SUPPLEMENTAL INTRASEPTAL ANESTHESIA IN PATIENTS WITH SYMPTOMATIC IRREVERSIBLE PULPITIS

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By
Stephen W. Webster, Jr., D.D.S.
Graduate Program in Dentistry
The Ohio State University
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Master’s Examination Committee:
Melissa Drum, D.D.S., M.S., Advisor
   Al Reader, D.D.S., M.S.
   John Nusstein, D.D.S., M.S.
   Sara Fowler, D.M.D., M.S.
   F. Michael Beck, D.D.S., M.A.
ABSTRACT

Introduction: Previous studies have reported high levels of success with the intraseptal injection for various dental procedures but provide limited focus on the use of the injection during endodontic treatment. Therefore, the purpose of this prospective study was to determine the anesthetic efficacy of the supplemental intraseptal technique in mandibular posterior teeth diagnosed with symptomatic irreversible pulpitis when the conventional inferior alveolar nerve block (IANB) fails.

Methods: One hundred patients experiencing moderate to severe pain with a symptomatic irreversible pulpitis in a mandibular posterior tooth were recruited. Following profound lip numbness after the administration of the conventional IANB, patients still experiencing moderate to severe pain during treatment were administered mesial and distal intraseptal injections, each with 0.7 mL of 4% articaine with 1:000,000 epinephrine, using the computer controlled local anesthetic delivery device. Success was defined as the ability to perform endodontic access and instrumentation with mild to no pain.

Results: Initial success with the IAN block was achieved in 25% of patients. The intraseptal injection was administered to 73 patients with moderate to severe pain
following profound lip numbness with the IANB. The intraseptal injection provided success in 21 out of 73 (29%) of patients.

**Conclusions:** Although the supplemental intraseptal injection achieved profound pulpal anesthesia in 29% of patients when the IANB failed, this low level of success did not provide predictable levels of anesthesia for patients requiring emergency endodontic treatment for symptomatic irreversible pulpitis in a mandibular posterior tooth.
DEDICATION

To Mom and Dad for believing in me and helping me to believe in myself. The confidence, support, and love you have given me make me feel like anything is possible.

To my four beautiful and amazing sisters who inspire me and support me in every way. I couldn’t be more proud of you and I owe so much of who I am to the love you have all given me.

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VITA

May 28, 1987……………………………………………………... Born: Mansfield, OH

April 2008……………………………………………………….. Bachelor of Science, Biology
Captain Men’s Tennis Team
Walsh University
North Canton, OH

June 2012……………………………………………………….. Doctor of Dental Surgery
The Ohio State University
College of Dentistry
Columbus, OH

August 2015…………………………………………………….. Specialization in Endodontics
Post-Doctoral Certificate
The Ohio State University
College of Dentistry
Columbus, OH

FIELD OF STUDY

Major Field: Dentistry
Specialization: Endodontics
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Chapter 1

INTRODUCTION

INFERIOR ALVEOLAR NERVE BLOCK (IANB)

Obtaining profound pulpal anesthesia is important to both general practitioners and endodontists alike for restorative and endodontic procedures. The standard and most common means of attempting to achieve pulpal anesthesia in a mandibular posterior tooth is through the administration of the inferior alveolar nerve block (IANB). Pulpal anesthesia may be defined in several different manners but anesthetic success for a nerve block in asymptomatic subjects can be defined as ‘the percentage of patients who have no response to electric pulp test (EPT) readings (two consecutive 80 readings) within 15 minutes of injection and continuously sustain the 80 reading for 60 minutes’.\(^1\) When using this definition of success and comparing the conventional administration of 1.8 mL of 2% lidocaine with 1:100,000 epinephrine for the IANB in asymptomatic subjects, success varies throughout the posterior mandible from 51% in the first molar to 65% in the second molar.\(^1\) It is important to note that in the above reference the values for success only include patients presenting with profound lip numbness, the traditional
means of determining the onset and success of the IANB in dentistry. This is important because it becomes easy to see that even with profound lip numbness in asymptomatic subjects, profound anesthesia in the posterior mandible is often not achieved with the IANB.

When related to endodontically treating posterior mandibular teeth in symptomatic patients, achieving adequate anesthesia with the IANB alone may be even more difficult. Compared to the success rates of the IANB, as tested with the EPT as noted above, previous studies have shown the success of the IANB in patients with symptomatic irreversible pulpitis (success defined as no to mild pain upon access and endodontic instrumentation) to be even less. With a success rate of only 13-57% for the conventional IANB during endodontic treatment for patients with lower posterior irreversible pulpitis\textsuperscript{1-11}, other measures are needed to provide a less painful treatment. Many of these studies focused on ways to improve the success of the traditional IANB in symptomatic irreversible patients or to supplement the IANB with other methods of delivering local anesthetics.

Research completed on ways to improve the success of the IANB for endodontic procedures includes the administration of different oral medications before the delivery of the IANB\textsuperscript{2-4,9,12-13}, administration of different anesthetic solutions and combinations given for the IANB\textsuperscript{8,10,14-18}, and the administration of nitrous oxide before giving the IANB.\textsuperscript{19} Some of the preoperative medications studied to improve the success of the IANB include 0.25 mg of sublingual triazolam 30 minutes before administration of the IANB\textsuperscript{2}, 800 mg of ibuprofen 45 minutes before the IANB\textsuperscript{3}, and the combination of 800
mg ibuprofen with 1000 mg acetaminophen 45 minutes before the IANB. Additionally Jena and co-authors studied the effect of preoperative administration of a placebo versus 600 mg of ibuprofen, 10 mg of ketorolac, 400 mg etodolac with 500 mg paracetamol, or 100 mg of aceclofenac with 500 mg of paracetamol. In the study by Jena, the medications were given 30 minutes before the administration of the IANB in patients with symptomatic irreversible pulpitis in a mandibular posterior tooth. All of the above studies investigating the effect of pre-operative medications on the efficacy of the IANB in patients with symptomatic mandibular posterior irreversible pulpitis, and other similar studies completed by Rodriguez-Wong and by Aggarwal, failed to show a statistically significant increase in the success of the IANB.

Another area of research has been the administration of different anesthetic combinations and injection solutions for the IANB in hopes to improve on the success of the block in patients with symptomatic irreversible pulpitis in the mandible. In a study comparing the efficacy of different epinephrine concentrations on the effect of a 2% lidocaine solution for IANB injections in patients with irreversible pulpitis, Aggarwal and co-authors found no significant difference between 1:80,000 or 1:200,000 epinephrine concentrations. Cohen and co-authors even found that there was no significant difference in anesthetic success in patients with symptomatic irreversible pulpitis between 3% mepivacaine or 2% lidocaine with 1:100,000 epinephrine for the IANB. Claffey et al. did not show any improved success for the IANB with the administration of 4% articaine versus 2% lidocaine (both with 1:100,000 epinephrine) for the IANB in patients with symptomatic irreversible pulpitis. Other studies showed the anesthetic success of 4%
articaine with 1:100,000 epinephrine for the IANB to be only 24% and 37%. When comparing the success of the IANB with the addition of 36 mg of meperidine to a 2% lidocaine with 1:100,000 epinephrine solution versus 2% lidocaine with 1:100,000 epinephrine for the IANB in patients with symptomatic irreversible pulpitis, Bigby and co-authors found no difference between the solutions. Likewise, Saatchi and co-authors studied the effect of buffering the anesthetic given for an IANB in patients with irreversible pulpitis by adding 0.18 mL of 8.4% sodium bicarbonate to a two cartridge solution of 2% lidocaine with 1:100,000 epinephrine and administering the block. The authors of this study found no significant difference in success of a buffered versus a non-buffered solution for the IANB in patients with irreversible pulpitis. A study by Schellenberg and co-authors, completed in patients with symptomatic irreversible pulpitis in mandibular posterior teeth, also found no significant difference in the efficacy of IANB whether patients received a buffered (with 8.4% sodium bicarbonate) or non-buffered IANB injection of 2.8 mL of 4% lidocaine with 1:100,000 epinephrine. While Shetty and co-authors found a significant increase in the success of the IANB in patients with symptomatic irreversible pulpitis when an IANB injection of 1 mL of magnesium sulfate USP 50% was administered one hour before a conventional IANB of 1.8 mL of 2% lidocaine with 1:100,000 epinephrine, the success with the IANB plus magnesium sulfate was still only 58%. Similarly, Kreimer and co-authors found increased success of the IANB in patients with symptomatic irreversible pulpitis with the addition of 0.5 mol/L of mannitol to a conventional lidocaine injection used for the IANB. However, even with the increased success, the IANB solution containing mannitol still only
provided success in 39% of patients, not enough to reliably provide pulpal anesthesia for patients during endodontic treatment of mandibular posterior teeth with symptomatic irreversible pulpitis.6

Other studies have studied anesthetic volume or changing the speed of injection has little effect on the success of the IANB in patients with symptomatic irreversible pulpitis.7,22-23 Kanaa and co-authors found that following a failed IANB for patients with symptomatic irreversible pulpitis, repeating the injection only resulted in a 32% rate of success.22 In a review of seven other studies involving symptomatic irreversible pulpitis, Fowler et al. showed that increasing the anesthetic volume between 1.8 mL of 2% lidocaine with 1:100,000 epinephrine and 3.6 mL of 2% lidocaine with 1:100,000 epinephrine made no significant difference in the efficacy of the injection.23 In another study by Aggarwal and co-authors, there was no statistically significant difference found in the success of IANB in patients with symptomatic irreversible pulpitis with 3.6 mL of 2% lidocaine with 1:100,000 epinephrine whether the injections were given at a rapid pace (30 seconds) or slow pace (120 seconds).7

Stanley and co-authors found that the administration of 30-50% nitrous oxide for five minutes before the administration of the IANB significantly improved the success of the IANB for treatment of patients with symptomatic irreversible pulpitis from 28% without nitrous up to 50% with nitrous.19 However, it is worth noting that a success rate of 50% is still an unreliable and insufficient means of achieving an adequate level of anesthesia for patients during endodontic treatment.19
Looking at the given information it becomes clear that even with the addition of oral medications, the use of various anesthetic solutions for the IANB injection, or with the administration of nitrous oxide, the conventional IANB alone is not enough to reliably provide successful anesthesia for endodontic treatment in patients presenting with mandibular symptomatic irreversible pulpitis without further supplemental anesthesia.

**SUPPLEMENTAL ANESTHESIA**

Supplemental injections are essential when pulpal anesthesia from the IANB is inadequate and the pain is too severe for the endodontist to proceed. Several different supplemental injections have been described and studied for their effect on both asymptomatic and symptomatic teeth for pulpal anesthesia. Among these supplemental injection techniques are buccal infiltrations, intraosseous injections, and periodontal ligament injections.

**BUCCAL INFILTRATION (BI)**

Buccal infiltration (BI) has been studied thoroughly as a primary means of pulpal anesthesia in mandibular posterior teeth. However, given the success rate and short duration of action for pulpal anesthesia when used alone, BI is generally used as a supplemental injection during endodontic treatment. In a study completed by Monteiro and co-authors, the efficacy of BI with 4% articaine with 1:100,000 epinephrine versus the efficacy of an IANB with 2% lidocaine with 1:100,000 epinephrine was compared in patients with symptomatic irreversible pulpitis in a mandibular posterior tooth. This study
found a higher success rate with the buccal infiltration alone versus the IANB alone, but with success rates for each injection not higher than 40%, pain-free endodontic treatment was unable to be achieved with single technique anesthesia. Supplemental techniques were needed to improve success rates.\textsuperscript{24}

In a study comparing buccal infiltration as a supplemental injection after a successful IANB failed to provide adequate anesthesia in patients with mandibular symptomatic irreversible pulpitis, Rogers and co-authors found the success rate for supplemental BI with 4% articaine with 1:100,000 epinephrine to be statistically superior to BI with 2% lidocaine with 1:100,000 epinephrine (62\% vs. 37\%).\textsuperscript{16} In a similar study on patients with mandibular symptomatic irreversible pulpitis comparing the efficacy of either 1.8 mL or 3.6 mL of 4% articaine with 1:100,000 epinephrine after the IANB failed to provide adequate anesthesia for endodontic treatment, Singla and co-authors found no significant difference between the solutions.\textsuperscript{17} Additionally, Singla et al found the BI in combination with the IANB to be successful in only 62-64\% of patients.\textsuperscript{17} Matthews et al found the success of a supplemental buccal infiltration of 1.8 mL of 4% articaine with 1:100,000 epinephrine following failed IANB in patients with symptomatic irreversible pulpitis to be 58\%.\textsuperscript{5} Other studies evaluating the success of a buccal infiltration of articaine following IANB failure in patients with symptomatic irreversible pulpitis have found success for the buccal infiltration ranging from 37-54\%.\textsuperscript{3-4,18,19,25} Separate studies by Fan et al and Kanaa et al evaluated the success of various supplemental injections for patients with irreversible pulpitis, and reported success with buccal infiltration following IANB in 81-84\% of cases.\textsuperscript{22,26}
INTRAOSSEOUS (IO)

The intraosseous (IO) injection is a commonly used injection technique in endodontics and its use has become more widespread in recent years. The IO injection allows the dental provider to administer local anesthetic solution directly into the porous cancellous bone around the tooth desired to be anesthetized by means of a port (X-tip™; Dentsply, York, PA) or perforating system (Stabident®; Fairfax Dental Inc., Miami, FL). A study completed by Gallatin and co-authors showed no difference in the effectiveness between the two systems.27

Razavian and co-authors compared the intraosseous injection with a traditional IANB as the primary anesthetic for patients with irreversible pulpitis. After administration of 1.8 mL of 2% lidocaine with 1:100,000 epinephrine for either the IANB or IO injection, subjects were pulp tested with EPT and the authors found that the IO had a higher rate of success than the IANB for primary anesthesia in patients with symptomatic irreversible pulpitis, though there was no significant difference.28

Other studies have looked at the IO injection as a supplemental injection in patients with symptomatic irreversible pulpitis when the IANB has failed to achieve adequate levels of pulpal anesthesia. Nusstein et al. administered a conventional IANB for patients with symptomatic irreversible pulpitis in the lower posterior region. Supplemental anesthesia was needed in 80% of the patients studied. For patients who experienced cold sensitivity to testing after the IANB or moderate to severe pain upon endodontic access, an IO injection of 1.8 mL of 2% lidocaine with 1:100,000 epinephrine
was administered using the Stabident® system. Anesthetic success in the study by Nusstein for the IO injection as a supplemental injection to the IANB was seen in 90% of patients. When studied by Verma and co-authors in 30 patients with mandibular symptomatic irreversible pulpitis experiencing moderate to severe pain upon endodontic access after receiving a traditional IANB, they found the administration of 2% lidocaine with 1:80,000 epinephrine through the X-Tip™ IO injection system to have a 93% success rate.

In a study by Pereira and co-authors, the efficacy of X-Tip™ IO injections as a means of supplemental anesthesia when the IANB failed for patients with symptomatic irreversible pulpitis was evaluated using 4% articaine concentrations with both 1:100,000 epinephrine and 1:200,000 epinephrine. Pereira found success rates of 96.8% for supplemental IO injections using 4% articaine with 1:100,000 epinephrine and 93.1% with the 1:200,000 epinephrine solutions. In a similar study using 4% articaine with 1:100,000 adrenaline, Bhuyan et al found a success rate of over 83% for IO as a supplemental injection when the IANB failed to provide adequate anesthesia for endodontic treatment.

In the study by Verma et al, injection pain for the intraosseous technique was reported as moderate to severe in 25% of patients. Another study found the needle insertion to be the most painful part of the IO injection with 14% of subjects rating it as moderately to severely painful.

PERIODONTAL LIGAMENT INJECTION (PDL)
The PDL injection has previously been studied for its use as a supplemental injection in patients with mandibular symptomatic irreversible pulpitis. In one of these studies, Nusstein and coauthors used the C-CLAD™ (Milestone Scientific, Deerfield, IL) to administer 1.4 mL of 2% lidocaine with 1:100,000 epinephrine to patients with mandibular irreversible pulpitis after the conventional IANB had failed. Of the patients who received the PDL injection in the previously mentioned study, adequate pulpal anesthesia was achieved in 56% of patients, allowing them to undergo emergency root canal therapy with no to mild pain. When Cohen and co-authors studied the supplemental PDL injection in patients with irreversible pulpitis following failed IANB, a 72% success rate was found. However, in Cohen’s study not all patients were symptomatic and success was defined as no response to pulp testing, (rather than no pain on endodontic access). In a study performed by Fan et al. a conventional IANB was administered followed then by supplemental BI or PDL injections of 0.4 mL of 4% articaine with 1:100,000 epinephrine. The authors found a success rate of over 81% for the IANB with BI group and over 83% for PDL injection when given after the IANB. While these results for success of BI are higher than most studies, including those previously mentioned, it is important to note that success rates reported by Fan et al included all patients who would have achieved adequate anesthesia with the IANB alone since the supplemental injections were given following IANB without determining IANB success. Also, the high success rates found by Fan for the PDL injection had no statistically significant difference as a supplemental injection compared to the BI and still
had a lower success rate than what has been reported by some of the supplemental intraosseous studies.\textsuperscript{3,29,31,34}

In another study looking at PDL injections, a previously mentioned study by Kanaa and co-authors evaluated the efficacy of repeated IANB versus supplemental buccal infiltration, intraosseous injection, or periodontal ligament injection in patients with irreversible pulpitis after the initial IANB had failed to deliver adequate anesthesia.\textsuperscript{22} In Kanaa’s study, if the IANB failed to provide adequate anesthesia, patients were randomly administered another IANB injection, 2 mL of 4% articaine with 1:100,000 epinephrine for buccal infiltration, 1 mL of 2% lidocaine with 1:80,000 epinephrine for IO injection, or PDL injection of 0.18 mL of 2% lidocaine with 1:80,000 epinephrine for each root of the tooth being treated. Kanaa’s study found high success rates for the buccal infiltration and IO injection (84% and 68% respectively), but found that supplemental PDL injections and repeated IANB had significantly lower success (48% and 32% respectively).\textsuperscript{22}

In a study to compare the efficacy of PDL supplemental injection to that of IO supplemental injection for patients with symptomatic irreversible pulpitis and inadequate anesthesia after administration of the IANB, Zarei et al found the PDL injection to be significantly less successful than the IO injection (70% for PDL versus 100% for IO).\textsuperscript{35} Although it is important to note that different volumes of anesthetic, types of anesthetic, and armamentarium used for the PDL injection have been studied and reported in the previously mentioned research, supplemental PDL injection for patients with irreversible
pulpitis is variable and may still be inferior to the IO supplemental injection for mandibular symptomatic irreversible pulpitis.

**INTRASEPTAL INJECTION**

Another injection that has been studied for its use in dentistry as both a primary and supplemental injection is the intraseptal injection. Intraseptal anesthesia is the deposition of the anesthetic solution directly into the interdental septum allowing solution to flow through the porous crestal alveolar bone and hence into the medullary bone surrounding the tooth. Intraseptal anesthesia has been evaluated previously.\(^{36-44}\) Success rates in previous studies have varied from 76% to 90% depending on how success was measured (extractions, restorative procedures, and experimental monitoring with an electric pulp tester). Heart rate increases have been reported in some studies\(^{37,39,40}\) but found insignificant in others.\(^{38}\)

The injection technique has been described by various authors with a variety of armamentarium, all with the same result in mind: to inject the anesthetic solution in the interdental papilla through the crestal bone with adequate pressure that facilitates the diffusion of the solution through the medullary bone. The injection is further described by Saadoun as being given in buccal keratinized tissue at a point “located at the center of the papillary triangle…equal distance from the adjacent teeth”.\(^{44}\) Saadoun goes on to recommend the orientation of the needle at a 90 degree angle to the soft tissue with the bevel of the needle directed apically.\(^{44}\) In a 2005 review of the injection technique by Woodmansey, the author suggests advancing the needle ‘until it contacts the underlying
bone’, impaling the osseous crest, and then firmly advancing into the interdental septum where the anesthetic should be delivered. Woodmansey also recommended repeating the intraseptal injection at mesial and distal aspects of the tooth desired to be anesthetized, as well as on the lingual papilla to gain complete pulpal anesthesia.

While some authors recommend the use of a Ligmaject® (Henke-Sass Wolf, Dudley, MA) or intraligamental syringe (N-tralig® Intraligamental Anesthetic Syringe, Septodont, France), and Woodmansey describes the injection using a standard anesthetic syringe, Biocanin and co-authors studied the injection using a computer-controlled local anesthetic delivery system (C-CLAD™). Biocanin states the “benefits in using controlled delivery approaches include improved pharmacokinetic response, greater ability to localize the drug adjacent to the place of action, and more control of local concentrations at a lower total dosage”.

The C-CLAD™ has been studied extensively for its benefit in use for controlled delivery of local anesthetics, decreased injection pain, and efficacy in various injection techniques. The C-CLAD™ allows for an injection to be given under a standardized and steady backpressure that is not affected by the operator as flow rate is controlled by a foot pedal and mechanized pump (See Materials and Methods). Studies using the C-CLAD™ in administration of the PDL injection, which is similar to the intraseptal injection in its aim to deliver anesthetic in a pressure driven manner into the porous cancellous bone around the tooth, have illustrated varied success with the use of the C-CLAD™. In a study by Jing et al using the C-CLAD™ to administer PDL injections in the posterior mandible to patients with symptomatic irreversible pulpititis, found a 76%
success rate.\textsuperscript{45} In the previously mentioned study by Nusstein and co-authors, a 56% success rate was found when the C-CLAD\textsuperscript{TM} was used to administer a supplemental PDL injection to patients with symptomatic irreversible pulpitis in mandibular posterior teeth when the IANB failed to provide profound pulpal anesthesia.\textsuperscript{33} Due to the ease of administration, ability to control backpressure and flow rate, and previous use in studies for PDL and intraseptal injections, the C-CLAD\textsuperscript{TM} was used for the delivery of the intraseptal injection in this study.

When considering the size of needle to select for the intraseptal injection, there is a considerable difference in sizes reported in the literature. Some authors\textsuperscript{36,38,42} recommend the use of a 30-gauge short needle, while others\textsuperscript{37,44} suggest using a stronger 27-gauge short needle. Saadoun et al describe using the 27-gauge short needle because “the needle should be thin enough to penetrate the alveolar crestal bone of the interdental septum and, at the same time, be rigid enough to prevent its bending during the injection”.\textsuperscript{44} The primary author of this study investigated the injection clinically on cadaver and live subjects before beginning this study to further assess the appropriate gauge and length of needle to use in order to insert the needle with enough force into the bony area without significant needle bending or deflection. The author determined that a 27-gauge, ½ inch needle was the smallest needle strong enough to allow for some cortical plate perforation. Therefore, a 27-gauge short (½ inch) needle was used for the delivery of the intraseptal injection in this study.

Furthermore, several different anesthetic solutions have been recommended for intraseptal anesthesia in literature. Marin recommends the use of 2% lidocaine with
1:100,000 epinephrine for shorter procedures and 2% lidocaine with 1:50,000 for appointments requiring longer anesthesia as in some endodontic procedures. In their study of intraseptal anesthesia for periodontal surgery, Saadoun and Malamed also used 2% lidocaine with 1:50,000 epinephrine. However, Woodmansey’s review on the injection technique stated he prefers 4% articaine with 1:100,000 epinephrine. Biocanin et al used 4% articaine with 1:100,000 epinephrine with high success rates for pulpal anesthesia, and argue that the intraseptal injection is similar to that of an intraosseous injection with success “depending on the penetration of the local anesthetic through the alveolar bone”. Biocanin goes on further to state his case for the use of articaine in that ‘unlike other amide-type local anesthetics, articaine contains a thiophene ring as the aromatic moiety and aromatic methoxycarbonyl substitute. The presence of the methoxycarbonyl-substituted thiophene is generally accepted to contribute to a higher lipophilicity of articaine compared to other amino amide local anesthetics, which gives articaine a better ability to penetrate bone and other tissues’. Due to this and other evidence of the superior bone penetration of articaine when compared to lidocaine, 4% articaine with 1:100,000 epinephrine was used for the intraseptal anesthesia in this study.

The variety in the armamentarium suggested for intraseptal anesthesia highlights, as Woodmansey points out, that “the materials employed are less important for success than the injection technique itself”. However, no study has investigated the efficacy of intraseptal anesthesia when used as a supplemental technique in patients with symptomatic irreversible pulpitis. Therefore, the purpose of this prospective study was to determine the anesthetic efficacy of the supplemental intraseptal technique in mandibular
posterior teeth diagnosed with symptomatic irreversible pulpitis when the conventional IAN block failed.
Chapter 2

MATERIALS AND METHODS

Patients recruited for this study were adult emergency patients of the College of Dentistry who were deemed to be in good health as determined by a health history and oral questioning. All patients included in this study had to meet the following criteria: 18 to 65 years of age; in good health (ASA classification I or II); informed consent granted. Exclusion criteria were: allergy to local anesthetics; history of significant medical problems (ASA classification III or greater); having recently taken CNS depressants (including alcohol or any analgesic medications within 6 hours prior to treatment); pregnancy; lactating; or inability to give informed consent. The Ohio State University Human Subjects Review Committee approved the study and written informed consent was obtained from each patient. After completion of the medical history and consent form, subjects completed the Corah’s Dental Anxiety Scale questionnaire.50

To qualify for the study, each patient had a vital mandibular posterior tooth (molar or premolar), was actively experiencing pain, and had a prolonged response to cold testing with Endo-Ice® (1,1,2 tetrafluoroethane; Hygenic Corp., Akron Ohio).
Patients with no response to cold testing, periradicular pathosis (other than a widened periodontal ligament), or no vital coronal pulp tissue upon access were excluded from the study. Therefore, each patient had a tooth that fulfilled the criteria for a clinical diagnosis of symptomatic irreversible pulpitis.

After obtaining informed consent, patients were asked to rate his or her initial pain on a 170 mm Heft Parker Visual Analog Scale (VAS). The VAS was divided into four categories. No pain corresponded to 0 mm. Mild pain was defined as greater than 0 mm and less than or equal to 54 mm. Mild pain included the descriptors of “faint”, “weak”, and “mild” pain. Moderate pain was defined as greater than 54 mm and less than 114 mm. Severe pain was defined as equal to or greater than 114 mm. Severe pain included the descriptors of “strong”, “intense” and “maximum possible”.

Patients were then given topical anesthetic (20% benzocaine; Benco Dental, Wilkes-Barre, PA) applied with a cotton-tip applicator at the site of inferior alveolar nerve block (IANB) for one minute. During this time, patients were instructed how to rate the pain of the IANB injection using the VAS form provided. The patients were informed that the operator would say three specific words that signaled different steps in the injection, while administering the IANB injection. Patients were asked to note the level of pain felt at each step of the injection (needle insertion, needle placement, and solution deposition) and then to rate that level of pain using the provided VAS following completion of the injection (Appendix G). Following patient acknowledgement of understanding of the VAS, each patient received a conventional IANB using a cartridge of 2% lidocaine with 1:100,000 epinephrine using a 27-gauge 22 mm needle (Monoject,
Mansfield, MA). No anesthetic was administered during needle insertion or needle placement phases and solution deposition took place over approximately one minute. Initial success of the IANB was determined by lip numbness within fifteen minutes of anesthetic administration. The provider verbally questioned the patient every five minutes for fifteen minutes, or until lip numbness was apparent. Patients that did not achieve complete lip numbness within fifteen minutes were disqualified from participation in the study but endodontic treatment was still performed after achieving adequate anesthesia. Following lip numbness, topical anesthetic (20% benzocaine) was placed in the buccal vestibule apical to the second molar in the area of the long buccal nerve for one minute. Then one-half cartridge of 2% lidocaine with 1:100,000 epinephrine was administered as a long buccal infiltration to ensure comfort during rubber dam placement. Patients were not asked to rate injection pain for this injection. The rubber dam clamp and dam were placed and endodontic treatment was initiated. Patients were asked to rate their pain during access or instrumentation on the VAS. If the IANB failed to provide adequate pulpal anesthesia during treatment (patient experienced moderate to severe pain during access or instrumentation), treatment was paused and the patient was asked to rate their pain using the VAS corresponding to the point during treatment (dentin, pulp, or instrumentation) in which they felt moderate to severe pain (Appendix H). Two patients, both treated during the first half of data collection within the study, experienced moderate to severe pain during treatment after receiving the IANB but did not tell the provider they were experiencing such pain until after treatment was complete. These patients were considered IANB failures since treatment caused moderate to severe pain, but further
supplemental anesthesia was not administered. All other patients experiencing moderate
to severe pain upon access or instrumentation received a supplemental intraseptal
injection.

The intraseptal injection was administered using 1.4 mL of 4% articaine with
1:100,000 epinephrine (Septocaine; Septodont, New Castle, DE). The anesthetic was
delivered using a C-CLAD™ (Computer Controlled Local Anesthetic Delivery system;
Milestone Scientific, Deerfield, IL) unit. This system is a microprocessor-driven device
that delivers a controlled infusion of anesthetic solution. The unit accepts standard glass
dental anesthetic cartridges. The microprocessor monitors and varies the infusion
pressure while maintaining a constant flow rate. An electronically driven plunger
contacts the rubber plunger in the cartridge and expels the anesthetic solution at a
precisely regulated rate. Sterile tubing connects the cartridge receptor to a pen-like,
hand-held plastic wand that is attached to a Luer-Lok needle, together forming a
disposable syringe assembly. A small portion of solution from a standard cartridge is lost
during the purge cycle and some of the solution remains in the cartridge and tubing, thus
only 1.4 mL of anesthetic solution from a standard cartridge is delivered using the C-
CLAD™ unit. Flow rate, initiation and cessation of flow, and aspiration are controlled
with a foot pedal. To prevent cross-contamination, the handpiece, micro tubing and
anesthetic cartridge are designed for single patient use only.

For the C-CLAD™ system in this study, a cartridge of the 4% articaine with
1:100,000 epinephrine was placed into the plastic barrel of the unit’s handpiece assembly,
and then placed into the cartridge holder socket with a quarter turn in a counter clockwise
direction. The cap was removed from the 25-gauge ½-inch Luer-Lok needle (Monoject; Sherwood Services, Mansfield, MA) and the foot pedal was depressed once to activate the purge cycle to remove air from the plastic tubing and fill the line with anesthetic solution.

The computer-assisted supplemental intraseptal injection was administered as follows. The patient was placed in a supine position. The 25-gauge ½-inch Luer-Lok needle was inserted through the middle of the intradental papilla on the mesial aspect of the involved tooth until bone was contacted. The needle was inserted with an approximate 30-degree angle to the long axis of the tooth in a buccal-lingual plane and the bevel of the needle was faced inferiorly (needle insertion phase). The operator then slowly placed the needle into the crestal bone with continuous pressure until it could not be advanced any further (needle placement phase). Approximately 0.7 mL of the anesthetic solution was deposited using the slow rate setting of the C-CLAD™ (solution deposition phase). That is, the computer-assisted injection system was activated at a slow rate (by partially depressing the foot pedal) for 8 seconds. By removing the foot from the foot pedal, the computer-assisted injection system unit was activated on continuous flow of anesthetic solution at the slow rate. One chime from the computer-assisted injection system machine corresponds to one second, allowing audible monitoring of the elapsed time. Approximately 1 drop of anesthetic solution is delivered every other second on the slow setting. Visually monitoring the green lights on the unit and audibly monitoring the corresponding chimes determined when the deposition of solution was complete. The time to administer 0.7 mL of anesthetic solution was approximately 2 minutes. The
author then waited 10 seconds before slowly removing the needle from the injection site. The patient was then asked to rate the pain of the injection, as was explained previously and reinforced during the injection, using three separate VAS forms for the three phases of the injection (needle insertion, needle placement, solution deposition (Appendix I). The intraseptal injection was then repeated on the distal aspect of the involved tooth using the same technique and sequence of steps outlined above and the patient was asked again to rate the pain of the injection. The amount of anesthetic solution delivered with the distal injection was approximately 0.7 mL.

For both injection sites, the author had direct vision of the injection site to monitor if anesthetic solution was expressed from the papilla. If notable solution escaped, depressing the foot pedal briefly stopped the flow of anesthetic solution and the needle was rotated with firm apical pressure into the papilla. If the needle became deformed, it was replaced with a new 27-gauge ½-inch needle.

Endodontic treatment continued and patients were instructed to notify the operator if they felt any pain during the endodontic procedure. If the patient experienced pain, the treatment was immediately stopped and the patient again rated their discomfort using the Heft-Parker visual analogue scale. The extent of access achieved when the patient felt pain was recorded as within dentin, entering the pulp chamber, or initial instrumentation. The success of the intraseptal injection was defined as the ability to access and instrument the tooth without pain (VAS score of zero) or mild pain (VAS rating less than or equal to 54 mm). Again, during the first half of data collection within the study, four patients experienced moderate to severe pain during treatment after receiving the intraseptal
injection but did not tell the provider they were experiencing such pain until after treatment was complete. These patients were considered intraseptal failures since treatment caused moderate to severe pain, but further supplemental anesthesia was not administered. All other patients experiencing moderate to severe pain upon access or instrumentation following the intraseptal injection received a supplemental buccal infiltration injection.

If the patient experienced moderate or severe pain, and rated the pain during treatment, instead of at the completion of treatment, a buccal infiltration with one cartridge of 4% articaine with 1:100,000 epinephrine was administered. For the buccal infiltration injection the patient was again asked to rate the pain of the injection using the VAS for needle insertion, needle placement, and solution deposition. The rubber dam was removed and the buccal infiltration was administered with a 27-gauge 22 mm needle advanced through the alveolar mucosa towards an area at or near the root apices of the involved tooth and the full cartridge was administered over a one minute period as outlined by Matthews et al. The operator then waited 5 minutes before replacing the rubber dam and continuing with treatment. If moderate or severe pain was felt during treatment, the level of pain and the corresponding phase of access (in dentin, in pulp chamber, or during instrumentation) was noted and treatment was halted. During the first half of data collection within the study, one patient experienced moderate to severe pain during treatment after receiving the buccal infiltration but did not tell the provider they were experiencing such pain until after treatment was complete. Buccal infiltration was considered a failure in this patient since treatment caused moderate to severe pain, even
though further supplemental anesthesia was not administered. All other patients experiencing moderate to severe pain upon access or instrumentation following the buccal infiltration received a supplemental intraosseous injection.

After removal of the rubber dam, one cartridge of 2% lidocaine with 1:100,000 epinephrine was administered with the intraosseous injection using the Stabident® system (Fairfax Dental Inc., Miami, FL) as outlined by Nusstein et al. The intraosseous injection was administered distal to the tooth in question unless the tooth being treated was a second or third molar since Coggins et al found successful second molar anesthesia with administration of intraosseous injection mesial to the second molar. Patients were again asked to rate the pain felt during the injection using the Heft-Parker VAS; the rubber dam was replaced and treatment continued. If moderate or severe pain was felt the procedure was stopped. The patient was asked to rate their pain using the same VAS corresponding to the level of access obtained and an additional intraosseous injection was administered on the mesial aspect of the tooth (distal aspect for second molars and mesial aspect repeated for third molars due to anatomic considerations).

During the first half of data collection within the study, two patients experienced moderate to severe pain during treatment after receiving the first intraosseous injection but did not tell the provider they were experiencing such pain until after treatment was complete. The first intraosseous injection was considered a failure in these patients since treatment caused moderate to severe pain, but further supplemental anesthesia was not administered. All other patients experiencing moderate to severe pain during treatment following the first intraosseous injection received a second intraosseous injection. The
second intraosseous injection was administered with the Stabident® system and one cartridge of 2% lidocaine with 1:100,000 epinephrine was used. The rubber dam was then replaced and treatment continued. If moderate or severe pain was felt during treatment, the level of pain and the corresponding phase of access (in dentin, in pulp chamber, or during instrumentation) was noted and treatment was halted.

If after two separate intraosseous injections adequate anesthesia was not achieved, additional supplemental anesthesia was administered in the form of periodontal ligament (PDL) injections. After rubber dam removal, PDL injections were administered using the C-CLAD™ with a 25-gauge ¼-inch Luer-Lok needle to deliver ¼ cartridge of 2% lidocaine with 1:100,000 epinephrine mesial to the tooth receiving treatment and ¼ cartridge of anesthetic distal to the tooth. The injection was administered with the needle oriented in the long axis of the tooth and the needle was advanced to the depth of the periodontal pocket or until bone was sounded. The C-CLAD™ was used during administration of the PDL injection to allow the operator to administer the injection with appropriate back pressure and delivery of the proper levels of anesthetic into the periodontal sulcus. After completion of both the mesial and distal portions of the PDL injection, the patient was asked to rate the overall pain upon needle insertion, needle placement, and solution deposition for the two PDL injection sites. Following PDL injection, the rubber dam was immediately replaced and treatment continued. If the patient felt moderate or severe pain during treatment the procedure was immediately stopped and rubber dam was removed. The patient was then asked to rate their pain using
the Heft-Parker VAS that corresponded to the appropriate point of treatment that was reached prior to stopping the procedure.

At this point, if endodontic access had reached the pulpal tissue and all other supplemental injections had failed to allow the operator to complete debridement without moderate or severe pain, 2% lidocaine with 1:100,000 epinephrine was administered intrapulpally with a standard 27-gauge short needle under significant backpressure. The intrapulpal injection was administered within the endodontic access in the direction of the canal orifices if they had already been located during access. Administration was focused in areas of the access that proved to be painful during access or instrumentation (i.e. specific orifices or canals). After the intrapulpal injection was complete, the patient was asked to rate the pain upon injection in the same manner as previous injections. If the patient was still feeling moderate or severe pain when treatment continued, or if endodontic access had not yet reached the pulp chamber (so as intrapulpal anesthesia was not possible), and all other supplemental injection techniques had failed, the patient was given the option to terminate the procedure or to continue with the procedure, despite their pain level.

After emergency endodontic treatment was completed, the principal investigator explained the use of the VAS satisfaction form and patients rated the degree of satisfaction with the treatment using the analog scale for assessing satisfaction (0 to 100 mm). The VAS for satisfaction was divided into four categories. Not satisfied corresponded to 0. Somewhat satisfied was defined as >0 mm and ≤33 mm. Moderately satisfied was defined as >33 mm but <66 mm. Completely satisfied was defined as ≥66
mm. The patients were also asked to complete a 170 mm VAS for the level of overall pain felt during the procedure. Patients were instructed to complete both ratings at the end of the appointment after the operator had left the room. The operator emphasized that the satisfaction survey would not affect the operator’s grades or standing in the residency and patients were encouraged to be honest in their assessment, as they were throughout the appointment. To maintain anonymity, the satisfaction survey was then given to the front desk staff when checking out.

The data from this study was collected and analyzed. Percent success and 95% confidence intervals for success were calculated for each injection. Confidence intervals were also calculated for injection pain and treatment pain for each injection and phase of treatment.
Chapter 3

RESULTS

One hundred eight patients in moderate to severe pain with an initial diagnosis of symptomatic irreversible pulpitis in a mandibular posterior tooth were enlisted in this study. Two patients were eliminated after failing to report lip anesthesia after administration of the IANB. Two patients were eliminated due to inability to complete the procedure. Four patients were eliminated due to non-vital tissue in the pulp chamber upon access, leaving the total number of patients who completed the research at 100. Sixty-five percent (65/100) of patients who completed the study were female and the mean age of the patients was 34 years old. Table 1 lists the characteristics of the 100 patients that completed the research. The range for anxiety ratings based on Corah’s Anxiety Scale covered the minimum and maximum possible response with a median response of 9, denoting moderate anxiety. All patients treated were required to be symptomatic and initially present with moderate to severe pain. Table 2 illustrates how the many of patients treated were in moderate (45/100) or severe pain before treatment.
(55/100). Tables 3 and 4 illustrate the particular teeth and tooth type treated in the study. Most of the teeth treated were mandibular first and second molars (85 out of 100).

Success was defined as the ability to perform emergency endodontic treatment without moderate to severe pain, rated as pain less than 55 mm on a 170 mm Heft-Parker Visual Analog Scale (VAS). Table 5 shows the success of each anesthetic step performed during treatment. In 25 of 100 patients treated, the IANB was the only anesthesia needed to provide treatment without moderate to severe pain. If treatment was unsuccessful with IANB alone, intraseptal anesthesia was administered. All but two of the 75 patients who failed to achieve successful anesthesia with the IANB alone received supplemental intraseptal anesthesia. A total of 73 of the 75 IANB failures received intraseptal anesthesia, and successful anesthesia was obtained in 21 of those patients yielding a success rate of only 29% with intraseptal anesthesia.

Table 5 further shows the anesthetic success of other supplemental anesthetic techniques used during this research. When intraseptal anesthesia failed, 48 of the 52 intraseptal failures received a buccal infiltration of 4% articaine with 1:100,000 epinephrine. Please refer to the Materials and Methods for further explanation of drop out of patients. Buccal infiltration was successful in 13 of these 48 patients for an overall success rate of 27%. Following buccal infiltration, if patients experienced moderate to severe pain during treatment they were administered an intraosseous injection (IO). Successful anesthesia following buccal infiltration failure was often achieved (59%) with only one IO injection; however 12 patients required a second IO injection (67%). Overall
combined success for the IO injection (either one or two) was seen in 28 of 32 patients, resulting in an IO success of rate of 88%.

Tables 6 and 7 show the results for injection and treatment pain following IANB. Most patients rated IANB injection pain as mild to moderate and patients rated needle placement as the step most often causing severe pain versus any other part of the IANB injection. Due to the non-normal distribution of data, median injection pain and treatment pain values are shown as a measure of central tendency throughout the tables. Tables 8 and 9 show the results for injection and treatment pain related to the intraseptal injection. Overall median pain scores for needle insertion, needle placement, and solution deposition fall into the mild category for both the mesial and distal portions of the injection, with the distal injection pain ratings ranking even lower than the mesial. Table 9 shows that most patients felt no to mild pain during all parts of both mesial and distal intraseptal injections. Similarly Table 10, 11, and 12 show the injection and treatment pain ratings associated with the other observed supplemental injection techniques (buccal infiltration and intraosseous). Patients reported intraosseous injection pain at a higher maximum pain and median pain values than buccal infiltration, however median pain values for both buccal infiltration and IO injections were rated as none to mild pain.

The success of intrapulpal anesthesia was not directly observed during this study as a supplemental injection technique but was administered to one patient that required it. However in Tables 13 and 14, when looking at the location of anesthetic failure (either dentin, pulp chamber, or canal instrumentation), it is possible to determine the number of failures while in dentin that would prevent a practitioner from being able to administer
intrapulpal anesthesia without adequate patient numbness. Sixty-five percent of failures with IANB (49 out of 75) and 40% of failures with intraseptal anesthesia (21 out of 52) occurred in dentin before it would have been possible to administer intrapulpal anesthesia.

All one hundred patients were asked to fill out post treatment pain ratings on a 170 mm VAS related to overall pain felt during treatment. Satisfaction ratings were rated on a 100 mm VAS. Both post treatment ratings were completed without the investigator present and were not viewed until the patient was dismissed. Tables 15, 16, and 17 show the results from these surveys. Although participation in this study often involved multiple injections and failed attempts to provide adequate anesthesia, median pain was rated at 54 mm (equal to the upper boundary of mild pain) with 95% confidence limits of 38 to 61 mm. The median satisfaction was 100 mm (equal to highest possible satisfaction). Sixty-one out of 100 patients rated their satisfaction at the maximum 100 mm. Table 17 shows that 96 out of 100 patients rated their satisfaction as complete satisfaction according to the treatment satisfaction categories.
Chapter 4

DISCUSSION

The purpose of this study was to investigate the efficacy of the intraseptal injection as a supplemental injection technique in providing adequate local anesthesia for root canal therapy in patients with mandibular posterior symptomatic irreversible pulpitis. Since the intraseptal injection is an uncommon and understudied anesthetic technique, the author had to first study the injection before investigating the efficacy in a specific clinical setting. The first step in this process was reviewing previous articles and research related to the injection and the appropriate armamentarium required to perform the injection.

The intraseptal injection, also referred to as transseptal injection in some literature, is an injection of anesthetic solution inserted into the interdental papilla with firm pressure with the aim of penetrating through the crestal bone. Ideally, once the needle is advanced through the crestal bone, anesthetic solution is then deposited into the more porous medullary bone and allowed to diffuse around the tooth in order to provide pulpal anesthesia. Several authors have published literature reviewing the injection technique and/or showing varying degrees of success with the injection.\textsuperscript{36-44}
Although limited publications discuss and investigate the use of the intraseptal injection, in a national survey of endodontic treatment trends, 7% of general dentists reported using a transseptal (or intraseptal) injection routinely for supplemental anesthesia while performing root canal therapy.\(^{56}\)

During this study, intraseptal anesthesia was delivered by administering 0.7 mL of 2% lidocaine with 1:100,000 epinephrine in the interdental papilla region both mesially and distally to the tooth receiving emergency endodontic treatment (for a total of 1.4 mL of anesthetic solution per tooth). The injection was given using the C-CLAD™ in order to control flow rate and further standardize the injection between patients. A ½ inch 25-gauge needle was selected for use as the largest needle that would allow for adequate pressure to be applied through the needle to perforate the cortical bone in the papillary region and yet small enough to make the perforation without the use of a perforating mechanism (X-Tip™ or Stabident®) commonly used in most intraosseous injections.

During the period before initiating the research, the principal investigator determined the appropriate needle length, gauge, and armamentarium by practicing and observing the injection technique on both cadaver models from the pre-doctoral anatomy lab at The Ohio State University and in volunteer subjects from the Advanced Endodontic program.

During needle insertion and placement for the intraseptal injection, various degrees of bony perforation were noted by the principal investigator. As previously mentioned, the needle for the intraseptal injection was inserted into the middle of the intradental papilla and advanced until bone was contacted or the needle could not be advanced any further. However, while administering the intraseptal injection in this
manner the principal investigator noticed bony contact and needle advancement differed among patients. While in some patients the needle appeared to be able to push through the cortical bone and into the intraseptal bone with relative ease, this was not the case in others. Oftentimes, needle advancement was halted immediately after initial bony contact and no further advancement could be made. In these patients it is likely that the solution was never truly deposited intraseptally, therefore potentially inhibiting the ability of the anesthetic solution to diffuse through the bone in the ideal and desired manner to provide adequate pulpal anesthesia. The exact number of times this happened was not recorded by the principal investigator due to the bone penetration being difficult to measure accurately. Other differences noted in depth of needle penetration related to thickness of the papillary tissue, quality or density of bone, and location of the injection (mesial or distal, presence or absence of adjacent teeth, molar or premolar). As mentioned previously, during the administration of the intraseptal injection, if notable solution escaped, the flow of anesthetic solution was stopped and the needle was rotated with firm apical pressure into the papilla to try to further advance the needle and prevent solution loss. Even with differences between patients, if solution was not deposited directly deep into intraseptal bone, full anesthetic volume was still delivered to the tissue. Ensuring full volume was administered regardless of bony penetration helped to standardize and minimize the effect of this variation on the results. During the study, full volume of anesthetic (0.7 mL) was administered in each injection site and each patient.

For deposition of the anesthetic solution during the injection, the C-CLAD™ was used. The C-CLAD™ allowed continuous, controlled, and standardized delivery of the
anesthetic once needle placement and advancement had been achieved. Administration of the intraseptal injection, due to its varied depth of penetration within soft or bony tissue, would require significant backpressure during administration, similar to a PDL injection, in an effort to administer adequate amounts of anesthetic. While some authors recommend the use of a Ligmajec® (Henke-Sass Wolf, Dudley, MA) or intraligamental syringe (N-tralig® Intraligamental Anesthetic Syringe, Septodont, France) commonly used for PDL injections as the route of administration for the intraseptal injection, other authors recommend the use of a standard syringe or C-CLAD™. Biocanin studied the intraseptal injection with high levels of success using the C-CLAD™ for administration and stated the “benefits in using controlled delivery approaches include improved pharmacokinetic response, greater ability to localize the drug adjacent to the place of action, and more control of local concentrations at a lower total dosage”. The C-CLAD™ has also been used in the successful delivery of other anesthetic injections, including the PDL injection, as studied by Nusstein et al, which also aims at delivering anesthetic into the medullary bone around the tooth instead of using a bony perforator. With its history of use with local anesthesia, ability to deliver adequate amounts of local anesthesia in a controlled and slow manner, and previous success when used with supplemental intraseptal and PDL injections, the C-CLAD™ was selected for use in the delivery of the intraseptal injection in this study.

Throughout the study patients were asked to rate the injection pain experienced with each of the injections given. When analyzing the injection pain ratings reported by patients and comparing those to other injection techniques it is important to look at the
patient’s anxiety level and overall pain state prior to the injection, as well how these values relate to values found in comparable studies. If values for anxiety, initial pain, and initial injection pain with IANB are similar across several studies, then it would be reasonable to compare other injection pain and success data to said studies.

Before treatment, patients were asked to rate their anxiety using Corah’s Anxiety Scale\textsuperscript{50} and initial pain using the Heft Parker VAS.\textsuperscript{51} The possible values in reporting anxiety using Corah’s Anxiety Scale range from 4 to 20, with 4 being the lowest possible anxiety and 20 representing the highest possible anxiety preceding dental treatment. Evaluating the data in Table 1, it is worth noting that patients enrolled in this study represented the full range of pre-treatment anxiety from the maximum to the minimum possible responses. Overall, the median anxiety was a 9 out of 20 on the Corah scale for patients participating in this study, which is equal to moderate anxiety. This compares favorably to values reported in similar anesthetic studies involving endodontic treatment of patients in moderate to severe pain caused by a mandibular posterior tooth with the diagnosis of symptomatic irreversible pulpitis.\textsuperscript{3,4,18,19,25,57} In these studies median anxiety levels ranged from 9 to 11 using Corah’s Anxiety scale, which is similar to the median value of 9 for patients in the current study.

Values for initial pain rated before treatment could range from 0 to 170 mm on the VAS. However, only patients reporting moderate to severe pain (85 to 170 mm on VAS) were enrolled in the study. Patients with less than moderate pain were not enrolled in the study due to the possible differences in achieving adequate anesthesia in symptomatic versus asymptomatic patients.\textsuperscript{58-60} The same preoperative pain inclusion
was used in other studies and the reported mean initial pain was found to be on average between 115 and 134 mm on the Heft Parker VAS.\textsuperscript{3-5,18,19,25,57} Mean initial pain numbers for the current study are represented in Table 1 where it should be noted that mean initial pain for subjects enrolled in this study are comparable to similarly conducted previous studies and fell well within the range found in those studies at 124 mm on the VAS.

Other measures used to compare and determine similar patient samples, including mean patient age and gender distribution, were used in the current study and in previous research completed on patients diagnosed with symptomatic irreversible pulpitis. For the current study, the mean age of the patients was 34 years old (Table 1) and 65\% of the patients that participated were female. For previous similarly designed studies conducted at The Ohio State University, average age ranged from 32-36 years of age\textsuperscript{3-5,18,19,25,57}, which compares favorably to the average age of 34 years for patients in the current study. While the sample in our study contained a higher percentage of females than found in the general population, the gender distribution is similar to that found in other studies focused on patients seeking emergency endodontic treatment and the overall patient population seen in the Advanced Endodontic Clinic at The Ohio State University. In recent studies of symptomatic patients at Ohio State, 54\% -71\% of the emergency patients treated in the studies were females.\textsuperscript{18,25,57} Also, a 2005-2006 American Dental Association survey of procedures completed by endodontists showed that almost 60\% of endodontic procedures are completed on women.\textsuperscript{61} These figures illustrate further that the patients participating in the current study not only compare favorably to previous studies
but also similarly represent the typical gender distribution of patients seeking endodontic
treatment across the country.

Patients included in this study experienced moderate to severe pretreatment pain in any posterior symptomatic irreversible pulpitis tooth. Distribution of posterior tooth type and number can be seen in Tables 3 and 4. Eighty-five of 100 teeth treated in the study were either first or second molars. This number falls in range with the mandibular molar tooth distribution percentages of 72 to 98% either first or second molars treated in similar Ohio State studies.\textsuperscript{3,4,18,19,25,57}

Another measure in analyzing the results found in this study is to compare the IANB injection pain and success found in the current study (Table 6) to some of the same previously mentioned studies focused on treatment and anesthesia for patients with symptomatic irreversible pulpitis. In comparable studies\textsuperscript{3-5,18-19,25} injection pain for IANB was initially given and rated in three parts (needle insertion, needle placement, solution deposition) using a 170 mm VAS. In these studies, mean injection pain on IANB needle insertion ranged from 50-73 mm, mean needle placement ranged from 46-75 mm, and mean solution deposition pain ratings ranged from 42-60 mm on the VAS. Mean and categorical injection pain values for the current study can be seen in Tables 6 and 7. Table 6 shows mean needle insertion pain was rated as 62 mm (falling within the range of 50-73 mm from previous studies), mean needle placement pain was rated as 59 mm (within range of 46-75 mm from previous studies), and mean solution deposition was rated as 56 mm (range of 42-60 mm from previous studies).\textsuperscript{3,4,18,19,25,62}
In comparing results for age and gender of patients as well as tooth distribution, initial patient anxiety, initial pain, and IANB injection pain, it is noted that all findings are similar to those found in previous studies completed at Ohio State.\textsuperscript{3-5,18-19,25,57,62} These studies focused on achieving pulpal anesthesia in patients seeking emergency endodontic treatment for pain related to mandibular posterior teeth diagnosed with symptomatic irreversible pulpitis. These strong similarities show the current study likely captured a fair sample of the specific patient population treated in the Advanced Endodontic Clinic at The Ohio State University, and in turn, validates the comparison of the results found in the current study to earlier studies completed in the same clinic setting.

All 100 patients who completed the study achieved profound lip numbness within 15 minutes of administration of the initial IANB. Two patients who were initially recruited for participation in the study, but did not achieve lip numbness within 15 minutes of administration of the IANB, were dismissed from the study and emergency endodontic treatment was performed without further participation or data collection. Therefore, the IANB was missed or failed to provide complete lip numbness in 2\% (2 out of 102) of patients initially recruited in the study within 15 minutes of administration. This value for missed blocks is even lower than the 7.7\% reported by Fowler et al for one cartridge IANB injections missed in patients with symptomatic irreversible pulpitis.\textsuperscript{63}

Overall, only 25\% of the 100 patients recruited and included in the study achieved pulpal anesthesia success with the IANB injection (Table 5), allowing for complete emergency endodontic treatment with no to mild pain. The results for IANB success in the current study are similar to those of other studies involving mandibular
symptomatic irreversible pulpitis. In previous studies at Ohio State involving similar patient populations IANB success has been reported to range from 13-57%.\textsuperscript{1-6,10,18,19,23,29} Likewise, other studies that also evaluated IANB success for symptomatic patients with irreversible pulpitis found success for the IANB alone to range from 20-51%.\textsuperscript{7-9,15-17,22,24}

When the IANB was not effective enough to achieve adequate pulpal anesthesia in the current study, the intraseptal injection was administered and evaluated for success as the primary supplemental injection. All but two patients out of 75 patients that were ruled as anesthetic failures after administration of the IANB injection were given the intraseptal injection as the first supplemental injection. The two patients that did not receive the intraseptal injection did not receive any further supplemental injection following the IANB. These patients were ruled failures as they rated their pain upon access (moderate to severe) after access was complete and no further anesthesia was needed. These patients were given verbal instruction to alert the provider during treatment if treatment caused moderate to severe pain and when questioned during treatment did not state that treatment was painful enough to require additional anesthesia. However, when the procedure was complete the patient rated the pain as moderate to severe and additional anesthetic should have been administered as per study protocol. These patients were considered anesthetic failures for the IANB injection even though no additional anesthetic was given.

Similarly, four other patients did not receive buccal infiltration injections following failed intraseptal injections. One patient considered a buccal infiltration failure did not receive an intraosseous injection, and two patients considered anesthetic failures
after the first intraosseous did not receive a second intraosseous injection (See Table 5) due to failure to report moderate to severe pain during treatment until after endodontic debridement had been completed. The failure to report moderate to severe pain during treatment was corrected halfway through the study as the primary investigator changed the questioning of the patient during data collection. This was done by the investigator further clarifying for patients to properly alert the investigator when moderate to severe pain was felt during treatment instead of waiting until after treatment to do so. Although most patients properly rated and reported pain throughout treatment, those who failed to do so were eliminated from further data analysis even though no other supplemental anesthesia was given.

Success for the intraseptal injection as the primary supplemental injection was 29%, or 21 of 73 patients, in this study (Table 5). This success rate is much lower than other reported success measures for the intraseptal injection in the limited literature that discusses the injection technique. Brkovic et al37 studied intraseptal anesthesia during the extraction of maxillary lateral incisors in patients who were pain-free preoperatively. Extractions were completed without pain in 76% of patients with intraseptal anesthesia alone by using an intraligamentary syringe to administer 0.2 mL of 2% lidocaine with 1:100,000 epinephrine at four different areas around each tooth (mesial and distal on both the buccal and palatal surfaces). Brkovic and co-authors enrolled 35 patients into their study and extracted one maxillary lateral incisor, as previously mentioned, using only intraseptal anesthesia. Two weeks later, the same 35 patients had their contralateral maxillary lateral incisor extracted using the intraligamentary syringe to administer PDL
injections of 0.2 mL of 2% lidocaine with 1:100,000 epinephrine at four different areas around each tooth (mesial and distal on both the buccal and palatal surfaces).\textsuperscript{37} Although Brkovic and co-authors found a high percentage of success with the intraseptal injection, success was determined by simple extraction of \textit{asymptomatic} maxillary lateral incisors and success was considered to be the ability to perform the extraction without severe pain.\textsuperscript{37} Even when patients experienced mild to moderate pain, success was awarded to the injection as long as no severe pain was felt by the patient during the procedure. Brkovic’s study also found no significant difference in the success rates of the intraseptal and PDL injections for the simple extraction of the asymptomatic maxillary lateral incisors.\textsuperscript{37}

In a later study by Biocanin and Brkovic\textsuperscript{38}, 90\% success rate was reported for pulpal anesthesia in vital and asymptomatic mandibular first premolars, as tested by electric pulp tester, after the administration of intraseptal injections using 4\% articaine with 1:100,000 epinephrine. Ninety patients, separated into three groups of 30 each, randomly received either intraseptal or PDL injections on a mandibular first premolar, followed by an appointment, at least 2 weeks later, in which they received the other injection on the same mandibular first premolar (repeated measures). Group 1 received 0.4 mL of anesthetic, group 2 received 0.6 mL of anesthetic at each visit, and group 3 received 0.8 mL of anesthetic at each visit. Half of the total volume administered was deposited mesial to the mandibular first premolar being tested and half was deposited distally.\textsuperscript{38} Both intraseptal and PDL injections were delivered using the C-CLAD\textsuperscript{TM} and consecutive maximum 80 readings on an electric pulp tester, tested at two minute
intervals, were considered successful anesthesia for the injection. Biocanin and co-authors found a 73% success for intraseptal anesthesia with the use of 0.4 mL of 4% articaine with 1:100,000 epinephrine and a 90% success for the intraseptal injections of either 0.6 or 0.8 mL of 4% articaine with 1:100,000 epinephrine. All reported success rates for the intraseptal injection in Biocanin’s study are significantly greater than in the PDL injections performed on the same patients. Although success rates of up to 90% for the intraseptal injection are high, reported PDL success rates for this same study are as high as 70%, and all teeth evaluated in the study were asymptomatic vital teeth.

Another intraseptal study by Borodina et al reported an 88% success rate for pain free treatment during restorative procedures using only intraseptal anesthesia on asymptomatic patients for various teeth throughout the mouth. Similarly, Doman et al found that the intraseptal injection of 4% articaine with 1:100,000 epinephrine allowed for restorative cavity preparation to be complete in mandibular molar and premolar teeth without pain or with only very minor pain in 87% of patients. Meanwhile, Marin reported 96% success for anesthesia when the intraseptal injection was given using 0.2 mL of 2% lidocaine with 1:100,000 epinephrine both mesial and distal to the tooth being treated using the intraligamentary syringe. Marin reported great success using this intraseptal anesthesia technique in over 300 cases including endodontic pulp extirpation, simple restorative procedures, and diagnostic procedures. However, Marin’s reported success was not reliable since his research was not done in a clinically controlled fashion with true repeated measures of standardization or success. Success was a relative term determined by the provider without patient pain reporting.
Intraseptal anesthesia has also been reported to be successful for soft tissue surgery as Saadoun reported successful soft tissue anesthesia and no pain or mild pain in 98% of patients during periodontal surgery. During the study by Saadoun and co-authors, the intraligamentary syringe was used as the primary injection technique to deliver 0.2 mL of 2% lidocaine with 1:50,000 epinephrine at each injection site for 100 periodontal flap surgeries in 54 different patients requiring periodontal treatment in large sextants or quadrants of teeth for osseous surgery, grafts, or root amputations. Four to 10 teeth were included in each surgery and the intraseptal injection was administered directly mesial to the flap, directly distal to the flap, and between each tooth included in the flap, both buccal and lingually if necessary, for up to 18 intraseptal injections per quadrant. Initial success for soft tissue anesthesia using the intraseptal injection was 92% and that increased to 98% when repeated a second time if necessary for adequate pain control. Again, in Saadoun’s study, success was measured by successful soft tissue anesthesia and the pulpal status of any teeth within the area of the periodontal flap was not disclosed.

Overall success for previous intraseptal studies is high and none of these studies show success values near the 29% found during this study. The low success numbers we found are initially disappointing since intraseptal anesthesia success in the previously mentioned studies was much higher and was studied as a primary means of anesthesia in those studies. It is also interesting that these previous studies used less total anesthetic volumes than what was administered in the current study. However, the definition for success in this study versus other intraseptal studies is quite different as success in this
study was defined as the ability to perform emergency root canal therapy in patients suffering from significant pain prior to treatment. Furthermore, treatment in this study was performed on mandibular posterior teeth with the diagnosis of symptomatic irreversible pulpitis, which is generally regarded as one of the most difficult procedures for which to achieve adequate anesthesia in dentistry and has been proven to be more difficult to numb than an asymptomatic tooth.\textsuperscript{58-60} Therefore, the standards for success and the difficulty in obtaining success were likely higher in this study than those for soft tissue anesthesia\textsuperscript{44}, non-surgical extractions\textsuperscript{37}, and pulp testing in asymptomatic teeth\textsuperscript{38}, resulting in lower rates of success.

While success for the intraseptal injection in the current study was much lower than previously reported success rates for the injection in other uses, it was also lower than success rates in this study for other supplemental injections given after failed intraseptal injections, as well as in other studies of supplemental injections. The most commonly used supplemental injections following the IANB are buccal infiltrations, intraosseous injections, and PDL injections. When intraseptal anesthesia failed in the current study, the next supplemental injection to be administered was buccal infiltration of articaine, followed by the intraosseous injection if the buccal infiltration failed. The intraosseous injection was then repeated at a different site if the patient was still not adequately numb, and this was successful in all but four patients enrolled in the study. The intraseptal injection compares most similarly to the intraosseous and PDL injections in its aim to deliver anesthetic in a manner that allows the anesthetic to get into the porous cancellous bone in greater volumes than through simple diffusion as compared
with buccal infiltrations. However, it is important to consider the intraseptal injection’s relative success and clinical relevance in treating patients with mandibular symptomatic irreversible pulpitis compared to other studies.

In research completed by Matthews and co-authors, the success of buccal infiltration as the primary supplemental infiltration in patients diagnosed with mandibular posterior symptomatic irreversible pulpitis was studied. After a failed IANB, one cartridge of 4% articaine with 1:100,000 epinephrine was administered directly buccal near the root apices of the symptomatic tooth. Matthews found a 58% success rate for the buccal infiltration after the IANB had failed. In another study by Rogers and co-authors, buccal infiltration of 4% articaine with 1:000,000 epinephrine after a failed IANB in patients with symptomatic irreversible pulpitis in mandibular molars resulted in a 62% success rate. Similarly, Singla evaluated the anesthetic efficacy of supplemental infiltrations of either 1.8 or 3.6 mL of 4% articaine with 1:100,000 epinephrine in patients with mandibular posterior teeth diagnosed as symptomatic irreversible pulpitis after failed IANB and found success rates of 62% and 64% with the two different volumes, respectively. Looking at these studies and the relative success of the articaine buccal infiltration as supplemental anesthesia, it is easy to see that although the success rate when using the injection is too low to recommend as the only supplemental injection for endodontic treatment of patients with mandibular posterior symptomatic irreversible pulpitis, success of the buccal infiltration is still much higher than that found in the current study for intraseptal anesthesia. Buccal infiltration with articaine is more successful than lidocaine due to its superior bony penetration, and its efficacy has been
proven to be superior in studies evaluating the two anesthetics in both mandibular symptomatic irreversible pulpitis cases and mandibular pulp vitality studies.\textsuperscript{16,17,53,64,65}

In the current study, 48 patients did not attain adequate anesthesia with the intraseptal injection and rated their pain as moderate to severe during treatment. Buccal infiltration of one cartridge of 4\% articaine with 1:100,000 epinephrine was administered and success was found in 13 of these 48 patients for 27\% success (Table 5). Although this percentage of success is lower than those discussed previously in this section\textsuperscript{5,16,17}, it is similar in value to the success found with the intraseptal injection in this study. This makes the buccal infiltration clinically ineffective and unreliable for routine treatment of mandibular symptomatic irreversible pulpitis. It is worth noting that our reported success rate of the buccal infiltration in this study was only 27\% after failed intraseptal injections, while the overall success of intraseptal injection alone or in combination with buccal infiltration was 49\%, which is similar to previously reported success rates of buccal infiltration in treatment of mandibular symptomatic irreversible pulpitis. Therefore, it is possible that any success achieved through the intraseptal injection and anesthetic diffusion into bone may have been achieved with the simpler and more widely used buccal articaine infiltration alone.

As previously mentioned, the intraosseous injection (IO) aims to provide a way to administer a large volume of anesthetic into the cancellous bone surrounding a symptomatic tooth. A comparison of the two injections (IO vs. intraseptal) and their success is important. Previous studies on the success of the intraosseous injection as a supplemental injection for irreversible pulpitis show success ranging from 83 to
In a study by Bhuyan and co-authors, 1.7 mL of 4% articaine with 1:100,000 epinephrine was administered using the X-Tip™ system for supplemental IO injection in patients with mandibular posterior symptomatic irreversible pulpitis when the IANB was ineffective, and a success rate of 83% was found. Likewise, Verma et al. found a 93% success for the IO injection in patients with lower symptomatic irreversible pulpitis after ineffective IANB using one cartridge of 2% lidocaine with 1:80,000 epinephrine. Other authors have shown success rates using 2% lidocaine with 1:100,000 epinephrine ranging from 88 to 91 percent. Reisman and co-authors even found 80% success for supplemental IO injections in patients with mandibular posterior symptomatic irreversible pulpitis with 3% mepivacaine plain, and success of 98% when the IO injection was repeated with a second cartridge if the first injection failed. In the current study, the supplemental intraosseous injection of one cartridge of 2% lidocaine with 1:100,000 epinephrine was administered distal to the symptomatic tooth when the intraseptal and articaine buccal infiltration failed. If the first intraosseous injection administered failed, a second intraosseous injection was administered mesially to the tooth receiving treatment. The first injection was always given distally and, if needed, the second was administered mesially. The exception was 3rd molars, in which mesial injection was administered due to anatomic considerations. In the current study, the intraosseous injection was successful in 88% of patients and only four patients were unable to be comfortably treated after the intraosseous injection (Table 5). The success in this study with the intraosseous injection is similar to the success reported in other studies.
in the treatment of mandibular posterior irreversible pulpitis, and is much greater than the success rate of the intraseptal injection in the current study.

For clinicians uncomfortable with the intraosseous injection and its unique armamentarium and technique, the PDL injection is the other supplemental injection that is similar to the intraseptal injection. Reviewing previous research related to the PDL injection, a study completed by Nusstein and co-authors looked at the efficacy of primary supplemental PDL injections of 1.4 mL of 2% lidocaine with 1:100,000 epinephrine in patients with lower symptomatic irreversible pulpitis with moderate to severe pain upon endodontic access after receiving an IANB. Nusstein and co-authors found that the PDL injection had a 56% success rate (success defined as none to mild pain upon access).\textsuperscript{33} Similarly, Kanaa and co-authors found a 48% success rate for the PDL injection as a supplemental injection in patients with symptomatic irreversible pulpitis in mandibular teeth.\textsuperscript{22} Another study by Fan and company measured the success of the IANB plus PDL injection for irreversible pulpitis in the mandibular first molar and reported success as high as 83%.\textsuperscript{26} While the PDL injection is similar to the intraseptal injection in its aim to deliver anesthetic into the more porous cancellous bone around the tooth without a bony perforator, the delivery method –using backpressure against the lamina dura rather than through the intraseptal bone –showed higher success rates of anesthesia when comparing our results with those of the PDL injection in previous studies. Although potentially superior in success rates when compared to the intraseptal success rates of the current study, the success for the supplemental PDL injection is still lower than that of the supplemental intraosseous injection. The PDL injection often fails to provide adequate
volumes of local anesthetic into the cancellous bone around the tooth, unlike the IO injection, and has a short duration of action.\textsuperscript{66-69} The IO injection allowed for successful treatment in all but four patients in the current study, and the IO injection is commonly administered by endodontists and endodontic residents throughout the country. Therefore, the PDL injection was not evaluated specifically in this study following the administration of the intraosseous injection to provide any additional information on success rates. However, the comparison of the PDL injection to the intraseptal injection is valuable and shows that, once again, the intraseptal injection success in the current study fails to support its use as a primary supplemental injection technique, when other supplemental techniques are more successful.

Another important comparison to be made is the injection pain for supplemental intraseptal anesthesia versus that of other supplemental injections previously studied. In the current study the mesial portion of the intraseptal injection, which was always given first, was rated as having a higher mean injection pain than the distal portion (Table 8). This is similar to the results found for intraseptal injection pain in the study by Pandrangi and company.\textsuperscript{74} The intraseptal injections were delivered with the mesial first followed by the distal injection in order to accurately compare injection pain ratings to those for studies of PDL\textsuperscript{75} and intraseptal injections\textsuperscript{74} in which the mesial injection was given before the distal injection. Mean distal injection pain was likely less than mean mesial injection pain due to soft tissue anesthesia in the distal injection site from the mesial injection, and due to patient familiarity and altered expectation of injection pain after already having received the injection in another location. Mean injection pain ratings for
both locations and all phases of the injection fell within the mild range and the majority of patients rated all parts of the intraseptal injection as either no pain or only mild pain (See Tables 8 and 9). In a similarly designed study, as previously mentioned, a buccal infiltration of one cartridge of 4% articaine with 1:100,000 epinephrine was used as the primary supplemental infiltration and injection pain was rated by the patients. Matthews et al found that injection pain was rated as either none or mild pain in more than 90% of the injection pain values recorded for all steps of the buccal infiltration. Other studies similar to that by Matthews et al also show mean injection pain for buccal infiltration as mild (less than 54 mm on VAS). \(^3,4,18,19,25,57\)

Intraosseous injection pain was observed in the current study and in many of the previous Ohio State studies when needed for supplemental anesthesia following failed attempts at anesthesia using other adjunct techniques. Reported supplemental injection pain for IO injection during some of these studies\(^3,4,18-19\) using one cartridge of 2% lidocaine with 1:100,000 epinephrine, found the majority of patients rating the intraosseous injection as causing mild or no pain during all parts of the injection. When comparing the findings of injection pain for buccal infiltration (BI) and IO from the current study (Tables 10-12) and the previously mentioned studies to those of intraseptal injection in the current study, similar pain ratings are found. None of the injection techniques’ average pain ratings were higher than their counterparts. Overall mean injection pain values were lower in the current study for BI than for the first IO injection and intraseptal injections. All mean injection pain values for intraseptal, BI, and both first and second IO injections were rated as only mildly painful (Tables 8, 10-12).
Although injection pain for the PDL injection was not collected on a large sample, PDL injection pain as reported in other studies was similar to that found in the current study as well as for the injection pain of the other supplemental techniques (mildly painful).\textsuperscript{33,66-69}

One issue worth noting concerning injection pain for the intraseptal injection was the addition of one-half cartridge of 2\% lidocaine with 1:100,000 epinephrine for long buccal infiltration following the initial IANB lip numbness. The purpose of the injection was to gain adequate buccal soft tissue anesthesia to allow for a more comfortable rubber dam clamp placement before initial endodontic access preparation. Although it is unlikely that this injection played any significant role in IANB success or pulpal anesthesia, especially for premolars or first molars, it is likely that it decreased the overall injection pain of the intraseptal injection. Median injection pain, as previously discussed, was rated as mild in all phases of both the mesial and distal portions of the intraseptal injection. However, other studies that have rated intraseptal injection pain, like the yet-to-be published research on the intraseptal injection as a primary injection for pulpal anesthesia in asymptomatic patients by Pandrangi\textsuperscript{74}, show similar injection pain ratings without the administration of the long buccal injection. Therefore, adding the long buccal injection before any supplemental pulpal anesthetic techniques were used was likely worth the benefit even though it had no bearing on the results of the current study.

When evaluating the efficacy of the intraseptal injection, it is important to look at the purpose of the injection and what it aims to accomplish. With any supplemental injection, efficacy is often the primary focus of research. Practitioners and researchers alike want to know if an injection works and how reliably it can help get patients numb.
However, if an injection works, but is difficult to deliver, then it is unlikely that clinicians will routinely use the injection in practice. The intraosseous injection (IO) has been proven to be highly effective as a supplemental injection both for asymptomatic and symptomatic patients\(^{29-32,34}\) and is considered to be much less painful to patients than a traditional intrapulpal injection. However, in a recent survey of 479 general dentists by Savani and co-authors\(^56\), 64% of dentists said they routinely use intrapulpal injections but only 8% use X-Tip™ IO injections and only 6% use Stabident® IO injections. One explanation for these findings is intrapulpal injections were taught to many dentists during their dental school training, while the use of IO injection likely was not.

The intraseptal injection is not a new injection as it has been discussed in previous literature as early as 1985 by Saadoun.\(^{44}\) The intraseptal injection is similar to the intraosseous injection and the PDL injection with the aim to deliver anesthetic solution directly into the porous cancellous bone around the tooth for which anesthesia is desired. Where the intraseptal injection differs the most from the IO is that most IO delivery techniques require the operator to create a tiny port or perforation in the buccal cortical plate mesial or distal to the tooth being anesthetized with a designated perforating device in order to then deliver anesthetic into the desired area. The intraseptal injection aims to simplify this process by perforating the cortical plate with the anesthetic syringe needle itself, and directly administer the anesthetic solution into the cancellous bone without creating an access point with a perforating device.

While the aim of the injection is to perforate bone with the needle used to deliver the anesthetic as the perforator, it is difficult to determine and find the appropriate needle
that is strong enough and small enough to do so (as previously discussed). While performing the study on patients of various ages, bone densities, and locations in the posterior mandible, the degree of needle penetration and bony perforation was noted. Unfortunately, even with the best of intentions and strict guidelines to prevent anesthetic backflow out from the tissue into the oral cavity, it was impossible to limit some of this anesthetic loss into the oral cavity and mucosa during intraseptal injections, and it was impossible to prevent or quantify the discrepancy between different patients and the injection. When noticeable fluid was being retained or no bony perforation was noted, the principal investigator would re-angulate or re-insert the needle into a more ideal position if possible. It is worth noting that articaine was selected as the anesthetic for this study due to its known improved bony penetration as compared to lidocaine, and proven increased success for infiltrations in the posterior mandible. Any anesthetic not directly delivered into the intraseptal bone would have the best chance to achieve the desired anesthetic affect.\textsuperscript{16,24,64}

During this study we administered 1.4 mL of anesthetic for the intraseptal injection using the C-CLAD\textsuperscript{TM}. In each patient 0.7 mL of anesthetic was delivered mesially and then 0.7 mL was delivered distally, as previously described, for the tooth receiving endodontic therapy. 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, thus only 1.4 mL of anesthetic solution from a standard cartridge is delivered using the C-CLAD\textsuperscript{TM} unit. Previous articles regarding intraseptal anesthesia describe the injection with varying amounts of anesthetic, including a commonly used volume of 0.2 mL of
anesthetic similar to most PDL injections, while others recommend up to 0.8 mL of anesthetic solution for the injection. In reviewing previous injection techniques and establishing the protocol for this injection, it was determined that increasing the volume for the intraseptal injection compared to previous studies would allow for fair comparison to the two injection techniques for which the intraseptal injection is most similar to, the PDL and IO injections. In a similarly designed study, Nusstein et al used the C-CLAD™ to administer 1.4 mL of anesthetic as supplemental PDL injections for patients with symptomatic irreversible pulpitis in mandibular posterior teeth. In previously mentioned intraosseous studies, volumes of 0.9 to 1.8 mL of anesthetic were most commonly used per IO injection. Therefore, in order to standardize the injection and allow for appropriate comparison to supplemental injection techniques that may deliver higher volumes of anesthetic, delivery of 1.4 mL of anesthetic using the C-CLAD™ was determined to be most likely to provide comparable results.

Even with a total volume of 1.4 mL, the use of articaine, and the deposition into both the mesial and distal aspects of each tooth, the intraseptal injection failed to show as much success as both intraosseous and PDL supplemental injections for mandibular posterior teeth with symptomatic irreversible pulpitis. A possible explanation for the decreased success found in the current study compared to those reported in previous intraseptal studies is related to the level of anesthesia required for the treatment of mandibular posterior teeth with symptomatic irreversible pulpitis. Previous intraseptal studies involved treatment protocols for nonsurgical extraction of an asymptomatic tooth, soft tissue periodontal surgery, restorative procedure, or pulp testing in
asymptomatic teeth.\textsuperscript{38} However, this does not fully explain why the success rate for the intraseptal injection in this study was lower than other supplemental injections also used in patients with mandibular posterior symptomatic irreversible pulpitis. Perhaps the location of the anesthetic delivery is the greatest reason for lower success in the intraseptal injection compared to the buccal infiltration and intraosseous injections. With articaine buccal infiltration, the full dose is deposited directly over the root apices of the tooth being treated and articaine diffusion takes place. Some of the success of the buccal infiltration may also be the proximity of the injection to the mental foramen and action of the anesthetic in this area, since the injection is more apical to the tooth. With the intraosseous injection, the cortical plate bone perforator usually allows the clinician to deliver a full cartridge of anesthetic directly into the cancellous bone around the tooth. In the current study, the varied bony perforation of the 25-gauge needle into the intraseptal bone likely limited the direct deposition into cancellous bone like in the intraosseous injection. Meanwhile, any anesthetic not deposited directly into the intraseptal bone, and instead contained within the coronal papillary soft tissue near the injection site, may not have had the same diffusion and infiltration to the location of the root apices, and possibly mental foramen, in order to achieve anesthesia in a way more similar to articaine buccal infiltration. This potentially leaves the intraseptal injection acting in a way that is neither an intraosseous injection nor buccal infiltration, but instead a less efficient version of the two.

In explaining of the inferior success of the intraseptal injection in the current study compared to the PDL injection, it is important to point out how the PDL injection
works. The PDL injection works best when delivered under backpressure.\textsuperscript{70,71,73} When delivered with backpressure it acts like an intraosseous injection by forcing anesthetic through the lamina dura and into the more porous bone around the tooth, not through actual infiltration of the PDL around the tooth.\textsuperscript{72,73} This method of action makes the PDL injection similar to an intraosseous injection. However, when the PDL injection fails to deliver anesthetic volumes into the cancellous bone comparable to the intraosseous injection, it is likely to have decreased success, as shown by the previously discussed studies.\textsuperscript{33-35} The intraseptal injection is unable to consistently deliver the same volume of anesthetic into the cancellous bone as the intraosseous injection or PDL injections due to the potential anesthetic fluid escape into the surrounding soft tissue.

Post-treatment satisfaction ratings and treatment pain ratings were also collected from patients. Patients were asked to mark their level of satisfaction with treatment on a 100 mm VAS and their treatment pain ratings on the previously discussed Heft-Parker 170 mm VAS (Appendix K). The operator exited the treatment area following the completion of treatment to allow patients to anonymously record overall treatment satisfaction as well as treatment pain ratings. Results from the two surveys can be seen in Tables 15, 16, and 17. With mean treatment pain falling into the upper level of the mild pain category (but less than moderate), treatment pain was similar to that reported by patients in previous studies.\textsuperscript{3-5,18,19,25,57} For satisfaction ratings, any rating on the VAS of 66 mm or higher was classified as completely satisfied, while ratings between 33 and 65 mm were classified as moderately satisfied, and ratings from 0 to 32 mm were classified as somewhat satisfied, as previously mentioned. For the current study, 96% of patients
were classified as being completely satisfied (>66 mm on VAS). This number is high but similar to satisfaction ratings completed in similar anesthetic studies.\textsuperscript{18,25,27} In studies completed by Fullmer, Click, and Schellenberg in emergency endodontic treatment for patients with mandibular posterior symptomatic irreversible pulpitis, patients rated their satisfaction as being completely satisfied 89\%, 94\%, and 92\% of the time, respectively.\textsuperscript{18,25,57} In this study 61 of 100 patients rated their satisfaction as 100 mm, resulting in a median satisfaction of 100 mm on the 100 mm VAS (Table 16). Even with some treatment pain most patients were highly satisfied with the overall treatment due to the level of compassion displayed by the provider during the procedure, the expectation of pain to be experienced during treatment, and the expectation of relief from future pain.

When intraseptal anesthesia was studied by Brkovic and co-authors, postoperative pain was reported in 71\% of the treated sites.\textsuperscript{37} However, in unpublished data from a study conducted by Pandrangi and co-authors\textsuperscript{74} focusing on the administration of intraseptal anesthesia using the C-CLAD\textsuperscript{TM} for pulpal anesthesia as a primary injection, postoperative pain was followed and reported far less than that seen by Brkovic et al\textsuperscript{37}. During the current study, no survey or standardized recall was used to investigate postoperative pain. Although it would be beneficial to observe postoperative pain for the intraseptal injection and compare it to other supplemental injection techniques, especially IO and PDL injections, the use of escape methods of supplemental anesthesia when the intraseptal anesthesia failed and other factors like rubber dam placement and pain reduction due to the emergency endodontic treatment itself would make any reported findings difficult to assess.

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Chapter 5

SUMMARY AND CONCLUSION

Achieving adequate pulpal anesthesia for the emergency endodontic treatment of mandibular posterior teeth diagnosed with symptomatic irreversible pulpitis can be very difficult. Previous studies have proven that the inferior alveolar nerve block alone is only effective in achieving profound pulpal anesthesia in 13-57% of such cases\(^1\)-\(^11\) and supplemental anesthetic techniques are often needed. Some of the most common supplemental injection techniques used are articaine buccal infiltration, periodontal ligament injections, and intraosseous injections. While supplemental articaine buccal infiltration has been proven to improve the success of the IANB in patients with mandibular posterior symptomatic irreversible pulpitis\(^5,16,17,53\), studies evaluating the success of the intraosseous injection have shown even greater success with the injection following failed IANB in patients with symptomatic irreversible pulpitis.\(^22,30,32,34,54,55\) The success of the intraosseous injection, both with the X-Tip\(^\text{TM}\) or Stabident\(^\text{®}\) systems, has led to many clinicians regularly using the injection as a means to achieve adequate pulpal anesthesia in these difficult to numb cases. However, the need for special equipment and a bony perforation has led inexperienced clinicians to shy away from the injection and
increased the need to continue to explore other successful supplemental injection techniques.

With the intraseptal injection the anesthetic solution is deposited directly into the interdental septum allowing placement of solution through the porous crestal alveolar bone and into the medullary bone surrounding the tooth. The intraseptal injection hopes to mimic the intraosseous injection without the need of a bony perforator, therefore resulting in a potentially easier yet as effective injection technique. Previous studies have observed the efficacy of the intraseptal injection as a primary anesthetic technique in asymptomatic teeth for periodontal surgery, routine restorative treatment, non-surgical extractions, and even with pulpal testing with high levels of success. However, no previous study had evaluated the intraseptal injection as a supplemental technique in the treatment of mandibular posterior symptomatic irreversible pulpitis. Therefore, the purpose of this prospective study was to determine the anesthetic efficacy of the supplemental intraseptal technique in mandibular posterior teeth diagnosed with symptomatic irreversible pulpitis when the conventional IAN block fails.

One hundred patients experiencing moderate to severe pain as rated on a Heft-Parker visual analog scale related to symptomatic irreversible pulpitis in a mandibular posterior tooth were recruited for the study. Following successful administration of the conventional IANB with profound lip numbness, but moderate to severe pain upon endodontic access or instrumentation, patients were administered the intraseptal injection. Two intraseptal injections of 0.7 mL of 4% articaine with 1:100,000 epinephrine were administered mesial and distal to the tooth being treated using the computer-controlled
local anesthetic delivery device (C-CLAD; Milestone Scientific, Deerfield, IL). Success was defined as the ability to perform emergency endodontic treatment without moderate to severe pain.

Initial success with the IANB was achieved in 25% of patients. The intraseptal injection had a 29% success rate. Following the intraseptal injection, patients were administered articaine buccal infiltration if there was moderate to severe pain upon access or instrumentation. The buccal infiltration provided success in 27% of patients still in pain. Similarly, if patients were still experiencing moderate to severe pain upon endodontic access or instrumentation following buccal infiltration, an intraosseous injection was administered. If the first intraosseous injection was unsuccessful then the injection was repeated at a different site. The combined success of the intraosseous injections was 88%.

Although the supplemental intraseptal injection provided pulpal anesthesia in 29% of patients when the IANB alone failed, this low level of success did not provide predictable levels of anesthesia for all patients requiring emergency endodontic treatment for symptomatic irreversible pulpitis in a mandibular posterior tooth. This level of success found in the current study is lower than the level of success found using different parameters for success in previous studies. The intraseptal injection’s success in the current study is also lower than those reported in previous studies related to the treatment of symptomatic irreversible pulpitis with supplemental buccal infiltration, intraosseous injections, or PDL injections. The intraseptal injection also showed a lower level of success in the current study when compared to buccal infiltration and intraosseous
injections. Therefore, it should not be used as the primary supplemental injection in the treatment of patients with mandibular posterior teeth diagnosed with symptomatic irreversible pulpitis when the initial IANB fails. The intraseptal injection may be helpful during treatment when all other measures have been exhausted, but it cannot be relied upon to regularly provide adequate anesthesia in such cases.
REFERENCES


APPENDIX A

TABLES
Table 1: Patient Age, Anxiety, and Initial Pain

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<th>Mean</th>
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<th>Median</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>34</td>
<td>11</td>
<td>32</td>
<td>39</td>
<td>32</td>
<td>18</td>
<td>63</td>
</tr>
<tr>
<td>Corah Anxiety (4-20)*</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>9</td>
<td>4</td>
<td>20</td>
</tr>
<tr>
<td>Initial Pain (mm)**</td>
<td>124</td>
<td>24</td>
<td>119</td>
<td>129</td>
<td>120</td>
<td>84</td>
<td>170</td>
</tr>
</tbody>
</table>

*Based on Corah’s Anxiety Scale. Possible values 4-20

**Based on 170 mm VAS

Table 2: Initial Pain by Category

<table>
<thead>
<tr>
<th>Initial Pain</th>
<th>Percentage (n/100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate (55-114 mm)*</td>
<td>45</td>
</tr>
<tr>
<td>Severe (115-170 mm)*</td>
<td>55</td>
</tr>
</tbody>
</table>

*Based on 170 mm VAS
### Table 3: Teeth Treated by Tooth Number

<table>
<thead>
<tr>
<th>Tooth Number</th>
<th>Percentage (n/100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>17</td>
<td>2</td>
</tr>
<tr>
<td>18</td>
<td>22</td>
</tr>
<tr>
<td>19</td>
<td>26</td>
</tr>
<tr>
<td>20</td>
<td>9</td>
</tr>
<tr>
<td>21</td>
<td>0</td>
</tr>
<tr>
<td>28</td>
<td>2</td>
</tr>
<tr>
<td>29</td>
<td>2</td>
</tr>
<tr>
<td>30</td>
<td>17</td>
</tr>
<tr>
<td>31</td>
<td>20</td>
</tr>
<tr>
<td>32</td>
<td>0</td>
</tr>
</tbody>
</table>

### Table 4: Teeth Treated by Tooth Type

<table>
<thead>
<tr>
<th>Tooth Type</th>
<th>Percentage (n/100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; Premolar</td>
<td>2</td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt; Premolar</td>
<td>11</td>
</tr>
<tr>
<td>1&lt;sup&gt;st&lt;/sup&gt; Molar</td>
<td>43</td>
</tr>
<tr>
<td>2&lt;sup&gt;nd&lt;/sup&gt; Molar</td>
<td>42</td>
</tr>
<tr>
<td>3&lt;sup&gt;rd&lt;/sup&gt; Molar</td>
<td>2</td>
</tr>
</tbody>
</table>
### Table 5: Anesthetic Success Summary

<table>
<thead>
<tr>
<th>Anesthetic Variable</th>
<th>Success (success/n^ = %)</th>
<th>Failure (failure/n^ = %)</th>
<th>Lower 95% CL for Proportion**</th>
<th>Upper 95% CL for Proportion**</th>
</tr>
</thead>
<tbody>
<tr>
<td>IANB Success</td>
<td>25/100 = 25</td>
<td>75/100 = 75</td>
<td>17</td>
<td>35</td>
</tr>
<tr>
<td>Intraseptal</td>
<td>21/73 = 29</td>
<td>52/73 = 71</td>
<td>19</td>
<td>41</td>
</tr>
<tr>
<td>Buccal Infiltration</td>
<td>13/48 = 27</td>
<td>35/48 = 73</td>
<td>15</td>
<td>42</td>
</tr>
<tr>
<td>Intraosseous</td>
<td>20/34 = 59</td>
<td>14/34 = 41</td>
<td>41</td>
<td>75</td>
</tr>
<tr>
<td>2nd Intraosseous</td>
<td>8/12 = 67</td>
<td>4/12 = 33</td>
<td>35</td>
<td>90</td>
</tr>
<tr>
<td>1st and 2nd IO Combined</td>
<td>28/32 = 88</td>
<td>4/32 = 13</td>
<td>71</td>
<td>96</td>
</tr>
</tbody>
</table>

**Exact Confidence Intervals

^ Two patients considered IANB failure did not receive intraseptal anesthesia. Four patients considered intraseptal failure did not receive buccal infiltration. One patient considered buccal infiltration failure did not receive an intraosseous injection. Two patients considered failure after first intraosseous did not receive a second intraosseous injection.
### Table 6: IANB Injection and Treatment Pain

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number</th>
<th>Median Pain (mm)*</th>
<th>Lower 95% CL for Median**</th>
<th>Upper 95% CL for Median**</th>
<th>Minimum Pain (mm)*</th>
<th>Maximum Pain (mm)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>IANB Insertion</td>
<td>100</td>
<td>62</td>
<td>55</td>
<td>77</td>
<td>0</td>
<td>170</td>
</tr>
<tr>
<td>IANB Placement</td>
<td>100</td>
<td>69</td>
<td>57</td>
<td>84</td>
<td>0</td>
<td>167</td>
</tr>
<tr>
<td>IANB Deposition</td>
<td>100</td>
<td>56</td>
<td>51</td>
<td>80</td>
<td>0</td>
<td>164</td>
</tr>
<tr>
<td>Pain in Dentin</td>
<td>100</td>
<td>0</td>
<td>0</td>
<td>84</td>
<td>0</td>
<td>158</td>
</tr>
<tr>
<td>Pain in Chamber</td>
<td>51</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>170</td>
</tr>
<tr>
<td>Pain in Canal</td>
<td>35</td>
<td>9</td>
<td>0</td>
<td>53</td>
<td>0</td>
<td>142</td>
</tr>
</tbody>
</table>

*Based on 170 mm VAS

**Distribution free confidence intervals

### Table 7: Categorical IANB Injection and Treatment Pain: Number (%)

<table>
<thead>
<tr>
<th>Variable</th>
<th>No Pain (0 mm)*</th>
<th>Mild Pain (1-54 mm)*</th>
<th>Moderate Pain (55-114 mm)*</th>
<th>Severe Pain (115-170 mm)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>IANB Insertion</td>
<td>5 (5)</td>
<td>32 (32)</td>
<td>52 (52)</td>
<td>11 (11)</td>
</tr>
<tr>
<td>IANB Placement</td>
<td>5 (5)</td>
<td>30 (30)</td>
<td>45 (45)</td>
<td>20 (20)</td>
</tr>
<tr>
<td>IANB Deposition</td>
<td>7 (7)</td>
<td>34 (34)</td>
<td>44 (44)</td>
<td>15 (15)</td>
</tr>
<tr>
<td>Pain in Dentin</td>
<td>51 (51)</td>
<td>0 (0)</td>
<td>31 (31)</td>
<td>18 (18)</td>
</tr>
<tr>
<td>Pain in Chamber</td>
<td>34 (69)</td>
<td>0 (0)</td>
<td>8 (16)</td>
<td>7 (14)</td>
</tr>
<tr>
<td>Pain in Canal</td>
<td>12 (34)</td>
<td>13 (37)</td>
<td>7 (20)</td>
<td>3 (9)</td>
</tr>
</tbody>
</table>

*Based on 170 mm VAS

For IANB Injection pain, n = 100

For Treatment pain, n= 100 for dentin; n= 49 for chamber; n= 35 for canal
Table 8: Intraseptal Injection and Treatment Pain

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number</th>
<th>Median Pain (mm)*</th>
<th>Lower 95% CL for Median**</th>
<th>Upper 95% CL for Median**</th>
<th>Minimum Pain (mm)*</th>
<th>Maximum Pain (mm)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesial Insertion</td>
<td>73</td>
<td>29</td>
<td>17</td>
<td>40</td>
<td>0</td>
<td>142</td>
</tr>
<tr>
<td>Mesial Placement</td>
<td>73</td>
<td>22</td>
<td>16</td>
<td>34</td>
<td>0</td>
<td>143</td>
</tr>
<tr>
<td>Mesial Deposition</td>
<td>73</td>
<td>21</td>
<td>9</td>
<td>37</td>
<td>0</td>
<td>114</td>
</tr>
<tr>
<td>Distal Insertion</td>
<td>73</td>
<td>11</td>
<td>3</td>
<td>21</td>
<td>0</td>
<td>112</td>
</tr>
<tr>
<td>Distal Placement</td>
<td>73</td>
<td>10</td>
<td>2</td>
<td>21</td>
<td>0</td>
<td>137</td>
</tr>
<tr>
<td>Distal Deposition</td>
<td>73</td>
<td>10</td>
<td>2</td>
<td>24</td>
<td>0</td>
<td>106</td>
</tr>
<tr>
<td>Pain in Dentin</td>
<td>73</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>142</td>
</tr>
<tr>
<td>Pain in Chamber</td>
<td>52</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>143</td>
</tr>
<tr>
<td>Pain in Canals</td>
<td>36</td>
<td>20</td>
<td>0</td>
<td>84</td>
<td>0</td>
<td>170</td>
</tr>
</tbody>
</table>

*Based on 170 mm VAS

**Distribution free confidence intervals
Table 9: Categorical Intraseptal Injection and Treatment Pain: Number (%)

<table>
<thead>
<tr>
<th>Variable</th>
<th>No Pain (0 mm)*</th>
<th>Mild Pain (1-54 mm)*</th>
<th>Moderate Pain (55-114 mm)*</th>
<th>Severe Pain (115-170 mm)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesial Insertion</td>
<td>16 (22)</td>
<td>36 (49)</td>
<td>18 (25)</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Mesial Placement</td>
<td>16 (22)</td>
<td>41 (56)</td>
<td>13 (18)</td>
<td>3 (4)</td>
</tr>
<tr>
<td>Mesial Deposition</td>
<td>19 (26)</td>
<td>41 (56)</td>
<td>13 (18)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Distal Insertion</td>
<td>26 (36)</td>
<td>36 (49)</td>
<td>11 (15)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Distal Placement</td>
<td>25 (34)</td>
<td>38 (52)</td>
<td>9 (12)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Distal Deposition</td>
<td>25 (34)</td>
<td>39 (53)</td>
<td>9 (12)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Pain in Dentin</td>
<td>52 (71)</td>
<td>0 (0)</td>
<td>17 (23)</td>
<td>4 (5)</td>
</tr>
<tr>
<td>Pain in Chamber</td>
<td>36 (69)</td>
<td>0 (0)</td>
<td>6 (12)</td>
<td>10 (19)</td>
</tr>
<tr>
<td>Pain in Canal</td>
<td>16 (44)</td>
<td>5 (14)</td>
<td>9 (25)</td>
<td>6 (17)</td>
</tr>
</tbody>
</table>

*Based on 170 mm VAS

For IANB Injection pain, n = 73

For Treatment pain, n = 73 for dentin; n = 52 for chamber; n = 36 for canal
<table>
<thead>
<tr>
<th>Variable</th>
<th>Number</th>
<th>Median Pain (mm)*</th>
<th>Lower 95% CL for Median**</th>
<th>Upper 95% CL for Median**</th>
<th>Minimum Pain (mm)*</th>
<th>Maximum Pain (mm)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>BI Insertion</td>
<td>48</td>
<td>4</td>
<td>1</td>
<td>18</td>
<td>0</td>
<td>84</td>
</tr>
<tr>
<td>BI Placement</td>
<td>48</td>
<td>3</td>
<td>1</td>
<td>10</td>
<td>0</td>
<td>90</td>
</tr>
<tr>
<td>BI Deposition</td>
<td>48</td>
<td>6</td>
<td>1</td>
<td>22</td>
<td>0</td>
<td>86</td>
</tr>
<tr>
<td>Pain in Dentin</td>
<td>48</td>
<td>0</td>
<td>0</td>
<td>83</td>
<td>0</td>
<td>142</td>
</tr>
<tr>
<td>Pain in Chamber</td>
<td>31</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>166</td>
</tr>
<tr>
<td>Pain in Canal</td>
<td>22</td>
<td>34</td>
<td>0</td>
<td>100</td>
<td>0</td>
<td>142</td>
</tr>
</tbody>
</table>

*Based on 170 mm VAS

**Distribution free confidence intervals
Table 11: 1st Intraosseous (IO) Injection and Treatment Pain

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number</th>
<th>Median Pain (mm)*</th>
<th>Lower 95% CL for Median**</th>
<th>Upper 95% CL for Median**</th>
<th>Minimum Pain (mm)*</th>
<th>Maximum Pain (mm)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st IO Insertion</td>
<td>34</td>
<td>30</td>
<td>16</td>
<td>55</td>
<td>0</td>
<td>141</td>
</tr>
<tr>
<td>1st IO Placement</td>
<td>34</td>
<td>29</td>
<td>17</td>
<td>68</td>
<td>0</td>
<td>141</td>
</tr>
<tr>
<td>1st IO Deposition</td>
<td>34</td>
<td>35</td>
<td>21</td>
<td>84</td>
<td>0</td>
<td>170</td>
</tr>
<tr>
<td>Pain in Dentin</td>
<td>34</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>114</td>
</tr>
<tr>
<td>Pain in Chamber</td>
<td>29</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>142</td>
</tr>
<tr>
<td>Pain in Canal</td>
<td>24</td>
<td>1</td>
<td>0</td>
<td>41</td>
<td>0</td>
<td>134</td>
</tr>
</tbody>
</table>

*Based on 170 mm VAS

**Distribution free confidence intervals
Table 12: 2\textsuperscript{nd} Intraosseous (IO) Injection and Treatment Pain

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number</th>
<th>Median Pain (mm)*</th>
<th>Lower 95% CL for Median**</th>
<th>Upper 95% CL for Median**</th>
<th>Minimum Pain (mm)*</th>
<th>Maximum Pain (mm)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>2\textsuperscript{nd} IO Insertion</td>
<td>12</td>
<td>8</td>
<td>1</td>
<td>37</td>
<td>0</td>
<td>55</td>
</tr>
<tr>
<td>2\textsuperscript{nd} IO Placement</td>
<td>12</td>
<td>8</td>
<td>1</td>
<td>83</td>
<td>0</td>
<td>83</td>
</tr>
<tr>
<td>2\textsuperscript{nd} IO Deposition</td>
<td>12</td>
<td>17</td>
<td>2</td>
<td>83</td>
<td>0</td>
<td>135</td>
</tr>
<tr>
<td>Pain in Dentin</td>
<td>12</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>114</td>
</tr>
<tr>
<td>Pain in Chamber</td>
<td>10</td>
<td>0</td>
<td>0</td>
<td>84</td>
<td>0</td>
<td>168</td>
</tr>
<tr>
<td>Pain in Canal</td>
<td>9</td>
<td>0</td>
<td>0</td>
<td>21</td>
<td>0</td>
<td>52</td>
</tr>
</tbody>
</table>

*Based on 170 mm VAS

**Distribution free confidence intervals
### Table 13: IANB Failure Location

<table>
<thead>
<tr>
<th>Failure Location</th>
<th>Number of IANB Failures</th>
<th>Percentage of IANB Failures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure in Dentin</td>
<td>49</td>
<td>49/75 = 65</td>
</tr>
<tr>
<td>Failure in Chamber</td>
<td>16</td>
<td>16/75 = 21</td>
</tr>
<tr>
<td>Failure in Canal</td>
<td>10</td>
<td>10/75 = 13</td>
</tr>
</tbody>
</table>

Total number of IANB failures = 75/100

### Table 14: Intraseptal Failure Location

<table>
<thead>
<tr>
<th>Failure Location</th>
<th>Number of Intraseptal Failures</th>
<th>Percentage of Intraseptal Failures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure in Dentin</td>
<td>21</td>
<td>21/52 = 40</td>
</tr>
<tr>
<td>Failure in Chamber</td>
<td>16</td>
<td>16/52 = 31</td>
</tr>
<tr>
<td>Failure in Canal</td>
<td>15</td>
<td>15/52 = 29</td>
</tr>
</tbody>
</table>

Total number of Intraseptal failures = 52/73

81
Table 15: Overall Treatment Pain Rating

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number</th>
<th>Median Pain (mm)*</th>
<th>Lower 95% CL for Median*</th>
<th>Upper 95% CL for Median*</th>
<th>Minimum Pain (mm)*</th>
<th>Maximum Pain (mm)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment Pain Rating</td>
<td>100</td>
<td>54</td>
<td>38</td>
<td>61</td>
<td>0</td>
<td>170</td>
</tr>
</tbody>
</table>

*Based on 170 mm VAS

**Distribution free confidence intervals
Table 16: Median Overall Treatment Satisfaction Rating

<table>
<thead>
<tr>
<th>Variable</th>
<th>Number</th>
<th>Median Pain (mm)*</th>
<th>Lower 95% CL for Median**</th>
<th>Upper 95% CL for Median**</th>
<th>Minimum Rating (mm)*</th>
<th>Maximum Rating (mm)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Satisfaction Rating</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>0</td>
<td>100</td>
</tr>
</tbody>
</table>

*Based on 100 mm VAS

**Distribution free confidence intervals

Table 17: Categorical Overall Treatment Satisfaction Rating

<table>
<thead>
<tr>
<th>Pain Rating</th>
<th>Number (n)</th>
<th>Percentage (%) (n/100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Satisfied (0 mm)*</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Somewhat Satisfied (0-32 mm)*</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Moderately Satisfied (33-65 mm)*</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Completely Satisfied (66-100 mm)*</td>
<td>96</td>
<td>96</td>
</tr>
</tbody>
</table>

*Based on 100 mm VAS
APPENDIX B

CONSENT FORM
The Ohio State University Consent to Participate in Research

Study Title: Supplemental intraseptal anesthesia in patients with symptomatic irreversible pulpitis

Principle Investigator: Melissa Drum DDS, MS

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.

- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.
1. Why is this study being done?

The purpose of this study is to see if an injection (shot) given on the sides of your teeth improves the success of numbing during root canal treatment.

2. How many people will take part in this study?

One hundred (100) people will take part in this study.

3. What will happen if I take part in this study?

You have a tooth, which is hurting (painful), and you are aware that it needs a root canal. If you decide to participate in this study, you will be required to completed a medical history questionnaire, a HIPPA authorization and consent form. If you are a woman able to have children, you will be required to take a urine pregnancy test before participation. The study requires one appointment but you will need at least one additional appointment to finish the root canal if you elect to save your tooth.

The following part of the study is associated with the research.

Before beginning the study you will be asked to complete a survey related to the amount of pain you are experiencing and to rate how anxious you may be. During treatment you will be asked to complete a simple survey if you are experiencing pain. Finally, a satisfaction survey will be complete at the end of treatment. The purpose of this study is to monitor the pain of your procedure throughout the procedure and to measure the effect a specific supplemental injection (shot) has on any pain you may experience during treatment.

The following procedures are needed for standard root canal treatment and will occur whether or not I take part in this study.

The tooth causing you pain will first be tested to ensure an accurate diagnosis. It will first be tested with a cold cotton pellet chilled with an ice spray. Your tooth may hurt for a few moments after being tested with the cold. The cold pellet will be removed
immediately after you feel the sensation in your tooth. The cold test is used routinely before root canal treatment. One injection (shot) will be given in the back of your jaw to numb your lower teeth (inferior alveolar injection) using 2% lidocaine with 1:100,000 epinephrine which is an anesthetic (numbing solution) similar to novocaine. Two percent lidocaine with 1:100,000 epinephrine has been used in the dental office for years and has been approved by the Food and Drug Administration. Following the anesthetic injection the doctor will check for lip numbness and if the lip is numb in the area then the doctor will proceed with treatment. Next, a small opening will be made in the top of your tooth to begin the root canal. If you feel pain, you will raise your hand and will be asked to rate the pain. If you have moderate or severe pain, two supplemental (extra) injections (shots) of 4% articaine with 1:100,000 epinephrine (another safe and commonly used numbing solution) will then be given on the sides of your tooth. This may be uncomfortable. Routine emergency root canal treatment will then be completed. You will then be asked to rate your satisfaction with the treatment you received.

4. How long will I be in the study?

You will have one appointment, which will last approximately 90 minutes.

5. Can I stop being in the study?

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. What risks, side effects or discomforts can I expect from being in the study?

There are no additional risks or side effects associated with this study that differ from those that are possible with routine emergency root canal therapy. Like most dental procedures you may have pain associated with the local anesthetic (numbing solution) or soreness at the site of the injections (shots) for approximately two days. Where you receive the injection, you may have swelling (hematoma—a collection of blood in your mouth) or a bruise may develop. You may experience a feeling of anxiety, lightheadedness or fainting, and or a temporary increase in your heart rate. Your toothache may stay the same or worsen during the study. The tingling sensation and/or
slight discomfort (pain) produced by the cold ice spray may be uncomfortable to you. You may have an allergic reaction to the local anesthetic (itching or hives, very rare), or have an unexpected infection (rare) which could result in permanent nerve damage. You may have soreness of your gum tissue for a few days or a possible altered sensation of your lip or tongue that may last up to a few weeks. Your tooth may feel sore to bite on for a few days.

If you are a woman able to have children, you will be questioned regarding pregnancy or suspected pregnancy and will not be allowed to participate if pregnant, suspect a pregnancy, trying to become pregnant, or nursing. Additionally, you will be required to take a urine pregnancy test before you can start this study.

The reason for excluding pregnant or potentially pregnant women is an attempt to minimize this population in the study because of the administration of pain medication during pregnancy. Patients/physicians differ in their acceptance of its use during pregnancy.

7. **What benefits can I expect from being in the study?**

You will not directly benefit from this study except for the $75.00 paid to you for your participation.

8. **What other choices do I have if I do not take part in the study?**

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

9. **Will my study-related information be kept confidential?**

Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

Also, your records may be reviewed by the following groups (as applicable to the research):
• Office for Human Research Protections or other federal, state, or international regulatory agencies;

• U.S. Food and Drug Administration;

• The Ohio State University Institutional Review Board or Office of Responsible Research Practices;

• The sponsor supporting the study, their agents or study monitors; and

• Your insurance company (if charges are billed to insurance).

If this study is related to your medical care, your study-related information may be placed in your permanent hospital, clinic, or physician’s office records. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

10. What are the costs of taking part in this study?

Because routine endodontic treatment will be performed, other costs (emergency root canal fees, parking, etc.) related to treatment will not be reimbursed in this study. The study will pay for the cost of the urine pregnancy test if necessary.

11. Will I be paid for taking part in this study?

Yes, you will be paid $75.00 for your participation in this study.
By law, payments to subjects are considered taxable income.

12. What happens if I am injured because I took part in this study?

If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

13. What are my rights if I take part in this study?

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

14. Who can answer my questions about the study?

For questions, concerns, or complaints about the study you may contact Dr. Melissa Drum or Dr. Stephen Webster, Jr. at 614-292-5399.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you
may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Melissa Drum or Dr. Stephen Webster, Jr. at 614-292-5399.

Signing the consent form

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

___________________________________________________________________________  _______________________________________________________________________
Printed name of subject                                             Signature of subject

AM/PM

___________________________________________________________________________
Date and time

___________________________________________________________________________
Printed name of person authorized to consent for subject (when applicable)  Signature of person authorized to consent for subject (when applicable)

AM/PM

___________________________________________________________________________
Relationship to the subject                                             Date and time
Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent  Signature of person obtaining consent

AM/PM

Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness  Signature of witness

AM/PM

Date and time

Printed name of witness  Signature of witness

AM/PM

Date and time
APPENDIX C

PRIVACY FORM
Title of the Study: Supplemental intraseptal anesthesia in patients with
symptomatic irreversible pulpitis

OSU Protocol Number: 2013H0376

Principal Investigator: Dr. Melissa Drum DDS, MS

Subject Name__________________________________________________________

Before researchers use or share any health information about you as part of this study, The Ohio State University is required to obtain your authorization. This helps explain to you how this information will be used or shared with others involved in the study.

- The Ohio State University and its hospitals, clinics, health-care providers and researchers are required to protect the privacy of your health information.
- You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you. Please carefully review this information. Ask if you have any questions or do not understand any parts of this notice.
- If you agree to take part in this study your health information will be used and shared with others involved in this study. Also, any new health information about you that comes from tests or other parts of this study will be shared with those involved in this study.
- Health information about you that will be used or shared with others involved in this study may include your research record and any health care records at the Ohio State University. For example, this may include your medical records, x-ray or laboratory results. Psychotherapy notes in your health records (if any) will not, however, be shared or used. Use of these notes requires a separate, signed authorization.

Please read the information carefully before signing this form. Please ask if you have any questions about this authorization, the University’s Notice of Privacy Practices or the study before signing this form.

Initials/Date: ________________
Those Who May Use, Share And Receive Your Information As Part Of This Study

- Researchers and staff at The Ohio State University will use, share and receive your personal health information for this research study. Other Ohio State University staff not involved in the study but who may become involved in your care for study-related treatment will have access to your information.

- Those who oversee the study will have access to your information, including:
  - Members and staff of the Ohio State University’s Institutional Review Boards, including the Western Institutional Review Board
  - The Office for Responsible Research Practices
  - University data safety monitoring committees
  - The Ohio State University Research Foundation

- Your health information may also be shared with federal and state agencies that have oversight of the study or to whom access is required under the law. These may include:
  - The Food and Drug Administration
  - The Office for Human Research Protections
  - The National Institutes of Health
  - The Ohio Department of Human Services

These researchers, companies and/or organization(s) outside of The Ohio State University may also use, share and receive your health information in connection with this study:

- NONE

The information that is shared with those listed above may no longer be protected by federal privacy rules.

Initials/Date__________________
Authorization Period

This authorization will not expire unless you change your mind and revoke it in writing. There is no set date at which your information will be destroyed or no longer used. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

Signing the Authorization

- You have the right to refuse to sign this authorization. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.
- You will not be able to take part in this study and will not receive any study treatments if you do not sign this form.
- If you sign this authorization, you may change your mind at any time. Researchers may continue to use information collected up until the time that you formally changed your mind. If you change your mind, your authorization must be revoked in writing. To revoke your authorization, please write to:
  Dr. Melissa Drum at the College of Dentistry, 305 w 12th avenue, the Ohio State University, Columbus, Ohio 43218 or Dr. Fonda Robinson at the College of Dentistry, 305 w 12th avenue, the Ohio State University, Columbus, Ohio 43218.
- Signing this authorization also means that you will not be able to see or copy your study-related information until the study is completed. This includes any portion of your medical records that describes study treatment.

Contacts for Questions

- If you have any questions relating to your privacy rights, please contact Dr. Fonda Robinson at the College of Dentistry, 305 w 12th avenue, the Ohio State University, Columbus, Ohio 43218.
- If you have any questions relating to the research, please contact Dr. Melissa Drum at the College of Dentistry, 305 w 12th avenue, the Ohio State University, Columbus, Ohio 43218.
Signature

I have read (or someone has read to me) this form and have been able to ask questions. All of my questions about this form have been answered to my satisfaction. By signing below, I permit Dr. Melissa Drum and the others listed on this form to use and share my personal health information for this study. I will be given a copy of this signed form.

Signature________________________________________
(Subject or Legally Authorized Representative)

Name______________________________________________
(Print name above)
(If legal representative, also print relationship to subject.)

Date___________ Time _________ AM / PM
APPENDIX D

HEALTH HISTORY QUESTIONNAIRE
Medical History

1. Do you have or have you had any of the following?

   a. rheumatic fever or rheumatic heart disease………………… NO YES
   b. heart murmur or mitral valve prolapse…………………… NO YES
   c. heart disease or heart attack……………………………… NO YES
   d. artificial heart valve……………………………………….. NO YES
   e. irreglar heart beat……………………………………….. NO YES
   f. pacemaker………………………………………………… NO YES
   g. high blood pressure……………………………………….. NO YES
   h. chest pains or angina……………………………………… NO YES
   i. stroke…………………………………………………… NO YES
   j. artificial joint…………………………………………… NO YES
   k. hepatitis/liver disease…………………………………… NO YES
   l. tuberculosis………………………………………………. NO YES
   m. thyroid problem………………………………………… NO YES
   n. kidney disease…………………………………………… NO YES
   o. diabetes (sugar)………………………………………… NO YES
   p. asthma…………………………………………………… NO YES
   q. HIV or other immunosuppressive disease………………….. NO YES
   r. radiation or cancer therapy………………………………… NO YES

2. Do you or have you had any disease, condition, or problem not listed here? NO YES

3. Have you ever been hospitalized? NO YES

4. Have you had excessive or prolonged bleeding requiring special treatment? NO YES

5. Have you had an allergic reaction to any drugs or medications?
   (Circle all that apply: penicillin; codeine; aspirin; anesthetics; other) NO YES

6. Are you currently under the care of a physician (M.D., D.O.)? NO YES

   When were you last seen by a physician?
   _______________________________________________________
   Name of Physician________________________________________
   Street address____________________________________________
   City, State, and Zip Code___________________________________
   Phone___________________________________________________

7. Are you pregnant or nursing? Estimated date of delivery______ NO YES
8. Have you had any trouble associated with previous dental treatment? NO YES

9. How often do you have dental check ups? _________ Date of last Exam___________

10. Do you have any lumps or sores in your mouth now? NO YES

11. Do you smoke or use smokeless tobacco? NO YES

12. Are you currently taking any drugs or medications (such as antibiotics, heart medicine, birth control pills?) NO YES

**Current Medications**

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<th>Trade Name</th>
<th>Generic Name</th>
<th>Dose/Frequency</th>
<th>Reason</th>
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**Summary of Patient’s Medical Status:** ___________________________________________________________

**Medical Risk Assessment**

- □ ASA I (healthy individual)
- □ ASA II (mild systemic disease)
- □ ASA III (severe disease but not incapacitating)
- □ ASA IV (incapacitating systemic disease)

**Medical Consultation Required**

- □ No (healthy and/or stabilized disease)
- □ Yes (ASA III or IV; cardiac murmur; vague hx; recent major disease; recent diagnosis/operation; uncontrolled disease; blood pressure; etc.)

To the best of my knowledge, the above information is correct and complete.

Patient’s Signature ___________________________ Date ___________________
APPENDIX E

INITIAL PAIN RATING VISUAL ANALOG SCALE
Initial Pain Rating

Date: __________
Code #: __________

1. Please mark a vertical line “|” on the line below to rank the level of pain you are feeling today.
APPENDIX F

CORAH’S DENTAL ANXIETY SCALE
Pt. #: __________________
Pre-Injection Questionnaire

PLEASE ANSWER THE FOLLOWING QUESTIONS BY CIRCLING THE ANSWER THAT BEST DESCRIBES HOW YOU FEEL.

1. If you had to go to the dentist tomorrow, how would you feel about it?
   a) I would look forward to it as a reasonably enjoyable experience.
   b) I wouldn't care one way or the other.
   c) I would be a little uneasy about it.
   d) I would be afraid that it would be unpleasant and painful.
   e) I would be very afraid of what the dentist might do.

2. When you are waiting in the dentist's office for your turn in the chair, how do you feel?
   a) Relaxed.
   b) A little uneasy.
   c) Tense.
   d) Anxious.
   e) So anxious that I sometimes break in a sweat or almost feel physically sick.

3. When you are in the dentist's chair waiting while she/he gets her/his drill ready to begin working on your teeth, how do you feel?
   a) Relaxed.
   b) A little uneasy.
   c) Tense.
   d) Anxious.
   e) So anxious that I sometimes break in a sweat or almost feel physically sick.

4. You are in the dentist's chair to have your teeth cleaned. While you are waiting and the dentist is getting out the instruments, which she/he will use to scrape your teeth around your gums, how do you feel?
   a) Relaxed.
   b) A little uneasy.
   c) Tense.
   d) Anxious.
   e) So anxious that I sometimes break in a sweat or almost feel physically sick.
APPENDIX G

IANB INJECTION PAIN RATING VISUAL ANALOG SCALE
Inferior Alveolar Nerve Block Pain Rating

Date: _________
Code #: __________

Needle Insertion

1. Please place an “X” on the line below to rank the level of pain felt during needle insertion

None | Faint | Weak | Mild | Moderate | Strong | Intense | Maximum

Needle Placement

2. Please place an “X” on the line below to rank the level of pain felt during needle placement.

None | Faint | Weak | Mild | Moderate | Strong | Intense | Maximum

Solution Deposition

3. Please place an “X” on the line below to rank the level of pain felt during solution deposition.

None | Faint | Weak | Mild | Moderate | Strong | Intense | Maximum
APPENDIX H

IANB ACCESS PAIN RATING VISUAL ANALOG SCALE
Inferior Alveolar Nerve Block Access Pain Rating

Date: __________
Code #: __________

**Dentin**

1. Please place an “X” on the line below to rank the level of pain.

None  Faint  Weak  Mild  Moderate  Strong  Intense  Maximum

**Pulp Chamber**

2. Please place an “X” on the line below to rank the level of pain.

None  Faint  Weak  Mild  Moderate  Strong  Intense  Maximum

**Instrument Canals**

3. Please place an “X” on the line below to rank the level of pain.

None  Faint  Weak  Mild  Moderate  Strong  Intense  Maximum
APPENDIX I

SUPPLEMENTAL INJECTION PAIN RATING VISUAL ANALOG SCALE
Supplemental Injection Pain Rating

Date: __________
Code #: __________

Needle Insertion

1. Please place an “X” on the line below to rank the level of pain felt during needle insertion

Solution Deposition

3. Please place an “X” on the line below to rank the level of pain felt during solution deposition.
APPENDIX J

SUPPLEMENTAL ACCESS PAIN RATING VISUAL ANALOG SCALE
Supplemental Access Pain Rating

Date: _________
Code #: __________

Dentin

1. Please place an “X” on the line below to rank the level of pain.

   None  Faint  Weak  Mild  Moderate  Strong  Intense  Maximum

Pulp Chamber

2. Please place an “X” on the line below to rank the level of pain.

   None  Faint  Weak  Mild  Moderate  Strong  Intense  Maximum

Instrument Canals

3. Please place an “X” on the line below to rank the level of pain.

   None  Faint  Weak  Mild  Moderate  Strong  Intense  Maximum
APPENDIX K

SATISFACTION RATING AND TREATMENT PAIN RATING VISUAL ANALOG SCALES
Pt. Number:____________________

**Satisfaction Rating**

Mark a vertical line “│” on the point on the scale line that best describes your satisfaction.

Not Satisfied │ Somewhat Satisfied │ Moderately Satisfied │ Completely Satisfied

**Treatment Pain Rating**

Do you remember feeling pain during the treatment, if yes, what was the greatest amount of pain you felt?

Please place an “X” on the line below to rank the level of pain.

None │ Faint │ Weak │ Mild │ Moderate │ Strong │ Intense │ Maximum