Clinical study of a newly developed bulk fill restorative material suitable for Class II restorations

Published: 14-09-2017
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3 year post market clinical follow-up study

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON55890

Source
ToetsingOnline

Brief title
Study of a bulk fill material for Class II restorations

Condition

- Other condition

Synonym
filling of dental cavities, restoration of caries lesions

Health condition

dental research

Research involving
Human

Sponsors and support

Primary sponsor: 3M Deutschland GmbH
Source(s) of monetary or material Support: 3M Deutschland GmbH

Intervention

Keyword: bulk, class II, material, restorative

Outcome measures

Primary outcome

Evaluation of restoration survival based on the FDI Criteria.

Secondary outcome

Evaluation of restoration quality based on the FDI Criteria and evaluation of

potential adverse effects.

Study description

Background summary

Resin composites are widely used as direct restorative materials for the restoration of tooth decay. Regular composites have to be applied in several layers to minimize possible shrinkage. Continuous advancements in the field of 3M restoratives have led to the development of an aesthetic bulk fill material that can be used for stress bearing Class II restorations. The material is a new composite resin material with nanofiller technology and two innovative methacrylate monomers for lower polymerization stress. The restoration can be applied within one layer, which results in a shorter treatment time. In this clinical study, the use of this new material for Class II restorations will be evaluated during a period of 3 years.

Study objective

3 year post market clinical follow-up study

Study design

This prospective non-controlled clinical study aims to evaluate the treatment of decayed teeth with a newly developed esthetic bulk fill material for Class

II restorations.

Intervention

The intervention of the study is treatment of a Class II restoration with a new bulk fill material.

Study burden and risks

Insertion of direct restorations is a standard method in today*s dentistry. Filtek One Bulk Fill is CE marked and thus can be used for routine clinical treatment. A benefit of using composite for restoration of teeth is the preservation of tooth substance due to limited invasiveness when compared to alternative treatment methods (inlay, onlay, partial crown, crown). There are no additional risks beyond those present during routine clinical restorative treatment to be expected when using the restorative materials. All subjects will be evaluated at baseline and after 6, 12, 24 and 36 months. This will require additional visits. During these visits, the restorations will be clinically examined and documented according to the FDI criteria. A digital light photograph from occlusal view prior to restoration placement and at every evaluation will be taken. At baseline and after 24 months, an impression will be taken.

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

- Subject is between 18 and 70 years of age
- Subject is in good general health and can be classified as ASA 1 or 2
- Subject is in need of at least one Class II restoration without cusp replacement. The restoration can be a replacement of a failed existing restoration
- Study teeth must have a good prognosis for the next 3 years (no increased tooth mobility, periodontal probing depth is * 5 mm, no signs of pulpitis, no pulp exposure during treatment, study teeth are vital, level of oral hygiene is sufficient)
- Each study restoration has at least one proximal contact and is stress bearing
- Subject volunteers to participate in the study and is available for recalls during the 3 years study duration

Exclusion criteria

- Subject does have known allergies against any study substances
- Study teeth with bad prognosis (increased tooth mobility, periodontal probing depth is > 5 mm, signs of pulpitis, pulp exposure during treatment, non-vital teeth, level of oral hygiene is insufficient)
- Subject undergoing treatment for bruxism, traumatic malocclusion, or erosion
- Study teeth with pulp exposure
- Subject being pregnant or breast feeding
- Subject participating in other dental studies that might interfere with this study

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-10-2017
Enrollment:	55
Type:	Actual

Medical products/devices used

Generic name:	restoration material
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	14-09-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	21-11-2017
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	09-03-2021
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL61285.029.17