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Restoring of primary anterior teeth destroyed due to caries

Submission date
20/06/2019

Recruitment status
No longer recruiting

Registration date
09/07/2019

Overall study status
Completed

Last Edited
16/07/2020

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Protocol serial number
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

Primary study design
Interventional

Study design
Interventional double-blind randomized trial

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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.

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

Healthy volunteers allowed
No

Age group
Child

Lower age limit
2 Years

Upper age limit
5 Years

Sex
All

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
00963

Sponsor information

Organisation
Tishreen University

ROR
https://ror.org/04nqts970

Funder(s)

Funder type
University/education

Funder Name
Tishreen University

Results and Publications

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