Clinical longevity of amalgam replacing extensive direct composite restorations; Up to 13 years follow up

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29414

Source
Nationaal Trial Register

Brief title
TBA

Health condition

Large posterior restorations in human teeth

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Kolff Institute, University Medical Center Groningen

Intervention

Outcome measures

Primary outcome

Survival of the restoration

Secondary outcome

FDI criteria for quality

Study description

Background summary

Background: Direct composite restorations are widely used to restore posterior teeth, with acceptable clinical performance. The replacement of inadequate, failed amalgam and composite restorations (due to fracture, secondary caries etc.) is a core occupation in dental practice. Many amalgam restorations are large and because of the undermining of cusps for macro mechanical retention these tend to fracture. There is restricted data on the performance of EDCRs (extensive direct composite restorations) involving one or more cusps.Therefore, there is a need for long-term follow up of EDCRs.

Main research question: What is the survival of extensive direct composite restorations involving one or more cusps after up to 13 years?

Design: This study has a cross sectional study design as one measurement per participant will be executed, however, these measurements will combined with other measurements from the previous study, which results in multiple evaluation times. Between January 2007 and September 2013, a total of 88 patients (57 women, 31 men; mean age: 51.6) received EDCRs (n = 118) in the posterior teeth. Population consists of adult, competent patients treated by Hans Scholtanus. These were evaluated up to 3,5 years. The present study will evaluate these restorations to a mean evaluation time of 13 years in a cross-sectional study design. Restorations will be scored using the modified FDI criteria by Hickel. Guidance and parafunctions will be checked. Restorations were scored as failed if any operative intervention was indicated for repair, partial or total replacement. Patient file will be checked on events. Outcome is the survival of extensive direct composite restorations after an mean follow up of 13 years.

Expected results: We expect a survival of around 90-95% of the composite restorations at a follow up of 13 years.

Study objective

The survival of extensive direct composite restorations involving one or more cusps after up to 13 years will be sufficient

Study design

The primary outcome, the survival of the restorations, will be determined during an appointment on which the status of the restorations will be analyzed. Events will be noted

based on the patient file. The secondary outcome, the FDI criteria, will be noted during the check-up appointment.There is only one measurement moment.

Intervention

Not applicable

Contacts

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Eligibility criteria

Inclusion criteria

Participant in the previous study ‘Clinical longevity of extensive direct composite restorations in amalgam replacement: up to 3,5 years follow up’

Exclusion criteria

Patients who didn’t sign the informed consent form

Study design

Design

Study type: Observational non invasive

Intervention model:	Other
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	24-11-2020
Enrollment:	88
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	NL9100
Other	CTC UMCG : 202000185

Study results