Original Article

ACDJ Volume 4, Issue1, January, 2025

COMPARING CONTROLLED FLOW DELIVERY DENTAPEN® TECHNIQUE TO TRADITIONAL SYRINGES ON PAIN PERCEPTION DURING THE ADMINISTRATION OF ANESTHESIA AMONG A GROUP of PEDIATRIC DENTAL PATIENTS:

A Split-Mouth Randomized Clinical Trial

Reham S.Al Shakhas*[1], Sherif B. El Tawil[2], Shereen H. Al Shami[3]

Abstract:

Objectives: To compare the effect of the controlled flow delivery Dentapen® technique to traditional syringes on pain perception during dental procedures among a group of pediatric dental patients. **Methodology:** A split-mouth study design was employed, involving twenty children aged 6-8 years who required Class I restorations on bilateral maxillary first primary molars. Participants' teeth were randomly allocated to two treatment groups. Group A received infiltration injection technique using the Dentapen® technique on one maxillary primary first molar, while group B received traditional syringe-based infiltration anesthesia on the contralateral maxillary first primary molar. Pain perception during the procedure was evaluated using the Wong-Baker Faces Rating Scale, heart rate monitoring, and the Sound, Eyes, and Motor Scale. Parametric data (heart rate) were analyzed using paired t-tests, while non-parametric data were analyzed using the signed-rank test. Statistical significance was set at $p<0.05$. **Results:** The Dentapen group exhibited significantly lower pain perception scores (2.80±1.51) compared to the traditional anesthesia group (7.50±0.89) ($p<0.001$). Both anesthesia methods resulted in a significant post-anesthesia increase in heart rate. However, traditional anesthesia induced a more significant increase (106.35±11.50) compared to Dentapen ($p=0.006$). Additionally, the Dentapen group exhibited significantly lower Sound, Eyes and Motor scores (1.30±0.66) compared to the traditional anesthesia group (2.80±0.41) ($p<0.001$).

Conclusion: The Dentapen system can be effectively employed to reduce pain perception during restorative procedures on maxillary primary molars in children compared to traditional syringe techniques. The Dentapen group demonstrated significantly lower pain perception scores compared to the traditional syringe group during local anesthesia administration.

Keywords: Pain; Local anaesthesia; Dentapen; Wong-Baker scale; SEM scale; Heart rate.

*[1]Master Candidate in Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Cairo University. E-mail: reham.salman@dentistry.cu.edu.eg

[2] Professor of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Cairo University.

[3]Lecturer of Pediatric Dentistry and Dental Public Health, Faculty of Dentistry, Cairo University.

Introduction:

Pain has been a longstanding concern in dentistry and has a complex relationship with patient behavior. It is often the primary reason that drives patients to seek dental care. Conversely, dental anxiety and fear can lead to avoidance behaviors, making patient management more challenging and hindering the delivery of dental services.(1)

Local anesthetic injections are frequently identified as a primary source of dental anxiety and fear.(2) Consequently, effectively managing pain, anxiety, and negative reactions related to local anesthesia injections isa significant clinical consideration in dentistry.(3)Local anesthesia is a standard practice in pediatric dentistry, employed for procedures, including pulpotomies, root canal treatments, and tooth extractions. The fear of needle injection, which can be exacerbated by the sight of the needle, can lead to a resistance to future local anesthetic injections.(4)

Local anesthesia can induce pain due to several factors: needle insertion trauma, pressure from solution injection, and the physical properties of the anesthetic solution, including its temperature and pH.Various strategies have been proposed to reduce pain during local anesthetic injections, including the use of topical anesthetics, smaller-gauge needles, and laser therapy at the injection site. Nevertheless, slowing down the injection speed appears to be the most effective technique for minimizing pain during local anesthetic administration.(5)

The infiltration technique is the most widely employed method for administering local anesthesia to the maxillary teeth.This technique utilizes a supraperiosteal injection, where anesthetic solution is administered superficially to the periosteum overlying the root apex.(6) Through diffusion through the alveolar bone, this injection anesthetizes large

terminal nerve endings of the dental plexus. This includes the mucous membrane, connective tissue, buccal periosteum, andpulp. The porous nature of the maxillary alveolar bone facilitates the diffusion of anesthetic solutions, contributing to the high success rates of profound anesthesia achieved with maxillary infiltrations. The success rate of maxillary infiltration injections ranges from 60% to 100%, with studies employing varying volumes and anesthetic solutions.(7)

Although traditional syringes remain the primary tool for delivering local anesthetics, computer-controlled local anesthetic delivery systems (C-CLADs) have been introduced since the mid-1990s to offer a more precise method. These systems regulate the rate at which anesthetic solution is dispensed through the needle. By considering the unique anatomical features of various tissues, C-CLADs can effectively reduce injection flow and provide a controlled, steady rate of delivery. Several studies have demonstrated that these systems offer superior pain control, particularly for palatal injections, compared to traditional techniques.(5)

One of the most recent CCLADs is the Dentapen, developed by Septodont. The Dentapen is an electronic, battery-powered syringe introduced in 2018. Its cordless, lightweight design (1.4 oz or 40 g) makes it the most compact computer-controlled local anesthetic device available. The device offers multiple injection settings, allowing for a traditional syringe-like or pen-like grip. It is compatible with a wide range of anesthetic cartridges and needles from various manufacturers.(8)

Thus, the objective of this clinical trial was to assess the efficiency of the Dentapen® controlled flow delivery technique on pain perception during dental procedures in pediatric patients compared to traditional syringe administration.

Subjects and methods:

Study design:

This study employed a randomized, double-blind, split-mouth design to investigate the Dentapen® controlled flow delivery technique. Participants were randomly assigned to two groups in a 1:1 ratio.

Trial Registration:

ClinicalTrial.gov ID: NCT05959642

Eligibility Criteria:

The study included healthy, cooperative children aged 6-8 years who were experiencing their first dental visit, provided assent, and whose parents provided informed consent. Study participants had bilateral primary maxillary first molars affected by caries and requiring restorative procedures. Radiographic findings were within normal limits, and participants were free from systemic health issues. Children who necessitate emergency dental care for conditions such as cellulitis or abscess, and those exhibiting indicators of pulpitis were excluded from this study.

Sample Size Calculation

A power analysis was conducted to calculate the necessary sample size to identify a statistically significant difference in perceived pain levels between the study groups during LA administration, employing a two-sided statistical test.The sample size of 20 participants was determined based on a power analysis based on the findings of (**Elshiekh and Ragab 2022**)*(9)* and expert opinion.

Grouping

Twenty children who met the inclusion criteria were recruited for this study. Each child was scheduled for two dental visits, at least one week apart. Restorative procedures for the participants were randomly divided into two groups of equal sizeas described below:

Group A (Intervention group):

The twenty children received local anesthesia via infiltration techniqueusing the Dentapen® (Juvaplus SA, Swiss Technology, Switzerland) technique at maxillary primary first molar at one side.

Group B (Control group) (n=20):

The same twenty children received infiltration injection technique using a traditional syringe (Asa Dental, Italy) technique at maxillary primary first molar at the contralateral side.

Study Setting

Twenty children, aged 6 to 8 years, with bilateral decay in their primary maxillary first molars were selected from the outpatient clinic of the Pediatric Dentistry and Dental Public Health Department, Faculty of Dentistry, Cairo University. These children were scheduled to receive composite restorations (40 maxillary first primary molars).

Informed Consent

Parents or legal guardians provided informed consent after receiving a comprehensive explanation of the study's aims, methods, and potential risks. Participants were afforded the opportunity to ask questions and subsequently provide informed consent. Each child participant also provided verbal assent.

Diagnosis

1. Personal and Medical History

A standardized diagnostic chart was used by the principal investigator to obtain and document detailed personal, medical, and dental information from each participant and their legal guardian.(10)

2. Clinical Examination

A detailed oral examination was performed by the principal investigator, including both intra-oral and extra-oral assessments with the aid of dental mirrors and probes. Radiographic evaluation, and cold sensitivity testing using endo-ice applied to the buccal surface of the tooth to verify adherence to inclusion criteria.(11)

3. Radiographic Examination

Prior to the procedure, the principal investigator obtained intraoral periapical radiographs (Image plate, Duerrdental company, Germany) of the suspected molar using a bisecting angle technique. These images were captured with an x-ray machine (X genus®, de Götzen® S.r.l. via Roma, 45 21057 Olgiate Olona VA, Italy). The aim was to rule out any existing pulpal or periapical pathology.

Randomization and Allocation concealment:

To ensure unbiased allocation of participants, a computer-generated randomization sequence was produced using (www.random.org) by an assistant supervisor. The principal investigator was blinded to the sequence assignment throughout the enrollment process. Forty sequentially numbered, opaque envelopes were sealed and prepared. Each child received an envelope in ascending order of enrollment. Participation was confirmed by a resident who documented the child's name, phone number, and ID on the envelope. Importantly, these envelopes were not opened until the treatment visit immediately prior to restoration. The selected envelopes were opened at the treatment visit prior to the restoration procedure. To ensure blinding, participants were allocated to either the treatment or control group using a pre-determined randomization sequence by an assistant supervisor, while the principal investigator recruited participants.

Blinding

To minimize bias, this study utilized a double-blind approach. Both the patients and the outcome assessors and statistician were kept unaware of treatment group assignments.

Intra-operative procedures

1. To administer a buccal infiltration, the cheek was stretched gently outward to expose the injection site, removed the needle cap, and positioned the needle (C-K Ject, CK Dental Ind. Co., LTD., Korea) at the mucobuccal fold above the selected

molar. The needle was inserted at a 45-degree angle relative to the tooth's long axis, with the bevel facing the bone.*(12)*

2. Following aspiration, a few drops of the anesthetic solution (Artinibsa, Lliçà de Vall, Barcelona, Spain) was deposited.*(13)*After a brief pause for seconds, the needle was inserted until bony contact was achieved. Subsequently, it was withdrawn slightly, and the remaining anesthetic solution was administered gradually over a 30-second period until a total of 1.5 ml of the solution was injected.*(14)*

3. The injection procedure was documented through video recording, capturing the child's eye movements, body movements, and vocalizations.*(15)*

4. Soft tissue numbness was inspected immediately following injection by probing the buccal gingival sulci.*(13)* The child had to wait three to five minutes to achieve deep anesthesia before beginning the planned treatment procedure.

5. The Dentapen® injection technique involved administering local anesthesia at a rate of 1.8 mL per 162 seconds, utilizing the device's ramp-up function. The noise produced by the Dentapen® syringe motor was masked by the combined sounds of the dental chair's suction system and background music.

6. To ensure a dry and isolated operating field during dental procedures, highly absorbent pads were used in conjunction with continuous saliva suction. Additionally, rubber dam isolation was employed to maintain an optimal clinical environment.*(16)*

7. Class I cavities were prepared using high-speed handpiece with 245 burs. The outline of cavity preparation was designed to remove the carious lesion. The preparation was designed to achieve a depth of at least 1.5 mm in the isthmus and load-bearing regions, and at least 1 mm in all other areas.*(17)*

8. Selective enamel etching was conducted with a 15-second application of 37% phosphoric acid (Meta Etchant, META BIOMED, Chungcheongbuk-do, Korea), while the dentin surface remained untreated.*(18)*The etched enamel was then rinsed with water for a duration of 20 seconds and carefully air-dried.*(19)*

9. A universal adhesive system (Dentsply, Tusla dental specialties, USA), suitable for deciduous teeth, was employed to etch and bond the dentin surface. The adhesive was applied as per the manufacturer's instructions and light-cured (FOX-DENTAL, Kirkland, California, united states) for 20 seconds at an intensity of 1,000 mW/cm².

10. The composite resin (Beautifil II, ShofuInc., Kyoto, Japan) was applied incrementally using an oblique technique, each increment was light-cured for 20 seconds. The initial increment of composite material was placed in a wedge-shaped configuration at the internal line angle, creating a 45-degree angle with the pulpal floor.Successive increments were no greater than 2 mm in thickness.*(20)*

11. After removing the rubber dam, the occlusion was verified using articulating paper. If necessary, the restoration was refined using finishing burs under water coolant.*(16)*

12. One-week post-treatment, the child returned for anesthesia and restoration of the contralateral maxillary first primary molar. The principal investigator administered a different local anesthetic technique, following the same clinical protocol.

Outcome assessment

Pain intensity were evaluated both pre- and post-administration of local anesthetic agents. To ensure consistency, the second author evaluated the study outcomes for all children. Before the injection, The Wong-Baker Faces Scale Rating Scale (WBFPS)was administered to each child to familiarize them with the tool. Verbal guidance was

provided to ensure their understanding of the scale and expectations for its use. The outcome assessment was done using three parameters:

1. The Wong-Baker Faces Pain Rating Scale (WBFPS):

WBFPS scale was used to assess pain intensity. This scale employs six facial expressions to represent pain levels, ranging from 0 (no pain) to 10 (severe pain).*(9)*Immediately following the injection, the child was presented with the scale. The child was explained that each face represents a person experiencing different levels of pain. The child was asked to indicate their current pain level by selecting a facial expression from the pain scale. The selected expression was recorded for analysis in a table.

2. Evaluation of pain using physiological changes:

Heart rate (HR) was monitored using a pulse oximeter (Contec Medical Systems, China). Pulse oximetry readings were measured at the beginning of the procedure and during needle insertion. Measurements were taken every two minutes and averaged. Given that the normal heart rate for children aged 6-12 years is 70-100 beats per minute*(21)*, the heart rate for each patient was recorded in a table**.**

3. Evaluation of pain using the Sound, Motor, Eye (SME) scale

To ensure objectivity and reliability, the injection procedure was video-recorded by a trained assistant from one meter away.*(15)*Independent evaluations of the child's response to the anesthetic injection were conducted by the principal investigator and assistant supervisor, who were unaware of each other's assessments. The SME scale was used to rate sound, eye movements, and overall movement on a 1-4 scale.*(22)* The primary investigator recorded numerical scores for each category, and the total score was calculated for each participant.

SME scale is a clinician-reported observational pain rating scale developed by *(23)***.** It assesses three physical

observations: sound, eye movements, and overall movement. These observations are categorized into four levels of comfort or pain, ranging from one (comfort) to four (painful).*(22)*

Statistical Analysis:

Data were analyzed using R statistical software (version 4.4.2) for Windows. Data normality was visually inspected and confirmed using the Shapiro-Wilk test. A paired t-test was employed to analyze the normally distributed heart rate data. The Wilcoxon signed-rank test was used to analyze non-parametric data. Statistical significance was established at $p < 0.05$ for all tests.

Results:

1. Demographic data:

A split-mouth study was conducted on twenty cases (ten male and ten female) aged 6.78 ± 0.64 years on average.

2. Pain assessment during local anesthesia delivery (Wong-Baker score):

The side with traditional anesthesia had significantly higher scores than the Dentapen side ($p<0.001$)**Table 1**.

3. Heart rate:

There was no statistically significant difference in pre-anesthetic heart rate between the two sides ($p=0.366$). However, following anesthesia, a significantly higher heart rate was recorded with traditional anesthesia compared to the Dentapen ($p=0.006$). Within both groups, Post-anesthetically, a marked increase in heart rate was recorded($p<0.001$) **Table 2**.

4. Behavior during injection of local anesthesia:

Statistical analysis revealed a highly significant difference ($p < 0.001$) in pain levels between the two groups. Patients receiving traditional anesthesia reported significantly higher pain scores than those treated with Dentapen **Table 3**.

Table 1. Intergroup and summary statistics for Wong-Baker score.

Measurement	Wong-Baker score		p-value
	Traditional	Dentapen	
Mean±SD	7.50±0.89	2.80±1.51	**<0.001***
Median (IQR)	8.00 (0.50)	2.00 (2.00)	

** Significant.*

Table 2. Intergroup and summary statistics for heart rate (BPM).

Interval	Measurement	Heart rate (BPM)		p-value
		Traditional	Dentapen	
Before anesthesia	**Mean±SD**	85.75±6.94	86.85±7.81	**0.366ns**
	Median (IQR)	89.50 (10.50)	89.50 (11.50)	
After anesthesia	**Mean±SD**	106.35±11.50	96.85±13.46	**0.006***
	Median (IQR)	108.00 (16.75)	97.50 (13.75)	
p-value		**<0.001***	**<0.001***	

** Significant, ns not significant.*

Table 3. Intergroup and summary statistics for SEM score.

Measurement	SEM score		p-value
	Traditional	Dentapen	
Mean±SD	2.80±0.41	1.30±0.66	**<0.001***
Median (IQR)	3.00 (0.00)	1.00 (1.00)	

** Significant.*

Discussion:

Pain is a complex, subjective phenomenon influenced by a variety of physiological and psychological factors. Traditional dental injections often induce feelings of pain and anxiety in patients. This anxiety can lead to avoidance of dental care, delayed treatment, and increased pain perception. Effective pain management during local anesthesia technique is essential for providing a positive dental experience and ensuring successful treatment outcomes for pediatric patients.*(24)* Thus, researchers continually explore alternative methods to avoid the intrusive and potentially uncomfortable process of anesthetic injection, aiming to improve the overall dental experience for patients.

A recent innovation in dental anesthesia delivery is the cableless, motorized Dentapen® system (the intervention group). This user-friendly device requires minimal training and offers flexibility in grip, accommodating both syringe-like and pen-like holds. It is compatible with a wide range of anesthetic needles and cartridges from various manufacturers.*(25)*

To our knowledge, there is a lack in the literature that has directly compared the perceived pain levels between Dentapen and conventional local anesthesia methods in pediatric dental treatment. Thus, the objective of this clinical trial was to determine whether the Dentapen technique, compared to traditional syringes, could reduce pain perception in young patients undergoing dental treatments.

To isolate the impact of injection technique, topical anesthetics were excluded from this study. While topical anesthetics are commonly used to reduce pain perception and anxiety, their inclusion could have potentially confounded the results. Topical anesthetics can penetrate mucosal membranes to provide anesthesia to a depth of approximately 2-3 mm.*(26)*By excluding topical anesthetics, the primary objective of this study was to

directly evaluate the influence of injection technique on pain perception.

Supra-periosteal infiltration was chosen over Posterior Superior Alveolar (PSA) nerve block for anesthetizing the maxillary primary first molar to block the terminal branches of the PSA nerve, a branch of maxillary division of the 5th cranial nerve (trigeminal nerve). This technique is highly effective in children due to the thin buccal cortical bone, which allows for efficient anesthetic diffusion.*(27)*

Moreover, infiltration anesthesia is a less invasive and more comfortable technique for pediatric patients, particularly in the posterior maxilla, where consistent anatomical landmarks facilitate accurate administration.*(28)*This approach, as suggested by ***Meechan (2010)****(29)*, minimizes the volume of anesthetic solution required. Furthermore, ***Ogle and Mahjoubi (2012)****(30)*noted that nerve block techniques can be perceived as more painful and anxiety-inducing by young children. Thus, infiltrative terminal anesthesia was administered to the posterior maxilla for all study groups. This technique allowed for a more controlled evaluation of how different anesthetic devices affected patient response.

A 45-degree angle was maintained during needle insertion, with the bevel facing the buccal bone to minimize periosteal trauma.The needle was inserted until it made contact with bone, then withdrawal slightly to administer the anesthetic solution supraperiosteally, minimizing pain perception. Aspiration was performed to prevent accidental intravascular injection. The anesthetic solution was injected slowly over 30 seconds to minimize tissue distension and discomfort.*(31)*

The severity of pain during the injection procedure was evaluated using the WBFPS.*(32,33)*WBFPS is a widely used tool for assessing pain in children. It uses a series of facial expressions to represent different pain intensities, allowing children to visually communicate their pain levels.

The WBFPS has proven effective in measuring pain during dental anesthesia.*(34,35)*

Versloot et al. (2004)*(36)*, compared pain assessments made by children, dentists, and independent observers during dental injections. They found a significant discrepancy between the assessments, with dentists underestimating pain compared to children's self-reports. Thus, to enhance the validity of self-report pain measures, combining them with objective measures such as behavioral and physiological measurements provide a more detailed and objective evaluation of pain sensation. To address this, the study utilized three different pain scales namely, WBFPS ***Elshiekh and Ragab (2022)****(9)*, SEM scale ***Hosny et al. (2021****(22)*and heart rate measurement.

As secondary outcomes, behavioral observations using SEM scale was employed. Given the limitations of self-report in young children, behavioral observations were considered crucial for a comprehensive evaluation of pain experience because their body language, facial expressions, and crying and complaining are crucial diagnostic indicators.*(37)*

Pain activates the autonomic nervous system, triggering physiological responses such as increased heart rate, vasoconstriction, pupillary dilation, sweating, and elevated levels of stress hormones. While these physiological parameters can provide additional information about pain response, they should not be solely relied upon as they can be influenced by various factors other than pain.*(28)*

As a reliable physiological indicator of pain, heart rate was measured instrumentally. Multiple studies have utilized pulse oximetry as an objective measure of anxiety.*(38,39)*

According to the demographic data statistics, the study participants' mean age was 6.78±0.64 years, and the distribution

of sexes was as follows: 50% of the children were male, and 50% were female. Given the split-mouth design, the study ensured equal distribution of age and sex between the intervention and control groups, enabling direct comparisons within each participant.*(40)*

Statistical analysis revealed a significant reduction in pain perception among patients in the Dentapen group (Group B) when compared to those in the traditional anesthesia group (Group A) ($p < 0.001$), indicating that Dentapen was associated with less pain. Thus, the null hypothesis was accepted.

The findings of this study are consistent with recent reviews and meta-analyses, such as that of ***Pozos-Guillén et al. (2020)****(41)*. Their review indicated that computer-controlled local anesthesia delivery systems, such as the Wand® system, can significantly reduce pain perception compared to conventional injections, particularly when assessed using the Facial Image Scale and WBFP Scale. However, this study did not assess the Wand® system.

Similarly, this finding aligns with ***O'Neal et al. (2022)****(8),*who reported that the Dentapen was associated with significantly less pain during solution delivery than traditional injection methods in adult study participants.

Feda et al. (2010)*(42)****; Mittal et al. (2015)****(43)****; Vitale et al. (2023)****(44),* reported that CCLAD reduced pain perception compared to traditional infiltration anesthesia. In ***Feda et al.'s*** study, a comparative analysis of pain perception was conducted using the SEM scale in 40 children who underwent both procedures. Our results, consistent with previous findings, indicate that CCLAD is associated with reduced pain compared to conventional injection techniques.

Our findings align with previous research by ***Langthasa et al. (2012)****(45),* demonstrating that computerized local anesthesia, can significantly reduce pain

perception compared to traditional syringe techniques. Furthermore, a crossover study by ***Luz San Martin-Lopez et al. (2005)****(46)*demonstrated that computerized injection systems can significantly reduce pain during dental anesthesia compared to traditional syringe techniques.

In contrast, a study by ***Kandiah and Tahmassebi (2012)****(47)*found that pain perception was not significantly different between the Wand system and conventional syringe methods when administered to preschool and school-age children.

Heart rate was measured before and during the injection procedure. Baseline heart rate measurements, taken before the start of each clinic session, did not differ between treatment groups. Baseline anxiety levels were comparable between groups at the start of the dental visit.

The current study demonstrated a greater increase in heart rate following traditional syringe injections compared to Dentapen injections. These findings align with previous studies *(32,48,49),* who also reported that compared to traditional methods, computerized injection techniques were led to a significantly higher increase in heart rate. These outcomes might result from the way that pain and anxiety raise heart rate.*(50)*

Conversely, both the traditional and CCLAD techniques resulted in similar heart rate measurements, indicating no significant physiological impact. ***Kumar et al. (2015)****(51)****; Mittal et al. 2015****(43)****; Thoppe-Dhamodhara et al. (2015)****(52)****; Araújo et al. (2015)****(53)****; El Hachem et al. (2019*)(54)and in a more recent study by ***Vitale et al. 2023****(44),* where both buccal and palatal infiltrations led to insignificant increases in heart rate with both traditional and computerized techniques.

Additionally, ***Fernández-Castellano et al. (2021)****(25)*found no significant differences in heart rate before and after injections using either Dentapen or traditional syringes.

CCLAD systems can deliver a consistent, predetermined flow rate of anesthetic solution, independent of tissue resistance variations.(43)This technique results in a controlled and less painful injection. Maintaining a consistent and optimal flow rate of anesthetic solution is crucial for achieving a controlled injection.*(55)* Our findings align with these observations, as most patients experienced mild pain. To ensure consistency, all injections were performed using the same anesthetic agents and standardized injection techniques.

The inconsistencies observed between the studies could be attributed to variations in their research designs. In ***Tahmassebi et al. (2009)****(56)*'s study, children were randomized to receive traditional anesthesia or Wand anesthesia, limiting the potential for direct comparison of pain perception within the same individual. In contrast, our study, and that of***Luz San Martin-Lopez et al. (2005)****(46)*, allowed for direct comparison of pain perception within the same patient, as both techniques were used in a split-mouth design.

Based on the collected data, the current study indicates that patients perceived less pain when traditional anesthetic techniques were used compared to the computerized technique. Therefore, our findings align with previous research demonstrating that CCLAD, specifically the Dentapen system, can significantly reduce pain perception during dental procedures compared to traditional techniques, despite the potential anxiety associated with both methods.

Limitations of the study:

1. A small sample size was used.
2. A convenience sample of children visiting the pediatric dentistry department was used for this study. It is important to consider that the sample may not be fully generalized to the entire population, and the findings may be more applicable to similar clinical settings.
3. It was not possible to examine the financial effects of Dentapen, which is

significantly more costly than the traditional method, because the children in the study received free medical care in an academic setting.

Conclusion:

The following conclusions can be drawn from the finding of the current study:

1. The Dentapen system can be effectively employed to reduce pain perception during restorative procedures on maxillary primary molars in children compared to traditional syringe techniques.

2. The Dentapen group experienced a significant reduction in pain perception during local anesthesia delivery, as compared to the traditional syringe group.

3. Compared to Dentapen, traditional anesthesia was associated with a significant elevation in heart rate following anesthesia. Additionally, patients who administered Dentapen exhibited significantly reduced behavioral pain scores compared to those receiving traditional anesthetic techniques.

Recommendations

1. Future studies should investigate the efficacy of Dentapen technique in a wider age range of children, in comparison to traditional anesthesia technique.

2. Further randomized clinical trials are needed to definitively determine the impact of topical anesthetics on pain perception during both traditional and computerized local anesthesia.

3. Future research should include a larger number of participants, particularly younger children (less than 6 years), to further assess the efficiency of the Dentapen system in a broader population and pre-cooperative children.

4. Randomized controlled trials are recommended to further investigate the intra-operative pain during pulp therapy and extractions, the duration and onset of pulpal anesthesia achieved with the Dentapen in comparison to traditional methods.

Conflict of Interest:

The authors have no competing interests to disclose.

Funding:

This research was conducted independently, without external funding from public, commercial, or non-profit sources.

Ethics:

Ethical approval for the study protocol was obtained from the Research Ethics Committee of the Faculty of Dentistry, Cairo University (Approval number: 14122023).

References:

1. Cianetti S, Lombardo G, Lupatelli E, Pagano S, Abraha I, Montedori A, et al. Dental fear/anxiety among children and adolescents. A systematic review. Eur J Paediatr Dent. 2017;18(2):121–30.
2. Wang YH, Wang DR, Liu JY, Pan J. Local anesthesia in oral and maxillofacial surgery: a review of current opinion. J Dent Sci. 2021;16(4):1055–65.
3. Grierosu C, Mihai C, Lungu II, Calin G, Stefanache A, Vasiliu MP, et al. Stress-induced variability in local anesthesia response: Exploring implications for dental anesthetic management. Romanian Journal of Oral Rehabilitation. 2024;16(1).
4. Ganapathi A, Pradeep D. An Update on Local Anesthesia for Pediatric Dental Patients. Res J Pharm Technol. 2019;12(7):3169–74.
5. Sreenivas A, Raj AS, Puthenpurackal VR, Haneef T, Pillai GR, Jose D, et al. Pain perception in different injection techniques in paediatric dentistry: an original research. European Journal of Molecular & Clinical Medicine. 2020;7(09):2020.
6. Sefidabi S, Dashti M. Dental Anesthesiology. Innovative Perspectives in Oral and Maxillofacial Surgery. 2021;369–77.

7. Yarborough LE, Nusstein J, Drum M, Fowler DDSS. Comparison of Maxillary Lateral Incisor Injection Pain Using Varied Flow Rates with the Dentapen and Syringe Injection. Ohio State University, Master's thesis. OhioLINK Electronic Theses and Dissertations Center. 2021.
8. O'Neal LY, Nusstein J, Drum M, Fowler S, Reader A, Ni A. Comparison of maxillary lateral incisor infiltration pain using the dentapen and a traditional syringe: a prospective randomized study. J Endod. 2022;48(7):840–4.
9. Elshiekh M, Ragab R. Clinical Effectiveness of Egyptian Articaine (4% Artpharmadent) Versus Imported Articaine (4% Artinibsa) in Extraction of Primary Molars: Randomized Clinical Trial. Advanced Dental Journal. 2022;4(3):228–37.
10. Newsome P, Smales R, Yip K. Oral diagnosis and treatment planning: Part 1. Introduction. Br Dent J. 2012;213(1):15–9.
11. Guelmann M, Pileggi R. Guidance to Achieve Clinical Pulpal Diagnosis and Operative Decisions. In: Contemporary Endodontics for Children and Adolescents. Springer; 2023. p. 111–25.
12. Reed KL, Malamed SF, Fonner AM. Local anesthesia part 2: technical considerations. Anesth Prog. 2012;59(3):127–37.
13. Mahmoud GMM, Mahmoud SA, Elchaghaby MA. Anaesthetic Efficacy of 4% Alexadricaine Versus 2% Mepecaine-L for Infiltration Anaesthesia in Extraction of Maxillary First Primary Molars in Children: A Randomized Controlled Pilot Study. Advanced Dental Journal. 2022;4(4):296–308.
14. KeskinYalcin B. Complications Associated with Local Anesthesia in Oral and Maxillofacial Surgery. Top Local Anesth. 2020;1–14.

15. Fox MA, Ayyangar R, Parten R, Haapala HJ, Schilling SG, Kalpakjian CZ. Self-report of pain in young people and adults with spastic cerebral palsy: interrater reliability of the revised Face, Legs, Activity, Cry, and Consolability (r-FLACC) scale ratings. Dev Med Child Neurol. 2019;61(1):69–74.
16. Ladewig NM, Sahiara CS, Yoshioka L, Olegário IC, Floriano I, Tedesco TK, et al. Efficacy of conventional treatment with composite resin and atraumatic restorative treatment in posterior primary teeth: study protocol for a randomised controlled trial. BMJ Open. 2017;7(7): e015542.
17. Pascon FM, Kantovitz KR, Caldo-Teixeira AS, Borges AFS, Silva TN, Puppin-Rontani RM, et al. Clinical evaluation of composite and compomer restorations in primary teeth: 24-month results. J Dent. 2006;34(6):381–8.
18. Lenzi TL, Gimenez T, Tedesco TK, Mendes FM, Rocha RDO, Raggio DP. Adhesive systems for restoring primary teeth: a systematic review and meta-analysis of in vitro studies. Int J Paediatr Dent. 2016;26(5):364–75.
19. Thalacker C. Dental adhesion with resin composites: a review and clinical tips for best practice. Br Dent J. 2022;232(9):615–9.
20. Suneelkumar C, Harshala P, Madhusudhana K, Lavanya A, Subha A, Swapna S. Clinical performance of class I cavities restored with bulk fill composite at a 1-year follow-up using the FDI criteria: a randomized clinical trial. Restor Dent Endod. 2021;46(2).
21. for Nursing OR, Ernstmeyer K, Christman E. General Survey. In: Nursing Skills [Internet]. Chippewa Valley Technical College; 2021.
22. Hosny N, Abd Al Gawad R, Aly M. Anesthetic efficacy of 4% artpharmadent versus 2% mepecaine-l for infiltration anesthesia in extraction of badly decayed lower first primary molars: a pilot study. Egypt Dent J. 2021;67(4):2875–84.

23. Wright GZ, Weinberger SJ, Marti R, Plotzke O. The effectiveness of infiltration anesthesia in the mandibular primary molar region. Pediatr Dent. 1991;13(5):278–83.
24. Aghababaie ST, Monteiro J, Stratigaki E, Ashley PF. Techniques for effective local anaesthetic administration for the paediatric patient. Br Dent J. 2020;229(12):779–85.
25. Fernández-Castellano ER, Blanco-Antona LA, Vicente-Galindo P, Amor-Esteban V, Flores-Fraile J. Pain experienced during various dental procedures: Clinical trial comparing the use of traditional syringes with the controlled-flow delivery Dentapen® technique. Medicina (B Aires). 2021;57(12):1335.
26. Bernardi S, Mummolo S, Ciavarelli LM, Vigni ML, Continenza MA, Marzo G. Cone beam computed tomography investigation of the antral artery anastomosis in a population of Central Italy. Folia Morphol (Warsz). 2016;75(2):149–53.
27. Mehrotra D. Fundamentals of Oral and Maxillofacial Surgery-E-Book. Elsevier Health Sciences; 2020.
28. Smolarek P de C, da Silva LS, Martins PRD, Hartman K da C, Bortoluzzi MC, Chibinski ACR. Evaluation of pain, disruptive behaviour and anxiety in children aging 5-8 years old undergoing different modalities of local anaesthetic injection for dental treatment: a randomised clinical trial. Acta Odontol Scand. 2020;78(6):445–53.
29. Meechan JG. Infiltration anesthesia in the mandible. Dent Clin North Am. 2010;54(4):621–9.
30. Ogle OE, Mahjoubi G. Local anesthesia: agents, techniques, and complications. Dental Clinics. 2012;56(1):133–48.
31. Motamedi MH. A Textbook of Advanced Oral and Maxillofacial

Surgery: Volume 3. BoD–Books on Demand; 2016.

32. Chavhan P, Jawdekar A, Deshpande S, Chandak S, Niswade G, Bhondey A. Comparison of pain perception during the administration of local anaesthesia with computerized delivery system (WAND) and conventional technique in pediatric dental procedure using Visual Analogue scale-A randomised controlled trial. Clin Epidemiol Glob Health. 2020;8(1):224–8.
33. Chengappa MMD, Prashanth AK. Evaluation of efficacy of computer-controlled local anaesthetic delivery system vs traditional injection system for minor pediatric surgical procedures in children. Med J Armed Forces India. 2022;78:S89–95.
34. Ching D, Finkelman M, Loo CY. Effect of the DentalVibe injection system on pain during local anesthesia injections in adolescent patients. Pediatr Dent. 2014;36(1):51–5.
35. Alanazi KJ, Pani S, AlGhanim N. Efficacy of external cold and a vibrating device in reducing discomfort of dental injections in children: a split mouth randomised crossover study. European Archives of Paediatric Dentistry. 2019; 20:79–84.
36. Versloot J, Veerkamp JSJ, Hoogstraten J. Assessment of pain by the child, dentist, and independent observers. Pediatr Dent. 2004;26(5):445–9.
37. Abdul Khalek AMG, Elkateb MA, Abdel Aziz WE, El Tantawi M. Effect of papacarie and alternative restorative treatment on pain reaction during caries removal among children: a randomized controlled clinical trial. Journal of clinical pediatric dentistry. 2017;41(3):219–24.
38. Ghaderi F, Banakar S, Rostami S. Effect of pre-cooling injection site on pain perception in pediatric dentistry:“A randomized clinical trial”. Dent Res J (Isfahan). 2013;10(6):790.

39. Solanki J, Jhamb V, Kiran S, Joshi A, Trivedi M, Jani M. Evaluation of Behaviour and Anxiety in Children During Local Anesthesia Administration Using Conventional Syringe Vs Custom Made Economic Sleeve Syringe: A Clinical Study. Advanced Dental Journal. 2023;5(4):901–9.
40. Pozos-Guillén A, Chavarría-Bolaños D, Garrocho-Rangel A. Split-mouth design in Paediatric Dentistry clinical trials. Eur J Paediatr Dent. 2017;18(1):61–5.
41. Pozos-Guillén A, Loredo-Cruz E, Esparza-Villalpando V, Martínez-Rider R, Noyola-Frías M, Garrocho-Rangel A. Pain and anxiety levels using conventional versus computer-controlled local anesthetic systems in pediatric patients: a meta-analysis. Journal of Clinical Pediatric Dentistry. 2020;44(6):371–99.
42. Feda M, Amoudi N Al, Sharaf A, Hanno A, Farsi N, Masoud I, et al. A comparative study of children's pain reactions and perceptions to AMSA injection using CCLAD versus traditional injections. Journal of Clinical Pediatric Dentistry. 2010;34(3):217–22.
43. Mittal M, Kumar A, Srivastava D, Sharma P, Sharma Sjj. Pain perception: computerized versus traditional local anesthesia in pediatric patients. Journal of Clinical Pediatric Dentistry. 2015;39(5):470–4.
44. Vitale MC, Gallo S, Pascadopoli M, Alcozer R, Ciuffreda C, Scribante A. Local anesthesia with SleeperOne S4 computerized device vs traditional syringe and perceived pain in pediatric patients: a randomized clinical trial. Journal of Clinical Pediatric Dentistry. 2023;47(1).
45. Langthasa M, Yeluri R, Jain AA, Munshi AK. Comparison of the pain perception in children using comfort control syringe and a conventional injection technique during pediatric

dental procedures. Journal of Indian Society of Pedodontics and Preventive Dentistry. 2012;30(4):323–8.

46. Luz San Martin-Lopez A, David Garrigos-Esparza L, Torre-Delgadillo G, Gordillo-Moscoso A, Francisco Hernandez-Sierra J, de Jesus Pozos-Guillen A. Clinical comparison of pain perception rates between computerized local anesthesia and conventional syringe in pediatric patients. Journal of Clinical Pediatric Dentistry. 2005;29(3):239–43.
47. Kandiah P, Tahmassebi JF. Comparing the onset of maxillary infiltration local anaesthesia and pain experience using the conventional technique vs. the Wand in children. Br Dent J. 2012;213(9): E15–E15.
48. Garret-Bernardin A, Cantile T, D'Antò V, Galanakis A, Fauxpoint G, Ferrazzano GF, et al. Pain experience and behavior management in pediatric dentistry: a comparison between traditional local anesthesia and the wand computerized delivery system. Pain Res Manag. 2017;2017 (1): 7941238.
49. Patini R, Staderini E, Cantiani M, Camodeca A, Guglielmi F, Gallenzi P. Dental anaesthesia for children–effects of a computer-controlled delivery system on pain and heart rate: a randomised clinical trial. British Journal of Oral and Maxillofacial Surgery. 2018;56(8):744–9.
50. Özer S, Yaltirik M, Kirli I, Yargic I. A comparative evaluation of pain and anxiety levels in 2 different anesthesia techniques: locoregional anesthesia using conventional syringe versus intraosseous anesthesia using a computer-controlled system (Quicksleeper). Oral Surg Oral Med Oral Pathol Oral Radiol. 2012;114(5): S132–9.
51. Kumar TDY, John JB, Asokan S, Priya PRG, Punithavathy R, Praburajan V. Behavioral response and pain perception to computer controlled local

anesthetic delivery system and cartridge syringe. Journal of Indian Society of Pedodontics and Preventive Dentistry. 2015;33(3):223–8.

52. Thoppe-Dhamodhara YK, Asokan S, John BJ, Pollachi-Ramakrishnan G, Ramachandran P, Vilvanathan P. Cartridge syringe vs computer controlled local anesthetic delivery system: Pain related behaviour over two sequential visits–a randomized controlled trial. J Clin Exp Dent. 2015;7(4): e513.
53. Araújo GM, Barbalho JCM, de Souza Dias TG, de Santana Santos T, de Holanda Vasconcellos RJ, de Morais HHA. Comparative analysis between computed and conventional inferior alveolar nerve block techniques. Journal of Craniofacial Surgery. 2015;26(8): e733–6.
54. El Hachem C, Kaloustian MK, Cerutti F, Chedid NR. Metallic syringe versus electronically assisted injection system: a comparative clinical study in children. Eur J Paediatr Dent. 2019;20(4):320–4.
55. Kwak EJ, Pang NS, Cho JH, Jung BY, Kim KD, Park W. Computer-controlled local anesthetic delivery for painless anesthesia: a literature review. J Dent Anesth Pain Med. 2016;16(2):81–8.
56. Tahmassebi JF, Nikolaou M, Duggal MS. A comparison of pain and anxiety associated with the administration of maxillary local analgesia with Wand and conventional technique. European Archives of Paediatric Dentistry. 2009; 10:77–82.