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A specific outcome that can occur after treatment of primary teeth which requires long follow-up

Submission date	Recruitment status	[ ] Prospectively registered
13/05/2019	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/05/2019	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
16/05/2019	Oral Health	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Our study aims to repair perforations (procedural accidents) that occur during treatment of the primary teeth, and teeth will be followed clinically and radiographically within 12 months and more than that if it is required. These teeth were usually extracted after perforation occurrence, subsequently later problems in the adjacent and opposite teeth will occur in some cases in spite of the presence of space maintainer (an appliance is applied to protect from distance losing after extraction in primary dentation), but this treatment will preserve the affected teeth functionally until normal exfoliation. We will use a biocompatible material called MTA which previously tested in the treatment of such these cases in permanent teeth and was successful at all follow-up periods. Iatrogenic furcal perforations occur during pulp treatment and may lead to loss of the affected teeth. Treatment may be significant when these teeth are strategically important. Numerous materials have been suggested to repair perforations in permanent and primary teeth, and Mineral Trioxide Aggregate has been the golden standard.

Who can participate?

The participants in this study should have a tooth that has a specific complication called furcal perforation which is a procedural accident that occurred during the treatment of primary teeth. The participants can be male or female and have a primary tooth with an indication of pulp treating that called pulpotomy subsequently they should be with ages ranged from 3 to 9 or 10 years at most

What does the study involve?

Eligible patients will have their teeth treated with MTA and will then be followed clinically and radiographically for 12 months and for more than that if the expected outcome "Internal resorption" has occurred.

What are the possible benefits and risks of participating?

This treatment will a child's teeth functionally, and protect them from later problems that may

occur if it remains untreated. This treatment involves minimal risk but going without treatment will lead to loss of the affected teeth. Side effects from this study will usually go away soon after the affected teeth are extracted.

Where is the study run from?
Tishreen University, Syria.

When is the study starting and how long is it expected to run for?
July 2015 to February 2019.

Who is funding the study?
The National Institutes of Health Clinical Center.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
3532

Study information

Scientific Title
Internal resorption associated with iatrogenic-furcal perforation repaired with MTA in a pulpotomized primary molar tooth: 24-month follow-up

Acronym
IRPM

Study objectives
Internal resorption may not be always considered as a pathologic radiographic sign, especially when it does not associate with periodontal defect or injury of the successor.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/07/2015, the IRB of Tishreen University (info@tishreen.edu.sy; 0096341420291), ref: 3532.

Study design
Case Report

Primary study design
Observational

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Internal resorption that occurred after repairing pulpotomized primary molar with MTA.

Interventions
The patient was examined and asked about general conditions that may interfere with the treatment, and then we started intervention and repairing the furcal perforation in the pulpotomized primary molar that occurred with the undergraduate student. A radiographic image was taken as a baseline image for later follow-up.

A 7-aged boy had an iatrogenic furcal perforation in the right second mandibular primary molar during pulpotomy procedure by an undergraduate student at the dental clinic, then he was sent immediately to the department of pediatric dentistry in Tishreen university- Lattakia- Syria for management. Medical history was taken again, and the parents had been told about the following procedure and the written concept was taken. We ensured that rubber dam in the right place, then we used a copious saline solution to removing pulp debris and eliminating the bleeding to confirm the presence of perforation, and then we used round and fisher diamond burs (Horico, DIAMANT, Germany) sized 014 and 010 respectively, to removing residual roof of the pulp chamber and amputating the coronal pulp, with copious saline irrigating. We used a cotton pellet moistened with 2.5% Sodium Hypochlorite (SH) (Al-Fares, Damascus, Syria) for several minutes to obtaining disinfection and hemostasis, and then MTA (MTA Cem, NEXOBIO, Chungcheongbuk-do, Korea) mixed with sterile water on a clean glass pad by using a sterilized spatula until obtaining the appropriate pasty texture, and the material was transferred to the pulp chamber using an amalgam carrier and condensed with a squeezed- cotton pellet that was moistened with sterile water. Then tooth was immediately restored with Glass Ionomer Cement

GIC (Cavitan Plus, SpofaDental, Markoca, Jicin, Czech) without moistened cotton pellet over MTA (using a moistened cotton pellet over MTA here leads to a soupy texture of the MTA because of the excess humidity which comes from the applied cotton pellet in addition to bleeding from the furcation area and canals orifices, subsequently setting will not happen). The tooth was prepared after one week for repairing with a stainless steel crown SSC (3M ESPE, St. Paul, USA).

Intervention Type
Procedure/Surgery

Primary outcome(s)
Clinical symptoms or sighns that may occur after this treatment are measured using clinical examination every three months until the eruption of the succedaneous tooth.

Key secondary outcome(s))
Radiographic signs that may occur after the treatment are measured using radiographic examination using periapical images every 6 months.

Completion date
20/02/2019

Eligibility

Key inclusion criteria
1. Teeth were treated with pulpotomy.
2. Mechanical perforations.
3. Teeth with sub-base material of ZOE (Zinc Oxide-Eugenol) that has been applied for one week at most.
4. Restorable teeth.
5. Aged 3-10 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
10 years

Sex
All

Key exclusion criteria

1. Cariously perforated- teeth.
2. Teeth which pulpotomy was not the real treatment by asking parents, using the previous periapical image, and excess/uncontrolled bleeding from the canal orifices).
3. Unrestorable teeth.
4. No presence of rubber dam during pulpotomy procedure.
5. Saliva contamination during pulpotomy procedure.

Date of first enrolment
20/10/2015

Date of final enrolment
20/10/2018

Locations

Countries of recruitment
Syria

Study participating centre
Tishreen University
Syria
Lattakia
Syria
00963

Sponsor information

Organisation
Tishreen University

ROR
https://ror.org/04nqts970

Funder(s)

Funder type
Government

Funder Name
NIH Clinical Center

Alternative Name(s)
National Institutes of Health Clinical Center, The NIH Clinical Center, NIH Clinical Center, Clinical Center National Institutes of Health, CC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

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	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes