ISRCTN52747143 https://doi.org/10.1186/ISRCTN52747143

Comparing the performance of two types of aesthetic crowns for children's primary teeth

Submission date
13/05/2025

Recruitment status
No longer recruiting

Registration date
27/05/2025

Overall study status
Completed

Last Edited
27/05/2025

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 aim
This study aims to evaluate the clinical performance of different types of prefabricated crowns used to restore second primary molars after pulpotomy (a common procedure to treat infected dental pulp in children). The crowns being studied include BioFlx, Zirconia, and stainless steel crowns with silver and gold coloring. The goal is to assess how well these crowns protect the treated teeth, maintain function.

Who can participate?
Children aged 6 to 10 years who need full-coverage restoration after pulpotomy, have good oral hygiene, and are cooperative during dental treatment may be eligible to participate. Written informed consent from parents or guardians is required.

What does the study involve?
Children will receive a pulpotomy on one or more second primary molars. The treated tooth will then be restored with one of the study crowns. Follow-up appointments will take place at 1, 6, and 12 months after treatment to check the crown's fit and oral health.

What are the possible benefits and risks of participating?
Benefits:
The child will receive a high-quality, full-coverage restoration.
Regular follow-up may help detect and manage any issues early.
The findings may help improve future pediatric dental care.

Risks:
Minor discomfort during treatment or follow-up.
Possible failure of the crown, requiring further dental treatment.

Where is the study run from?
Department of Pediatric Dentistry, Faculty of Dentistry, University of Damascus, Syria

Who is funding the study?
This study is self-funded by the principal investigator and supported by the Faculty of Dentistry, University of Damascus.

Who is the main contact?
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Protocol serial number
UDDS-1157-30122024/SRC-1550

Study information

Scientific Title

Evaluation of the clinical performance of two types of prefabricated aesthetic crowns in the restoration of primary molars: a randomized controlled trial

Acronym
PEARP

Study objectives
This study is based on the following null hypotheses:
Marginal Adaptation: There is no difference between prefabricated aesthetic crowns (BioFlx and Zirconia) and stainless-steel crowns (silver and gold colored) in terms of marginal adaptation on primary molars.

Gingival Health: There is no difference between prefabricated aesthetic crowns (BioFlx and Zirconia) and stainless-steel crowns (silver and gold colored) regarding their impact on gingival health.

Dental Arch Length: There is no statistically significant difference between prefabricated aesthetic crowns (BioFlx and Zirconia) and stainless-steel crowns (silver and gold colored) in their influence on dental arch length maintenance.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/12/2024, Biomedical Research Ethics Committee of Damascus University (University Presidency Building, University Campus, Baramkeh 23J89, Damascus, 00000, Syria; +963 1133923012; president@damasuniv.edu.sy), ref: 1157

Primary study design
Interventional

Study design
Single-center interventional randomized controlled trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Extensively decayed second primary molars requiring pulpotomy and full coronal restoration

Interventions
Participants were randomly assigned to one of four study groups using computer-generated block randomisation (block size = 8). An independent researcher generated the sequence and prepared sealed, opaque envelopes to ensure allocation concealment. Envelopes were opened only after participant eligibility was confirmed.

Following participant inclusion, baseline clinical parameters will be recorded by the examiner, including the Oral Hygiene Index-Simplified (OHIS), Gingival Index (GI), Plaque Index (PI), Bleeding on Probing (BOP), and assessment of contact points. Local anesthesia will be administered prior to tooth preparation.

Primary molars allocated to receive BioFlx (Experimental), Gold stainless steel (Experimental), and silver stainless steel (Control) will be prepared using the following protocol:
Occlusal reduction of 1–1.5 mm
Axial reduction of 20–30% using a tapered bur
Rounding of axial walls
Trial fitting to ensure occlusal accuracy
Final cementation with Fuji I glass ionomer cement
Occlusal adjustment as needed

Primary molars allocated to receive Zirconia Crowns (Experimental) will be prepared using the following protocol:
Occlusal surface reduction of 1–2 mm using a flame-shaped bur
Opening of interproximal areas
Axial reduction of 20–30% (approximately 0.5–1.25 mm), maintaining a natural tooth contour
Finishing of all tooth walls with a subgingival margin (1–2 mm)
Occlusal adjustment as needed
All procedures will be performed under rubber dam isolation when feasible and in accordance with the manufacturers' recommendations.

Intervention Type
Procedure/Surgery

Primary outcome(s)
The following primary clinical and photographic evaluations are carried out at 1, 6, and 12 months:
1. Oral Hygiene Index-Simplified (OHIS), defined as 0 = No debris; 3 = Debris > 2/3 of surface. Interpretation: 0–1 = Good, 1–2 = Fair, 2–3 = Poor
2. Plaque Index (PI), defined as 0 = absence of plaque, 1= Thin film of plaque, 2= moderate accumulation of plaque 3 = Large amount of Plaque
3. Gingival Index (GI), defined as 0 = Normal, 1= mild inflammation, 2= moderate inflammation 3 = Severe inflammation
4. Bleeding on Probing (BOP), defined as (-) = No bleeding, (+) = Bleeding after probing
5. Marginal integrity, defined as 0 = No gap, 2 = Visible gap

Key secondary outcome(s)
Contact points (0 = Normal, 2 = Open), Crown fracture (0 = Intact, 1 = Minor chipping, 2 = Cracks, 3 = Full fracture), measured using clinical and photographic evaluations to the United States Public Health Service (USPHS) Criteria at 1, 6, and 12 months

Completion date
01/10/2026

Eligibility

Key inclusion criteria
1. Age 6–10 years
2. Good/acceptable oral hygiene
3. Positive or definitely positive Frankl behavior rating
4. Indication for full-coverage restoration (endodontically treated teeth)
5. Absence of mobility or sinus tract

6. Healthy child (no systemic illness or medication-induced gingival overgrowth)
7. Normal occlusion, no bruxism
8. Presence of opposing and adjacent teeth
9. Signed informed consent and commitment to follow-ups

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 Years

Upper age limit
10 Years

Sex
All

Key exclusion criteria
1. Poor oral hygiene or presence of uncontrolled plaque or gingivitis
2. Uncooperative behavior, defined as negative or definitely negative on the Frankl behavior rating scale
3. Children with systemic illnesses or conditions that may affect gingival health (e.g., medication-induced gingival overgrowth)

Date of first enrolment
01/05/2025

Date of final enrolment
15/07/2025

Locations

Countries of recruitment
Syria

Study participating centre
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Sponsor information

Organisation
Damascus University

ROR
https://ror.org/03m098d13

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Ahmad Taleb; ahmed.taleb1195@gmail.com
Data Availability:
IPD will be made available to researchers after the study's final publication in a de-identified format to protect participant privacy.
Access:
Researchers can request access to the data by submitting a research proposal for review by the study's ethics or data access committee.
Timeline:
Data will be shared within [6 months] after the study's final publication.
Security:
Data will be anonymized and stored in secure, password-protected databases with access restricted to authorized personnel.
Ethics and Consent:
Participants have given consent for their de-identified data to be used for future research. Data sharing will comply with the study's ethical guidelines.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			27/05/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes