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

Submission date
22/02/2013

Recruitment status
No longer recruiting

Registration date
12/03/2013

Overall study status
Completed

Last Edited
29/10/2013

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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 are 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

Study type(s)
Treatment

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

Key secondary outcome(s))
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)

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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)

ROR
https://ror.org/05wg1m734

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Radboud University Nijmegen Medical Centre (Netherlands)

Results and Publications

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes