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Case report

PLACEBO-CONTROLLED SUBJECTIVE AND OBJECTIVE EVALUATION OF LASER ANALGESIA EFFICACY – a case report

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ABSTRACT

BACKGROUND: Pre-emptive laser analgesia (LA) is considered as bio-photomodulation of pulpal reactivity aiming reduction of nociceptive impulse formation and thus presenting a current non-pharmacological mean for painless conservative treatment. The aim of this investigation is efficacy approbation of a modified protocol for LA with Er:YAG laser.

CASE DESCRIPTION: A 12 y.o. female patient underwent two single-visit treatments, receiving LA and placebo analgesia (PA) prior to laser ablation of similar carious lesions in two permanent maxillary first molars bilaterally. Efficacy of analgesic protocol was assessed by following outcomes: primary – self-reported pain felt during treatment on VAS; secondary: changes in pulpal sensibility to electrical and cold-stimuli via EPT and Cold-test; pain-related behavior on FLACC-scale; pulse frequency. Subjective and objective pain evaluation revealed no pain during caries ablation after LA and little pain after PA. Pulp sensibility towards electrical and thermal stimulation decreased more significantly after LA induction.

DISCUSSION: Results suggest that Er:YAG therapy under applied parameters may be effective in achieving pulpal analgesia. The aforementioned tests could be valuable means for investigating the occurrence of any pulpal analgesic effect obtained by dental lasers.

CONCLUSION: Assessment of results of this case report should facilitate development of a laser analgesia protocol. The clinical adequacy of proposed protocol is to be separately estimated as part of a currently conducted double-blind randomized clinical trial with split-mouth design.

Keywords: laser analgesia, er:yag laser, low level laser therapy, laser dentistry, photobiomodulation, photomodulation, pulp testing,

INTRODUCTION

Painless treatment is an integral element of quality pediatric dental care whereas achieving local anesthesia in children is one of its most critical aspects. A current non-pharmacological mean for attaining painless conservative treatment is presented by the laser analgesia method.

Laser analgesia is considered a non-thermogenic photomodulation of the dental pulp's reactivity aiming for reduction of nociceptive nerve impulse formation [1]. It is hypothesized that laser pulses alter the cell membrane behavior of the pulpal nerve fibers by hyperpolarization and loss of impulse conduction, and thus an analgesic effect is achieved [2-4]. The 2 types of sensory nociceptive nerve fibers in the pulp are myelinated A-delta fibers and unmyelinated C fibers. The A-delta fibers are able to generate a fast, sharp pain that is easily localized [4]. Rapid temperature change by application of Cold-test and electric pulp testing (EPT) produce a strong response in A-delta fibers [5], due to their dependence on ionic movement. The assessment of changes in pulp's sensory responses can be explored by pulp sensibility testing towards thermal or electric stimulation [6].

The rationale based on the neurophysiology of the pulp, led to choosing both electric and cold testing as means for evaluating the pulpal analgesic effect of the Er:YAG pulp laser. The pulp sensibility testing, along with the assessment of subjective and objective pain sensation during treatment should help estimate the clinical adequacy of the laser analgesia method.

OBJECTIVES

The intention of the technique of "pre-emptive laser analgesia" is to reduce sensation in that small percentage of patients who may experience unpleasant sensations during caries removal. Currently no consensus is reached regarding a detailed protocol with laser parameter settings for pre-emptive laser analgesia. It is hypothesized that when operating at low level densities, the laser energy leads to loss of nociceptive impulse formation by coinciding with the natural resonance frequency (15-20 Hz) of cell membranes of nerve fibers in the dental pulp [7].

Aim of this investigation is efficacy approbation of a modified protocol for laser analgesia with Er:YAG. The main objectives of the clinical approbation were to compare pain felt during treatment in laser and placebo analgesia control group and to register the reactivity of the pulp towards cold and electrical stimuli before and after inducing laser or placebo analgesia.

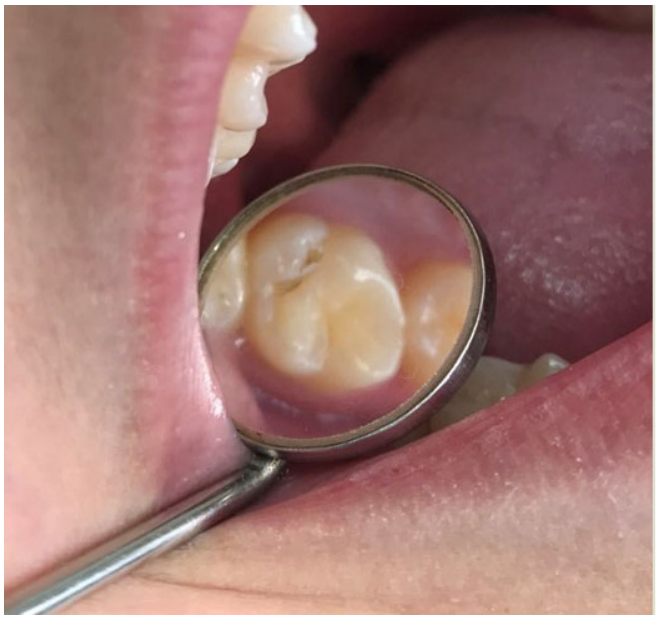
To our best knowledge, no study before has explored the analgesic effect of a dental laser with thermal stimulation complementing the EPT results, combined with subjective and objective pain evaluation.

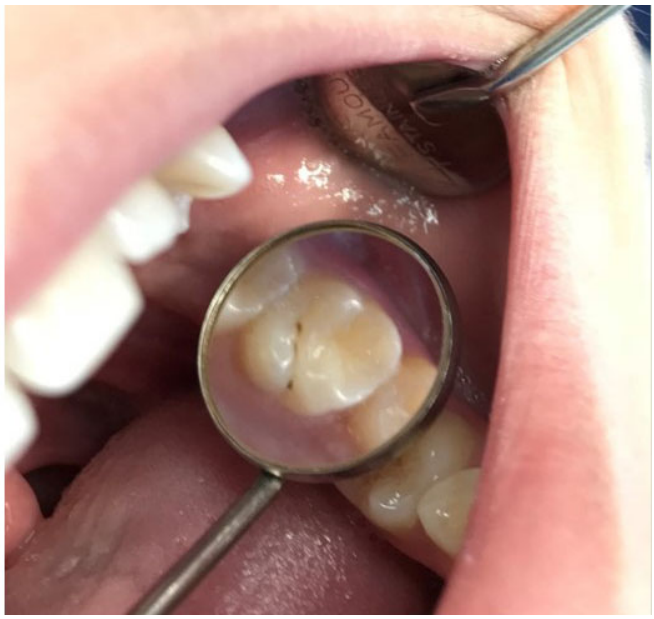
CASE DESCRIPTION

Background

Clinical examination of a 12 y.o. female patient revealed localized loss of tooth structures due to carious decay occlusally in two permanent maxillary first molars bilaterally, diagnosed by ICDAS as code 03, without prior restorations or sealants, shown in figure 1.

Fig. 1. Caries lesions on tooth 16 (left) and 26 (right).





Patient reported provoked transient pain and hypersensitivity in connection to both maxillary first molars. The child was qualified as positive by Frankl behavioral rating scale and was not a first time ever dental patients. Anamnestic interview with a parent confirmed absence of any general acute or chronic disease and excluded cognitive impairment, as well as therapy with neurological, sedative, analgesic and/or anti-inflammatory drugs 7 days prior to treatment. Informed consent was obtained from a parent to participate in the study, in which laser treatment and study procedures were explained in appropriate manner.

Interventions

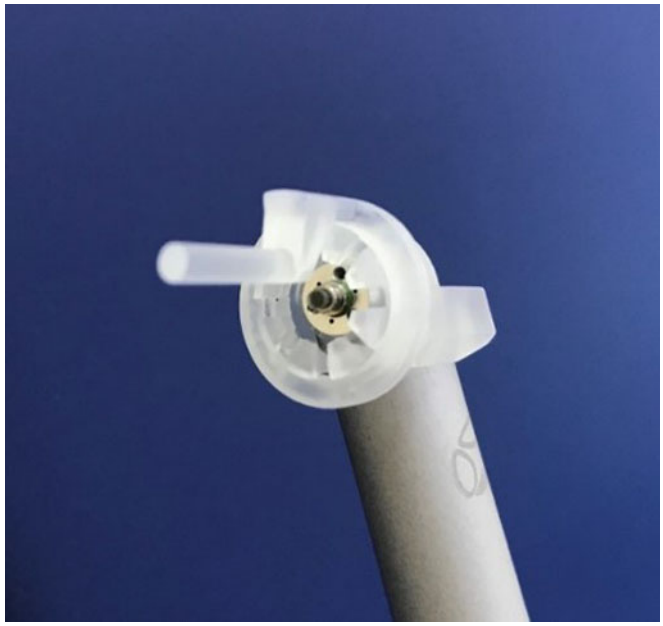
Dental Er:YAG laser (LiteTouch™, Light Instruments LTD) was used as means to attain analgesia and caries removal. Laser specifications can be found in table 1. Chosen protocol parameters are modified based on previously conducted studies [7-9].

Table 1. Laser specifications

Active medium:	Pulsed YAG:Er state S
Laser Classification	IV
Emission Mode	Impulsed
Max Pulse Energy	700 mJ
Pulse Repetition Energy	10 - 50 Hz
Co-axial aiming beam	N/A
Delivery system	Gold plated mirrors
Output divergence:	180 miliradian
Mode	Non-contact
Delivery tip used:	1.3 x 6.3 mm sapphire tip

Laser analgesic protocol: Water mist spray set to "maximum", non-contact handpiece with sapphire tip. Tip-to-tissue distance 10 mm from the tooth neck, achieved by using a spacer, shown in figure 2,

Fig. 2. Adjustable spacer, providing tip-to-tissue distance 10 mm, developed for the study.



Energy is delivered to the enamel above the gingival margin adjacent to the cemento-enamel junction (perpendicularly towards the dental pulp) on each of the four line angles of the tooth for 30s, moving the laser hand-

piece in a sweeping action. Pulse energy – 0.2 W/ 10 Hz/ 20 mJ. Follows increase of energy and repetition of protocol - 0.6 W/ 15 Hz/ 40 mJ. Total duration of LA-induction – 240s.

Placebo analgesic protocol: No pulse energy applied. Moving the laser handpiece in a sweeping motion repeating actions to imitate laser analgesia placement.

Application parameters during caries ablation: Hard tissue preconditioning: 1.5 W/ 15 Hz/ 100 mJ for one minute; Enamel removal – 3 W/ 15 Hz/ 200 mJ; Dentin removal – 2 W/ 10 Hz/ 200mJ. Smear layer removal: 2 W/ 10 Hz/200 mJ.

Loss of tooth structure was restored with esthetic composite.

Outcomes measures

To evaluate efficacy of laser analgesia protocol, assessment of following outcomes was performed:

Primary outcome measure was pain felt during the treatment, reported by the patient on a visual analogue scale (VAS) at the end of the treatment session. The chosen VAS for assessment was Wong-Baker FACES Pain Rating Scale, which allows children to pick a facial expression, that corresponds with their pain and see a number that matches it.

Secondary outcome measures: (1) changes in pulpal sensibility to electrical stimuli before and after laser/ placebo analgesia, evaluated by electrical pulp tester; (2) changes in pulpal sensibility to cold stimulation before and after laser/placebo analgesia by Cold-test - pain is reported by the patient on visual analogue scale; (3) patient experience during analgesic/placebo procedure, evaluated by questionnaire; (4) pain-related behavior, evaluated by the outcomes assessor using Faces, Legs, Activity, Cry, Consolability (FLACC) Behavioral Pain Rating Scale during treatment; (5) dynamics of patient's heart rate during the experiment, registered via pulse oximeter.

Clinical protocol

The patient underwent two single-visit treatments, receiving laser analgesia (LA) prior to treatment of 26 and placebo analgesia (PA) for tooth 16. Same clinical protocol was applied for both visits. After obtaining informed consent from the parent, the child was approached alone explaining verbally and showing visually the procedures that will be performed, using the tell-show-do technique. Pulse oximeter was connected to patient's index finger in the waiting room. Start of heart rate monitoring and recording – 7 minutes prior treatment until end of treatment. Blind for chosen method investigator evaluated the initial reactivity of the pulp with electrical pulp tester (Digitest II Parkwell – Edgewell, NY, figure 3) 5 minutes prior laser or placebo analgesia. Four minutes before applying chosen method same investigator performed Cold-test with propane-butane gas (Pulp spray, Cercamed, figure 3), applied on a cotton pad on the selected tooth and patient was asked to evaluate pain perception on the VAS. At the first visit, placebo analgesia was applied prior to treatment of tooth 16. Laser analgesic procedure was performed at the second visit on tooth 26. Patient experience during analgesic or placebo procedure was evaluated by a patient questionnaire immediately after the procedure. The child was asked to answer four questions with possible answers "yes" and "no": "Did you feel pain when we put your tooth to sleep?"; "Were you frightened when we put your tooth to sleep?"; "Do you feel any pain now that your tooth is put to sleep?"; "Do you feel any tingling sensation now that your tooth is put to sleep?". After LA/PA procedure, caries ablation was performed under aforementioned laser parameters. No rotary instruments or other excavation techniques were applied. Five minutes after LA/PA procedure outcomes assessor evaluated the sensibility of the pulp with EPT and six minutes after, performed Cold-test on same tooth. At the 20th minute after LA/PA, EPT testing was performed. At the 21st minute a Cold-test was applied and the pain perception was registered again on VAS. Pain-related behavior was registered using the FLACC Behavioral Pain Rating Scale. Immediately after placement of restoration the patient was asked to use the VAS to quantify the level of pain felt during treatment.

Fig. 3. Pulp sensibility testing. Electrical pulp tester (EPT) - Digitest II Parkwell Edgewell (left); Cold-test - Pulp spray, Cercamed (right).

RESULTS

For both laser and placebo analgesia patient reported negative answers to questions regarding pain, tingling sensation or fear during the procedure. Subjective pain evaluation revealed no pain (VAS = 0) during caries ablation after laser analgesia and very little pain (VAS = 2) after placebo analgesic procedure. Pain-related behavior on FLACC scale was registered as '0 = relaxed and comfortable for both visits.

The increase of EPT score was more evident after LA in comparison to PA-induction, shown in table 2, indicating heightened threshold of nerve impulse firing after the procedure.

Table 2. Pulp sensibility testing - EPT results.

Method	5 min before	5 min after	20 min after
LA	13	24	23
PA	19	13	18

Initial pain score after Cold-test for both teeth was determined by the patient as little pain. After LA induction pulp sensibility towards cold stimulation decreased, reported as '0 = no pain', in comparison to PA, whereas sensibility remained relatively constant as shown in table 3.

Table 3. Self-reported pain score on VAS after Cold-test application.

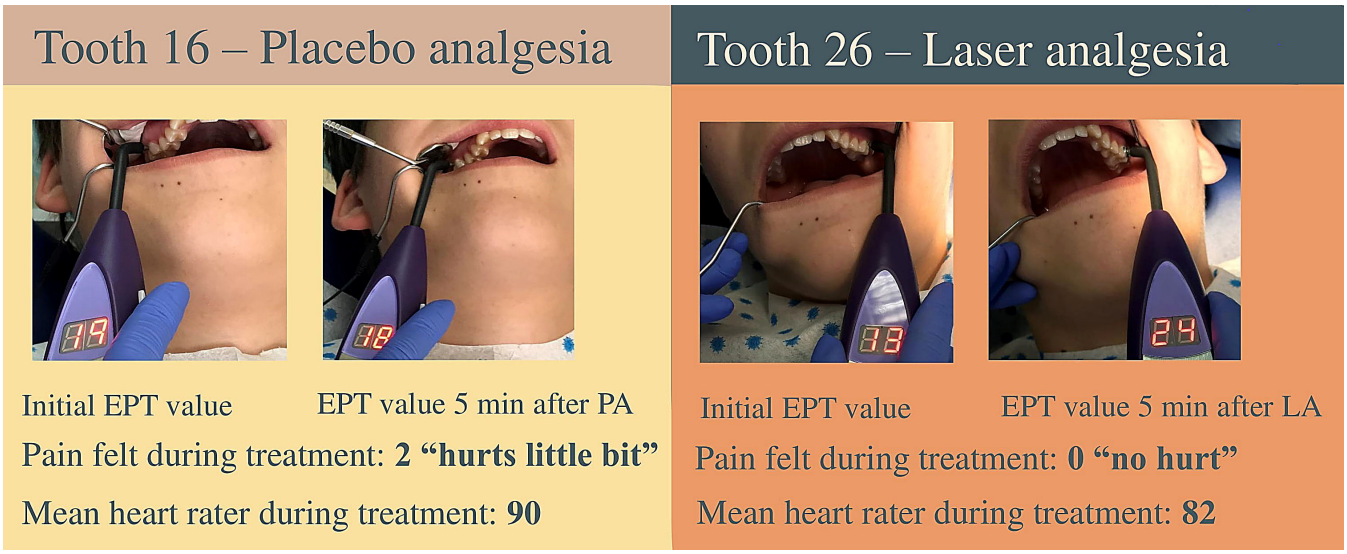
Method	4 min before	6 min after	21 min after
LA	2	0	0
PA	3	2	2

Mean pulse frequency was slightly lower during caries ablation after LA procedure in comparison to PA, shown in table 4. Summarized results are illustrated in figure 4.

Table 4. Pulse frequency – mean heart rate.

Method	Waiting room	LA/PA procedure	Caries removal
LA	86	85	82
PA	91	86	90

Fig. 4. Summarized results from both visits – first visit (left) and second visit (right).



DISCUSSION

Different possible explanations have been suggested for low-level laser action (photobiomodulation) regarding pain relief [10] and several wavelengths have been considered as means for obtaining dental laser analgesia. Currently no consensus is reached regarding a detailed protocol with reliable laser parameter settings for pre-emptive laser analgesia, and some research lacks necessary parameter detail, presenting challenges to repeat or reproduce [9]. Many studies agree that to obtain pulpal analgesia, it is necessary to take advantage of low energy and power densities [1, 9, 11, 12] by circular irradiation of the tooth neck area from a distance 3-10 mm.

It is hypothesized that when operating at low level densities, the laser energy leads to loss of nociceptive impulse formation. According to this theory the laser frequency coincides with the natural resonance frequency (15-20 Hz) of cell membranes of A-delta and C nerve fibers in the dental pulp inducing depressed excitation [7]. Albeit the authors' theory is widely accepted as a baseline for other studies, including the currently conducted one, no scientific information was found regarding the value of the natural resonance frequency of pulp's nerve fibers.

Since impulses from electrical stimuli are transmitted through A-delta fibers, the electrical pulp tester (EPT) was chosen as method for registration of any changes in pulpal sensibility. Few clinical studies have investigated the method of laser analgesia by analyzing alteration in EPT threshold, but results are contradictory [9, 11]. It is possible that the EPT does not provide an accurate meas-

ure of pulpal analgesia [11] and it may be preferable to assess the clinical adequacy of a dental analgesia by supplemental methods such as thermal stimulation. According to authors [13], ideally, EPT should be used in conjunction with cold testing so that the results from one test will verify the findings of the other test. Cold testing causes contraction of the dentinal fluid within the dentinal tubules by creating 'hydrodynamic forces' acting on the A-delta nerve fibers within the pulp–dentine complex, leading to a sharp sensation lasting for the duration of the thermal test [14].

The rationale behind the chosen test supports our hypothesis that if any analgesic effect is attained, then the patient is expected to report lower cold-related pain VAS-scores. To our best knowledge, no study before has explored the analgesic effect of dental laser with Cold-test, complementing the EPT results.

In this case report the efficacy of Er:YAG laser for achieving pre-emptive dental analgesia was investigated in a complex manner. The split-mouth design offers advantages such as the removal of inter-individual variability from the estimates of the treatment effect. Following precautions were taken in account to minimize variables in results: the patient was classified as positive according to Frankl behavior scale; the age of the patient ensured cognitive skills for adequate cooperation and was compliant with the need for full root development of teeth to be examined with EPT. Both carious lesions were similar in depth (moderate caries) and on bilaterally placed teeth on the same dental arch without previous restorations.

This case report is part of a currently conducted double-blind randomized placebo-controlled clinical trial with split-mouth design, registered on a publically accessible database - trial registration: ClinicalTrials.gov NCT03412721, according to ICMJE (International Committee of Medical Journal Editors) guidelines for registration of clinical trials in a public trials registry as a condition of consideration for publication. A study protocol of the trial is published as well [15]. Pre-test on 20 subjects resulted in n=41 patients needing to be recruited.

CONCLUSION

Currently no consensus is reached regarding a detailed protocol with laser parameter settings for pre-emptive laser analgesia. Pulp sensibility testing, along with the assessment of subjective and objective pain during treatment of similar cases should help estimate the clinical adequacy of the laser analgesia method. Assessment of results from this case report should facilitate development of a laser analgesia protocol. The clinical adequacy of proposed protocol should be separately estimated.

Abbreviations

EPT = electrical pulp testing,

ER:YAG = erbium-doped yttrium aluminium garnet,

FLACC = Faces, Legs, Activity, Cry, Consolabilty scale,

ICMJE = International Committee of Medical Journal Editors,

LA = laser analgesia,

LASER = light amplification by stimulated emission of radiation,

PA = placebo analgesia,

VAS = visual analog scale.

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