FACTS ABOUT CERAMIR® CROWN & BRIDGE

ceramir®
CROWN & BRIDGE

Bioceramic luting agent

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PRODUCT DESCRIPTION

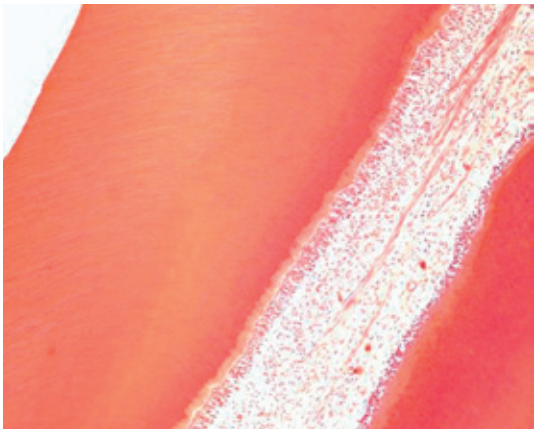
Ceramir® Crown & Bridge (Ceramir C&B) is a bioceramic luting agent produced for permanent cementing of conventional prosthetics, including all-ceramic constructions on lithium disilicate, aluminium oxide or zirconium dioxide (Alumina or zirconia) frames. Ceramir C&B is the first product based on Ceramir technology, which belongs to the material group, Nanostructurally Integrating Bioceramics (NIB). In this product conventional glass ionomer technology has been interlaced with Ceramir technology to give Ceramir C&B its unique handling characteristics.

BIOCOMPATIBILITY

Ceramir technology has been subjected to extensive tests to determine its usability in orthopedics – amongst other things as a cement in the treatment of fractured vertebrae of the spine. Above and beyond all that, Ceramir C&B has also undergone a great array of tests designed to determine the product's biocompatibility profile, specifically as a dental cement. These tests have included measurements of toxicity, irritation and sensitivity as well as evaluation of pulp histology.

At the end of testing, an independent report was requested from one of the leading experts in the field, C.H. Pameijer, Professor Emeritus at the University of Connecticut. The report shows that Ceramir C&B possesses exceptionally good biocompatibility characteristics and that the material displays extremely high pulp-friendliness.

In a direct comparison made between Ceramir C&B and RelyX Unicem (3M ESPE) as pulp-capping material it was expressed that Ceramir C&B displayed a high degree of pulp-friendly properties, while RelyX Unicem exclusively produced necrotic pulps after 85 days.



The above illustration shows an H&E colored histological section where Ceramir C&B has been used as a cement of a class V deposition in vivo. No inflammation or other signs of irritation can be observed. Enlargement is 100x and the remaining dentine thickness is 0.6 mm. The section was taken 83 days after cementing.

SEALING

Ceramir C&B has the same good wetting and sealing properties that have previously been attributed to Ceramir. Utilisation of nanotechnology and nanostructural integration makes it possible to minimize leakage between tooth and material over time. Leakage is normally measured by varying tests of micro- and nano-leakage. In these tests, differing kinds of coloration is used together with thermocycling to produce artificial aging of the joint. Ceramir C&B has been tested in both micro-leakage and bacterial-leakage models.

As a reference for the micro-leakage tests, a glass ionomer, Ketac Cem (3M ESPE) was used. Glass ionomers are the material group on the market which hitherto have generally displayed the lowest leakage factors. In the study, gold crowns were cemented to teeth which had been stored for 24 hours in a phosphate buffer at 37°C. After that, one group was thermocycled 2000 times from 5 to 55°C while the second group was placed directly into methylene blue dye. The teeth were then sectioned and each segment was then studied for leakage at each edge surface and evaluated. The test showed a significantly better seal of the surface edge when Ceramir C&B was used compared with Ketac Cem (see table).

As a complement to the micro-leakage tests, bacteria leakage evaluation was also carried out in a modified model designed for the testing of root-filling material. In this case, the control materials employed were a glass ionomer (Ketac Cem) and a resin-modified glass ionomer (RelyX Luting, 3M ESPE). After 60 days, the results of the study showed that both Ceramir C&B and RelyX Luting displayed generally low leakage and that both had significantly lower levels when compared to Ketac Cem.

Test Group	Medial leakage (grades) (Ceramir C&B n=120, Ketac Cem n=60)
Ceramir C&B after 24 hours	0,06
Ceramir C&B thermocycled	0,69
Ketac Cem after 24 hours	0,58
Ketac Cem thermocycled	1,22

Scale used in the above table: 0°= zero leakage, 1° = 0–1 mm from crown cement surface, 2°= 1–2 mm, etc. Study published by C.H. Pameijer et al.

PHYSICAL AND MECHANICAL PROPERTIES

Ceramir C&B has been developed and tested in order to yield optimal functionality in permanent installation of oral prosthetic constructions, crowns and bridges.

Ceramir C&B has been tested according to the established standards for water-based cements, ISO 9917-1:2007, and furthermore in a number of other important tests appropriate to the application. Many of these tests have been carried out by independent experts with a great deal of experience in testing dental material. All tests, whenever possible, have been undertaken in conditions adapted for Ceramir technology – for example, storage in phosphate solutions and testing at body temperature.

The most basic properties of a dental cement are working time, setting time, film thickness and mechanical strength. Against each of these criteria, Ceramir C&B yields excellent results. Working time for Ceramir C&B is two minutes, which is relatively long; meanwhile

it has a setting time of approximately five minutes. Furthermore, Ceramir C&B has a low film thickness of around 15µm, which is a prerequisite for restorations to fit well. Mechanical strength has been measured in terms of compression strength and gives 170 MPa after 24 hours, comfortably on par with the best resin-based materials. Ceramir C&B fulfils the requirements of ISO 9917-1:2007 in terms of acidity-resistance after 24 hours and has a radio-opacity corresponding to 1.5 mm Al.

Retention

Retention has been tested by cementing crowns with an exaggerated convergence angle (32°). The purpose of the test was to measure the cement's retention ability without assistance of the preparation in mechanical retention. The results showed that Ceramir C&B has a retention on par with, or better than, RelyX Unicem against both Gold and zirconium dioxide.

Cement	Retention (gold crown) kg/force
MaxCem (Kerr)	15.9 ± 9.3
Ketac Cem	26.6 ± 4.4
Zinc phosphate	13.9 ± 4.5
Ceramir C&B	38.6 ± 8.5
RelyX Unicem	39.8 ± 15.3

For Ceramir C&B and RelyX Unicem retention was also measured with zirconium dioxide crowns (Cercon, Degudent).

Cement	Retention (zirconium dioxide crowns) kg/force
RelyX Unicem	27.8 ± 11.3
Ceramir C&B	32.6 ± 6.7

As well as for actual retention, a range of tests have also been carried out for so-called "Shear Bond Strength" with various other materials and compared with Ketac Cem's performance. Ceramir C&B displayed no significant differences between the various materials.

Shear Bond Strength (SBS) S d ~ 2 MPa (in all tests)	Ceramir® C&B (MPa)	Ketac Cem (MPa)
Dentine	11.0	4.7
Enamel	8.4	8.4
Gold	10.2	2.8
Aluminium oxide	7.5	6.6
Zirconium dioxide	8.2	3.7

Dimensional Stability

Dimensional stability is a very important parameter for all dental cement. Ceramir C&B is a non-shrinking cement, which is regarded as a great benefit since this precludes potentially harmful stresses between tooth and material. During tests of Ceramir C&B's linear expansion characteristics, a "worst case" measurement was sought. It was dependent on the contribution made by crystal growth, which was taken into account and then the result was around 0.4%. This is somewhat less than, for example, RelyX Unicem.

To achieve more clinically relevant results other test methods were used. One example of these was as follows: Entirely ceramic feldspar porcelain crowns were cemented with Ceramir C&B. These were evaluated over a period of time by passing light through them to test for micro-cracks. The tests were made on a number of occasions over 45 weeks and no cracks could be detected. Yet another test was carried out to get an idea of what pressure the material exerts on its surroundings. The material was placed in a glass tube with well-defined resistance against internal pressure. The largest tubes were the least tolerant of the force of expansion. The tests were evaluated with a focus on crack formation over time. The study compared Ceramir C&B with Dyract Cem Plus (Dentsply) and Fuji Plus (GC). None of the glass tubes were broken by Ceramir C&B, while the other two cements cracked four and three tubes, respectively. The results are shown below.

Results of the study:

Ceramir C&B

50 weeks: No visible cracks in any of the glass tubes

Dyract Cem Plus

2 weeks: One 5-mm glass tube broken

4 weeks: One 7-mm and one 9-mm glass tube broken

19 weeks: One 10-mm glass tube broken

Fuji Plus

3 weeks: One 7-mm glass tube, one 9-mm glass tube and one 10-mm glass tube broken

Compression Strength and Elasticity

Compression strength has been tested and published by S. R. Jefferies et al.
During the development phase of the product, Ceramir Crown & Bridge was called XeraCem.

	RelyX Luting Cement	Fuji Plus	RelyX Unicem	XeraCem	XeraCem 8 days	XeraCem 30 days
Strength (MPa)	96 ± 10	138 ± 15	157 ± 10	160 ± 27	176 ± 10	196 ± 7

The development of compression strength for Ceramir C&B was also tested over time:

	24 hrs	8 days	30 days	90 days
Strength (MPa)	160 ± 27	176± 24	196 ± 18	210 ± 24

Ceramir C&B's modulus of elasticity was measured at 4.7 GPa in combination with its compression strength evaluation.

CLINICAL PUBLICATIONS

Summary – 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 bicuspids 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.

Doxa – 25 years of research and development

Ceramir Crown & Bridge is a Swedish product from Doxa, an Uppsala-based company founded in 1987 by Professor Leif Hermansson and his wife Irmeli. The company's focus has been on the research and development of bioceramics for use within orthopedics and odontology. Doxa is today a world leader in the development of bioceramics and its proprietary technology has been reviewed in more than 60 publications. Doxa's patent portfolio incorporates over 25 foundational patents and more than 100 national patents and patent applications.

In 2009, Doxa reorientated the focus of its activities and took the step from being a development company to that of a dental marketing and sales organisation. With the patient in focus, Doxa aims at developing dental materials which are user-friendly, biocompatible and environmentally friendly.

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**Ceramir Crown & Bridge was previously called XeraCem*

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