

EFFECT OF TOPICAL APPLICATION OF CLOVE GEL VERSUS BENZOCAINE GEL ON PAIN PERCEPTION IN CHILDREN UNDERGOING SIMPLE DENTAL PROCEDURES: A RANDOMIZED CONTROL TRIAL

Farah Ihab El Sharkawy*^{ID}, Nada Wassef**^{ID}
and Marwa Aly Fouad***^{ID}

ABSTRACT

Aim: This study aims to evaluate the effectiveness of topical clove gel (4.7% Pain Out Clove Dental Gel) application compared to 20% benzocaine gel in reducing pain in children undergoing simple dental procedures.

Methodology: Forty-four children aged 6 to 10 years were randomly divided into two groups: Group A (22 children) received a clove topical gel, while Group B (22 children) received conventional Benzocaine topical gel. Pain was assessed during the application of a rubber dam clamp or matrix band using the Wong-Baker Pain Rating Scale, and the child's behavior was evaluated using the Sound Eye Motor Scale. A pulse oximeter was used to measure the heart rate.

Results: Regarding intraoperative pain, Group A showed lower values than Group B, as measured using the Wong-Baker Pain rating scale, Sound Eye Motor scale, and pulse oximeter. The results showed no statistically significant differences in pain perception between children treated with clove gel and those treated with benzocaine gel during clamps/matrix band application.

Conclusion: The present study concludes that clove gel is equally effective as 20% benzocaine gel in managing procedural pain in pediatric dental patients. As a natural topical agent, clove gel stands out for its practicality and affordability, making it a readily available and cost-effective alternative to conventional anesthetic gels in routine pediatric dental practice.

KEYWORDS: Child Behavior, Pediatric Dentistry, Anesthesia, Dental Anxiety.

* MSc Student, Department of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry Cairo University, Giza, Egypt

** Professor of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Cairo University and Newgiza University

*** Associate Professor of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Cairo University

INTRODUCTION

Managing pediatric patients is considered one of the most fulfilling aspects of dental practice. However, one of the most significant challenges in this field is addressing the fear and anxiety commonly triggered by the clinical environment, particularly during procedures involving local anesthesia administration. Effective reduction of anxiety and pain in children is essential for achieving cooperative behavior and ensuring a positive and high-quality dental experience (**Singh et al., 2024**).

Dental procedures are frequently associated with considerable fear and anxiety in children, which may result in uncooperative or hostile behavior during treatment. Although local anesthetics are routinely administered for pain control, the use of conventional syringes is often perceived by children as intimidating and painful, thereby intensifying their distress. In this context, topical anesthetic agents offer a less invasive and potentially more acceptable alternative to injectable anesthesia in pediatric dental care (**Wambier et al., 2018; Remi et al., 2023**).

Topical anesthesia in children has always been essential before many dental procedures, including reducing local anesthesia needle prick pain, placement of rubber dam clamps, and extraction of mobile primary teeth with partially resorbed roots (**Tirupathi & Rajasekhar, 2022**).

Topical anesthetics have both pharmacological and psychological effects. They form an essential tool for managing pain efficiently in children. Properly selecting a topical anesthetic is crucial for effective pain management in pediatric dentistry (**Kotian et al., 2021; Tirupathi & Rajasekhar, 2022**).

The World Health Organization (WHO) reports that the global utilization of herbal medicine surpasses that of conventional pharmaceuticals by two to three times, with approximately 75% to 80% of the population relying on it for primary healthcare needs. Herbal treatments are frequently favored due

to their lower incidence of adverse effects, cost-effectiveness, and accessibility within local communities. Recent advancements in dental research have explored the integration of plant-derived extracts into dental formulations, yielding encouraging preliminary outcomes. Clove (*Syzygium aromaticum*), a widely used medicinal plant, is particularly notable for its natural analgesic and anesthetic actions. Emerging investigations have begun to assess the therapeutic potential of herbal topical anesthetics as alternatives to standard synthetic formulations. However, the clinical application of herbal anesthesia in dentistry remains relatively under-investigated, highlighting the need for further studies to test its safety and efficacy (**Havale et al., 2021; Tirupathi et al., 2022**).

Havale et al. (2021) conducted a study in India to evaluate pain perception in children following the topical application of various anesthetic agents before intraoral injection. The study included 60 children aged 6 to 10 years who met the inclusion criteria and were randomly divided into four groups. Each group received a different topical agent: 2% lignocaine gel, 4.7% clove gel (Pain Out Clove Dental Gel), 10% betel leaf extract gel, or ice applied for one minute before infiltration anesthesia administration. Pain perception during needle insertion was assessed using the Wong-Baker FACES Pain Rating Scale (WBFPRS) and the Sound-Eye-Motor (SEM) scale. Results showed that the betel leaf and clove oil groups recorded the highest WBFPRS scores, followed by the ice and lignocaine groups. In terms of SEM scores, the clove, ice, and betel leaf extract groups demonstrated equally elevated scores, while the lignocaine group showed lower values. The authors concluded that betel leaf extract was effective in reducing injection pain and may serve as a viable alternative to conventional topical anesthetics.

Ibrahim et al. (2023) conducted a study in Egypt to assess the effectiveness of three topical anesthetic agents 2% lignocaine gel, a eutectic

mixture of local anesthetics (EMLA), and a clove-based gel on pain perception in children before intra-oral injection. The study was conducted at Al-Azhar University, Cairo, Egypt. The sample size was 96 children in the age range (6-10 years) divided into three groups: Group A (EMLA), Group B (Clove Oil), and Group C (Lignocaine 2%). The pain was evaluated using the Wong-Baker FACES pain rating scale and the Sound Eye Motor Scale (SEM) by observing the child's behavior during infiltration anesthesia administration. The authors concluded that both EMLA and clove oil had superior results in pain relief compared to lignocaine.

Sudha et al. (2024) conducted a study to evaluate and compare the effectiveness of 2% lidocaine gel, topical clove oil (Pain Out Clove Dental Gel), and precooling with an ice cone before intraoral anesthetic injection. The study was performed in the Department of Pediatric and Preventive Dentistry in India and involved 90 children aged 8 to 10 years. The primary aim was to assess both pain perception and anxiety levels associated with each intervention. Anxiety was measured preoperatively and postoperatively using the Modified Venham Picture Scale (MVPS). At the same time, pain perception was assessed using the Visual Analogue Scale (VAS) and the Sound, Eye, Motor (SEM) scale. Participants were randomly allocated into three groups: Group A received 2% lidocaine gel, Group B experienced precooling of the injection site with an ice cone, and Group C received clove oil as a topical anesthetic. All participants subsequently received 0.9 ml of 2% lidocaine infiltration anesthesia. The findings indicated that clove oil provided the most effective anesthetic outcome, as evidenced by the lowest pain scores among the three groups.

Few studies have specifically investigated the use of topical anesthetics for purposes beyond alleviating discomfort associated with needle injections (**Padminie et al., 2020**). This study seeks to contribute to the growing interest in natural and

potentially safer alternatives by assessing their role in non-invasive pain management within pediatric dentistry. Accordingly, the present research was designed to evaluate the clinical efficacy of a clove-based herbal topical gel in comparison with conventional benzocaine gel during routine dental procedures in children.

PARTICIPANTS AND METHODS

This study is a split-mouth, randomized clinical trial with a 1:1 allocation ratio. The trial is registered on www.clinicaltrials.gov with protocol ID NCT05507359. The Faculty of Dentistry, Cairo University, Ethics Committee revised and approved the protocol on January 31, 2023, regarding scientific content and adherence to research and human subjects regulations.

Eligibility criteria:

Inclusion criteria:

- Medically free children.
- Cooperative children were mentally able to communicate, which was classified with a rating of 3 (positive) or 4 (definitely positive) according to Frankl's behavior rating scale.
- Children aged 6-10 years.
- Children with deep pits and fissures that were indicated for sealant in the lower first permanent molars.
- Fully erupted first permanent molars that allow rubber dam placement.
- Children with class II cavities in their deciduous mandibular second molars indicated for restoration limited to the enamel.

Exclusion Criteria:

- Children with acute dentoalveolar abscess.
- Children with an allergy to conventional topical anesthetic agents or clove.

- Patients who had taken analgesics within twelve hours before the procedure.
- Parental or child refusal of participation.

Sample Size:

The sample size was calculated depending on the results of a previous study (Yoon & Chussid, 2009). With the response of the Wong-Baker pain rating scale within each subject group being normally distributed, the estimated mean difference was 1.12. When the power was set at 80%, and the type 1 error probability was 0.05, the minimally accepted sample size was 18 per group. The sample size was increased to 22 per group to compensate for the small sample size. The sample size will be 11 for the rubber dam and 11 for the matrix band per group.

Grouping of the participants:

The whole sample was split into the following two groups:

Group A (Intervention group):

Twenty-two children received clove gel topical anesthesia, and a clamp was applied to 11 children, while a matrix band was applied to 11 children.

Group B (Control group):

Twenty-two children received conventional topical anesthesia, and a clamp was applied to 11 children, while a matrix band was applied to 11 children.

Informed Consent:

Each parent was asked to sign the informed consent form, in addition to obtaining verbal assent from the child participating in the study. Parents had complete freedom to participate in the study.

Randomization and allocation concealment:

Subjects were randomly assigned to the intervention and control groups using simple randomization with a 1:1 allocation ratio. The True Random Number Service, available online at www.random.org, was used to obtain a computer-generated random sequence. Two codes, A and B, were generated, corresponding to the intervention and the control group, respectively. Each subject number was assigned to one of the two codes identified in the generated list.

Blinding:

Both the intervention and control have different smells and bottle shapes; therefore, neither the operator nor the patients could be blinded, but the statistician was blinded.

Intraoperative procedures:

The patient was introduced to the clinic and seated on the dental chair. Psychological preparation of the child was performed using positive reinforcement techniques. Before starting the procedure, the pulse rate was measured using the pulse oximeter attached to the index finger. Additionally, the Wong-Baker pain rating scale score was recorded by asking the child to choose a face that best described how they felt after a detailed explanation in simple terms of what each face represented. Another investigator recorded the Sound Eye Motor (SEM) scale results by evaluating the child's reactions. The child was told we would "make the tooth go to sleep" using a magic gel. Using the dental mirror, the principal investigator retracted the cheek, then dried the tissues at the muco-buccal fold below the molar using the cotton roll, turned the roll around, and held the topical analgesic gel (20% benzocaine gel or 4.7% Pain Out Clove Dental Gel) against the tissues for 1 minute, during which the child was distracted. The other investigator held a stopwatch to adjust the duration to 1 minute. The rubber dam

clamp/matrix band was then applied, and the other investigator evaluated the pain using the Sound Eye Motor (SEM) scale by assessing the child's reaction. After the rubber dam clamp and matrix band were removed, the children were presented with the Wong-Baker FACES pain rating scale (WBFPRS). The children were then asked to choose a facial expression that demonstrated the level of pain they were experiencing, and the principal investigator recorded the score (Havale et al., 2021). The pulse oximeter was reattached to the index finger to measure the heart rate and evaluate the child's dental anxiety.

The composition of the Opahl topical anesthetic 20% Benzocaine gel (Dharma Research Inc., Miami, Florida, USA) is benzocaine, alcohol, flavor, polyethylene glycol, sodium saccharin, and hydrocarbon propellant. While the composition of Pain Out Clove Gel (Colgate Palmolive, India Ltd., Solan, India) includes eugenol, camphor, menthol, excipients, preservatives, artificial sweeteners, and sodium saccharin.

Assessment of the outcomes:

Primary outcome: Pain perception during matrix band/clamp placement was assessed using the Wong-Baker Face Rating Scale (subjective method). Secondary outcome: Heart rate during matrix band/clamp placement was measured using a pulse oximeter, and the child's behavior was assessed using the Sound Eye Motor Scale (an objective method).

Statistical analysis:

Statistical analysis was performed using SPSS 20®, GraphPad Prism®, and Microsoft Excel 2016. All data were explored for normality using the Shapiro-Wilk and Kolmogorov-Smirnov normality tests and presented as minimum, maximum, mean, and standard deviation (SD) values.

The tests used were the Shapiro-Wilk and Kolmogorov-Smirnov tests for normality exploration, the Wilcoxon signed-rank test to compare preopera-

tive and post-measurement values, and the Mann-Whitney test to compare values between groups A and B.

RESULTS

Pain assessment during rubber dam clamp placement:

1. Demographic characteristics

- Regarding age, the mean age in Group A (8.09 ± 0.92) was higher than that in Group B (6.82 ± 0.81), with no statistically significant difference between them.
- Regarding the gender distribution, in group A, males represented 36.4%, while females represented 63.6%. In Group B, males represented 18.2%, while females represented 81.8%.

2. Pain perception (Wong-Baker rating scale):

- Preoperative pain perception in Group A (0.91 ± 1.87) was higher than in Group B (0.55 ± 1.29), with no statistically significant difference, with a difference of (0.36 ± 0.69) between them ($P = 0.74$).
- Postoperative pain perception in Group A (0.36 ± 0.81) was lower than in Group B (1.82 ± 2.44), with no statistically significant difference, with a difference of (1.45 ± 0.78) between them ($P = 0.21$), as shown in Table 1.

3. Pulse rate (Pulse oximeter):

- Preoperative heart rate in Group A (86.55 ± 22.48) was higher than in Group B (90.36 ± 18.04), with no statistically significant difference, with a difference of (3.82 ± 8.69) between them ($P = 0.69$).
- Postoperative heart rate in Group A (90.36 ± 16.42) was lower than in Group B (94.18 ± 14.56), with no statistically significant difference, with a difference of (3.82 ± 6.62) between them ($P = 0.74$), as shown in Table 2.

4. Child behavior (Sound Eye Motor Scale):

- Preoperative children's behavior measurements in Group A (3.27 ± 0.65) were higher than in Group B (3.45 ± 0.93), with no statistically significant difference, with a difference of (0.18 ± 0.34) between them ($P=0.74$).
- Postoperative children's behavior measurements in Group A (4.00 ± 1.00) were lower than in Group B (4.36 ± 1.69), with no statistically significant difference, with a difference of (0.36 ± 0.59) between them ($P=0.89$), as shown in Table 3.

Pain assessment during matrix band placement**Demographic data of the participants:**

- Regarding age, the mean age in Group A (7.27 ± 1.1) was lower than the mean age in Group B (7.82 ± 1.59), but there was no statistically significant difference between groups ($P=0.36$).
- Regarding gender, in Group A, males represented 54.5%, while females represented 45.5%. In Group B, males represented 9.1%, and females represented 90.9%, with no statistically significant difference between the two groups ($P = 0.02$).

Pain perception (Wong-Baker rating scale):

- Preoperatively, there was an insignificant difference in preoperative pain perception between groups, as preoperative pain perception in Group A and Group B was (0.00 ± 0.00).

- Postoperatively, there was an insignificant difference in postoperative pain perception between groups, as postoperative pain perception in Group A and Group B was (0.55 ± 0.93), as shown in Table 4.

3. Pulse rate (Pulse oximeter):

- Preoperative heart rate in Group A (100.09 ± 11.26) was higher than in Group B (96.64 ± 16.88), with no statistically significant difference, with a difference of (3.45 ± 6.12) between them ($P=0.99$).
- Postoperative heart rate in Group A (97.91 ± 8.69) was lower than in Group B (104.09 ± 15.37), with no statistically significant difference, with a difference of (6.18 ± 5.32) between them ($P=0.61$), as shown in Table 5.

4. Child's behavior (Sound Eye Motor Scale):

- Preoperatively, the children's behavior measurements in Group A (3.00 ± 0.0) were lower than in Group B (3.09 ± 0.30), with no statistically significant difference, with a difference of (0.09 ± 0.09) between them ($P=0.21$).
- Postoperatively, the children's behavior measurements in Group A (3.82 ± 0.87) were higher than in Group B (3.55 ± 0.82), with no statistically significant difference, with a difference of (0.27 ± 0.36) between them ($P=0.74$), as shown in Table 6.

TABLE (1) Comparison between Group A (Clove gel) and Group B (Control) measurements of the Wong-Baker rating scale regarding rubber dam clamp placement:

Wong-Baker rating scale	Group A (Clove Gel Group)		Group B (Control Group)		Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference		P value
	Mean	Standard Deviation	Mean	Standard Deviation			Lower	Upper	
pre	0.91	1.87	0.55	1.29	0.36	0.69	-1.07	1.79	0.74
post	0.36	0.81	1.82	2.44	1.45	0.78	-3.07	0.16	0.21

*: Significance as $P \leq 0.05$

TABLE (2) Comparison between Group A (Clove gel) and Group B (Control) measurements of pulse oximeter regarding rubber dam clamp placement:

		Group A (Clove Gel Group)		Group B (Control Group)		Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference		P value
		Mean	Standard Deviation	Mean	Standard Deviation			Lower	Upper	
Pulse rate	pre	86.55	22.48	90.36	18.04	3.82	8.69	-21.95	14.31	0.69
	post	90.36	16.42	94.18	14.56	3.82	6.62	-17.62	9.98	0.74

*: Significance as $P \leq 0.05$

TABLE (3) Comparison between Group A (Clove gel) and Group B (Control) measurements of the Sound Eye Motor Scale regarding rubber dam clamp placement:

Sound Eye Motor Scale	Group A (Clove Gel Group)		Group B (Control Group)		Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference		P value
	Mean	Standard Deviation	Mean	Standard Deviation			Lower	Upper	
pre	3.27	0.65	3.45	0.93	0.18	0.34	-0.90	0.53	0.74
post	4.00	1.00	4.36	1.69	0.36	0.59	-1.60	0.87	0.89

*: Significance as $P \leq 0.05$

TABLE (4) Comparison between Group A (Clove gel) and Group B (Control) Wong-Baker rating scale measurements regarding matrix band placement:

Wong-Baker rating scale	Group A (Clove Gel Group)		Group B (Control Group)		Mean Difference	Std Error Difference	95% Confidence Interval of the Difference		P value
	Mean	Standard Deviation	Mean	Standard Deviation			Lower	Upper	
pre	0.00	0.00	0.00	0.00	----	----	----	----	----
post	.55	.93	.55	.93	0.00	0.40	-0.83	0.83	1.000

*: Significance as $P \leq 0.05$

TABLE (5) Comparison between the pulse rate during matrix band placement of Group A (Clove gel) and Group B (Control) regarding matrix band placement :

Pulse rate	Group A (Clove Gel Group)		Group B (Control Group)		Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference		P value
	Mean	Standard Deviation	Mean	Standard Deviation			Lower	Upper	
pre	100.09	11.26	96.64	16.88	3.45	6.12	-9.30	16.21	0.99
post	97.91	8.69	104.09	15.37	6.18	5.32	-17.29	4.92	0.61

*: Significance as $P \leq 0.05$

TABLE (6) The descriptive results of preoperative and postoperative Sound Eye Motor Scale measurements during matrix band placement.

Sound Eye Motor Scale						Paired Differences									
						Descriptive				Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		P value
													Lower	Upper	
		Minimum	Maximum	Mean	Standard Deviation										
Group A	pre	3.00	3.00	3.00	0.00	0.82	0.87	0.26	-1.41	-0.23	0.02*				
	post	3.00	5.00	3.82	0.87										
Group B	pre	3.00	4.00	3.09	0.30	0.45	0.82	0.25	-1.01	0.10	0.10				
	post	3.00	5.00	3.55	0.82										

*: Significance as $P \leq 0.05$

DISCUSSION

Topical anesthetics are used daily in dental clinics, particularly with children, to reduce discomfort and enhance their cooperation during dental procedures. In recent years, the application of medicinal plants and their bioactive extracts in dentistry has received increasing attention. This growing interest in herbal alternatives is due to their favorable safety profile, particularly when compared to synthetic anesthetics, which carry a significant risk of systemic adverse effects such as anaphylactic reactions, seizures, and methemoglobinemia. Several recent studies have highlighted the potential of herbal topical formulations to provide adequate surface anesthesia while minimizing the likelihood of side effects. (Tirupathi et al., 2022).

Although various herbal formulations exhibiting local anesthetic effects have been utilized in both medical and dental fields, their application in dentistry remains a relatively under-investigated (Tsuchiya, 2017; Zambrano-Achig et al., 2022). In light of this, the present study was conducted to assess and compare the analgesic efficacy of topically applied clove gel with that of 20% benzocaine gel in managing pain.

The newly introduced 4.7% clove gel (Pain Out Dental Gel) was selected as the intervention because it offers many advantages. According to Havale et al. (2021), Clove gel provides a significantly more economical alternative to conventional topical anesthetic agents, with its cost being over five times lower. This affordability can substantially reduce the overall financial burden of dental treatment. Furthermore, its widespread accessibility, including in rural and underserved areas, enhances its utility in public health contexts. By limiting systemic drug absorption, clove gel may also contribute to safer clinical outcomes. Its practicality is particularly valuable in developing countries, where cost constraints and limited supply often hinder the adoption of topical anesthesia. As such, clove gel

presents a promising alternative to standard topical anesthetics, with the potential to enhance access to pain management in dental care globally.

Benzocaine 20% gel was chosen as the control group because it is the most popular topical anesthetic among children, due to its rapid onset of action and acceptable taste (Dasarraju & SVSG, 2020).

Both the intervention and control groups have different colors; therefore, neither the operator nor the patients could be blinded to the treatment assignment. The outcome assessor was blinded to the group allocations to minimize detection bias and ensure the objectivity of the data collection process, as they were unaware of which gel was used and did not observe the application of either the intervention or the control. The statistician was also blinded to avoid reporting bias (Ilaifel et al., 2022; van der Ende et al., 2023; Wierichs et al., 2023).

Heart rate was selected for evaluation as it is the most frequently recognized physiological marker associated with anxiety and fear. It also represents one of the most straightforward biological indicators to measure. Research has demonstrated that fluctuations in heart rate closely correlate with anxiety levels experienced during dental visits, more so than other physiological parameters. Moreover, studies have shown that self-reported anxiety, as a subjective assessment tool, exhibits comparable outcomes to heart rate monitoring as an objective measure of stress. Therefore, integrating both subjective methods, such as numeric or facial expression scales, and objective physiological indicators is considered a reliable approach for assessing anxiety in pediatric dental patients (Shindova et al., 2022).

The self-report pain assessment tool was chosen because it is considered the gold standard for evaluating pain in pediatric patients, as it remains the most direct measure of the individual's pain experience. Among the available self-report tools,

the Wong-Baker FACES Pain Rating Scale is widely recognized for its extensive use and acceptance in children. Moreover, it has been consistently validated as a reliable and accurate instrument for pediatric pain assessment (**Abdelmoniem & Mahmoud, 2016; Nagarwal et al., 2022**).

The SEM (Sound, Eye, Motor) scale serves as an observational tool designed to assess children's behavioral responses to pain. It evaluates how pain manifests through ocular reactions, vocal expressions, and physical movements. This method offers an objective means of evaluation and is recognized for its validity and reliability in clinical pain assessment. (**Sharaf & Kabel, 2022**).

Regarding the current study results, there was no significant difference in preoperative and postoperative pain perception between groups during the placement of the rubber dam clamp/matrix band. Postoperative pain perception in Group A was lower than in Group B, although there was no statistically significant difference between the two groups.

These findings align with the results of **the Anantharaj et al. (2020)** study, which showed that both topical benzocaine and clove–papaya–based anesthetics reduced pain perception. The results are in agreement with **Havale 2021**, who showed that the analgesic effect of clove is comparable to that of cryotherapy using ice. Similarly, **Alqareer et al. (2006)** found that the application of both the formulated clove gel and benzocaine gel resulted in a reduction of mean pain scores. However, the difference between the two groups was not statistically significant, indicating comparable analgesic efficacy.

However, **Sudha et al. (2024)** concluded that clove oil displayed superior anesthetic properties compared to lignocaine gel. These contradictory outcomes can be explained by the fact that pain is a complex, multidimensional phenomenon, in which

biological, psychological, emotional, cultural, and environmental factors can affect each individual's pain experience (**Gazerani et al., 2021**).

Regarding the children's behavior, there was no significant difference in behavior between groups during the placement of the rubber dam clamp/matrix band, either preoperatively or postoperatively. Specifically, postoperative behavior in Group A was lower than in Group B, but the difference was not statistically significant.

These findings disagreed with **Anantharaj et al. (2020)** and **Havale et al. (2021)**, who stated that clove oil has shown a Sound Eye Motor scale score higher than that of a conventional topical gel.

Raghavenra et al. 2005 mentioned that eugenol, the principal bioactive compound in clove oil, is thought to produce analgesic effects by inhibiting the synthesis of prostaglandins and other pro-inflammatory mediators. Clove oil contains a variety of pharmacologically significant constituents, including eugenyl acetate, eugenol, and gallic acid, which are responsible for its broad spectrum of therapeutic actions, such as antimicrobial, anti-inflammatory, antifungal, antidiabetic, antithrombotic, anesthetic, and pain-relieving effects. The proposed analgesic mechanism involves modulation of ion channels, particularly those regulating chloride and calcium ions in neuronal ganglia, thereby altering pain signal conduction.

Regarding the heart rate measurements, there was no significant difference in preoperative and postoperative heart rate measurements between groups during the placement of the rubber dam clamp/matrix band. Postoperative heart rate measurements in Group A were lower than those in Group B, but there was no significant difference between the two groups. No papers were found measuring the heart rate when comparing clove gel and conventional topical gel.

CONCLUSION

Clove gel is as effective as 20% benzocaine gel in managing procedural pain in pediatric dental patients. Children in the Clove gel group exhibited better behavior and lower heart rate measurements during the application of the matrix band/clamp. As a natural topical agent, Clove gel can be a safe, affordable, practical, and readily available alternative to conventional anesthetic gels in routine pediatric dental practice.

Conflict of interest

The authors disclosed no conflicts of interest.

Funding

The researcher received no particular grant from a public, private, or nonprofit organization for this research.

Ethical approval

This study protocol was approved by the ethical committee of the Faculty of Dentistry, Cairo University, with approval number 13 12 23.

REFERENCES

- AAPD. (2021). Behavior guidance for the pediatric dental patient. *Reference Manual of Pediatric Dentistry*, 40(6), 306–324. <https://doi.org/10.1016/b978-0-323-60826-8.00024-9>
- Abdelmoniem, S. A., & Mahmoud, S. A. (2016). Comparative evaluation of passive, active, and passive-active distraction techniques on pain perception during local anesthesia administration in children. *Journal of Advanced Research*, 7(3), 551–556. <https://doi.org/10.1016/j.jare.2015.10.001>
- Afshari, E., Sabbagh, S., Khorakian, F., & Shirazi, A. S. (2023). Reducing pain and discomfort associated with rubber dam clamp placement in children and adolescents : a systematic review and meta-analysis of effectiveness. *BMC Oral Health*, 1–22. <https://doi.org/10.1186/s12903-023-03115-7>
- Al-Sheyab, N. A., Alomari, M. A., Khabour, O. F., Shattnawi, K. K., & Alzoubi, K. H. (2019). Assent and consent in pediatric and adolescent research : school children's perspectives. *Adolescent Health, Medicine and Therapeutics*, 10, 7–14.
- Alqareer, A., Alyahya, A., & Andersson, L. (2006). The effect of clove and benzocaine versus placebo as topical anesthetics. *Journal of Dentistry*, 34(10), 747–750. <https://doi.org/10.1016/j.jdent.2006.01.009>
- Anantharaj, A., Sabu, J. M., Ramakrishna, S., Jagdeesh, R. B., Praveen, P., & Shankarappa, P. R. (2020). A comparative evaluation of pain perception following topical application of benzocaine gel, clove-papaya-based anesthetic gel, and precooling of the injection site before intraoral injections in children. *A. Journal of Indian Society of Pedodontics and Preventive Dentistry*, 38(2), 184–189. <https://doi.org/10.4103/JISPPD.JISPPD>
- Babu, G., Mallikarjun, S., Wilson, B., & Premkumar, C. (2014). Pit and fissure sealants in pediatric dentistry. *SRM Journal of Research in Dental Sciences*, 5(4), 253. <https://doi.org/10.4103/0976-433x.145131>
- Beltramini, A., Milojevic, K., & Paterson, D. (2017). Pain assessment in newborns, infants, and children. *Pediatric Annals*, 46(10), e387–e395. <https://doi.org/10.3928/19382359-20170921-03>
- Chan, A. W., Tetzlaff, J. M., Gøtzsche, P. C., Altman, D. G., Mann, H., Berlin, J. A., Dickersin, K., Hróbjartsson, A., Schulz, K. F., Parulekar, W. R., Krleža-Jerić, K., Lau-pacis, A., & Moher, D. (2013). SPIRIT 2013 explanation and elaboration: guidance for protocols of clinical trials. In *BMJ*. <https://doi.org/10.1136/bmj.e7586>
- Dasaraju, R. K., & SVSG, N. (2020). Comparative efficacy of three topical anesthetics on 7-11-year-old children: a randomized clinical study. *Journal of Dental Anesthesia and Pain Medicine*, 20(1), 29. <https://doi.org/10.17245/jdpm.2020.20.1.29>
- Donnell, C. C., Flavell, T., & Wilson, K. E. (2022). LARA-GA – Pharmacological behavior management in pediatric dentistry in the UK. *Pediatric Dental Journal*, 32(2), 100–109. <https://doi.org/10.1016/j.pdj.2022.04.002>
- Gazerani, P., Aloisi, A. M., & Ueda, H. (2021). Editorial: Differences in Pain Biology, Perception, and Coping Strategies: Towards Sex and Gender Specific Treatments. *Frontiers in Neuroscience*, 15(June), 1–4. <https://doi.org/10.3389/fnins.2021.697285>
- Hariton, E., & Locascio, J. J. (2018). Randomized controlled trials – the gold standard for effectiveness research: Study design: randomized controlled trials. *BJOG*:

- An International Journal of Obstetrics and Gynaecology, 125(13), 1716. <https://doi.org/10.1111/1471-0528.15199>
- Havale, R., Rao, D. G., S P, S., M Tuppadmath, K., Tharay, N., Mathew, I., & Taj, K. E. (2021). Comparative evaluation of pain perception following topical application of clove oil, betel leaf extract, lignocaine gel, and ice before intraoral injection in children aged 6–10 years: a randomized control study. *Journal of Dental Anesthesia and Pain Medicine*, 21(4), 329. <https://doi.org/10.17245/jdamp.2021.21.4.329>
 - Iflaifel, M., Bartlett, C., Bell, J., Cook, A., Gamble, C., Julius, S., Juszczak, E., Linsell, L., Montgomery, A., & Sprange, K. (2022). Blinding of study statisticians in clinical trials: a qualitative study in UK clinical trials units. *Trials*, 23(1), 1–11. <https://doi.org/10.1186/s13063-022-06481-9>
 - Kotian, N., Mani, G., & Ramakrishnan, M. (2021). Comparative evaluation of two different topical anesthetic agents in controlling pain during intraoral local anesthetic administration in children: A split-mouth triple-blinded randomized clinical trial. *International Journal of Clinical Pediatric Dentistry*, 14(2), 180–182. <https://doi.org/10.5005/jp-journals-10005-1905>
 - Krogh, H. B., Storebø, O. J., Faltinsen, E., Todorovac, A., Ydedahl-Jensen, E., Magnusson, F. L., Holmskov, M., Gerner, T., Gluud, C., & Simonsen, E. (2019). Methodological advantages and disadvantages of parallel and crossover randomized clinical trials on methylphenidate for attention deficit hyperactivity disorder: A systematic review and meta-analyses. *BMJ Open*, 9(3), 1–10. <https://doi.org/10.1136/bmjopen-2018-026478>
 - Nagarwal, P., Rana, V., Srivastava, N., & Kaushik, N. (2022). Levels of pain assessment tools for pediatric dental patients: a narrative review. *International Journal Of Community Medicine And Public Health*, 9(7), 3034. <https://doi.org/10.18203/2394-6040.ijcmph20221778>
 - Nair, M., & Gurunathan, D. (2019). Comparative evaluation of the efficacy of two anesthetic gels (2% lignocaine and 20% benzocaine) in reducing pain during administration of local anesthesia – A randomized controlled trial. *Journal of Anaesthesiology Clinical Pharmacology*, 35(1), 65–69. <https://doi.org/10.4103/joacp.JOACP>
 - Priyatham, S., & Nuvvula, S. (2016). Intraoral topical anesthesia in pediatric dentistry: Review. *International Journal of Pharma and Bio Sciences*, 7(4), B346–B353. <https://doi.org/10.22376/ijpbs.2016.7.4.b346-353>
 - Rahul, S., Saikiran, K. V., Elicherla, N. R., Anchala, K., Singaraju, A., & Nuvvula, S. (2024). Evaluation of child's behavior during the pit and fissure sealant administration using the rubber dam and MiniDam: A randomized clinical trial. *Journal of Indian Society of Pedodontics and Preventive Dentistry*, 42(June), 119–125. <https://doi.org/10.4103/jisppd.jisppd>
 - Remi, R. V., Anantharaj, A., Praveen, P., Prathibha, R. S., & Sudhir, R. (2023). Advances in pediatric dentistry: new approaches to pain control and anxiety reduction in children - a narrative review. *Journal of Dental Anesthesia and Pain Medicine*, 23(6), 303. <https://doi.org/10.17245/jdamp.2023.23.6.303>
 - Sharaf, R. F., & Kabel, N. (2022). Biological evaluation of the efficacy of two different anesthetic solutions in pain control during the extraction of mandibular second primary molars. *Bulletin of the National Research Centre*, 46(1). <https://doi.org/10.1186/s42269-022-00772-6>
 - Shindova, M. P., Belcheva-Krivorova, A., & Taralov, Z. (2022). Pulse Oximetry in Paediatric Dentistry. *Folia Medica*, 64(2), 202–206. <https://doi.org/10.3897/folmed.64.e60567>
 - Singh, K., Jhingan, P., Mathur, S., Malik, M., & Kashyap, K. (2024). Intercomparison of Efficacy of Transcutaneous Electrical Nerve Stimulation and Precooling Vibration Device on Pain and Anxiety Management during Administration of Local Anesthesia Injection in 6–12-year-olds. *International Journal of Clinical Pediatric Dentistry*, 17(3), 297–302. <https://doi.org/10.5005/jp-journals-10005-2807>
 - Sudha, P. M., Mathew, B. M., Rajasudhakar, H., Duraisamy, V., Jacob, M., & Thamburaj, M. V. (2024). An In Vivo Comparative Analysis of Pain Perception in Children Following Lidocaine Gel, Clove Oil, and Precooling for Intraoral Injections : A Pilot Study. 257, 3–7.
 - Tirupathi, S., Gopalakrishnan, D., & Deshkar, S. (2022). Herbal topical anesthetics in dentistry: an exploratory review. *Journal of Dental Anesthesia and Pain Medicine*, 22(6), 419. <https://doi.org/10.17245/jdamp.2022.22.6.419>
 - Tirupathi, S., & Rajasekhar, S. (2022). Topical Anesthesia in Pediatric Dentistry: An Update. *International Journal of Clinical Pediatric Dentistry*, 15(2), 240–245. <https://doi.org/10.5005/jp-journals-10005-2355>
 - Tsuchiya, H. (2017). Anesthetic agents of plant origin: A review of phytochemicals with anesthetic activity. *Molecules*, 22(8). <https://doi.org/10.3390/molecules22081369>

- van der Ende, N. A. M., Roozenbeek, B., Broderick, J. P., Khatri, P., Lingsma, H. F., & Dippel, D. W. J. (2023). Blinding of outcome assessors and its association with outcome in a randomized open-label stroke trial. *International Journal of Stroke*, 18(5), 562–568. <https://doi.org/10.1177/17474930221131706>
- Wambier, L. M., De Geus, J. L., Boing, T. F., Brancher, J. A., Chibinski, A. C., Wambier, D. S., Farago, P. V., Loguercio, A. D., & Reis, A. (2018). A randomized clinical trial evaluating rubber dam clamp pain reduction from a new topical liposomal anesthetic gel. *Pediatric Dentistry*, 40(3), 190–194.
- Wierichs, R. J., Bourouni, S., Kalimeri, E., Gkoutsoyianni, S., Meyer-Lueckel, H., & Kloukos, D. (2023). Short-term efficacy of caries resin infiltration during treatment with orthodontic fixed appliances. A randomized controlled trial. *European Journal of Orthodontics*, 45(2), 115–121. <https://doi.org/10.1093/ejo/cjac040>
- Yoon, R. K., & Chussid, S. (2009). Topical anesthesia for rubber dam clamp placement in sealant placement: Comparison of lidocaine/prilocaine gel and benzocaine. *Pediatric Dentistry*, 31(5), 377–381.
- Zambrano-Achig, P., Viteri-García, A., & Verdugo-Paiva, F. (2022). Chemo-mechanical removal versus conventional removal for deep caries lesions. *Medwave*, 22(1). <https://doi.org/10.5867/medwave.2022.01.8320>