Randomized clinical trial on the performance of direct and indirect composite restorations in patients with severe tooth wear

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Aim of this study is to investigate the clinical performance of two restoration techniques, making use of 'direct' and an 'indirect' composite restorations as a minimal invasive intervention in patients with severe tooth wear....

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

Summary

ID

NL-OMON34996

Source
ToetsingOnline

Brief title
Treatment of severe tooth wear

Condition

- Other condition

Synonym
Dental tooth wear, loss of vertical dimension of occlusion

Health condition

Tandheelkundige aandoeningen

Research involving

Human

Sponsors and support

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

Intervention

Keyword: Composite restorations, Etiological factors, Minimally invasive treatment, Severe tooth wear

Outcome measures

Primary outcome

- The percentage of failed restorations

- Number of interventions needed after bite raise to make patients accept

bite-raise within 6 months

Secondary outcome

Secondary outcome parameters regarding the necessity of the appliance on the

short-term (until six months after treatment):

- Time to clinical acceptance of bite raise

- Restoration of chewing function

- Adjustment to increased occlusal height

- Patient satisfaction, pain and comfort

- 'Quality of Life' related to Oral Health

Secondary outcome parameters for the comparison between the two restoration

techniques on the long-term, after 1 - 5 years:

- Restoration performance

- Patient satisfaction

- Association between clinical performance and wear etiology

- Maintenance costs

- Tooth and restoration material loss

- 'Quality of Life' related to Oral Health

Study description

Background summary

In clinical dentistry there is an increase in the prevalence of tooth wear among younger subjects. It is recognized that tooth wear has two main etiological causes: 1) erosion by chemical etching of the enamel and dentine by acids from either extrinsic, e.g., soft drinks, or intrinsic, gastric, sources, and 2) mechanical wear by grinding tooth contacts or food. In the Netherlands erosive tooth wear has been shown to have increased over the past years among youngsters (Truin et al., 2005). In a recent longitudinal study, the prevalence of erosive tooth wear at 16 yr was ± 40%, with about 10% already showing localized complete loss of enamel (El Aidi et al., 2010). In that study the prevalence as a result of mechanical wear was not specifically studied. In a systematic review on tooth wear, independent of the etiological factors, it was found that the predicted percentage of adults presenting severe tooth wear increases from 3% at the age of 20 years to 17% at the age of 70 years (Van *t Spijker et al., 2009). Also in the deciduous dentition of children the prevalence of severe wear into the dentin significantly increases with age, however, a large range, between 0 and 82%, was found in literature (Kreulen et al., accepted 2010). In these reviews, tooth wear was defined as wear exposing the dentin of teeth, which is commonly depicted as the starting point of severe tooth wear.

It seems reasonable to conclude that the prevalence of tooth wear increases, the individual severity does as well. However, the natural course of severe tooth wear has never been described. We do not know whether those 10% of the youngsters showing already wear into dentin are at risk for severe tooth wear in the future. Severe tooth wear often leads to functional problems, difficulty with and pain during eating and speaking and esthetical problems, due to shortening of front teeth.

Thus, patients with severe generalized pathological tooth wear present a complex problem in dentistry and a challenge for the general dental

practitioner. Loss of tooth tissue due to caries leads to lesion progression into the deep of the tooth and are usually restored with direct *fillings*, the most common dental restorative procedure. As a contrast, in tooth wear the outer surface of the tooth is lost, including the morphological and functional features. The restoration of the morphological form and function of the worn dentition is often highly complicated by the fact that these worn teeth are much shorter and smaller, which has resulted in a loss of vertical dimension of occlusion (VDO). Therefore, to restore form and function, an increase of vertical dimension of occlusion is necessary (the distance between the jaws has to be increased to provide space for the restorations).

To increase the vertical dimension of occlusion several materials and techniques are used. Traditionally, the more invasive technique, crowns are placed. Nowadays, also composite materials are frequently used, based on the principle of 'minimally invasive'. Meaning that no additional tooth material has to be removed and that the technique is reversible. These composite materials, intended for direct use in the oral cavity, show to have improved mechanical characteristics which can be used for extensive crown-like restorations to build-up teeth (Kuijs et al., 2006; Hamburger et al., submitted 2010). Based on these studies, use of composite restorations is the first treatment of choice when the loss of vertical dimension is less than 3 mm. In case the tooth wear is more severe, also the more invasive techniques can be used.

There is no established evidence based protocol for the treatment of patients with severe tooth wear. Traditionally, when the loss of vertical dimension is more than 3 mm, the approach is to use indirect, dental technician made, dental crowns and/or uplays and where needed removable prosthetic appliances. The disadvantage of this technique is the removal of sound tooth tissue in order to obtain sufficient retention to the worn dentition.
Composite materials, intended for direct use in the oral cavity, show to have improved mechanical characteristics which can be used for extensive crown-like restorations to build-up teeth (Kuijs et al., 2006; Hamburger et al., submitted 2010). There is substantial clinical experience that *direct* as well as *indirect* composite restorations are feasible alternatives in the treatment of severe tooth wear. Moreover, another advantage of this technique are the adhesive properties of the composite material, compared to the traditional, more invasive, technique using metal-porcelain crowns. However, no clinical evidence exists that there is a difference in clinical performance between the restorations made with the two techniques.

If a person suffers from pathological wear (>=3mm loss of vertical dimension), the restoration of the teeth includes a direct and indirect adhesive technique to build up the worn dentition and to raise the bite. However, it is not known which intervention is preferable in these patients. Therefore, we hypothesize that both techniques present equal clinical performance; furthermore, no temporary bite-raise appliance (splint) is necessary to test the increase of

vertical dimension of occlusion.

Study objective

Aim of this study is to investigate the clinical performance of two restoration techniques, making use of 'direct' and an 'indirect' composite restorations as a minimal invasive intervention in patients with severe tooth wear. '
Moreover, the clinical necessity of a removal temporary bite-raise appliance (splint) is investigated

Study design

Randomized controlled clinical trial, with two independent variables:
1) Placement technique (direct versus indirect)
2) Pre-testing of the new vertical dimension (with or without use of temporary bite-raise appliance)

Intervention

Patients will be randomized (block-randomization) divided over two treatment protocols (indirect and direct) and over the use of a temporary appliance (with or without).

Study burden and risks

The whole procedure is identical to that of a 'normal' dental treatment when using direct and indirect composite restorations, with the exceptions of using questionnaires regarding the Quality of Life, making dental impressions and intra-oral light-photographs.

After finishing the treatment, patients will be recalled after 1, 3 and 5 years.
During those visits, dental impressions and intra-oral light-photographs will be made to register the status of the restorations and a questionnaire regarding the Quality of Life will be filled in.
Normal regular dental check-up will be performed by their own general dentist.

The most important benefit for the patients is the rehabilitation of their dentition. Functionality (teeth are less sensitive, a better occlusal stability, etc) and esthetics will be improved immediately after finishing the treatment

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

- Generalized tooth wear
- Clear demand for treatment
- Necessary increase of vertical dimension of occlusion >=3 mm
- Continious dental arches with a minimum of three posterior teeth (premolars and molars) per quadrant
- A maximum of one edentulous space in need for treatment
- This space has a maximum span of one tooth-width

Exclusion criteria

- ASA 4

- Necessary increase of vertical dimension of occlusion < 3 mm
- Edentulous space has a span exceeding 1 tooth-width
- Functional problems (mouth opening <5cm, severe Tempero Mandibular Dysfunction)
- Severe periodontitis

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2011
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	17-08-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-08-2012
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL31371.091.10