

Effect of occlusal loading on secondary caries development in situ

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The aim of this in situ study is to investigate whether occlusal loading leads to increased secondary caries formation in loaded compared to unloaded samples in a near-clinical environment.

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

Summary

ID

NL-OMON48451

Source

ToetsingOnline

Brief title

ELCIS

Condition

- Other condition

Synonym

caries adjacent to fillings, recurrent caries

Health condition

secundaire cariës

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Stichting voor bevordering tandheelkundige kennis

Intervention

Keyword: Gaps, In situ model, Occlusal loading, Secondary caries

Outcome measures

Primary outcome

The main study parameters are lesion depth (μm) and integrated mineral loss ($\mu\text{m.vol\%}$) in the tooth sample close to the restoration margin. These will be measured through the microradiographic technique T-WIM.

Secondary outcome

Secondary study parameters include:

- salivary flow (ml/min)
- location and measure of chewing forces, measured using T-scan device

Study description

Background summary

Secondary caries is tooth decay next to an existing restoration and one of the main reasons to replace restoration in general dental practice. Previous research has shown that secondary caries lesions can develop when a small gap is present between the tooth and restorative material. Gaps as small as $30\ \mu\text{m}$ have been shown to develop secondary caries lesions in vitro and in situ [Kuper et al., 2014; Maske et al., 2019; Maske et al., 2017].

Presence of a gap allows the formation of a wall and surface lesion next to a dental restoration. An in vitro study by Kuper et al. [2013] showed that an increased hydrodynamic flow in the gap between composite and tooth material leads to an increase in wall lesion development.

A more recent study by Askar et al. [2017] found that loading a tooth-restoration sample containing a gap of $100\ \mu\text{m}$ width led to increased

caries lesion formation compared to unloaded samples. They theorized that the loading on the sample containing a gap could lead to compression of the gap area. When the force is released, the compression ends, and the gap returns to normal. This cyclic deformation of the gap area could possibly lead to an increased hydrodynamic flow, which explains the increase in lesion formation in loaded samples.

Since only in vitro data is available on this topic, the clinical relevance is so far unclear. Whether the effect of loading of restorations still influences the secondary caries process in a more variable clinical environment, is unknown.

Study objective

The aim of this in situ study is to investigate whether occlusal loading leads to increased secondary caries formation in loaded compared to unloaded samples in a near-clinical environment.

Study design

A mono-center, single blind in situ study, with split-mouth design. Edentulous subjects will receive a duplicate of their lower denture containing sterilized tooth samples in slots. Half the samples will be placed in occlusal contact with the upper denture. The other half will be placed slightly lower, out of contact. The appliance has to be dipped in 20% sucrose solution 4 times a day for 10 minutes. The appliance containing samples needs to be worn for 6 weeks, 24 hours a day.

Study burden and risks

No intervention is carried out specifically on the participants themselves, since the samples are removable and can be exposed and analysed out of the volunteers* mouths. There are four visits associated with participation in this study.

The volunteers are requested to wear the denture close to 24 hours a day for 6 weeks and are only removed for cleaning. This increases the risk of soft tissue discomfort, since dentures are usually worn only 16-18 hours a day.

Swallowing one of the tooth samples is a relative risk. Securing the tooth samples in the slots of the appliance with the help of composite material in an undercut has proven to minimize this risk in earlier studies (NL33528.01.11, NL.47343.091.14). No benefit can be expected since no intervention is performed directly on the volunteers.

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

- Adults (>18 years)
- Have a full denture in the lower jaw
- Have a lower denture height of at least 8 mm

Exclusion criteria

- ASA score >2
- Unable to give informed consent
- Unable to understand written patient information

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 10-11-2020

Enrollment: 16

Type: Actual

Ethics review

Approved WMO

Date: 19-12-2019

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

CCMO

Other

ID

NL71551.091.19

NL8031