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Adhesives procedures in paediatric dentistry

Submission date
22/10/2019

Recruitment status
No longer recruiting

Registration date
25/11/2019

Overall study status
Completed

Last Edited
17/10/2022

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In Pediatric Dentistry there is a growing interest in adhesive systems that allow consistent adhesion to enamel and dentin with a shorter working time possible. Self-etch adhesive systems are potential and particularly interesting for clinical practice with children as they can decrease the time of restorative protocol and/or the complexity of the technical steps.
During long, restorative treatments recommended for temporary and permanent teeth were similar because it was thought there were no significant differences both in composition and microstructure of the tissues that form these two types of teeth. However, nowadays these divergences are properly described in the literature and include several differences such as the amount of intertubular dentin, density of tubules and amount of microtubules transverse to dentinal tubules; primary dentin, according to some authors, also features a lower concentration of phosphate and calcium ions. All these facts might hinder or individualize the adhesion process in deciduous dentin and enamel, making it crucial to study and develop specific adhesive restorative strategies equally effective for temporary dentition.
Although all the materials in study are already legally approved for clinical use, does not exist, so far, any publications in indexed journal that embraces an assessment regarding prospective clinic efficacy of different types of adhesives in temporary teeth. Following a line of investigation already initiated that includes in vitro studies, it seems pertinent to analyse, compare and quantify the results obtained with an in vivo study.

Who can participate?
Patients aged 4-8 years with molar lesions

What does the study involve?
Our research group performed a prospective randomized clinical trial to evaluate the clinical effectiveness of three adhesive systems: a self-etch of two steps with selective enamel etching, a self-etch of one step, and an etch-and-rinse system in deciduous dentition at 6, and 12 months. Participants had standard treatment of tooth lesions. Restoration of the tooth was carried out using one of three different adhesives assigned randomly to participants

What are the possible benefits and risks of participating?
The procedures allows that the existing caries injury is treated with materials that are already legally approved for clinical use, avoiding biological, functional and structural complications that could advise from the non-treatment. There is no increased risk with this clinical procedure since

the restorative protocol used is the conventionally recommended and the teeth to be covered need treatment effectively

Where is the study run from?
School of Dentistry, Faculty of Medicine of the University of Coimbra, Portugal

When is the study starting and how long is it expected to run for?
September 2016 to August 2018

Who is funding the study?
University of Coimbra, Portugal

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

Nil known

Study information

Scientific Title
Randomized clinical trial of three adhesives in primary molars restoration

Study objectives
Significant differences would be detected among the clinical behavior of the three adhesive systems in primary molars in any of the recall periods (6 and 12 months)

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 30/09/2015, Ethics Committee of the Central Hospital of University of Coimbra (Ethics Committee of the Centro Hospitalar e Universitário de Coimbra) (CHUC) (Praceta Prof. Mota Pinto, 3000-075 Coimbra, Portugal; +351 239400400; gai@huc.min-saude.pt), ref: CHUC 056-15
2. Approved 25/03/2015, Ethics Committee of Faculty of Medicine, University of Coimbra (FMUC) (Unidade Central, Pólo das Ciências da Saúde, Azinhaga de Santa Comba, Celas, 3000-354 COIMBRA – PORTUGAL;+351 239857700; comissaoetica@fmed.uc.pt), ref: CE-010/2015

Study design
Single-center randomized interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Oral health, paediatric dentistry

Interventions
Our research group performed a prospective randomized clinical trial to evaluate the clinical effectiveness of three adhesive systems: a self-etch of two steps with selective enamel etching, a self-etch of one step, and an etch-and-rinse system in deciduous dentition at 6, and 12 months.

Carious lesions removal was ensured with drilling and dentin spoon excavators. The restorative procedures were performed by one single operator. After application of the respective randomly assigned adhesive system under manufacturer's directions a composite resin (Ceram. X® Universal; A3) was placed incrementally and light-cured using a LED-curing unit (S.P.E.C.®3)

Experimental groups:
1. Clearfil™ S3 Bond : Apply adhesive on surface and scrub it in a rubbing motion for 10 s; gentle air-blow for 5 s; light-cure for 10 s
2. Clearfil™ SE Protect Bond: Apply primer and leave undisturbed for 20 s; gentle air-blow for 5 s; apply bonding agente for 10 s; gentle air-blow for 5 s; light-cure for 10 s
3. Prime&Bond® XP: Apply etchant for 15 s; rinse for 15 s; air-dry for 5 s; apply adhesive on surface and wait 20 s; gentle air-blow for 5 s; light-cure for 20 s

One single experienced and calibrated operator performed all restorative treatments. In all cases was made a prior polishing of the tooth with a prophylactic brush and water to remove plaque and salivary film remaining. Was then administered local anesthesia. Isolation with rubber-dam was done in all procedures. After cavity preparation a collaborator selected randomly the adhesive system (Prime&Bond active TM, ClearfilTM S3 Bond Plus and ClearfilTM SE Protect), which was applied according to the manufacturer's instructions. The restorations were made with a light-cured nano hybrid composite resin (Ceram.X®) and with the support of a sectional matrix system (Palodent®Plus) and, applied according to the incremental technique and the manufacturer's indications. Finishing and polishing were made using diamond drills, cups and brushes (Enhance® and Ceram.X® gloss). All the restorations were recorded using digital photography and analyzed by two blinded calibrated evaluators (calibration model approved by the FDI – World Dental Federation) in two different moments: on the day of execution and after 6 months. The evaluation was based on aesthetic, functional and biological factors adapted to the specificity of this study.

Randomisation was performed using a sealed envelope technique

Intervention Type
Other

Primary outcome measure
Fracture of material and retention measured using the FDI evaluation criteria at baseline, 6 and 12 months

Secondary outcome measures
Using FDI evaluation criteria applied at baseline, 6 and 12 months:
1. Esthetic Properties (surface lustre, marginal and surface staining, anatomical form)
2. Biological Properties (postoperative hypersensitivity and tooth vitality; recurrence of caries; tooth integrity; adjacent mucosa)

Overall study start date
01/09/2016

Completion date
31/07/2018

Eligibility

Key inclusion criteria
1. Deciduous molars with caries lesion on the interproximal face with dentinal involvement, without pulp pathology
2. Caries lesion with margins entirely in enamel
3. Presence of antagonistic tooth with occlusal contact
4. Collaborating patients
5. Aged 4 to 8 years
6. Available for compliance with control appointments

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
34 participants with carious proximal lesions were initially selected. 101 restorations (at least 33 for research group) in 34 patients were obtained

Total final enrolment
34

Key exclusion criteria
1. Teeth with structural changes (such as hypoplasia or hypomineralization)
2. Teeth with mobility
3. Systemic pathology that conditioned oral health (oncological pathology, asthmatics, diabetics, etc.)
4. Taking medicines with recognized oral repercussions
5. Inability of the child and/or parents to ensure proper oral hygiene
6. Presence of periodontitis and/or gingivitis
7. Impossibility of adequate isolation
8. Refusal by parents/legal guardians and/or child (if applicable) to sign informed consent

Date of first enrolment
01/09/2016

Date of final enrolment
23/12/2016

Locations

Countries of recruitment
Portugal

Study participating centre
School of Dentistry, Faculty of Medicine of the University of Coimbra
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Sponsor information

Organisation
University of Coimbra (Portugal)

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Sponsor type
University/education

ROR
https://ror.org/04z8k9a98

Funder(s)

Funder type
University/education

Funder Name
University of Coimbra (Portugal)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2019

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	primary outcome results	13/09/2022	17/10/2022	Yes	No