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The effect of cement material on performance of Zirconia dental crowns in children

Submission date
09/01/2021

Recruitment status
No longer recruiting

Registration date
19/02/2021

Overall study status
Completed

Last Edited
30/06/2023

Condition category
Oral Health

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

Plain English summary of protocol

Background and study aims
Early childhood tooth decay is a significant public health problem with consequences on both oral and general health. Maintaining healthy teeth in children is important for the child's overall health and well being. Several treatment options have been proposed for restoring carious (decayed) primary (baby) teeth in children. Recently, Zirconia crowns have been introduced as a realistic and good looking option. Despite the increasing use of these crowns, there are only a few clinical trials assessing the clinical outcomes and the survival of these crowns. One of the aspects that have been scarcely investigated in the clinical settings is the type of cement used to secure these crowns.

Who can participate?
Children (age 3-6 years) with at least two upper incisors that require full coverage with Zirconia crowns, and who are otherwise medically healthy or having mild medical illness.

What does the study involve?
Pair-matched incisors will be randomly assigned to receive a type of cement material (either Bio-active cement or Glass Ionomer cement) for crown cementation.
The crowns will be clinically evaluated for retention, and gingival (gum) condition at 1 week, 1 -,3- , 6- , 12- and 24-month follow up appointments.

What are the possible benefits and risks of participating?
Children are expected to benefit from the provision of Zirconia crowns for the treatment of their decayed front teeth. In addition to treating decay, these crowns restore esthetics and function. Zirconia crowns are safe and biocompatible. Regular checkups will be scheduled to participants as part of the study.
There are no particular potential risks associated with the provision of these crowns. If the treatment is going to be provided under general anesthesia (i.e. if the child is going to be put to sleep to get this treatment done), then any potential risks will be discussed/explained by the anesthetist.

Where is the study run from?
Jordan University of Science and Technology

When is the study starting and how long is it expected to run for?
February 2020 to June 2026

Who is funding the study?
Jordan University of Science and Technology

Who is the main contact?
Dr Thikrayat Bani-Hani, tgbanihani@just.edu.jo

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
70-2020

Study information

Scientific Title
Clinical evaluation of pediatric Zirconia crowns cemented with two luting cements: a split-mouth randomized controlled trial

Study objectives
The study seeks to compare the efficacy of using bio-active cement versus glass ionomer cement with anterior zirconia crowns.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 31/03/2020, JUST (Jordan University of Science and Technology) Institutional Research Board (IRB) (Ar Ramtha 3030, Irbid, 112200, Jordan; +962 7200600, ext 450102; irb@just.edu.jo), ref: 70-2020

Primary study design
Interventional

Study design
Split-mouth randomized clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Two or more carious primary maxillary incisors that require full coverage with Zirconia crowns.

Interventions
This is a split-mouth randomized clinical trial involving 25 three- to six-year-old children with a total of 25 pairs of maxillary incisors requiring primary zirconia crowns.

All potential participants will be examined by the principal investigator for their treatment needs. Only those who require comprehensive oral treatment under General Anesthesia (GA) will be involved in the study to ensure symmetrical preparations and eliminate any potential influences due to behavioral/cooperation factors..

According to the AAPD, and excluding patients with physical or mental disability and patients with acute infections for the purpose of the current study, the following are the criteria for listing patients for dental treatment under GA:
1. Patients who are extremely uncooperative, fearful, anxious, or uncommunicative
2. Patients who require significant surgical procedures or immediate, comprehensive oral/dental care

Dental treatment will be provided under general anesthesia at King Abdullah University Hospital (KAUH). All teeth will be restored by one dentist who is trained in tooth preparation for zirconia crowns. Local anesthesia and rubber dam isolation will be used whenever applicable.
Each participant will receive a minimum of two and a maximum of four Zirconia crowns according to each case needs.

Pair-matched incisors will be randomly assigned to receive either bio-active cement or glass ionomer cement for crown cementation. Randomisation is going to be computer-generated using Excel.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Crowns retention will be checked by gently probing around the crown at 1 week, 1-, 3-, 6- , 12- and 24-months by the dental surgeon

Key secondary outcome(s)

Gingival health will be measured using the gingival index at 1 week, 1-, 3-, 6- , 12- and 24-months by the dental surgeon

Completion date
01/06/2026

Eligibility

Key inclusion criteria
1. Children aged 3 - 6 years with at least two or more carious primary maxillary incisors that require full coverage with Zirconia crowns. Indications for zirconia crowns:
1.1. Multiple surface caries
1.2. Large single surface caries
1.3. Involvement of incisal edge
1.4. Minor caries but high-risk pt
1.5. Following pulp therapy
2. ASA I and ASA II who will receive treatment under general anesthesia
3. Patients available for recalls as outlined in the study protocol

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 Years

Upper age limit
6 Years

Sex
All

Key exclusion criteria
1. Patient is ASA III or higher
2. Incisors with multiple hypoplastic defects or developmental disturbances
3. Carious primary incisors that are not indicated for zirconia crowns:
3.1. Incisors with root/subgingival caries
3.2. Incisors with very little tooth structure that is inadequate for crown retention , i.e. unrestorable
3.3. Incisors with signs or symptoms of extensive pathology such as mobility grade II or more, internal resorption or excessive external root resorption involving more than one-third of the root, or with significant inter radicular/periapical radiolucency (root and inter radicular /periapical area will be assessed based on a preoperative radiographic examination (with

periapical or anterior occlusal radiograph) in cooperative patients)
3.4. Incisors that are expected to exfoliate in 6 - 12 months
4. Patients that show signs of severe bruxism or teeth clenching

Date of first enrolment
01/06/2021

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
Jordan

Study participating centre
Jordan University of Science and Technology and King Abdullah University Hospital
Ar Ramtha 3030
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Sponsor information

Organisation
Jordan University of Science and Technology

ROR
https://ror.org/03y8mtb59

Funder(s)

Funder type
University/education

Funder Name
Jordan University of Science and Technology

Alternative Name(s)
, JUST

Funding Body Type

Government organisation

Funding Body Subtype
Local government

Location
Jordan

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request