ISRCTN13550429 https://doi.org/10.1186/ISRCTN13550429

Comparing survival of teeth after restoration using two types of filling material

Submission date
03/02/2019

Recruitment status
No longer recruiting

Registration date
15/02/2019

Overall study status
Completed

Last Edited
22/02/2019

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Atraumatic restorative treatment (ART) is an approach to dental treatment that uses only hand-powered instruments. Electricity, anaesthetics and advanced tools are not needed, which means that this approach can be used in developing countries to treat dental cavities, which are otherwise often treated by removing the tooth. ART can also be used in patients who have a dental phobia. However, ART treatment of teeth with complex cavities can have a higher chance of failing than conventional treatment. This trial aims to investigate compare two types of cement material used to fill cavities using the ART approach.

Who can participate?
Secondary school students aged 15 or 16 years who have at least one premolar or molar tooth with decay that has resulted in a cavity.

What does the study involve?
Participants will be randomly allocated to one of two groups. Participants in both groups will have their cavities treated using ART. The cavities will be filled with one filler or the other depending on which group they were allocated to. The participants will come back for a dental examination at 1 week and 6, 12, 18 and 24 months after the treatment and the success of the tooth restoration will be assessed each time.

What are the possible benefits and risks of participating?
The procedure is the same for both groups and might involve some discomfort when the decay is being cleaned out of the cavity. One of the fillers might result in a lower chance of the filling and the tooth remaining sound.

Where is the study run from?
Cairo University Dental School (Egypt)

When is the study starting and how long is it expected to run for?
November 2010 to May 2016

Who is funding the study?
The researcher is funding the study.

Who is the main contact?
Enas Mobarak, enasmobarak@hotmail.com

Contact information

Type(s)
Scientific

Contact name
Prof Enas Mobarak

Contact details
Faculty of Oral and Dental Medicine
Cairo University
11 El Saraya Street
Manial
Cairo
Egypt
12311

Type(s)
Scientific

Contact name
Dr Jo Frencken

ORCID ID
https://orcid.org/0000-0001-9612-1752

Contact details
Radboud University College of Dental Science
Nijmegen
Netherlands
6525 XZ
-
Jo.Frencken@radboudumc.nl

Additional identifiers

Protocol serial number
RHD-IRB0000687-13oct2014-EM02

Study information

Scientific Title

Survival of multiple-surface ART restorations using a zinc-reinforced glass-ionomer restorative after 2 years: A randomized triple-blind clinical trial

Study objectives
The survival of multiple-surface atraumatic restorative treatment (ART) zinc-reinforced high-viscosity glass-ionomer cement (HVGIC) restorations in permanent posterior teeth is significantly higher than that of comparable restorations using conventional HVGIC after 2 years.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/10/2014, ethical committee at Ministry of Health and Population, Government Health Insurance in Egypt, ref: RHD-IRB0000687-13Oct2014-EM02

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Tooth cavity in more than one surface

Interventions
Randomisation:
The test intervention was a new restorative material (zinc-containing glass-ionomer cement [ChemFil Rock]). The control intervention was a commonly used glass-ionomer material, FUJI IX GP. First a computer programme randomised a test/control restoration over the four operators and by gender. Using envelopes with marks for gender, the student chose the envelope of his /her gender and presented it to a third person who, using a randomised list of restorative materials, informed the operator which restorative was to be used. The intervention was masked for operator, evaluation (using replicas) and statistician (test-control group only known by chief investigator).

Intervention:
Tooth cavities were prepared entirely using hand instruments. Soft carious dentine was excavated using ART hand excavators. Then the cavity was wiped with water-soaked cotton pellets, dried using dry cotton pellets and cautiously inspected for the presence of soft dentine, which was then removed when necessary.
In the control arm, a dentine conditioner was applied to the floor and the walls of the prepared cavity for 10 s. The conditioner was rinsed out using a cotton pellet soaked in water until no remnant of the conditioner was visible (about 10 s). Then, the cavity was blotted using dry cotton pellets (5 s). This procedure was not performed in the test arm. A prefabricated matrix band and a wedge were inserted. A high-viscosity glass-ionomer cement (HVGIC) was the filling material. In the test group, HVGIC Chemfil Rock was inserted in the tooth cavity and in the control arm, HVGIC Fuji IX GP was used. Excess HVGIC was removed with a large excavator and

ART contouring instrument and left to harden for 25-30 s. The wooden wedge and matrix band were then removed and the height of the filling was checked using an articulating paper. Participants were instructed neither to eat nor to brush the restored side of the mouth for at least 2 h, and to brush the teeth twice daily with a fluoride containing toothpaste every day thereafter. The participant was also advised to contact the operator in case of having any dental problems or pain.

Evaluation:
Using intra-oral photographic mirrors, digital clinical photographs of the occlusal and approximal surfaces were taken preoperatively after cavity preparation and postoperatively at baseline (1 week post-restoration) and at each of the four follow-up time points (6, 12, 18 and 24 months) using a digital camera Nikon D40 and a Macro lens supplied with a ring flash.
A replica of each restored tooth was produced at each of the evaluation points. Two independent evaluators assessed the restorations using ART restoration assessment criteria and those of the FDI (World Dental Federation). In case of disagreement, the case was discussed and consensus reached. Restoration survival curves were estimated and difference between variables were tested with a Wald (chi-square) test.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Survival of multiple-surface ART restorations after 2 years

Key secondary outcome(s)
Main reason for failure of restorations after 2 years

Completion date
31/05/2016

Eligibility

Key inclusion criteria
1. Secondary school students
2. Healthy patients without any history of any medical condition that could interfere with the study protocol or affect clinical results
3. Good oral hygiene (Simplified Oral Hygiene Index (S-OHI ≤0.5%)
4. Caries prevalence (DMFS) <12
5. Without adverse oral habits that could affect the study results
6. Presence of natural antagonist tooth that is not restored
7. Presence of at least one tooth with a cavitated or dentine carious lesions including at least occlusal-proximal (multi-surface) surface in first or second permanent premolars/molars situated in any side of the jaw
8. Presence of adjacent tooth to the cavity and being fully erupted, normally positioned (not titled or rotated) and having natural (not restored) contact
9. Occluso-proximal cavities with size (Site/Stage 2.2, 2.3 and 2.4)
10. Absence of apparent enamel crack or fracture
11. No pulp involvement or symptoms of pulpitis or apical periodontitis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
218

Key exclusion criteria
1. Teeth without antagonist teeth or with a prosthetic antagonist
2. Occlusal-proximal cavities limited to enamel layer
3. Deciduous teeth
4. Abnormal oral habits with excessive occlusal function or parafunction, such as pencil chewing or bruxism
5. Daily consumption of citrus juices

Date of first enrolment
01/03/2012

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
Egypt

Netherlands

Study participating centre
Cairo University Dental School
14 El Ansar Street
Dokki
Cairo
Egypt
12311

Study participating centre
Radboud University Medical Centre
P.O. Box 9101

Nijmegen
Netherlands
6500 HB

Sponsor information

Organisation
Dental School, University of Cairo

ROR
https://ror.org/03q21mh05

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data were stored at the Radboud University Medical Centre, Geert Grooteplein Zuid 10, 6525 GA Nijmegen, The Netherlands. The availability of the data is unknown and there is no data sharing plan.

IPD sharing plan summary
Stored in repository