



EVALUATION OF EFFECT OF LOW-LEVEL LASER THERAPY ON ANXIETY LEVEL IN 6 TO 12 YEARS OLD CHILDREN UNDERGOING DENTAL TREATMENT UNDER LOCAL ANAESTHESIA: A RANDOMIZED CONTROLLED PILOT STUDY

Dentistry

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ABSTRACT

Aim - To evaluate the effect of Low-Level LASER Therapy on anxiety level by assessing facial image scale and comparing pulse rate and oxygen saturation level of blood in 6-12 years old children undergoing dental treatment under local anaesthesia. **Materials & Methods**- A total of 40 randomly selected children (females and males) aged 6 to 12 years were included in the study. Oral examination was done. Children were divided into two groups randomly. Group 1: Low Level LASER Therapy (LLLT group), Group 2: Placebo therapy (Placebo group). Pulse rate and oxygen saturation of blood and facial image scale were used for assessment. Pulse rate and oxygen saturation of blood were measured using pulse oximeter before intervention and after administration of local anaesthetic agent. The readings were noted accordingly. In FIS children were asked which face on the scale he/she relates with and scores were given accordingly. **Results**- The study showed Low Level LASER Therapy exhibited the lowest mean scores of anxiety depicted by pulse rate, oxygen saturation and FIS scale. The differences in scores recorded were found to be statistically significant. **Conclusion**- Low Level LASER Therapy significantly reduces anxiety in children undergoing dental treatment. **Clinical Significance**- This treatment modality is a safe, non-invasive and painless technique beneficial especially in children. In pediatric dentistry, LLLT can serve as an effective means of managing anxiety in children and promote positive dental attitude.

KEYWORDS

Anxiety, Laser Acupuncture, Local Anesthesia, Photobiomodulation,

INTRODUCTION

Anxiety is a physiological and/or emotional reaction to known and/or unknown reasons that can range from a normal reaction to severe malfunction. Examples of these reactions include perspiration, tension, restlessness, and a fast heartbeat. Both patients and dental professionals face significant challenges due to dental anxiety. Treatment is difficult because children with dental anxiety frequently avoid dental procedures. This widespread avoidance pattern brought on by anxiety is strongly correlated with a deterioration in oral and dental health, which feeds the cycle of increasing worry and avoidance.¹ Dental anxiety is ranked fifth among often feared circumstances, despite improvements in clinical practice and technologies.¹ Both pharmacological and non-pharmacological techniques are frequently used in dentistry settings to get around this. The safety of using pharmaceutical techniques is still debatable. Non-pharmacological approaches are therefore favored. Low Level LASER Therapy (LLLT) / LASER acupuncture is one of the more recent methods that have been introduced as a result of the ongoing need to use alternative approaches to address the time constraints in clinical practice. The foundation of acupuncture is the notion that all living things possess an inner force known as "Qi," whose imbalance or disruption results in illness and disease. Rebalancing the flow of Qi is the main goal of acupuncture therapy, which is increasingly becoming recognized as a primary or supplemental treatment. Since 2002, the WHO has recommended acupuncture as an effective treatment for a number of illnesses across all age groups and health care levels. An essential component of TCM, acupuncture has been demonstrated to be a safe and successful treatment for insomnia. The acupoint HT7, also called shenmen, is a crucial acupoint along the heart meridian on the wrist for treating insomnia in Chinese medicine. The point is referred to as "the gate of spirit" because of its meridian and location. It is used to treat a number of mental illnesses, including sleeplessness, absentmindedness, sadness, agitation, and mental disease. According to one study, acupuncture can enhance the quality of sleep with relatively little side effects.⁵ In the past, stones, needles,

and other objects were used to stimulate the skin at particular acupoints. In more recent times, practitioners have started stimulating acupoints with nonthermal, low-intensity laser irradiation. Because it is noninvasive, painless, and brief, Low Level LASER Therapy (LLLT) or, more formally, photobiomodulation (PBM), is convenient for the pediatric population.³ LLLT utilizes non-ionizing, non-thermal light energy—typically in the red to near-infrared spectrum—to induce photochemical and photophysical changes within cellular components. The core mechanism involves the absorption of light photons by cytochrome c oxidase in the mitochondria. This enhances cellular metabolism and coupled with the local release of nitric oxide (NO) it improves microcirculation, leads to beneficial therapeutic effects including anti-inflammatory action, analgesia, and, critically, neuromodulation. In the context of anxiety, LLLT applied over specific acupoints has been shown to modulate neurotransmitter release and neuronal activity, thereby exerting a calming, regulatory effect on the autonomic nervous system. Due to its narrow exposure zone, nonthermal nature, and inability to generate microtrauma, it is comparatively harmless. The need for this type of non-pharmacological, non-invasive technique is particularly acute in pediatric dentistry, where managing patient anxiety quickly and safely is paramount to successful treatment.

Despite the recognized efficacy of acupuncture for anxiety and the clear advantages of LLLT as a non-needle application, there is a significant scarcity of dedicated research in the literature specifically assessing the efficacy of LASER acupuncture in mitigating anxiety among children undergoing dental procedures. The widespread issue of dental fear, leading to treatment avoidance and subsequent deterioration of oral health, necessitates the validation of practical and patient-friendly solutions. Therefore, the present study is designed to bridge this critical knowledge gap by providing objective evidence on the anxiolytic effects of laser acupuncture in this sensitive population. Therefore, the present study aims to assess the effect of low-level LASER therapy on anxiety levels of children aged 6-12 years

undergoing dental treatment under local anesthesia, using facial image scale, pulse rate and oxygen saturation of blood.

MATERIALS & METHODS

This was a randomized controlled in vivo study conducted at the Department of Pediatric and Preventive Dentistry, Government Dental College and Hospital, Mumbai.

The sample size was estimated using G*Power version 3.0.1 (Franz Faul, Universität Kiel, Germany) for an independent-samples t-test. Based on a desired minimum statistical power of 80% ($\beta=0.20$), an effect size of 0.7, and a two-sided significance level (α) of 0.05, the total calculated sample size was 68 subjects. To account for potential dropouts and ensure robust analysis, the sample size was rounded to a total of 80 subjects (40 subjects per group). A preliminary pilot study was conducted on 40 children to refine the methodology and confirm the feasibility of the procedure.

Ethics Committee Approval:

Institutional Ethics Committee (IEC) and Review Board approval was secured for the study prior to commencement. The approval number for the study is [1190/2024]. Written informed consent was obtained from parents or legal guardians for all participating children before any procedure was performed.

The study was conducted between July 2024 and September 2024, spanning a total duration of 3 months. A total of 40 children (both females and males) aged 6 to 12 years from outpatients visiting the Department of Pediatric and Preventive Dentistry were randomly selected for the study and assigned into two groups, with 40 subjects in each group.

Inclusion Criteria:

1. Children aged 6 to 12 years.
2. Children requiring at least one dental procedure necessitating local anesthesia (e.g., restorative treatment, extraction).
3. Children with Frankl's Behaviour Rating 2 or 3.
4. Presence of a willing and consenting parent/legal guardian.

Exclusion Criteria:

1. Children with systemic diseases or neurological disorders.
2. Children taking anxiolytic or sedative medications within 24 hours of the appointment.
3. Children with a history of seizures or photosensitivity.
4. Children with severe intellectual disability or communication barriers.
5. Children with any skin lesions or pathological conditions over the acupoints (Shenmen 1 and Shenmen 2).

Study Groups:

Group 1: Low-Level LASER Therapy (LLLT Group): (n=20) Received active LASER acupuncture.

Group 2: Placebo Therapy (Placebo Group): (n=20) Received sham LASER acupuncture.

Randomization and Blinding

A simple randomization method was used to assign subjects to the two groups (LLLT or Placebo) in a 1:1 allocation ratio. Group assignment was determined by a statistician not involved in the execution of the study using a computer-generated random number sequence.

Single blinding was employed. The children and the interpreter (the person recording and analyzing the pulse rate, oxygen saturation, and FIS scores) were blinded to the group assignment (i.e., whether the active or placebo device was used). The operator performing the LASER application was not blinded.

Intervention Protocol

For both groups, the intervention was delivered 15 minutes prior to the administration of the local anesthetic agent.

A. Acupoint Selection and Location:

LASER acupuncture was performed at two key anxiolytic sites:

* Shenmen 1 (Auricular Point): Located in the triangular fossa of the auricle (outer ear).

* Shenmen 2 (Spirit Gate Point): Located on the transverse crease of

the wrist, on the radial side of the flexor carpi ulnaris tendon (on the Heart meridian, HT7).

Group 1: Low Level LASER Therapy (LLLT group)

Using the apparatus (Fig 1), LASER acupuncture was executed at 2 sites (Fig 2 & 3) : Shenmen 1 on ear and Shenmen 2 on hand for 10 seconds each, 15 minutes before administration of local anesthetic agent (Fig 4).

Parameters: 635-910 nanometers (red spectrum), power: 2-3 milliwatts, exposure : 10-20 seconds for auricular point and 20-40 seconds for corporal point.

Group 2: Placebo therapy (Placebo group)

The same procedure was executed with the help of placebo (LASER acupuncture device switched off). The device was held at the specified acupoints for the same duration (10 seconds per point) to ensure the tactile and timing elements of the procedure were indistinguishable from the active group.

Outcome analysis:

Three distinct parameters were analyzed to assess the outcome of the procedures: Pulse rate, oxygen saturation of blood and Facial image scale.

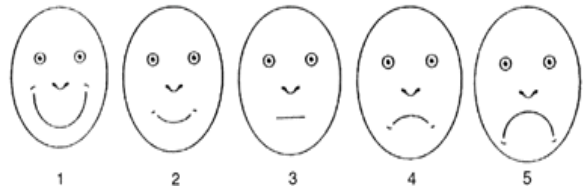
Pulse rate and oxygen saturation of blood:

Measured non-invasively using a finger-clip pulse oximeter. Readings were noted at two time points:

- T1 (Baseline): Immediately before the intervention (LLLT/Placebo).
- T2 (Post-Intervention): After administration of the local anesthetic agent..

Facial Image Scale (FIS) Scale:

FIS comprises a row of five faces ranging from very unhappy face scored as 5 to very happy face scored as 1. Each patient was evaluated using FIS for measuring anxiety after administration of local anaesthetic agent. In FIS children were asked which face on the scale he/she relates with and scores were given accordingly (Fig 5).



FIGURES:



Fig 1: LASER equipment ; Fig 2: Shenmen 1 point; Fig 3: Shenmen 2 point; Fig 4: LASER application; Fig 5: Facial Image Scale Response

Statistical analysis:

All collected data were entered into a standardized database. Statistical analysis was performed using SPSS (Statistical Package for the Social Sciences Inc Chicago, IL) software, version 21.

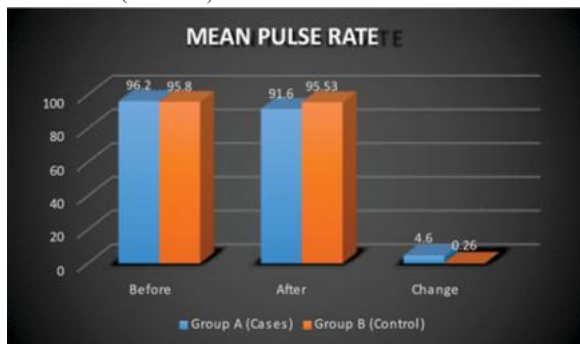
Descriptive Statistics: Mean and Standard Deviation (SD) were calculated for continuous variables (Pulse Rate and SpO2). Data normality was checked by using Shapiro – Wilk test.

Inferential Statistics: Independent Samples t-test: Used to compare the mean changes in Pulse Rate and Oxygen Saturation between the LLLT and Placebo groups. Mann-Whitney U Test used to compare the change in FIS scores between the two groups. Paired Samples t-test used to compare the change from Baseline (T1) to Post-Intervention (T2) within each group. A p-value of < 0.05 was considered statistically significant.

RESULTS.

The statistical analysis performed across the groups revealed a distinct physiological advantage for patients in Group A (LLLTT), though the results for patient-reported comfort were non-significant. A comparison of the change in pulse rate (Graph 1, Table 1) demonstrated a statistically significant difference between the groups (t=-2.054, p=0.048). Specifically, Group A experienced a mean post-procedure decrease in pulse rate of 5.8 beats/min (SD 7.72), which was substantially greater than the minimal mean decrease of 0.2 beats/min (SD 4.42) observed in Group B (Placebo). This significant reduction in pulse rate in the LLLT group is inferred to represent a mitigation of the sympathetic stress response or a reduction in procedural anxiety when LLLT is used as an adjunct.

Conversely, the use of LLLT did not result in a statistically significant difference in either patient oxygenation or self-reported comfort. The intergroup comparison for the change in peripheral oxygen saturation (Graph 2, Table 2) was non-significant (t=-0.709, p=0.482), suggesting that the LLLT method is safe and does not compromise systemic respiratory function compared to the conventional technique. Furthermore, despite the mean Facial Image Scale (FIS) score (Table 3) being numerically lower in Group A (1.93, SD 1.09) compared to Group B (2.33, SD 1.17), this difference was not statistically significant (t=-0.963, p=0.344 (NS)). This finding suggests that while LLLT may have a positive physiological effect (pulse rate reduction), it did not translate into a statistically demonstrable difference in the patient's conscious, self-reported perception of comfort or satisfaction. In summary, based on Graphs & Tables 1, 2 and 3, the key inference of this study is that the administration of local anesthetic using Low-Level Laser Therapy provides a measurable, statistically significant benefit in reducing procedure-related physiological stress (pulse rate) without negatively impacting patient oxygenation, but this benefit was not significantly reflected in the specific measure of self-reported comfort used (FIS score).



Graph 1: Mean Pulse Rate in both the groups



Graph 2: Mean SpO2 levels in both the groups

Table 1: Intergroup comparison of pulse rate

Pulse Rate	Before	After	Change
Group A (Cases)	96.2 (9.48)	91.6 (9.47)	4.6 (7.72)

Group B (Control)	95.8 (7.61)	95.53	0.26 (4.43)
Unpaired t test	t = 0.127	t = -1.283	t = 1.884
P value, Significance	p = 0.9	p = 0.210	p = 0.048*

p>0.05 – not significant *p<0.05 – significant difference

Table 2: Intergroup comparison of SpO2

SpO2	Before	After	Change
Group A (Cases)	98.2 (1.08)	98.8 (1.01)	-0.6 (1.18)
Group B (Control)	98.2 (1.08)	97.8 (1.2)	0.4 (1.5)
Unpaired t test	t = 0.00	t = 2.457	t = -2.025
P value, Significance	p = 1.000	p = 0.02*	p = 0.042*

p>0.05 – not significant *p<0.05 – significant difference

Table 3: Intergroup comparison of FIS score

SpO2	Mean	SD
Group A (Cases)	1.93	1.09
Group B (Control)	2.33	1.17
Unpaired t test	t = -0.963	
P value, Significance	p = 0.344 (NS)	

p>0.05 – no significant difference

DISCUSSION

Local anesthetic, which is required for a painless dental procedure, is the cornerstone of pain control techniques. However, giving local anesthetic injections is one of the most terrifying treatments for kids. Effective pain management during pediatric dental treatment is the cornerstone of successful behavior guiding. Although several methods exist to reduce dental anxiety in children, there is limited evidence on the use of Low-Level Laser Therapy (LLLTT) to reduce anxiety specifically during local anesthetic injection. Most previous LLLT studies focus on pain control in other dental conditions. Therefore, this study provides new information on the ability of LLLT to reduce both subjective fear and physiological stress responses during one of the most anxiety-inducing procedures in pediatric dentistry.

Age is one factor that affects how anxious they are about their teeth. Patients between the ages of 6 and 12 were taken into consideration for the study since they had strong cognitive ability. The FIS scale, pulse rate, and oxygen saturation were chosen to measure patients' anxiety levels because they are easy to use, dependable, and suitable for all age groups. A study by Buchanan⁷ suggest that the FIS is a valid means of assessing child dental anxiety status in a clinical context. The recorded FIS scores provided a clear picture of how uncomfortable children were throughout the local anesthetic injection. The LLLT approach reduced patients' pain, according to the FIS scores. This was consistent with Sattayut's research.⁸ The results were also in agreement with the studies of Jagtap et al.⁹ and Ezzat et al.¹⁰

The degree of dental anxiety and dread may be reflected in some psychological stress indicators that are known to connect with anxiety or fear. Numerous metrics, including heart rate and pulse, nerve activity, and muscle activity, may allow for continuous and real-time monitoring at various stages of treatment.¹¹ According to study done by Hegde et al.,¹² the changes in blood pressure and pulse rate in children less than 10 years of age was found to be highly significant. During normal dental examinations and treatments, it has been noted that children exhibit a physiological stress reaction that might alter their blood pressure and heart rate.¹³ Regardless of the cause of pain, researchers have discovered that anxious and stressed reactions are present. They came to the conclusion that a child's anxiousness can cause circulatory abnormalities even during a straightforward dental operation like tooth repair. The patient's cardiovascular reactions are lessened by effective analgesic and stress-reduction methods.

The results of this study show that Low Level Laser Therapy significantly decreases anxiety in children receiving dental treatment by lowering blood oxygen saturation and pulse rate. The results of our study were consistent with the studies done by Aras and Gungormus,¹⁴ Gray et al.¹⁵ Researchers have also demonstrated the effectiveness of LLLT in reducing pain during surgical endodontic therapy as well as in individuals with temporomandibular joint pain, hypersensitivity, myalgia, aphthae, and trigeminal neuralgia.¹⁶

Several recent studies further support the findings of the present investigation and highlight the growing evidence for the use of LLLT

in pediatric pain control. Multiple randomized clinical trials have demonstrated that LLLT significantly reduces the pain associated with local anesthetic injections in children, confirming its analgesic and anxiolytic potential. Nakamura et al.¹⁷ reported that pre-injection LLLT produced lower pain scores and improved anesthetic acceptance compared with conventional methods. Similarly, Moghadam et al. observed that LASER-acupuncture stimulation at the LI4 point resulted in reduced pain perception and anxiety during dental injections.¹⁸ These results align with Jain et al., who found that LLLT was more effective than other behavior-guiding pain-control techniques such as precooling, topical anesthesia, and vibration.¹⁹ In a more recent 2024 randomized controlled trial, Zhang et al. demonstrated that pre-anesthetic photobiomodulation significantly reduced injection pain compared with topical anesthetic gel, reinforcing its value as a non-pharmacologic adjunct.²⁰

Beyond injections, evidence also shows that LLLT can decrease pain during various pediatric dental procedures. Eden and Levent found that children receiving LLLT before cavity preparation reported significantly lower pain scores.²¹ Similarly, Silva et al. showed that PBM reduced postoperative pain following endodontic treatment in children, supporting its broader analgesic applications.²² A systematic review by Prado et al. further concluded that LLLT applied to acupuncture points can improve comfort and reduce procedural anxiety in pediatric dental settings, though protocols varied.²³ Collectively, these findings support the present study's results and highlight the potential for LLLT as a reliable, non-invasive method for improving the child's dental experience. This facilitates a positive dental experience for the child and allows the dentist to treat patients more easily and effectively.

This study has some limitations: The sample size was small and it was conducted in a single center. Only immediate effects were measured; long-term anxiety reduction was not evaluated. Other factors that influence anxiety, such as previous dental experiences or parental anxiety, were not assessed. Future studies with larger samples and randomized controlled designs are recommended.

The results indicate that LLLT is a safe and useful method to reduce anxiety in children during local anesthetic injection. By lowering both subjective fear and physiological stress responses, LLLT can help improve child cooperation, reduce the need for additional behavior management techniques, and create a more positive dental experience. Clinicians may consider using LLLT as an adjunct tool for managing pediatric dental anxiety.

CONCLUSION

The study concludes that utilizing Low-Level Laser Therapy (LLL) as an adjunct during the administration of local anesthetic yields a statistically significant advantage in managing procedure-related physiological stress. The LLLT group demonstrated a significantly greater reduction in pulse rate compared to the conventional control group ($p=0.048^*$). This finding is inferred to indicate an anxiolytic or stress-reducing effect of LLLT, improving the patient's physiological well-being during the procedure. Critically, LLLT was found to be safe, as evidenced by the lack of significant changes in patient oxygen saturation. Although the difference in self-reported comfort (FIS score) was not statistically significant, the demonstrable mitigation of the sympathetic response (pulse rate) supports LLLT as a valuable, non-pharmacological modality to enhance the patient experience and manage objective clinical signs of anxiety during the delivery of local anesthesia.

CLINICAL SIGNIFICANCE:

This method of treatment is safe, non-invasive, and painless; it is especially helpful for kids. LLLT is a tool that can control the inflammatory and emotional reactions, promote wound healing, and lessen pain. LLLT can effectively manage children's anxiety and foster a positive dental attitude in pediatric dentistry. To validate the findings, more research using various wavelengths and acupressure points in various age groups with bigger study populations is required.

Abbreviations:

LASER- Light Amplification by Stimulated Emission of Radiation, LLLT- Low Level LASER Therapy, FIS- Facial Image Scale

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