Effect of a novel ceramic filling material on plaque formation and marginal gingiva

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The aim of this clinical investigation was to evaluate a novel ceramic (CF) filling material (DoxaDent) compared to resin composite (RC) and enamel in regard to plaque formation and gingival inflammation. The CF material is inorganic, non-metallic, and contains calcium aluminate, silicate, and water. To make intra-individual comparisons possible, each participant had at least one set of three test surfaces: two Class V restorations with subgingival cervical margins (one of the novel CF material and one of a hybrid RC) and one non-filled enamel surface (E). The amounts of plaque, gingival crevicular fluid, and clinical signs of gingival inflammation were intra-individually compared in 20 sets of the three test surfaces. In a cross-sectional study (CSS), the effect of oral hygiene on plaque formation and gingivitis around the surfaces was evaluated. In a following 10-day experimental gingivitis study (EGS), plaque formation and the induction of gingivitis during refrain from oral hygiene was compared. In the CSS, no significant differences were found between the surfaces in terms of amount of plaque and degree of gingival inflammation. At the end of the EGS the restorative materials showed a significantly higher amount of plaque (CF versus E, $P = 0.014$; RC versus E, $P = 0.034$), but no significant differences were found in degree of gingival inflammation. In conclusion, the ceramic filling material was comparable to RC regarding plaque formation and gingival inflammation with customary oral hygiene. With neglected oral hygiene, significantly less plaque growth and a non-significant tendency toward lower amounts of gingival crevicular fluid were observed on enamel surfaces. □ *Biofilm; cements; clinical trials; composites; gingivitis*

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The demand for alternatives to amalgam restorations has resulted in an increased search for new biocompatible restorative materials. Resin composites (RC) have become a popular alternative owing to their esthetic properties and tooth substance saving preparation technique. Polymerization shrinkage causes marginal defects and gaps which may harbor microbial plaque (1–5). Partly due to incomplete monomer-polymer conversion, numerous substances are released from the set restoration into the adjacent tissues and oral cavity (6). Acrylic resins, as well as initiators, activators, and stabilizers, have the potential to induce cytotoxic and/or contact allergic reactions (7–10).

Dental ceramics are chemically stable in the oral environment and are considered biocompatible (11–13). A lower tendency to accumulate plaque on ceramic crowns has been reported (14–16). However, heat-treated ceramics are brittle and an adhesive luting technique, preferably with RC, is necessary (17). A novel filling material has recently been developed and is marketed by the manufacturer as a 'bioceramic' restorative. The material is inorganic and non-metallic. It contains calcium aluminate, silicate, and water. Like amalgam, the calcium aluminate cement is inserted directly and condensed into the cavity. It is suggested for use in posterior and cervical cavities (18).

The aim of this clinical investigation was to evaluate a novel ceramic filling (CF) material in comparison with RC and enamel with regard to plaque formation and gingival inflammation.

Materials and methods

During a 6-month period, all recall patients who participated in an ongoing clinical follow-up of Class V restorations of the CF were evaluated. Individuals taking antibiotics, anti-inflammatory drugs, and/or oral antimicrobial agents within the period 3 months prior to the start of the study were not included. Fifteen individuals (11 M and 4 F, mean age 63.0 years, range 40–85) who fulfilled the inclusion criteria agreed to participate in the study. To make intra-individual comparison possible, each participant had at least one set of three test surfaces: two Class V restorations (one of the novel CF material [CF; DoxaDent, DoxaCertex, Uppsala, Sweden] and one of a mid-filled hybrid RC) and one non-filled enamel surface (E). Twenty sets of the three test surfaces were included.

The evaluation included a cross-sectional study (CSS), followed by a 10-day experimental gingivitis study (EGS) (19). The three surfaces selected were situated close to each other in the same dental arch in the premolar-molar or in the premolar-cuspidate region. They were situated buccally in 18 sets and lingually in 2 sets. The restorations had subgingivally located cervical margins and had to be at least 3 months old and well polished. Surfaces with an

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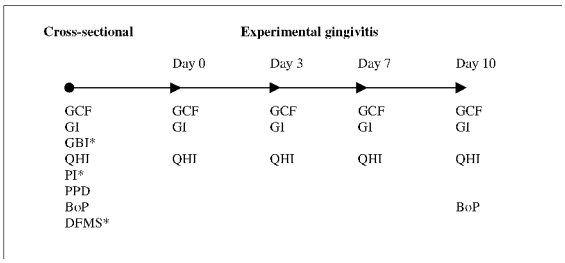

Fig. 1. Distribution of the clinical parameters included during the study period. Sampling of gingival crevicular fluid flow (GCF), gingival index according to Löe (GI), gingival bleeding index (GBI), modified Quigley & Hein's plaque index (QHI), plaque index according to Lenox & Kopzcyk (PI), bleeding on probing (BoP), probing pocket depth (PPD). Descriptive variable of oral characteristics (*).

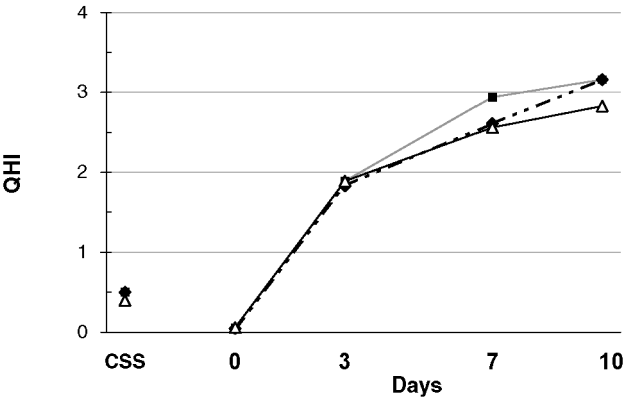

Fig. 2. Mean modified Quigley Hein plaque index values (score 0–5) of the ceramic filling material (◆), resin composite (■), and enamel (△) in the cross-sectional study (CSS), and on days 0, 3, 7, and 10 of the experimental gingivitis study.

adjacent probing pocket depth exceeding 3 mm were not included. The individuals gave informed consent to participation and the ethics committee of the University of Umea approved the study.

Oral and general characteristics

At the start of the study, the oral hygiene regime and different oral index of participants was recorded. Three different oral hygiene regimes could be found: 8 participants used only daily tooth brushing with dentifrice, 6 also used proximal hygiene twice a week, and 6 used daily proximal hygiene. The Lenox & Kopczyk plaque index, recorded in each dentition, ranged between 18% and 80% (mean 27%), and the Ainamo & Bay gingival bleeding index ranged between 0% and 18% (mean 5%) (20, 21). The DMFS index ranged between 35 and 106. Four participants, who represented one intra-individual comparison set each, were smokers (>10 cigarettes a day).

Cross-sectional study

The effect of participants' oral hygiene regimes on plaque removal and on gingival state around the test surfaces was evaluated. While participants were requested to carry out their customary oral hygiene, no performance of oral hygiene was allowed in the 2 h prior to assessment.

The test surfaces were evaluated for clinical indices of plaque and gingivitis, and by collection of gingival crevicular fluid (GCF) in the following order (Fig. 1). Before collection of GCF, gingival redness and swelling were estimated with the gingival index (GI) according to Löe (22). The experimental area was carefully sprayed with water to remove saliva and was isolated with cotton rolls. A saliva ejector was used. The site of collection was gently dried using an air syringe for 10 sec. A paper strip (Periopaper, ProFlow, Amityville, NY, USA) was inserted at the orifice of the gingival crevice until mild resistance was felt and left there for 30 sec. Fluid volume on the strip was immediately measured with a Periotron 6000 (Periotron, Pro Flow) calibrated as described by Deinzir et al. (23). The amount of plaque was determined with a disclosing solution and scored ranging from 0 to 5 according to the Quigley-Hein plaque index (QHI) modified by Turesky et al. (24). Gingival bleeding was assessed with the GI (22). Bleeding on probing (BoP) was recorded within 30 sec of insertion of a periodontal probe (Hu-Friedy, PCP 11) to the bottom of the gingival crevice.

After the examination, all teeth were polished. The participants were started on an oral hygiene regime to eliminate all marginal inflammation in the experimental region until the QHI and the GI approached zero.

Experimental gingivitis study

The participants were then asked to refrain from oral hygiene during the following 10 days in order to allow plaque to accumulate and to induce gingivitis (25, 26). No polishing was done at the start of the study. The QHI, GI, and GCF volumes of each surface were measured on days 0, 3, 7, and 10 (Fig. 1). BoP was recorded on days 0 and 10. After measuring, non-test surfaces in the opposite jaw were polished, except for baseline.

Statistical analyses

The data were processed using the SPSS (Statistical Package for the Social Sciences, version 10.0). Frequency distribution of the test values was described. GCF volumes were averaged for each category (CF, RC, E) and the differences were tested with the paired t test. The Wilcoxon signed-rank test was used to calculate the significance of intra-individual differences between the surfaces in the QHI, the GI, and BoP. The null hypothesis was rejected at the 5% level.

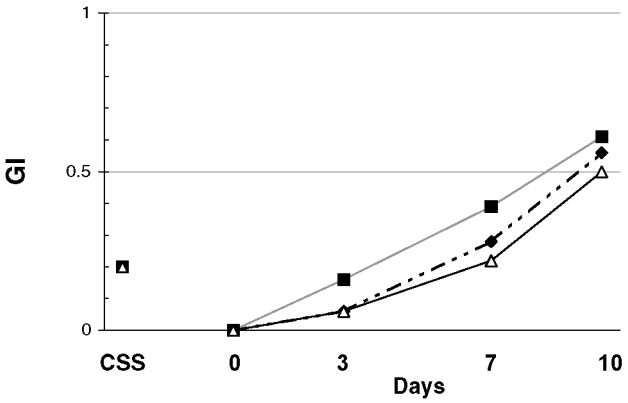

Fig. 3. Mean gingival index scores according to Löe (score 0–3) of the ceramic filling material (◆), resin composite (■), and enamel (△) in the cross-sectional study (CSS), and on days 0, 3, 7, and 10 of the experimental gingivitis study.

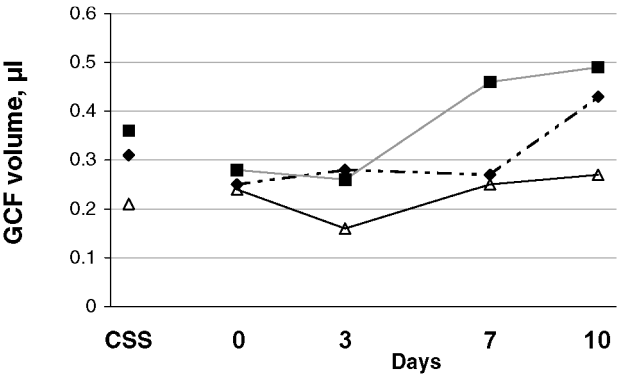

Fig. 4. Mean values of the gingival crevicular fluid volume in µl (*s*) of the ceramic filling material (◆), resin composite (■), and enamel (△) in the cross-sectional study (CSS), and on days 0, 3, 7, and 10 of the experimental gingivitis study.

Results

Cross-sectional study

In the CSS, the means of the QHI for CF, RC, and E, were 0.5, 0.4, and 0.4 respectively (Fig. 2). No visible amount of plaque was observed on 75% of the surfaces. The mean of the GI was 0.2 for each category (Fig. 3). One surface (RC) showed BoP. The mean volumes of GCF were: CF 0.31 µl (*s* 0.31), RC 0.36 µl (*s* 0.42), and E 0.21 µl (*s* 0.23) (Fig. 4). No significant differences in QHI, GI, and GCF flow were found between the CF, RC, and E (*s* = standard deviation).

Experimental gingivitis study

Two participants (1 M and 1 F) discontinued the EGS, both because of infectious disease. At baseline, no significant differences were found between the surfaces in the parameters included.

The respective means of the QHI for CF, RC, and E, are shown in Fig. 2. The differences in the QHI between day 0 and day 10 were highly significant for each category ($P < 0.001$). On day 10, plaque was present on all surfaces. A significantly lower QHI was observed on E compared to CF ($P = 0.014$) and RC ($P = 0.034$). No significant difference was found between CF and RC.

The mean GI for each category is shown in Fig. 3. The increase in GI between day 0 and day 10 was highly significant for E ($P = 0.003$), RC ($P = 0.001$), and CF ($P = 0.008$). On day 10, clinical signs of gingivitis developed on approximately half of the surfaces in each category. Two surfaces (CF) showed a GI score of 2. No significant differences were found between CF, RC, and E. None of the surfaces showed BoP at baseline and one surface (CF) on day 10.

The mean collected volumes of GCF were: CF 0.25 µl (*s* 0.30), RC 0.28 µl (*s* 0.33), and E 0.24 µl (*s* 0.26) at baseline (Fig. 4). At the end of the experimental period, the mean volumes were: CF 0.43 µl (*s* 0.30), RC 0.49 µl (*s* 0.47), and E 0.27 µl (*s* 0.25). The differences between the three categories and the increase in collected volumes of GCF during the experimental period were not significant.

Discussion

No differences in plaque accumulation and gingival inflammation were found clinically between the novel CF material, RC, and E in the CSS. This indicates that it was possible to remove plaque satisfactorily from both restorative materials despite the subgingival localized cervical margins of the restorations. However, it should be noted, as shown by the generally low incidence of gingival bleeding, that the participants in this study had fairly good oral hygiene. The tested surfaces were situated mainly buccally. This localization is more accessible and often shows a lower degree of plaque accumulation and gingivitis than proximal surfaces (26). In a similar CSS, no differences in plaque accumulation, GCF flow, or clinical signs of gingivitis were found between 1-year-old Class V restorations of glass ionomer, RC, and buccal surfaces of enamel (27). It seems that individuals with good oral hygiene regimes can remove plaque efficiently from the different buccal restorative surfaces, despite large differences in surface characteristics. However, aging of RCs results in an increase of plaque retention and degraded surfaces, which may favor bacterial recolonization and complicate plaque removal (19, 28, 29).

At the end of the EGS, plaque had accumulated equally on the ceramic cement and RC, but there was less plaque on enamel. The variety of plaque growth on different materials has been related to surface characteristics of the materials, i.e. surface-free energy and surface roughness (14–16, 30). Initially, the adhesion of saliva proteins and the composition of the pellicle can be affected by the adherent surface, but variations in surface topography do

not sufficiently explain differences in early bacterial adhesion to various restorative materials (31). However, in a TEM study, no principal differences in the ultrastructure of the pellicle were observed for the different dental materials during the 6 h of pellicle formation (32). Neither were any differences found in early plaque formation (33). Nevertheless, surface roughness is likely to have a greater influence on retention of plaque than surface-free energy (34). Defects and rough surfaces can serve as plaque reservoirs and speed up the rate of accumulation and maturity of the plaque (35). Our research group investigated the effects of different polishing systems on CF in vitro and found that relatively smooth surfaces could be obtained with the system, but with higher Ra values than amalgam (36). Preliminary findings of a study in which we compared the cytotoxic effects of CF with other restorative materials showed that CF is one of the most biocompatible restorative filling materials. However, difficult handling properties of CF in the clinic may cause porosities. Clinical observations showed degradation of the surface on aging, such as erosion and small chip formation, resulting in an inhomogeneous surface. As observed with aging RC, this favored bacterial recolonization and complicated plaque removal, which may explain the fact that no differences were found between these two test materials.

Similar to defects of the restorations, marginal gaps can harbor microbial plaque. The CF material studied hardens via an acid-base reaction. The manufacturer claims that the hardening process is accompanied by a small volumetric expansion which may counteract marginal gaps (18). Several studies have shown that polymerization shrinkage of RCs results in marginal gap formation (1, 4, 37, 38). These marginal defects are usually more obvious at the cervical region of the restoration (39). To some extent, water absorption of the RC may reduce the gap width (39–41), but may also result in over-hanging margins, which are known to affect periodontal health negatively (42, 43). All restorations studied had a subgingival located margin. Surface characteristics of the restorative materials and the non-optimal cervical marginal adaptation at a microscopic level may contribute to the higher plaque formation on the CF material and RC compared to enamel. Investigations of the marginal adaptation and volumetric changes in the CF over time are ongoing.

Microbial plaque at the gingival margin provokes a gingival inflammatory response, which is associated with an increase in GCF flow (44–47). The increase in GCF flow could be used as an indicator of initial gingivitis (48). A tendency toward more pronounced subclinical signs of gingival inflammation, measured by GCF volumes, was observed for the CF material and for RC compared to the enamel. This was in accordance with findings in other experimental gingivitis studies of different Class V and Class III restoratives (19, 27). The GCF flow is a complicated and dynamic process that can be affected by factors such as mechanical stimuli, smoking, female hormones, and diurnal rhythm (47). The increase in GCF flow observed in this study was not unambiguous in separate individuals. High standard deviations were found, indicating great individual differences. Polishing the opposite jaw, as performed in this study, may contribute to slower plaque growth and delayed development of gingivitis (33, 34). A more pronounced gingivitis could have been obtained with a longer experimental period. However, a high degree of inflammation can also hide the differences between the materials due to an extensive tissue response. Analysis of inflammatory markers in the sampled crevicular fluid is in progress and may shed light on the effects on the surrounding gingival tissues of the restorative materials.

In conclusion, the novel CF material was comparable to RC regarding plaque formation and gingival inflammation with customary oral hygiene. With neglected oral hygiene, significantly less plaque growth and a non-significant tendency toward lower amounts of gingival crevicular fluid were observed on enamel surfaces.

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