

Evaluation of BRIX3000 and Carisolv in chemomechanical caries removal in immature permanent first molars

Submission date 06/11/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/11/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/06/2025	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

This study aimed to assess and compare the efficacy of Brix 3000, Carisolv, and the conventional rotary-mechanical method for caries removal, as well as to evaluate the pain level and the requirement for local anesthesia during caries excavation in immature mandibular PFMs of pediatric patients aged 7 to 9 years. The conventional rotary instrumentation method is widely used and has demonstrated its efficacy. Nevertheless, this method presents multiple drawbacks, including damaging thermal impacts on the pulp tissue and unnecessary removal of tooth structure, as well as discomfort, anxiety, and fear caused by the associated noise and vibrations. Various alternative techniques have been established, including lasers, air abrasion, smart burs, and chemomechanical caries removal (CMCR) methods, to address these limitations. Recently, there has been growing interest in CMCR methods, alongside a shift towards non-surgical treatments to alleviate pain and anxiety, particularly for pediatric patients.

Who can participate?

Healthy pediatric patients aged 7-9 years old with radiographically confirmed lesions reaching the middle or inner third of the dentine (D2/3) in immature mandibular PFMs

What does the study involve?

A total of seventy-five specimens were assigned randomly to five groups. Grouping was as follows:

Group 1 (Carisolv): CMCR utilizing Carisolv (CarisolvTM, MediTeam AB, Sävedalen, Sweden), n = 15.

Group 2 (BRIX3000): CMCR utilizing BRIX3000 (BRIX3000[®], BRIX Medical Science, Santa Fe, Argentina), n = 15.

Group 3 (Conventional method): Control group, caries excavation utilizing conventional rotary-mechanical method, n = 15.

What are the possible benefits and risks of participating?

Benefits: Participants will receive a restorative treatment.

Risks: There is a risk that the treatment would be painful.

Where is the study run from?
Damascus University, Syria

When is the study starting and how long is it expected to run for?
September 2021 to October 2024

Who is funding the study?
Damascus University, Syria

Who is the main contact?
Dr. Mawia Karkoutly, mawia95.karkoutly@damascusuniversity.edu.sy,
mawiamaherkarkoutly@hotmail.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

Dr Mawia Karkoutly

ORCID ID

<https://orcid.org/0000-0003-0227-1560>

Contact details

Mazzeh highway
Damascus
Syria

-
+963 (0)992 647 528
mawiamaherkarkoutly@hotmail.com

Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Comparative evaluation of BRIX3000 and Carisolv in chemomechanical caries removal in immature permanent first molars: A randomized controlled trial

Study objectives

The null hypothesis is that Brix3000, Carisolv, and the conventional rotary-mechanical method would be equally effective in caries removal and patient comfort.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 13/09/2021, The Biomedical Research Ethics Committee of the University of Damascus (Mezzeh Highway, Damascus, -, Syria; +963 992 647 528; not@provided), ref: N3182

Study design

Double-blind randomized parallel-group active-controlled trial with three arms

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Dental caries

Interventions

A total of seventy-five specimens were assigned randomly to five groups with the help of an online randomization tool <https://www.randomizer.org/>. The total number of sets consisted of 3, with each set containing 15 samples, and the range of numbers spanned from 1 to 45.

Grouping was as follows:

Group 1 (Carisolv): chemomechanical caries removal (CMCR) utilizing Carisolv (CarisolvTM, MediTeam AB, Sävedalen, Sweden), n = 15.

Group 2 (BRIX3000): CMCR utilizing BRIX3000 (BRIX3000®, BRIX Medical Science, Santa Fe, Argentina), n = 15.

Group 3 (Conventional method): Control group, caries excavation utilizing conventional rotary-mechanical method, n =15.

This was a double-blind study in which both participants and those assessing outcomes were unaware of the group assignments.

Intervention

After pediatric patients' enrollment and legal guardians signed informed consent, a periapical X-ray was captured for each immature mandibular PFM using an intraoral periapical sensor (i-sensor, Guilin Woodpecker Medical Instrument Co., LTD., Guilin, China) to ensure that lesions only reach the middle or inner third of the dentine. Topical anesthetic (Iolite, Dharma Research Inc., Florida, United States) was applied before applying the rubber dam to achieve adequate isolation. For the BRIX3000 group, the gel was used in the carious cavity for two minutes according to the manufacturer's instructions. Similarly, for the Carisolv group, the gel was applied according to the manufacturer's instructions for thirty seconds. The softened carious dentine was scraped utilizing a curette (CarisolvTM, MediTeam AB, Sävedalen, Sweden), and the procedure was repeated until the gel color became clear. For the conventional method group, a contra-angle handpiece (NAC-EC, NSK Nakanishi Inc., Tochigi-ken, Japan) was utilized to excavate dentine caries with a round tungsten carbide bur (Round E 0123, Dentsply Maillefer, Ballaigues, Switzerland). For all study groups, the caries detector (Caries Marker, VOCO GmbH,

Lower Saxony, Germany) was applied for 10 seconds, and the procedure was repeated until all caries were removed and the dentin reached a firm texture and showed no signs of resistance. The cavities were restored with composite resin (TetricN-Ceram, Ivoclar Vivadent, New York, United States).

After caries excavation, the cavity was evaluated by two blinded examiners (ICC > 0.8). The efficacy of caries removal was recorded utilizing Ericson et al. scale by visual-tactile examination and utilizing the caries detector, the Ericson et al. scale score was presented as follows:

0 = Complete caries excavation.

1=Caries located at the base of the cavity.

2=Caries located at the base of the cavity and/or the wall.

3=Caries located at the base of the cavity and/or two walls.

4=Caries located at the base of the cavity and/or more than two walls.

5=Caries located at the base and the margins of the cavity and two walls.

Objective pain assessment

The Sound, Eye, Motor (SEM) scale was utilized to objectively assess pain during the excavation of caries. This SEM scale emphasizes the child's vocalizations, eye movements, and physical reactions as noted by external observers. It was evaluated by two blinded examiners (ICC > 0.8), and SEM scoring criteria was presented as follows:

Sound

1. Score "1" = Comfort. No sound.

2. Score "2" = Mild discomfort. Non-specific sound.

3. Score "3" = Moderate discomfort. Louder sound, specific verbal complaint.

4. Score "4" = Severe discomfort. Shouting, crying, and verbal complaints indicate severe pain.

Eye

1. Score "1" = Comfort. No sign.

2. Score "2" = Mild discomfort. Dilated eye without tears (anxiety sign).

3. Score "3" = Moderate discomfort. Tears, and sudden eye movements.

4. Score "4" = Severe discomfort. Heavy crying.

Motor

1. Score "1" = Comfort. Relaxed body.

2. Score "2" = Mild discomfort. Muscular contraction indicates pain.

3. Score "3" = Moderate discomfort. Sudden and random movements of body and hand.

4. Score "4" = Severe discomfort. Hand movements for defense, pulling head away.

Subjective pain assessment

The Wong-Baker FACES scale was utilized to evaluate the child's pain levels during caries excavation by prompting them to select the face that best reflects their emotions. This scale features six faces that vary in expression, starting with the happy face at level 0, indicating no pain, and culminating with the crying face at level 10, which signifies the most intense pain.

Requirement of local anesthesia

Cases where anesthesia was requested during treatment were documented as follows:

- The child asked for anesthesia.
- The child did not ask for anesthesia.

Intervention Type

Procedure/Surgery

Primary outcome(s)

The efficacy of caries removal was measured by two blinded examiners (ICC > 0.8) using the Ericson et al. scale by visual-tactile examination and utilizing the caries detector of the Ericson et al. scale after caries excavation

Key secondary outcome(s)

1. Objective pain assessment measured using the Sound, Eye, Motor (SEM) scale by two blinded examiners (ICC > 0.8), and SEM scoring criteria during the excavation of caries
2. Subjective pain assessment measured using the Wong-Baker FACES scale during caries excavation
3. Requirement of local anesthesia measured using data collected in the study records during caries excavation

Completion date

17/10/2024

Eligibility

Key inclusion criteria

1. Healthy pediatric patients aged 7-9 years old
2. Pediatric patients were classified as either definitely positive or positive based on Frankel's behavior rating scale
3. Radiographically, lesions reaching the middle or inner third of the dentine (D2/3) were observed in immature mandibular PFMs
4. Caries lesions fell under ICDAS code 4

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

7 years

Upper age limit

9 years

Sex

All

Total final enrolment

45

Key exclusion criteria

1. Special health care needs for pediatric patients
2. Immature mandibular PFMs were exhibiting pulpal and/or periodontal issues

3. Unintentional pulp exposure occurred during the excavation process
4. Immature mandibular PFMs with dental anomalies

Date of first enrolment

03/08/2024

Date of final enrolment

12/10/2024

Locations

Countries of recruitment

Syria

Study participating centre

Damascus University

Mazzeah highway

Damascus

Syria

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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 datasets generated during and/or analysed during the current study will be available upon request from Dr Mawia Karkoutly, Mawiamaherkarkoutly@hotmail.com. The type of data that will be shared includes anonymised demographic information that will be available after publication. Consent from participants was required and obtained.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		03/06/2025	04/06/2025	Yes	No