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

Gepubliceerd: 24-11-2020 Laatst bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29414

Bron
Nationaal Trial Register

Verkorte titel
TBA

Aandoening

Large posterior restorations in human teeth

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: Kolff Institute, University Medical Center Groningen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Survival of the restoration

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Not applicable

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients who didn’t sign the informed consent form

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	24-11-2020
Aantal proefpersonen:	88
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9100
Ander register	CTC UMCG : 202000185

Resultaten