Effect of occlusal loading on secondary caries development in situ’

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21363

Source
NTR

Brief title
ELCIS

Health condition

secondary caries

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Stichting Bevordering Tandheelkundige Kennis

Intervention

Outcome measures

Primary outcome

Lesion depth, measured through transversal microradiography

Secondary outcome

Integrated mineral loss, measured through transversal microradiography

Study description

Background summary

Rationale:
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 µm 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 µm 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.

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 population:
Healthy edentulous volunteers (>18 years old) who wear a full denture in the lower jaw. A sample size of n=14 will be aimed for.

Main study parameters/endpoints:

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

Study objective

Compressive occlusal loading of a space between composite and tooth material will lead to an increase in lesion depth and mineral loss in these samples.

Study design

Start of wearing denture containing samples = t0
Samples are worn for 6 weeks. Samples are measured afterwards = t42

Intervention

Lower dental prosthesis is copied and equipped with samples. No direct intervention on subjects. Samples are dipped in sucrose solution 4 times a day.

Contacts

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Eligibility criteria

Inclusion criteria

• Adults (>18 years)
• Wear 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:	Interventional
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	14
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8031
Other	ABR : 71551

Study results