

Partial indirect restorations with deep margin elevation in the posterior region: long term results

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27874

Source

NTR

Brief title

TBA

Health condition

Caries, periodontal disease, pulpal disease

Sponsors and support

Primary sponsor: University Medical Centre Groningen

Source(s) of monetary or material Support: University Medical Centre Groningen

Intervention

Outcome measures

Primary outcome

Indirect restorations with DME stand a good chance on long term survival.

Secondary outcome

Indications of degradation are seen in time. Ceramic indirect restorations exhibit less wear than composite resin restorations but are more abrasive to the antagonist. Composite resin indirect restorations and restorations on non-vital teeth are associated with a higher incidence of fractures of both restorations and teeth.

Study description

Background summary

Deep margin elevation (DME) relocates the cervical outline of large-sized cavity dimensions in the posterior area supragingivally, using a resin composite in a direct technique. The aim of this study is to evaluate the long-term clinical performance of partial indirect restorations with DME and compare the effects of selected baseline variables on the (quality of) survival of the restorations.

All teeth that were restored in combination with indirect restorations and DME between 2007 and 2016 were eligible for inclusion in this retrospective cohort study. Overall cumulative survival rates were calculated (Kaplan-Meier estimates) and compared among subsets of variables that were considered of influence over time (prior endodontic treatment, material used for the indirect restoration, quality of the emergence profile of the DME, cusp coverage, quality of the contact point; Log Rank Mantel-Cox).

Qualitative evaluation of all surviving restorations was performed using the modified United States Public Health Service (USPHS) criteria. The outcomes of the USPHS clusters were also compared among the potential influential factors, as well as in time (<3 years old, >3 years old) to evaluate if they impacted the quality and degradation behavior of the indirect restorations with DME (Chi-square tests).

A total of 197 indirect restorations in 120 patients could be included. Restorations or teeth presenting with secondary caries, fracture of the restoration / tooth, debonding of the indirect restoration, root caries, severe periodontal breakdown or pulpal necrosis were considered as absolute failures (n=8) to an overall cumulative survival rate of 95.9% (SE 2.9%) after more than 10 years, with an average evaluation time of 57.7 months.

Some indication of degradation of the restorations was seen over time (more: margin discoloration ($X^2(2)=9.02$, $p=0.01$), fracture of restoration ($X^2(2)=42.03$, $p=0.000$), fracture of tooth ($X^2(2)=23.18$, $p=0.000$) and caries ($X^2(2)=9.02$, $p=0.000$)). Composite restorations show more degradation (more: fracture of restoration ($X^2(2)=38.52$, $p=0.000$), fracture of tooth ($X^2(2)=31.39$, $p=0.000$), wear restoration ($X^2(2)=14.82$, $p=0.01$). More wear of the antagonist is observed when they are opposed to ceramic restorations ($X^2(2)=6.62$, $p=0.04$). Endodontic treatment negatively impacts the occurrence of fracture of restorations and teeth ($X^2(2)=38.52$, $p=0.000$) and respectively $X^2(2)=20.67$, $p=0.000$). All other predefined variables were not of statistically significant influence, either on survival or quality of survival of the restoration ($p>0.05$).

Indirect restorations with DME stand a good chance on long term survival. However, indications of degradation are seen in time. Ceramic indirect restorations exhibit less wear than composite resin restorations but are more abrasive to the antagonist. Composite resin indirect restorations and restorations on non-vital teeth are associated with a higher

incidence of fractures of both restorations and teeth.

Study objective

Long term survival rates with DME treated teeth. Better prognosis of indirect ceramic restorations in comparison to indirect composite restorations especially when taking degradation into account.

Study design

Initial, baseline, <3 years, >3 years of follow up, up to 10 years of follow up.

Intervention

Deep margin elevation (DME) that relocates the cervical outline of large-sized cavity dimensions in the posterior area supragingivally, using a resin composite in a direct technique.

Contacts

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Eligibility criteria

Inclusion criteria

Candidates had to be at least 18 years old, physically and psychologically able to tolerate conventional restorative procedures, without active periodontal or pulpal diseases, not allergic to resin-based materials, not pregnant or nursing, and willing to return for follow-up examinations as outlined by the investigators.

Exclusion criteria

Not willing to enroll in the study, changing dentist or having moved to another city or dental practice after restoration.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-03-2007
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description

All patients agreed on participation in the clinical trial, METC approved the trial and the trial was non WMO as there is no extra contribution for the patient.

Ethics review

Positive opinion	
Date:	26-06-2019
Application type:	First submission

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	NL7851
Other	METC UMCG : METC201900133

Study results

Summary results

We will try to publish in a Q1 journal.