ISRCTN98762227 https://doi.org/10.1186/ISRCTN98762227

Bioactive composite in restoring class II cavities in primary teeth

Submission date 07/06/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 17/06/2024	**Overall study status** Completed	
Last Edited 17/06/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
To evaluate the clinical success of ACTIVA™ KIDS BioACTIVE restoration and to compare it with RMGIC (GC FUJI® II 2 LC CAPSULE) and conventional composite (Tetric®n-ceram, Ivoclar Vivadent). The study hypothesis is that there is a significant difference between ACTIVA™ KIDS BioACTIVE and RMGIC (GC FUJI® II 2 LC CAPSULE) and the conventional composite (Tetric®n-ceram, Ivoclar Vivadent) in clinical success.

Who can participate?
Children resident in Al-Aman orphanage aged between 6 to 9 years old. The sample size will consist of 40 restorations in 20 children for study 1 and 40 restorations in 20 children for study 2.

What does the study involve?
The study participants will be divided into two groups 1) The cavities will be restored with ACTIVA™ KIDS BioACTIVE, and conventional composite (Tetric®n-ceram, Ivoclar vivadent) and, 2) The cavities will be restored with ACTIVA™ KIDS BioACTIVE, and RMGIC (GC FUJI® II 2 LC CAPSULE), both as a split-mouth technique.

The selected teeth will be on either side of the jaw, upper or lower jaw, and both primary molars (first and/or second) with occlusal and proximal enamel/dentine caries with a 4/5 score according to ICDAS. All teeth should be vital, restorable and free of these symptoms: spontaneous pain, swelling, fistula, abscess or tenderness on percussion, and pathological mobility.

The teeth will be anesthetized by Lidocaine 2% + Epinephrine 1/100000 (Lignospan® standard) and isolated using a rubber dam. Caries will be removed using a high-speed diamond bur. The proximal box will be prepared to take into consideration the following dimensions :
The bucco-lingual dimensions involve the middle third of the intercuspal space of the occlusal surface of the tooth.
The buccal and lingual outlines of the box are parallel to the buccal and lingual surfaces of the tooth.
The gingival floor should exceed the contact point.
The axial wall should be perpendicular to the gingival floor.

The cavo-surface margin is not beveled.
The unsupported enamel should be removed.
Any residual caries will be removed by a low-speed handpiece or excavator.
After caries removal, a metal matrix band (YOUNG ™, USA) and a wedge will be inserted to preserve the gingival interproximal embrasure.
The restorative materials will be chosen according to the randomization and placed in the cavity according to the manufacturer's instructions

Evaluation criteria:
All the teeth will be evaluated for anatomical form, marginal integrity, marginal discoloration, color stability, recurrent caries, and surface texture after 3, 6 and 9 months by two blinded and calibrated evaluators using modified United States Public Health Service (USPHS) Ryge Criteria.

What are the possible benefits and risks of participating?
many benefits can be achieved such as treating orphan patients, founding an alternative material for composite in treating class II cavities in primary teeth, such material can release ions and trigger remineralization so we can reduce the risk of caries for these patients. No risks were expected in this study.

Where is the study run from?
Damascus University

When is the study starting and how long is it expected to run for?
October 2021 to September 2025

Who is funding the study?
1. Damascus University
2. Pulpdent company provided the study materials for free

Who is the main contact?
Dr Safaa Bassam Shihabi, safaa2671991@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Safaa Bassam Shihabi

Contact details
Al-Mojtahed
Damascus
Syria
7203
+963 0934101164
safaa2671991@gmail.com

Additional identifiers

Study information

Scientific Title
Evaluation of the effectiveness of bulk-fill bioactive composite in restoring class II cavities in primary teeth and comparing it with traditional composite and resin-modified glass ionomer (randomized-split mouth-clinical trial)

Study objectives
Null hypothese (1): there is no statistically significant difference between bioactive composite and traditional composite.
Alternative hypothese (1): there is a statistically significant difference between bioactive composite and traditional composite.
Null hypothese (2): there is no a statistically significant difference between bioactive composite and RMGI.
Alternative hypothese (2): there is a statistically significantdifference between bioactive composite and RMGI.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 18/10/2022, Faculty of Dentistry Ethical Committee Board of Damascus University (Almazzah, Damascus, 72039, Syria; None available; mohannad1.laflouf@damascusuniversity.edu.sy), ref: None provided

Primary study design
Interventional

Study design
interventional double-blinded randomized controlled trial.

Study type(s)
Prevention, Treatment, Efficacy

Health condition(s) or problem(s) studied
Restoring of Class II dental caries with bioactive composite, traditional composite and resien modified glass inomer

Interventions
This is an experimental prospective double-blinded (the patient and the examiner) split-mouth randomized controlled trial. The study patients will be divided into two groups using the randomization website (www.randomization.org), for example, patient number one in group 1, and patient number 6 in group 2. Then in the same group, the child will throw the dice numbered from 1 to 6 to select the side of the restoration right or left (1, 3, 5 refers to the right side of the jaw) and (2, 4, 6 refers to the left side of the jaw), then the patient throws the second dice to select the restoration (1, 3, 5 refers to composite restoration and 2, 4, 6 refers to bioactive restoration) dice 3 (1, 3, 5 refers to bioactive restoration and 2, 4, 6 refers to RMGI restoration).

1. The first study: The cavities will be restored with ACTIVA™ KIDS BioACTIVE, and conventional composite (Tetric®n-ceram, Ivoclar vivadent) using a split-mouth technique.

2. The second study: The cavities will be restored with ACTIVA™ KIDS BioACTIVE, and RMGIC (GC FUJI® II 2 LC CAPSULE) using a split-mouth technique.

Informed consent:
An informed consent will be signed by the parents after their approval to participate in the study.

Sample size:
The sample size will consist of 40 restorations in 20 patients for study 1 and 40 restorations in 20 patients for study 2.

Inclusion criteria:
The selected teeth will be on either side of the jaw, upper or lower jaw, and both primary molars (first and/or second) with occlusal and proximal enamel/dentine caries with a 4/5 score according to ICDAS. All teeth should be vital, restorable and free of these symptoms: spontaneous pain, swelling, fistula, abscess or tenderness on percussion, and pathological mobility.

Exclusion criteria:
If one or more of the above-mentioned criteria is not obtained, the patient will be excluded from the study.

Clinical procedures:
The teeth will be anesthetized by Lidocaine 2% + Epinephrine 1/100000 (Lignospan® standard) and isolated using a rubber dam. Caries will be removed using a high-speed diamond bur. The proximal box will be prepared to take into consideration the following dimensions:
1. The buccolingual dimensions involve the middle third of the intercuspal space of the occlusal surface of the tooth
2. The buccal and lingual outlines of the box are parallel to the buccal and lingual surfaces of the tooth.
3. The gingival floor should exceed the contact point
4. The axial wall should be perpendicular to the gingival floor
5. The cavo-surface margin is not beveled
6. The unsupported enamel should be removed

Any residual caries will be removed by a low-speed handpiece or excavator.
After caries removal, a metal matrix band (YOUNG ™, USA) and a wedge will be inserted to preserve the gingival interproximal embrasure.
The restorative materials will be chosen according to the randomization and placed in the cavity according to the manufacturer’s instructions. (Randomization will be determined ahead of time).

Evaluation criteria :
All the teeth will be evaluated after 3, 6 and 9 months by two blinded and calibrated evaluators using modified United States Public Health Service (USPHS) modified Ryge Criteria.
The included criteria were: Anatomical form, marginal integrity, marginal discoloration, color stability, recurrent caries, and surface texture.

Intervention Type
Procedure/Surgery

Primary outcome(s)

Anatomical form, Marginal integrity, Marginal discoloration, Color stability, Recurrent caries, Surface texture of all the restored teeth measured by two blinded and calibrated evaluators using modified United States Public Health Service (USPHS) Ryge Criteria at 3, 6 and 9 months

Key secondary outcome(s)
The following secondary outcome variables will be measured by two blinded and calibrated evaluators using modified United States Public Health Service (USPHS) Ryge Criteria at 3, 6 and 9 months:
1. Clinical success and caries degree
2. Clinical success and within the restoration in the upper or lower jaw
3. Clinical success and within the restoration mesial or distal
4. Clinical success and within the restoration in the first or second molar

Completion date
30/09/2025

Eligibility

Key inclusion criteria
1. An informed consent will be signed by the parents after their approval to participate in the study
2. All the patients should be healthy (ASA1) and cooperative
3. All the selected teeth will be on either side of the jaw, upper or lower jaw, and both primary molars (first and/or second) with occlusal and proximal enamel/dentine caries with a 4/5 score according to ICDAS
4. All teeth should be vital, restorable and free of these symptoms: spontaneous pain, swelling, fistula, abscess or tenderness on percussion, and pathological mobility

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
9 Years

Sex
Male

Key exclusion criteria

1. Unhealthy patient
2. Uncooperative patient
3. If one or more of the abovementioned inclusion criteria is not obtained

Date of first enrolment
30/12/2023

Date of final enrolment
30/12/2024

Locations

Countries of recruitment
Syria

Study participating centre
Al_Aman Orphanage
Al-Mojtahed
Damascus
Syria
72039

Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
University/education

Funder Name
Damascus University

Alternative Name(s)
University of Damascus, , DU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Syria

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			17/06/2024	No	Yes
Protocol file			17/06/2024	No	No