A randomised clinical study on indirect lithium disilicate versus direct composite restorations in severely compromised endodontically treated molar teeth

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To investigate the performance of indirect glass ceramic and direct composite endocrowns in the restoration of severe structurally compromised endodontically treated molar teeth.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55487

Source
ToetsingOnline

Brief title
Direct versus indirect endocrowns

Condition

- Other condition

Synonym
heavily filled endodontically treated molars

Health condition

tandheelkunde, herstel kiezen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Ceramic, Composite, Endocrown, Restorations

Outcome measures

Primary outcome

Complete failure.

Secondary outcome

Quality of survival.

Study description

Background summary

After endodontic treatment, a good coronal seal is a prerequisite for long term success. There are several methods of establishing such a coronal seal and restoring the function of a tooth: 1) a direct restoration made of composite and 2) an indirect restoration made of indirect composite, glass ceramic, high performance ceramic or metal-ceramic.

In the past, indirect restorations on endodontically treated teeth were often supported by a post-and-core build-up. However, this requires a post preparation, which further weakens the tooth.

Endocrowns are a viable alternative to the traditional post-and-core build-up in severe structurally compromised molar teeth. Endocrowns are monolithic restorations that extend into the pulp chamber of endodontically treated teeth with severe loss of coronal hard tissue. An endocrown can be made directly (composite) of indirectly (porcelain).

In the case of severe structurally compromised molar teeth where no or only a single coronal wall remains that require restoration, the clinician and patient have to consider treatment alternatives in relation to costs and durability. Indirect restorations are relatively costly and frequently overstretch the patients* financial budget, particularly immediately after an (expensive)

endodontic treatment. The possible alternative could be a directly made massive composite build-up. This is a clinical challenge since it is difficult to provide proper marginal adaptation and adequately restore anatomical form directly in the mouth.

There is a lack of evidence concerning the survival and clinical performance of the aforementioned two restoration types.
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Study objective

To investigate the performance of indirect glass ceramic and direct composite endocrowns in the restoration of severe structurally compromised endodontically treated molar teeth.

Study design

Randomised 5-year clinical study and evaluation of direct versus indirect endocrowns fabricated on endodontically treated molars.

Intervention

The patient will be allocated at random to a direct or indirect endocrown. Direct endocrowns will be fabricated in one session using composite. During the indirect procedure, a preparation will be made and subsequently scanned. The restoration will be milled in dental laboratory. In a second session the restoration will be cemented onto the molar.

Study burden and risks

No additional risks are anticipated. Both treatment modalities are being used nowadays in the clinic. Clinical data are collected during regular checkups, no different from the usual clinical procedure. The process of collecting data for the research is only little extra time consuming and is anticipated to be an extra hour, with one extra session involved.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient should be over 18 years of age; ASA-score I or II (de Jong, 1994). This ASA score is already known before participation, due to regular check-ups; Asymptomatic endodontically treated and heavily restored upper and lower molar teeth with an indication for a (new) restoration; Patients should have given written informed consent.

Exclusion criteria

ASA-score III or higher; symptomatic endodontically treated molars.

Study design

Design

Study type: Interventional
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-11-2015
Enrollment:	102
Type:	Actual

Ethics review

Approved WMO Date:	07-10-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	22-12-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-08-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	31-10-2019
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	06-07-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL53678.042.15