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# Long-term outcomes of tooth restoration in high-caries-risk patients

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 09/08/2021 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 11/08/2021 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [X] Individual participant data |
| 15/02/2022 | Oral Health | |

## Plain English summary of protocol

Background and study aims
Depending on the stage of the disease and the age of the child, different types of interventions can be used to treat early childhood caries. As a result, there isn't enough clinical evidence to show that one kind of restoration is better than another. The goal of this study was to compare the results of 36 months of clinical performance of primary incisors restorations using an incremental layering technique with the nano-ceramic composite ceram.x® SphereTECTM one (Dentsply) or a full-coverage technique with transparent strip crowns (Frasaco GmbH) with the same composite in children with or without biological caries risk factors.

Who can participate?
Pediatric dental patients with the presence of two class-four caries cavities on the central incisors

What does the study involve?
Participants were randomly allocated to receive one of the two types of restoration under investigation and followed up for 36 months.

What are the possible benefits and risks of participating?
There were no special benefits/risks for the patients, as the study was aimed to compare the results of clinical performance of central incisors restorations in primary dentition depending on the type of two recommended by the AAPD restorative techniques used. Both the techniques are well-known and do not have any specific characteristics or benefits.

Where is the study run from?
Institute of Immunology and Physiology (Russia)

When is the study starting and how long is it expected to run for?
April 2017 to May 2020

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Alexey Sarapultsev, a.sarapultsev@gmail.com

# Contact information

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Scientific

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# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
D-16-4-2017

# Study information

## Scientific Title
36 months' clinical performance of primary incisors restorations among high-caries-risk patients depending on the type of restorative technique used: a randomized controlled trial

## Study objectives
The null hypothesis was that in children with a presence of biological factors of caries risk, the long-term results of restorative treatment would be worse than in children without those factors and that the method of complete overlapping of the crown of the tooth with composite materials via strip crowns would provide better long-term results in them, compared to the restoration via incremental layering technique

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 14/04/2017, Ethics Committee of the Institute of Immunology and Physiology of the Ural Branch of the Russian Academy of Sciences (106 Pervomayskaya str., 620049 Ekaterinburg, Russia; +7(3434)3740070; pharmusma@rambler.ru ), ref:D-16-4-2017

## Study design
Single-center prospective randomized controlled trial

## 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
Primary incisors restoration

## Interventions
The study compares the results of 36 months of clinical performance of primary incisors restorations using an incremental layering technique with the nano-ceramic composite ceram.x® SphereTECTM one (Dentsply) or a full-coverage technique with transparent strip crowns (Frasaco GmbH) with the same composite in children with or without biological caries risk factors.

After their selection for the study, the patients underwent a thorough clinical examination. The research coordinator randomly assigned them between the two pediatric dentists. The

examination included: 1) medical and dental history; 2) examination of maxillofacial area, oral cavity, dentition, and soft tissues; 3) radiographic assessment of hard teeth and periapical tissues (periapical X-ray in all cases; 4) caries risk assessment.

Intraoral radiography was used to detect any abnormalities of the crown and root structures as well as the surrounding bone. Periapical X-ray at maxillary central-lateral projection with #1 or #0 size Phospourous Image plate (PIP) was done to every patient. The paralleling technique was used to take periapical X-rays in all the cases. The film holder was used to get the best possible PIP positioning. The PIP and film holders as well as film scanner “VistaScan Mini” from Duerr Dental AG were used for the X-ray examination in this study.

Patients were divided into two main groups according to the restoration techniques applied. In the DCR group (80 restorations), cavities were restored by direct composite restoration with an incremental layering technique, in the SCR group (80 restorations)—with full coverage technique with transparent strip crowns. The block scheme was used as a common randomization method. Two lists of random numbers were created, one corresponding to the restoration technique used and the other to presence of biological factors of caries risk according to the AAPD Guideline.

Local anesthesia with 3% Mepivacaine solution (plain) was used. The dosage of the anesthetic did not exceed the maximum recommended amount of 4.4 mg/kg.
Cavities were prepared with the high-speed turbine burs under copious water cooling at the enamel level, and with the low-speed carbides burs and hand excavator at the dentin level. The conservative tooth preparation was implemented in all the cases (there was no extra retentive preparation done, like boxes, groves, etc, only a small enamel bevel was prepared to removed unsupported enamel prisms). The prepared cavities were disinfected with 1% chlorhexidine solution. The operative field isolation was conducted by a rubber dam fixed by cords and floss to make the procedure atraumatic and comfortable for pediatric patients.
The selective enamel etching technique and self-etch adhesive system were used in all the subgroups. 37% phosphoric acid gel (Vococid, VOCO) was applied on enamel for 20 seconds and after copious rinsing for 40 seconds and indirect drying with water/air syringe the bonding agent Prime and bond NT (Dentsply) was applied.
The class IV cavities of DCR groups (DCR_1 and DCR_2) were restored with the incremental layering technique using the nano-ceramic composite ceram.x® SphereTEC™ one (Dentsply, York, PA, USA). The same composite material was used to restore the cavities in subgroups SCR groups (SCR_1 and SCR_2) using the full-coverage technique with transparent strip crowns (Frasaco GmbH, Tettnang, Germany). The finishing adjustment was made with the Sof-Lex™ Contouring and Polishing Discs (3M, Brownwood, USA), and final polishing was conducted with the Enhance Finishing and PoGo Polishing systems (Dentsply).

## Intervention Type
Procedure/Surgery

## Primary outcome measure
Quality of the conducted restoration by independent observers according to the modified Ryge Criteria at baseline, 6, 12, 24, and 36 months). The cavosurface marginal discoloration and color match was evaluated visually after air-drying the tooth and after removing the plaque (if necessary).

## Secondary outcome measures
There are no secondary outcome measures

### Overall study start date
14/04/2017

### Completion date
01/05/2020

## Eligibility

### Key inclusion criteria
Pediatric dental patients with the presence of two class-four caries cavities on the central incisors

### Participant type(s)
Patient

### Age group
Child

### Sex
Both

### Target number of participants
84

### Total final enrolment
80

### Key exclusion criteria
1. History of coronary artery disease
2. Pre-excitation syndromes
3. Motor impairments (cerebral palsy and epilepsy)
4. Pacemakers
5. Drug addicts
6. Patients whose parents or guardians refused to give their consent to participate

### Date of first enrolment
01/05/2017

### Date of final enrolment
01/09/2017

## Locations

### Countries of recruitment
Russian Federation

### Study participating centre

**Medical firm Vital EBB**
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# Sponsor information

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**Sponsor type**
Research organisation

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# Funder(s)

**Funder type**
Other

**Funder Name**
Investigator initiated and funded

# Results and Publications

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

**Intention to publish date**

10/08/2021

## Individual participant data (IPD) sharing plan

The datasets generated during and analysed during the current study are stored in a publicly available repository (https://data.mendeley.com/datasets/62nwbs22ph/1; DOI: 10.17632/62nwbs22ph.1). The additional information will be available upon request from the investigators (Alexey Sarapultsev, a.sarapultsev@gmail.com).

## IPD sharing plan summary

Stored in publicly available repository

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | | 22/10/2021 | 08/02/2022 | Yes | No |
| Dataset | | 18/02/2019 | 15/02/2022 | No | No |