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Comparing the treatment of deciduous teeth in children with the Er:YAG laser to the traditional method

Submission date 26/06/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 20/07/2024	**Overall study status** Completed	
Last Edited 19/07/2024	**Condition category** Oral Health	

Plain English summary of protocol

Background and study aims
Various working methods are used in children's dental treatment. Among the standard treatment methods, among others, the classic mechanical development of caries defects using rotational instruments and the possibility of using a dental laser. The use of classical methods is associated with a high probability . The use of dental lasers, despite the sometimes longer duration of the procedure, is conducive to lowering pain and perception of dental visit as less traumatic.
The purpose of the study is to assess the parameters of the dental laser which constitute a standard in the preparation of caries defects in milk teeth in children.

Who can participate?
The study may participate in the developmental period corresponding to the period of deciduous teeth inhabited in the Polish Lower Silesian Voivodship.

What does the study involve?
Participants will be covered by an examination and conservative treatment of milk dentition using the proposed method of using dental lasers.

What are the possible benefits and risks of participating?
The expected benefits of participation in the project are minimizing the frequency of caries in the treatment of children along with minimizing stress related to dental visits.

Where is the study run from?
Wroclaw Medical University the Department of Dental Surgery (Poland)

When is the study starting and how long is it expected to run for?
November 2021 to August 2024

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KB-547/21

Study information

Scientific Title
A randomized and split-mouth clinical trial conducted to compare the treatment of deciduous teeth in children with the Er:YAG laser to the traditional method

Study objectives
The study aimed to determine the optimal Er:YAG laser settings for carious lesions in the enamel and dentine of primary teeth on occlusal, tangential, and smooth surfaces

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 25/11/2021, Local Ethics Committee of the Medical University of Wroclaw, Faculty of Dentistry (Passteura 1, Wroclaw, 50-361, Poland; +48 71 784 10 14; bioetyka@umw.edu.pl), ref: KB - 547/2021

Study design
Single-center interventional double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Dental clinic, University/medical school/dental school

Study type(s)
Diagnostic, Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Treatment of carious lesions of primary teeth in children using lasers

Interventions
The randomized clinical split-mouth trial involved 66 teeth with deep caries in 33 subjects (female and male; age: 3–8 years). Each tooth on the test side (n=33) of the maxilla or mandible was treated with the Er:YAG laser, while the teeth on the opposite side (n=33) served as a control group (conventional treatment) .

Following the administration of an adaptive visit, a dental examination was conducted using the DIAGNOcam caries diagnostic device (KaVo, Biberach, Germany) to identify occlusal and proximal caries of primary teeth. Patients presenting with carious lesions in unicuspidal teeth of similar severity were eligible for inclusion in the study. The decision as to which tooth would be treated with the conventional method and which with the laser method was determined through computerized randomization. Similarly, the method of first cavity preparation was selected by computer randomization. The computer program determined whether the first preparation would be conducted using conventional methods or with the Er:YAG laser.

The initial visit did not include any form of caries treatment. Instead, the children were immediately taken through a series of adaptive visits, which were conducted following their age and individual needs. This was followed by a comprehensive dental examination, which included oral hygiene instruction, dietary guidelines, and a procedure to clean all teeth of plaque. At the subsequent visit, the children were treated with a conservative approach to the management of their milk teeth.

Treatment procedures
One group of patients was treated with the Er:YAG laser (MORITA AdvErL Evo, Kyoto, Japan), while the other group was treated with a turbine with diamond drills, water and air cooling, and a slow-speed tip with rose drills and air cooling.

Characteristics of the conventional method
In the traditional method, a turbine with blue-coated diamond drills 19 mm long in sizes 012 – 018 with water and air cooling was employed to create the cavities and work on the enamel. A slow-speed carbide tip 22 mm long in sizes 018 – 021 with air cooling was used for dentin preparation. The restorative material was glass ionomer.

Characteristics of the laser settings
A summary of the settings of the laser utilized for each group of cavities is presented in Table 3. The following Er:YAG laser parameters were employed in the enamel on all surfaces: a frequency of 10 Hz for cavity opening and 20 Hz for enamel modification; a pulse of energy of 160 mJ with a 400 µm diameter applicator and 230 mJ. The 600 µm diameter applicator was used to develop cavities on proximal and chewing surfaces, while on smooth surfaces (palatal and labial) of anterior teeth, 150 mJ – 600 µm and 180 mJ – 800 µm were applied.
In the surface modification procedure, the energy pulse was 50 mJ and 70 mJ for 400 µm and 600 µm diameter applicators, respectively. The liquid water values oscillated between 2.5 - 3 mL /min, and the air cooling was set to 7 on a scale of 1 to 10.
The parameters employed in dentin across all cavity classes were as follows: frequency 10 Hz, a pulse of energy 120 mJ with a 600 µm diameter applicator, and 150 mJ with an 800 µm diameter applicator, respectively. The liquid water was used at a rate of 2–2.5 mL/min with air cooling at 7 on a scale of 1 to 10.
The pulse duration was maintained at 300 µs throughout the enamel and dentin treatment.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Pulp reaction to treatment. The Pulp Vitality Tester was employed to assess dental pulp vitality. The device quantifies pulp vitality on a scale of 0 to 80 µA (0–40 µA – vital pulp; 40–80 µA – pulpitis; over 80 µA – necrotic pulp). The pulp responses of deciduous teeth were studied using both traditional and laser methods following the treatment
2. The working time for conventional and laser method for each method was recorded using a stopwatch
3. Following the conventional and laser treatment visit, patients were asked to rate their pain sensations using emoticons according to the VAS scale

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
25/11/2021

Completion date
30/08/2024

Eligibility

Key inclusion criteria
1. Children who had visited a dental office for the first time in their lives for a dental examination and possible conservative treatment
2. The patients in the study were healthy children who were not taking any medication

3. They also did not report any pain when coming to the office
4. The patients were aged between 3 and 8 years
5. The patients exhibited unicuspidal deciduous teeth with deep caries

Participant type(s)
Patient, Health professional

Age group
Child

Lower age limit
3 Years

Upper age limit
8 Years

Sex
Both

Target number of participants
47

Total final enrolment
97

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
25/11/2021

Date of final enrolment
26/06/2024

Locations

Countries of recruitment
Poland

Study participating centre
Wroclaw Medical University the Department of Dental Surgery
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Sponsor information

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Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
We planned the publication in the JCM Journal

Intention to publish date
25/12/2024

Individual participant data (IPD) sharing plan
The datasets generated during the curent study will be available upon request from DSS Agnieszka Milc
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IPD sharing plan summary

Available on request