprising of two (2) endodontically treated abutment teeth, was also included in the study. Of the remaining twenty three (23) single crowns, 19 were on vital and 4 on non-vital teeth. Twenty-three (23) of the crown and bridge units involved anterior, and fifteen (15) posterior teeth.

The study protocol and informed consent form were approved by the Institutional Review Board at Temple University, Kornberg School of Dentistry. All participating subjects signed an informed consent form prior to participation in the study.

This tested cement is a water-based composition comprising of calcium aluminate and glass ionomer components. The detailed composition has been described by Lööf (14). It has been demonstrated to be bioactive and is currently approved for marketing in the United States.

The cement was provided in powder-liquid form. The powder was supplied in pre-dosed vials and the liquid in a dropper bottle. Powder and liquid were dispensed and mixed by each of three evaluators according to the manufacturer's instructions.

The target mixing time was one minute and the corresponding working time 2 - 2.5 minutes. The cement parameters evaluated by the investigators

were: dispensing, mixing, working time, and setting time, seating characteristics and ease of cement removal (Table 1).

Clinical baseline data consisted of: gingival inflammation index (GI) (13) and pre-cementation

© **Table 1.** Parameters used in a Clinical Study of a bioactive luting agent (Ceramic C&B®)

Handling characteristics	Clinical parameters
Dispensing	Sensitivity (Categorical)
Working-Time	Retention
Mixing	Soft Tissue Reaction
Seating Characteristics	Marginal Integrity
Setting-Time	Marginal Discoloration
Ease of Cement Removal	Caries
	Visual Analogue Scale (VAS) - Sensitivity
	Gingival Inflammation Index (GI)

sensitivity according both to categorical and Visual Analogue Scale (VAS) based measurements (see Table 1). Post-cementation parameters were pulpal reactions, soft tissue reactions, marginal integrity, discoloration of cement margin, retention, post-cementation sensitivity and gingival inflammation index (GI), (Table 1).

A one-week post-op telephone call recorded subjectively the patient's comfort. Full recall examinations were carried out after 30 days, 6 months and 12 months. Marginal adaptation was measured clinically using a modified so-called Ryge USPHS Criteria (4). During the try-in appointment the units were evaluated for their clinical acceptance.

After cementation the crowns was evaluated for marginal fit and marginal staining using the same modified Ryge/USPHS criteria. The gingival appearance was evaluated pre and post operatively by means of the gingival index. Finally, clinical photographs were made of selected restorations immediately following placement of the crown(s) or fixed partial denture(s), and also at one, six and twelve month recall appointments. These photographs consisted of digital color (2x2) photographs taken at a magnification of approximately 1:1.

Results

Baseline data

The examination of the cement handling characteristics showed that mixing of the cement, cement working time, and viscosity of the cement during placement and seating was satisfactory. The ease of mixing, the excellent working time (2-2.5 minutes), and the low, "mousse-like" viscosity were consistently favorably commented on by all three investigators. Clinically, it was determined that the final setting time was within 4 to 5 minutes.

In all cases, try-in of restorations prior to cementation indicated complete seating of the casting(s) with respect to fit and marginal adaptation. The favorable consistency and viscosity of the cement appeared to insure complete seating of all castings. Removal of excess set cement from the margins was also noted to be "easy" for all restorations. No patients noted any adverse taste and no patients experienced immediate post-cementation hypersensitivity. In 16 of the 17 patients, there was no immediate post-cementation tissue response. In one patient slight bleeding occurred after cementation probably due to soft tissue reactions from the temporary restoration.

Assessments conducted immediately after cementation indicated "Excellent" readings (Alpha according to the Ryge/USPHD system) for post-cementation marginal integrity, as well as for marginal discolorations (= no evidence of discolorations).

Baseline data on key clinical performance characteristics are summarized in Tables 2 and 3.

Tooth sensitivity:

The mean pre-cementation Visual Analogue Assessment score (VAS) was 7.63 + 11.63 millimeters (range 0 - 32 millimeters), but only 7 of 17 subjects registered VAS scores above zero. In all these subjects, the positive VAS score correlated to a subjective, categorical rating to sensitivity higher than "none".

© **Table 2.** Number of subjects and restorations evaluated in a one-year study of a bioactive luting agent and results of quality evaluations of crown retention and post-operative sensitivity

	Baseline	1 Month	6 Months	1 Year
No. of Subjects	17	17	17	16*
No. of Restoration /Abutments	38	38	38	35*
% Alpha – Retention	100%	100%	100%	100%
% Alpha – Categorical, Subjective Post-Operative Sensitivity	58.8%	88.2%	100%	100%

© **Table 3.** Number of subjects and restorations evaluated in a one-year study of a bioactive luting agent and results of Gingival Index measurements (GI) and quality evaluations of marginal integrity and discolorations and the presence of caries.

	Baseline	1 Month	6 Months	1 Year
No. of Subjects Recalled	17	17	17	15
No. of Restoration/Abutments	38	38	38	31*
% Alpha – Absence of Caries	100%	100%	100%	100%
% Alpha – Marginal Integrity	100%	100%	100%	100%
% Alpha – Marginal Discoloration	100%	100%	100%	100%
Average VAS Score	7.6 mm	3.1 mm	0.4 mm	0.2 mm
Average Gingival Index	0.56	0.10	0.11	0.16

The patient-based assessments of tooth sensitivity showed that 7 of 17 subjects had experienced some degree of pre-cementation sensitivity but phone contacts at seven to ten days after cementation showed that only four patients still indicated some degree of slight post-operative discomfort. One of these patients, who had pre-existing dentinal sensitivity due to exposed dentin below the marginal finish line in tooth #8, characterized the response as "slight to none" and also noted that the situation had improved substantially since the cementation of the restorations. Another patient noted slight sensitivity to hot and cold, while the third one indicated a sensation of pressure around his bridge work, rather than any specific tooth sensitivity. In this patient the discomfort disappeared spontaneously without intervention. All three patients were offered the opportunity to return immediately prior to their scheduled one-month recall appointment, but all of them indicated the situation was not severe and could wait until the one-month recall.

One patient returned between the initial cementation visit/seven-day phone contact and the one-month recall with sensitivity related to a hyperocclusion. This problem disappeared spontaneously after an occlusal adjustment.

Periodontal conditions and Caries:

16 out of the 17 patients presented GI-scores of 0-1 during the pre-cementation period. Nine of these patients scored baseline GI- values of zero (0), while the rest scored a value of 1. Only one patient registered a gingival index score of 2.

No caries lesions were recorded in any of the participating subjects.

One and six-month data:

Detailed one-month and six-month recall data have been reported elsewhere (7). At both one and six-month examinations the cement performed well without failures or undesirable side-effects.

12 month data:

After 12 months 15 subjects and 31 out of 38 restorations/abutments were available for clinical examination. One of the two patients that were unavailable for recall had relocated over 500 miles from the study site and did not respond to a certified-return receipt letter. The other subject was unable to attend due to a serious illness. When contacted by telephone, this subject, however, indicated that all cemented restorations were in place and functioning well. This subject's responses were therefore included in the calculations for retention and subjective post-operative sensitivity.

The 12 month recall data for key clinical performance parameters are presented in Tables 2 and 3. Data presented in Tables 2 and 3 show that at the one-year recall none of the fifteen patients reported any tooth/tissue sensitivity and that for all the restorations both the marginal integrity and discoloration criteria received "Excellent" scores. Furthermore, no caries was noted in association with any of the examined restorations. Thirteen out of 15 patients had GI scores of 0, indicating very low levels or absence of gingival inflammation. One patient scored a GI index of 2 and another one of 0.5. In general terms these data indicate that the gingival situation around the cemented restorations had improved from baseline to 12 months.

Statistical analyses:

The twelve-month data included mean GI-scores of 0.16 ± 0.51 , which compare favorably with the baseline, pre-cementation scores of 0.56 ± 0.62 . A statistical analysis (Student's t-test for paired data) showed a statistically significant difference with a p-value of 0.049.

At the twelve-month recall, the mean VAS scores were 0.2 ± 0.78 mm, with a range of 0 to 3 millimeters. Additionally, 14 of 15 subjects were noted to register VAS scores of zero at the 12-month recall. These values are one order of magnitude less than the corresponding pre-cementation scores, and at or below the scores registered at six-months. A statistical analysis (Student's t-test for paired data) of these data showed a statistically highly significant difference between the pre-cementation and twelve-

months values ($p=0.036$). Furthermore, none of the examiners recorded any tooth/tissue sensitivity.

Discussion

While the apparent longevity and stability of zinc phosphate luting cement is still useful as a basis for comparison^{1,9,10}, cements for luting of fixed dental restorations have undergone significant compositional changes over the last 50 years. A wide range of cements with a variety of chemistries are thus available for permanent cementation of fixed restorations⁽⁸⁾. As cement failures are still a major complication in fixed prosthodontics^(3,7) there is, however, still a need for development of better luting cements.

A number of the presently available cements have undergone systematic clinical evaluations e.g. by *Pameijer*⁽¹⁶⁾, *Jokstad & Mjör*⁽⁹⁾, and *Jokstad*⁽¹⁰⁾. Most studies conclude that acid-base reaction cements, such as zinc phosphate and glass-ionomer cements, perform well over long-term periods^(9,10,16), but that newer cement chemistries, such as resin-modified glass ionomers, resin cements, and self-adhesive resin cements, also appear to display acceptable clinical performance. In many instances, however, these new cements have been tested over relatively short time-periods^(1,12,19).

Long-term success of cemented restorations depends on retention as well as maintenance of the integrity of the marginal seal. Marginal seals can in general terms be established through bonding/adhesive techniques or mechanical interlocking. Efforts to obtain chemical adhesion (as in polycarboxylate and glass ionomer cements) have been one approach to improving the performance of dental luting cements. The presence of fluoride to many of these cements aims at protecting the tooth in the event of cement breakdown or disintegration. Only limited data exist, however, to support such a protective mechanism e.g. in glass ionomer cements⁽¹⁵⁾.

The cement (Ceramis C&B) tested here introduces an additional possible retentive and protective mechanism, namely bioactivity. When this cement is immersed in physiological phosphate buffered saline solutions, hydroxyapatite (HA) is formed⁽¹⁴⁾. This formation of HA, which appears after about 7 days, demonstrates that the cement possesses dynamic self-sealing properties, and it can be speculated that actual remineralization may take place also under clinical conditions. Such a protective mechanism could provide a durable seal e.g. of the tooth/cement/restoration interfaces. Furthermore, the areas of marginal breakdown that may appear over

time, may potentially also be addressed through a bioactive resealing via deposition of hydroxyapatite. Additional research will be necessary to test these potential capabilities.

The introduction of any new luting cement necessitates systematic assessments of its clinical performance with controlled observations from pre-cementation to long post-cementation time periods.

The objective of this study was therefore to provide initial one year data regarding the clinical performance of this water-based cement with calcium aluminate and glass ionomer components for permanent cementation of high noble all-metal and porcelain-fused-to-metal restorations.

Three independent clinical investigators concluded that hand mixing of the powder and liquid components was easy resulting in a smooth, creamy mix and that the working and setting times (2 - 2.5 and 4 - 5 min. respectively) were comparable and perhaps superior to those of other cements. These unanimous observations indicate that the cement is easy to handle during a key stage of any permanent cementation procedure.

The observations are furthermore in line with the expected character of an aqueous mix with essential Newtonian flow properties. The consequent lack of substantial visco-elasticity is probably a main reason for the fact that there was no evidence of premature setting or viscosity build-up and no difficulty to seat the restorations during placement. It could also contribute to the observation that the "clean-up" for the cement was rated as "easy" and that cement removal was found to be similar to that of resin modified glass ionomers (RMGI), i.e. a distinct gel consistency formed within a few minutes permitting easy removal. Here it should also be noted that in contrast to resin-modified glass ionomer (RMGI) and self-adhesive resin cements, this new cement does not form an oxygen inhibited layer on its surface thereby making "clean-up" even easier. Therefore there is 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.

Post-operative sensitivity is a fairly common early complication in fixed prosthodontics (12). This factor was measured both qualitatively and quantitatively and demonstrated that the situation improved from the baseline level up to the 1 year recall. Recorded incidents of post-cementation tooth sensitivity were further subjectively characterized as "slight", and not directly associated with the cement.

Rather, the noted post-cementation occurrences of sensitivity were found either to be due to occlusal pre-maturities or to the presence of exposed, sensitive root dentin below the marginal finish line of the final restoration. All incidences responded either to minor occlusal adjustments or diminished with the passing of time. As noted in Table 2, at the 1 year recall period, all the recalled subjects indicated absence of pain or discomfort associated with the cemented restorations. This is indicative of a high degree of biocompatibility of the tested cement.

The gingival situation was noted to improve from pre-cementation to post-cementation levels as demonstrated by the results of statistical analyses of the GI scores.

No retentive failures were noted at recall examinations. As the angle of convergence (AC) of all prepared teeth was recorded, it should be noted that the majority of preparations were described as being "normal". It is of interest to note that although a small number of preparations were described as having greater than preferred AC, none have experienced failure thus far. Crowns and abutments that are used as retainers for removable partial dentures are exposed to comparatively higher varying functional stress levels. Some such crowns were incorporated in this study but none has experienced any untoward retentive failures. Caries was not an issue at any time during this study, but can be so especially in prolonged studies including patients with a history of recurrent caries attacks. The possible caries preventive actions from the above mentioned bioactivity and the incorporation of fluorides need to be tested in longer term studies.

While further clinical assessment of this cement is necessary, it can be concluded that thus far, its clinical performance has been good and warrants further investigation, particularly as its potential bioactive properties offers promising advantages.

Acknowledgements

This study was supported by Doxa Dental AB, Uppsala

References

1. Behr M, Rosentritt M, Wimmer J, Lang R, Kolbeck C, Bergers R, Handel G. Self-adhesive resin cement versus zinc phosphate luting material: a prospective clinical trial begun 2003. *Dent Mater* 2009;25: 601-4
2. Black SM, Charlton G. Survival of crowns and bridges related to luting cements *Rest Dent*. 1990;6: 26-30

3. Burke FJ, Lucarotti PS. Re-intervention on crowns: what comes next? *J Dent* 2009;37:25-30
4. Cvar JF and Ryge G. Criteria for the clinical evaluation of dental restorative materials, US Public Health Services Publication No 790-244. San Francisco: Government Printing Office, 1971
5. Drago C. Clinical and laboratory parameters in fixed prosthodontic treatment *J Prosthet Dent* 1996;76: 233-8
6. Dijken van JW. Resin-modified glass ionomer cement and self-cured resin composite luted ceramic inlays. A 5-year clinical evaluation. *Dent Mater* 2003;19:670-4
7. Glantz P-O, Nilner K, Jendresen MD, Sundberg H. Quality of fixed prosthodontics after twenty-two years. *Acta Odontol Scand* 2002;60: 213-8
8. Hill EE. Dental cements for definitive luting: a review and practical clinical considerations. *Dent Clin North Am* 2007;51: 643-58
9. Jokstad A, Mjör IA. Ten years' clinical evaluation of three luting cements. *J Dent* 1996;24: 309-15
10. 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: 411-6
11. Jefferies SR, Pameijer CH, Lööf J, Appleby D, and Boston D. Clinical Performance with a Bioactive Dental Luting Cement - A Prospective Clinical Pilot Study. In Press.
12. Kern M, Kleimeier B, Schaller HG, Strub JR: Clinical comparison of postoperative sensitivity for a glass ionomer and a zinc phosphate luting cement. *J Prosthet Dent* 1996;75:159-62
13. Loe H and Silness J, Periodontal disease in pregnancy. *Acta Odont Scand*. 1963; 21:533-51
14. Lööf J, Svahn F, Jarmar T, Engqvist H, Pameijer CH. A comparative study of the bioactivity of three materials for dental applications. *Dent Mater* 2008;24: 653-9
15. Muzynski BL, Greener E, Jameson L, Malone WF. Fluoride release from glass ionomers used as luting agents. *J Prosthet Dent* 1988;60:41-4
16. Pameijer CH, Nilner K. Long term clinical evaluation of three luting materials. *Swed Dent J* 1994;18:59-67
17. Tammaro S, Berggren U, Bergenholtz G. Representation of verbal pain descriptors on a visual analogue scale by dental patients and dental students. *Eur J Oral Sci*. 1997;105:207-12
18. White SN, Furuichi R, Kyomen SM. Microleakage through dentin after crown cementation. *J Endod* 1995;21:9-12
19. Yoneda S, Morigami M, Sugizaki J, Yameda T. Short-term clinical evaluation of a resin-modified glass-ionomer luting cement. *Quintessence Int* 2005;36: 49-53

Address:

Dr P-O Glantz
Faculty of Odontology
Carl Gustavs väg 34
SE-214 21 Malmö
Sweden