

Efficacy of a computerized local anesthesia device in pediatric dentistry

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Abstract

Purpose: The purpose of this study was to evaluate the efficacy of a computerized anesthesia delivery system in reducing pain during injections when compared with a traditional delivery system (i.e., syringe).

Methods: Subjects consisted of 57 patients between the ages of 5 and 13 needing operative dentistry using local anesthesia. Patients were randomly assigned to either the computerized or traditional anesthesia delivery system. Inferior alveolar block injections, palatal, and buccal infiltrations were the only injections administered throughout this study. Pain behavior was videotaped and coded throughout the study. Pain perceptions were rated using a 10 point visual analogue rating scale. Subjects were also asked to rate their overall satisfaction and approval of the dentist and the treatment received.

Results: Results of multivariate analysis of variance indicated that there were no significant differences between the computerized and the traditional method of administering local anesthesia when comparing pain ratings and pain behavior. Average pain ratings for the computerized method were 4.5 while the average ratings for the traditional method were 3.6. In addition, all subjects reported overall satisfaction with their dental treatment and that they would be willing to return in the future.

Conclusions: A computerized anesthesia injection method was found to be comparable to the traditional method of anesthesia injection. (*Pediatr Dent* 21:421-424, 1999)

Since the introduction of local anesthetics, the injection has produced pain and anxiety in patients. Yet, local anesthesia is necessary and is arguably the greatest advance in pediatric dental care.¹ For most operative procedures in dentistry, when anesthesia is properly administered, it is a dentist's greatest aid in treating children comfortably. Today, there is little excuse for not using local anesthesia because it offers the advantage of child/patient comfort, cooperation, and operator's better performance.¹ Unfortunately, even with this advance in dentistry, pain and anxiety continue to be a problem with injections. Numerous studies have been conducted in an effort to try to achieve a painless injection.^{2,3,4} However, studies continue to show that 30-40 million people in the United States are "phobic" and avoid dental treatment, while 90% of dental patients report being anxious about receiving dental injections.

To deal with these concerns, dentists have used topical anesthesia and prolonged injection time during the administration of local anesthesia in an effort to reduce pain. These techniques have helped, but they have not eliminated the pain associated with anesthesia injections; and administering local anesthesia with the traditional syringe continues to be painful for children and adults alike. This is a particular concern in pediatric dentistry, where nearly one in four children present with significant management problems associated with pain during treatment. There is also evidence that dental fear and anxiety in adults is often learned in childhood.^{5,6,7} Thus, dentists continue to search for techniques to make injections less painful.

Recently, a computerized local anesthetic delivery system has been developed as a possible means of eliminating injection pain.⁸ The "Wand" delivers anesthetic at a constant pressure and controlled volume, regardless of the resistance in the tissues. Slow injections can be regulated more precisely by this computerized system than the traditional syringe. Precise regulation is important because pressure and volume are thought to be directly related to pain.^{9,5} Although dentists have tried to regulate the pressure and volume of anesthetic given by pushing slowly with their thumbs, manual gauging is not perfect. Gauging the pressure and volume of the anesthetic injection is difficult because the amount of resistance and pressure needed varies with each individual. A computerized system, however, offers considerable promise of reducing pain precisely because it can control pressure and volume. Several uncontrolled clinical reports offer promising data yet no well-controlled studies have been conducted to empirically evaluate this potential.^{10,11} In addition, no data exist evaluating the efficacy of a computerized anesthesia system with children.

The purpose of this investigation was to provide a well-controlled empirical evaluation of the effects of a computerized anesthetic injection system for reducing the pain and discomfort experienced by children during local injections. Given the proposed ability of the system to provide delivery of anesthesia under constant pressure and controlled volume, we hypothesized that those children who experienced anesthesia administered by the "Wand" would report less pain, exhibit less pain behavior, and report greater satisfaction with treat-

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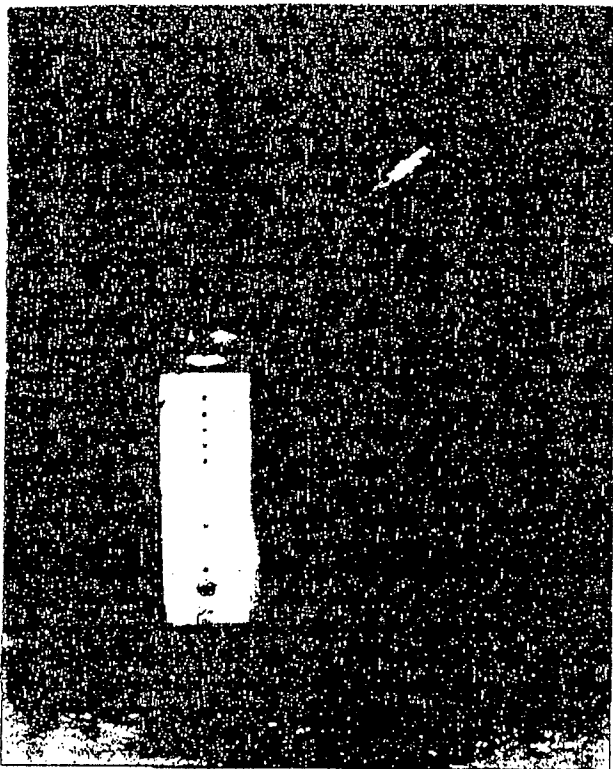


Fig 1. Computerized local anesthesia delivery system.

ment, when compared to children who experienced a traditional anesthetic injection method.

Method

Subjects

Fifty-seven children ranging in age between five and 13 years of age were used in this study. They were a sample of patients who were in need of operative dentistry using local anesthesia. There was no gender, race, or ethnic restrictions used in the study. Subjects were selected based solely on their need for operative dentistry requiring local anesthesia and meeting the age criteria. Patients were excluded from the study if they had significant behavioral management problems. The parent or guardian gave both written and verbal consent for the institutionally approved study.

Equipment

The local anesthetic was delivered using either the Wand or the traditional syringe. The Wand (Figure 1) is a U.S. Food and Drug Administration (FDA) approved device and is a product of Milestone Scientific.⁹ All injections consisted of 2% Xylocaine with 1:100,000 epinephrine, administered with a 30-gauge needle. Anesthetic could be delivered at two rates. The

1.8cc), buccal infiltrations (carpule/.90cc), palatal infiltrations (1/8 carpule/.23cc). Nitrous oxide was not used during any of the injections. Prior to the initiation of the study, a pilot

study was performed to refine the dentist's skill in administering local anesthesia using the Wand.

Dependent Measures

Perceptions of pain were provided by each child using a 10 point visual analogue scale (VAS). About the size of a small plastic ruler, one side of the VAS consisted of an interval scale ranging from 0, representing no pain or discomfort, to 10, representing maximum pain and discomfort. On the opposite side of the VAS was a color bar with varying gradients of red. The bottom of the bar was white and narrow, representing no pain. The bar gradually widened and graduated to increasingly darker shades of red, representing maximum pain and discomfort.

Pain behavior was measured using an established pain behavior code.^{12,13,14} The four pain behavior categories used were 1) non-interfering body movements, 2) crying, 3) movement disruptive to treatment, and 4) movement requiring restraint. (Table 1) A research assistant observed all treatment sessions and coded occurrence of these behaviors on a 15-second interval recording system.

Treatment satisfaction was evaluated using a modified version of the Abbreviated Acceptability Rating Profile.¹⁵ Subjects rated, using a six point Likert-type rating scale, their agreement with five statements regarding their satisfaction with treatment, their comfort level, and their willingness to return to the clinic (Table 2). A total score above 20 was considered favorable.

Finally, the actual amount of time required to administer each injection was recorded for each type of administration.

Procedure

Subjects were drawn from a continuous sample of patients on record in a Pediatric Dental Clinic at a large midwestern medical center in an urban setting. Each of the patients was scheduled for operative appointments requiring local anesthesia. Prior to entering the dental operator, the research was explained and informed consent was obtained from the parent or guardian. The subject was then escorted by the research assistant to a small consultation room where the VAS was explained. Each child then assisted in developing their own anchor points for the pain rating scale. Each subject was then randomly assigned to either the Wand or the traditional syringe condition for administration of local anesthesia.

The tissues were dried with 2x2 gauze then topical anesthetic was placed and remained in place for 30-45 seconds. The in-

| Code | Description |
|------|---|
| B | Body movement (B): Movement of any part of the body of 15 cm or more. This could be one motion or a continuum of uninterrupted motions without a break. Scoring occurred during the interval occurred or when the criterion was met. |
| C | Crying (C): Any crying, complaining, or vocalizations in general were scored within this category. Not included were responses to questions from dentist or dental assistant, laughing, or talking that was patently not due to pain. |
| D | Dentist interference (D): This included any disturbance that interfered with the dental procedure and caused the dentist to stop temporarily. |

child to prepare for possible disturbance were not counted.

| Table 3. Treatment Satisfaction and Acceptability Survey | | | | | |
|--|---------------|------------------------|---------------------|------------|---------------------|
| I liked the dentist who worked on my teeth today. | | | | | |
| 1 Strongly Disagree | 2 Disagree | 3 Slightly Disagree | 4 Slightly Agree | 5 Agree | 6 Strongly Agree |
| The treatment I received today did NOT hurt. | | | | | |
| 1 Strongly Disagree | 2 Disagree | 3 Slightly Disagree | 4 Slightly Agree | 5 Agree | 6 Strongly Agree |
| I enjoyed my trip to the dentist today. | | | | | |
| 1 Strongly Disagree | 2 Disagree | 3 Slightly Disagree | 4 Slightly Agree | 5 Agree | 6 Strongly Agree |
| I liked how I was treated today. | | | | | |
| 1 Strongly Disagree | 2 Disagree | 3 Slightly Disagree | 4 Slightly Agree | 5 Agree | 6 Strongly Agree |
| I am willing to come back to see this dentist again. | | | | | |
| 1 Strongly Disagree | 2 Disagree | 3 Slightly Disagree | 4 Slightly Agree | 5 Agree | 6 Strongly Agree |

jection was then administered. Infiltrations and inferior alveolar nerve blocks were the only injections given. For the Wand, the procedures were those specified by the manufacturer. A slow rate of administration was used prior to needle insertion. The handpiece was then rotated upon insertion, to reduce needle deflection. Upon evidence of negative aspiration, the fast rate of administration was used, per manufacturer instructions. Once anesthesia was obtained, dental treatment was delivered. The tell-show-do technique was used with every patient. However, the subjects were kept blind to which delivery system was used (i.e., patients were visually shielded from seeing the injection device) and no subject was used in the study twice. The same operator was used throughout the study.

Behavior coding began when the dentist was both looking at and touching the mouth of each subject. Coding stopped when the dentist looked away or ceased touching the patient for five seconds. Coding also ceased during the pain scale rating procedure. Pain ratings were solicited after each injection. The treatment satisfaction rating scale was administered at the conclusion of treatment by the research assistant while the dentist was out of the room.

Results

Overall, the subjects' average ratings of pain for the Wand was 4.5 while the average pain rating for the traditional method

was 3.6. Average pain behavior was observed during 29% of injection intervals for children who experienced the Wand and during 33% of the injection intervals for children who experienced the traditional method of injection. A multivariate analysis of variance was conducted to evaluate these differences between injection methods across measures of both pain ratings and pain behavior. The statistical analysis found no significant differences between the Wand and the traditional method of administering local anesthesia ($F=1.18, P=.31, N=128$).

To see if there was an interaction between the location of the injection and the injection method used, data were broken down by three injection locations: inferior alveolar block, buccal infiltration, and palatal infiltration (Table 3). An interaction model of the MANOVA was used and no significant interactions were found for duration of injection, pain ratings, or pain behavior ($F=.84, P=.44$).

Finally, the average post-treatment acceptability and satisfaction scores were averaged, revealing mean scores of 22.4 for the Wand and 24.4 for the traditional injection. A two-tailed, unequal variance t-test found no significant difference in these scores ($t=.133, P=.89$).

Discussion

Contrary to what was expected, the results suggest that the computerized system of anesthetic injection did not produce significantly less pain or pain behavior in children undergoing anesthetic injections when compared with children who experienced a traditional injection by syringe. Analysis of overall means for each of the dependent measures suggest that children who were exposed to the traditional method of injection were not more likely to report significant pain, were not more likely to exhibit disruptive pain behavior, and were not more likely to report dissatisfaction with treatment. In general, all the subjects in the study reported only mild-moderate pain and discomfort and were generally satisfied with treatment.

Given that this is the first controlled investigation of a computerized anesthetic injection method with children, it would be premature to discard the Wand as ineffective. Certainly, additional studies will be required before any conclusions can be drawn with confidence. In addition, there are several limitations to this study that require the results to be interpreted with caution. First, the sample population must raise ques-

| Injection Site | Duration (sec) | | % Disruptive Behavior | | Pain Rating | |
|----------------|----------------|-------------|-----------------------|-------------|-------------|-------------|
| | Wand | Traditional | Wand | Traditional | Wand | Traditional |
| Block (N=37) | 61.6 | 64.7 | 48 | 46 | 5.00 | 4.062 |
| Buccal (N=66) | 15.3 | 20.0 | 39 | 52 | 4.38 | 3.35 |
| Palatal (N=25) | 11.4 | 11.7 | 45 | 33 | 3.80 | 3.93 |

tions about the generalizability of the results. The study population consisted primarily of low-income families who might have significantly different dental histories than children from middle and upper income families. Families with fewer resources might delay dental treatment until more invasive procedures are necessary. As a result, their children might have early dental experiences that are more uncomfortable than those who practice good preventive maintenance. Future research will need to explore the effectiveness of this type of device with different populations.

Second, there may be some question regarding the validity of asking children to rate their own pain. Although, visual analogue scales are widely regarded as valid for children over five years of age.¹⁶ In addition, independent pain behavior measures were significantly correlated with the pain ratings ($r = .40$, $P < .01$, $N = 128$), suggesting that the pain ratings were valid estimates of discomfort.

Third, the dentist in this investigation was not blind to the hypothesis. In addition, the dentist was also one of the investigators, making the results subject to experimenter bias. But it seems unlikely that bias would have played a factor, given that the results were counter to what had been anticipated. Indeed, one might argue that this fact lends even more credence to the results.

Finally, the manufacturer suggested that the rate and location of administration might be critical variables that influenced the outcome in this investigation. For example, the Wand is promoted as a device that is particularly effective with palatal and periodontal ligamental (PDL) injections. While we did not perform PDL injections, we did not find any differences with the palatal injections. It was also suggested that using the slower rate of administration for a longer period of time might have improved the outcome. While we closely followed the directions provided with the equipment, the effect of using an even slower administration time warrants further investigation.

Perhaps one of the most important aspects of this investigation to keep in mind is that pain is a complex phenomenon that is impacted by a wide variety of contextual variables. While the pressure and volume of anesthetic administration might be two important variables, there are others that might impact directly on the efficacy of a computerized administration device. For example, the skill level of the dentist in administering injections with syringes might be important. A less skilled dentist might find the Wand more beneficial. Likewise, the perceptions of the child and the anticipated discomfort may be a critical factor. Children who are actually introduced to the Wand and who can hear about its operation and benefits may then experience the device as truly beneficial. Each of these areas will need to be explored in greater detail to ultimately determine the efficacy and limitations of a computerized anesthetic device for children.

Conclusion

1. A computerized anesthetic injection method was found to be comparable to the traditional method of anesthesia injection.

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