ISRCTN15852623 https://doi.org/10.1186/ISRCTN15852623

# Evaluation of EQUIA Forte® HT as a restorative material for primary molars

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 16/08/2023 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 21/08/2023 | Completed | [ ] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 21/08/2023 | Oral Health | [ ] Record updated in last year |

## Plain English summary of protocol

Background and study aims
Restorative treatments are performed on children worldwide on a regular basis. Although the placing of restorations is a common treatment strategy in clinical practice, it has been noted that there is little scientific data to determine which filling material is the best for treating caries in primary dentition. Since their introduction, resin composites have grown in popularity and are now considered the most often utilized restorative materials. Due to the special qualities of glass ionomer cement (GIC), it has been employed in pediatric patients for many years. The drawbacks in the physical properties of GICs limited their use in high-stress locations. EQUIA Forte® HT Fil with its coating EQUIA Forte® Coat are a recently introduced restorative system marketed as a strong biocompatible long-term bulk fill option for the treatment of pediatric patients. The aim of this study is to evaluate the clinical and radiographic success rate of EQUIA Forte® HT Fil (GC Corp, Tokyo, Japan) as a restorative material for proximal caries for primary molars in comparison to nanohybrid composite (Tetric® N-Ceram, Ivoclar Vivadent, Schaan, Liechtenstein).

Who can participate?
Children aged from 4-11 years old with primary molars that have proximal carious lesions with no signs of pulpal involvement

What does the study involve?
Teeth will be randomly restored by either Tetric® N-Ceram (control group) or EQUIA Forte® HT Fil (experimental group). The teeth will be evaluated clinically and radiographically after 6 and 12 months.

What are the possible benefits and risks of participating?
This study will help to enhance the existing knowledge and the quality of evidence in the management of dental caries in primary molars.
Study participants will benefit from this study as the material used in the control group (resin composite) is considered the most used material to be used in restorative treatment. The precursor materials of the experimental material also showed a good success rate in the studies available. The limited data published about the experimental material in lab studies showed promising results. The manufacturer stated that the new material was introduced to improve

the physical properties of the restoration to overcome the drawbacks of its precursor. There is a risk if the material is ingested or comes in contact with eyes, and to overcome these risks all the restorative procedures will be done with either rubber dam or cotton roll isolation and with the use of protective eyeglasses. The risk of immediate restoration failure is rare and usually associated with misdiagnosis and results in pain, teeth sensitivity and tenderness to bite. Failed teeth will receive the proper treatment which include redo of restoration, pulpotomy, pulpectomy or extraction and space maintainer.

Where is the study run from?
Dental University Hospital, King Saud University (Saudi Arabia)

When is the study starting and how long is it expected to run for?
June 2022 to June 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Saleh Yousif Alqasabi, s.alqasabi@gmail.com

# Contact information

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Scientific

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
E-22-6878

# Study information

### Scientific Title
Evaluation of EQUIA Forte® HT as a restorative material for primary molars

### Study objectives
Null hypothesis: there is no significant difference in the success rate between EQUIA Forte® HT and Tetric® N-Ceram as restorative materials for proximal caries for primary molars.
Alternative hypothesis: there is a significant difference in the success rate between EQUIA Forte® HT and Tetric® N-Ceram as restorative materials for proximal caries for primary molars.

### Ethics approval required
Ethics approval required

### Ethics approval(s)
approved 20/06/2022, Institutional Review Board, College of Medicine, King Saud University (PO Box 7805, Riyadh, Zip/postal code not provided, Saudi Arabia; (+966-11) 469-1531; rdeocampo@ksu.edu.sa), ref: E-22-6878

### Study design
Double-blind randomized clinical trial

### Primary study design
Interventional

### Study type(s)
Treatment

### Health condition(s) or problem(s) studied
Restoring carious primary teeth in children

### Interventions

Study design:
This study will be a randomized clinical trial (double-blinded to participants and evaluator), following the CONSORT guidelines. The study will be conducted at the Dental University Hospital (DUH) in King Saud University (KSU), Riyadh, Saudi Arabia.

Sample selection:
The sample will be selected from healthy children (ASA I and II) aged between 4-11 years old, who attend pediatric dental clinics at DUH with positive or definitely positive behavior according to the Frankl behavior scale and have code 4 or 5 proximal carious lesions according to the International Caries Detection and Assessment System II (ICDAS II) in one or more primary molar. In the study protocol, risks and benefits will be explained to the parents or legal guardians and informed consent will be obtained from them if they agree to participate. Primary molars satisfying the following criteria will be included in this trial;
Clinically:
1. Restorable primary molars with one proximal carious lesions (code 4 or 5 proximal carious lesions according to ICDAS II)
2. No signs of pulpal involvement (spontaneous or persistent pain, pathological mobility, tenderness to percussion)
3. Have a good likelihood of recall availability
Radiographically:
1. Proximal radiolucency in the outer half of the dentin.
2. No more than two-thirds of physiologic root resorption
3. No radiographic signs of pulp pathologies such as (widening of the PDL, internal or external root resorption, apical or furcal radiolucency).

Sample size calculation: The G*Power program (Version 3.1.9.4) was used to calculate the sample size. With an effect size of 0.48, with a power: 0.9 and level of significance is set to be 0.05, a minimum of 80 teeth should be included (40 for each group), To overcome any loss of follow up, the sample size increased to 100 teeth (50 for each group). Randomization: The teeth will be randomly assigned into one of two groups, control group (Tetric® N-Ceram, ivoclar vivadent, Schaan, Liechtenstein) and experimental group (EQUIA Forte® HT Fil, GC Corp, Tokyo, Japan) using a list of random numbers generated online with a randomization program (http://www.randomizer .org). The list of randomization will be kept with an assigned assistant. After the removal of the caries, the assigned dental assistant will check the randomization list and according to the tooth order in the study, she will provide either (Tetric® N-Ceram) or (EQUIA Forte® HT) to fill the cavity. The patients will not have any clue about the material used. However, the operator could not be blinded due to the difference in material handling.

Clinical procedure:
A complete medical and dental history will be taken for all patients. Oral prophylaxis will be performed, followed by a full mouth examination including clinical and radiographic assessments. Both operators will be trained and calibrated on using the ICDASII criteria by an experienced consultant. Clinical assessment under the light of the dental unit will start by drying the teeth with an air syringe and using a blunt probe to clean the grooves. Then a standardized bitewing and periapical radiograph will be taken for the teeth to evaluate the carious lesions levels using the Snap A-Ray device (Dentsply Sirona, Johnson City, TN, USA). The teeth satisfying the inclusion criteria will be booked. The clinical procedure will be standardized for all included teeth, starting with topical anesthesia application for at least two minutes (20% Benzocaine, Ultracare, Ultradent Products, Inc, UT, USA) after drying the mucosa with a gauze. Local anesthesia using 2% Lidocaine with 1:10000 epinephrine (Housebrand, NY, US) will be administrated as buccal infiltration for maxillary molars and inferior alveolar nerve block or infiltration for mandibular molars, then isolation using a rubber dam or cotton roll with saliva

ejector depending on clinical evaluation. The access and cavity outline will be prepared using a sterile high-speed carbide bur #330 (Housebrand, NY, US). Slowspeed tungsten round carbide burs (Housebrand, NY, US) will be used to remove soft carious dentin. T band dental matrix system and interdental wedge will be used for the treatment. Then, the tooth will receive (Tetric® N-Ceram) or (EQUIA Forte® HT) according to the randomization table. All restorative procedures will be conducted by two senior post-graduate pediatric dentistry residents.

Glass Ionomer restoration:
Before applying EQUIA Forte® HT, the dentin and enamel of the cavities will be conditioned with 20% polyacrylic acid for 20 seconds (Cavity Conditioner, GC Corp., Japan), washed, and briefly dried. Then the restorative material will be injected into the cavity then adapted and shaped by hand instruments (explorer and burnisher). After the manufacturer's recommended setting time of 2.5 minutes, the restoration may be finished using polishing diamond burs with an air/ water coolant. After the restoration had been briefly dried, EQUIA Forte® Coat (cavity varnish, GC Corp, Japan) will be applied and lightcured (Ultradent, South Jordan, UT, USA) for 20 seconds.

Composite resin restoration:
The dentin and enamel of the cavities will be conditioned with 37% phosphoric acid for 20 seconds (CharmEtch, Dentkist, Korea). A bonding system will be used (Tetric® N-Bond, Ivoclar Vivadent, Schaan, Liechtenstein) and cured for 20 seconds. Tetric® N-Ceram will be applied incrementally (in 2 mm layers) and then lightcured ValoLED curing light (Ultradent, South Jordan, UT, USA) for 20 seconds. Finally, the restoration will be shaped with composite finishing burs and Extra Thin Discs (Sof-Lex™, 3M ESPE, St. Paul, MN, USA).

Follow-up evaluation:
All patients will be followed up closely, a contact number will be given to the guardian in case of any emergency or concern about the study. Treated teeth will be followed up for clinical and radiographic evaluation at 6 and 12 months. A modification of the United States Public Health Service (USPHS) criteria will be used to evaluate the following parameters: retention, color matching, marginal discoloration, secondary caries, anatomical form, marginal adaptation, and postoperative sensitivity (Cvar and Ryge 2005). Restorations will be scored as "Alpha" (ideal clinical outcome), "Bravo" (clinically acceptable), or "Charlie" (clinically unacceptable). Restorations will be scored for radiographic evaluations as "Alpha" (no evidence of secondary caries, no detectable radiolucencies, no periradicular, or furcal radiolucency), "Charlie" (evidence of caries along the margin of the restoration, radiolucencies adjacent to the restoration, and presence of periradicular or furcal radiolucency).
Teeth will be evaluated clinically and radiographically by two calibrated blinded experienced dentists. The inter and intra- examiner reliability will be calculated using Cohen unweighted kappa statistics. Any disagreement between the evaluators will be discussed and if no consensus was reached the worst evaluation will be considered.

## Intervention Type
Device

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
EQUIA Forte® HT Fil, Tetric® N-Ceram, Ivoclar Vivadent

### Primary outcome(s)
Treated teeth will be followed up for clinical and radiographic evaluation at 6 and 12 months:
1. Clinical criteria: a modification of the United States Public Health Service (USPHS) criteria will be used to evaluate the following parameters: retention, color matching, marginal discoloration, secondary caries, anatomical form, marginal adaptation, and postoperative sensitivity. Restorations will be scored as “Alpha” (ideal clinical outcome), “Bravo” (clinically acceptable), or “Charlie” (clinically unacceptable).
2. Radiographic criteria: secondary caries, detectable radiolucency, furcal radiolucency, periapical radiolucency. Restorations will be scored for radiographic evaluations as “Alpha” (no evidence of secondary caries, no detectable radiolucencies, no periradicular, or furcal radiolucency), “Charlie” (evidence of caries along the margin of the restoration, radiolucencies adjacent to the restoration, and presence of periradicular or furcal radiolucency).

Teeth will be evaluated clinically and radiographically by two calibrated blinded experienced dentists. The inter and intra- examiner reliability will be calculated using Cohen unweighted kappa statistics. Any disagreement between the evaluators will be discussed and if no consensus was reached the worst evaluation will be considered.

### Key secondary outcome(s))
The McNemar test will be used to observe temporal changes after 6, and 12 months for each group. Logistic regression might be used if needed to calculate the odds ratio

### Completion date
20/06/2024

## Eligibility

### Key inclusion criteria
Clinical participant inclusion criteria:
1. Restorable primary molars with one proximal carious lesion (code 4 or 5 proximal carious lesions according to ICDAS II)
2. No signs of pulpal involvement (spontaneous or persistent pain, pathological mobility, tenderness to percussion)
3. Have a good likelihood of recall availability

Radiographic participant inclusion criteria:
1. Proximal radiolucency in the outer half of the dentin
2. No more than two-thirds of physiologic root resorption
3. No radiographic signs of pulp pathologies such as (widening of the PDL, internal or external root resorption, apical or furcal radiolucency)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit

4 years

### Upper age limit
11 years

### Sex
All

### Total final enrolment
100

### Key exclusion criteria
1. Parents who refuse to consent
2. Non-restorable primary molars
3. Teeth with clinical or radiographic signs of pulpal involvement
4. More than two-thirds of physiologic root resorption

### Date of first enrolment
01/09/2022

### Date of final enrolment
30/12/2022

## Locations

### Countries of recruitment
Saudi Arabia

### Study participating centre
**Dental University Hospital, King Saud University**
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## Sponsor information

### Organisation
King Saud University

### ROR
https://ror.org/02f81g417

# 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 are/will be available upon request from Saleh Alqasabi (s.alqasabi@gmail.com)

**IPD sharing plan summary**
Available on request

**Study outputs**

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