

Restoring of primary anterior teeth destroyed due to caries

Submission date 20/06/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/07/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 16/07/2020	Condition category Oral Health	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Primary anterior teeth that have been destroyed due to trauma or caries in very young children are hard to treat with dental restorations due to many reasons, especially the small amount of remaining tooth body, which cannot support the restoration. The only treatment of such cases was to extract the affected teeth, but this may cause many problems to the child such as aesthetic problems and speech problems. Short glass fiber post restorations and short composite post restorations are two different techniques that may be used to reconstruct the destroyed primary anterior teeth since the post will be inserted into the root canal of the teeth so it supports the crown restoration. The aim of this study is compare the effectiveness of using short glass fiber posts and short composite posts to support the aesthetic restorations of destroyed primary anterior teeth.

Who can participate?

Children with destroyed upper primary anterior teeth

What does the study involve?

Chosen teeth are randomly allocated into two groups for restorations supported with either short glass fiber post or short composite post. All teeth are assessed clinically at 3, 6, 9 and 12 months and radiographically at 6 and 12 months after treatment.

What are the possible benefits and risks of participations?

The treatment may prevent the extraction of the affected teeth and re-build their appearance and function. There are no known risks to participants as any failed treatments will be re-done using another method.

Where is the study run from?

Department of Pediatric Dentistry, Tishreen University, Lattakia (Syria)

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

April 2016 to September 2019

Who is funding the study?
Tishreen University (Syria)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2698

Study information

Scientific Title
Clinical and radiographic comparative study to evaluate the efficacy of restoring destroyed primary incisors using two different techniques

Study objectives

There is no difference between glass fiber post technique and composite post technique in restoring destroyed primary incisors.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Institutional Review Board of Tishreen University, 07/06/2016, Approval No. 2698

Study design

Interventional double-blind randomized trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Management of destroyed primary incisors due to early childhood caries

Interventions

The destroyed teeth of the participants were consecutively allocated to either group A or group B. Group A received restorations supported with glass fiber posts, and group B received restorations supported with composite posts. Participants were asked to attend follow-up examinations with clinical evaluations at 3, 6, 9 and 12 months post- treatment and radiographic evaluations at 6 and 12 months.

Intervention Type

Procedure/Surgery

Primary outcome measure

Retention of the restorations evaluated according to the FDI criteria (World Dental Federation) clinically using visual inspection and dental explorer at 3, 6, 9 and 12 months post-treatment.

The outcome is considered to be successful if the post and crown were in situ with no debonding or fracture of the post or the root or the crown.

Secondary outcome measures

1. Secondary caries evaluated clinically using visual inspection at 3, 6, 9 and 12 months post-treatment and radiographically at 6 and 12 months post-treatment
2. Marginal integrity evaluated clinically using visual inspection and dental explorer at 3, 6, 9 and 12 months post-treatment

The outcome is considered to be successful if there are no secondary caries and no marginal gapping reaches to the dento-enamel junction.

Overall study start date

24/04/2016

Completion date

01/09/2019

Eligibility

Key inclusion criteria

1. Healthy children with no medical histories
2. No malocclusion and no abnormal oral activities
3. Aged from 2 to 5 years old
4. Destroyed maxillary primary incisors (more than 50% of the crowns)
5. Sound root structure (external resorption not more than one third of the root)

Participant type(s)

Patient

Age group

Child

Lower age limit

2 Years

Upper age limit

5 Years

Sex

Both

Target number of participants

36 teeth

Total final enrolment

36

Key exclusion criteria

1. Mobility of the teeth
2. Subgingival crown destruction

Date of first enrolment

09/11/2017

Date of final enrolment

22/03/2019

Locations**Countries of recruitment**

Syria

Study participating centre

Tishreen University

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Sponsor information**Organisation**

Tishreen University

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Sponsor type

University/education

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Funder(s)**Funder type**

University/education

Funder Name

Tishreen University

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact reviewed journal.

Intention to publish date

11/09/2019

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyzed during the current study are/will be available upon request from Dr Seba Ibrahim (seba.ibrahim1@gmail.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2020	16/07/2020	Yes	No