Inferior Alveolar Nerve Block Injection Pain Using a Computer-Controlled Local Anesthetic Device (CCLAD): A Prospective, Randomized Study

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There is evidence that the Computer-Controlled Local Anesthetic Device (CCLAD) decreases the pain of oral injections. The purpose of this study was to evaluate injection pain of the inferior alveolar nerve block (IANB) using the CCLAD in an upright position versus a supine position. Additionally, we evaluated solution deposition pain with the CCLAD when compared to previous studies using a traditional syringe. One hundred ten asymptomatic subjects were randomly given IANBs using 2% lidocaine with 1:100,000 epinephrine while in an upright sitting position and supine position, at 2 different appointments, spaced at least 2 weeks apart. Each subject rated the pain for needle insertion, needle placement, and solution deposition on a Heft-Parker visual analogue scale. Pain ratings were compared between the upright and supine positions using a repeated-measures analysis of variance with post hoc testing using the Tukey-Kramer procedure. Moderate to severe pain was reported by 10% to 13% of the patients for needle insertion, 74% to 75% for full needle placement, and 8% to 10% for solution deposition. There was no significant difference between groups for phases of the injection. When comparing the injection phases within the groups, the needle placement phase of the injection was statistically more painful than both the needle insertion phase and solution deposition phase ($p = .0001$). Using the CCLAD, IANB injection pain of the supine and upright positions was not statistically different. Needle placement was the most painful phase of the injection. Solution deposition pain was less with the CCLAD when compared to other studies of the IANB using a traditional syringe.

Key Words: CCLAD; Injection pain; Inferior alveolar nerve block.

The inferior alveolar nerve block (IANB) has the potential to be a painful injection.¹ One method to decrease this pain is to use a slow injection technique. Hochman et al² and Kudo et al³ measured injection pressures of dental injections. They found injecting with low pressures (slow injection) significantly reduced pain and anxiety.^{2,3} Therefore, a slow injection during deposition of anesthetic solution decreases pressure and patient discomfort during injection. Kanaa et al⁴

found a slow IANB injection (60 seconds) was reported to be more comfortable than a rapid injection (15 seconds).

The Computer-Controlled Local Anesthetic Device (CCLAD) system (Milestone Scientific, NJ), formerly referred to as the Wand, has the advantage of administering a slow injection. The CCLAD system delivers 1.4 mL of anesthetic solution over a time period of 4 minutes and 45 seconds (referred to as ControlFlo). There is also a faster rate (referred to as RapidFlo). The majority of the literature on CCLAD systems has dealt with the pain of injection with the CCLAD compared with standard injections using a syringe.^{5–31} From 20 published studies, there is good evidence that the CCLAD system decreases the pain of injections and reduces disruptive behavior in children.^{5–25} Five studies showed no difference in pain,^{26–30} and 1 study showed higher pain ratings.³¹ While the CCLAD system

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decreases pain of the injection, the system does not produce a painless injection.^{5–25}

Fear of the dental injection is one of the major causes of apprehension in dental patients.^{32–34} Kaufman et al³⁵ found that the IANB resulted in more discomfort than infiltration, intraligamentary injection, and mental nerve block. Therefore, reduction in injection pain for the IANB is still needed.

Our initial study³⁶ evaluated the difference in anesthetic success between the upright and supine positions for the IANB. The authors found the supine and upright positions were equally successful in the molars and anterior teeth. The supine position was more successful in the premolars. Clinically, however, neither position for the IANB administration would provide complete pulpal anesthesia. Because each IANB for the 2 positions was given with the CCLAD, we wanted to evaluate what the pain would be compared to the historical pain of the IANB without the CCLAD.

Many previous studies have not divided the phases of the injection into needle insertion, needle placement, and solution deposition. Additionally, the use of the CCLAD in the current study standardized the rate of injection for the IANB and evaluated if there was a decrease in the pain of solution deposition for slower injections. Further studies may be helpful in evaluating injection pain of the IANB using the CCLAD system. Therefore, the purpose of this prospective study was to evaluate injection pain of the IANB using the CCLAD in an upright position versus a supine position. Additionally, we evaluated solution deposition pain with the CCLAD when compared to previous studies using a traditional syringe.

MATERIALS AND METHODS

One hundred ten adult, asymptomatic subjects, who were in good health as determined by a health history and oral questioning, participated in this study. Exclusion criteria were as follows: subjects who were younger than 18 years and older than 65; history of significant medical problems (American Society of Anesthesiologist class III or higher); taken central nervous system depressants or any analgesic medication within 8 hours; pregnancy; allergy to lidocaine; or unable to give informed consent. The Ohio State University Human Subjects Review Committee approved the study and informed consent was obtained from each subject.

In a crossover design, the subjects randomly received an IANB, with the subject in a supine position or with the subject in an upright sitting position, at 2 separate appointments, spaced at least 2 weeks apart. We chose to use the upright and supine positions to evaluate the

success of the IANB, and the results have been reported previously.³⁶ With the crossover design, there were 220 IANBs administered and each subject served as his or her own control. An equal number of IANBs were administered on the right side and the left side. The same side randomly chosen for the first IANB was used again for the second IANB.

Before the experiment, the 2 positions for the IANBs were randomly assigned 6-digit numbers from a random number table. Each subject was randomly assigned to 1 of the 2 positions for the IANB to determine which would be administered at each appointment. Only the random numbers were recorded on the data collection sheets to help blind the experiment.

Before the injection, each subject was trained to rate the pain of the IANB using the Heft-Parker visual analogue scale (VAS)³⁷ (Figure). Each subject rated the pain for initial needle insertion, needle placement to the target site, and deposition of the anesthetic solution at the target site. The VAS was a 170-mm line with various descriptive terms. The subjects placed a mark on the scale where it best described their pain level. To interpret the data, the VAS was divided into 4 categories. No pain corresponded to 0 mm on the scale. Mild pain was defined as >0 mm and ≤54 mm. Mild pain included the descriptors of faint, weak, and mild pain. Moderate pain was defined as >54 mm and <114 mm. The descriptor term was moderate. Severe pain was defined as ≥114 mm. Severe pain included the descriptors of strong, intense, and maximum possible.

The IANB was administered with the subject in 2 positions—upright or supine. The upright position was defined as the position where the subject's mandibular occlusal plane was parallel to the floor when the mouth was in an open position. The back of the dental chair was set to a 75-degree angle to the floor, as measured using a protractor equipped with a weighted string. The operator was standing during the administration of the IANB. The supine position was defined as the position where the subject was reclined so that their feet were slightly higher than their head and their body was parallel with the floor. The operator was sitting during the administration of the IANB. The principal investigator (C.C.) administered all IANBs.

Before each injection, topical anesthetic gel (20% benzocaine, Patterson Dental Supply, Inc., St. Paul, MN) was passively placed with a cotton tip applicator for 60 seconds at the injection site. A standard IANB injection³⁸ was administered with the CCLAD (Milestone Scientific) and a 27-gauge 1½ inch needle (Sherwood Medical Co., St. Louis, MO). The needle was attached to the end of the sterile plastic CCLAD tubing. A cartridge of 2% lidocaine with 1:100,000 epinephrine (Xylocaine, Dentsply Pharmaceutical, York, PA) was

Place a mark on the line below to show the amount of pain that you feel.

Heft-Parker 170-mm visual analogue scale.

placed into the unit's handpiece assembly, and this was placed into the cartridge holder with a quarter turn in a counter clockwise direction. By depressing the foot pedal, the CCLAD automatically initiated a priming cycle, removing air from the tubing.

For the injection, the needle was inserted through the mucosal tissue (needle insertion). The computer-assisted injection system was activated at the slow rate (ControlFlo). The principal investigator then slowly guided the needle to the target site over a 10-second time period (needle placement). One chime from the computer-assisted injection system corresponded to 1 second, allowing audible monitoring of the elapsed injection time. No anesthetic solution was deposited during needle placement. Following aspiration, the anesthetic solution was deposited over a 1-minute time period on the slow setting and then the CCLAD was activated to the faster rate (RapidFlo) and the remaining solution was deposited for a total deposition time of 1 minute and 52 seconds (solution deposition). A total of 1.4 mL was deposited because a small portion of solution from a standard cartridge was lost during the purge cycle and some of the solution remained in the cartridge and tubing.

Pain ratings for needle insertion, needle placement, and solution deposition were compared between the upright and supine positions using a repeated-measures analysis of variance with post hoc testing using the Tukey-Kramer procedure. Comparisons were considered significant at $p < .05$. With a nondirectional alpha risk of 0.05 and assuming a correlation of 0.4 and a standard deviation of 35,¹³ a sample size of 100 pairs of subjects would be necessary to demonstrate a difference of ± 15 mm on the VAS scale with a power of 0.945.

RESULTS

One hundred ten adult subjects, 55 men and 55 women ranging in age from 20 to 36 years, with an average age of 26 years, participated in this study.

The Table summarizes the injection pain ratings for each phase of the IANB injection. There was no significant difference between the supine and upright positions. When comparing the injection phases, the needle placement phase of the injection was statistically more painful than both the needle insertion phase and solution deposition phase ($p = .0001$).

Pain Ratings for Each Injection Phase for the Supine and Upright Positions

<i>Injection Phase</i>	<i>None</i>	<i>Mild</i>	<i>Moderate</i>	<i>Severe</i>	<i>Mean $\pm$ SD (mms)</i>
Needle insertion*:					
Supine	16% (18/110)	71% (78/110)	13% (14/110)	0% (0/110)	25 $\pm$ 19
Upright	24% (26/110)	66% (73/110)	10% (11/110)	0% (0/110)	22 $\pm$ 19
Needle placement*:					
Supine	1% (1/110)	25% (28/110)	69% (76/110)	5% (5/110)	67 $\pm$ 26
Upright	2% (2/110)	23% (25/110)	67% (74/110)	8% (9/110)	68 $\pm$ 29
Solution deposition*:					
Supine	27% (30/110)	65% (71/110)	7% (8/110)	1% (1/110)	22 $\pm$ 21
Upright	29% (32/110)	61% (67/110)	10% (11/110)	0% (0/110)	23 $\pm$ 22

* There were no significant differences ($p > 0.05$) between the 2 anesthetic techniques.

DISCUSSION

In the current study, moderate to severe pain was reported 10 to 13% of the time for needle insertion (Table). Nusstein et al,³⁹ in a retrospective study of 1635 IANBs, found needle insertion resulted in moderate to severe pain from 14 to 22% of the time. The pain ratings are similar to the results in the current study.

Regarding the use of a 27-gauge needle to administer the IANB, Fuller et al⁴⁰ and Flanagan et al⁴¹ found no significant differences in the perception of pain produced by 25-, 27-, and 30-gauge needles. Therefore, needle gauge sizes used in the oral cavity do not seem to affect the pain of needle insertion.

The use of topical benzocaine did not eliminate needle insertion pain. Nusstein and Beck,³⁹ Nakanishi et al,⁴² Meechan et al,⁴³ and McCartney et al⁴⁴ reported 20% benzocaine was not completely effective in reducing needle insertion pain for the IANB. Martin et al⁴⁵ found if patients thought they were receiving topical anesthetic, whether they did or not, they anticipated less pain on injection. Further research needs to address ways to reduce pain during needle insertion.

The finding that there was no significant difference between the supine and upright positions would be expected because all subjects received topical anesthetic, the technique of needle insertion was the same for both positions, and no local anesthesia was administered during needle insertion.

For needle placement, moderate to severe pain was reported 74 to 75% of the time (Table). Nusstein et al⁴⁶ found needle placement resulted in moderate to severe pain from 39 to 54% of the time. Even though the pain ratings were higher in the current study than previous studies, the results indicated that slowly placing the needle to the target site over a 10-second time period, while also administering anesthetic solution at the slow rate using the CCLAD, was not effective in decreasing moderate to severe pain. McCartney et al⁴⁴ found, in patients with painful irreversible pulpitis, placing the needle to the target site resulted in an incidence of 48 to 60% moderate pain and 23 to 26% severe pain. Interestingly, depositing 0.2 to 0.4 mL of anesthetic solution during needle placement did not significantly reduce pain versus just placing the needle to the target site without depositing solution. Therefore, slowly administering the anesthetic solution as the needle is advanced does not effectively anesthetize the tissue in the path of the advancing needle. The CCLAD delivers the anesthetic solution at a set rate. Therefore, the small amount of anesthetic solution delivered as the needle is advanced is not enough to adequately anesthetize the tissue.

The current study found needle placement was the most painful phase of the IANB (Table). Nusstein et al⁴⁶ also found that needle placement to the target site was more painful than needle insertion and anesthetic solution deposition. McCartney et al⁴⁴ found a similar result. There were no differences between the supine and upright positions. While no significant difference in pain was expected when comparing the upright and supine positions, we studied these 2 positions in order to determine the pain of the IANB using the CCLAD. The 2 positions were part of a previous study comparing the anesthetic success rate.³⁶

A 2-stage injection has been suggested as a way to decrease the pain of needle placement.^{46–48} The method uses initial placement of the anesthetic solution just under the mucosal tissue. After waiting a few minutes for regional numbness, the injection is resumed and the remaining anesthetic solution is deposited at the target site. Nusstein et al⁴⁶ compared the pain of a traditional 1-stage IANB injection to a 2-stage IANB technique in a crossover design. For the 2-stage injection, the needle was inserted submucosally and 0.4 mL of 2% lidocaine with epinephrine was slowly given over 1 minute. After 5 minutes, the needle was reinserted and advanced to the target site (needle placement) and 1.8 mL of 2% lidocaine with epinephrine was deposited. For the traditional IANB, following needle penetration, the needle was advanced while depositing 0.4 mL of 2% lidocaine with epinephrine (needle placement) and then 1.8 mL of 2% lidocaine with epinephrine was deposited at the target site. They found there was significantly less pain with the 2-stage injection when compared to the 1-stage injection (22 vs 52% moderate pain, respectively) for needle placement in women. The 2-stage injection significantly reduced the pain of needle placement for women when compared to the traditional IANB technique. Further research needs to address ways to reduce the pain during needle placement.

For anesthetic solution deposition, moderate to severe pain was reported 8 to 10% of the time (Table). Various authors,^{49–54} using a 60-second deposition time in asymptomatic subjects, have reported the incidence of moderate to severe pain ranged from 20 to 63%. Moderate to severe pain was reduced in the current study when compared to these previous studies. Considering the previous literature supporting the use of the CCLAD to reduce anesthetic solution deposition,^{5–25} the use of the CCLAD may be clinically advantageous.

Nusstein et al⁴⁶ found the 2-stage injection technique did not decrease the pain of solution deposition. Apparently, there was not enough of the anesthetic deposited initially to affect solution deposition pain. Schellenberg et al⁵⁴ determined the effect of 4% buffered

lidocaine on injection pain of the IANB in patients experiencing symptomatic irreversible pulpitis. One hundred emergency patients diagnosed with symptomatic irreversible pulpitis of a mandibular posterior tooth randomly received a conventional IANB using either 2.8 mL 4% lidocaine with 1:100,000 epinephrine or 2.8 mL 4% lidocaine with 1:100,000 epinephrine buffered with sodium bicarbonate in a double-blind manner. The CCLAD was used to administer the IANB. They found injection pain ratings for the IANBs were not significantly ($p = .9080$) different between the buffered and nonbuffered formulations. Pain ratings for the solution deposition phases of the injection for both formulations resulted in a 38–48% incidence of moderate to severe pain with no significant difference between the 2 anesthetic formulations. McCartney et al⁴⁴ recorded a higher incidence of moderate to severe pain for solution deposition (70%) using a standard syringe. Overall, lower values for injection pain were recorded with the CCLAD used in the study by Schellenberg et al⁵⁴ when compared with McCartney's results using a standard syringe. The majority of studies on the use of the CCLAD have also found lower pain scores.^{5–25}

In conclusion, IANB with the CCLAD injection pain in the supine and upright positions was not statistically different. Needle placement was the most painful phase of the injection. Solution deposition pain was less with the CCLAD when compared to other studies of the IANB using a traditional syringe.

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The authors deny any conflicts of interest related to this study.

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