A two-year clinical evaluation of a new calcium aluminate cement in Class II cavities

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A calcium aluminate cement (Doxa Certex, Uppsala, Sweden) has recently been developed intended for use as direct restorative filling material for posterior restorations. The material is inorganic and non-metallic and the main components are CaO, Al_2O_3, SiO_2, and water. The aim of this study was to evaluate intra-individually the experimental calcium aluminate cement (CAC) and a resin composite (RC) in Class II restorations. Each of 57 participants received at least one pair of restorations of the same size, one CAC and one RC (Tetric Ceram). Sixty-one pairs were performed. The restorations were evaluated clinically, according to slightly modified USPHS criteria, at baseline, after 6 months, 1, and 2 years. One-hundred-and-twenty restorations were evaluated at 2 years. Postoperative sensitivity was reported for 5 restorations (2 RC, 3 CAC). Significantly better clinical durability was shown for RC. Five non-acceptable CAC restorations (8.2%) were observed at 6 months, 10 CAC (16.7%) and 2 RC (3.3%) at 12 months, and 11 CAC (18.3%) at 24 months. This resulted in a cumulative failure frequency of 43.3% for the CAC material and 3.3% for the RC material. Main reasons for failure for the CAC were partial material fracture (7), cusp fracture (5), and proximal chip fracture (6). The CAC showed a non-acceptable clinical failure rate for Class II restorations, probably caused by its difficult handling and low mechanical properties. □ *Cement; ceramic; clinical; composite resin; dental restorations*

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A growing demand for esthetics and concern about the biocompatibility of amalgam have increased the use of posterior tooth-colored restorations. Despite the popularity of resin composites (RC) and improvements obtained in recent years, problems related to polymerization shrinkage and biocompatibility can still be seen. To achieve high mechanical properties, the RC should obtain a high degree of conversion after polymerization. However the resulting polymerization stress may cause debonding from the cavity walls, cohesive fractures of the restoration material or tooth structure, and decrease the durability of the restoration. A non-optimal cured resinous material may cause adverse reactions, clinical or subclinical, which can be toxic and/or allergic (1–3). An increasing number of published reports describe occupational skin reactions among dental personnel caused by the uncured acrylic resins of the dental resinous materials (4–7). The range of dental materials is now very diversified with the introduction of different intermediary materials between RC and glass ionomer cements. However, the use of non-resinous alternative materials such as the glass ionomer and glass cermet cements is limited to non-stress-bearing areas because of relatively poor mechanical properties.

Recently, a new calcium aluminate cement (CAC) has been developed in Scandinavia intended to be used in Classes I, II, and V direct restorations (8). The material is claimed to be a "bioceramic" alternative to amalgam and resin composite. The material is inorganic and non-metallic and thus falls within the definition of a ceramic material. It is based on two essential constituents, alumina (Al_2O_3) and calcium oxide (CaO), and small amounts of ZrO_2, Fe_2O_3, and SiO_2. Fused together at high temperature, small particles of calcium-aluminates are formed which have a cement-forming potential. To start the hydration reaction a calcium aluminate tablet is brought into contact with the supplied liquid, which contains water and small amounts of Li^+ as accelerator. An acid-base reaction is initiated during which water acts as a weak acid and calcium aluminate dissolves to form Ca^{2+}, $Al(OH)_4^-$ and OH^-. The solutes precipitate to form a gel. Gradually, the amorphous gel changes into a crystalline phase of mainly katoite $[(CaO)_3(Al_2O_3)(H_2O)_6]$. The post-set hardening takes several days.

No clinical evaluations of the material have been reported. The hypothesis to be tested was that posterior restorations of the CAC showed similar durability as restorations of a commercial resin composite. The aim of this study was to compare, intra-individually, Class II restorations of the CAC with resin composite restorations in a 2-year clinical follow-up.

Materials and methods

During the period November 1999 to April 2000, every patient who, at the yearly examination of the author's university clinic needed similar-sized Class II restorations, was invited to join the study. All the patients invited

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participated in the study. Each patient provided informed consent to participate in the study, which was approved by the ethics committee of the University of Umeå. No patient was excluded because of caries activity, periodontal condition, or parafunctional habits. In 57 patients (28 women and 29 women) with a mean age of 51.7 years (range 30–85 years), a total of 122 posterior restorations were placed. All restorations were replacements of Class II amalgam fillings for secondary caries, fracture, or "non-amalgam" reasons. Each patient received, at random, at least two restorations of the same size. One experimental calcium aluminate filling (CAC; Doxa Certex, Uppsala, Sweden) and one control RC placed if possible in the same type of tooth in order to make an intra-individual comparison possible. All teeth were in occlusion and had at least one proximal contact with an adjacent tooth. One dentist (JvD), well experienced with both materials, placed all pairs of restorations. The 61 Class II CAC restorations were situated in the lower arch in 19 premolars and 13 molars; in the upper arch in 17 premolars and 12 molars. The RC was a hybrid small-particle resin composite with an average particle size of 1 μm (Tetric Ceram, Vivadent, Schaan, Liechtenstein). The 61 Class II RC restorations were situated in the lower arch in 17 premolars and 17 molars, in the upper arch in 13 premolars and 14 molars. The material contained silanized barium glass (49.5w%), mixed oxides (5w%), silanized barium aluminofluorosilicate glass (5w%), silanized high-dispersed silica (1w%), and ytterbiumtrifluorid (17w%). The monomers consisted of Bis-GMA (8.5w%), urethane dimethacrylate (7.8w%) and TEGDMA (4.4w%). The CAC cavities were prepared with slightly conical cavity walls. Fifty percent of the proximal cervical margins were situated apical to the cement-enamel junction. No bevelling of the cavity margins was performed. The operation field was isolated with cotton rolls and a saliva suction device. After placement of a thin metallic matrix band and wooden wedges the cavities were sprayed with water. The materials were applied according to the instructions of the manufacturers.

Calcium aluminate cement

No conditioning of the cavity or base material was recommended by the manufacturer. One CAC tablet at a time was partially immersed in and allowed to absorb the liquid supplied. Subsequently, the tablet was totally immersed in the liquid, and then blot dried on a piece of absorbant tissue, placed in the cavity, and condensed with a stopper under maximum hand pressure. The procedure was repeated with new tablets until the cavity was filled with excess. The restorations were formed directly after initial hardening, when the cement permitted carving. The patients were requested to be careful during the first 24 h concerning occlusal loading of the restorations. The restorations were finished after at least 2 days with fine finishing diamonds and polishing stones and strips (Shofu finishing points, Brownie/Greenie, Shofu Inc., Kyoto, Japan).

Resin composite

The RC cavities were acid-etched with 35% phosphoric acid (Ultra-etch, Ultradent Products Inc., South Jordan, UT, USA). The gel was first placed on the enamel, while the dentin part of the cavity was conditioned during the last 5 s of the 20-s etching time. The cavity was then thoroughly rinsed with air-water spray for 15–20 s and carefully dried, allowing a wet bonding technique. The primer (Excite, Vivadent) was applied for 20 s and then carefully air blowed to remove the primer's ethanol. A second layer primer was applied, directly followed by air blowing and 10 s light curing. The RC was applied in 3 mm layers maximum. The first layer in the proximal box was 2 mm. Each layer was light-cured for 60 s with a regularly controlled light curing unit (Luxor, ICI, Macclesfield, UK; 350 mW/cm^2). In none of the restorations was a $Ca(OH)_2$ base placed. The restorations were finished with fine diamond or carbide finishing burs to remove gross excess, followed by Shofu finishing points and strips. The final finishing was performed after checking occlusion/articulation.

Evaluation

Each restoration was evaluated after final finishing (baseline) and after 6, 12, and 24 months. A slight modification of the USPHS (United States Public Health System) criteria was used to evaluate the quality of the restorations (Table 1; 9) of two calibrated observers. Disagreement was resolved by consensus. The evaluated characteristics of the restorations were described by descriptive statistics, using frequency distributions of the scores. Postoperative sensitivity was noted (10). Bitewing radiographs were taken of all restorations and in addition color slides were made of selected cases. The caries risk for each patient at baseline was estimated by the treating clinician by means of clinical and socio-demographic information routinely available at the annual clinical examinations, e.g. incipient caries lesions and former caries histories (11–13).

Statistical analysis

The evaluated characteristics of the restorations, including the number of non-acceptable restorations (failures), are described by descriptive statistics by using frequency distributions of the scores. Durability of the two restorative techniques was compared intra-individually and tested using the Friedman two-way analysis of variance test (14). The null hypothesis was rejected at the 5% level.

Table 1. Criteria for direct clinical evaluation (modified USPHS criteria; van Dijken, 1986)

Category	Score: Acceptable	Score: Unacceptable	Criteria
Anatomical form	0		The restoration is contiguous with tooth anatomy
	1		Slightly under- or over-contoured restoration; marginal ridges slightly undercontoured; contact slightly open (may be self-correcting); occlusal height reduced locally.
		2	Restoration is undercontoured, dentin or base exposed; contact is faulty, not self-correcting; occlusal height reduced; occlusion affected.
		3	Restoration is missing partially or totally; fracture of tooth structure; shows traumatic occlusion; restoration causes pain in tooth or adjacent tissue.
Marginal adaptation	0		Restoration is contiguous with existing anatomic form, explorer does not catch.
	1		Explorer catches, no crevice is visible into which explorer will penetrate.
	2		Crevice at margin, enamel exposed.
		3	Obvious crevice at margin, dentin or base exposed.
		4	Restoration mobile, fractured or missing.
Color match	0		Very good color match.
	1		Good color match.
	2		Slight mismatch in color, shade or translucency.
		3	Obvious mismatch, outside the normal range.
		4	Gross mismatch.
Marginal discoloration	0		No discoloration evident.
	1		Slight staining, can be polished away.
	2		Obvious staining cannot be polished away.
		3	Gross staining.
Surface roughness	0		Smooth surface.
	1		Slightly rough or pitted.
	2		Rough, cannot be refinished.
		3	Surface deeply pitted, irregular grooves.
Caries	0		No evidence of caries contiguous with the margin of the restoration.
		1	Evidence of superficial caries, no operative treatment necessary.
		2	Caries is evident contiguous with the margin of the restoration, operative treatment indicated.

Results

All except one patient with 2 restorations (1 CAC and 1 RC), a drop-out because of prosthetic bridge therapy after 1 year, were evaluated during the 2-year period. Post-operative sensitivity was reported by 4 of the participating patients. Two RC molars and 3 CAC restorations were sensitive for occlusal forces and/or cold-air. The symptoms diminished after occlusal adjustment but were slightly left after 1 year for 1 of the CAC restorations. The anatomical form, marginal adaptation, and surface roughness scores of the restorations at the different recalls are given in Table 2. Because of its high opacity for all restorations the CAC material showed a score 4 color match. The RC showed a 100% acceptable color match, where the score 2 frequency increased from baseline 2.9% to 8.7% at 2 years. It was not possible to observe marginal discoloration contiguously with the CAC because of the opaque character of the cement. At 2 years, slight and obvious marginal discoloration scores contiguous with the RC restorations were observed in 4.2% and 2.8%, respectively.

Non-acceptable restorations and the reasons for failure are indicated in Table 3. Five non-acceptable CAC restorations (8.2%) were observed at 6 months, 10 CAC (16.7%) and 2 RC (3.3%) at 12 months, and 11 CAC (18.3%) at 24 months. This resulted in a significantly

Table 2. The scores of the evaluated criteria for the Class II restorations at baseline, 6, 12, and 24 months (%). CAC = experimental calcium aluminate cement; RC = resin composite

			0	1	2	3	4
Anatomical form*	CAC	Baseline	55.7	44.3	0	0	
		6 months	59.0	32.8	3.3	4.9	
		12 months	40.0	35.0	13.3	11.7	
		24 months	31.7	25.0	16.7	26.7	
	RC	Baseline	85.3	14.7	0	0	
		6 months	93.4	6.6	0	0	
		12 months	90.0	6.7	0	3.3	
		24 months	88.4	8.3	0	3.3	
Marginal adaptation*	CAC	Baseline	91.8	4.9	3.3	0	0
		6 months	75.4	14.8	4.9	1.6	3.3
		12 months	61.7	18.3	10.0	1.6	8.4
		24 months	43.3	18.3	11.7	10.0	16.7
	RC	Baseline	96.7	3.3	0	0	0
		6 months	83.6	16.4	0	0	0
		12 months	83.3	13.3	1.7	0	1.7
		24 months	78.3	18.3	1.7	0	1.7
Surface roughness	CAC	Baseline	86.9	13.1	0	0	
		6 months	46.6	51.7	1.7	0	
		12 months	24.1	60.4	13.8	1.7	
		24 months	19.2	57.3	19.2	4.3	
	RC	Baseline	96.7	3.3	0	0	
		6 months	85.2	11.5	3.3	0	
		12 months	79.7	13.6	6.7	0	
		24 months	77.6	15.5	6.9	0	

* Cumulative scores.

Table 3. The number of non-acceptable restorations and reasons for failure at the 6, 12, and 24 month recalls

	6 months		12 months		24 months	
	CAC	RC	CAC	RC	CAC	RC
Partial fracture	1		3		3	
Cusp fracture	1		1	1	4	
Proximal chip fracture	2		3		1	
Erosion	1		2		2	
Endodontic treatment				1	1	
Caries and fracture			1			
Total no. failures	5	0	10	2	11	0
% failures	8.2	0	16.7	3.3	18.3	0

higher cumulative failure frequency of 43.3% for the CAC material compared to 3.3% for the RC material ($P <$ 0.001). Main reasons for the failure of the CAC were partial material fracture (7), cusp fracture (5), and proximal chip fracture (6). Two restorations were treated endodontically (1 CAC and 1 RC) due to pulpitis symptoms. One CAC restoration showed deep secondary caries in combination with a partial fracture. A prediction of the caries risk showed that 11 (19.2%) of the patients were considered as high-risk patients. Owing to the short follow-up and the low secondary caries frequency observed, no further analysis was performed. Five restorations showed extensive erosion of the CAC material. Small defects, but still acceptable, in the form of marginal ridge chip fractures, were observed in another 12 CAC restorations.

Discussion

Over the years, dental filling materials with different formulations, such as macrofilled, microfilled, and hybrid RC, conventional and resin modified glass ionomer cements, glass cermet cement, polyacid-modified resin composites, and ormocers have been introduced onto the dental market. Changes in the characteristics of some of these materials have been made and several new products, such as high-density glass ionomers and "packable" RC, were introduced with claims that the materials were able to condensate like amalgam. However, because of their plasticity, development of RC with a condensability approaching that of amalgam was not reached (15, 16). The investigated calcium aluminate cement belongs to a new group of restorative materials which have not been used in operative dentistry. The material received CE approval 2001, which, however, does not imply clinically acceptable mechanical properties or a good durability. It was therefore important that the properties of the material were highlighted. The surface roughness, biological interaction with oral tissues, and the mechanical properties of the CAC material were recently evaluated (8, 17, 19). The flexural strength of CAC reached only about 20% of the strength of the polyacid-modified resin composite and the resin composites, materials that are commonly used for Class II restorations, and similar to that of zinc phosphate cement.

Laboratory investigations have served as the screening model before human clinical trials, although long-term clinical trials are considered the ideal method for validating the quality of new materials and systems. However, factors such as patient compliance, recall failure, and operator variability render these studies complicated as well as time-consuming to complete. In the present study we had a recall rate of 98.2%.

The durability of the CAC differed significantly from the RC restorations. The null hypothesis was therefore not accepted. The dramatically lower flexural strength of the CAC was manifested in the present study in a relatively high incidence of large chip and bulk fractures. A cumulative 2-year failure frequency of 43.3% was observed for the CAC compared to 3.3% for the RC material. The failure rate of Class I CAC restorations in a parallel ongoing study is 10% and for Class I RC restorations 0%. The two materials investigated differed concerning preservation of the tooth substance. The retention of RC is based on micromechanical entanglement with conditioned tooth substance, while the CAC material shows no adhesive properties and retention is the same as for amalgam macro-mechanically. High annual failure rates have been reported for other materials with inadequate mechanical properties in stress-bearing areas, like the glass ionomer and glass cermet cement restorative materials. Hickel et al. (21) reported 3.3% and 14.3% annual failure rates for Classes I and II restorations, respectively. Smales et al. (22) observed 14.4% failure rate for Class I restorations and Krämer et al. (23) 2.6% and 7.1% annual failures for Class I and II restorations, respectively. Most restorations failed, like for the CAC, because of bulk fracture due to their poor mechanical strength.

Over the years, several dental materials have been marketed which have not fulfilled the marketing claims in clinical follow-ups (10, 21–25). In June 1993, the EU Counsel Directive 93/42 EEC concerning medical devices was published (26). Medical devices are products that largely achieve their effect by physical means. They are classified in three classes and dental filling materials belong to Class IIa. All materials used in dental offices after 14 June 1998 should have a CE (Communauté Europeéne) marking. A CE marking indicates medical device conformity with the provisions of the Directive to enable them to move freely in all EC member states. For conformity assessment procedures for Class IIa devices the intervention of a notified body is compulsory at the production stage. Since the introduction of CE, marking for dental materials, claims for guidelines of clinical acceptance, like the provisional and full approval criteria of the ADA or the modified criteria of NIOM for posterior restorations, have more or less disappeared in Europe. The dental profession probably assumed that CE approval would replace the clinical claims of these guidelines. Unfortunately, the

directive for medical devices mostly concerns general requirements such as design, construction, and manufacturing of the device but no direct clinical evaluation requirement is included. However, the annex of the Directive also states that the manufacturers still have a clinical responsibility after obtaining CE marking. It is prohibited to place medical devices on the market if there are founded reasons for suspecting that they compromise the safety and health of the patient when properly applied. Failure of dental restoratives will probably not influence general health, but degeneration and material and/or tooth fracture will certainly compromise dental health, which is unfortunately not included in the directive requirements. The annex of the Directive also states that it is prohibited to place medical devices on the market if these are claimed to have a performance they do not have or that the deceptive impression is given that application of the given medical device is certain to be successful and/or that no harmful effects result when the device is used as intended or used for a prolonged period of time. The results of the present and the above-mentioned recently published follow-up studies indicate clearly the necessity to include clinical evaluation of new restoratives in the CE marking if medical devices are to provide dental patients with a high level of protection.

Good handling characteristics of dental materials are an important clinical property toward obtaining homogeneous restoratives (27). Handling the CAC was difficult. After initial crushing of the tablet, the material took on a crumbly and difficult to condensate character. In a scanning electron microscope investigation of the interfacial adaptation of the CAC material, an experienced operator familiar with the cement during a shorter period received significantly worse adaptation compared to an operator well familiar with the CAC (28). A high frequency of less packed material with larger air pores was observed in the Class II restorations of the first operator. It can be expected that difficulties obtaining a correct material consistency among less experienced operators will be higher. Usually, this will compromise the properties of the material. The operator who placed all restorations in the present study had long experience in handling the CAC and optimal handling of the material was performed. It has been stated that clinical studies have generally been carried out under optimal conditions, and that reported longevity is unlikely to be achieved in routine general dental practice. A higher failure rate of the CAC, as obtained in the present study, may therefore be expected in a group of operators with a high variability in material handling and less experience.

Cusp fracture of posterior teeth is a common phenomenon in dental practice (29, 30). There are few reports in the literature describing the occurrence of tooth fractures (31–33). Cusp fractures are a significant dental health problem, in many cases caused by the conventional preparation technique for amalgam restorations with large undercuts in posterior teeth and designed to obtain macromechanical retention (34–36). Mastication has been reported as the most frequent cause of cusp fracture, although in one-third of cases the cause was unknown (29). In restored teeth, cuspal deflection under a continuous occlusal loading of the weakened cusps will result in horizontal crack formation and cusp fractures (34, 35). Adhesive bonding of RC to the cavity walls, in combination with the new amphiphilic bonding systems, has reduced this problem (37, 38). This was confirmed by the frequency of cusp fractures in the RC group in the present study, only one RC compared to 5 in CAC teeth. In the clinical evaluation of a so-called "smart" RC, a high frequency observed cusp fracture was reported, probably caused by expansion of this RC (10). RC in general absorbs low amounts of water for up to several months. Recently, a high frequency of enamel fractures perpendicular to the margins of 1-month-old Class II CAC restorations was reported in a scanning electron microscope investigation of the cement (28). It was suggested that a high expansion of the cement causes these enamel fractures, which probably also contributed to the cusp fractures observed in the present study.

It can be concluded that the CAC showed a non-acceptable clinical failure rate for Class II restorations, probably caused by its difficult handling and poor mechanical properties.

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