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The influence of different restorative materials on secondary caries development *in situ*

Françoise H. van de Sande [a,b,*], **Niek J.M. Opdam** [a], **Gert Jan Truin** [a], **Ewald M. Bronkhorst** [a], **Johannes J. de Soet** [c], **Maximiliano S. Cenci** [b], **Marie-Charlotte Huysmans** [a]

[a] *Department of Cariology, Endodontology and Pedodontology, Radboud University Medical Center, Philips van Leydenlaan 25, 6525 EX Nijmegen, The Netherlands*

[b] *Graduate Program in Dentistry, School of Dentistry, Federal University of Pelotas, Gonçalves Chaves 457, 96015-560 Pelotas, RS, Brazil*

[c] *Department of Preventive Dentistry, Academic Centre for Dentistry Amsterdam (ACTA), Gustav Mahler Laan 3004, 1081 LA Amsterdam, The Netherlands*

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ABSTRACT

Objectives: The effect of direct restorative materials on caries lesion formation was investigated with an 8-week *in situ* study with split-mouth design, testing the hypothesis that no difference in mineral loss next to a restoration would be found between different composite-based-materials and amalgam.

Methods: Six groups ($n = 18$) of restored dentine samples were prepared using amalgam, a microhybrid, a nanohybrid and a silorane composite. The composites were adhesively bonded with systems with or without an antibacterial monomer (Clearfil-SE-Protect, Clearfil-SE-bond, respectively), except for the silorane group (Silorane-System-Adhesive). Non-restored dentine samples were used as control (primary caries). Samples were inserted into slots, in lower prosthesis especially made for the experiment. Subjects were instructed to dip the lower prosthesis in a sucrose solution 4 times per day. At baseline and 8 weeks, samples were radiographed extra-orally and the integrated mineral loss was calculated. Data were statistically analyzed using multiple linear regression with a multilevel model ($p = 0.05$).

Results: Nine subjects were selected, and only outer lesions were observed. The hypothesis was partially rejected, as the microhybrid composite bonded with the antibacterial system and the nanohybrid composite presented statistically significant lower mineral loss compared to amalgam. Also, no significant differences were seen for these groups compared to control.

Conclusion: Within the limits of this study, the restorative material may influence outer lesion progression. Amalgam was not found to be related to lower secondary caries progression in dentine compared to composite-based materials after 8 weeks *in situ*.

Clinical Significance: Although patient factors play a major role in caries progression, the restorative material may affect outer secondary lesion progression.

* *Corresponding author at*: Graduate Program in Dentistry, School of Dentistry, Federal University of Pelotas: Gonçalves Chaves 457, 96015-560, Pelotas-RS, Brazil. Tel.: +55 53 3225 6741; fax: +55 53 3225 6741.
E-mail addresses: vandesandefh@gmail.com, fvandesande@gmail.com (F.H. van de Sande).

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1. Introduction

Secondary or recurrent caries is defined as a caries lesion developing adjacent to a dental restoration[1] and is along with fracture the predominant reason for failure of posterior restorations.[2,3] It has been proposed that secondary caries lesions develop as outer lesions on the tooth surface next to the restoration margins and as wall lesions, within the tooth/restoration interface[4,5] While wall lesion formation would occur when interfacial gaps are present,[6,7] outer lesions would develop similarly to primary caries on the tooth surface.[8]

Secondary caries has been often related to the restorative material used. In clinical studies, failure for secondary caries has been less frequently found for amalgam than composite restorations.[9,10] Some factors could contribute to this finding, such as the surface deterioration of resin composites leading to an increase in surface roughness[11] and decrease in surface hardness,[12] the elution of unpolymerized monomers from composites and dentine-bonding agents stimulating the growth of cariogenic microorganisms,[13] and the polymerization shrinkage, leading to microgap formation[14,15] and microleakage.[14]

Developments in biomaterials science frequently aim to counteract those shortcomings. Of the strategies in use, some have shown beneficial properties, at least *in vitro*. The use of smaller inorganic fillers in nanocomposites were found to promote lower surface roughness,[16] while silorane-based composites showed lower polymerization shrinkage[17] and lower quantity of adhering streptococci compared to methacrylate-based restorative materials.[18] Another proposed strategy is to add antibacterial components into the adhesive system and composites to reduce the bacterial growth over the surfaces,[19] to inhibit the metabolic activity of cariogenic microorganisms[20] and to disinfect cavities from residual bacteria.[21]

In the present study, secondary lesion formation next to different restorative materials was investigated *in situ*. The null hypothesis tested was that no effect in lesion development next to a restoration would be found between different composite-based materials and amalgam.

2. Materials and methods

The study was submitted to an Ethical Committee Board and approved (CMO code NL 33526091-11).

2.1. Study design

This was a mono-centre, randomized (regarding teeth distribution and sample holders among patients), single blinded (statistician) *in situ* study, with split-mouth design regarding materials. Independent variables were the restorative materials with varying bonding modalities and unrestored dentine (control), whereas the outcome variable was integrated mineral loss.

2.2. Sample size

The present study was exploratory, and therefore having a proper sample size calculation was not possible. However, the number of patients was at some level estimated based on the study of Thomas et al. (2007).[8] In that study, average lesion progression in dentine samples restored with composite was 83.9 μm (SD 23 μm). We worked under the concept that differences on lesion progression lower than 30% (25.17 μm) would not be meaningful. Then, since a split mouth design would be used, the equation applied was $n = f(\alpha,\beta)^{*}\delta^2/(\mu_1 - \mu_2)^2$,[22] from which a sample size of 9 patients was obtained for 5% significance level with 90% power.

2.3. Volunteers

For inclusion, the following criteria were applied: subjects between the ages of 18 and 75 years wearing full prosthesis; good general health; salivary flow ≥0.2 ml/min (unstimulated) and ≥0.7 ml/min (stimulated). Exclusion criteria were medication that affects immunological system or salivary glands, systemic diseases influencing oral and salivary function and subjects categorized as ASA > 2 (according to the physical status classification system adopted by American Society of Anesthesiologists). The recruiting of volunteers was completed within 2 weeks at Arnhem Dental (Arnhem, NL) and all subjects gave written informed consent. A copy of the lower prosthesis–the trial prosthesis, was made for each volunteer.

2.4. Samples

Dentine samples (A- sized 3.0 · 2.0 · 1.0 mm) and half that size dentine samples (B- 1.5 · 2.0 · 1.0 mm) were prepared from extracted sound human molars (Fig. 1a). The enamel portion was removed by grinding in a vertical plate under water cooling and the exposed dentine was prepared using 600-grid papers (Siawat Abrasives, Bern, Switzerland), also under water cooling. Approximately 4 dentine samples were obtained from each tooth at the middle third (2 from the mesial site and 2 from the distal site) using a water cooled diamond saw at low speed. The whole sized dentine samples (A) were left unrestored to provide a primary caries development control group. The half-sized sections (B) were randomly distributed and built up with different restorative materials/techniques, with the orientation of the dentine tubuli positioned perpendicular to the outer surface, assessed under magnification lenses. This resulted in whole-sized (3.2 · 2.0 · 1.0 mm) samples of dentine/material (Fig. 1a). Materials selected were: amalgam (Tytin), two methacrylate-based composites – one microhybrid (Clearfil AP-X) and one nanohybrid composite (Filtek Supreme), and a silorane-based composite (Filtek Silorane). In total, 6 groups of dentine/material were prepared, which are described in Table 1. The silorane group was bonded with its own adhesive system, whereas the microhybrid composite, used in three groups, was adhesively bonded to dentine with systems with or without the antibacterial monomer MDPB – methacryloyloxydodecylpyridinium bromide (Clearfil SE Protect, Clearfil SE bond, respectively). One microhybrid group (bonded with Clearfil SE Protect) received 6 layers of Clearfil SE Protect over the composite surface, which was made in an attempt to simulate an antibacterial composite. The nanohybrid composite was bonded with Clearfil SE bond. The amalgam group was not bonded, and the mechanical retention was accomplished by having two