Clinical evaluation of posterior glass-ceramic partial restorations luted in conjunction with Immediate Dentin Sealing

No registrations found.

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

Summary

ID

NL-OMON27451

Source
NTR

Brief title
TBA

Health condition

Caries, periodontal disease, pulpal disease, fracture

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Indirect restorations with IDS at preparation are likely to survive on the long-term.

Secondary outcome

Restorations are likely to present with some degradation in time due to intra-oral function. Quality of survival will be measured by the use of certain variables and USPHS criteria on digital photographs and X-rays.

Study description

Background summary

Large sized cavities can be restored using partial indirect ceramic restorations since these restorations can properly restore the morphology and function of the tooth. However, lithium disilicate restorations are prone to bulk fracture, chipping and adhesive problems. Adhesive problems are combatted by the use of Immediate Dentin Sealing (IDS). IDS has proven to significantly increase the fracture strength of lithium disilicate restorations.
Not many long term clinical knowledge is present on the survival and performance of these restorations in combination with IDS. Therefore, this clinical trial investigates the survival rate of partial indirect lithium disilicate restorations in conjunction with IDS.
Approximately 2000-3000 restorations will be included in the study. The primary outcome will be the survival of the lithium disilicate restorations. Data will be collected from digital light photo’s, X-rays and patient files. These are part of regular dental care and therefore no extra burden for the patient. This study will be registered as a non-objection study. Data will be analyzed using a Kaplan-Meier survival analysis with Log rank tests and Cox regression multi-level analysis with paired data (with frailty model). Overall survival rates after 7-9 years of evaluation are expected to be over 90%. Moreover, this study might be able to identify the influence of risk factors and patient factors on survival.

Study objective

Overall survival rates after 7-9 years of evaluation will be over 90%.

Study design

Initial at baseline, at every check up (every 6 months), up to 15 years of follow-up

Intervention

Indirect restoration of ceramic material with application of Immediate Dentin Sealing at preparation.

Contacts

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Eligibility criteria

Inclusion criteria

All patients who received indirect partial lithium disilicate restoration from 2008 are eligible for inclusion. Patients have to be at least 18 years of age and have to be physically and psychologically able to tolerate restorative procedures. IDS must be applied at every preparation. Moreover, the candidate is a patient at Buijs Tandartsen.

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):	01-01-2021
Enrollment:	3000
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Plan description
All patients agreed on participation by a register of non-objection. This research is approved by the METc Groningen as non-WMO, since no extra burden will be brought to the patient.

Ethics review

Positive opinion

Date:	28-10-2020
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	NL9026

Register	ID
Other	METC UMCG : METC202000588

Study results

Summary results

This retrospective database is aimed to be published in a Q1 journal.