

A Comparative Study of Children's Pain Reactions and Perceptions to AMSA Injection using CCLAD versus Traditional Injections

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*Pain control is an important part of dentistry, particularly in pediatric dentistry. Recently, a computer-controlled local anesthetic delivery system (CCLAD) has been developed to reduce pain related to the local anesthetic injection. In conjunction with this technology, a new approach to the anterior and middle superior alveolar nerves (AMSA) has been induced. Studies evaluating the CCLAD in pediatric dentistry showed variable results regarding its use in pediatric dentistry. Further evaluation of this technique is needed to provide sound scientific evidence on the use of the CCLAD at this specific injection site in children. **Aim:** To assess children's pain reactions and pain perceptions of the AMSA injection using the CCLAD compared to the traditional buccal/palatal injections. **Materials and methods:** Children's pain reactions and perceptions to both techniques were measured in a group of 40 children who received both anesthetic techniques alternatively on two visits. The pain reactions were scored using the SEM scale, whereas the pain perception was evaluated by the Eland color scale. Statistical analysis was carried out using SPSS version 10.0. **Results:** The AMSA injection delivered with the CCLAD had significantly lower mean pain reaction scores compared to traditional buccal and palatal injections. The prolonged injection time required for delivering the CCLAD injection had no negative impact on the children. The children's pain perception scores when using the CCLAD were also significantly lower compared to the traditional injection. **Conclusion:** The AMSA injection delivered with the CCLAD was found to be a promising device, and had significantly lower pain reaction and perception scores compared to the traditional buccal and palatal injections.*

Keywords: Anesthesia, primary molars, wands, pulpotomy extraction, children

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INTRODUCTION

Pain control is an important part of dentistry and particularly of pediatric dentistry. In most dental procedures pain is usually controlled with the use of local anesthetics. However, administering local anesthesia injection is still the most common method used in dentistry. Unfortunately, the anxiety and pain that accompany it continue to be a problem for the profession. Recently, a computer-controlled local anesthetic delivery system (CCLAD) has been developed as a possible solution to reduce the pain related to the local anesthetic injection. The core technology of this system, which is called the "Wand" is a constant slow rate delivery of local anesthetic solution with controlled pressure regardless of variations in tissue resistance. The manufacturers claim that the computerized system delivers the anesthetic at a rate below the threshold of pain, allowing for a potentially pain free injection. In conjunction with this technology, a new palatal injection has been introduced; this

injection is a palatal approach to the anterior and middle superior alveolar nerves (AMSA). The anesthetic solution diffuses through the porous bone of the maxilla producing anesthesia from the second premolar to the central incisor.¹

Studies testing children's pain reactions and perceptions to the CCLAD used at different oral sites are few and beginning to emerge. The sites used to deliver the CCLAD injection varied; some administered the CCLAD injection at the same traditional injection sites.²⁻⁷ Others used the CCLAD to give periodontal ligament injections.⁶⁻¹¹ and only few used the CCLAD to administer the newly introduced approach of AMSA and PASA blocks.^{10,12,13} Their data showed contradictory results; however, most of the studies found that the CCLAD had indeed produced significantly lower pain reactions compared to the traditional injections. On the other hand, only two of these studies^{2,3} found that the CCLAD was comparable to the traditional injections. These two studies however, had few limitations that might have affected their results. First, the CCLAD anesthesia was administered at the same injection sites of the traditional injections. The AMSA, PASA and the PDL injections recommended by the manufacturer were not used in these studies. Furthermore, Asarch *et al.* (1999)² in their study used a fast injection rate. Following their publication, the manufacturer emphasized the use of slower rate during the palatal injection procedure.

Besides testing the pain reactions, efforts were made to evaluate the children's own pain perception to the CCLAD, as rated subjectively by each child. Contrasting results were also found; some studies^{4,5,9} reported that the CCLAD scored significantly lower pain perception scores compared to the traditional injections. On the other hand, other studies,^{2,10,12} reported that no significant difference was found in pain perception between the CCLAD and the traditional injections. However, some factors might have affected this conclusion, for instance, children included in these studies were very young to rate pain perception (5 & 4 years). Additionally, each child was not used as his own control, which might introduced potential confounding variables.

Reviewing the dental literature provides some controversy regarding the use of the CCLAD in pediatric dentistry. The children's pain reactions and pain perception when administering the CCLAD injection needs further evaluation to provide sound scientific evidence on the use of the CCLAD at specific injection sites.

MATERIALS AND METHODS

Sample selection

The sample included 40 children attending the dental clinics in King Abdulaziz University Hospital (KAUH).

The patients selected fulfilled the following criteria: the age of the children ranged from 7–10 years, children were in a healthy physical and mental state, children were assessed as being cooperative, having behavioral ratings "positive" or "definitely positive" according to the Frankl scale (1962)¹⁴ and children had bilateral maxillary primary molars that required dental treatment under local anesthesia. Each patient was randomly assigned to receive a local anesthetic

injection on one side of the maxilla using either the CCLAD or the traditional syringe in the first visit. The other technique was administered on the other side during the next visit one week later. Each child served as his/her own control. Rating of the patients' reactions and pain perception to the injection technique was carried out regardless of the type of treatment performed.

The procedures' possible discomforts or risks, as well as the possible benefits, were fully explained to the parent or guardian and an informed consent was obtained.

The local anesthetic solution was delivered using either the CCLAD (Wand) or a traditional syringe. The Wand is a U.S. Food and Drug Administration (FDA) approved device and is a product of Milestone Scientific.¹⁵ The anesthetic solution used was Lidocaine HCl 2% with 1:100,000 epinephrine. A 30-gauge short needle was used with both methods of delivery.

A topical anesthetic of benzocaine 20% was placed for 1 min prior any injection.

The traditional technique: A buccal infiltration of 0.8ml was administered at the mucobuccal fold above the apices of the buccal roots of the molars to be anesthetized. A palatal infiltration of 0.2ml was also administered on the palatal side midway between the free gingival margin and the midline. The rate of solution deposition was 1 ml/min.

The CCLAD (Wand): A cotton tip applicator was pressed firmly to the tissue at the proposed injection site. For the palatal approach to the AMSA, an injection was administered half way between the mid-palatal raphe and the free gingival margin bisecting the first and second primary molars. Administration of anesthesia was carried out at the slow rate of (0.5ml/min). After 5 seconds, slight tissue penetration was established. The slow rate of delivery was continued while the needle penetrated the soft tissue. This allowed an anesthetic pathway to develop prior to further tissue penetration. Once the needle tip reached the level of the bony palate, the slow rate of administration was continued until slight blanching of surrounding tissue was visualized. This technique was carried out according to the specifications of the Wand manufacturer (Milestone Scientific). The average amount of local anesthetic administered using the Wand was 1.0ml.

Methods of assessment

Sounds, eyes and motor (SEM) scale for pain reaction: the SEM scale was coded during administering all types of injections; the Wand's single AMSA injection and the traditional buccal and palatal injections. Data was recoded every 15 seconds in both anesthetic techniques. For each injection an average of the intervals scores was calculated. The SEM scale used ranged from 3 to 12, where 3 is the minimum amount of pain and 12 the maximum.

A trained research assistant observed the technique of anesthesia administered and coded the pain behaviors during administering injections in the CCLAD and traditional injection groups.

A pilot study was carried out during which a trained

research assistant evaluated 15 patients who were selected according to the study criteria. The pilot study sample was not used in the main study.

The modified Eland color scale for pain perception: a modification of The Eland color scale,^{16,17} which is a subjective scale, was used to record the patients' pain perception. In this scale, patients were asked to recall events that hurt them in the past. Their past experiences were rated as severe, moderate, mild and no pain. These responses were coordinated with four colors of their choice. The following procedure was conducted: six colored shapes (yellow, orange, red, green, blue, and purple) were placed in a row on a white background and were presented to each child in the same order, the child was asked, "Of these colors which is like?" (The event identified by the child as hurting the most). That color shape was placed on the board away from other colors (it represented severe pain and was given a numerical value of 4), the child was asked the same question for the events identified by him as moderate, mild, and no pain, and the corresponding numerical values of 3, 2 and 1, were given respectively. After each injection, the child was asked to choose the color representing how he felt. The Eland score was recorded as the following: 1= no pain, 2 = mild pain, 3 = moderate pain, and 4 = severe pain.

Statistical analysis

Statistical analysis was carried out using SPSS version 10.0. The ANOVA with repeated measures test was used to compare pain reactions to the CCLAD and the traditional buccal and palatal injections and to compare pain reactions between different time intervals for each type of injection. The Wilcoxon Signed Ranks test was used to compare the pain perception of CCLAD with the traditional (buccal and palatal) injections. A P value of <0.05 marked statistical significance.

RESULTS

A total of 40 children, randomly received the traditional injections (buccally and palatally) at one visit and the CCLAD at the next one. The age of the sample ranged from 84 months (7 years) to 131 months (10 years and 9 months) with a mean age of 98.4 ± 11.28 and the sample consisted of 18 males (45%) and 22 females (55%).

Pain reactions to CCLAD, Traditional buccal and Traditional palatal at the initial time interval:

Table (1a) shows the mean SEM values of initial interval scores recorded following the administration of the CCLAD and the traditional buccal and traditional palatal injections.

Table 1a: Mean SEM scores of the three types of injections (CCLAD, Traditional buccal and Traditional palatal) at the 1st time interval

Initial injection	Mean	SD
CCLAD	4.550	0.172
Traditional buccal	4.375	0.192
Traditional palatal	5.500	0.221

Table (1b), showed that the mean score of the traditional palatal injection was significantly higher than those of both the CCLAD and the traditional buccal scores (P< 0.000).

Table 1b. P-values comparing mean SEM scores of all injections at the 1st time interval

Initial injection	Traditional buccal	Traditional palatal
CCLAD	0.323	<.000*
Traditional buccal		<.000*

* Statistical significance P < 0.000

Pain reactions mean values of CCLAD, Traditional buccal and Traditional palatal

Table (2a) shows the mean values of all SEM scores recorded at each time interval for each type of injection. Statistical comparisons presented in table (2b) showed that the CCLAD's SEM mean was significantly lower than those of the traditional buccal and traditional palatal mean scores (P< 0.000). The mean SEM score of the traditional buccal was also significantly lower than that of the traditional palatal. (P< 0.000).

Table 2a. Mean SEM score of all time intervals for the three types of injections (CCLAD, Traditional buccal, Traditional palatal)

Injection	Mean	SD
CCLAD	3.261	0.037
Traditional buccal	3.925	0.158
Traditional palatal	5.500	0.221

Table 2b. P-values comparing mean of all time intervals SEM scores for all injections

Injection	Traditional buccal	Traditional palatal
CCLAD	0.000*	.000*
Traditional buccal		.000*

* Statistical significance P < 0.000

Pain reactions recorded at each time intervals during the two injection procedures

Table (3a) shows the mean SEM scores recorded at a 15 second time interval using the CCLAD. The highest mean value recorded at the initial injection (4.55 ± 1.08) was

Table 3a. Mean SEM scores recorded at all time intervals using the CCLAD

Time interval	Mean	SD
Initial injection	4.55	1.08
15 sec	3.48	0.78
30 sec	3.08	0.35
45 sec	3.10	0.50
60 sec	3.03	0.16
75 sec	3.08	0.35
90 sec	3.05	0.22
105 sec	3.00	0.00
120 sec	3.00	0.00

significantly higher than all other interval scores ($P < 0.0001$) (table 3b). The least mean values were recorded at 105 sec, (3.00 ± 0.00) and 120 sec (3.00 ± 0.00).

Table 3b. P-values comparing mean SEM scores recorded at each time interval using the CCLAD

Time interval	15 sec	30 sec	45 sec	60 sec	75 sec	90 sec	105 sec	120 sec
Initial	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*	<0.0001*
15 sec		0.001*	0.004*	<0.0001*	0.002*	0.002*	<0.0001*	<0.0001*
30 sec			0.800	0.421	1.000	0.711	0.183	0.183
45 sec				0.372	0.800	0.570	0.210	0.210
60 sec					0.160	0.570	0.323	0.323
75 sec						0.711	0.183	0.183
90 sec							0.160	0.160
105 sec								0.160

Table (4a) shows the mean SEM scores recorded at each 15 second time interval using the traditional buccal injections. The mean value recorded at the initial injection (4.37 ± 0.192) was significantly the highest among all other time interval scores ($P < 0.01$) (table 4b). The mean scores recorded at the following time intervals decreased gradually with no significant difference.

Table 4a. Mean SEM scores recorded at all time intervals using the traditional buccal injection

Time interval	Mean	SD
Initial injection	4.375	0.192
15 sec	3.950	0.209
30 sec	3.725	0.164
45 sec	3.650	0.154

Table 4b. P-values comparing the mean SEM scores recorded at each time interval using the traditional buccal injections

Time interval	15 sec	30 sec	45 sec
Initial	0.006*	0.000*	0.000*
15 sec		0.183	0.052
30 sec			0.538

* Statistical significance ($P < 0.01$)

Pain perception

Table (5) shows the children’s response to anesthetic injections, rated on the Eland color scale. The mean score for

Table 5. Pain perception scores to the CCLAD and traditional injections according to the Eland color scale

Pain level	CCLAD		Traditional injections	
	Frequency n = 40	Percent (%)	Frequency n = 40	Percent (%)
1 – No Pain	16	40.0	0	0.0
2 – Mild	17	42.5	12	30.0
3 – Moderate	7	17.5	22	55.0
4 – Severe	0	0.0	6	15.0
Total	40	100.0	40	100.0

the CCLAD was 1.78 ± 0.73 .

Pain perception recorded for the traditional (buccal and palatal) injections had a mean score of 2.85 ± 0.66 .

Table (6) shows that the children’s mean score of pain perception after administering the CCLAD (1.78 ± 0.73) was significantly lower than that recorded after administering the traditional buccal and palatal injections (2.85 ± 0.66) ($P < 0.0001$).

Table 6. Pain perception means of the CCLAD vs. the traditional injections according to the Eland color scale

Injection	N	Mean	SD	P-value
CCLAD	40	1.78	0.73	<0.0001*
Traditional injections	40	2.85	0.66	

* Statistical significance ($P < 0.0001$)

DISCUSSION

The SEM scale was used in this study to record pain reactions since it is considered a sensitive scale recording detailed levels of eye, sound or motor reactions.¹⁸⁻²⁰ The Eland color scale which was chosen to record pain perception was modified by reducing the number of colors presented to the child to choose six colored shapes.

The age range of the study group (7–10 years) was selected because younger children might encounter some difficulty in recalling and prescribing their pain experience. Criteria for selecting children also included behavioral rating of “positive” or “definitely positive” according to Frankl’s scale (1962),¹⁴ to avoid age related uncooperative responses that may be misinterpreted as pain during recording the pain reactions using the SEM scale.

Intergroup comparisons of pain reactions during the first time interval clearly showed that more pain reactions with the traditional palatal injections is the only significant difference existed than those both CCLAD and traditional buccal injections. However, no significant difference was found between the CCLAD and the traditional buccal injection. The results were supported by previous researches^{10,12,13} who used the palatal approach with the CCLAD (the AMSA and PASA injections). Although the method of recording pain reactions differed, the results were still similar as reported by Gibson *et al.* (2000)¹² in a group of children aged 5 to 13 years and whose study group aged 2–5 years.¹³ Similarly, the study of Versloot *et al.* (2005)¹⁰ reported consistent observation although a different analysis of data was used, as several injection techniques of the CCLAD (AMSA, PASA, or PDL) were grouped together and compared to a single group of several traditional injection techniques (buccal, palatal or mandibular). Accordingly, the injection site was not evaluated as an independent variable in its own right.

Intergroup comparisons revealed that the CCLAD’s mean SEM score was the significantly lowest one. The mean SEM score of the traditional buccal was also significantly lower than that of the traditional palatal. The observation regarding the CCLAD’s technique as being significantly less painful

may be justified by the extended duration of this technique, as the SEM scores tended to decrease by time, resulting in a lower total mean for all intervals. The traditional buccal injection was also less traumatic, in comparison to the traditional palatal injection, because of the firmness of palatal tissues and their inability to absorb the solution readily. For this reason they are considered to be a very traumatic experience for many dental patients.^{21,22}

Pain reactions to both the CCLAD, and the traditional injections has been the subject of comparison in many studies since 1999.²⁻¹³ These studies used several injection sites with the CCLAD. Studies that used the CCLAD with the AMSA injections^{10,12,13} reported results similar to those found in the present study regarding the overall pain reactions. Gibson *et al.* (2000)¹² who compared data using only the first six intervals of the CCLAD reported a significantly lower pain reaction scores with the CCLAD and the traditional buccal compared to the traditional palatal injection. In contrast to our findings there was no significant difference between the CCLAD and the traditional buccal injection. Probably the use of data only from the first six time intervals of the CCLAD, might have contributed to this variation. Our results also agreed with the study of Allen *et al.* (2002),¹³ although in their study the disruptive behaviors were recorded separately for the traditional buccal and palatal injections, data from both traditional injections were collected in one group when overall comparisons were done with the CCLAD. Similarly in the study of Versloot *et al.* (2005),¹⁰ comparisons of only the first two time intervals of the CCLAD group with the traditional group showed that children in the CCLAD group showed less pain related behaviors than children in the traditional injection group. The site of injection of the CCLAD was also evaluated.

Several studies have been conducted to test children's pain reactions to the CCLAD using sites other than the palatal AMSA and PASA.²⁻¹¹ These studies tested the CCLAD at the traditional injections sites (infiltrations and inferior alveolar blocks), as well as a periodontal ligament injection. The majority found the CCLAD to have significantly lower pain scores compared to the traditional injections, whereas, two of the previous studies^{2,3} reported comparable data with the traditional methods of injection. In the study of Asarch *et al.* (1999),² the fast injection rate which was used in contrast to the manufacturer's instructions might have influenced the study outcome.

Regarding pain reactions to the CCLA at different time intervals, comparisons revealed that the initial time interval scored the significantly highest mean value. However, a gradual decrease in mean SEM scores took place afterwards. Accordingly, it can be assumed that the long time needed for the CCLAD injection had no negative impact on the children and on the contrary, might have allowed them to calm down. This supports the manufacturers' claim that this slow rate is precisely what allows the CCLAD to deliver painless anesthesia.^{1,23} Additionally, this longer injection time may offer an opportunity for the child to cope with the injection experience. This finding was also supported by Gibson *et al.*

(2000),¹² who found that the disruptive behaviors of the children in the CCLAD group diminished over time. In contrast to our results the study of Allen *et al.* 2002 showed an increase in the disruptive behavior among nearly half of the patients in the CCLAD group. It is important to note that their study was carried out in a group of children whose ages ranged between 2 and 5 years, which might indicate that the CCLAD injection may result in restless behavior among the preschoolers. Similar findings were noticed in the studies of Gibson *et al.* (2000)¹² and Allen *et al.* (2002).¹³ In the work of Gibson *et al.* (2000),¹² the first two intervals were the most painful ones, followed by a decline in pain behaviors at the remaining four intervals. The same trend was also found in the study of Allen *et al.* (2002).¹³

Pain perception: The split mouth design was used so that each child would serve as his or her own control to eliminate potential confounding variables.

Pain perception comparisons revealed a significantly lower pain perception score with the CCLAD technique. This finding indicates that children considered the CCLAD less painful than the traditional injections. In the study of San Martin Lopez *et al.* (2005),⁵ who used the VAS to compare children's pain perception to buccal and palatal infiltrations given through the CCLAD or through traditional syringes, revealed that children experienced less pain with the computerized method. Similar results were also obtained when the CCLAD was used as a periodontal ligament injection in comparison to the inferior alveolar block in the studies of Palm *et al.* (2004)⁴ and Oztas *et al.* (2005).⁹ In all previous studies, the age of children was above six years and each child received both computerized and traditional injections.

On the other hand, some studies reported contrasting results.^{2,10,12} No significant difference was found between the CCLAD and the traditional injections. However the studies revealed a few limitations that might have affected the outcome. First, the age limit of children in the Asarch *et al.* (1999)² and Gibson *et al.* (2000)¹² studies was five years, and even younger in the Versloot *et al.* (2005)¹⁰ study. Describing pain perception using the VAS with reliable precision is questionable among children at this age. The VAS is considered more reliable measure for children aged eight and older.^{5,24,25} Another limitation was that two separate groups of children were studied; the control group received the traditional injections and the test group received the CCLAD, therefore the children did not serve as their own controls, and potential intra-individual variability might be introduced.

Based on the results of this study, it can be assumed that the CCLAD caused significantly lower pain reaction and pain perception scores compared to the traditional injections. Although an effort was made to reduce bias, there were few unavoidable limitations. First, the dentist was not blind to the type of injection being delivered. Despite of the attempt made to control this bias by using an independent observer to code the pain reactions; unfortunately, this observer was also not blind to the anesthetic technique

administered. Second, the children were not blind to the method of anesthesia used, which might have affected their pain perception scores. Other studies blindfolded the children in an attempt to reduce bias. The option of blindfolding the children was not preferred since it will hide eye responses that are essential in recording pain reactions, and might increase their anxiety, resulting in an exaggerated response to the injections.

CONCLUSIONS

In conclusion, the study revealed that the CCLAD was found to be a promising device that provided a more comfortable method of anesthesia. Additionally, the prolonged injection time required to deliver the CCLAD injection did not have any negative impact on the children. This new anesthetic system may present a good alternative for the conventional manual syringe, and may be a useful tool to help our pediatric patients to better accept dental treatment. However, further research is needed to evaluate the effectiveness of the CCLAD at different sites and on different primary teeth in children.

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