

# Restoring of primary anterior teeth destroyed due to caries

<b>Submission date</b> 20/06/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/07/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/07/2020	<b>Condition category</b> 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?  
1. Dr Seba Ibrahim  
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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

Lattakia

Lattakia

Syria

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## Sponsor information

**Organisation**

Tishreen University

**Sponsor details**

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**Sponsor type**

University/education

**Website**

[www.tishreen.edu.sy](http://www.tishreen.edu.sy)

**ROR**

<https://ror.org/04nqts970>

## 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?
<a href="#">Results article</a>	results	01/10/2020	16/07/2020	Yes	No