

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Clinical evaluation of three adhesive systems for the restoration of non-carious cervical lesions

Protocol summary

Summary

The aim of this study is to compare the clinical performance of three different adhesive systems over a period of 18 months in noncarious Class V lesions. Thirty patients, male and female, (aged 20-50 years) with at least three noncarious cervical lesions were enrolled in the study. Subjects were healthy and without any systemic or periodontal disease. The selected teeth must have contact with opposite teeth without any high occlusion stress. Subjects with poor oral hygiene and under treatment with anti sensitivity materials excluded from the study. One operator placed ninety restorations in thirty patients. The teeth were restored randomly with one adhesive and manufacturers' instructions were followed. The deep of cervical lesion should not be more than 2 mm. The teeth were restored with three adhesive systems including; Opti Bond FL (total etch, three steps), Opti Bond Solo (total etch, two steps) and Opti Bond All-in-one (self etch, one-step) and then with Herculite (Kerr) resin composite. Thirty restorations were placed in cavities with no marginal bevels and no mechanical retentions for each adhesive system. The restorations are photographed at baseline and at recall periods. Patients will be recalled at 6, 12 and 18 months after intervention, and two examiner will evaluate the restorations using the USPHS criteria for color match, marginal discoloration, marginal adaptation, caries formation, anatomic form, postoperative sensitivity, surface roughness, and retention. Finally, the ranking of restorations will be done for three different studied adhesives from the standpoint of clinical performance in three recall evaluation times.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138709301509N1**

Registration date: **2009-05-03, 1388/02/13**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2009-05-03, 1388/02/13

Registrant information

Name

Horieh Moosavi

Name of organization / entity

Dental School of Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

The Research Council of Mashhad and Tabriz University of Medical Sciences, Mashhad, Tabriz Iran.

Expected recruitment start date

2008-06-21, 1387/04/01

Expected recruitment end date

2008-11-21, 1387/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical evaluation of three adhesive systems for the restoration of non-carious cervical lesions

Public title

Clinical evaluation of three adhesive systems for the restoration of non-carious cervical lesions

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Age 20 to 50 years, signing informed consent prior to commencement of any treatment, Presence of at least have three NCCLs, having contact with opposite teeth without any high occlusion stress for selected teeth, cavity cervical margins placed on cementum with no more than 50% put on enamel, assessable isolation and observable and easily accessible gingival margins during tooth restoration, Exclusion Criteria: Any systemic disease, any periodontal disease, history of periodontal surgery three months prior to study, poor oral hygiene, treatment with anti sensitivity materials such as desensitizer dentifrices, high-risk caries, cervical lesions with caries and restricted to the labial area with extending to proximal surfaces, cervical lesions with severe degree of sclerosis, presence of any caries or restorations except in cervical area of the tooth labial portion, the deep of cervical lesion more than 2 mm (probe measurement), depth of lesion more than usual that need to liner placement such as calcium hydroxide.

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features

All restorations will be done by One operator. Two examiners will recall and examine the restorations.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical Sciences

Street address

Official Center of Mashhad university of Medical Sciences , University street.

City

Mashhad

Postal code

13131-91389

Approval date

2008-11-06, 1387/08/16

Ethics committee reference number

86470

Health conditions studied**1****Description of health condition studied**

Noncarious cervical lesions

ICD-10 code

K03.1

ICD-10 code description

Abrasion of teeth

2**Description of health condition studied**

Noncarious Cervical Lesions

ICD-10 code

K03.2

ICD-10 code description

Erosion of teeth

Primary outcomes**1****Description**

Color match

Timepoint

Baseline, 6 month, 12 month and 18 month after first appointment

Method of measurement

Visual inspection with mirror at 45 cm and periodic photography

2**Description**

Retention

Timepoint

Baseline, 6 months, 12 months and 18 months after intervention

Method of measurement

Visual inspection with explorer and mirror

Secondary outcomes**1****Description**

Anatomic form

Timepoint

Baseline, 6 months, 12 months and 18 months after intervention

Method of measurement

Visual inspection with explorer and mirror, if needed

2

Description

Caries formation

Timepoint

Baseline, 6 months, 12 months and 18 months after intervention

Method of measurement

Visual inspection with explorer, mirror, radiographies, if needed

3

Description

Marginal adaptation

Timepoint

Baseline, 6 months, 12 months and 18 months after intervention

Method of measurement

Visual inspection with explorer and mirror, if needed

4

Description

Marginal discoloration

Timepoint

Baseline, 6 months, 12 months and 18 months after intervention

Method of measurement

Visual inspection with mirror at 45 cm

5

Description

Postoperative sensitivity

Timepoint

Baseline, 6 months, 12 months and 18 months after intervention

Method of measurement

Questioning the patients

6

Description

Surface roughness

Timepoint

Baseline, 6 months, 12 months and 18 months after intervention

Method of measurement

Visual inspection with explorer and mirror

Intervention groups

1

Description

Seventh Generation, One step, Optibond All-in-One (Kerr)

Category

Treatment - Other

2

Description

Fifth Generation, Total-etch, two step, OptiBond Solo (Kerr)

Category

Treatment - Other

3

Description

Fourth generation, total-etch, three steps, OptiBond FL(Kerr)

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic of Mashhad Health Center and Mashhad Dental School

Full name of responsible person

Rajabali Khodadadi

Street address

No. 24, Faramarz abasi 25

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Mashhad and Tabriz Universities of Medical Sciences.

Full name of responsible person

Dr. Horieh Moosavi

Street address

No. 44, Daneshjo 24,Blv. Daneshjo, Blv. Vakil Abad.

City

Mashhad

Grant name

86470

Grant code / Reference number

86470

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor for Research, Mashhad and Tabriz Universities of Medical Sciences.

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Dental Research Center of Mashhad Dental School
Full name of responsible person
Dr. Horieh Moosavi
Position
Assistant professor
Other areas of specialty/work
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Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty