CERAMIR™ CROWN & BRIDGE LUTING AGENT – A TREATISE ON BIOCOMPATIBILITY

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ABSTRACT

CERAMIR C&B is a new calcium aluminate/glass ionomer self-etching hybrid luting agent with unique physical properties that makes it particularly suitable for use in crown and bridge applications. The material has undergone extensive testing according to the ANSI/ADA Specification #41 (ISO 7405), Recommended Standard Practices for Biological Evaluation of Dental Materials and meets all requirements for a luting agent. This review presents an overview of currently available luting agents (cements) and briefly discusses their advantages and disadvantages. A major emphasis of this manuscript is the presentation of the results of the biocompatibility test on CERAMIR C&B and to view them in the context of currently commercially available luting agents. Analysis by means of histology from four animal studies established biocompatibility and demonstrated a lack of irritation of the material, whether a CaAl formula, or a CaAl/glass ionomer hybrid. This was manifested in diverse applications such as placement in bone in subhuman primates, in indirect and direct pulp capping and when applied under hydraulic pressure, as is the case when cementing crowns. Additional favorable data was reported in a retrospective clinical evaluation in humans of ortho and retrograde root fillings. Furthermore, data from a clinical
pilot study on post-cementation hypersensitivity provided further support for the lack of irritation. Post-cementation hypersensitivity appears not to be an issue, which is not always the case with currently used materials. Based on an analysis of the data that has been gathered from ex vivo and in vivo testing it can be concluded that CERAMIR C&B meets all requirements of a luting agent and in addition possesses physical properties not found in other cements. When compared to what is currently on the market, CERAMIR C&B appears to possess superior properties with respect to biocompatibility and post cementation comfort. However, long-term evaluations need to confirm the favorable data that has been generated thus far.
REVIEW OF LUTING AGENTS

The need for a luting agent or dental cement for crowns and bridges was recognized by the dental profession late 1800, for the cementation of crowns and small bridges. The Dental Cosmos reported, also late 1800, a technique for the fabrication of a 4-unit pin ledge bridge, which required a cement for fixation. In 1879 zinc phosphate cement was introduced and although the formulation has been refined during more than a century of use, it is a luting agent that has consistently successfully been used in clinical practice and even today is still considered the “Golden Standard”.

ZINC PHOSPHATE CEMENT

The cement comes as a powder and liquid and is classified as an acid-base reaction cement. The basic constituent of the powder is zinc oxide. Magnesium oxide is used as a modifier (+ 10%) while other oxides such as bismuth and silica may be present.

The liquid is essentially composed of phosphoric acid, water, aluminum phosphate and sometimes zinc phosphate. The water content is approximately 33 ± 5% and is an important factor as it controls the rate and type of powder/liquid reaction (Philips, 1982).

When the powder reacts with the liquid a considerable amount of heat is generated (exothermic reaction) and the mixture reaches a pH=3.5. Since the cement is placed on and in prepared teeth in a “wet consistency” and not all liquid reacts with the powder, unreacted phosphoric acid liquid with a low pH of approximately 1.5, when in contact with the preparation, causes an immediate (within 5s) dissolution of the smear layer and smear plugs. Since cementation causes a considerable amount of hydraulic pressure, the unreacted acid is pushed in the dentinal tubules and depending on the remaining dentin thickness (RDT) can cause more or less irritation of the pulp. Therefore the pulp has to cope with not only heat but acidity as well. The greater the RDT, the more beneficial the buffering action of the fluid in the dentinal tubules is and the less
the effect of the acid. Furthermore a greater RDT also diminishes the thermal effect. When fully reacted the set cement reaches a pH=6.7 after 24 hours. Post-cementation hypersensitivity is indeed a frequently experienced clinical problem, which either resolves over time or may result in endodontic treatment. If it resolves it is through the protective action of secretion of secondary dentin by the odontoblasts. This however, does not start in humans until 3 weeks after the insult has taken place and deposition of secondary dentin occurs in microns per day. If the irritation cannot be handled by the body, the pulp becomes necrotic, which then requires root canal treatment. Therefore, although the material may be biocompatible, post cementation discomfort is a known unfavorable side effect when using this cement.

POLYCARBOXYLATE CEMENT

Since it is a minor player in the field of luting agents, polycarboxylate cements will not be discussed. In spite of favorable biological properties and being very kind to the pulp, the cement does not have the physical properties that can compete with other commercially available luting agents. It is frequently used when a long-lasting provisional cement is required.

GLASS Ionomer CEMENT

Glass ionomer cements (GIC) were invented in the late 1960s in the laboratory of the Government Chemist in Great Britain and first reported on by Wilson and Kent (1971). GIC set by means of chelation as a result of an acid-base reaction. They strongly adhere to enamel and to some extent to dentin and release fluoride. Initially used as a restorative material, GI further evolved into a luting agent, which is now the predominant application.

The powder consists of alumino silicates with a high fluoride content. The material is formed by the fusion of quartz, alumina, cryolite, fluortite, aluminum trifluoride and aluminum phosphate at ambient temperatures of 1100 or 1300° C.
This glass frit is cooled to a dull glow and quenched in water. It is subsequently ground into 45µm particles.

The liquid is composed of poly acrylic acid and tartaric acid, the latter to accelerate the setting reaction. The reaction of the powder with the liquid causes decomposition, migration, gelation, post-setting hardening and further slow maturation. The poly acrylic acid degrades the outer surface of the particles resulting in release of calcium, aluminum and fluoride ions. When a sufficient amount of metal ions has been released gelation will occur. Hardening will continue for about 24 hours.

GIC display a relatively low curing shrinkage; within the first 10 minutes 40-50% of shrinkage has occurred.

Also with the use of GIC as a luting agent frequent post-cementation sensitivity has been reported. The at that time accepted ANSI/ADA Specification 41, Recommended Standard Practices for Biological Evaluation of Dental Materials stipulated that luting agents should be tested for pulp reaction in primates by inserting passively a heavier than luting consistency in Class V restorations in primates. Indeed the results of these tests demonstrated that cement was biocompatible and non-irritating (Pameijer and Stanley, 1988). In a subsequent study, also in primates, crowns were cemented adhering to a clinically standardized cementation protocol, while the cement had a luting consistency (Pameijer et al 1991).

In this study hydraulic pressure during cementation tested the true post-cementation reaction of the pulp. It was clearly demonstrated that, depending on the RDT, GIC caused pulpal inflammation, which rather than subsiding over time, increased in severity. It was this study that resulted in a change in protocol in the ANSI/ADA Specification #41 (2005), which now calls for a pressure insertion technique. Rather than using a laborious indirect technique cementing gold crowns as was used in the aforementioned study, Cl V composite resin inlays are
fabricated and cemented. When using this technique hydraulic pressure is generated that is similar to complete crown cementation.

**RESIN CEMENTS**

As an alternative to acid-base reaction cements, resin cements were introduced in the mid 1980s, which setting reaction is based on polymerization. Resin cements are polymer based to which a filler has been added as well as fluoride. Cement film thickness is not favorable for some, while others have reported 9 µm (Permalute, Ultradent products Inc). One of the first resin cements was marketed by Dentsply/Caulk under the name Biomer, around 1987. In two clinical studies by Pameijer (unpublished data) the cement performed well over a one-year period of evaluation. However, polymer degradation due to hydrolysis, and a lack of bonding to enamel and dentin made the cement unsuitable as a stand-alone luting agent, leading to leakage and failure of the restoration. Incomplete polymerization can lead to irritation of the pulp by unreacted monomers. In combination with a dentin bonding agent, however, many resin cements have superior properties and are frequently used for the cementation of porcelain laminate veneers. What has been described in endodontics as a “monobloc”, the combination bonding agent, resin cement and adhesion to silane treated porcelain offers the same advantages. Nevertheless there is a reluctance on the part of practitioners to do a total etch of complete crown preparations, which is a required step for many bonding agents. Even the self-etching dentin bonding agents are not ideal out of fear for post-operative sensitivity.

**RESIN MODIFIED GLASS IONOMER (RMGI) CEMENTS**

Hybrid cements are indicated to lute crowns and bridges, as well as inlay and onlay restorations. They are essentially hybrid formulations of resin and glass ionomer components. The RMGI cements are relatively easy to handle and are suitable for routine application with metal-based crown and bridgework. However, their use is limited when adhesively cementing ceramics with low retentive surfaces. Adhesion to tooth structure is not strong with these materials.
Additionally, excess water sorption causes swelling and frequently results in ceramic fracture. Commercial examples of the RMGI cements are: RelyX Luting, RelyX Luting Plus (3M/ESPE), Fuji Plus (GC).

In a recent article the biological effects of resin-modified glass-ionomer cements as used in clinical dentistry were described, and the literature reviewed on this topic (Nicholson JW & Czarnecka B, 2007). Information on resin-modified glass-ionomers and on 2-hydroxyethyl methacrylate (HEMA), the most damaging substance released by these materials, was collected from over 50 published papers. These were mainly identified through Scopus. It is known that HEMA is released from these materials, which has a variety of damaging biological properties, ranging from pulpal inflammation to allergic contact dermatitis. These are therefore potential hazards from resin-modified glass-ionomers. However, clinical results with these materials that have been reported to date are generally positive. According to the above authors Resin-Modified Glass Ionomers cannot be considered biocompatible to nearly the same extent as conventional glass-ionomers. Care needs to be taken with regard to their use in dentistry and, in particular, dental personnel may be at risk from adverse effects such as contact dermatitis and other immunological responses. Interestingly enough, RMGI have a better clinical track record than glass ionomer cements.

In general few complaints have been received about postoperative cementation hypersensitivity. Yet, RMGI are in the category of resin cements and water sorption and degradation through hydrolysis are negative features that cannot be ignored or underestimated.

**ADHESIVE RESIN CEMENTS**

The poor adhesive properties of the RMGIs have led to further development of resin-based luting agents, which have resulted in the introduction of adhesive resin cements. These cements do not require pretreatment and bonding agents to maximize their performance. In order for these cements to be self-adhesive new monomers, filler and initiator technology was created. Examples are:
MaxCem (Kerr), RelyX Unicem (3M/ESPE), Breeze (Pentron), Embrace Wet Bond (Pulpdent Corporation) to name a few.

In spite of the numerous research methodologies that are at our disposal conflicting results are frequently reported either using the same technique and tests on the same materials, or using different techniques and testing the same materials. RMGI are such an example. While controversial data has been generated, successful clinical use seems to contradict these findings.

Once again, ultimately a post cementation pulpal reaction under clinical conditions is dependent on three factors:

1. Composition of the cement

2. The RDT – the larger the RDT the less risk of pulp irritation due to the increase in buffering capacity of the fluid in the dentinal tubules.

3. Time elapsed from preparation to moment of cementation – the longer this period the better the pulp has been able to recover from the trauma of preparation.

DEVELOPMENT OF CERAMIR CROWN & BRIDGE

CERAMIR C&B is a new dental luting agent intended for permanent cementation of crowns and bridges, gold inlays and onlays, prefabricated metal and cast post and cores and all-zirconia or all-alumina crowns. The cement is a water-based hybrid composition comprising of calcium aluminate and glass ionomer components that is mixed with distilled water. The material has been demonstrated to be bioactive (Lööf et al, 2007). The setting mechanism of CERAMIR C&B is a combination of a glass ionomer reaction and an acid-base reaction of the type occurring in hydraulic cements. The incorporation of the Calcium Aluminate component gives several unique properties compared to conventional GIC’s. A few features that strongly contribute to the biocompatibility profile of the material are the following. After setting, the material is slightly
acidic, pH ~4. After 1 h the pH is already neutral and after 3-4hrs it reaches a basic pH of ~8.5. This means that the fully hardened material is basic and stays basic throughout its service. This basic pH is the most important prerequisite for the material to be bioactive i.e. creating apatite on its surface when in contact with phosphate containing solutions. The apatite forms during hardening but continues when the hardened material is in contact with phosphate solutions. The basic pH is also an important factor in the biocompatibility profile of the material. The material also produces an excess of Ca$^{2+}$ ions, which also contributes to its bioactivity. The incorporation of Calcium Aluminate fixes the GIC structure and hinders the ionomer glass from continuously leaking over time. CERAMIR C&B has an initial fluoride release comparable to a glass ionomer, which tapers off over time. Unique properties such as apatite formation and remineralization develop quickly and continue to be active.

The main emphasis of this treatise is a review of the tests that were performed to determine biocompatibility and to compare the data with what is currently known of commercially available luting agents. In addition to the review of publications, supportive unpublished data from animals test will be presented.

**CaAl as a Retrograde Filling Material and Restorative**

One of the earliest biocompatibility tests was done on a formula previous to the addition of the glass ionomer component. The material, essentially a CaAl formula, was tested as a restorative material and a retrograde filling material. This has resulted in one publication (Pameijer et al 2004) and one report (Pameijer 2001).

Both studies were carried out in vivo on baboons and favorable results were reported. As a retrograde filling material CaAl did not interfere with the normal healing of bone and may actually have aided in bone repair by the stimulation of osteoblasts. The material can be recommended for retrograde fillings based on its favorable biological properties and insolubility. As a restorative material the material was tested in CI V preparations in baboons and evaluated at three time
periods, 5, 25 and 70 days, according to the ANSI/ADA Specification #41 (2005). Even at the short and intermediate periods of evaluation the material was described as reacting very bland and causing hardly any inflammation.

From these studies it was concluded that the CaAl formula that was tested was biocompatible.

**CERAMIR CROWN & BRIDGE - HYBRID CaAl/GLASS Ionomer**

Subsequently CERAMIR C&B the hybrid CaAl/glass ionomer material was tested as a luting agent for biocompatibility through the evaluation of pulp reactions in *Rhesus Macaques* subhuman primates.

**MATERIALS AND METHODS**

The methodology for this study conformed to the ANSI/ADA: “Recommended Standard Practices for Biological Evaluation of Dental Materials” (2005) which describes in detail the tests that are recommended to determine whether new materials can safely be used in humans. (This test is similar to the ISO 7405; 2008)

For the CERAMIR C&B study 2 *rhesus macaques* were used. After initial sedation with Ketamine HCL (10 mg/Kg body weight) administered IM one peripheral venous catheter was inserted into a hind limb vein and 0.9% NaCl was infused at 5 ml/kg/hr. The animals were further anesthetized with Tiletamine+zolazepam (Telazol) (5 mg/kg body weight) in combination with Fentanyl (0.10 mcg /Kg body weight), injected intramuscularly as needed. The analgesic Buprenorphine (0.01mg/kg) was administered IM to all monkeys at 12-hour intervals for 3 days after surgery. Temperature and vital signs were constantly monitored during all surgeries and postoperatively until full recovery was observed.

Class V inlay preparations were prepared in 7 teeth of one quadrant using a high speed hand piece and copious water cooling. Using saliva as a separating medium, direct composite resin inlays were fabricated. The preparations and
restorations were thoroughly rinsed and dried and disinfected with chlorhexidine 2%. The composite inlays were then cemented with CERAMIR C&B Luting agent mixed in a powder/liquid ratio of 3.2. Excess cement was removed after setting and the inlay finished flush with the tooth surface. The animals were then sacrificed at two time intervals, medium period of 30 days, and a long-term observation of 83 days.

**Euthanasia**

At the designated time periods the animals were perfusion euthanized with 10% neutral buffered formalin, and the jaws dissected and further fixed for 48 hours in 10% formalin followed by standard processing for routine histological evaluation, imbedding in paraffin and finally six micron thick sections were selectively cut and stained with hematoxylin and eosin.

**Results**

Histological data after 30 and 85 days:

All Remaining Dentin Thickness (RDT) values were below 1mm. Superficial and deep inflammation were absent in all but one specimen (0.5⁰). A mean of 1.5⁰ of inflammation on a scale of 0-4⁰ is considered acceptable. Obviously one out of 7 seven samples with 0.5⁰ inflammation and 6 with a 0⁰ score, results in a mean that is well below what is acceptable (1.5⁰ is the acceptable limit).

After 85 days the mean RDT was 0.85mm and no inflammation was observed.

All other parameters were negative (deep inflammatory response, hyperaemia, secondary dentin formation, fibrosis).

To summarize the findings, CERAMIR C&B was remarkable for its lack of irritation. The histological data chart can be seen in appendix 1 and shows that even at a minimum distance from the pulp essentially no irritation was recorded that resulted in inflammation (Appendix 1).
A representative histological slide is shown below. The black arrow indicates the RDT in a straight line from the floor of the preparation to the pulp. In reality the dentinal tubules run at an angle and therefore the distance is greater (in the new guidelines both measurements are recommended to be scored). Another feature attesting to the blandness of CERAMIR C&B that can be seen on the histology slide is and absence of a secondary dentin layer adjacent to the odontoblast opposite the floor of the cavity preparation. Usually when irritation occurs this layer is thicker than elsewhere in the pulp.

Fig. 1. Typical histological features of a pulp after cementation with the cement (CERAMIR C&B). No inflammation or other signs of irritation were observed. [Magnification 100X, Remaining Dentin Thickness 0.6mm (see arrow), H&E staining, 83 days post-operative time interval]
Based on the three biocompatibility studies that have been reported above:

1. CaAl as a restorative material
2. CaAl as a retrograde filling material and
3. Ceramir C&B luting agent,

it can be concluded that CaAl alone and the hybrid formula (Ceramir C&B) meet all biocompatibility requirements as described by the ANSI/ADA Specification #41 (ISO 7405).

FURTHER EVIDENCE

Further evidence of biocompatibility was demonstrated in the following two studies:

1. A 5-year endodontic study in humans in which CaAl was used as a retrograde filling material (Kraft et al 2008) and,
2. Clinical Performance & Post-Operative Sensitivity with a Bioactive Dental Luting Cement- A Prospective Clinical Pilot Study (Jefferies et al 2009)

1. A five-year retrospective clinical study of calcium-aluminate in retrograde endodontics

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Objectives: To conduct a long-term 5-year clinical study using a calcium aluminate based material as root canal sealer and as a retrograde filling material.
The material had been determined biocompatible in a previous study conducted in 2002 and published in 2004. Materials and Methods: This study was conducted on human volunteers who had signed an informed consent form. A total of 18 patients were treated who were diagnosed with either a chronic periapical lesion or who were in need of a retrograde filling in failed endodontically treated teeth. A total of 8 orthograde treatments and 14 retrograde fillings were placed. The orthograde root canal treatments were carried out according to standardized established techniques, using NiTi files and NaOCl. Gutta-percha cones were used in conjunction with the calcium aluminate, which was mixed in a ratio specified by the manufacturer. The retrogrades were carried out using an operating microscope. All teeth had a pre-operative, immediate post-operative and 2 and 5 year post-operative X-rays. Recall visits were scheduled after 2 and 5 years. The success was based on the following scoring system. 1= Complete healing; 2=Incomplete healing, occasional symptoms; 3=Questionable result; 4=Failure, symptoms and no change in periapical radiolucency. Results: After 2 years a 95.4% recall rate was recorded. 21 out of 22 teeth were judged successful, either healed or symptom free. One case failed due to a complicated multi-rooted anatomy. After 5 years, 2 patients had passed away, one tooth had to be extracted and 14 patients were free of symptoms. Conclusions: Orthograde and retrograde endodontic treatments using an experimental calcium aluminate material were judged successful after a 5-year recall evaluation. These clinical results confirmed the above referenced biocompatibility study. Supported in part by Doxa Dental AB.

Based on the performance of CaAl reported in the above-mentioned studies it was hypothesized that a CaAl, or a hybrid formula with glass ionomer could potentially be an effective pulp capping agent. Therefore the following pulp capping study was conducted in Rhesus Macaques. This resulted in the following protocol and observations:
Histopathological Evaluation of three pulp capping agents in subhuman primates, Ca Aluminate, CERAMIR C&B and RelyX Unicem

Introduction

The objective of this project was to determine whether a Ca Aluminate would be a suitable material for pulp capping. Previous studies have determined that Ca Aluminate is kind to the dental pulp and with a pH in the range of 8-10 it would theoretically stimulate odontoblasts and odontoblast-like cells to generate reparative dentin.

MATERIALS AND METHODS

Two animals were used and each material was tested in 7 teeth over 2 time periods.

**Group 1. Ca Aluminate.** Class V cavities were prepared followed by exposure evidenced by bleeding. Following hemostasis with sterile saline and disinfection with Consepsis for 60s, the Consepsis was gently rinsed. Saline was applied again for 60s and dried lightly. Ca Aluminate per manufacturer’s instructions was applied to the exposed pulp. Once the material had set the cavity was restored using an acid etch/bonding agent/composite resin technique.

**Group 2. CERAMIR C&B.** The preparation technique was similar to Group 1. However, CERAMIR C&B was applied to the exposed pulp per manufacturer’s instructions. Once the set was complete the cavity was restored as described for Group 1.

**Group 3. RelyX Unicem.** This group was prepared as described for Group 1 and 2, except RelyX Unicem was used as a capping agent.

Euthanasia was performed after 25 and 85 days.
HISTOLOGICAL INTERPRETATION

Medium period of 25 days

Neither Group 1 nor 2 exhibited predictable bridge formation or attempts at bridge formation. The histological slides showed mostly vital pulps, without a bridge, with particles (Ca aluminate) imbedded in pulp tissue or lining pulp tissues at the exposure site. No encapsulation was observed of the capping material and there appeared to be no attempt at breaking down the material. In other words no macrophages were present. Of note is that no inflammation was observed. This leads to the conclusion that after 25 days the material reacted so bland that it did not stimulate bridge formation, or caused an inflammatory reaction. While the pulps remained vital, preference is given to a material that generates bridge formation thus protecting the underlying pulp with a mineralized barrier.

Group 3, Rely X Unicem caused mostly necrotic pulps. No bridging was observed.

Long Term period of 85 days

Observations for Group 1 and 2 were similar as observed after 25 days, however, Group 2 behaved slightly different.

Here too, the pulps were vital with capping material lining the exposure or being imbedded in pulp tissue without causing an inflammatory reaction or being encapsulated (Except tooth 2.7 of the group with the Ceramir C&B material) However in Group 2 a few bridges were observed, in contrast to the teeth in Group 1. The difference in composition between Group 1 and 2 is mostly based on the incorporation of a glass ionomer component. Apparently the stimulating effect of the glass ionomer component was conducive to promoting bridge formation in some teeth, albeit not consistently and at a rather late time interval. Materials such as a calcium hydroxide or MTA form thin bridges after 25 days in sub human primates. The bridges observed for Ceramir C&B were thin and
porous and do not compare favorably to bridges formed by calcium hydroxide or MTA, of which especially the latter can form a bridge resembling dentin. What differed when comparing Groups 1 and 2 was the presence of secondary dentin in the teeth of Group 2. This was present not in the form of a bridge but lined the walls beyond the exposure extending into deeper portions of the pulp space. Apparently the glass ionomer component had a stimulating action, however not enough to form a bridge, except in a few teeth.

Group 3, as expected because of the 25-day data, after 85 days no bridge formation was seen and the pulps were either necrotic or totally washed-out in the histology sections.

**Summary**

Calcium aluminate alone and CERAMIR C&B acted so bland on exposed pulps that no bridge formation was observed with a few exceptions during the long-term period of observation. On the one hand this data confirms the previous study in which CERAMIR C&B was tested in indirect pulp capping as a luting agent as well as the clinical feed back from patients in the Kornberg/Temple study (presented next), however, for a pulp capping material to be effective it needs a certain amount of stimulating (irritating) effect to activate pre-odontoblasts or odontoblast-like cells to generate a bridge. It is a bridge that will shield the underlying pulp from the cavity and protect it.

RelyX Unicem as a pulp capping material is contraindicated.
Figure 1. Group 1 – 85 days. At the right bottom is the exposure of the pulp with black granules (capping material - CaAL). The capping material is also present in the actual pulp. Top of slide. (Tooth 1.1; 40X H&E).
Figure 2. Group 1 – 85 days. Higher magnification of Figure 1 showing Ca aluminate capping material in pulp tissue. No inflammation. The material is dispersed in connective tissue of pulp without causing inflammation. (Tooth 1.1; 100X, H&E)
Figure 3. Group 1 – tooth 1.5, 85 days. This is an example of the tooth that had a bridge, but also had a massive amount of secondary dentin extending into the pulp. The capping material is at the bottom of the slide (black). (40X, H&E)
Figure 4. Higher magnification. This is a thin bridge after 85 days in Group 2 with extensive secondary dentin extending into the deeper pulp. There are also remnants of the capping material in the pulp tissue itself. (200X, H&E)
Figure 5. Group 2 after 85 days. Note poor quality bridge (porous), massive secondary dentin and remnant of capping material at exposure. This much secondary dentin is most likely due to the ionomer component. The pulp is vital. (40X tooth 1.3, H&E)
Figure 6. Group 2, tooth 2.7. An example after 85 days of a tooth without a bridge and a superficial to deep grade 3 inflammatory reaction. The deeper pulp is still vital, however. Inflammation was most likely caused by bacterial leakage.
POST CEMENTATION HYPERSENSITIVITY FROM DATA OF A CLINICAL PILOT STUDY AT KORNBERG/TEMPLE UNIVERSITY.

The data of this study will be reported in a manuscript that has been submitted for publication. Therefore, for this manuscript only the post cementation hypersensitivity observations will be discussed.

Methods and Materials:

This study examined the performance of CERAMIR C&B after cementation of high-gold alloy and porcelain-fused-to-metal (PFM) single crowns and bridges. A total of 38 crowns and bridge abutments were cemented in 17 patients, 31 were on vital, 7 on non-vital teeth. Six (6) were bridges with 14 abutment teeth (12 vital/2 non-vital). Post-cementation sensitivity; was evaluated as categorical and by means of a VAS (Visual Analog scale). A one-week post-operative telephone call recorded subjectively the patients’ comfort level. Results: 13 of 17 patients reported no post-cementation sensitivity after 7 days. Four reported a low-grade sensitivity. All 17 patients were seen for recall examinations at 30 days and 6 months. Of the 4 sensitivity cases, three (3) were related to hyper-occlusion, which disappeared spontaneously after adjustment. One case was due to post-cementation pressure from a 3-unit bridge, which disappeared without intervention. Average VAS score for tooth sensitivity decreased from 7.63 mm at baseline to 0.44 mm at six month recall. Conclusion: After 6 months CERAMIR C&B performed favorable as a luting agent for permanent cementation. Post cementation hyper sensitivity appeared not be an issue. Non-solicited comments by patients were unanimously favorable. Patients that had prior experience with cementation of crown and bridgework preferred CERAMIR C&B.

DISCUSSION

Luting agents for permanent cementation of crown and bridge restorations have to meet many requirements before they can safely be used in humans. ANSI/ADA (ISO) specifications provide a road map outlining tests that are
required in order to meet these requirements. Physical properties such as hardness, flexural strength, solubility, etc. are extremely important but if the material lacks biocompatibility, excellent physical properties are meaningless. Therefore the main objective of this treatise is a review of the biocompatibility tests that have been conducted on Ceramir C&B and to compare the data to commercially available materials that are currently being used. As far as a patient is concerned, a luting agent that causes no post-cementation hypersensitivity is highly desirable. Dentistry is still perceived by many, as being “a painful experience” and every effort on the part of the dentist should be made to make the treatment as comfortable as possible. One such step is the final cementation of a fixed crown and bridge work, whether a single unit or a bridge. A restoration may be esthetically pleasing and functional at the time of cementation, but a sequel of post-cementation hypersensitivity can generate questions from the patient as to the success of the treatment, time from the practitioner to address the problem and possible complications that require further treatment. Extra visits may be required, all of which constitute a loss of time and money not only for the practitioner, but also for the patient. Although Ceramir C&B cannot boast a record of clinical success based on a larger number of clinical cases, animal data and clinical experience gained from a pilot study at the Kornberg School of Dentistry/Temple University are most encouraging and promising.

Although zinc phosphate cement is still the “gold standard”, advances in luting agents over the last 30 years have produced new luting agents, which most likely will eventually replace zinc phosphate cement all together. If we look at the three acid-base reaction cements, zinc phosphate, polycarboxylate and glass ionomer cement and compare them to Ceramir C&B, two of the three cements (zinc phosphate and glass ionomer cements) have known and reported post-cementation hypersensitivity problems. This has frequently resulted in the need for root canal treatment after permanent cementation of the fixed unit. Typical complaints of a patient are sensitivity to hot and cold and chewing. Assuming the occlusion is not a causative factor, the only explanation is irritation caused by the cement. Clearly, if the patient was comfortable during the interim with a
provisional restoration the problems point towards the irritation caused by the permanent cement. Mostly the pain will subside, more so with zinc phosphate cement than glass ionomers, but this may take weeks or more and the practitioner can only guess at the ultimate outcome. In vivo research has shown that indeed post cementation with zinc phosphate cement and glass ionomers cause pulpal irritation, which would explain the complaints from patients (Pameijer et al 1991).

As pointed out before, although polycarboxylate cements are kind to the pulp, they do not have the physical properties that make them ideal for permanent cementation.

RMGI also have a record of occasional post cementation hypersensitivity due to their questionable biocompatibility (Nicholson and Czarnecka). Especially unreacted monomers are highly toxic and irritating.

Little clinical data is available on self-adhesive cements. Empirical data suggest that they are tolerated by the pulp, perhaps based on the change in acidity upon complete set, to a basic material.

Ceramir C&B has generated histological data from 3 in vivo studies in subhuman primates and subjective data supported by X-rays from one clinical study in humans that unequivocally have demonstrated the material to be extremely bland and nonirritating. While patient complaints are subjective, histological data provides undisputable evidence as to the effect of a material on the pulp or peri-apical tissues. Compared to other luting agents Ceramir C&B stands out. The histological evaluations and clinical feed back from the human pilot study provide ample evidence as to its non-irritating properties. Given the fact that remaining dentin thickness is often difficult to assess in full-coverage preparations for indirect restorations (pin-point or “functional” pulpal exposures can be present in a preparation), a cement with documented improved pulpal biocompatibility may well address an important, unmet, clinical need.
CONCLUSIONS

The test results of CaAl as a single component and CERAMIR C&B as a hybrid luting agent are very favorable. The several animal studies combined with clinical data retrieved from ortho and retrograde root canal fillings as well as clinical data from a clinical pilot study corroborate each other very well. Each study arrived at the same conclusion, CERAMIR C&B has exceptional biocompatibility properties. CERAMIR C&B appears to react very bland if not to say not to react with the pulp after cementation compared to some currently used commercial luting agents. However, the data is limited and was collected from tightly well-controlled studies. The true test will be the use by general practitioners and specialists. As with all new materials, long-term data needs to be collected, preferably from prospective studies.
REFERENCES


Pameijer CH. Histopathological evaluation of Doxadent restorative material. Unpublished data.


