THE EFFECT OF BUFFERED LIDOCAINE ON THE SUCCESS OF
THE INFERIOR ALVEOLAR NERVE BLOCK IN PATIENTS WITH
IRREVERSIBLE PULPITIS

A Thesis
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ABSTRACT

Studies have suggested that buffering local anesthetic may increase the ability to achieve pulpal anesthesia. The purpose of this study was to determine the effect of buffered lidocaine on the anesthetic success of the inferior alveolar nerve (IAN) block in patients experiencing symptomatic irreversible pulpitis. One hundred emergency patients diagnosed with symptomatic irreversible pulpitis of a mandibular posterior tooth randomly received a conventional IAN block using either 2.8 ml of 4% lidocaine with 1:100,000 epinephrine or 2.8 ml of 4% lidocaine with 1:100,000 epinephrine buffered with sodium bicarbonate. For the buffered solution, each cartridge was buffered with 8.4% sodium bicarbonate to produce a final concentration of 0.18 mEq/mL of sodium bicarbonate. Fifteen minutes after administration of the IAN block, profound lip numbness was confirmed and endodontic access was initiated. Success was determined as no or mild pain (≤54 mm on a 170 mm visual analog scale) on access or instrumentation of the root canal. The success rate for the IAN block was 32% for the buffered group and 40% for the non-buffered group, with no significant difference (p = 0.41) between the groups. For mandibular posterior teeth, a buffered lidocaine solution did not result in a statistically significant increase in the success rate of the IAN block in patients with symptomatic irreversible pulpitis.
DEDICATION

To my wife, Brittany, for her total love and support. To my children, Ellie, Emma, and Jensen, for the purpose they give to my life. To my loving family and parents, for the examples they have always been to me.
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Thank you for your friendship, patience, and selflessness, especially when I had a study patient. It was a pleasure to work, travel, learn, and grow with you. You will be my lifelong friends and I will miss you all.
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CHAPTER 1

Introduction

The Axon and neurophysiology:

Pain is conveyed from the periphery to the central nervous system via sensory neurons which consist of three main portions. The distal portion encompasses free nerve endings that are responsible for experiencing stimuli which are then transmitted to the second portion termed the axon. The axon is responsible for transmitting the sensory impulse to the third portion, the nuclei. These nuclei in the central nervous system will then send the stimuli to higher brain centers for interpretation. Odontogenic pain is usually the result of a noxious physical stimulus or the release of inflammatory mediators that stimulate receptors located on the terminal endings of nociceptive afferent C and A delta fibers of the trigeminal nerve. These fibers send the pain signal via the trigeminal nerve to the trigeminal nuclear complex in the medulla, particularly the nucleus caudalis, also termed the medullary dorsal horn. The signal then travels to the thalamus and then to the cerebral cortex for final perception of pain.¹

Nerve Conduction and Propagation:

If the stimulation of the peripheral nociceptive free nerve ending is great enough, it will produce an action potential. This action potential is transmitted along the entire length of the peripheral nerve until it reaches the central nervous system. The nerve axon
that these pain signals travel on, is a long cylinder of axoplasm surrounded by a thin sheath termed the axolemma. Some of these axons, depending on the nerve type, are covered by a thin layer of lipid termed myelin. At rest a sensory nerve has an electrical potential of -70mV. This potential is created by a difference of ions inside and outside the membrane of the nerve. At rest, positively charged sodium ions are concentrated outside the cell while positively charged potassium is concentrated inside. This concentration is held by membrane bound gated channels that remain closed when the nerve is at rest. Once the nerve is excited, and the threshold has been met, the nerve will depolarize. This depolarization is a combination of sodium ions entering the nerve along with potassium ions rushing out until the membrane potential reaches +40mV. This depolarization will then be propagated down the nerve resulting in subsequent depolarization of adjacent nerves.

**Sodium Channels:**

Sodium channels are membrane-bound, protein molecular structures that mediate sodium permeability and are closed at rest. These channels are found throughout the axon and are composed of two subunits, alpha and beta. The alpha subunits are the actual channel where sodium flows, while the beta subunits stabilize the channel into the membrane. The alpha subunit has 4 domains (I-IV) each composed of six segments (S1-S6) through the membrane. The S4 segment contains the voltage sensor which opens in response to depolarization. Depolarization causes a conformational change of the channel resulting in opening of the pore and a rush of sodium ions into the nerve along the
concentration and electrical gradient. This depolarization (influx of sodium ions) then propagates down the axon.

**Where and How Local Anesthetics Work?**

Local anesthetics exert their pharmacologic actions on the nerve membrane. Many theories have tried to explain the mechanism of action of local anesthetics. The acetylcholine theory states that acetylcholine is involved in nerve conduction. No research evidence indicates that acetylcholine is involved in neural transmission along the body of the neuron. The calcium displacement theory states that local anesthetics displace calcium which, in turn, opens the sodium channels of a neuron. Evidence that varying the concentration of calcium ions bathing a nerve does not affect local anesthetic potency, thus this theory has diminished in credibility. The surface charge theory proposes that local anesthetics act by binding to the nerve membrane and changing the electrical potential. Recent research shows that when local anesthetics are applied, the resting membrane potential does not change and does not become hyperpolarized. The membrane expansion theory states that local anesthetics produce a general disturbance in membrane structure, expanding some regions in the membrane, producing a change in configuration of the membrane. This results in a decreased size of the sodium channels, which in turn anesthetize the neuron. No direct evidence suggests that nerve conduction is entirely blocked by membrane expansion. However, it has been demonstrated that nerve membranes do expand and become more fluid when exposed to local anesthetics. The specific receptor theory is the most accepted theory today. This theory holds that local anesthetics bind to specific receptors within the sodium channel which results in
decreased or eliminated sodium permeability. Local anesthetics bind the helical segments of sodium channels. Once bound, the sodium channels restrict movement of sodium across the membrane and keep sodium channels in an inactive configuration. The result is an ultimate failure of action potential and propagation down the neuron.

Local anesthetics are said to produce a use-dependent block. This concept suggests that local anesthetics are particularly effective in blocking high frequency nerve impulses because local anesthetics are better able to reach their site of action within the sodium channel during a channel’s inactive state following depolarization. If a nerve is rapidly firing, the channels will be active more frequently increasing the opportunity for local anesthetic to reach the site of action, resulting in a use-dependent blockade of nerve impulse.

Local Anesthetic Molecules:

Local anesthetic molecules are tertiary amines that consist of three segments; an aromatic group, an intermediate chain, and an amino end terminus. All local anesthetics are both lipophilic and hydrophilic in nature. The aromatic segment is lipophilic while the hydrophilic segment is the amino terminus. These two segments are connected by an intermediate hydrocarbon chain containing either an ester or amide chain. Local anesthetics are classified as either an ester or an amide type. Lidocaine is an amide-linked local anesthetic that is relatively resistant to hydrolysis. Local anesthetic molecules are basic molecules that are unstable when exposed to air. They are combined with acids to form local anesthetic salts, in which they are quite soluble in water and stable. They are
usually combined with hydrochloride salt (lidocaine HCl) and dissolved in sterile water or saline.

One of the major differences between an ester and an amide anesthetic compound is the method by which they are metabolized. Ester compounds are hydrolyzed in plasma by the enzyme pseudocholinesterase. This produces paraaminobenzoic acid (PABA) which is capable of inducing allergic reactions. The amide compounds are degraded in the liver and do not produce metabolites which induce allergic responses.\textsuperscript{10}

The pKa of a compound is defined as the pH at which the ionized and nonionized forms exist in equilibrium. It is the nonionized form of the compound that penetrates the nerve membrane. As the pH of an anesthetic solution is increased and the hydrogen ion concentration decreased, the equilibrium will shift toward the free base form and relatively more local anesthetic agent will exist in free base form. At tissue pH of 7.4, 2-40\% of the available anesthetic compound exists in the nonionized form.\textsuperscript{11}

\textbf{Lidocaine:}

Lidocaine (diethyl-2,6-dimethyl acetanilide) has a pKa value of 7.7.\textsuperscript{9} Lidocaine is prepared as a hydrochloride salt to improve its water solubility and stability in aqueous solutions. It has an intermediate lipid solubility, protein binding ability, and in vivo potency when compared to other local anesthetic agents. Vasoconstrictor is added to lidocaine to counteract its vasodilation properties. Without a vasoconstrictor, absorption is increased, local efficacy is decreased, and toxic levels are reached more quickly.
**Vasoconstrictors:**

Vasoconstrictors are agents which are able to constrict blood vessels. They are added to local anesthetics to counteract the vasodilation properties of the anesthetics. The addition of vasoconstrictor to local anesthetic prolongs and increases the depth of local anesthesia by retarding the removal of the agent from the injection site, reduces the peak plasma levels of the anesthetic, and provides some hemostasis in the area of the injection site. Epinephrine is the most commonly used vasoconstrictor in dentistry. Epinephrine acts mostly on beta receptors (in the heart and lungs), but does also act on alpha receptors (in the peripheral vasculature). Stimulation of alpha receptors results in smooth muscle contraction of peripheral vasculature. Beta-1 receptors increase systolic and diastolic blood pressure, heart rate, strength of contraction, stoke volume, cardiac output, and myocardium oxygen consumption. Beta-2 receptors cause bronchodilation and vasodilation in skeletal muscle. The maximum recommended dose for epinephrine is 0.2 mg per appointment for a healthy individual. The maximum recommended dosage of epinephrine for cardiac impaired individuals is 0.04 mg per appointment. By adding a vasoconstrictor to a local anesthetic, the pH drops from an average of 5.5 to 3.5.

**What is Pulpitis?**

Pulpitis in human dentition can be described as a diseased state of teeth caused by any insult that disrupts the healthy pulp. This pathology can cause intermittent or spontaneous pain. Teeth in this state can respond differently to stimuli that would be considered normal. This is referred to as hypersensitivity or alldynia. An extremely cold stimulus can be very helpful in the diagnosis of pulpitis. Pressure, heat, and
especially cold sensations can be exaggerated and/or prolonged. When pulpal disease has progressed to a state in that the body’s normal immune response is unable to repair the damage from this disease, a diagnosis of irreversible pulpitis is made. The presence of pulpitis can be of significance when administering an IAN block. Lack of success of the IAN block can be due to possible heightened or hypersensitivity of the tooth.

Inferior Alveolar Nerve Block (IANB)

Many studies have been performed with the goal to increase success rates of the IANB. Researchers have studied adding hyaluronidase to the anesthetic solution, adding carbonation to the anesthetic solution, using dyphenhydramine as an anesthetic solution, using 0.5% bupivacaine, using 3% mepivacaine and 4% prilocaine, using articaine, administering the block using a peripheral nerve stimulator for accurate placement, changing the epinephrine concentration, administering more anesthetic, changing the amount and concentration of lidocaine, or combining meperidine and lidocaine. Interestingly, none of these studies were able to show significant increases in the success rate of the IANB.

Rood et al. reported that there is some benefit to be gained from the use of 5% lidocaine in the IAN block. He stated that by using a higher percentage of anesthetic, the success of anesthesia is increased. Beckett and Gilmour endorse Rood’s findings with a case report of a local anesthetic “resistant” patient in whom a 5% lidocaine solution enabled painless dental treatment to be performed.

Chaney et al. studied the difference between lidocaine hydrocarbonate compared to lidocaine hydrochloride for the IANB. Results showed that 2.2% lidocaine
hydrocarbonate with 1:100,000 epinephrine and 2% lidocaine hydrochloride with
1:100,000 epinephrine showed no significant differences in providing a successful
inferior alveolar block.

Whitcomb et al. \(^{31}\) examined the effect of buffered 2% lidocaine with 1:100,000
epinephrine, using a sodium bicarbonate formulation in IAN blocks of asymptomatic
patients. The objective of the study was to determine whether buffering the anesthetic
solution to a higher pH, 7.50 versus the non-buffered 6.40, would result in increased
pulpal anesthesia and reduced pain of injection. They found no statistical difference in
pain of injection, anesthesia onset, or anesthetic success between non-buffered 2%
lidocaine with 1:100,000 epinephrine and buffered 2% lidocaine with 1:100,000
epinephrine for the inferior alveolar nerve block.

**IAN in Symptomatic Irreversible Pulpitis Patients**

Clinical studies in patients with symptomatic irreversible pulpitis have found
success with the IANB occurred between 15-57% of the time. \(^{32}\) These studies would
indicate that anesthesia is often difficult to achieve in symptomatic irreversible pulpitis.

Claffey et al. \(^{33}\) compared the anesthetic efficacy of 4% articaine with 1:100,000
epinephrine to 2% lidocaine with 1:100,000 epinephrine for inferior alveolar nerve blocks
in patients experiencing irreversible pulpitis in mandibular posterior teeth. The success
rate for the IANB using articaine was 24% and for lidocaine 23%. They found no
significant difference between the articaine and lidocaine solutions.
Tortamano et al.\textsuperscript{34} also found that articaine and lidocaine had no significant difference in anesthetic success of the inferior alveolar nerve block and that neither solution resulted in a successful rate of anesthesia in posterior mandibular teeth.

Sherman et al.\textsuperscript{35} compared 4\% articaine with 1:100,000 epinephrine with 2\% lidocaine with 1:100,000 epinephrine for Gow-Gates blocks in patients experiencing symptomatic irreversible pulpitis. No difference between the 2 anesthetics was found.

Aggarwal et al.\textsuperscript{36} studied pretreatment medication with nonsteroidal anti-inflammatory drugs. Placebo gave 29\% success rate. Premedication with ketorolac gave 39\% success and ibuprofen gave 27\% success. There was no significant difference between the 3 groups in patients with symptomatic irreversible pulpitis mandibular posterior teeth. Oleson et al.\textsuperscript{37} also studied the effect of preoperative ibuprofen of the success of the inferior alveolar nerve block in patients with irreversible pulpitis. The success rate for the IANB was 41\% with preoperative ibuprofen and 35\% with placebo with no significant difference between the 2 groups. Simpson et al.\textsuperscript{38} studied the effect of preoperative ibuprofen/acetaminophen combination. The success rate for the IANB was 32\% for the combination of ibuprofen/acetaminophen group and 24\% for the placebo, with no significant difference.

Bigby et al.\textsuperscript{27} compared the anesthetic efficacy of lidocaine with epinephrine to lidocaine plus meperidine with epinephrine for inferior alveolar nerve blocks in patients with mandibular posterior teeth experiencing irreversible pulpitis. The success rate for the inferior alveolar nerve block using the lidocaine solution was 26\%, and for the
lidocaine/meperidine solution, the success rate was 12%. There was no significant difference (p = 0.28) between the two solutions.

Studies have also been performed looking at the needle placement. Kennedy et al.\textsuperscript{39} studied the significance of needle deflection in success of the inferior alveolar nerve block in patients with irreversible pulpitis. No significant difference was noted and neither technique resulted in an acceptable rate of anesthetic success in patients with irreversible pulpitis. Steinkruger et al.\textsuperscript{40} et al. evaluated the significance of needle bevel orientation for a successful inferior alveolar nerve block and revealed that needle bevel position away or toward the mandibular ramus does not affect anesthetic success. Hannan et al.\textsuperscript{41} noted that accurate placement of the needle via ultrasound technology also does not result in more successful pulpal anesthesia, showing that the accuracy of needle placement is not a primary reason for pulpal anesthetic failure in the mandible. Berns et al.\textsuperscript{42} researched radiographic methods to locate the mandibular foramen, to help give an accurate injection, but discovered it did not increase the rate of anesthetic success. Simon et al.\textsuperscript{43} studied accurate placement of solution deposition to the inferior alveolar nerve via a peripheral nerve stimulator and showed no increase in success rate of pulpal anesthesia when compared with a conventional inferior alveolar nerve block.

Accessory innervation via the mylohyoid nerve is hypothesized to contribute to inferior alveolar nerve block failure, specifically regarding pulpal anesthesia of the first mandibular molar.\textsuperscript{44} However, Clark et al.\textsuperscript{45} showed that a combination inferior alveolar nerve block and mylohyoid nerve block did not improve pulpal anesthesia, nor does a mylohyoid nerve block predictably ensure pulpal anesthesia in mandibular teeth.
Supplemental Anesthesia

Matthews et al.\textsuperscript{46} studied articaine for supplemental buccal mandibular infiltration anesthesia in patients with symptomatic irreversible pulpitis when the inferior alveolar nerve block failed. They concluded that anesthetic success was obtained in 58\% of the mandibular posterior teeth that were unsuccessful after the IANB alone.

Supplemental intraosseous injections have also been studied in patients with irreversible pulpitis. Nusstein et al.\textsuperscript{47} studied patients with symptomatic irreversible pulpitis. Eighty-one percent of the mandibular teeth and 12\% of maxillary teeth required intraosseous injections due to failure to gain pulpal anesthesia.

Reisman et al.\textsuperscript{48} studied the efficacy of a supplemental intraosseous injection of 3\% mepivacaine in irreversible pulpitis. Seventy-five percent of patients required an intraosseous injection because of failure to gain pulpal anesthesia. The inferior alveolar block was 25\% successful. The intraosseous injection increased success to 80\%.

Injection Pain in Patients with Irreversible Pulpitis

McCartney et al.\textsuperscript{49} studied the pain associated with needle insertion, placement, and solution deposition for the conventional inferior alveolar nerve block in patients with irreversible pulpitis. She found that moderate-to-severe pain may occur 57\% to 89\% of the time with the inferior alveolar nerve block. Needle placement was more painful than needle insertion in men and more painful than either insertion or deposition for women. There was no statistical difference between the pain for men or women with respect to needle insertion, placement, or deposition pain. The use of topical anesthesia did not eliminate needle insertion pain.
Slow Injection

The speed of injection has been linked to the pain of injections. The majority of literature has found that the slower the injection, the less painful. Kudo et al.\textsuperscript{50} assessed injection pressure, pain, and anxiety at the start of injection of a local anesthetic into the oral mucosa. A significant correlation was evident between injection pressure and pain (p = .00124). Kudo therefore recommended that local anesthetic be injected under low pressure (less than 306 mm Hg) to minimize pain and anxiety among dental patients. Kanaa et al.\textsuperscript{51} also studied the speed of injection related to the pain of such injections and the overall efficacy of such injections. Slow IANB produced more episodes of no response to maximal pulp stimulation than rapid IANB in molars, premolars, and lateral incisors. Kanaa concluded that slow IANB was more comfortable than rapid IANB (p = 0.021) and had more anesthetic success.

One way to give a slow injection is to use the CompuDent\textregistered{} (Milestone Scientific) CCLAD\textsuperscript{TM} system (Wand\textregistered{}). This system delivers 1.4 mL of anesthetic solution over a time period of 4 minutes and 45 seconds on the slowest setting. In the literature there is very good evidence that the CCLAD\textsuperscript{TM} unit decreases the pain of injections. Hochman et al.\textsuperscript{52} studied this system. The study was designed to determine if there are changes in the perception of pain when the flow rate and pressure of an injected anesthetic are precisely controlled. The Wand\textregistered{} injector was found to be statistically (p < .001) less painful than the manual injection. Gibson et al.\textsuperscript{53} also evaluated the efficacy of the computerized anesthesia delivery system (e.g., Wand\textregistered{}) compared to a traditional anesthesia administration. They found that the Wand\textregistered{} injections produced significantly
fewer patients who exhibited disruptive behavior during the initial 15 seconds of an injection when compared with those who received a traditional palatal injection. Nicholson et al.\textsuperscript{54} studied maxillary infiltration and mandibular inferior alveolar nerve block injections with both a traditional syringe and the Wand\textsuperscript{®}. Injection discomfort ratings with the Wand\textsuperscript{®} were lower than with the syringe. Reduced postoperative discomfort using the Wand\textsuperscript{®} for the inferior alveolar nerve block was significant. Other Studies have also come to the same conclusion, that injections using the wand system are less painful.\textsuperscript{55,56}

Some studies show no difference in pain between the CCLAD\textsuperscript{™} unit and a traditional injection. Asarch et al.\textsuperscript{57} evaluated the efficacy of a computerized anesthesia delivery system in reducing pain during injections when compared with a traditional delivery system (i.e., syringe). They concluded that there were no significant differences in pain between the computerized and syringe. Saloum et al.\textsuperscript{58} compared the pain response to the Wand\textsuperscript{®} with the response to syringe injections. They found no significant difference in pain between the two groups. Tahmassebi et al.\textsuperscript{59} compared the Wand\textsuperscript{®} computer controlled local analgesia system and a conventional technique in children of pre-school and school age. No statistical difference in pain sensation and anxiety was found when the Wand\textsuperscript{®} was used, compared with the conventional technique (p = 0.976). Versloot et al.\textsuperscript{60} also found no clear difference in the pain response between an injection with the Wand\textsuperscript{®} or the traditional syringe.

One study shows higher pain ratings with the CCLAD\textsuperscript{™} unit. Goodell et al.\textsuperscript{61} studied the Wand\textsuperscript{®} versus a conventional atraumatic syringe injection technique. Patients
experienced significantly lower overall postinjection anxiety and pain of injection and had significantly more positive overall experience ratings with the conventional technique than with the Wand®.

**Buffered Local Anesthetics**

Buffered local anesthetics have a higher pH and may be more efficient in achieving pain control for the inferior alveolar nerve block. Amide local anesthetics, such as lidocaine, have a weak base component. This basic nature and the coinciding pH have important implications in the mechanisms of local anesthesia. Lidocaine with epinephrine is a mixture of two chemical forms: a de-ionized, uncharged free base form and an ionized, charged cationic form. The de-ionized form of the local anesthetic is the active lipid-soluble form that readily enters the nerve membrane and blocks nerve conduction. The presence of a sufficient amount of de-ionized free base anesthetic is necessary to induce adequate anesthesia.

Catchlove et al. concluded that “carbon dioxide potentiates local anesthesia by three mechanisms: a direct depressant effect of carbon dioxide on the axon, by concentrating local anesthetic inside the nerve trunk, and by decreasing the pH inside the nerve which will allow a greater conversion of anesthetic to its active cation form once inside the membrane”.

The efficacy of buffered local anesthetics has been examined thoroughly in medicine. Many of the studies involving buffered anesthetics use the pain of injection as their assessment. McKay et al. found that a non-buffered lidocaine with epinephrine solution had the higher mean pain score compared to a buffered solution. Both lidocaine
with commercial epinephrine and plain lidocaine were significantly more painful than the corresponding buffered solutions. Steinbrook et al.\textsuperscript{67} also studied pain of injection of buffered local anesthetics. They also found that lidocaine buffered with sodium bicarbonate caused significantly less pain on skin infiltration. Masters et al.\textsuperscript{68} also found that the buffered solutions were significantly less painful than the control solutions. These authors as well as several others\textsuperscript{69-76} concluded that pain of injection was reduced by a statistically significant amount when using buffered local anesthetics versus non-buffered solutions. These results are supported by the results of three systematic reviews of the literature\textsuperscript{70,71,72} that also concluded that buffered local anesthetics result in less pain on injection than non-buffered solutions.

Some authors were unable to establish any significant difference in the pain of injection between buffered and non-buffered local anesthetics. Gershon et al.\textsuperscript{73} found that there was no statistically significant difference in pain scores between the two local anesthetic solutions. Serour et al.\textsuperscript{74} also found no significant decreases in the pain of injection for dorsal penile nerve block when using buffered solutions versus standard local anesthetic solutions.

In dentistry, Hobiech et al.\textsuperscript{75} also found no difference in pain of injection or onset by using a buffered anesthetic, in a dental model. Whitcomb et al.\textsuperscript{31} also evaluated the efficacy of sodium bicarbonate buffered 2\% lidocaine with 1:100,000 epinephrine in inferior alveolar nerve blocks. They found no significant differences in the pain of injection, the onset of anesthesia, or the anesthetic success.
Younis et al.\textsuperscript{76} and Curatolo et al.\textsuperscript{77} determined that buffered local anesthetics result in significantly improved anesthesia with a faster onset of action, and a higher degree anesthesia in a non-dental model. However, Chaney et al.\textsuperscript{16} found that buffered local anesthetics did not improve the efficacy of the solution as an anesthetic. They found that 2.2\% lidocaine hydrocarbonate with 1:100,000 epinephrine was equivalent to 2\% lidocaine hydrochloride with 1:100,000 epinephrine in inferior alveolar nerve blocks for pulpal anesthesia.

Some researchers did find significant differences using a dental model. Bowles et al.\textsuperscript{78} studied maxillary infiltrations in the first molar region. Overall, they found significantly less pain reported on infiltration of buffered lidocaine solution. Al-Sultan et al.\textsuperscript{79} also studied buffered anesthetic using a dental model and found a significant decrease of pain on injection, significantly faster onset, and less pain on extraction of patients that presented with periapical lesions using buffered local anesthetic.

In contrast Balasco et al.\textsuperscript{80} studied pain of injection, and pain of incision and drainage using a buffered lidocaine solution compared to a non-buffered anesthetic solution, in a dental model. They found no significant difference between the two anesthetic solutions with regard to pain of injection or pain of the incision and drainage.

No study has investigated the efficacy of a buffered lidocaine solution in increasing the success of the inferior alveolar nerve block in patients with symptomatic irreversible pulpitis. Therefore, the purpose of this prospective, randomized, double-blind study is to determine the effect of buffered lidocaine on the anesthetic success of
the inferior alveolar nerve block in patients experiencing symptomatic irreversible pulpitis.
CHAPTER 2

Materials and Methods

One hundred five adult patients participated in this study. All were emergency patients of the College of Dentistry and in good health as determined by an oral and written medical history.

Inclusion criteria were: 18 years and older; in good health (ASA classification I or II); informed consent granted. Exclusion criteria were: allergy to lidocaine; history of significant medical problem (ASA classification III or greater); taken CNS depressants within 6 hours prior to treatment; taken any analgesic medications 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 (Appendix B) and consent form (Appendix B) the subjects completed the Corah’s Dental Anxiety Scale questionnaire (Appendix B). 81

To qualify for the study, each patient had a vital mandibular posterior tooth (molar or premolar), was actively experiencing moderate-to-severe pain, and had a prolonged response to cold testing with Endo-ice™ (1,1,1,2 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. Each patient had a tooth with a diagnosis of symptomatic irreversible pulpitis.

Each patient rated his or her initial pain on a Heft-Parker Visual Analog Scale (VAS) (Appendix B). 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”.

The blinded subjects randomly received inferior alveolar nerve blocks using 4% lidocaine with 1:100,000 epinephrine or 4% lidocaine with 1:100,000 epinephrine/0.18 mEq/mL sodium bicarbonate. The 4% lidocaine and epinephrine were mixed as follows: under sterile conditions, 1.8 mL of 4% lidocaine (Hospira, Lake Forest, IL) was drawn into a sterile 3 mL Luer-Lok disposable syringe using a 30-gauge needle (Becton-Dickinson & Co., Rutherford, NJ). This 4% lidocaine was then loaded into expired dental cartridges that had been emptied, washed, placed in sterilization sleeves, and sterilized using a hot steam autoclave. To this cartridge, 18 µg of epinephrine from a 1 mL ampule of 1:1000 epinephrine (Abbott Laboratories, North Chicago, IL) was added using a calibrated micropipette (Sherwood Medical, St. Louis, MO). Eighteen µg of 1:1000 epinephrine added to a standard dental cartridge of 1.8 ml resulted in a 1:100,000 concentration of epinephrine. The micropipette was calibrated according to the settings in the user manual. The 1:1000 epinephrine ampules were only used once and then
discarded. The 1.8 mL formulation contained 72 mg of 4% lidocaine with 18 µg epinephrine. The rubber plugger was then replaced into the cartridge, and using a 30-gauge needle (Becton-Dickinson & Co., Rutherford, NJ) through the top, the excess air was released from the cartridge. This process was then repeated for a total of 2 standard dental cartridges consisting of a solution of 4% lidocaine with 1:100,000 epinephrine. This was completed immediately prior to the first injection by the primary provider in the Graduate Endodontics Clinic at The Ohio State University.

Before the experiment, the two anesthetic formulations were randomly assigned a five-digit number from a random number table generated using www.random.com. Each patient was randomly assigned to one of the two anesthetic formulations to determine which anesthetic formulation was administered at the appointment. Only the random numbers were recorded on the data collection sheets to blind the experiment.

After the anesthetic cartridges were made, the grouping code was broken by an endodontic resident not involved in the investigation who prepared either a buffered or mock buffered solution for injection. For the buffered solution, each cartridge was buffered with 8.4% sodium bicarbonate to produce a final concentration of 0.18 mEq/mL of sodium bicarbonate using the Onset® buffering system (OnPharma Inc., Los Gatos, CA). The 8.4% sodium bicarbonate solution was replaced fresh everyday, along with the cartridge holder and adapter. All formulations were prepared immediately prior to each injection. The Onset® system dial was set at 18 and a cartridge containing the fresh 4% lidocaine with 1:100,000 epinephrine was placed in the cartridge holder. The cartridge was then moved to position 3 according to the instruction manual provided where the
bicarbonate solution was injected into the anesthetic cartridge. The cartridge was then removed and immediately given to the primary investigator. The primary investigator and patients were both blinded as to the solution received. After the first injection was administered the aiding resident then mixed and supplied the primary investigator with the second cartridge. The assisting resident took the same amount of time whether the buffered or the unbuffered (mock) cartridge was prepared. Thus each patient received either 2 cartridges (2.8 ml) of 4% lidocaine with 1:100,000 epinephrine or a buffered 4% lidocaine with 1:100,000 epinephrine. The non-buffered group was given a total of 112 mg (2.8 ml at a 4% solution) of lidocaine and 0.028 mg of epinephrine for the IAN block, where the buffered group received 104 mg of lidocaine and 0.026 mg of epinephrine due to the fact that some anesthetic is replaced with the sodium bicarbonate in the buffering process.

The two anesthetic formulations had their pH values determined using a pH/millivolt meter (Thermo Scientific, Orion Products, OH). The pH was measured on 10 buffered 4% lidocaine with 1:100,000 epinephrine solutions and 10 plain 4% lidocaine 1:100,000 epinephrine solutions. These pH readings were measured using fresh solutions prepared immediately prior to measuring similar to the study technique.

An inferior alveolar nerve block was administered using 2.8 ml of the 4% solutions (buffered or non-buffered) using a conventional technique. The anesthetic was delivered using a CCLAD™ (Computer Controlled Local Anesthetic Delivery system, Milestone Scientific, Deerfield, IL) unit. This is an approved anesthetic delivery system routinely used for anesthetic injections. This system is a microprocessor-driven device
that delivers a controlled infusion of anesthetic solution. The unit accepts standard dental anesthetic glass 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 each cartridge is delivered for a total of 2.8 ml of anesthetic. Flow rate, initiation and cessation of flow, and aspiration are controlled with a foot pedal.

For the CCLAD™ system, a cartridge of the buffered or non-buffered lidocaine solution was placed into the plastic barrel of the unit’s handpiece assembly, and placed into the cartridge holder socket with a quarter turn in a counter clockwise direction. The cap was removed from the 27-gauge needle and the foot pedal depressed once to activate the purge cycle to remove air from the plastic tubing and fill the line with anesthetic solution.

The computer-assisted injection was administered as follows. The subject was placed in a supine position. Topical anesthetic gel (20% benzocaine, Patterson Dental Supply, Inc., St. Paul, MN) was passively placed at the inferior alveolar nerve block injection site for 60 seconds using a cotton tip applicator. The 27-gauge 1½-inch needle was inserted through the mucosal tissue (insertion phase). 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 to cruise control (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 injection time. Approximately 1 drop of anesthetic solution was 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 primary investigator then slowly placed the needle to the target site over a 10-second time period (placement phase). The anesthetic solution was deposited over a one-minute time period on the slow setting of the CCLAD™ and then the CCLAD™ was activated to the faster rate and the rest of the solution was deposited (solution deposition phase) for a total deposition time of 1 minute and 52 seconds. Prior to the injection, the primary investigator explained to each patient that each injection had three phases: insertion, placement and deposition. The patient was instructed to complete a VAS corresponding to pain felt during the three stages: insertion, placement, and deposition. The primary investigator noted each phase out loud as it was done. The patient recorded the pain ratings after each injection was complete. After around one minute of time allotted, to the patient, to rate the pain of injection of the first injection, the second injection was administered with the CCLAD™ unit on the fast setting. The pain of the second inferior alveolar injection was also recorded. A separate buccal nerve block was administered using a standard syringe and 2% lidocaine with 1:100,000 epinephrine for molar teeth. A
half cartridge volume was used for the buccal nerve block technique. The pain of the buccal nerve block was not recorded.

The patient was questioned every minute for 15 minutes if his/her lip was numb following completion of all injections. If profound lip numbness was not recorded at 15 minutes, the block was considered missed. The patient was dismissed from the study and they received appropriate emergency care for their tooth (additional injections and supplemental anesthesia). Four patients were dismissed from the study due to missed blocks.

The study tooth was then isolated with a rubber dam and endodontic access performed. Patients were instructed to definitively rate any pain felt during the endodontic procedure. If the patient felt pain, the treatment was immediately stopped and the patient rated their discomfort using another Heft-Parker VAS. The extent of access achieved when the patient felt pain was recorded as either; within dentin, entering the pulp chamber, or canal instrumentation. The success of the inferior alveolar nerve block 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).

If the patient experienced moderate or severe pain, additional supplemental anesthesia was administered using the CCLAD™ system on the fast rate. First, the rubber dam was removed and one cartridge of 4% articaine with 1:100,000 epinephrine was given as a buccal infiltration over 1 minute at the site of the emergency tooth’s root apices. The patient was instructed to complete a VAS corresponding to pain felt during the buccal infiltration related to three stages: insertion, placement, and 1-minute
deposition. The insertion phase was the initial placement of the 27-gauge 1.5-inch needle next to the tooth. The placement phase was the needle advancement to the level of the apex of the affected tooth. The deposition phase was the 4% articaine with 1:100,000 epinephrine being deposited near the apex of the tooth. After 5 minutes elapsed to allow for sufficient anesthesia\textsuperscript{97}, the rubber dam was replaced and endodontic treatment resumed. If the patient felt no pain or mild pain, treatment continued. If the patient felt moderate-to-severe pain (55 mm or higher on the VAS), treatment was again stopped and the level of access noted: dentin, pulp chamber, or canal instrumentation. The success of the buccal infiltration was defined as the ability to access and instrument the tooth with no or mild pain (VAS score of zero or less than or equal to 54 mm, respectively).

If the buccal infiltration was unsuccessful, an intraosseous injection was administered after removal of the rubber dam. One cartridge of 2% lidocaine with 1:100,000 epinephrine was utilized with the Stabident intraosseous anesthetic delivery system (Fairfax Dental Inc., Miami, FL). The protocol was as follows: using a slow speed handpiece and a Stabident perforator the attached gingiva and cortical bone were perforated. Using a standard dental syringe, a 27-gauge 8 mm needle was inserted into the perforation and a cartridge of 2% lidocaine 1:100,000 with epinephrine was deposited into the medullary bone adjacent to the affected tooth over a total of 30 seconds. For premolars and first molars the injection was administered distal to the affected tooth. In second molars the injection was made mesial to the affected tooth. The patient was again instructed to complete a VAS corresponding to pain felt during the related three stages: insertion, placement, and deposition. The rubber dam was replaced and treatment
continued. If moderate-to-severe pain was felt again (VAS rating greater than 54 mm), the intraosseous injection was repeated. For premolars and first molars the injection was placed just distal to the affected tooth and for second molars another mesial injection was placed. If moderate-to-severe pain was felt again, intrapulpal injections were administered using 2% lidocaine with 1:100,000 epinephrine. Patients who received the intrapulpal injection had achieved sufficient anesthesia at this point in their treatment to unroof the pulpal chamber, thereby allowing the administration of the intrapulpal injection. All patients who received the intrapulpal injection were able to complete root canal treatment.

Root canals were cleaned and shaped with hand and rotary instruments, using K-type hand files and Vortex (Tulsa Dentsply, Tulsa OK) rotary instruments along with sodium 3% hypochlorite irrigation. Oral post-operative instructions were given when treatment was completed and pain management prescriptions were supplied as indicated. If the patient requested an extraction rather than emergency endodontic treatment, access and canal instrumentation were completed and then the tooth was extracted immediately in an oral surgery clinic.

After receiving emergency endodontic treatment, patients rated the degree of satisfaction with the treatment they received using an analog scale (0-100) for assessing satisfaction (Appendix B). Not satisfied corresponded to 0 mm. Somewhat satisfied was defined as greater than 0 mm and less than or equal to 33 mm. Moderately satisfied was defined as greater than 33 mm and less than 66 mm. Completely satisfied was defined as equal to or greater than 66 mm. Patients were also asked to rate, using the 170-mm Heft
Parker VAS, the overall treatment pain of the procedure and the data was recorded. It was emphasized that the satisfaction survey did not affect the operator’s grades or standing in the residency so that patients were encouraged to be honest in their assessment. All forms were collected by the primary investigator, in the operatory room, and the patients were compensated for the study.

Patients were reappointed for completion of root canal therapy at a later date or referred for extraction of the tooth as appropriate. The patient received $75.00 cash for their participation.

Comparisons between the buffered and non-buffered lidocaine groups for gender and anesthetic success were analyzed using the chi-square test, whereas differences in age, initial pain scores, anxiety, and degree of satisfaction were analyzed using the Mann-Whitney-Wilcoxon test. With a two-sided alpha risk of 0.05 and assuming a success rate of 28%\(^\text{82}\), a sample size of 50 subjects per group was required to detect a difference of \(\pm30\) percentage points in anesthetic success with a power \(>0.87\). However, because of potential withdrawal by subjects, the total number was set to 110. Comparisons were considered significant if \( p < 0.05 \).
CHAPTER 3

Results

One-hundred five patients participated in this study (Table 1). Three patients (2.8%) were disqualified because of missed inferior alveolar block (no lip numbness at 15 minutes after injection) (one patient in the buffered group and 2 patients in the non-buffered group) and two patients (1.9%) were disqualified because of lack of vital tissue in the tooth (pulpal necrosis) (both in the buffered group), for a total of 100 patients analyzed. In the non-buffered group the mean age of the participating patients was $35.5 \pm 10.7$ years while the mean age of the buffered group was $34.8 \pm 11.3$ years. There was no statistically significant difference between the two groups. To qualify for participation, the patient needed to be experiencing moderate-to-severe pain at the time of treatment, as assessed on a 170 mm Heft-Parker Visual Analog Scale. The initial mean pain experienced by patients in the non-buffered group was $115.4 \pm 24.9$ mm, and the mean pain experienced by patients in the buffered group was $116.3 \pm 22.6$ mm. There was no significant difference between the two groups. Table 1 also illustrates the anxiety level of each patient as assessed by Corah’s Dental Anxiety Scale. A score was given between 4 and 20, with a higher number indicating more anxiety. The median anxiety score for patients in the non-buffered group was 7.5, and the median anxiety score for patients in the buffered group was 9. There was no statistically significant difference
between the two groups. Table 1 also analyzes the tooth type and gender. The majority of studied teeth for both groups were molars, as there were only 3 premolars studied in the non-buffered group, and 6 premolars studied in the buffered group. There was no statistically significant difference between the two groups for tooth type. Of the 50 participants in the non-buffered group, 21 were male and 29 were female. Of the 50 participants in the buffered group, 18 were male and 32 were female. There was no statistically significant difference between the two groups for gender.

Table 2 shows the categorical initial pain of both groups. All patients in the non-buffered and buffered groups had moderate or severe pain. In the buffered group 44% had moderate pain on the VAS while 56% had severe pain. In the non-buffered group 34% had moderate initial pain, where 66% had severe initial pain. There was no statistically significant difference between the two groups for categorical initial pain levels.

Table 3 illustrates the pulpal anesthetic success rates of the IANB, mandibular buccal infiltration injection, and intraosseous injection. The IANB was successful in 20 of 50 patients in the non-buffered group (40%), and 16 of 50 in the buffered group (32%). For this study, success 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). Following the IAN block, 30 non-buffered patients and 34 buffered patients required additional anesthesia using a buccal infiltration of 4% articaine with 1:100,000 epinephrine. This proved successful in 11 of the 30 non-buffered patients (37%), and 13 of the 34 buffered patients (38%). Following failure of the buccal infiltration, 19 non-
buffered patients and 21 buffered patients required additional anesthesia using an intraosseous technique with 2% lidocaine with 1:100,000 epinephrine. This proved successful in 13 of the 19 non-buffered patients (68%), and 16 of the 21 buffered patients (76%). Following the intraosseous technique 6 non-buffered patients and 5 buffered patients required additional anesthesia using a second intraosseous injection with 2% lidocaine with 1:100,000 epinephrine. This proved successful in 3 of the 6 non-buffered patients (50%), and 5 of the 5 buffered patients (100%). Three non-buffered patients required intrapulpal injections which all resulted in pulpal anesthetic success. There were no statistically significant differences for success with the IAN block, buccal infiltration injection, or intraosseous injections.

Table 4 shows the IANB success by gender between the non-buffered and buffered 4% lidocaine 1:100,000 epinephrine groups. No significant difference was found between males and females in either the buffered or the non-buffered group.

Table 5 demonstrates the IAN block success by tooth type between the buffered and non-buffered groups. Most teeth studied in each group were 1st molars followed by 2nd molars and then premolars. In both groups the IAN block success was highest in the premolars followed by the 1st molars. The least successful IAN block was in the 2nd molars.

Table 6 shows the success of the articaine mandibular buccal infiltration injection by group and tooth type. Most teeth were 1st and 2nd molars for both the buffered and non-buffered groups. There were similar success rates for the 1st and 2nd molar groups and the other groups were too small for comparison.
Table 7 illustrates the success of supplemental intraosseous injections, with 2% lidocaine 1:100,000 epinephrine, by group and tooth type. There were similar success rates between groups.

Table 8 illustrates the pain of injection for the IANB using either 4% lidocaine buffered or non-buffered. Table 10 illustrates the pain of injection for the buccal infiltration injection using 4% articaine 1:100,000 epinephrine. Table 11 shows the pain of injection for the supplemental intraosseous injection using 2% lidocaine 1:100,000 epinephrine. No significant differences were found in any of the 3 stages, (insertion, placement, deposition) of the three injection types when comparing the non-buffered group and buffered group for the IANB, buccal infiltration and supplemental intraosseous injections.

Table 9 shows the categorical values of the pain of injection of buffered or non-buffered IAN blocks using the Heft-Parker Visual Analog Scale. For both non-buffered and buffered groups, most patients felt mild-to-moderate pain during all three phases of injection with needle placement being the most painful portion in both the buffered and non-buffered groups. There was no difference found between the two groups.

Table 12 demonstrates the post-treatment satisfaction ratings and the remembered maximum pain ratings. Post-treatment satisfaction was measured on a 100 mm scale. The higher the number on the scale, the more satisfied the patient. The non-buffered group mean was 92.1 ± 17.2 mm and the buffered group mean was 88.2 ± 16.4 mm. There was no significant difference between the satisfaction ratings between the two groups and both groups were highly satisfied. The remembered maximum pain ratings were
performed on a 170 mm Heft-Parker Visual Analog Scale. The buffered group maximum remembered pain was 56.0 mm (moderate pain) and the non-buffered was 43.2 mm (mild pain). There was no significant difference in the maximum pain remembered between the buffered and non-buffered groups.

Table 13 shows the pain of intraoperative access and instrumentation using 4% lidocaine 1:100,000 epinephrine either buffered or non-buffered for IAN blocks. There was no significant difference in intraoperative pain between the two groups during dentin access, chamber access, or canal instrumentation. Table 14 shows the pain of intraoperative access and instrumentation using buffered and non-buffered IANB injections followed by supplemental 4% articaine 1:100,000 epinephrine buccal infiltrations. No significant difference was found in intraoperative pain between the initial buffered IANB and non-buffered IANB injections and following supplemental buccal infiltration of articaine.

Table 15 shows the treatment stage in which moderate-to-severe pain was felt (i.e. point of failure). The majority of anesthetic failures were found to be during dentin exposure following IAN block with either buffered or non-buffered 4% lidocaine with 1:100,000 epinephrine (40% for the buffered group, and 30% for the non-buffered group). Following supplemental 4% articaine 1:100,000 epinephrine mandibular buccal infiltrations, most failures for the non-buffered group were still in dentin (37%), while most failures for the buffered group were in the chamber (35%). Following supplemental intraosseous injections with 2% lidocaine 1:100,000 epinephrine, most failures for the non-buffered group were still in dentin (21%), while most failures for the buffered group
were in the chamber (14%). If the patients were still experiencing moderate-to-severe pain following the intraosseous injection, a second intraosseous injection was administered. In the buffered group 100% were successful and in the non-buffered group 50% still failed in the chamber. All failures following the second intraosseous injection were in the chamber and intrapulpal injections were given which resulted in complete success.

Table 16 shows the pH readings obtained from 10 buffered and 10 non-buffered solutions. The buffered solutions were prepared by using the Onset™ (Onpharma) mixing pen. Both the buffered and non-buffered solutions used a fresh batch of anesthetic (4% lidocaine), epinephrine (1:1,000), and sodium bicarbonate (8.4%). Each pH measurement was made immediately. The final solutions of the anesthetic formulations had their pH values determined using a calibrated pH/millivolt meter. The non-buffered 4% lidocaine 1:100,000 epinephrine solution average pH was 4.507. The buffered 4% lidocaine 1:100,000 epinephrine solution average pH was 7.049.
CHAPTER 4

Discussion

Preoperative Statistics

Table 1 shows the number of patients participating in this study, 50 in the non-buffered group and 50 in the buffered group. Between the two groups, no statistical difference was noted among the variables of initial pain, age, gender, tooth type or preoperative anxiety.

Patients had to present with moderate-to-severe initial pain as reported on a 170 mm VAS, to qualify for the study. The inflammation taking place within the nervous tissue of their teeth may significantly affect their perception of pain. Studies have reported that preoperative pain resulting from symptomatic irreversible pulpitis affects the success rate of the conventional IAN block.\(^{35,38,39,40,48,49,50,91}\) If one group presented with higher initial pain scores than the other, the results of this study could be misleading. The mean initial pain reported by the non-buffered group was 115.4 ± 24.9 mm and the buffered group reported a mean initial pain value of 116.3 ± 22.6 mm on the VAS. As Table 1 shows, these values are not significantly different (p = 0.9918). Additionally, Table 2 shows the initial pain for both groups was considered moderate-to-severe. This is consistent with the idea that a patient experiencing symptomatic irreversible pulpitis typically presents with significant pain.\(^{35,36,38,39,48,49,50}\) Since, there was no statistically
significant difference between the buffered and non-buffered groups with regard to initial pain, this helped to eliminate initial pain as a confounding variable.

The buffered group had a minimum age of 18 years and maximum age of 62 years. The mean age and standard deviation for this group was 34.8 years ± 11.3 years (Table 1). For the non-buffered group, the minimum age was 18 and the maximum age was 64. The mean age and standard deviation for the non-buffered group was 35.5 years ± 10.7 years (Table 1). Some evidence shows age-related differences in pain perception. Some authors 83,84,85 have shown differences in pain perception in older patients. They have found that older patients tend to have an increase in pain threshold compared to younger patients. Nordenram et al. 86 studied the effect of age on anesthetic efficacy. They studied duration of tooth anesthesia, frequency of anesthesia, onset time, and soft tissue numbness of commonly used dental local anesthetics in healthy older subjects. They found that the anesthetic solutions tested were more effective in older people than younger people. Nordenram et al. stated that this might be due to a higher pain threshold in the older group due to reduced vascularity or secondary dentin formation. There was no significant difference between groups in the current investigation with regard to age (p = 0.7001). Therefore, age was not a confounding factor in pain perception between the non-buffered and buffered groups.

Table 1 also shows no significant differences by gender in the preoperative demographics. The buffered group had 32 (64%) females and 18 (36%) males. The non-buffered group had 29 (58%) females and 21 (42%) males (p = 0.6821). It was important that there were no significant differences between the groups with regard to gender
because the experience of pain may vary between males and females. Some studies have reported that women report more pain. \(^{87,88}\) Ravine et al. \(^{89}\) in a recent review on gender-related differences in pain perception found mixed results. Though the majority of reviewed studies showed no significant differences among males and females, some evidence for gender-related differences were found. The review noted pain from pressure tests were lower in females than males. The review concludes that there is no reliable pattern of sex differences in human pain sensitivity. Should one of the groups had more of one gender than the other, the difference in success could have come from the gender as opposed to which anesthetic was delivered. Therefore, gender was not a confounding factor in pain perception between the non-buffered and buffered groups.

Table 1 also shows the preoperative anxiety levels as measured by a Corah Dental Anxiety Scale. \(^{81}\) The data demonstrates that most subjects in both treatment groups had low-to-moderate anxiety. For the buffered group the median score was 9 on a scale from 4 to 15, and the non-buffered median anxiety score was 7.5 (\(p = 0.1832\)). Research shows that patients who are apprehensive may have a lower pain threshold. \(^{90,91,92}\) Because most subjects in both the buffered and the non-buffered groups reported low-to-moderate Corah scores and there was no significant difference between the two groups, anxiety did not play a major role in influencing the pain associated with the injection or treatment procedures. Stanley et al. \(^{82}\) noted no difference (\(p = 1.000\)) in the Corah scores of their nitrous oxide group (11 ± 4) and placebo group (11 ± 4). Simpson et al. \(^{38}\) noted anxiety scores of 10 ± 3 in their ibuprofen/acetaminophen pretreatment group and 9 ± 3 in their placebo group (\(p = 0.508\)) in their investigation of the effects of premedication on the
efficacy of the conventional IANB in patients with symptomatic irreversible pulpitis. The current study matches with these similarly designed studies with subjects reporting low-to moderate anxiety. Therefore, anxiety was not a confounding factor in pain perception between the non-buffered and buffered groups.

Tooth type is also identified on Table 1. The results could potentially be influenced without a random sampling of teeth. If one group of subjects were treated primarily for molars and the other for premolars, there may be some bias in anesthetic success since premolars are shown to have a higher incidence of pulpal anesthesia following a conventional IAN block injection of 2% lidocaine with 1:100,000 epinephrine.93 This study found no statistically significant difference (p = 0.5138) in tooth types undergoing treatment. Should one group have had significantly more of one type of tooth than the other, it would have been possible for a difference in treatment pain to be attributable to tooth type instead of type of anesthetic given. It should be noted that we did not try to get equal numbers of specific teeth in each group. The lack of significant difference of specific teeth in each group was by chance. Therefore, tooth type was not considered a confounding factor in pain perception between the non-buffered and buffered groups.

Irreversible Success

In the current study, all subjects reported moderate-to-severe initial pain. Therefore, we would expect a lower IAN block success rate compared with asymptomatic teeth.94
Table 3 presents the pulpal anesthetic success of the buffered and non-buffered formulations. The buffered formulation had a 32% success rate while the non-buffered formulation had a 40% success rate (p = .4046). The IAN block success rates in this study are very similar to other studies done by Cohen et al.\textsuperscript{95}, Claffey et al.\textsuperscript{33}, Kennedy et al.\textsuperscript{39}, Nusstein et al.\textsuperscript{47}, Bigby et al.\textsuperscript{27}, Reisman et al.\textsuperscript{48}, Lindemann et al.\textsuperscript{96}, Matthews et al.\textsuperscript{46}, and Fullmer et al.\textsuperscript{97}. In this study, success was defined as the ability to access and instrument the tooth without pain (a VAS score of zero) or mild pain (VAS score less than or equal to 54 mm).

Following the initial block injection, 34 patients in the buffered group and 30 patients in the non-buffered group required a buccal infiltration of one cartridge of 4% articaine with 1:100,000 epinephrine. This supplemental technique provided successful pulpal anesthesia in 13 of the 34 subjects in the buffered group (38%) and 11 of the 30 subjects in the non-buffered group (37%) with no significant difference between the two groups (p = 0.8971).

Twenty-one patients in the buffered group and 19 patients in the non-buffered group did not achieve successful pulpal anesthesia following the buccal infiltration and were given an additional cartridge of 2% lidocaine with 1:100,000 epinephrine intraosseously. This supplemental injection provided successful anesthesia for 16 of the 21 subjects (76%) in the buffered group and 13 of 19 (68%) subjects in the non-buffered group with no significant difference found between the two groups (p = 0.5826). A second intraosseous injection was administered for subjects that did not achieve successful pulpal anesthesia up to this point, 5 in the buffered group and 6 in the non-
buffered group. The second intraosseous injection provided successful anesthesia to 5 of 5 subjects (100%) in the buffered group and 3 of 6 subjects (50%) in the non-buffered group. Three patients in the non-buffered group were still unsuccessful at this point and required intrapulpal injections. There was no instance in which an intrapulpal injection did not achieve successful pulpal anesthesia. There was no instance in which a subject could not finish the emergency procedure for any reason. There was no significant difference in IAN block success between the buffered and non-buffered groups for the initial IAN block, or for additional supplemental anesthesia.

It is useful to compare the buffered 4% lidocaine 1:100,000 epinephrine and non-buffered 4% lidocaine 1:100,000 epinephrine success rates against the historical controls of the conventional IANB studies to evaluate whether or not either of these two tested anesthetics provide clinically superior anesthesia. Some of the main questions posed are as follows: Is a 4% lidocaine solution more successful than a standard 2% lidocaine solution when comparing historical results? Why did the buffered solution have similar results to the non-buffered solution in the current study? Are the success rates of the current study similar to other studies that have also studied mandibular teeth diagnosed with irreversible pulpitis? Why do local anesthetics sometimes fail?

There are many reasons for local anesthetic failure. Strichartz et al.\textsuperscript{98} stated “The damage to periapical tissues from inflammation and bacterial insult cause chemokines/cytokines (TNF-alpha, IL-6, prostaglandin E2, and prostacyclin) to enhance the excitability of nociceptors (Na\textsubscript{v} 1.7, Na\textsubscript{v} 1.8 and Na\textsubscript{v} 1.9) and increase the activation of transient receptor potential vanilloid-1 (TRPV-1)”. With prolonged peripheral pain,
central sensitization occurs which may account for tactile allodynia. These factors may help explain why local anesthesia is not always effective for patients in pain. For example, Na, 1.9 channels have a low sensitivity to local anesthetics.

Another explanation for failure is that nerves arising from inflamed tissue have decreased excitability thresholds and altered resting potentials. Modaresi et al. found that conduction velocity was significantly lower in nerves of inflamed pulp as compared to nerves without inflamed pulp. The authors induced inflammation on one canine of a cat, and left the other canine inflammation free. They then measured the conduction needed to produce a response and found the conduction needed to induce a nerve to fire was less when the tooth was inflamed and that local anesthetic agents were not sufficient to prevent impulse transmission due to these lowered excitability thresholds. This theory fails to explain that when local anesthetic is given at a distant site from the inflammation, as in an inferior alveolar nerve block, mandibular pulpitis is not readily anesthetized. Tsuchiya et al. found that local anesthetics might actually work better in acidic inflamed tissues. They found that when nerves were treated with an acidic solution, similar to the acidity of inflamed tissues, lidocaine was more successful.

Another factor would be the tetrodotoxin-resistant (TTXr) class of sodium channels that have been shown to be resistant to the action of local anesthetics. It is also possible that there is increased expression of sodium channels in the pulps of teeth
diagnosed with symptomatic irreversible pulpitis. The lower pain thresholds of anxious patients may as well be a factor in the failure of local anesthesia.

The central core theory may be our best explanation as to why patients don’t get numb. It states that nerves on the outside of the nerve bundle supply molar teeth, and nerves on the inside supply incisor teeth. The anesthetic solution may not diffuse into the nerve trunk to reach all nerves and produce an adequate nerve block.

It is useful to compare the success rates of the current study to other historical studies that have researched lower symptomatic irreversible teeth and compare the data to see if either the 4% buffered solution or the 4% non-buffered solution were better or worse.

Cohen et al. studied mandibular posterior symptomatic irreversible pulpitis teeth and found 23 out of 61 (38%) subjects required supplemental anesthesia because the IAN block failed, thus Cohen found pulpal anesthetic success of 62%. Twenty-seven of the sixty-one subjects received a standard 2% lidocaine solution whereas 34 subjects received a 3% mepivacaine solution. The reported IAN block success of 62% is higher than other studies, which may be due to how pulpal anesthesia was determined. Cohen’s group pulp tested with DDM (dichlorodifluormethane), instead of clinically performing endodontic treatment with an access preparation, which may not have accurately determined pulpal anesthesia. Jespersen et al. found in 2013 that the accuracy of determining sufficient anesthesia by using cold is 94%, and the accuracy of EPT is 75%. The current study had a lower IAN block success rate of 32-40% depending on the group,
which is most likely lower because pulpal anesthesia was determined via endodontic access rather than pulp testing the symptomatic teeth.

Nusstein et al.\textsuperscript{47} studied supplemental intraosseous injections of 2% lidocaine with 1:100,000 epinephrine. They found the success of the IAN block to be 19% in posterior mandibular symptomatic irreversible pulpitis teeth. Administration of the intraosseous injection increased success rates from 19% to 90%. This is lower than the 32% success rate in the buffered group and 40% success rate in the non-buffered group. The difference may be due to the number of patients sampled or population differences.

Reisman et al.\textsuperscript{48} studied 3% mepivacaine as an intraosseous injection in patients diagnosed with symptomatic irreversible pulpitis, the authors found the inferior alveolar nerve block to be 25% successful using 2% lidocaine 1:100,000 epinephrine solution. They then found the first intraosseous injection of 3% mepivacaine increased the success rate to 80% and the second intraosseous injection increased the success rate to 98%. The 25% success rate of the inferior alveolar block alone in the same patient population evaluated in our study is again lower than our 32% success rate for the buffered solution and the 40% success rate of the non-buffered solution. Both studies used tooth access to determine anesthetic success.

The significance of needle deflection in success of the inferior alveolar nerve block in patients with symptomatic irreversible pulpitis, was studied by Kennedy et al.\textsuperscript{39} Sixty-four adult patients were included and randomly received 2.8 mL of 2% lidocaine with 1:100,000 epinephrine with either a conventional IAN block or a bidirectional-rotation-technique, using the Wand II computer-assisted anesthesia system. The
anesthetic success rate for the conventional IAN block was found to be 50% whereas the bidirectional IANB technique yielded a 56% success rate. The study revealed no significant differences between the success rates of these two techniques, indicating that the orientation of the needle bevel and subsequent potential for deflection, does not affect pulpal anesthesia. The success rate of 50% and 56% are both higher in comparison to our study’s success rates of 32% using the buffered solution and 40% using the non-buffered solution. These results are possibly due to the lower number of subjects that were studied by Kennedy, et al.

Claffey et al. 33 compared the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine to 2% lidocaine with 1:100,000 epinephrine for inferior alveolar nerve blocks in patients experiencing symptomatic irreversible pulpitis in mandibular posterior teeth. Seventy-two emergency patients diagnosed with symptomatic irreversible pulpitis randomly received, in a double-blind manner, 2.2 ml of 4% articaine with 1:100,000 epinephrine or 2.2 ml of 2% lidocaine 1:100,000 epinephrine using a conventional inferior alveolar nerve block. Success was determined by instrumentation of the tooth, the same definition of success as the current study. The success rate for the IANB using articaine was 24% and 23% for lidocaine. They found no significant difference between the articaine and lidocaine solutions. Tortamano et al. 34 agreed with Claffey’s results and reported that articaine and lidocaine had no significant difference in anesthetic success. Tortamano’s success rate of the IAN block using 3.6 mL 2% lidocaine with 1:100,000 epinephrine in patients with symptomatic irreversible pulpitis was 45%. Our study IANB success was 32% for the buffered group and 40% for the non-buffered group which were
both higher than the success rate found by Claffey et al., yet less than the 45% success rate found by Tortamano et al.

Aggarwal et al.\textsuperscript{36} hypothesized that premedication with nonsteroidal anti-inflammatory drugs might improve the success rates in patients with inflamed pulps. Sixty-nine patients actively experiencing pain participated in the double blind study. The patients were divided into 3 groups and were randomly given 1 of the 3 drugs including ibuprofen, keotorolac, and placebo 1 hour before anesthesia. All patients received standard inferior alveolar nerve block of 2% lidocaine with 1:200,000 epinephrine. Success was recorded as none or mild pain upon instrumentation of the tooth. Placebo gave a 29% success rate. Premedication with ketorolac gave a 39% success and ibuprofen gave a 27% success. There was no significant difference between the 3 groups in patients with symptomatic irreversible pulpitis in mandibular posterior teeth. The success of the IANB in our study was similar to Aggarwal et al. where the buffered group had a success rate of 32% and the non-buffered was successful 40% of the time.

Oleson et al.\textsuperscript{37} also studied the effect of preoperative ibuprofen on the success of the inferior alveolar nerve block in patients with symptomatic irreversible pulpitis with a similar study design to the current study. One hundred patients diagnosed with symptomatic irreversible pulpitis of a mandibular posterior tooth randomly received, in a double-blind manner, either 800 mg ibuprofen or placebo 45 minutes before the administration of a conventional IAN block. Success was defined as no or mild pain on access or instrumentation. The success rate for the IAN block was 41% with ibuprofen and 35% with placebo with no significant difference between the two groups. The
success of IANB in our study was similar to the findings of Oleson et al., 37 where the buffered group had a success rate of 32% and the non-buffered was successful 40% of the time.

Simpson et al. 38 studied the effect of a preoperative ibuprofen/acetaminophen combination. The protocol of the study was similar to Oleson et al. 37 but an 800 mg ibuprofen and 1000 mg acetaminophen combination was given 45 minutes prior to treatment. The success rate for the IAN block was 32% for the combination of ibuprofen/acetaminophen group and 24% for the placebo, with no significant difference. Our investigation noted a 32% success rate with the buffered anesthetic and 40% in the non-buffered group, certainly within range of Simpson et al. 38

Fullmer et al. 97 evaluated the effect of preoperative hydrocodone/acetaminophen on the success of the inferior alveolar nerve block in patients with symptomatic irreversible pulpitis using a similar study design to the current study. Each patient either received a hydrocodone/acetaminophen combination 1 hour prior to the initial access or placebo. The patients were then given a 2% lidocaine 1:100,000 epinephrine IAN block. Fullmer’ group found successful anesthesia of 32% in the hydrocodone/acetaminophen group and 28% in the placebo group. They found no statistical difference between the two groups and concluded that preoperatively giving a hydrocodone/acetaminophen combination did not increase the success of the IAN block. The current study found a success of 32% in the buffered group and 40% in the non-buffered group, both groups were similar in success to those who were given the hydrocodone/acetaminophen combination and the placebo in Fullmer’s study.
Bigby et al.\textsuperscript{27} performed a prospective, randomized, single-blind study to compare the anesthetic efficacy of lidocaine with epinephrine to lidocaine plus meperidine with epinephrine for inferior alveolar nerve blocks in patients with mandibular posterior teeth experiencing symptomatic irreversible pulpitis. Root canal treatment was performed on 48 emergency patients and block success was defined as no or mild pain upon endodontic access or instrumentation. There was no significant difference (\(p = 0.28\)) between the two solutions. The study revealed that the addition of 36 mg of meperidine to a lidocaine solution administered in a conventional IAN block did not improve the success rate over a standard lidocaine solution. The success rate for the inferior alveolar nerve block using the lidocaine solution was 26%, and for the lidocaine/meperidine solution, the success rate was 12%. The success rates evaluated in their study is again lower than our 32% success rate for the buffered solution and the 40% success rate of the non-buffered solution. The current study had 100 subjects while Bigby et al.\textsuperscript{27} had a total of 48 subjects.

Matthews et al.\textsuperscript{46} evaluated the anesthetic efficacy of the supplemental infiltration injection of 4% articaine with 1:100,000 epinephrine in mandibular posterior teeth diagnosed with symptomatic irreversible pulpitis when the conventional IAN block failed. Success was recorded as none or mild pain upon endodontic access and instrumentation of the tooth. Twenty-seven out of fifty-five (33%) patients had anesthetic success in Matthews et al. where our study success was 32% for the buffered group and 40% in the non-buffered group. The two studies had similar designs and the
determination of anesthetic success was the same as the current study, so the comparison is valid.

Rogers et al. compared the efficacy of 4% articaine to 2% lidocaine, both with 1:100,000 epinephrine, for supplemental buccal infiltrations after an ineffective IANB in mandibular molars with IP. In addition, the use of articaine for IANB and intraosseous injections was investigated. One hundred emergency patients diagnosed with IP of a mandibular molar were selected and received an IANB with 4% articaine. Patients with ineffective IANB (positive pulpal response to cold or pain on access) randomly received 4% articaine or 2% lidocaine as a supplemental BI. Seventy-four patients failed to achieve pulpal anesthesia after IANB with 4% articaine, resulting in IANB success rate of 26%. Success rates for supplemental BIs were 62% for articaine and 37% for lidocaine. The current study used a 4% lidocaine solution for the IANB while Rogers et al. used 4% articaine. Similar results were found for IANB success.

As seen above in our comparison of literature, this study would suggest that the 4% buffered lidocaine with 1:100,000 epinephrine injections and the 4% non-buffered lidocaine with 1:100,000 epinephrine injections did not provide any additional anesthetic success or improvement over the other studied inferior alveolar nerve block regimens. The pulpal anesthetic success rate of the buffered and non-buffered solution injections, as found in this study (32% and 40%, respectively) corresponds with the success rates found by other authors evaluating similar patient populations (patients diagnosed with symptomatic irreversible pulpitis) when using the conventional inferior alveolar nerve block and 2% lidocaine with 1:100,000 epinephrine.
Table 4 presents pulpal anesthetic success of the IANB (buffered and non-buffered) by gender. In the buffered group females had an IANB anesthetic success of 25%, while the males were successful 44% of the time (p = 0.1571). In the non-buffered group females had an IANB anesthetic success of 45% and the males were successful 33% of the time (p = 0.5602). The buffered group consisted of 50 subjects, 32 of which were female, whereas the non-buffered group consisted of 50 subjects, 29 of which were female. There was no significant difference noted, in anesthetic success between men and women in either the buffered and non-buffered groups. Similar results have been found in studies that have looked at the success rate of the IAN block between males and females. 29,35,39,40,48,91

Table 5 shows the IAN block success by groups and tooth type. Previous research has reported that premolars and second molars are shown to have a slightly higher incidence of pulpal anesthesia following a conventional IANB injection in asymptomatic patients of 2% lidocaine with 1:100,000 epinephrine when compared to first molars. 104 This study showed a better success rate of the first molar compared to the second molar in both test groups (buffered and non-buffered). In the buffered group the first molar pulpal success was 32% whereas the second molar was 19%. In the non-buffered group the same tendencies were shown. The first molar was 48% whereas the 2nd molar was 29%. This finding differs from previous research that found the 1st molar to be less successful. 27,37,38,46,82,97 This could be due to an inadequate sample size. There were very few premolars studied in both groups of this study with only six in the buffered group and three in the non-buffered group. In the buffered group 50% were successful and in the
non-buffered group the success rate was 67%. Both groups had a higher percentage success in the premolars than the molars which corresponds with previous research.

4% Lidocaine Success

Due to the mechanism of action of local anesthetics (reviewed in the introduction), it was postulated that a higher concentration of anesthetic would be more effective than a lower concentration. This is due to the fact that a higher concentration has more anesthetic molecules which can block nerve conduction and inhibit pain. The current study used a 4% lidocaine solution compared to the standard 2% lidocaine solution for inferior alveolar nerve blocks.

Vreeland et al.\textsuperscript{26} evaluated the volumes and concentrations of lidocaine in inferior alveolar nerve blocks on asymptomatic patients. With the electric pulp tester, they measured anesthetic efficacy of 1.8 ml of 2% lidocaine with 1:100,000 epinephrine, 3.6 ml of 2% lidocaine with 1:200,000 epinephrine, and 1.8 ml of 4% lidocaine with 1:100,000 epinephrine. Thirty subjects randomly received each of the solutions at three successive appointments. No significant differences in anesthetic success or failure were found among the three solutions. This result corresponds with the current study which found similar success rates with 4% lidocaine compared to previous studies that used a 2% lidocaine 1:100,000 epinephrine solution as a control. The current study found the non-buffered 4% lidocaine 1:100,000 epinephrine solution was 40% successful. This success rate can be compared to previous studies using symptomatic irreversible pulpitis patients and that used a 2% lidocaine 1:100,000 epinephrine solution such as Kennedy et al.\textsuperscript{39} (success rate of 50%), Claffey et al.\textsuperscript{33} (success rate of 23%), Aggarwal et al.\textsuperscript{36}
(success rate of 29%), Oleson et al.\textsuperscript{37} (success rate of 35%), Simpson et al.\textsuperscript{38} (success rate of 24%), Bigby et al.\textsuperscript{27} (success rate of 26%), Matthews et al.\textsuperscript{46} (success rate of 33%), and Fullmer et al.\textsuperscript{97} (success rate of 28%). The increase in lidocaine concentration (increase in the number of lidocaine molecules to block nerve conduction) did not improve IAN block success as found when comparing the current study which used a 4% lidocaine solution compared to other studies that used a 2% lidocaine solution.

Rood et al.’s.\textsuperscript{105} results disagree with Vreeland’s and the current study. Rood stated that 2% lidocaine with 1:100,000 epinephrine was satisfactory for 95% of dental procedures, and concluded there is benefit to be gained from the use of 5% lidocaine in such dental procedures as extraction and pulpectomy when a 2% lidocaine solution does not work. Rood found out of a total of 115 patients, 70% were a complete success, 9% were a partial success, and 21% were complete failure when using a 5% lidocaine solution. Rood has often been cited in the literature supporting a higher percent solution being more successful. Unfortunately there are several problems with Rood’s study that put his results in question. Rood did not study symptomatic patients. He only studied 6 mandibular teeth (only 1 was a molar), therefore his power was very low, and he also studied different treatments such as extraction, restorative, and endodontics which all need different levels of anesthesia. Beckett et al.\textsuperscript{106} endorsed Rood’s findings with a case report of a local anesthetic “resistant” patient in whom a 5% lidocaine solution enabled painless dental treatment to be performed.

Smith et al.\textsuperscript{107} looked at the anesthetic efficacy of 127.2 mg of lidocaine with 50 ug epinephrine compared to 127.2 mg lidocaine with 50 ug of epinephrine plus 0.5 M
mannitol in asymptomatic IAN blocks. The total of 127.2 mg of lidocaine were given in 3.18 ml formulations for a 5% lidocaine solution. The current study used 112 mg of lidocaine in the non-buffered group, whereas the buffered group had 104 mg of lidocaine. They found similar results using a higher concentration of lidocaine to previous research that used a 2% solution.

As seen in the results of the current study, the increase of the number of lidocaine molecules (concentration) did not appear to increase the success rate of lidocaine when given as an inferior alveolar nerve block injection. Although the current study did not compare 2% and 4% lidocaine solutions, the 4% solution was not better when comparing our results to the results of studies where 2% lidocaine was evaluated. This could be due to the fact that the inferior alveolar nerve block is given in a limited anatomic space and all the anesthetic solution cannot at one time bathe the nerve. Only a certain amount of anesthetic molecules can bathe the nerve at any one time, and those binding sites may become saturated.

Fowler et al.25 determined the success of the IAN block using either 3.6 mL or 1.8 mL 2% lidocaine with 1:100,000 epinephrine in patients presenting with symptomatic irreversible pulpitis. Three hundred nineteen emergency patients presenting with symptomatic irreversible pulpitis received either a 1.8-mL volume or 3.6-mL volume of 2% lidocaine with 1:100,000 epinephrine in an IAN block. One hundred ninety patients received a 1.8-mL volume, and 129 received a 3.6-mL volume. Success of the 1.8 mL volume was 28%, and for the 3.6 mL volume it was 39%. There was no statistically significant difference between the 2 volumes. Although Fowler et al. used 2% solution, 2
cartridges of 2% solution has the same amount of anesthetic molecules as 1 cartridge of a 4% solution. Thus, they found no increase in success with an increase of anesthetic molecules, which corresponds with the current study.

The theory for the current study was to evaluate the effect of anesthetic concentration (specifically for lidocaine) for inferior alveolar nerve block injections. We also wanted to compare 4% lidocaine buffered and non-buffered because there are no studies that have compared these solutions. The thought was that if the concentration of lidocaine (2%) in the standard cartridge was doubled (4%), the efficacy of lidocaine may increase because double the number of lidocaine molecules would be available to inhibit nerve conduction. However, according to the success rates of the current study compared to the studies looking at 2% lidocaine, the results were similar and the 4% lidocaine solution did not increase pulpal anesthesia.

Buffering Success

Another explanation why anesthetics fail, relates to the theory that the lowered pH of inflamed tissue reduces the amount of the free base form of anesthetic to penetrate the nerve membrane. Therefore, there is less of the ionized form within the nerve to achieve anesthesia. Most local anesthetics are weak bases with $pK_a$ ranging from 7.5 to 9.0. According to Yagiela et al.\textsuperscript{108}, “local anesthetics, which are acidic, are quickly neutralized by tissue fluid buffers, and a portion of the cationic form is converted to the nonionized base”. The amount of the drug that is converted to nonionized base form is determined by the Henderson-Hasselbalch equation, which is:

$$\text{pH} = pK_a + \log ([A^-]/[HA]).$$
This equation is dependent on the surrounding body pH and the local anesthetic pK$_a$. Buffered local anesthetics have a higher pH (Table 16) and may be more efficient in achieving pain control for the inferior alveolar nerve block. Amide local anesthetics, such as lidocaine, have a weak base component. Lidocaine with epinephrine is a mixture of two chemical forms: a non-ionized, uncharged free base form and an ionized, and charged cationic form.$^{62,63}$ The non-ionized form of the local anesthetic is the active lipid soluble form that readily enters the nerve membrane and blocks nerve conduction.$^{64}$ The presence of a sufficient amount of non-ionized free base anesthetic is necessary to induce anesthesia.

Lidocaine with epinephrine enters the body at a lower pH (in this study it was 4.5) than that of the physiologic pH of 7.4. At this lower pH, lidocaine must be buffered by the body to convert enough anesthetic to the de-ionized form to produce anesthesia.$^{109,110}$ Creating a solution that is buffered before injection could result in a more effective anesthetic. Galindo et al.$^{111}$ used buffered local anesthetic solutions (pH of 7.4) in peripheral nerve blocks and regional anesthesia. They found that higher pH solutions established better quality anesthesia.

There are several proposed mechanisms for the improved nature of buffered anesthetics. One concept involves the idea that a higher pH of injected solution is less irritating to the tissues than the more acidic non-buffered conventional solutions.$^{112}$ Another mechanism states that the de-ionized anesthetic will enter the nerve sheath more quickly and result in the aforementioned faster onset of anesthesia.$^{113}$ Anesthetic solutions are buffered with sodium bicarbonate, resulting in the release of water and
carbon dioxide. The subsequent effects of carbon dioxide has been shown, in combination with lidocaine, to have a depressant effect upon the nerve axon.\textsuperscript{114}

The most common technique for the buffering of local anesthetics is by the addition of sodium bicarbonate. Each 84 mg of sodium bicarbonate contains 1 mg of sodium ions and 1 mg of bicarbonate ions. An 8.4\% solution of sodium bicarbonate would contain 1 mEq each of sodium and bicarbonate ions per mL. The 10:1 local anesthetic to bicarbonate ratio has been shown to raise the pH to a more physiologic range.\textsuperscript{112} Our study researched the idea that local anesthetics are more successful in an IAN block when the solution is buffered opposed to a non-buffered solution in symptomatic irreversible pulpitis patients.

When a standard local anesthetic of 2\% lidocaine with 1:100,000 epinephrine is prepared, it typically has a low pH of around 5-5.5 to increase stability and shelf life. Because of this low pH, the body tissues, with a physiologic pH of 7.4, buffers the solution which increases the concentration of the non-ionized form. The theory behind buffering of local anesthetics is reasonable according to the Henderson-Hasselbalch equation: if a local anesthetic solution is buffered to a pH that is closer to its pKa (7.9), more of the non-ionized form will be accessible to enter the nerve sheath, resulting in a less painful injections and faster onset.\textsuperscript{5}

The current study used a pH/millivolt meter to measure pH of both the buffered and non-buffered solutions. The average pH of the buffered solution was 7.049 and the average pH of the non-buffered was 4.057. In a recent published study, using the same Onset (Onpharma) mixing pen, Balasco et al.\textsuperscript{80} measured the pH of 2\% lidocaine
1:100,000 epinephrine buffered or non-buffered. Balasco found the pH of the buffered group to be 6.97 and the pH of the non-buffered group to be 4.60. These values are similar to the current study which found 7.049 and 4.057, respectively. Whitcomb et al. also measured pH of a 2% lidocaine solution buffered and non-buffered. He found a 2% lidocaine solution with 1:100,000 epinephrine to be 6.40, and a 2% lidocaine with 1:100,000 epinephrine buffered solution to be 7.50. The current study found a lower pH (4.057) in the non-buffered group than did Whitcomb in his non-buffered group (6.40). This may be due to the fact that he used a 2% solution, when the current study used a 4% solution. However, Whitcomb found a similar pH (7.50) of the buffered group as the current study (7.049). Nydegger et al. measured the pH of 4% lidocaine with 1:100,000 epinephrine. He found the pH to be 6.097. This difference could be due to the source of the anesthetic. Nydegger et al. used 4% lidocaine 1:100,000 epinephrine compounded by a local pharmacy rather than a manufactured 4% lidocaine used in the current study. There may be an inherent variation in the formulation of anesthetic compounded by pharmacies.

Younis et al. and Curatolo et al. found that buffered local anesthetics resulted in significantly improved anesthesia. Younis et al. found that buffered 1% xylocaine with 1:200,000 epinephrine resulted in less pain during vasectomy procedures than non-buffered local anesthetic. Curatolo et al. found that a buffered 2% lidocaine resulted in higher pain thresholds, faster onset of action, and a higher degree of motor block in epidural anesthesia. The current study did not find any significant difference between the success rate of buffered and non-buffered solutions. This could be due to the fact that the
current study used a symptomatic dental model while Younis et al. and Curatolo et al. did not.

Some researchers found significant differences in anesthetic success using a dental model. Al-Sultan et al. studied 200 patients receiving maxillary infiltrations for dental extraction. Patients were given either a non-buffered 2% xylocaine with 1:80,000 epinephrine solution or a buffered 2% xylocaine with 1:80,000 epinephrine solution with a pH of 7.2. They found less pain on extraction using the buffered local anesthetic. Bowles et al. studied 35 volunteers who received a series of two maxillary infiltrations in the first molar region. Patients received 1 injection of a non-buffered 2% lidocaine with 1:100,000 epinephrine anesthetic solution in the area of tooth number 3 or 14, and received another infiltration of a buffered 2% lidocaine with 1:100,000 epinephrine solution with sodium bicarbonate on the contralateral side. Overall, there was significantly less pain reported on infiltration using the buffered lidocaine. It should be noted that our study looked at symptomatic patients using an IAN block while Bowles et al. and Al-sultan et al. studied asymptomatic patients in the maxilla.

Chaney et al., in a dental model, studied a 2.2% lidocaine hydrocarbonate solution, a 2.2% lidocaine hydrocarbonate with 1:100,000 epinephrine solution, and 2% lidocaine hydrochloride with 1:100,000 epinephrine solution in inferior alveolar nerve blocks. They found that 2.2% lidocaine hydrochloride with 1:100,000 epinephrine solution was equivalent to the 2.2% lidocaine hydrocarbonate with 1:100,000 epinephrine solution in inferior alveolar nerve blocks for pulpal anesthesia while a 2.2% lidocaine
hydrocarbonate solution without vasoconstrictor was not as effective as either solution with a vasoconstrictor.

Whitcomb et al.\textsuperscript{31} studied the effect of buffered 2\% lidocaine with 1:100,000 epinephrine in an IAN block. An electric pulp tester was used on asymptomatic patients to determine pulpal anesthetic success on mandibular teeth. Whitcomb found no statistical difference in pain of injection or anesthetic success between non-buffered 2\% lidocaine with 1:100,000 epinephrine and buffered 2\% lidocaine with 1:100,000 epinephrine for the inferior alveolar nerve block. It should be noted that the patients in Whitcomb et al. were asymptomatic compared with the current study which studied symptomatic patients. It should also be noted that Whitcomb mixed buffering solution by hand, where the current study used the OnSet\textsuperscript{TM} mixing pen to dispense the buffering solution. Differences could be attributed to the fact that they used a multiuse vial, from a different manufacturer, of sodium bicarbonate mixed by hand.

Balasco et al.\textsuperscript{80} studied a buffered solution in anesthetic success of incision and drainage procedures in oral, symptomatic, swollen patients. Eighty-one adult patients were randomly divided into 2 treatment groups who received 2 infiltrations (mesial and distal to the swelling of the same formulation) using either 2\% lidocaine with 1:100,000 epinephrine buffered with 0.18 mL 8.4\% sodium bicarbonate or 2\% lidocaine with 1:100,000 epinephrine. Patients rated pain of needle insertion, placement, and solution deposition for each infiltration. An incision and drainage procedure was performed, and the pain of incision, drainage, and dissection was recorded. Balasco found no significant differences between the 2 anesthetic formulations for pain of solution deposition for
either the mesial or distal site infiltrations. Moderate-to-severe pain was experienced in the majority of patients with the incision and drainage procedure and no significant differences were found in anesthetic success between the 2 formulations. Balasco concluded that the addition of a sodium bicarbonate buffer to 2% lidocaine with 1:100,000 epinephrine did not result in significantly decreased pain of the incision and drainage procedure when compared with 2% lidocaine with 1:100,000 epinephrine in symptomatic patients with a diagnosis of pulpal necrosis and associated acute swelling. It should be noted that Balasco et al. used an infiltration injection near the site of inflammation, while the current study used an inferior alveolar nerve block in a non-swollen patient.

Upon evaluation of previous literature, it is not clear if buffering a lidocaine solution is more successful in achieving anesthesia. Most of the previous studies were done on asymptomatic patients while the current study was on moderate-to-severe pain patients. The current study found no difference in success of anesthesia which corresponds with Hobeich, Whitcomb, Balasco, and Chaney, while other authors, such as Younis, Al-sultan, and Bowles disagreed with the current study and found that a buffered solution was more successful in achieving anesthesia. The current study is the first study performed using a buffering solution on symptomatic irreversible pulpitis teeth. It also is the first study using an inferior alveolar nerve block on symptomatic patients using a buffered solution.

Tables 6 and 7 show the success of the supplemental articaine and intraosseous injections following failure of the primary IAN block injection by tooth type. No
significant differences were noted in the supplemental success of articaine or intraosseous in either the buffered or non-buffered group.

**Pain of Injection**

With a buffered local anesthetic solution it would be expected that the local anesthetic would cause less pain on injection than a non-buffered local anesthetic. Tables 8 and 9 show the pain associated with needle insertion, needle placement, and solution deposition scores of the buffered 4% lidocaine with 1:100,000 epinephrine and non-buffered 4% lidocaine with 1:100,000 epinephrine injections as rated by patients on a 170 mm VAS. In a retrospective study, McCartney et al.\textsuperscript{49} noted that patients presenting with symptomatic irreversible pulpitis experience moderate-to-severe pain 57-89% of the time with the three phases (insertion, placement, deposition) of injection in the conventional IAN block. They also reported that needle insertion resulted in moderate pain in 59% of women and 55% of men (57% total) and severe pain in 9% of women and 2% of men (6% total). They found needle placement to be significantly more painful than the insertion phase for men, and significantly more painful than insertion or deposition for women. Placement for men resulted in 58% of subjects recording moderate pain and 13% recording severe pain; for women, moderate pain during placement was recorded for 70% of the subjects and severe pain for 10% of the subjects. For the solution deposition phase, both men and women recorded 52% as moderate and 21% of women and 14% of men rated deposition pain as severe. McCartney noted that a higher incidence of pain among these three stages compared to pain experienced in these stages among asymptomatic patients is likely due to the fact that the subjects in their study were in pain.
and possibly more anxious. Research has suggested that a buffered solution would be less painful when injected because the pH of the solution is closer to the physiologic pH. However, there should be no difference in needle insertion and placement pain, due to the fact that the standard IAN block technique was used for both groups.

In the current study, no significant difference was found between injection of a buffered local anesthetic and a standard non-buffered local anesthetic for the IAN block in any of the three phases of injection. These findings do not coincide with the findings of some other studies that investigated the pain of injection using buffered local anesthetics. Numerous dermal injection studies have been conducted on the forearms of asymptomatic patients. Mckay et al. studied the pain of intradermal injections in the forearm of 24 asymptomatic subjects. Each subject received an injection of plain 1% lidocaine, 1% lidocaine with epinephrine, buffered 1% lidocaine with epinephrine, and a buffered plain 1% lidocaine anesthetic solution. The group found that lidocaine with epinephrine was the most painful solution. Both lidocaine with epinephrine and plain lidocaine were significantly more painful than the corresponding buffered solutions and the buffered plain lidocaine solution was significantly less painful than all others. Bancroft et al. injected a plain 1% lidocaine solution and three different buffered solutions of 1% lidocaine with pH readings of 6.8, 7.0, or 7.2. Pain was measured via a 100 mm linear visual analogue scale. Bancroft et al. found that the plain lidocaine solution was more painful on injection and that all buffered 1% solutions significantly reduced pain compared to the plain solution. McGlone et al. injected saline, 1% lignocaine with a pH of 5.0, 1% lignocaine with a pH of 6.7, and 1% lignocaine with pH
of 7.35. The injections were given on the asymptomatic forearms. Subjects assessed the pain of injection on 100 mm visual analogue scales. McGlone and coworkers found a significant reduction in injection pain when using buffered 1% lignocaine compared to the non-buffered lignocaine solution. Steinbrook et al.\textsuperscript{123} studied infiltration injections of either 1% lidocaine or buffered 1% lidocaine with 0.1 mEq/mL of sodium bicarbonate prior to IV placement at different sites including the forearm, hand, or wrist. Subjects rated their pain of injection of both the anesthetic and the intravenous catheter placement on a 100 mm visual analog scale. Steinbrook et al. found that the buffered 1% lidocaine caused significantly less pain on skin infiltration ($p < 0.008$). Fitton et al.\textsuperscript{124} studied non-buffered 1% lignocaine with 1:200,000 epinephrine in a soft tissue injection of one ear and buffered 1% lignocaine with 1:200,000 epinephrine in the other ear. They found that the buffered solution was significantly less painful on injection than the non-buffered lignocaine. They also concluded that the buffered 1% lignocaine with 1:200,000 epinephrine solution was significantly less painful at both room and body temperature. Younis et al.\textsuperscript{116} also compared a buffered 1% xylocaine with 1:200,000 epinephrine to a non-buffered 1% xylocaine with 1:200,000 epinephrine. They studied patients undergoing a vasectomy who rated the pain of injection on a 100 mm visual analogue scale. Younis et al. found that the pain of injection was significantly decreased using the buffered solution compared to the non-buffered anesthetic. They also reported that patients tolerated the vasectomy procedure significantly better when the buffered solution was used.
Along with these previous studies, three reviews of the medical literature\textsuperscript{71,70,72} concluded that buffered local anesthetics resulted in significantly less pain on injection than non-buffered solutions. Several others\textsuperscript{69} concluded that pain of injection was reduced by a statistically significant amount when using buffered local anesthetics versus non-buffered solutions. These conclusions did not concur with the current study. The current study found no difference in pain of solution deposition between the buffered and non-buffered groups. There are several reasons that this investigation may have found different conclusions than the previous studies. The above studies were done using small numbers of subjects. Based on the power analysis performed at the beginning of this investigation, a minimum of 100 subjects, 50 subjects per group, were required to detect a difference in pain if a difference did exist. The current study looked at symptomatic patients while the other studies looked at asymptomatic patients. It should be noted that many of the previous studies were all conducted using infiltration dermal injections while the current study researched the inferior alveolar nerve block.

Buffered lidocaine has also been studied with intraoral infiltration injections. Bowles et al.\textsuperscript{78} studied maxillary infiltrations in the first molar region. Patients received 1 injection of a non-buffered 2\% lidocaine with 1:100,000 epinephrine in the area of tooth number 3 or 14 and received another infiltration of a buffered 2\% lidocaine with 1:100,000 epinephrine with sodium bicarbonate on the contralateral side over the first molar. Overall, there was significantly less pain reported on infiltration of buffered lidocaine.
Primosch et al.\textsuperscript{56} studied the effect of buffered lidocaine during intraoral maxillary labial and palatal infiltrations of asymptomatic permanent canines. They used a non-buffered 2\% lidocaine with 1:100,000 epinephrine and a buffered 2\% lidocaine with 1:100,000 epinephrine. Primosch et al. found no significant differences in pain at either site when buffered 2\% lidocaine with 1:100,000 epinephrine was used versus the non-buffered solution.

Hobeich et al.\textsuperscript{75} also studied if an injected buffered solution is less painful. He studied the pain of injection of 2\% lidocaine 1:100,000 epinephrine compared to a 2\% lidocaine 1:100,000 epinephrine buffered with 5\% and 10\% sodium bicarbonate in maxillary infiltrations. Thirty subjects randomly received all three maxillary infiltrations injections. Pain on needle penetration and deposition of anesthetic solution was recorded. They found no significant difference in pain on needle penetration or anesthetic deposition between the 3 anesthetic solutions tested. It should be noted that these studies used infiltration injections while the current study used the IAN block.

Buffered anesthetic solutions have also been studied in nerve blocks. Bartfield et al.\textsuperscript{62} investigated digital nerve blocks by injection of a buffered lidocaine on either the radial or ulnar side of the finger near the neurovascular bundle. Pain of injection was assessed using a 100 mm VAS and they found that buffered lidocaine was significantly less painful to administer than plain lidocaine. Malamed et al.\textsuperscript{125} also studied the pain of injection of a buffered and non buffered solution in a dental model. They studied 20 subjects, each receiving one non-buffered and one buffered IAN block injection. The group found 72\% of the subjects rated the buffered injection as more comfortable, 11\%
rated the non-buffered injection as more comfortable, and 17% reported no preference. Forty-four percent of the patients receiving buffered anesthetic rated the injection pain as zero ("no pain") on a 100 mm VAS, compared to 6% of the patients who received non-buffered anesthetic (p = 0.056). Malamed concluded “that buffering lidocaine with epinephrine toward physiologic pH immediately before injection significantly reduces discomfort of the injection”. The current study contradicts the results of Malamed et al. The current study had 100 subjects compared to 20 used by Malamed’s group. The current study also was on symptomatic patients, where Malamad used asymptomatic volunteers. Whitcomb et al.³¹ studied a buffered 2% lidocaine with 1:100,000 epinephrine in inferior alveolar nerve blocks. Forty asymptomatic subjects randomly received two inferior alveolar nerve blocks using a non-buffered 2% lidocaine with 1:100,000 epinephrine and a buffered 2% lidocaine with 1:100,000 epinephrine with 0.17 mEq/mL sodium bicarbonate at 2 separate appointments. Patients rated their pain on needle insertion, needle placement, and solution deposition. The group found no significant differences in the pain of injection. Whitcomb et al. does correspond with the current study in that no difference was found in pain of injection in patients receiving an inferior alveolar nerve block. It should be noted that Whitcomb et al. studied asymptomatic patients while the current study researched symptomatic patients.

Most of the previous medical and dental studies evaluated injections in asymptomatic subjects due to the nature of the procedures. The dermal injections, in the forearm, were for asymptomatic removal of moles, etc. This may explain why many of these studies were able to detect a significant difference in the pain of injection using
buffered local anesthetics in contrast to the current study that found no difference between the buffered and non-buffered solutions. One possible reason that no difference was found in pain of injection between the buffered and the non-buffered injections, may be that both injections were given slowly. It may not make a difference if the anesthetic is buffered, if the injection is given slowly.

Another aspect that could increase the pain of injections is the concentration of the anesthetic used. Vreeland et al.\textsuperscript{26} demonstrated that increasing the concentration of lidocaine in solution did not increase the amount of pain experienced by subjects during solution deposition. Therefore, we did not expect to see differences between the current study and previous studies that used a standard 2\% lidocaine with 1:100,000 epinephrine. In comparison to previous studies\textsuperscript{37,38,46,47,97}, the current study had less pain of deposition for an inferior alveolar nerve block. Pain was assessed on the Heft-Parker VAS as anything lower that 54 mm was considered mild pain, anything between 54 mm and 114 mm was considered moderate pain, and anything above 114 mm was considered severe pain. Fullmer et al.\textsuperscript{97} had a control group of 2\% lidocaine 1:100,000 epinephrine. He found the pain on deposition was 59.8 mm (moderate pain). The current study found 39.9 mm (mild pain) for deposition pain using the non-buffered 4\% lidocaine 1:100,000 epinephrine. Stanley et al.\textsuperscript{82} used a similar control group as Fullmer with 2\% lidocaine 1:100,000 epinephrine. His values of deposition pain was 58 mm (moderate pain) on a 170 mm scale. Oleson et al.\textsuperscript{37} found deposition pain using a standard 2\% lidocaine with 1:100,000 epinephrine to be 56.0 mm (moderate pain). These values are higher than the current study. These three studies all reported moderate pain during deposition while the
current study reported mild pain. It should be noted that not only did we use a 4% solution, but we also gave a slower injection using the Wand®. Thus we cannot conclude that a 4% lidocaine solution is less painful alone, but we can consider that a 4% lidocaine solution given slowly may be less painful than a standard 2% lidocaine solution given more quickly.

**Slow Injection**

The speed of injection has also been linked to the pain of injections. The current study used the CompuDent® (Milestone Scientific) CCLAD™ system of giving injections. This system delivers 1.4 mL of anesthetic solution over a time period of 4 minutes and 45 seconds on the slowest setting. In the literature there is evidence that the CCLAD™ unit decreases the pain of injections. Hochman et al.126 studied this system. Fifty dentists were given contralateral palatal injections. One side was injected with the Wand® injector, the control side was injected using a standard manual syringe. The Wand® injector was found to be statistically less painful (p < .001) by two- to three-times than the manual injection.

The majority of literature has found that the slower the injection, the less painful it is reported. Kudo et al.50 evaluated injection pressure, pain, and anxiety of injection of a local anesthetic into the oral mucosa in an infiltration injection. Twenty-eight subjects were given an injection of 0.5 ml of local anesthetic solution submucosally at a speed of either 30 or 160 sec/ml using the Wand. Injection pressure was measured and pain was assessed. Injection pressure was measured continuously in real time by using an invasive sphygmomanometer and analytical software, and pain was assessed on a visual analogue
scale and anxiety on the Faces Anxiety Scale. A significant correlation was evident between injection pressure and pain. Kudo et al. recommended that local anesthetic be injected under low pressure (less than 306 mm Hg) to minimize pain and anxiety among dental patients.

Kanaa et al.\textsuperscript{51} also studied the speed of injection related to the pain. They examined the efficacy and pain of injection associated with slow (60 seconds) and rapid (15 seconds) inferior alveolar nerve blocks using 2.0 ml of 2% lidocaine with 1:80,000 epinephrine in mandibular first molar, premolar and lateral incisor pulp anesthesia in 38 asymptomatic adult volunteers. Injection pain was recorded by the volunteers on 100 mm visual analogue scales. Kanaa concluded slow IAN blocks were less painful than rapid IAN blocks ($p = 0.021$). The current study gave a much slower injection (112 seconds) compared to the slow injection given by Kanaa (60 seconds).

Aggarwal et al.\textsuperscript{127} studied speed of injection on the anesthetic efficacy of the IAN block in patients with symptomatic irreversible pulptitis. Fifty-nine symptomatic patients either received a slow or rapid injection IAN block. Slow and rapid injections gave 43\% and 51\% success rates respectively. There was no significant difference noted. They did find that slow injections produced less solution deposition pain that rapid injections.

Gibson et al.\textsuperscript{53} also studied pain of injection using the Wand\textsuperscript{®} compared to a traditional syringe anesthesia administration. Sixty-two asymptomatic patients between the ages of 5 and 13 requiring local anesthesia for dental restorations in the posterior maxilla were evaluated. Patients either received the Wand\textsuperscript{®} or the traditional anesthetic
syringe system. They found that the Wand® injections produced significantly fewer patients who displayed disruptive behavior (less likely to cry, to exhibit disruptive body movements, and to require physical restraint) during the initial 15 seconds of an injection when compared with those who received a traditional injection.

Nicholson et al.\textsuperscript{54} examined thirty patients who received maxillary infiltration and mandibular inferior alveolar nerve block injections with both a traditional syringe and the Wand®. Patients rated their injection pain and noted their preference for either system. Nicholson et al. found the Wand® to be significantly less painful and more dentists and patients preferred the Wand® over the traditional syringe. Other studies have also come to the same conclusion, that injections using the wand system are less painful\textsuperscript{55,56}.

Some studies show no difference in pain between the Wand® and a traditional injection. Asarch et al.\textsuperscript{57} evaluated the efficacy of the Wand® in reducing pain during injections when compared with a traditional syringe. Asymptomatic pediatric patients were randomly assigned to either the Wand® or traditional syringe anesthesia. Subjects received inferior alveolar nerve block injections, palatal, and buccal infiltrations. Pain behavior was videotaped and coded throughout the study. Subjects were asked to rate their pain and overall satisfaction. Asarch et al. found no significant differences between the Wand® and the syringe method of administering local anesthesia when comparing pain ratings and pain behavior. They concluded that the Wand® anesthesia injection was found to be comparable to the traditional method of syringe anesthesia injection.

Saloum et al.\textsuperscript{58} compared the pain of injection of a group of 40 asymptomatic volunteers using either the Wand® or a syringe injection. A total of 240 injections were
given, 120 with the Wand® system, and 120 with a traditional syringe. They studied three intraoral injections: injections to the middle superior alveolar (MSA) of the maxillary right first premolar and the maxillary left first premolar; palatal injections of the maxillary right first premolar and the maxillary left first premolar; and inferior alveolar nerve injection of both the right and the left sides. Saloum et al. found no significant difference between the two injection techniques and that both caused only mild pain.

Tahmassebi et al. also compared pain when injections were given using the Wand® or conventional syringe technique in children of pre-school and school age. The Wand® group consisted of 20 children, and the syringe group consisted of 18 children. Pain sensation was rated using the VAS by the operator, each child and their parent. No statistical difference in pain sensation or anxiety was found when the Wand® was used, compared with the syringe technique (p = 0.710, p = 0.976). They concluded there was no difference in the pain or anxiety experienced by the children in the conventional and Wand® group.

Versloot et al. assigned patients to either the Wand® or traditional injection. One hundred and forty-seven subjects participated in the study. Pain was determined by behavior displayed during the injection and by a self-reported pain scale after the injection. No significant difference was found between an injection with the traditional syringe or the Wand®.

One study showed higher pain ratings with the Wand® unit. Goodell et al. studied the Wand® versus syringe injection technique. Dental injection anxiety
questionnaires were completed by 80, both asymptomatic and symptomatic, endodontic patients immediately before and after administration of local anesthetic. Patients also completed visual analog scales to rate their pain perception immediately following the injection. Patients experienced significantly lower overall postinjection anxiety and pain of injection with the conventional syringe technique than with the Wand®. They concluded a conventional syringe injection technique was superior to a controlled injection pressure system (the Wand®) in pain perception and procedure tolerance and in reducing postinjection dental anxiety.

So the question remains, does a slow injection reduce pain of injection of the inferior alveolar nerve block? The current study used a slow injection for both the buffered and the non-buffered solutions. It is sensible to compare the non-buffered injection pain of the current study with previous irreversible pulpitis studies that used a standard syringe for the inferior alveolar nerve block. Fullmer et al. had a control group receiving 1.8 ml of 2% lidocaine 1:100,000 epinephrine with a standard syringe over a 60 second deposition. They found the pain on injection to be as follows: insertion was 73 mm on a 170 mm scale, placement was 74.6 mm and deposition was 59.8 mm. The current study (112 second deposition) found 46.4 mm for insertion, 51.8 mm for placement, and 39.9 mm for deposition. The non-buffered group in the current study was less painful on all three phases of injection than the three phases of Fullmer et al. Stanley et al. used a similar control group as Fullmer et al. with 2% lidocaine 1:100,000 epinephrine over a 60 second deposition. His values were as follows: insertion pain was 54 mm, placement pain was 61 mm, and deposition was 58 mm on a 170 mm scale.
These values were also higher than the current study. Oleson et al.\(^{37}\) also used a standard syringe with 2\% lidocaine 1:100,000 epinephrine over a 60 second deposition. He found insertion pain to be 59.4 mm, placement pain to be 61.1 mm, and deposition pain to be 56.0 mm on the same 170 mm scale. All three of these studies found moderate pain on deposition. The current study found mild pain on solution deposition. A 4\% lidocaine solution given slowly (112 second deposition) (slow rate for 1 minute and then 52 seconds on the fast rate) may be less painful than a standard 2\% lidocaine solution given with a syringe over 60 seconds, although there was no a direct comparison. This decrease in pain is most likely due to the fact that the injection was given slowly, rather than the 4\% solution used. It would not make sense that a higher concentration would be less painful, but most of the previous research shows that a slower injection is less painful but may not always be practical due to time constraints of the dentist.

**Categorical Pain of Injection**

Table 9 shows the categorical pain values of the buffered and non-buffered injections of the IAN block. For the needle insertion phase 40\% showed moderate pain and no subject had severe pain in the buffered group and 42\% had moderate pain and 6\% had severe pain in the non-buffered group. In the placement phase 44\% had moderate pain and 4\% had severe pain in the buffered group, and 48\% moderate pain and no subject had severe pain in the non-buffered group. In the deposition phase 48\% had moderate pain and 4\% had severe pain in the buffered group, and 36\% had moderate pain and 2\% had severe pain in the non-buffered group. Notably, most subjects reported the three stages of the injection to be mild or moderate in nature for both solutions. These
values compare favorably with values found by McCartney et al.\textsuperscript{49}, who found needle insertion rates to be reported as 35\% mild and 57\% moderate, placement among men and women to range from 14\% - 30\% as mild and 48\%-60\% as moderate, and deposition rates reported as 26\% mild and 52\% moderate. In our study, no statistically significant difference was found between the two solutions in the needle insertion, placement, or solution deposition phases (Table 8). Of the three injection phases (insertion, placement, and deposition) the highest mean recordings for females were found in the placement phase for both the buffered group (51.8mm ± 35.8mm) and non-buffered group (51.0 mm ± 34.3 mm), and in the male group the highest mean pain was the deposition for the buffered group (54.3 mm ± 41.7 mm) and the insertion for the non-buffered group (53.0 mm ± 39.5 mm). This is different than values found by McCartney et al. in their evaluation of the IAN block in which placement was found to be the most painful stage of the injection for both males and females. Interestingly, in the male buffered group, although no significant difference was found, the deposition phase was the most painful when compared to the insertion and placement. In a buffered solution, one would expect to see less pain in the deposition phase than when the solution is not buffered. No such difference was found. In McCartney et al. there was a total of 102 patients compared to the 100 total in the current study.

Placement pain values may be lower because the current study injected as the needle was placed. Steinkruger et al. evaluated the pain of injection using a 2 stage injection compared to a single stage injection. Using a crossover design, 51 subjects randomly received, either the traditional IAN block or the 2-stage IAN block in 2
appointments spaced at least 1 week apart. For the 2-stage injection, the needle was inserted submucosally and 0.4 mL of 2% lidocaine with epinephrine was slowly given over 1 minute. There were no significant differences between needle insertion and solution deposition for the 2 techniques in men or women. However, there was significantly less pain with the 2-stage injection for needle placement in women. In conclusion, the 2-stage injection significantly reduced the pain of needle placement for women when compared to the traditional IAN technique.

**Satisfaction and Remembered Maximum Pain**

Table 12 shows the subjects’ post-treatment remembered maximum pain and the subjects’ post-treatment satisfaction ratings. Patients were asked to recall the level of the most pain felt during treatment on a 170 mm VAS. No statistically significant difference was noted between the two groups (p = 0.8402). The mean post-treatment remembered maximum pain for the buffered group was 56.0 ± 37.7 mm with a maximum score of 143 mm, where the mean of the non-buffered group was 54.4 ± 43.2 mm with a maximum score of 147 mm. These two groups were very similar. In comparison, Fullmer et al.’s\(^\text{97}\) placebo group (N = 50) reported a remembered pain of 45.29 ± 47.98 mm. This is similar to both buffered and non-buffered subjects’ reported remembered pain. The large standard deviation should also be noted, which may indicate an inherent variability of subjects’ responses when asked to report post-treatment remembered maximum pain.

Table 12 illustrates subjects’ post-treatment satisfaction ratings. No significant difference was noted among subjects receiving the buffered or the non-buffered injections. Patients were asked to rate their satisfaction with treatment on a 100 mm scale
where 0 mm indicated, “not satisfied” and ≥ 66 mm to 100 mm indicated, “completely satisfied.” The mean satisfaction rating for the buffered group was found to be 88.2 ± 16.4 mm and the mean for the non-buffered group was 92.1 ± 17.2 mm. The overall findings in this study are similar with other studies such as Stanley et al. whose placebo group noted a 96 mm rating and Fullmer et al.’s placebo group who showed an 88.7 mm mean rating. This indicates that despite experiencing moderate-to-severe pain during treatment, patients will accept pain if they feel their problems are being treated.

**Failure Point**

Table 15 illustrates the failure point of anesthesia, or when subjects felt moderate-to-severe pain during treatment, in either the buffered or the non-buffered group. This failure point was in dentin for the majority of subjects after the IAN block. Among subjects receiving the buffered injection, 40% reported moderate-to-severe pain in dentin after the initial block injection and 30% of non-buffered subjects reported moderate-to-severe pain in dentin after the initial block injection. Both groups in this study compare to previous studies such as Simpson’s, Oleson’s, Stanley’s, Matthews, and Fullmer’s groups who received conventional IAN blocks, in which 34-49% of subjects failed while the operator was in dentin. After an articaine infiltration, the majority of anesthesia again failed in dentin in the non-buffered group (37%), where in the buffered group the majority of failures were in the pulp chamber (35%). Once the first intraosseous injection was given, 5% of the subjects in the buffered group had anesthetic failure in dentin, where 14% failed in the chamber. After the first intraosseous injection, in the non-buffered group 21% failed in dentin and 5% failed in the chamber. After a
second intraosseous injection, there were no failures in the buffered group and all the failures in the non-buffered group were in the chamber (50%). These numbers are important because they show that with failures occurring primarily in dentin after the initial IAN block and also after the buccal infiltration of articaine, the intrapulpal technique cannot always be utilized. The buccal infiltration and intraosseous injections are excellent tools with which to create at enough pulpal anesthesia to access the chamber, thereby allowing for administration of an intrapulpal injection to complete anesthesia if necessary. Studies such as Oleson et al.\textsuperscript{37}, Simpson et al.\textsuperscript{38}, Stanley et al.\textsuperscript{82}, and Fullmer et al.\textsuperscript{97} substantiate this point with failure of anesthesia in dentin occurring 31-42\% of the time after a buccal infiltration of articaine and 0-6\% after an intraosseous injection. Without the intraosseous injection, it can be seen from this study’s results as well as those of others, that access and instrumentation of pulpal nerve tissue would not be possible without inflicting at least moderate and as much as severe pain to patients diagnosed with symptomatic irreversible pulpitis.

The price of the Onset\textregistered mixing pen is $299.99 with cartridge connectors $49.80 (box of 4) and sodium bicarbonate $210.10 (box of 4). The sodium bicarbonate needs to be replaced once per day with the connectors replaced for every patient. The time required for each patient is about 1 minute to set up the assembly and less than 15 seconds to mix the solutions. After taking into account the price along with the time required, the author does not recommend the use of the Onset\textregistered buffering system.
CHAPTER 5

Summary and Conclusions

The purpose of this study was to increase the success rate of the IAN block in patients diagnosed with symptomatic irreversible pulpitis in mandibular posterior teeth. The study evaluated the use of a buffered 4% lidocaine 1:100,000 epinephrine solution in order to achieve increased inferior alveolar nerve block success. Previous studies have used a buffered solution to increase anesthetic success rates, using infiltration and block injections, and have reported contradictory findings.\(^ {31,76,77,78,79}\) No study has investigated the use of a buffered local anesthetic, given as a block injection, in patients experiencing moderate-to-severe pain and diagnosed with symptomatic irreversible pulpitis. It was hypothesized that using a buffered lidocaine local anesthetic solution in patients experiencing symptomatic irreversible pulpitis would increase the success rate of the inferior alveolar nerve block and/or reduce injection pain due the mechanism of action of the buffered solution.

We found there to be no significant difference between the buffered local anesthetic formulation and non-buffered anesthetic formulation in pain of injection or anesthetic success. The success rate of the IAN block for the non-buffered group was 40% and the success rate for the buffered group was 32%.
In the context of this study, a buffered anesthetic offers no advantage over a non-buffered formulation given that no significant difference was found in anesthetic success. We have concluded that using a 4% buffered lidocaine with epinephrine formulation for patients diagnosed with symptomatic irreversible pulpitis does not significantly increase the success rate of the inferior alveolar nerve block.
CHAPTER 6

TABLES AND FIGURES
Table 1. Preliminary Data For Buffered and Non-Buffered Groups.

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<th>Non-Buffered Group</th>
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<td>Total Subjects Analyzed</td>
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<td>Gender</td>
<td>Female 32/50 (64%) Male 18/50 (36%)</td>
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<td>Age (Mean +/- SD) yrs</td>
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<td>Initial Pain (Mean +/- SD) mm</td>
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<td>Tooth Type</td>
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*Fischer exact test  
** Mann-Whitney-Wilcoxon test  
*** Randomization Test  
‡2 Subjects Disqualified Because of Pulpal Necrosis, 1 Subject Disqualified Because Missed IANB  
⁺ 2 Subjects Disqualified Because of Missed IANB
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Table 2. Initial Pain VAS.
*Randomization Test
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<tr>
<td>IAN Block Success</td>
<td>16/50 (32%)</td>
<td>20/50 (40%)</td>
<td>0.40466*</td>
</tr>
<tr>
<td>n=100 (BUF=50, NB=50)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buccal Infiltration Success</td>
<td>13/34 (38%)</td>
<td>11/30 (37%)</td>
<td>0.89708*</td>
</tr>
<tr>
<td>n=64 (BUF=34, NB=30)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intraosseous Success</td>
<td>16/21 (76%)</td>
<td>13/19 (68%)</td>
<td>0.58263*</td>
</tr>
<tr>
<td>n=40 (BUF=21, NB=19)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intraosseous #2 Success</td>
<td>5/5 (100%)</td>
<td>3/6 (50%)</td>
<td></td>
</tr>
<tr>
<td>n=11 (BUF=5, NB=6)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Intrapulpal Success</td>
<td>3/3 (100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=3 (BUF=0, NB=3)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 3. Anesthetic Success by Experimental Groups (BUF=Buffered, NB=Non-Buffered).

* Chi-Square Test
<table>
<thead>
<tr>
<th>Group</th>
<th>Gender</th>
<th>IANB Success</th>
<th>Count</th>
<th>Percent</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>BUF</td>
<td>Female</td>
<td>Yes</td>
<td>8/32</td>
<td>25</td>
<td>0.1571</td>
</tr>
<tr>
<td>BUF</td>
<td>Male</td>
<td>Yes</td>
<td>8/18</td>
<td>44</td>
<td></td>
</tr>
<tr>
<td>NB</td>
<td>Female</td>
<td>Yes</td>
<td>13/29</td>
<td>45</td>
<td>0.5602</td>
</tr>
<tr>
<td>NB</td>
<td>Male</td>
<td>Yes</td>
<td>7/21</td>
<td>33</td>
<td></td>
</tr>
</tbody>
</table>

Table 4. IANB Success by Gender (BUF=Buffered, NB=Non-Buffered).

*Chi-square test
<table>
<thead>
<tr>
<th>Tooth Type</th>
<th>Buffered Group n=50</th>
<th>Non-Buffered Group n=50</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Molar</td>
<td>9/28 (32%)</td>
<td>12/25 (48%)</td>
</tr>
<tr>
<td>2nd Molar</td>
<td>3/16 (19%)</td>
<td>6/21 (29%)</td>
</tr>
<tr>
<td>3rd Molar</td>
<td>0/0</td>
<td>0/1 (0%)</td>
</tr>
<tr>
<td>1st Premolar</td>
<td>1/1 (100%)</td>
<td>0/0</td>
</tr>
<tr>
<td>2nd Premolar</td>
<td>3/5 (60%)</td>
<td>2/3 (67%)</td>
</tr>
</tbody>
</table>

Table 5. IAN Block Success by Group and Tooth Type.
<table>
<thead>
<tr>
<th>Tooth Type</th>
<th>Buffered</th>
<th>Non-Buffered</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=34</td>
<td>n=30</td>
</tr>
<tr>
<td>1st Molar</td>
<td>7/19 (37%)</td>
<td>6/13 (46%)</td>
</tr>
<tr>
<td>2nd Molar</td>
<td>4/13 (31%)</td>
<td>4/15 (27%)</td>
</tr>
<tr>
<td>3rd Molar</td>
<td>0/0</td>
<td>1/1 (100%)</td>
</tr>
<tr>
<td>1st Premolar</td>
<td>0/0</td>
<td>0/0</td>
</tr>
<tr>
<td>2nd Premolar</td>
<td>2/2 (100%)</td>
<td>0/1 (0%)</td>
</tr>
</tbody>
</table>

Table 6. Articaine Buccal Infiltration Success by Group and Tooth Type.
<table>
<thead>
<tr>
<th>Tooth Type</th>
<th>Buffered</th>
<th></th>
<th>Non-Buffered</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=21</td>
<td>n=19</td>
<td></td>
</tr>
<tr>
<td>1st Molar</td>
<td>8/12 (67%)</td>
<td>4/7 (57%)</td>
<td></td>
</tr>
<tr>
<td>2nd Molar</td>
<td>8/9 (89%)</td>
<td>8/11 (73%)</td>
<td></td>
</tr>
<tr>
<td>3rd Molar</td>
<td>0/0</td>
<td>0/0</td>
<td></td>
</tr>
<tr>
<td>1st Premolar</td>
<td>0/0</td>
<td>0/0</td>
<td></td>
</tr>
<tr>
<td>2nd Premolar</td>
<td>0/0</td>
<td>1/1 (100%)</td>
<td></td>
</tr>
</tbody>
</table>

Table 7. Intraosseous Success by Group and Tooth Type.
<table>
<thead>
<tr>
<th>Gender</th>
<th>Group</th>
<th>Variable*</th>
<th>N</th>
<th>Mean</th>
<th>Std Dev</th>
<th>Min</th>
<th>Max</th>
<th>p-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEMALE</td>
<td>BUF</td>
<td>IAINS</td>
<td>32</td>
<td>46.4</td>
<td>30.7</td>
<td>0</td>
<td>85</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IAPLC</td>
<td>32</td>
<td>51.8</td>
<td>35.8</td>
<td>0</td>
<td>120</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IADEP</td>
<td>32</td>
<td>39.9</td>
<td>36.2</td>
<td>0</td>
<td>126</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>NB</td>
<td>IAINS</td>
<td>29</td>
<td>49.6</td>
<td>37.5</td>
<td>0</td>
<td>142</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>IAPLC</td>
<td>29</td>
<td>51.0</td>
<td>34.3</td>
<td>0</td>
<td>113</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>IADEP</td>
<td>29</td>
<td>43.4</td>
<td>32.0</td>
<td>0</td>
<td>119</td>
<td></td>
</tr>
<tr>
<td>MALE</td>
<td>BUF</td>
<td>IAINS</td>
<td>18</td>
<td>40.7</td>
<td>34.5</td>
<td>0</td>
<td>113</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IAPLC</td>
<td>18</td>
<td>46.2</td>
<td>35.0</td>
<td>0</td>
<td>139</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IADEP</td>
<td>18</td>
<td>54.3</td>
<td>41.7</td>
<td>1</td>
<td>145</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>NB</td>
<td>IAINS</td>
<td>21</td>
<td>53.0</td>
<td>39.5</td>
<td>0</td>
<td>142</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>IAPLC</td>
<td>21</td>
<td>45.5</td>
<td>37.9</td>
<td>0</td>
<td>113</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>IADEP</td>
<td>21</td>
<td>41.0</td>
<td>30.5</td>
<td>0</td>
<td>102</td>
<td></td>
</tr>
</tbody>
</table>

Table 8. Pain of Buffered (BUF) and Non-Buffered (NB) IANB Injections by Stage Using the Heft-Parker Visual Analog Scale (mm) by Gender.

** Step-down Bonferroni method of Holm
*IAINS=IANB Needle Insertion, IAPLC=IANB Needle Placement; IADEP=IANB Solution Deposition
<table>
<thead>
<tr>
<th>Group</th>
<th>Stage</th>
<th>N</th>
<th>None (0mm*)</th>
<th>Mild (&gt;0 mm, ≤54 mm*)</th>
<th>Moderate (&gt;54 mm, &lt;114 mm*)</th>
<th>Severe (≥114 mm*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buffered</td>
<td>Insertion</td>
<td>50</td>
<td>6 (12%)</td>
<td>24 (48%)</td>
<td>20 (40%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Placement</td>
<td>50</td>
<td>6 (12%)</td>
<td>20 (40%)</td>
<td>22 (44%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td></td>
<td>Deposition</td>
<td>50</td>
<td>6 (12%)</td>
<td>24 (48%)</td>
<td>18 (36%)</td>
<td>2 (4%)</td>
</tr>
<tr>
<td>Non-Buffered</td>
<td>Insertion</td>
<td>50</td>
<td>3 (6%)</td>
<td>23 (46%)</td>
<td>21 (42%)</td>
<td>3 (6%)</td>
</tr>
<tr>
<td></td>
<td>Placement</td>
<td>50</td>
<td>6 (12%)</td>
<td>20 (40%)</td>
<td>24 (48%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Deposition</td>
<td>50</td>
<td>6 (12%)</td>
<td>25 (50%)</td>
<td>18 (36%)</td>
<td>1 (2%)</td>
</tr>
</tbody>
</table>

Table 9. Pain of Buffered and Non-Buffered Injections of First IANB by Stage Using Categorical values of the Heft-Parker Visual Analog Scale.

<table>
<thead>
<tr>
<th>Group</th>
<th>Stage</th>
<th>N</th>
<th>None (0mm*)</th>
<th>Mild (&gt;0 mm, ≤54 mm*)</th>
<th>Moderate (&gt;54 mm, &lt;114 mm*)</th>
<th>Severe (≥114 mm*)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buffered</td>
<td>Insertion</td>
<td>50</td>
<td>40 (80%)</td>
<td>10 (20%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Placement</td>
<td>50</td>
<td>39 (78%)</td>
<td>10 (20%)</td>
<td>1 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Deposition</td>
<td>50</td>
<td>37 (74%)</td>
<td>12 (24%)</td>
<td>1 (2%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>Non-Buffered</td>
<td>Insertion</td>
<td>50</td>
<td>41 (82%)</td>
<td>9 (18%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Placement</td>
<td>50</td>
<td>45 (90%)</td>
<td>5 (10%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td></td>
<td>Deposition</td>
<td>50</td>
<td>43 (86%)</td>
<td>7 (14%)</td>
<td>0 (0%)</td>
<td>0 (0%)</td>
</tr>
</tbody>
</table>

Table 9b. Pain of Buffered and Non-Buffered Injections of Second IANB by Stage Using Categorical values of the Heft-Parker Visual Analog Scale.
<table>
<thead>
<tr>
<th>Gender</th>
<th>Group</th>
<th>Variable*</th>
<th>N</th>
<th>Mean</th>
<th>Std Dev</th>
<th>Min</th>
<th>Max</th>
<th>P - value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>BUF</td>
<td>ARTINS</td>
<td>24</td>
<td>16.9</td>
<td>27.8</td>
<td>0</td>
<td>84</td>
<td>0.8340</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ARTPLC</td>
<td>24</td>
<td>13.6</td>
<td>28.5</td>
<td>0</td>
<td>113</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ARTDEP</td>
<td>24</td>
<td>22.7</td>
<td>35.8</td>
<td>0</td>
<td>141</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>NB</td>
<td>ARTINS</td>
<td>16</td>
<td>3.2</td>
<td>5.2</td>
<td>0</td>
<td>21</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ARTPLC</td>
<td>16</td>
<td>3.6</td>
<td>5.5</td>
<td>0</td>
<td>21</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ARTDEP</td>
<td>16</td>
<td>10.6</td>
<td>20.1</td>
<td>0</td>
<td>81</td>
<td>1.0000</td>
</tr>
<tr>
<td>Male</td>
<td>BUF</td>
<td>ARTINS</td>
<td>10</td>
<td>3.1</td>
<td>3.8</td>
<td>0</td>
<td>11</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ARTPLC</td>
<td>10</td>
<td>3.1</td>
<td>3.8</td>
<td>0</td>
<td>9</td>
<td>0.1498</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ARTDEP</td>
<td>10</td>
<td>7.0</td>
<td>10.5</td>
<td>0</td>
<td>27</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>NB</td>
<td>ARTINS</td>
<td>14</td>
<td>2.5</td>
<td>8.5</td>
<td>0</td>
<td>32</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ARTPLC</td>
<td>14</td>
<td>0.1</td>
<td>0.5</td>
<td>0</td>
<td>2</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ARTDEP</td>
<td>14</td>
<td>2.1</td>
<td>7.2</td>
<td>0</td>
<td>27</td>
<td>1.0000</td>
</tr>
</tbody>
</table>

Table 10. Pain of Articaine Injection Following Buffered (BUF) and Non-Buffered (NB) IANB by Stage Using the Heft-Parker Visual Analog Scale (mm) by Gender.

** Step-down Bonferroni method of Holm
*ARTINS=Articaine Needle Insertion; ARTPLC=Articaine Needle Placement; ARTDEP=Articaine Solution Deposition
<table>
<thead>
<tr>
<th>Gender</th>
<th>GROUP</th>
<th>Variable*</th>
<th>N</th>
<th>Mean</th>
<th>Std Dev</th>
<th>Min</th>
<th>Max</th>
<th>p - value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>FEMALE</td>
<td>BUF</td>
<td>IOINS</td>
<td>14</td>
<td>2.9</td>
<td>5.3</td>
<td>0</td>
<td>17</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IOPLC</td>
<td>14</td>
<td>3.9</td>
<td>7.4</td>
<td>0</td>
<td>25</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IODEP</td>
<td>14</td>
<td>6.2</td>
<td>11.8</td>
<td>0</td>
<td>33</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td>NB</td>
<td>IOINS</td>
<td>10</td>
<td>1.1</td>
<td>1.4</td>
<td>0</td>
<td>4</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IOPLC</td>
<td>10</td>
<td>0.5</td>
<td>0.8</td>
<td>0</td>
<td>2</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IODEP</td>
<td>10</td>
<td>12.5</td>
<td>31.2</td>
<td>0</td>
<td>100</td>
<td>1.0000</td>
</tr>
<tr>
<td>MALE</td>
<td>BUF</td>
<td>IOINS</td>
<td>7</td>
<td>9.4</td>
<td>18.2</td>
<td>0</td>
<td>50</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IOPLC</td>
<td>7</td>
<td>5.1</td>
<td>9.9</td>
<td>0</td>
<td>27</td>
<td>0.8164</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IODEP</td>
<td>7</td>
<td>29.3</td>
<td>11.6</td>
<td>15</td>
<td>50</td>
<td>0.0036</td>
</tr>
<tr>
<td></td>
<td>NB</td>
<td>IOINS</td>
<td>9</td>
<td>1.3</td>
<td>3.6</td>
<td>0</td>
<td>11</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IOPLC</td>
<td>9</td>
<td>0.2</td>
<td>0.4</td>
<td>0</td>
<td>1</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>IODEP</td>
<td>9</td>
<td>2.6</td>
<td>6.9</td>
<td>0</td>
<td>21</td>
<td>1.0000</td>
</tr>
</tbody>
</table>

Table 11. Pain of Supplemental IO Injection Following Buffered (BUF) and Non-Buffered (NB) IANB and Articaine by Stage Using the Heft Parker Visual Analog Scale (mm) by Gender.

** Step-down Bonferroni method of Holm
*IOINS=IO Needle Insertion; IOPLC=IO Needle Placement; IODEP=IO Solution Deposition
<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Mean (mm)</th>
<th>Std Dev (mm)</th>
<th>Min (mm)</th>
<th>Max (mm)</th>
<th>p - value*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Satisfaction</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buffered</td>
<td>50</td>
<td>88.2</td>
<td>16.4</td>
<td>15</td>
<td>100</td>
<td>0.2613</td>
</tr>
<tr>
<td>Non-Buffered</td>
<td>50</td>
<td>92.1</td>
<td>17.2</td>
<td>0</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>Treatment Pain</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buffered</td>
<td>50</td>
<td>56.0</td>
<td>37.7</td>
<td>0</td>
<td>143</td>
<td>0.8402</td>
</tr>
<tr>
<td>Non-Buffered</td>
<td>50</td>
<td>54.4</td>
<td>43.2</td>
<td>0</td>
<td>147</td>
<td></td>
</tr>
</tbody>
</table>

Table 12. Post Treatment Satisfaction Ratings and Remembered Maximum Pain Rating.
*Randomization test
<table>
<thead>
<tr>
<th>Gender</th>
<th>Group</th>
<th>Variable*</th>
<th>N</th>
<th>Mean (mm)</th>
<th>Std Dev</th>
<th>Min (mm)</th>
<th>Max (mm)</th>
<th>p - value*</th>
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<tbody>
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<td>Female</td>
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<td>14</td>
<td>108.1</td>
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<td>IACMB</td>
<td>8</td>
<td>116.6</td>
<td>22.3</td>
<td>87</td>
<td>150</td>
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<td>2</td>
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<td>10.6</td>
<td>83</td>
<td>98</td>
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<td></td>
<td>NB</td>
<td>IADEN</td>
<td>9</td>
<td>124.4</td>
<td>24.3</td>
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<td>160</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>IACMB</td>
<td>5</td>
<td>106.4</td>
<td>18.8</td>
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<td>126</td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td>IACMB</td>
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<td>107.3</td>
<td>25.9</td>
<td>85</td>
<td>141</td>
<td>1.0000</td>
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<td>IACANL</td>
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<td>.</td>
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<td>IADEN</td>
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<td>IACMB</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>IACANL</td>
<td>3</td>
<td>91.7</td>
<td>10.7</td>
<td>85</td>
<td>104</td>
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Table 13. Pain of Intraoperative Instrumentation using Buffered (BUF) and Non-Buffered (NB) IANB Injections.
* IADEN=Dentin access; IACMB=Chamber access; IACANL=Canal access.
*Step-down Bonferroni method of Holm
<table>
<thead>
<tr>
<th>Gender</th>
<th>Group</th>
<th>Variable*</th>
<th>N</th>
<th>Mean (mm)</th>
<th>Std Dev</th>
<th>Min (mm)</th>
<th>Max (mm)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>BUF</td>
<td>ARTDEN</td>
<td>5</td>
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<td>9</td>
<td>114.6</td>
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<td>88</td>
<td>143</td>
<td>1.0000</td>
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<tr>
<td></td>
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<td>-</td>
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<td>ARTDEN</td>
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<td>1.0000</td>
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<tr>
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<td>107</td>
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<td></td>
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<td>140</td>
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<tr>
<td>Male</td>
<td>BUF</td>
<td>ARTDEN</td>
<td>4</td>
<td>126.0</td>
<td>29.4</td>
<td>109</td>
<td>170</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
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<td>102.7</td>
<td>18.0</td>
<td>85</td>
<td>121</td>
<td>1.0000</td>
</tr>
<tr>
<td></td>
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<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>NB</td>
<td>ARTDEN</td>
<td></td>
<td>5</td>
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<td>108</td>
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</tr>
<tr>
<td></td>
<td>ARTCMB</td>
<td></td>
<td>3</td>
<td>100.3</td>
<td>21.5</td>
<td>86</td>
<td>125</td>
<td></td>
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<tr>
<td></td>
<td>ARTCANL</td>
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<td>1</td>
<td>117.0</td>
<td>-</td>
<td>117</td>
<td>117</td>
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</tbody>
</table>

Table 14. Pain of Intraoperative Instrumentation using Buffered (BUF) and Non-Buffered (NB) IANB Injections Followed by Supplemental Articaine Injections.

*ARTDEN=Dentin access; ARTCMB=Chamber access; ARTCANL=Canal access.
*Step-down Bonferroni method of Holm
<table>
<thead>
<tr>
<th>Injection</th>
<th>Anesthetic Failure Point</th>
<th>Buffered</th>
<th>Non-Buffered</th>
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<tr>
<td>IAN Block</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BUF (n=50)</td>
<td>None</td>
<td>16/50 (32%)</td>
<td>20/50 (40%)</td>
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<tr>
<td>NB (n=50)</td>
<td>Dentin</td>
<td><strong>20/50 (40%)</strong></td>
<td><strong>15/50 (30%)</strong></td>
</tr>
<tr>
<td>Chamber</td>
<td>12/50 (24%)</td>
<td>10/50 (20%)</td>
<td></td>
</tr>
<tr>
<td>Canals</td>
<td>2/50 (4%)</td>
<td>5/50 (10%)</td>
<td></td>
</tr>
<tr>
<td>Articaine Infiltration</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BUF (n=34)</td>
<td>None</td>
<td>13/34 (38%)</td>
<td>11/30 (37%)</td>
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<tr>
<td>NB (n=30)</td>
<td>Dentin</td>
<td>9/34 (26%)</td>
<td><strong>11/30 (37%)</strong></td>
</tr>
<tr>
<td>Chamber</td>
<td><strong>12/34 (35%)</strong></td>
<td>6/30 (20%)</td>
<td></td>
</tr>
<tr>
<td>Canals</td>
<td>0/34</td>
<td>2/30 (7%)</td>
<td></td>
</tr>
<tr>
<td>IO #1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BUF (n=21)</td>
<td>None</td>
<td>16/21 (76%)</td>
<td>13/19 (68%)</td>
</tr>
<tr>
<td>NB (n=19)</td>
<td>Dentin</td>
<td>1/21 (5%)</td>
<td><strong>4/19 (21%)</strong></td>
</tr>
<tr>
<td>Chamber</td>
<td><strong>3/21 (14%)</strong></td>
<td>1/19 (5%)</td>
<td></td>
</tr>
<tr>
<td>Canals</td>
<td>1/21 (5%)</td>
<td>1/19 (5%)</td>
<td></td>
</tr>
<tr>
<td>IO #2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BUF (n=5)</td>
<td>None</td>
<td>5/5 (100%)</td>
<td>3/6 (50%)</td>
</tr>
<tr>
<td>NB (n=6)</td>
<td>Dentin</td>
<td>0/5</td>
<td>0/6</td>
</tr>
<tr>
<td>Chamber</td>
<td>0/5</td>
<td><strong>3/6 (50%)</strong></td>
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</tr>
<tr>
<td>Canals</td>
<td>0/5</td>
<td>0/6</td>
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Table 15. Anesthetic Failure Point and Patient Distribution.

*All three failures were given intrapulpal injections that were successful.
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<th>Buffered 4% Lidocaine</th>
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<tbody>
<tr>
<td>1</td>
<td>4.42</td>
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<tr>
<td>10</td>
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<td>Average</td>
<td><strong>4.507</strong></td>
<td><strong>7.049</strong></td>
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Table 16. pH of Non-Buffered and Buffered 4% lidocaine 1:100,000 Epinephrine.
References


Clause DW, Zach GA. Reaction to diphenhydramine (Benadryl) used as a local anesthetic. Gen Dent. 1989;37:426-7.


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Hochman MN, Friedman M, Williams W. Interstitial tissue pressure Associated with Dental Injections: A clinical Study. Quintessence Int. 2006;37:469-76.

APPENDIX A

GENERAL CONSENT FORM

The Ohio State University Consent to Participate in Research
Study Title: Effect of buffered Lidocaine on the success of the inferior alveolar nerve block in patients with symptomatic irreversible pulpitis.

Principal Investigator: Dr. Melissa Drum

Sponsor: Not applicable

- **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 Lidocaine/buffered combination (like Novocaine) improves the ability to get numb during emergency endodontic 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 you 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 complete a medical history questionnaire. Local anesthetic will then be administered in a routine manner to make your tooth numb. The mixture of Lidocaine/buffered combination you receive will be chosen at random (by chance, like flipping a coin). Neither your doctor nor you will know which one you will receive. Lidocaine and buffering solution have been used in the dental office and have been approved by the Food and Drug Administration (FDA) for dental and medical use. The purpose of this study is to see if Lidocaine/buffered combination helps your tooth get numb.

If you are a female and are pregnant or nursing, you will not be able to participate. 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.

You will be asked to rate the pain you are having prior to any treatment. The tooth causing your pain will first be tested to insure 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.

An injection (shot) will be given in the back of your jaw to numb your lower teeth (inferior alveolar injection) using 4% Lidocaine with 1:100,000 epinephrine (buffered or non buffered) which is an anesthetic (numbing solution) similar to Novocaine. You will be asked to rate the amount of pain you feel when the injection is being given. You will do this by marking your pain with a pencil on a line graph.

Following the anesthetic injections the doctor will begin asking you every minute for 15 minutes whether you are experiencing lip numbness. At 15 minutes if your lip is not numb, you will be given extra anesthesia (shots). 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, a supplemental (extra) injection (shot) will then be given directly beside 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.
Your participation or non-participation will have no effect on whether you will receive emergency root canal treatment. You understand that if you want to save the treated tooth (provided it is restorable or savable) further root canal treatment and restorative treatment such as a filling and or a crown will be needed. You are responsible for the emergency root canal fee.

4. How long will you be in the study?

You are aware that you will have one appointment, which will last approximately 120 minutes.

5. Can you 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 you expect from being in the study?

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 the potential risks to the fetus and nursing baby are unknown.

7. What benefits can you 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 you have if you do not take part in the study?

You may have the emergency endodontic procedure completed without participating in the study. You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled.

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

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

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

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

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

12. What happens if you are injured because you 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 your rights if you 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 your questions about the study?

For questions, concerns, or complaints about the study you may contact Dr. Melissa Drum or Dr. Jared Schellenberg 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. Jared Schellenberg 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.

<table>
<thead>
<tr>
<th>Printed name of subject</th>
<th>Signature of subject</th>
<th>AM/PM</th>
</tr>
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<table>
<thead>
<tr>
<th>Printed name of person authorized to consent for subject (when applicable)</th>
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<table>
<thead>
<tr>
<th>Relationship to the subject</th>
<th>Date and time</th>
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**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.

<table>
<thead>
<tr>
<th>Printed name of person obtaining consent</th>
<th>Signature of person obtaining consent</th>
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**Witness(es)** - *May be left blank if not required by the IRB*
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<th>Printed name of witness</th>
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APPENDIX B

PATIENT PRIVACY FORM

THE OHIO STATE UNIVERSITY

AUTHORIZATION TO USE

PERSONAL HEALTH INFORMATION IN RESEARCH
Effect of buffered Lidocaine on the success of the inferior alveolar nerve block in patients with symptomatic irreversible pulpitis.

OSU Protocol Number:

Principal Investigator: Dr. Melissa Drum

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. 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. 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.
- 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. Henry Fischbach 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 Manju Ooman 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 [insert name of Principal Investigator] 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)
APPENDIX C

HEALTH HISTORY QUESTIONNAIRE

THE OHIO STATE UNIVERSITY
COLLEGE OF DENTISTRY

Subject # ___________________________
Date ______________________________
Date of Birth ________________________

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. irregular 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**

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>Generic Name</th>
<th>Dose/Frequency</th>
<th>Reason</th>
</tr>
</thead>
</table>

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Summary of Patient’s Medical Status: ____________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________
____________________________________________________________________________

Medical Risk Assessment

☐ ASA I (healthy individual) ☐ ASA III (severe disease but not incapacitating)
☐ ASA II (mild systemic disease) ☐ 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 D

CORAH’S DENTAL ANXIETY QUESTIONNAIRE

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.
Pt. Number:____________________

Satisfaction Rating

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

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

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