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Ceramir C&B Abstracts 2008 - 2013

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Evaluation of the retentive properties and 3-year clinical results with Ceramir® Crown & Bridge

Title: A Bioactive Dental Luting Cement—Its Retentive Properties and 3-Year Clinical Findings. Published by: Jefferies SR, Pameijer CH, Appleby DC, Boston D, Lööf J. Published in: Compendium of Continuing Education in Dentistry (2013); 34(2): Supplement.

Aim of the study: The main objective of this study was to assess the 3-year clinical performance of Ceramir C&B, a self-sealing bioactive luting cement. The evaluated clinical criteria included retention, gingival health, marginal integrity, post-operative sensitivity and the presence or absence of secondary caries. Handling characteristics at the time of restoration placement were also assessed. Using a separate in vitro test, a further objective was to assess the retentive properties of Ceramir C&B used with cast gold alloy and all-ceramic restorative materials.

Method: For the in vivo clinical study, the investigators used Ceramir C&B to seat cast high-gold alloy crowns and porcelain-fused-to-metal (PFM) crowns and bridges, as well as one splint. The luting cement was used in accordance with the manufacturer's instructions. For the in vitro retention study, newly extracted human bicuspid teeth were embedded in self-curing resin and the exposed crowns of the teeth were prepared on a jeweler's lathe with a diamond disc, creating preparations with a total angle of convergence of 32 ± 1.0 and an occlusal table of ± 4 mm in diameter. Chrome cobalt preparations of the same design were created for use with lithium disilicate copings. Cast gold alloy copings were fabricated, as well as CAD/CAM all-ceramic lithium disilicate and pre-sintered zirconia copings. A series of each of these custom copings was cemented with test luting cements, using a jig to apply a standardized 4.8 kg of pressure during cementation. These samples were then allowed to bench set for 10 minutes before being stored in sterile phosphate buffer at 37°C for 24 hours. The retentive properties of the luting cements were tested by applying tensile force to each sample using an Instron tensile testing machine and measuring the force required to separate the copings from the teeth.

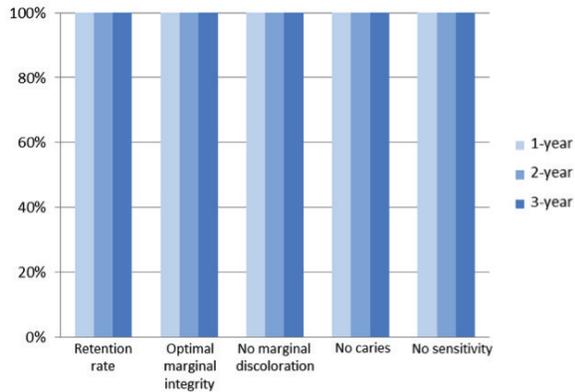
Results: At the three-year recall no loss of retention, secondary caries or marginal discolorations were found, and the marginal integrity of all observed restorations was clinically sound. In addition, no gingival inflammation was observed and no sensitivity was reported, statistically significant differences compared to the baseline pre-cementation scores three years earlier. Handling of the cement at the time of cementation had been rated as being clinically favorable. In the in vitro test, Ceramir C&B and RelyX Unicem were statistically significantly more retentive than zinc phosphate and glass ionomer cements, and with no statistically significant differences between them. There were also no statistically significant differences between Ceramir C&B and RelyX Unicem (with zirconia copings) or Vivaglass (with lithium disilicate copings).

Conclusions: This 3-year clinical study demonstrated that Ceramir C&B performs well clinically and is suitable for the cementation and long-term clinical success of metal and PFM restorations. Based on the results of the laboratory tests, Ceramir C&B provides superior retention compared to conventional luting cements.

Evaluation of the retentive properties and 3-year clinical results with Ceramir® Crown & Bridge

Clinical performance of Ceramir C&B

Clinical results at 3-year recall



Observation period: 3 years

Patients at baseline: 8 Males and 9 Females; 25-79 years of age

Restorations at baseline:

23 single unit crowns

5 three-unit bridges and

1 five-unit bridge (16 abutments); 1 two-unit splint

Status of teeth: 31 vital; 7 prior RCT

Recall:

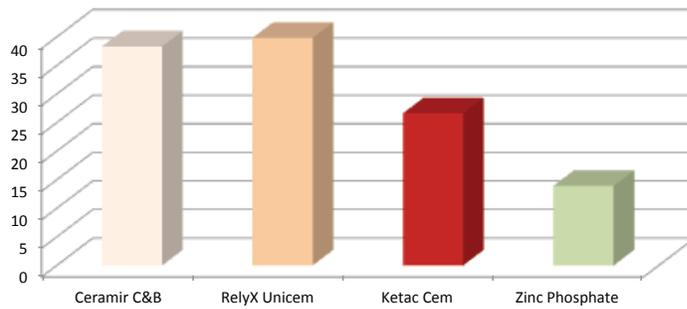
88% at 1-year

78% at 2-year

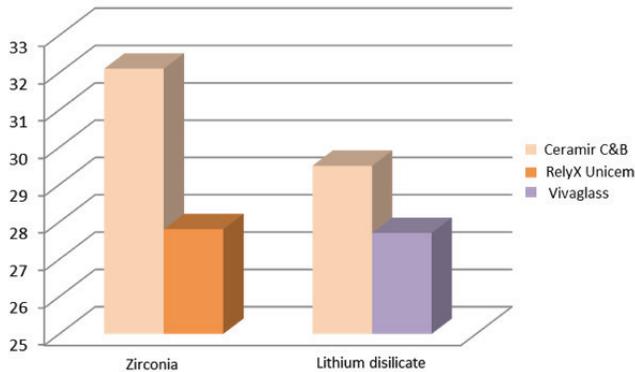
65% at 3-year

Comparative retention of Ceramir C&B and conventional luting cements

Average force (kg) required to rupture luting cement (cast gold alloy copings)



Average force (kg) required to rupture luting cement (all-ceramic copings)



Restorations with a new bioactive luting cement, Ceramir® Crown & Bridge, after 2 years in vivo.

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

Published by: SR Jefferies, CH Pameijer, D Appleby, D Boston, C Galbraith, J Lööf, P-O Glantz.

Published on-line in: J Prosthodont Res. 2011

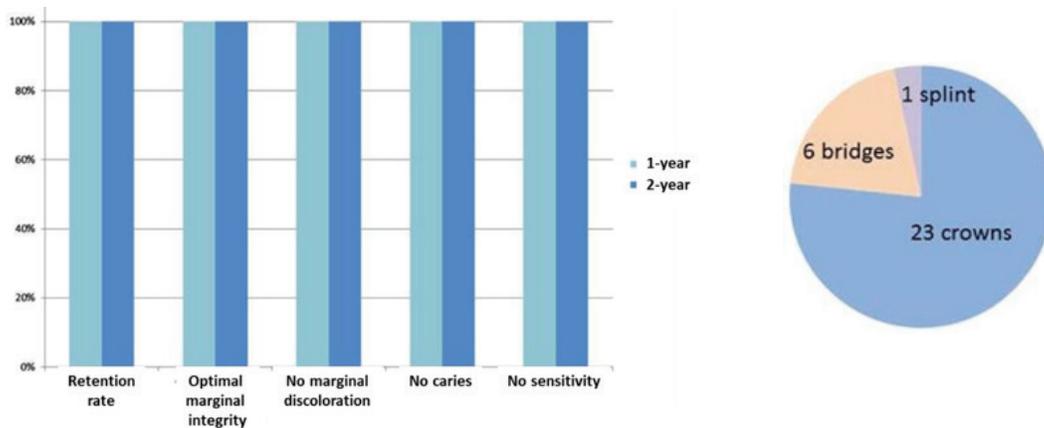
Aim of the study: The objective of the study was to determine the clinical performance of Ceramir C&B, a new bioactive, self-adhesive luting cement. The evaluated clinical criteria included retention, post-operative sensitivity, marginal integrity, marginal discoloration, and secondary caries. In addition, the handling characteristics at the time of cementation were assessed.

Method: The investigators used Ceramir C&B to seat all-metal and porcelain-fused-to-metal (PFM) crowns and bridges, as well as one splint. In accordance with the manufacturer's instructions, only the self-adhesive cement was used (i.e., no etchant, bonding agent or conditioner were used).

Results: The handling characteristics and working time for Ceramir C&B were favorable at the time of restoration placement. At two-year recall, all restorations were present, and no subjective sensitivity was reported. No secondary caries or marginal discolorations were found, and the marginal integrity of all observed restorations was sound. In addition, no associated gingival inflammation or pulpal response was observed.

Conclusions: Ceramir C&B performed well clinically over a two-year period and is suitable for the cementation of metal and PFM restorations.

Clinical Results at 2-year recall



Observation period: 2 years
Patients: 8 Males and 9 Females
Ages: 25 to 79 Years
Restorations: Recall: 88% at 1-year; 78% at 2-year
23 single unit crowns
5 three-unit bridges and 1 five-unit bridge (16 abutments);
1 two-unit splint
Status of teeth: 31 vital; 7 prior RCT

Evaluation of the antibacterial properties of Ceramir® Crown & Bridge.

Title: Antibacterial properties of dental luting agents: Potential to hinder the development of secondary caries.
Published by: E Unosson, Y Cai, X Jiang, J Lööf, K Welch, H Engqvist.
Published as: International Journal of Dentistry (2012): Article ID 529495.

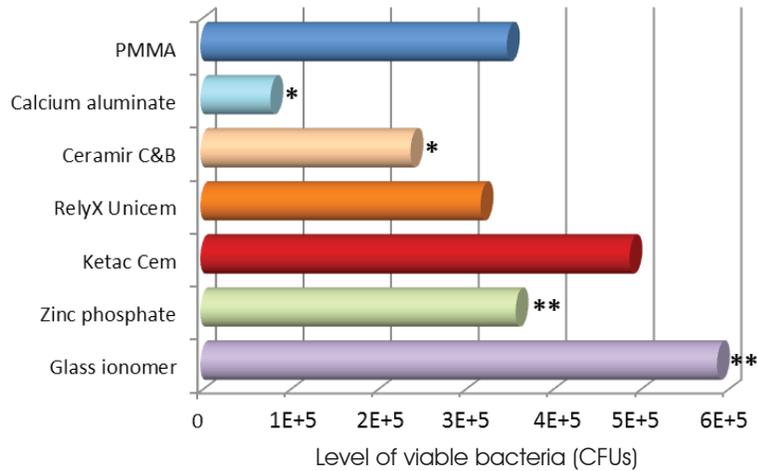
Aim of the study: The objective of the study was to determine the antibacterial properties of Ceramir C&B, compared to four commercially-available luting cements.

Method: The investigators performed in vitro testing to assess the antibacterial properties of Ceramir C&B and four other commercially-available luting cements, comparing these to a glass ionomer cement and polymethyl methacrylate (PMMA) (control). Samples of the mixed cements were placed in molds (1.5 mm by 5 mm) to set at 37°C for 7-10 minutes, except RelyX Unicem which was light-cured. PMMA samples with the same dimensions were cut from a PMMA rod. Six samples of each material were then placed in an oven at 37°C for each time period: 10 minutes, 1 day and 7 days. At the end of each time point, the respective six samples were placed individually in sterile wells and a standardized *Streptococcus mutans* suspension was applied to their surface. After incubating the samples for 1 hour at 37°C, the level of viable bacteria present was determined. This was measured by using blue resazurin, which becomes pink fluorescent resorufin when metabolized by bacteria. Since the degree of fluorescence observed has a direct linear relationship with the level of colony-forming (viable) bacteria (CFUs), the lower the fluorescence the fewer viable bacteria remain. Separately, since pH level as well as fluoride concentrations are associated with antibacterial activity, and considering that some of the cements tested release low levels of fluoride, in vitro testing was conducted for these parameters. Samples of a *Streptococcus mutans* suspension were prepared in buffer solutions ranging from pH 1-11 and incubated at 37°C for 10 hours, or in fluoride broth solutions of differing concentrations. The level of viable bacteria present was measured for each sample using spectrophotometry and compared to baseline.

Results: A statistically significant reduction in bacteria was found at all time points for calcium aluminate ($p < 0.0005$) and for Ceramir C&B at 10 minutes and 1 day ($p \leq 0.004$), compared to PMMA. RelyX™ Unicem demonstrated a significant reduction at 10 minutes only ($p = 0.022$). No antibacterial effect was observed for any other cements. With respect to pH and fluoride, an alkaline pH gave increased antibacterial activity.

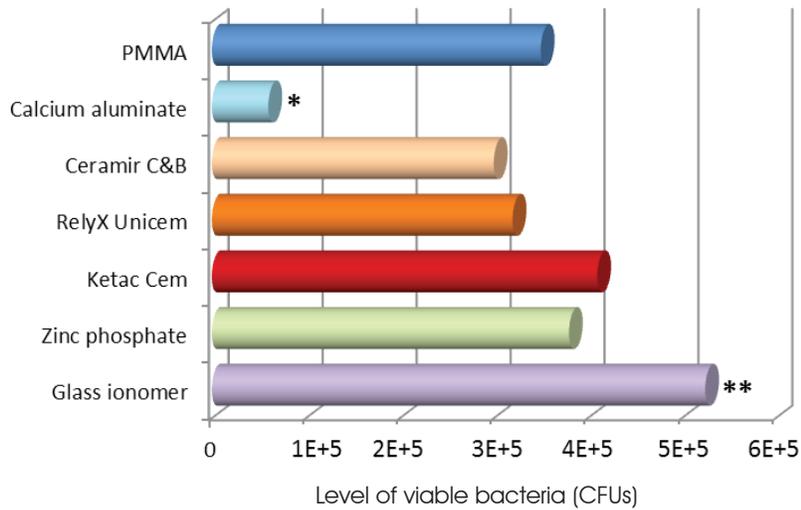
Conclusions: Based on the in vitro testing, the highest levels of antibacterial activity were observed with calcium aluminate cement followed by Ceramir C&B. Some antibacterial activity was also observed with RelyX Unicem. No antibacterial activity was observed with any other cement tested.

Comparative antibacterial activity of Ceramir Crown & Bridge



* Significantly fewer CFUs, indicating antibacterial activity ($p < 0.05$ vs. control)

** Significantly more CFUs than control ($p < 0.05$ vs. control)



* Significantly fewer CFUs, indicating antibacterial activity ($p < 0.05$ vs. control)

** Significantly more CFUs than control ($p < 0.05$ vs. control)

Evaluation of the ability of Ceramir® Crown & Bridge to form hydroxyapatite in human saliva.

Title: Hydroxyapatite formation on a novel dental cement in human saliva.

Published by: J Engstrand, E Unosson, H Engqvist.

Published as: ISRN Dentistry (2012): Article ID 6224056.

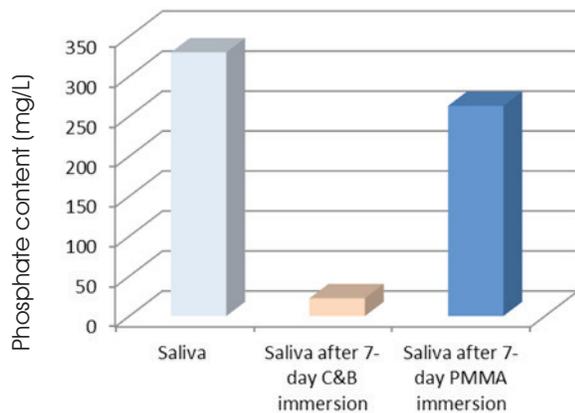
Aim of the study: The objective of the study was to assess the surface reactions on Ceramir C&B, with respect to hydroxyapatite (HA) formation in human saliva.

Method: The investigators performed an in vitro study using cylindrical discs of Ceramir C&B cement that had been placed in molds (8 mm by 3 mm) to set at 37°C for 10 minutes, gently polished and then submerged in water at 37°C for 3 hours. Six samples were next immersed for 7 days in stimulated whole saliva (test samples) and six in phosphate buffered saline (positive control), then rinsed with distilled water and dried. Polymethyl methacrylate (PMMA) discs of the same dimensions were also stored for 7 days in saliva (negative control). The samples were then tested using scanning electron microscopy (SEM), X-ray diffraction and X-ray photoelectron spectroscopy to assess the deposition of crystals and their composition. In addition the storage solutions were analysed for phosphate concentration using flow injection analysis (UV-VIS).

Results: The phosphate concentrations of both the stimulated whole saliva and phosphate buffered saline decreased significantly following immersion of the Ceramir C&B samples. This demonstrated that the phosphate, which is essential for HA formation, had been deposited at the surface of the samples. The SEM and X-ray diffraction tests, together with the calcium to phosphorus ratios observed with the spectroscopy test, indicated crystal deposition and HA formation at the surface for the C&B samples immersed in saliva or saline. There was no evidence of HA crystal formation on the PMMA negative control samples.

Conclusions: Based on these in vitro tests, Ceramir C&B promotes HA formation at its surface, and could be expected to promote natural HA formation at the restoration-tooth interface.

Phosphate content of saliva pre- and post-immersion



Note the very low phosphate content of saliva following immersion of the C&B samples, indicating deposition of the phosphate at the surface of the samples

Evaluation of the sealing properties of Ceramir® Crown & Bridge (formerly XeraCem™), a new bioactive self-sealing luting cement.

Title: Sealing properties of a calcium aluminate luting agent.
Published by: CH Pameijer, O Zmener, S Alvarez Serrano, F Garcia-Godoy.
Published in: Am J Dent. 2010; 23:121-124.

Aim of the study: The objective of the study was to determine the self-sealing properties of Ceramir® Crown & Bridge (formerly XeraCem™), a new calcium aluminate-based luting cement and to compare it to a glass ionomer cement (Ketac™ Cem) and a resin-modified glass ionomer cement (Rely X Luting Plus).

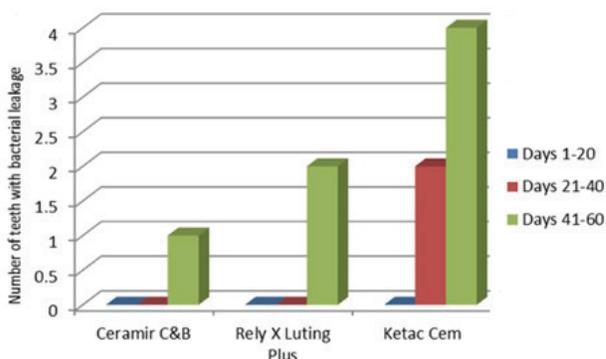
Method: The investigators used a bacterial leakage test to assess the sealing properties of the three selected luting cements over a period of 60 days. Thirty extracted human bicuspids were randomly assigned to each test group and prepared for full cast gold crowns. After autoclaving the prepared teeth and the cast gold crowns, the crowns were then cemented onto the samples, after which they were left for 10 minutes to bench set and thermocycled (2000 cycles at 5-55°C; dwell time of 35 seconds). Prior to testing, all restored teeth were sterilized to ensure lack of contamination, and after storage in a sterile phosphate buffer solution for 7 days all samples were subjected to identical bacterial leakage testing using a dual chamber and E. coli.

Results: No statistically significant differences were found for bacterial leakage using Ceramir C&B and Rely X Luting Plus ($p > 0.05$). In contrast, a statistically significant difference was found for Ketac Cem, which was found to result in greater bacterial leakage ($p < 0.05$).

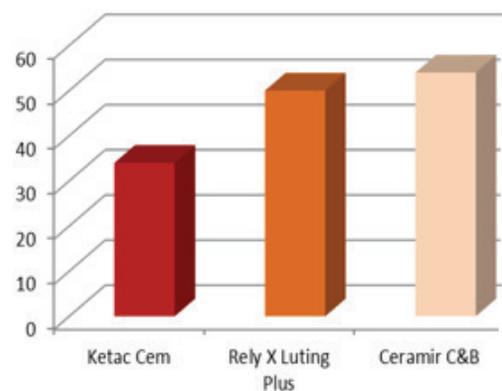
Conclusions: Based on the results of the bacterial leakage testing, Ceramir C&B and RelyX Luting Plus provide for an acceptable marginal seal.

Bacterial leakage with Ceramir Crown & Bridge, RelyX Luting Plus and Ketac Cem

Bacterial leakage at selected time periods



Number of days to first bacteria leakage



Evidence for the biocompatibility of Ceramir® Crown & Bridge (formerly XeraCem™).

Title: Ceramir® Crown & Bridge Luting Agent - A Treatise on Biocompatibility.
Author: CH Pameijer, 2009

A number of pilot studies have investigated the biocompatibility of Ceramir C&B, a new bioactive, self-adhesive and self-sealing luting cement. These studies assessed the pH of Ceramir C&B after setting, and whether its use influenced inflammation, pulpal irritation or hypersensitivity.

pH Testing: The results from this study show that Ceramir C&B is slightly acidic (pH4) immediately after setting and that the pH rapidly rises to reach an alkaline pH of 8.5 within 3- 4 hours. This alkaline pH is essential for the cement to be bioactive and to create apatite on its surface when in contact with phosphate-containing solutions, as well as for the production of excess calcium ions.

Early Material Testing: Calcium aluminate material was tested as a restorative for Class V preparations and as a root canal filling material in vivo (Pameijer 2004, 2001). When used as a retrograde endodontic cement, the material did not interfere with normal bone healing and may have promoted it. As a restorative material, inflammation was negligible; the material was found to be very bland at 5, 25 and 70 days. These tests confirmed the biocompatibility of the calcium aluminate formulation. A small 5-year endodontic study was then conducted in vivo in humans using calcium aluminate as a retrograde and orthograde endodontic cement together with gutta percha (Kraft et al., J Dent Res. 2008. #1333). Of 22 endodontic treatments (14 retrograde fills and 8 orthograde fills) performed for 18 patients, at two years 21 of 22 treatments were successful with one failure due to complicated root anatomy. At five years, one tooth was extracted and the remaining teeth observed at recall were symptom-free.

Pulpal Reactions to Ceramir C&B: In vivo animal testing demonstrated that the use of Ceramir C&B luting cement for composite resin inlays resulted in no inflammation at 85 days; the remaining dentin thickness (RDT) was 0.85 mm, well below the 1.50 mm level considered acceptable. The blandness of Ceramir C&B was also demonstrated by the absence of secondary dentin formation adjacent to the luting cement in the floor of the preparation, attesting to a lack of irritation. A second study included use of Ceramir C&B as a pulp capping material to test for irritation (not to test for suitability as a pulp capping material). Ceramir C&B was placed directly over the exposed pulp after decontamination of the preparations and prior to placement of direct composite restorations. The absence of any bridge over the pulp at day 25, and minimal bridge formation at day 85, demonstrated the non-irritating nature of Ceramir C&B as it neither stimulated dentinal bridge formation nor resulted in necrosis.

Post-cementation Hypersensitivity: Ceramir C&B used as a luting agent for 38 restorations in a small in vivo study did not result in hypersensitivity being an issue for patients. The majority of patients (76%) experienced no post-cementation hypersensitivity and only very mild hypersensitivity was experienced by the other four patients.

Overall Conclusions: Based on the results of the in vitro and in vivo testing, Ceramir C&B offers excellent biocompatibility.

Biocompatibility of Ceramir[®] Crown & Bridge (formerly XeraCem[™]).

Title: In vitro and in vivo biocompatibility tests of XeraCem[™].

Published by: CH Pameijer, SR Jefferies, J Lööf, L Hermansson, Wiksell E.

Published as: IADR Poster #3097, Toronto, 2008.

Aim of the study: The objective of the study was to assess the biocompatibility of Ceramir[®] Crown & Bridge (formerly XeraCem[™]).

Method: The investigators conducted both in vitro and in vivo tests. In vitro testing was conducted in accordance with ISO specifications, and consisted of an Ames test (reverse mutation assay) to assess the mutagenicity of Ceramir C&B and a cytotoxicity test utilizing soft tissue cells. A hamster pouch study and a sensitization test in guinea pigs were conducted, again in accordance with ISO specifications. In addition, an in vivo study was conducted in Rhesus macaques, in accordance with ANSI/ADA specifications; this study was conducted to assess pulpal reactions after cementation of Class V composite resin inlays using Ceramir C&B.

Results: No mutagenicity was observed in in vitro testing of Ceramir C&B, and minimal-to-no cytotoxicity. It was also found in testing that Ceramir C&B did not induce irritation or skin sensitization. In addition, with the exception of one sample showing superficial inflammation, no inflammation, edema, or other signs of inflammation were found with in vivo testing of Ceramir C&B.

Conclusion: Based on the results of this study, it can be concluded that Ceramir C&B offers favorable biocompatibility.

Microleakage evaluation of Ceramir® Crown & Bridge, a bioactive luting cement (formerly XeraCem™).

Title: Microleakage Evaluation of XeraCem™ in Cemented Crowns.
 Published by: CH Pameijer, SR Jefferies, J Lööf, L Hermansson.
 Published as: IADR Poster #3098, Toronto, 2008.

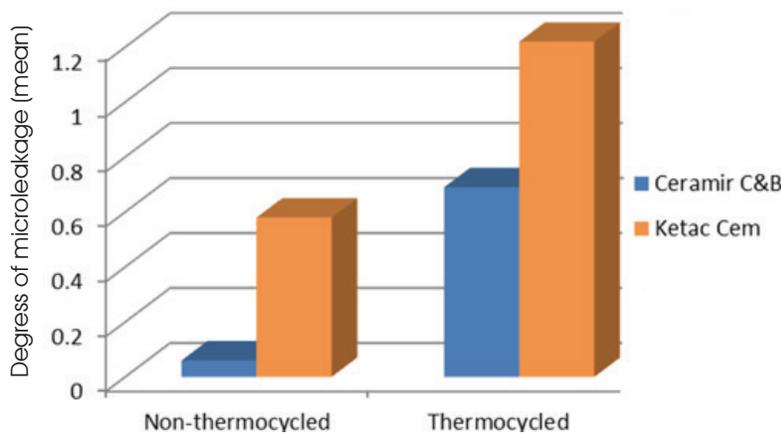
Aim of the study: The objective of the study was to determine the self-sealing capabilities of Ceramir® Crown & Bridge (formerly XeraCem™), a new bioactive, self-adhesive luting cement in comparison to a commercially-available glass ionomer luting cement (Ketac™ Cem).

Method: The investigators used Ceramir C&B or Ketac Cem to cement full cast gold crowns on preparations prepared from thirty freshly extracted human molars and bicuspid. All teeth were prepared with full chamfers, a total angle of convergence of 10-12 degrees, and clinical conditions were simulated by applying pressure for 2 minutes at the time of cementation. Half of each test group was then thermocycled (2000 cycles at 5-55°C) and with a dwell time of 25 seconds. All samples were then coated with block-out resin ending 1 mm from the margins, immersed in 0.5% methylene blue for 24 hours, rinsed, embedded in self-curing resin and sectioned. Dye leakage was then assessed for each test group.

Results: A statistically significant difference ($p < 0.01$) was found for microleakage in both thermocycled and non-thermocycled samples using Ceramir C&B or Ketac Cem.

Conclusions: Ceramir C&B demonstrated minimal microleakage, and significantly less microleakage than Ketac Cem. In conclusion, Ceramir C&B showed superior marginal integrity compared to the use of traditional luting cement for cementation of full cast gold crowns.

Microleakage of Ceramir Crown & Bridge and Ketac Cem



Number of non-thermocycled samples:
 10 Ceramir C&B and 5 Ketac Cem

Number of thermocycled samples:
 10 Ceramir C&B and 5 Ketac Cem

Number of margins tested:
 12 per tooth (6 cross-sections per tooth)

Degrees	Microleakage (mm)
0 degrees	0mm
1 degree	0 - 1 mm
2 degrees	2 - 3mm

Evaluation of the retentive properties of Ceramir® Crown & Bridge (formerly XeraCem™), a new self-sealing luting cement.

Title: A comparative crown retention test using XeraCem™.
Published by: CH Pameijer, SR Jefferies, J Lööf, L Hermansson.
Published as: IADR Poster #3099, Toronto, 2008.

Aim of the study: The objective of the study was to determine the retentive properties of Ceramir® Crown & Bridge (formerly XeraCem™), a new self-sealing luting cement, compared to other commercially-available luting cements.

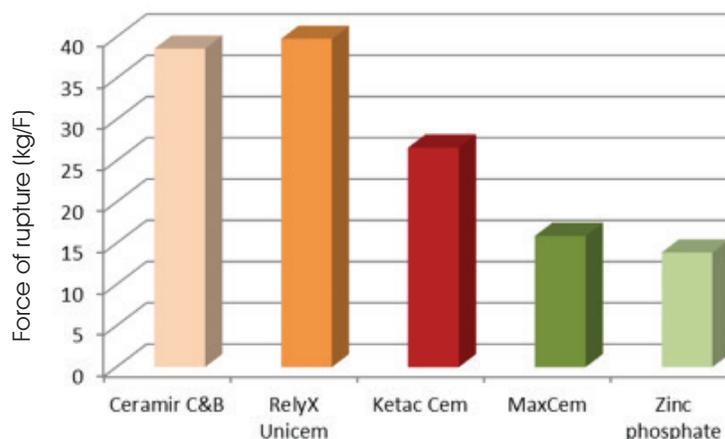
Method: The investigators used an in vitro test to assess the retentive properties of Ceramir C&B and four other commercially-available luting cements. Freshly extracted human bicuspid teeth were embedded in resin and prepared with identical angles of convergence (320 ± 1) and occlusal tables with diameters of ± 4 mm. Custom copings were cast for each sample and cemented with one of the test luting cements, using a jig to standardize the amount of pressure applied during cementation (4.8 kg for 4 minutes). The samples were then allowed to bench set for 10 minutes and stored in sterile water at 37°C for 24 hours. The retentive properties of the luting cements were tested by applying tensile force to each sample using an Instron tensile testing machine and measuring the force required to separate the copings from the teeth.

Results: Ceramir C&B and RelyX™ Unicem demonstrated statistically equivalent retention, and also demonstrated greater retentive properties that were statistically significant ($p < 0.01$) compared to the other three luting cements tested (MaxCem™, Ketac™ Cem, zinc phosphate).

Conclusions: Based on the results of the tests, Ceramir C&B provides superior retention compared to conventional luting cements.

Comparative retention of Ceramir Crown & Bridge and conventional luting cements

Average force required to rupture luting cement



Evaluation of the net setting time, film thickness and compressive strength of Ceramir® Crown & Bridge (formerly XeraCem™).

Title: Physical properties of XeraCem™.

Published by: SR Jefferies, J Lööf, CH Pameijer, D Boston, C Galbraith, L Hermansson.

Published as: IADR Poster #3100, Toronto, 2008.

Aim of the study: The objective of the study was to determine the net setting time, film thickness and compressive strength of Ceramir® Crown & Bridge (formerly XeraCem™).

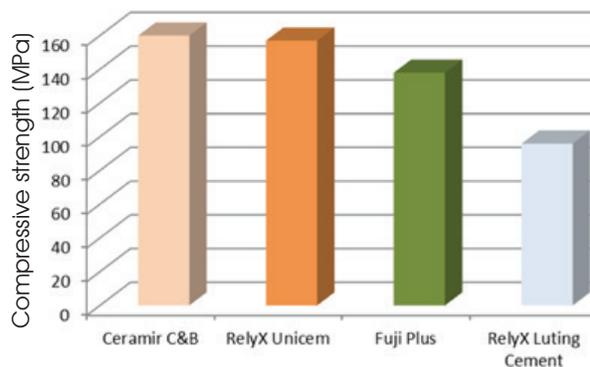
Method: The investigators used in vitro tests in accordance with ISO specifications (ISO 9917-1) to assess these three physical properties. For the net setting time, mixed cement was placed in a copper chamber at 37°C and a relative humidity of 90% and a Gilmore needle was used to test for indentations in the cement during setting. Film thickness was assessed by placing 0.1 ml of cement between two glass plates, applying a force of 150 N for 10 minutes starting two minutes after mixing had been completed, and measuring the difference in total thickness of the two glass plates with and without the set cement. Compressive strength was measured by compressing cylindrical samples of Ceramir C&B and four other luting cements and comparing these at 24 hours. The compressive strength of Ceramir C&B at 30 days was also measured.

Results: Based on the in vitro tests, the net setting time for Ceramir C&B was 4.8 minutes (+/- 0.1 min) and the film thickness was 15 µm (+/- 4). The compressive strength demonstrated a statistically significant difference ($p < 0.05$) compared to RelyX Luting cement, and a statistically significant increase ($p < 0.05$) in compressive strength over a period of 30 days.

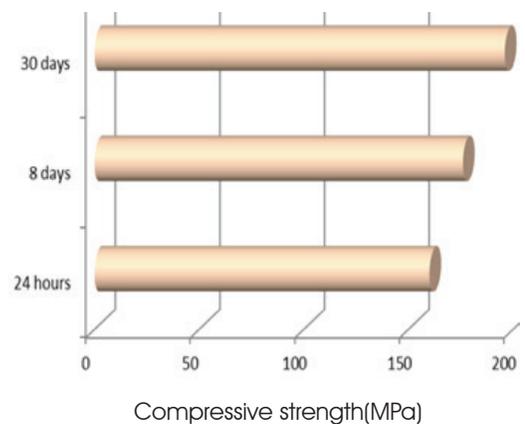
Conclusions: Based on the results of the tests, the net setting time and film thickness of Ceramir C&B are well within ISO-specifications. The compressive strength of Ceramir C&B was superior to RelyX Luting cement, within ISO specifications, and increased over a period of 30 days.

Comparative strength of Ceramir Crown & Bridge and conventional luting cements

Compression strength of luting cements at 24 hours



Compressive strength of Ceramir C & B over time



Evaluation of the bioactivity of Ceramir® Crown & Bridge.

Title: A comparative study of the bioactivity of three materials for dental applications.

Published by: J Lööf, F Svahn, T Jarmar, H Engqvist, CH Pameijer.

Published as: Dental Materials (2008) 24: 653–659.

Aim of the study: The objective of the study was to determine the bioactive properties of Ceramir C&B.

Method: The investigators conducted in vitro testing to assess the bioactive properties of Ceramir C&B (a hybrid of calcium aluminate and glass ionomer cement), calcium aluminate cement and glass ionomer cement. The cements were mixed, placed in standardized molds with a glass cover to flatten the surface of the cements and allowed to set for 10 minutes at 37°C. They were then removed, polished and stored in phosphate buffered saline at 37°C. Two samples of each material were stored in the saline for each of the time periods (1 hour, 1 day, 7 days and 4 weeks). They were then removed, rinsed and dried for a minimum of 7 days prior to testing.

Scanning electron microscopy (SEM), grazing incidence X-ray diffraction and transmission electron microscopy analyses were performed to determine the presence of a surface layer, timing of its formation (if present), the crystallinity of the surface layer and crystal morphology. The crystal structure of this surface layer was further assessed using electron diffraction, and the elements present determined using energy dispersive X-ray spectroscopy. Lastly, the pH was measured after removal of the samples for up to 7 days and compared to the baseline pH of the saline prior to immersion of the samples.

Results: Hydroxyapatite crystals formed as a surface layer on the Ceramir C&B samples between 24h and 7 days, while calcium aluminate formed its surface layer prior to 24 hours. No hydroxyapatite layer was formed on the glass ionomer cement samples. The pH following immersion of calcium aluminate and C&B Ceramir cements was found to be conducive for bioactivity and hydroxyapatite formation. Electron diffraction in the TEM confirmed that the surface layer on Ceramir C&B was hydroxyl apatite. The Ceramir C&B surface layer was plate-like, consisting of randomly-oriented, small, dense, nano-sized crystals (19-30 nm) that were also present at 4 weeks.

Conclusions: Based on the results of these in vitro tests, Ceramir C&B is bioactive, enabling the formation of a surface layer of hydroxyapatite crystals. Clinically, this may translate into a protective hydroxyapatite layer at the tooth-restoration interface.