

To
The chairman of the scientific jury,
determined by Order № P - 66 / 18.01.2021
of the Rector of Medical University - Plovdiv
15A V. Aprilov Blvd., 4002 Plovdiv

Pursuant to Art. 30 of the Regulations for application of the Law on Dental Medicine and in connection with the procedure for awarding the educational and scientific degree "Doctor of Philosophy - PhD" to Dr. Elitsa Veneva - Raichinova, PhD student in self-study at the Department of Pediatric Dentistry, Faculty of Dental Medicine, MU - Plovdiv, after preliminary discussion by extended Departmental Council (ex. № 134/17.12.2020) and acceptance by the Faculty Council (ex. № 8/21.12.2020) of the Faculty of Dental medicine for the developed dissertation on the topic:

"Non-pharmacological strategies for pain and anxiety control associated with local analgesia in children"

with scientific supervisor Prof. Dr. Ani Belcheva, PhD

Attached I present: A Review

In connection with the procedure for awarding the educational and scientific degree "Doctor of Philosophy - PhD" of Dr. Elitsa Veneva - Raichinova, PhD student in self-study at the Department of Pediatric Dentistry, Faculty of Dental Medicine, MU-Plovdiv

Prepared the review:

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REVIEW

**From Assoc. Prof. Dr. Lilia Borisova Doichinova, PhD
Faculty of Dental Medicine - Sofia
Department of Pediatric Dentistry**

In connection with the procedure for awarding the educational and scientific degree "Doctor of Philosophy - PhD" under the doctoral program "Pediatric Dentistry" to Dr. Elitsa Veneva - Raichinova, PhD student in self-study at the Department of "Pediatric Dentistry", FDM, MU-Plovdiv, the developed dissertation on the topic "Non-pharmacological strategies for pain and anxiety control related to local analgesia in children" with supervisor Prof. Dr. Ani Belcheva MD, in professional field 7.2. Dental medicine, field of higher education 7. Health and sports.

The presented set of materials on paper and electronic media by the dissertation is in accordance with Art. 2014.

I. Biographical data and professional development.

Dr. Elitsa Veneva - Raychinova, was born on May 1, 1988 in the town of Kyustendil.

She graduated from high school in 2007 at the English Language School "Plovdiv" with intensive study of German and English. In 2013 she graduated from FDM of MU-Plovdiv. After graduation she started working in her own dental practice. In 2017, through a competition, she was selected as a full-time assistant professor in the Department of Pediatric Dentistry at Medical University – Plovdiv, where she still works today.

Since taking office as an assistant professor, Dr. Veneva has been involved in teaching Bulgarian and English-speaking students of all courses.

She is a trainee specializing in pediatric dentistry.

She is a member of BUA, BNDDM, NSLDDM.

Fluent in written and spoken English and German - level C1.

II. Structure of the dissertation

The presented dissertation is written on 193 pages, of which: Contents - 3 pages; Abbreviations - 1 page; Introduction - 2 pages; Literary review - 29 pages; Purpose and objectives - 1 page; Own research - 105 pages; Main conclusions - 1 page; Bibliography - 20 pages; Addendum - 27 pages; Contributions - 2 pages; Publications and scientific reports related to the dissertation - 2 pages. It is illustrated with 37 figures and 17 tables and 7 appendices. The bibliography includes 214 titles, of which 18 in Cyrillic and 196 in Latin. A review of the bibliography shows a serious study of the scientific literature by the doctoral student.

The structure, design and technical implementation of the dissertation is at a very good level, and meet the procedural requirements.

II. Topicality

Painless treatment is an integral part of quality dental care in childhood. In 2015, the World Health Organization and the International Association for the Study of Pain gave a precise definition of pain as "an unpleasant sensory and emotional experience associated with or described in relation to actual or potential tissue damage." Effective pain control in the child-patient during dental treatment is the basis for successful management of his behavior.

Applying local anesthesia is the key to controlling pain during dental procedures, and children are a special challenge. Advances in research in pain management have led to the development of devices that allow the clinician a therapeutic approach to reduce pain relate to local anesthesia, which is essential to address anxiety in the pediatric patient. Through successful pain management, trust can be built between the dentist and the patient, and foster a positive attitude towards future dental treatment.

The gate control theory of pain proposed decades ago by Melzack and Wall is a widely accepted concept of pain perception. This theory is used to explain the analgesic effect of vibration. According to her, A- β (beta) nerve fibers transmit information from the receptors for touch and vibration in the skin and stimulate inhibitory interneurons (neurons located in the posterior horns of the spinal cord that receive information from the spinal ganglia). These neurons respond to pain, temperature, vibration, proprioceptive stimuli. They work to reduce the amount of pain signal transmitted by A- δ (delta) and C fibers through the midline of the spinal cord and thence to the brain. Pain is thought to be transmitted from the peripheral nervous system to the central nervous system by afferent pain receptors - A- δ (delta) fibers carrying signals for acute pain triggered by injection and by non-myelinated slower C-fibers carrying signals for chronic pain. They are blocked by fast-acting nerve fibers called A- β (beta), which transmit signals caused by vibrations.

In recent years, several innovative dental products have been developed based on this theory - Accupal, DentalVibe (DV), Vibraject (Chaudary et al.), extraoral massager to relieve pain in children during local anesthesia (Aminah et al.) and other. Their action is expressed in the principle of masking the pain of the needle penetration by applying pressure, vibration, microoscillations or a combination of them. Applied physical stimuli alter or interfere with pain signals by closing the neural gate of the cerebral cortex in order to reduce the sensation of pain due to distraction.

A number of authors report on the efficacy of the vibrotactile method for reducing injection pain and the emphasis on children's preference for it over traditional injectable analgesia. Despite the potential that the method suggests, the results of clinical trials are still insufficient to establish it as an effective method for reducing injection pain during infiltrative anesthesia techniques in childhood. Additional studies are needed to assess the clinical adequacy of the infiltration method, assisted by vibrotactile devices, to establish the possibility of performing local anesthesia with reduced discomfort.

The DentalVibe Gen4 Comfort Injection injection system is designed to reduce injection pain by applying pressure and vibration to the injection site. The number of clinical trials conducted on its efficacy and use in pediatric patients is insufficient to confirm the method as effective and applicable in this age group.

All this makes the topic of the dissertation developed by Dr. Veneva very relevant and extremely important, because the results of the study of DentalVibe, as a new non-pharmacological tool for achieving painless local anesthesia will help improve the quality of care in pediatric dentistry through assessment of its clinical adequacy.

III. Knowledge of the problem by the doctoral student

Dr. Veneva demonstrates excellent knowledge of modern scientific literature on this issue. With a short **introduction**, the dissertation presents the essence of this current problem in pediatric dentistry.

The **literature review** is written in a volume of 37 pages. It shows the doctoral student's ability to research and analyze in detail the available scientific literature. It presents current information on modern and alternative technologies, tools, methods for providing local anesthesia, as well as techniques aimed at painless infiltration of anesthetic agents in childhood.

The review ends with a summary and listing of unresolved issues in order to justifiably and logically motivate the chosen topic of the dissertation.

The entire literature review illustrates the excellent knowledge and handling of terminology in the field of the developed topic.

I appreciate the literature review as modern and very highly informative, which gives the right direction for their own research and facilitates their interpretation by the doctoral student.

IV. Methodology of the investigation

The **aim** of the present dissertation is precisely and clearly formulated: to study the possibilities for non-pharmacological management of pain and anxiety associated with local analgesia in pediatric patients. It is realized through five set objectives, with two subtasks of the fourth, which are performed sequentially and with demonstration of very good, professional knowledge and correct clinical thinking.

The **objectives** are: to study the efficacy of the DentalVibe device for reducing anxiety and pain during local infiltrative anesthesia in pediatric patients; to investigate the efficacy of a virtual reality device for reducing anxiety and pain during local infiltrative anesthesia in pediatric patients; to compare the efficacy of two non-pharmacological methods of distraction - through DentalVibe and virtual reality, to reduce pain and anxiety during local injection anesthesia (LA) in childhood; to study the possibility of photobiomodulation with Er: YAG laser to achieve safe preemptive laser analgesia in pediatric patients with two subtasks: study of the morphology of the enamel surface after laser analgesia with Er: YAG - scanning electron microscope (SEM) study and study the efficacy of a modified Er: YAG laser protocol

to achieve preemptive laser analgesia in pediatric patients; to develop recommendations for non-pharmacological control of pain and anxiety associated with local analgesia in dental patients in childhood.

All objectives help the doctoral student to successfully achieve the goal.

Appropriate clinical and statistical methods have been used for the conducted researches, where the serious scientific potential of the realized clinical research is seen and the in-depth and mature scientific thinking of the doctoral student is evident.

The methodologies are described very precisely and in detail. The statistical analysis of the collected data is professionally done. Modern statistics are used. The various **statistical methods** are adequately used and enable the dissertation to reach reliable results and conclusions. The systematization, processing and analysis of the obtained results are realized with the help of the statistical package of the software for social sciences IBM SPSS Statistics v. 22. Graphical analysis was performed using Microsoft Excel Office 2013.

V. Characteristics and evaluation of the dissertation and contributions

The dissertation is a personal work of the doctoral student and its structure is in accordance with modern requirements and contains all necessary sections: introduction, literature review, purpose and objectives, material and methods, results and discussion on individual tasks, conclusions, contributions and bibliography.

An essential part of Dr. Veneva's dissertation are the results and their discussion. The obtained **results** are well illustrated and are directly related to the solved tasks. They are presented very well, with detailed analysis in tables and graphs, with statistical data processing and derived statistical reliability and dependencies. Diagrams, tables and figures are clear and properly structured.

The results are subject to in-depth discussion, which deserves high praise. This further confirms the precise work done by Dr. Veneva in developing the dissertation.

Each task ends with conclusions, which show the doctoral student's ability to summarize the results and form very accurate conclusions, which helps to better perceive the results.

I believe that with the obtained results and their analysis Dr. Elitsa Veneva has fully achieved the goals and objectives of her dissertation.

The results of the doctoral student's own research are presented in detail.

In the discussion the doctoral student demonstrates good competence and criticality in the comparative analysis of his own results with the data published in the scientific literature.

I fully support the recommendations made in the implementation of the fifth task to parents, dentists, professional organizations and faculties of dentistry.

The **conclusions** made on each of the tasks are exhaustive and reflect in a synthesized form the

results of the research and the discussion and bring the scientific contribution of a dissertation:

On the first objective - An assessment of the subjective and objective sensation of pain and anxiety during treatment confirms the clinical adequacy of the method of infiltration with DentalVibe, establishing the possibility of local anesthesia with reduced discomfort. It is proved that the method is easily applicable in everyday practice, and its disadvantage is indicated only by the high cost of the device and its consumables.

Objective Two - The use of a virtual reality device has been shown to be an effective and applicable non-pharmacological method for reducing injection pain and anxiety in children. Given the progress and increasing availability of technology for clinical use, it is clear that this technology has the potential to be a useful addition to modern pediatric dental practice.

Third objective - It is stated that the two modern non-pharmacological methods are effective in reducing anxiety and pain during local anesthesia compared to conventional injection anesthesia without distraction. No superiority of one method over the other has been established. Distraction techniques through the use of vibrotactile stimulation or virtual reality devices have been found to be effective in reducing the fear of dental treatment and injections by aiding the administration of injectable local anesthesia.

Under the **first sub-objective to the fourth objective** - It was proved that the applied parameters for photobiomodulation, used in order to achieve laser analgesia, can cause changes in the surface morphology of the enamel. The results reveal structural changes corresponding to the applied energy densities and water levels. The settings for higher power and low water cooling correspond to the increasing roughness and cratering of the surface.

When operating at an energy of 0.6 W / 15 Hz / 40 mJ, maximum water cooling must be applied to achieve subablative laser action at a distance of 10 mm.

At laser parameters equal to or exceeding 0.75 W / 15 Hz / 50 mJ with or without maximum water cooling, the effect of the laser from a distance of 10 mm is proven to be ablative and unsuitable for performing a laser analgesic procedure. The evaluation of the results of this CEM study facilitated the development of a modified laser analgesia protocol.

On the **second sub-objective to the fourth objective** - It is established that the treatment of medium-deep caries with Er: YAG laser according to the proposed parameters is of very low pain, regardless of whether a protocol for laser analgesia is performed.

Removal of the carious mass does not cause an increase in anxiety in patients. Surgical time is a valuable resource for the clinician, and it can be saved by performing a simplified work protocol without a preemptive analgesic procedure. The subjective component in determining sensation during EPT makes it difficult for children, and the operator, to determine the outcome.

The use of a Cold test to assess the subjective sensation of pain on a VAS scale helps in addition to determining the threshold of pulp sensitivity. Performing it several times, however, could reduce the sensation.

The final **conclusions** made are correctly formulated and are a logical consequence of the set goals and objectives.

1. Non-pharmacological methods of dissipation with passive factors help to reduce pain and anxiety during local analgesia in patients aged 8 to 12 years and have a positive effect on its perception.

2. Vibrotactile and audio-visual stimulations are available new technologies with easy application for efficient non-pharmacological management of behavior during local anesthesia.

3. The photobiomodulation created during conservative treatment of caries with Er: YAG laser is sufficient for almost painless treatment. The operator can save time from not performing preemptive laser analgesia while maintaining patient comfort.

4. The type of upcoming treatment - conservative or surgical, does not affect dental fear and fear of injections. The behavioral management, the presentation of the manipulation in an age-appropriate manner, and the atraumatic performance of local anesthesia predispose the pediatric patient to a positive attitude and cooperation, regardless of the forthcoming treatment.

The **contributions** formulated by Dr. Veneva make a strong impression. They are the personal work of the doctoral student and are correctly reflected. They are:

Scientific-theoretical - the effect of laser settings used for preemptive laser analgesia with Er: YAG on the surface morphology of the enamel by scanning electron microscopy has been studied, determining laser parameters that do not damage its integrity.

Methodological - For the first time in the world a clinical protocol for preemptive laser analgesia is being developed, which has been proven to be safe, reproducible and publicly available before the results of the study are published. It was published in a prestigious journal.

The occurrence of laser analgesic effect is examined by an original method, and thermal testing is included to complement the electric pulp testing. In combination with pulp sensitivity testing, the assessment of subjective and objective pain sensation during treatment forms an original unused protocol.

Scientific - applied - For the first time in our country the possibilities for non-pharmacological influence of pain and anxiety during local anesthesia through vibrotactile device and virtual reality are proved, without establishing superiority of one method over the other, which allows the clinician to choose the appropriate agent for the patient.

It has been shown that during conservative laser treatment, the operator can save time by not following a preemptive analgesia protocol without compromising patient comfort.

Recommendations for non-pharmacological control of pain and anxiety related to analgesia in

children have been developed, aimed at parents, dentists and institutions responsible for the oral health of children in Bulgaria.

Confirmatory - The effectiveness of virtual reality distraction and vibrotactile stimulation on reducing injection pain in pediatric patients has been demonstrated.

It was found that electric pulp testing as a stand-alone method for testing pulp sensibility in childhood is insufficient and should be supplemented by another objective method.

It has been confirmed that conservative treatment of moderately deep dental caries with Er: YAG laser is almost painless and does not require local anesthesia.

The contributions of the dissertation justify the efforts made by the dissertation and demonstrate in a very clear way the serious scientific benefit of pediatric dentistry.

In the 1980s, various strategies were applied to address children's fears and anxieties for better acceptance of dental treatment through desensitization, the use of rewards to promote good behavior, including various techniques such as "Tell Show Do" (TSD) - relaxation, voice control, hypnosis, bio-feedback with guided images, distraction with storytelling, use of audio or audio-visual means.

This dissertation fills the existing gap in scientific knowledge on the problems of non-pharmacological interventions affecting fear and anxiety in children.

VII. Assessment of the doctoral student's publications and personal contribution

The list of scientific publications in connection with the dissertation includes 3 real publications in which Dr. Elitsa Veneva is a leading author. She also has 11 participations in Bulgarian and international forums, where she is also a leading author.

VIII. Author's review

The author's abstract is prepared according to the requirements and faithfully reproduces in summary form on 51 pages the most important of the content of the dissertation. It is composed of parts that present the structure and content of the dissertation, reflecting the main results achieved by the dissertation. Scientific conclusions, contributions, publications and participation in Bulgarian and international congresses are included.

IX. Conclusion

Dr. Elitsa Veneva - Raichinova, presents a completed and very well-designed **dissertation with thematic relevance, containing scientific results that represent an original contribution to science and meet the requirements of Law on the development of the academic staff in the Republic of Bulgaria and the Regulations of Medical University - Plovdiv.**

I find the topic developed by the doctoral student very current and timely. The dissertation is thoroughly developed, well illustrated and presented in accessible and good professional language. It is an example of conscientious and precise scientific work.

All this gives me reason to evaluate positively the dissertation, which categorically confirms that **Dr. Elitsa Veneva - Raychinova has in-depth theoretical knowledge and professional skills in the field of Pediatric Dentistry**, showing qualities and skills to conduct independent research, and presents the necessary publication activity.

I give a *positive assessment* of the presented dissertation on the topic - "Non-pharmacological strategies for pain and anxiety control related to local analgesia in children" and *will confidently vote "YES" and offer the esteemed scientific jury to award the educational and scientific degree "Doctor of Philosophy - PhD"* of **Dr. Elitsa Veneva - Raichinova** in a doctoral program in "Pediatric Dentistry".



Assoc. Prof. Dr. Lilia Borisova Doichinova, PhD

Sofia

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