The influence of interfacial gaps of different sizes on recurrent caries lesion formation next to composite resin restorative material and on plaque acid formation and composition.

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Aim of this in situ study is to investigate the development of wall lesions in the presence of different interfacial gap sizes.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON36568

Source
ToetsingOnline

Brief title
Recurrent caries associated with different gap sizes.

Condition

- Other condition

Synonym
cavities next to fillings, secondary caries

Health condition

cariës

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: National Institutes of Health;USA (gedeeltelijk)

Intervention

Keyword: composite restoration, gap size, in situ, recurrent caries

Outcome measures

Primary outcome

lesion depth and mineral loss of (recurrent) caries wall lesions

Secondary outcome

biofilm acidogenicity and composition

Study description

Background summary

Recurrent caries is the disease in which cavity formation occurs next to existing fillings. It is the most common reason for replacing restorations. There are many theories which trie to explain how recurrent caries develops. One of those theories is that when a small gap exists at the restoration-tooth interface, bacteria can form a biofilm and produce acids which will result into demineralisation of the tooth and development of a new cavity next to a restoration. The aim of this study is to closely monitor if recurrent caries develops in presence of a gap and what size of gap promotes recurrent caries lesion development.

Study objective

Aim of this in situ study is to investigate the development of wall lesions in the presence of different interfacial gap sizes.

Study design

It's a mono-center, single-blind in situ study. The volunteers will wear a removable appliance with 10 samples, made of tooth and filling, during a period of 8 weeks, 24 hours per day. Once a day the removable appliance will be removed for cleaning with a fluoride-toothpaste. Four times a day the samples will be dipped in a sucrose-solution for 5 minutes, then it will be rinsed with water and reinserted in the mouth.
Lesion depth and mineral loss will measured every two weeks by making a sort of X-rays of the samples outside the mouth. Also, after 4 and 8 weeks plaque will be collected from the samples and biofilm and acidogenicity will be investigated.

Intervention

Strictly speaking no intervention is carried out with the subjects themselves. They will wear appliances with tooth samples placed next to restoration material with different interface characteristics: ideally bonded, non-bonded, 100 µm gap, 200 µm gap, 400 µm gap. The appliances will be dipped in sucrose solutions 4 times per day, and brushed 1 time per day.

Study burden and risks

The burden for participating volunteers exists of wearing a removable appliance in which the tooth samples are placed during a period of 8 weeks, for 24 hours per day. Every two weeks they must visit our laboratory for measurement of the samples extra-oral. Swallowing one of the tooth samples is a relative risk. Mounting the tooth samples in the removable appliance with the help of composite material in an undercut has proven to minimize this risk in earlier studies (NL 28303.091.09). No benefit can be expected as no interventions are done.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

>= 18 yrs
healthy (no disease, no medication, ASA I)
healthy dentition (no active caries, no periodontitis)
able to wear appliance in lower jaw

Exclusion criteria

ASA >= 2
DPSI>= 2 (periodontal disease)
active caries
removable prosthesis lower jaw

Study design

Design

Study type: Observational non invasive

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-12-2012
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	28-07-2011
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL33528.091.11