

Adhesive restorations for fractured teeth: evaluation of performance of tooth tissue saving restorative techniques

Submission date 22/02/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/03/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 29/10/2013	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Tooth-colored composite material is nowadays commonly applied in dental practice. Even larger cavities can be filled with this material. For teeth that are severely broken down, however, a full crown is the traditional treatment of choice. This is for instance the case with teeth that are affected by fracture of one of the cusps (a pointed or rounded projection on the chewing surface of a tooth). Despite the longevity of full crowns, a disadvantage of this restoration is that removal of a substantial amount of sound tooth tissue is required. Composite cusp-replacing restorations may provide a tooth tissue saving alternative for the full crown.

Research data show that fracture of a cusp is a common phenomenon. In most cases, cusp fracture occurs in teeth that are weakened by previous decay and restorations. In combination with chewing forces, this may lead to fracture of a cusp. Teeth with cusp fracture can be restored with both direct and indirect composite techniques. Direct composite restorations are made by the dentist in one treatment session and are relatively cheap.

Indirect composite restorations are made in the dental laboratory, which offers better control. The involvement of the dental technician, however, implies two treatment sessions and higher financial costs. It is not known to whether the clinical performance of composite restorations replacing cusps is dependent on the restorative technique.

The purpose of the study is to compare the short and long term clinical performance of direct and indirect cusp-replacing composite restorations.

Who can participate?

Patients with a fractured small back tooth (premolar) without root canal treatment.

What does the study involve?

Patients that participated in this study had a tooth with a fractured cusp. First the tooth was prepared for a cusp-replacing restoration, which means that old restoration material and carious tissue if present- was removed. Second, the tooth was provided with either a direct or indirect composite cusp-replacing restoration. The treatment technique to which a participant was

allocated was decided by a process called randomization, which is like a coin toss. After treatment, patients were invited for a check-up after one month and subsequent yearly check-ups.

What are the possible benefits and risks of participating?

The benefits for those taking part are that their fractured tooth will be treated with a tooth tissue saving restoration. Treatment is free of charge. The benefit for future patients is that information on the performance of adhesive restorations for fractured teeth becomes available. It is expected that, based on these results, a choice between direct and indirect restorations can be made.

The main risk of participating is that the performance of adhesive restorations replacing cusps is unknown. In case the result of the treatment with a adhesive restoration appears to be not sufficient, however, the traditional treatment (full crown) is still available.

Where is the study run from?

The study is single-centre and run from the Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands.

When is the study starting and how long is it expected to run for?

Inclusion of patients started at December 1, 2001 and stopped at April 30, 2007. Follow-up period is 5 years minimum.

Who is funding the study?

Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands

Who is the main contact?

Dr Willem Fennis

w.fennis@dent.umcn.nl

Contact information

Type(s)

Scientific

Contact name

Dr Willem Fennis

Contact details

Philips van Leijdenlaan 25

Nijmegen

Netherlands

6525 EX

+31 24 361 40 04

w.fennis@dent.umcn.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Adhesive restorations replacing cusps in fractured teeth: a comparison of minimal invasive direct and indirect techniques - A randomized clinical trial

Study objectives

Cusp fracture of restored posterior teeth is frequently observed in dental practice. The conventional treatment is to restore the tooth with a metal-ceramic crown. Despite the high survival rate of crowns, a disadvantage of this technique is that it requires removal of a large part of the remaining sound cusp to create retention and resistance. It is expected that resin composite restorations do not require extensive mechanical retention for their adhesive nature. They may thereby prevent complications like pulpal damage. Resin composite restorations have been used in Class I and II cavities with success. Long-term data on adhesive restorations replacing cusps are, however, not available yet. For a long time, it is stated that resin composite is not appropriate as an occlusion-bearing restoration material and it would be valuable to examine whether this assertion is true.

Resin composite restorations can be made with direct and indirect techniques. Direct restorations are preferred for reasons of minimal intervention. They can be made in one treatment session at relatively low costs, without an intermediate cement layer. Indirect restorations are advocated to overcome problems related to shrinkage. Furthermore, the indirect technique offers a higher degree of polymerization and the possibility to shape external surfaces extra-orally. Clinically no significant difference in survival rates of direct and indirect resin composite restorations was found. For adhesive restorations replacing cusps in particular, both direct and indirect techniques are adequate to restore morphology and function, but long-term data are not available.

The objective of this randomized clinical trial (RCT) was to compare the long-term clinical performance of direct and indirect resin composite restorations replacing cusps.

The null hypothesis tested was that there was no difference in survival for direct and indirect restorations.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Committee on Experimental Research on Man of the Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands. January 11, 2001, Ref 2001/166

Study design

Single centre randomized clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Tooth fracture (dental diseases)

Interventions

Participants are randomly allocated to a direct resin composite cusp-replacing restoration or a indirect resin composite cusp-replacing restoration.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Difference in long-term survival of direct and indirect resin composite restorations replacing cusps

Secondary outcome measures

Differences between direct and indirect adhesive restorations replacing cusps regarding:

1. Efficacy and (cost) effectiveness
2. Failure mode at restoration level (for instance fracture of restoration) and at tooth level (for instance caries)

Overall study start date

01/12/2001

Completion date

30/04/2007

Eligibility**Key inclusion criteria**

Patient (male and female, minimum age for participation in the study was 18 years) with a fracture of one of the cusps of a vital (no root canal treatment present or necessary) premolar.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

176

Key exclusion criteria

1. Premolar with fracture of both cusps
2. Tooth mobility grade III (>1 mm horizontal tooth mobility and vertical tooth mobility)

Date of first enrolment

01/12/2001

Date of final enrolment

30/04/2007

Locations

Countries of recruitment

Netherlands

Study participating centre

Philips van Leijdenlaan 25

Nijmegen

Netherlands

6525 EX

Sponsor information

Organisation

Radboud University Nijmegen Medical Centre (Netherlands)

Sponsor details

College of Dental Science

Philips van Leijdenlaan 25

Nijmegen

Netherlands

6525 EX
+31 24 361 40 04
w.fennis@dent.umcn.nl

Sponsor type

Hospital/treatment centre

Website

<http://www.umcn.nl>

ROR

<https://ror.org/05wg1m734>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Radboud University Nijmegen Medical Centre (Netherlands)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2006		Yes	No
Results article	five-year results	01/01/2014		Yes	No