Efficacy of Pulpal Anesthesia using a Needle-less Syringe

ABSTRACT

Dentistry utilizes many resources with the intention of reducing patient anxiety during local anesthetic administration. Objective: The purpose of this study was to compare the use of a new needle-less intraligamentary injection device, the Numbee by BioDent (Simi Valley, CA) to the traditional Inferior Alveolar Nerve (IAN) block. This study evaluated pain upon injection and potential to achieve pulpal anesthesia during a caries restorative procedure on mandibular teeth. Methods: A randomized, split-mouth design of 15 adult subjects receiving two anesthetic dental injections using 2% lidocaine with 1:100,000 epinephrine was conducted. Subjects received an IAN block on one side of the mandibular arch and a Numbee injection on the same tooth type (molar, premolar) on the contralateral side. Subjects recorded injection pain using the Visual Analog Scale (VAS) and the injection technique they generally preferred. An electric pulp tester (EPT) was used to assess pulpal anesthesia at 5-, 15-, 30-, 45- and 60-minute intervals. Anesthesia was considered profound with two consecutive EPT readings of 80 (EPT maximum output). If subjects became symptomatic during the restorative procedure, rescue anesthesia was administered. Results: A Wilcoxon Signed Rank Test revealed no statistically significant difference (P=0.078) in VAS scores with pain upon injection between the Numbee (median 33.0 mm, IQR 39.9 mm) and IAN block (median 44.0, IQR 34.6). However, a Pearson Chi-Square Test found a significant difference in the ability of the two injections to achieve profound anesthesia (p=0.003) and the need for rescue anesthesia during the corresponding restorative procedure (p=0.025). The IAN block required rescue anesthesia during 20% of procedures and the anesthesia was determined to be profound during 46% of procedures. The Numbee injection required rescue anesthesia during 60% of procedures and the anesthesia was never determined to be profound (0%). Patient preference was evenly split (50%) between the two techniques. Conclusions: No statistically significant difference in pain upon injection or patient preference was found between Numbee and IAN block. The IAN block outperformed the Numbee in achieving profound anesthesia and required less rescue anesthesia.
INTRODUCTION

Fear of the dentist is as common as it is ageless. According to the study “The Epidemiology of Common Fears and Phobia”, the “dentist” has previously ranked in the top 11 common fears ahead of injury, illness, and death. [1] Dental anxiety can cause a multitude of negative thoughts and feelings, avoidance behaviors, loss of sleep and even social affects interfering with work and personal relationships.[2] Epidemiological studies have concluded that much of the population choose to not seek dental treatment on a regular basis, primarily because of the fear of the needles.[3-5] Despite the effective use of local anesthetic, pain associated with dental injections can be a source of fear and anxiety for patients and become a great obstacle in dental care.[6-9] Moreover, the vast majority of medical emergencies that occur in dentistry happen during or immediately after local anesthetic administration.[10] Great amounts of resources have been used with the intention of reducing patient fear and anxiety during local anesthetic administration. Techniques and/or equipment such as topical anesthetic, cold spray, applying pressure, vibratory devices, distraction techniques, sedation medications, mechanical and computer-assisted injection equipment, even various needle-less injection devices have been developed or utilized with the intention of reducing pain or fear of dental injections or increasing efficacy of anesthesia.[6, 7, 9, 11, 12]

The Numbee by BioDent (Simi Valley, CA) is one such device that claims to be “the first and only device to provide atraumatic delivery of local anesthesia without a hypodermic needle.” According to the manufacturer, the Numbee is a small metal cannula ensconced with a silicone-like material that is to be used for intraligamentary injections without penetration of the periodontal ligament (PDL). Instead, instructions state to create a seal between the Numbee tip and the PDL (diagram shows Numbee tip at base of the gingival sulcus). Local anesthetic is then infused into the tissue with slow exerted pressure on the plunger of the syringe. According to the manufacturer, the Numbee can be used with any anesthetic syringe with a standard screw attachment, thus replacing the use of the hypodermic needle traditionally attached in these syringes. The manufacturer also sells an intraligamentary, pen-style syringe to be used with the Numbee; the syringe
is similar to a Citoject syringe (Kulzer, South Bend, IN). Biodent’s website states “great for pediatric patients, patients with bleeding disorders and any patient who has a strong fear of needles.” The website also provides promotional videos with claims the device can be used for “painless and comfortable, ouch-less anesthesia.” Claims of providing single-tooth anesthesia for endodontic, operative and exodontia dentistry with duration being comparable to local infiltration are also presented. Diagrams show application locations for both maxillary and mandibular teeth.[13]

The intraligamentary or PDL injection is by no means considered a new pulpal anesthesia technique. The technique was originally described as the peridental injection in local anesthesia textbooks dating from 1912 to 1923.[10, 14, 15] The technique gained popularity in the 1970’s when high pressure syringes were introduced. The PDL injection and other intraosseous techniques involve the deposition of local anesthetic solution into the teeth’s supporting cancellous bone. Traditionally, a PDL injection includes a short 27- or 30-gauge dental needle inserted into the gingival sulcus on the mesial and distal aspect of the tooth. The needle is then advanced, with the bevel oriented toward the root surface, into the PDL between the root surface and adjacent alveolar bone. Instead of being forced down the PDL to the tooth apex, the deposited local anesthetic is redirected from the coronal segment of the PDL to surrounding cancellous bone through the fenestrations in the alveolar socket.[16]

Today, the PDL injection is frequently used to supplement failed or partially successful traditional injection techniques.[10] Despite its common use as a supplemental technique, the PDL injection has historically been demonstrated through published clinical assessment to have success rates ranging from 60% for endodontic therapies to 100% for periodontal therapies and tooth extractions together with a rapid onset of anesthesia lasting for 30-45 minute duration.[16-18] Advantages include anesthesia limited to single tooth and up to one or two adjacent teeth, rapid onset, less injection pain, safety of patients with bleeding disorders and small volume anesthetic administered with less risk of systemic toxicity. [16, 19, 20] In comparison, the traditional inferior alveolar nerve (IAN) block achieves an 80-85% success rate.[10, 21] Supraperiosteal injection or “local infiltration” has a 95% success rate in the maxillary dentition. In a study evaluating pain, pressure and discomfort induced by common oral local anesthesia injections, Kauffman
found that pain response was generally higher in the IAN block, followed by the PDL injection, mental nerve block and infiltration.[22] A 2013 clinical study looking at the efficacy of intraligamentary injections in comparison to IAN block for mandibular molars found pain was less with intraligamentary technique and achieved a success rate of 90% compared to IAN block’s 60% success rate.[19] Adverse reactions to the traditional PDL injection include pain during administration, post-injection pain after treatment, sense that the tooth was elevated in occlusion or “high” after treatment, variable duration of local anesthesia, slight increases in heart rate, damage to the pulpal or periodontal tissues and reported cases of enamel hypoplasia and hypomineralization in adjacent unerupted permanent teeth. In most studies damage to tissue was considered minimal or reversible and the protruding sensation, along with excessive tissue damage, can be minimized if the dentist avoids using excessive pressure and volume during anesthetic deposition.[16, 18, 19, 23, 24]

Studies have reported successful pulpal anesthesia with needle-less injection devices, Madajet XL (Mada, Carlstadt, NJ) and Injex (Injex UK Ltd, Ross on Wye, Herefordshire, United Kingdom), that substitute a traditional hypodermic needle with a high velocity spray injector of anesthetic solution forced under high pressure into the oral mucosa leading to mechanical infiltration of the compound through mucosa.[3, 12] However, the Injex study reported that 17.6% of patients experienced pain during injection, 32.3% reported feeling dread or fear from the explosion of the injector as it released the anesthetic, 11.8% experienced intense pain in the area of the injection after anesthesia subsided, and following treatment 52.8% reported preference of the traditional needle injection compared to 17.6% preference for the Injex.[12] To date, no study has investigated the efficacy of a cannula-based, needle-less, intraligamentary injection system such as the Numbee.

The purpose of this study was to evaluate the use of the Numbee intraligamentary injection device in the potential to achieve pulpal anesthesia for sufficient duration, and reduction or elimination of pain upon injection and post-injection pain when compared to the traditional anesthetic technique of IAN block for mandibular teeth. The injection pain experienced by the patients was evaluated through the use of a visual analogue scale (VAS). The VAS is reliable, self-reporting device used to measure subjective phenomena
in an experimental setting, specifically in this study, a patient’s level of pain. The null hypotheses tested were that there would be no difference in perceived pain based on type of injection technique and no difference in ability to achieve pulpal anesthesia for sufficient duration.

MATERIALS AND METHODS

The Institutional Review Board at Wilford Hall Ambulatory Surgical Center approved protocol #FWH20180045H. This study enrolled 15 active duty or Department of Defense beneficiaries ages 18 years or older who were treatment planned to receive routine restorative dental procedures. Patients were selected from a pool of patients available for treatment at Dunn Dental Clinic, JBSA-Lackland, Texas. All selected patients were of good health as indicated by the American Society of Anesthesiologists I or II classification. Dental patients with a chronic pain condition and non-vital teeth were excluded from this study.

All subjects signed an informed consent document prior to any study-related procedures. Specific treatments selected for this study included routine restorative dental procedures limited to a class one (occlusal), class two (proximal), class five (facial or lingual) restoration planned on a tooth and the same tooth type (molar, premolar) on the contralateral side within the same mandibular arch. The size of carious lesions included in the study was controlled based on the 2015 ADA Dental Caries Classification System (CCS). Only initial or moderate caries per CCS were included. Moreover, per Radiographic Caries Classification, D1 or D2 carious lesions were included where caries extended to the outer third or to middle third of the dentin, respectively.

A randomized, split-mouth design was conducted using one local anesthetic injection of 2% lidocaine with 1:100,000 epinephrine on each side of the mouth following application of a topical anesthetic gel (Henry Schein, Melville, NY). The Numbee injection was compared to a traditional injection method of the Inferior Alveolar Nerve block to evaluate perceived pain upon injection, effective pulpal anesthesia, duration of anesthesia. The sequence of treatment was randomized using a block design to determine the side to be injected first and method of injection. Eight subjects were injected with the Numbee first and seven subjects were injected with the control first. Also, seven
subjects were injected on the left side first and eight subjects were injected on the right side first.

Subjects received a total of two injections. Subjects received restorative procedures on mandibular teeth following an IAN injection (control injection) using a 27-gauge Monoject (Covidien AG, Neuhausen am Rheinfall, Switzerland) long needle with a standard dental anesthetic syringe on one side and the Numbee tip with BioDent Intraligamentary syringe on the same tooth type (molar, premolar), contralateral side of the arch.

An electric pulp tester (EPT) (Vitality Scanner, Sybron Endo, Orange, CA) was used to assess the initial vitality of the teeth prior to administration of any local anesthetic. The EPT was used to assess pulpal anesthesia at the 5-, 15-, 30-, 45- and 60- minute interval following local anesthetic injection. Anesthesia was considered profound with two consecutive pulp test readings of 80 (meaning the subject evidenced no response at the maximum output on the EPT).

Benzocaine 20% topical gel (Topex, Sultan Dental Products, Hackensack, NJ) was used to anesthetize the sites receiving the inferior alveolar and intraligamentary (Numbee) injections. The method of application was as follows: 1) the gel was preloaded in a syringe, and 0.1 mL was placed on a cotton-tip applicator; 2) the mucosa at the sites of injection was dried with a 2- x 2-cm gauze; and 3) the gel on the cotton-tip applicator was applied to the mucosa for 2 minutes.

Following the placement of the topical anesthetic, the Primary Investigator (PI) prepared the syringe to be used for local anesthetic injection. The syringe was either a Biodent intraligamentary syringe with Numbee tip or a standard dental syringe with a 27-gauge long needle. The PI provided instruction on which side of the mouth to inject based on the randomized block design. Injections were completed just prior to their respective restorative procedure. Immediately after each injection, the patient was allowed to rate the pain experienced during injection using the VAS on a preprinted form. Following the second injection, a qualitative statement was given to the patient asking which injection he/she preferred, the first or second injection, and why?

For intraligamentary injection using the Numbee, the PI followed the manufacturer instructions obtained from BioDent’s website. BioDent’s instructions state that while using
the Numbee on the BioDent intraligamentary syringe, each squeeze of the syringe should take 10-15 seconds to deliver roughly 0.06 mL of anesthetic per injection site. Instructions state that two squeezes of the BioDent intraligamentary syringe per injection site is sufficient. Injection site locations were guided by a diagram provided by BioDent that illustrates suggested injection locations (3-5 sites) for each tooth. For the IAN injection, one cartridge was administered over 30 seconds. A metronome application (Metronome, Gismart) was used to pace the PI during the delivery of anesthetic.

The restorative procedure was then completed for that side. Then the contralateral injection was completed, followed by its respective restorative procedure. EPT testing was completed at intervals previously mentioned per injection. A qualitative statement was also recorded by the PI as to whether or not the local anesthesia was profound enough for the patient to experience analgesia during the restorative procedure. If the injection method did not allow the patient to experience analgesia during the restorative procedure, rescue anesthesia was administered by any method necessary to allow the restorative procedure to be completed during the same appointment. Anesthesia was considered successful if no pain was reported and no rescue anesthesia was needed during the restorative procedure.

As stated, the patient's report of injection pain was recorded using the VAS. The VAS is a 100-mm horizontal line with descriptive anchors at each end. The left end was labeled no pain and the right end was labeled worst possible pain. The patient was instructed to mark a vertical line within the 100-mm scale to indicate his or her level of discomfort after each injection. The VAS pain score was calculated by measuring the millimeter distance from the left end of the scale using a digital caliper (Empire, Mukwonago, WI). A larger score was translated to a higher pain intensity experienced by the patient. The sample size of 15 subjects provided 80% power to detect a 1 standard deviation difference when using a Wilcoxon Signed Rank Test with an alpha level of 0.05 to compare the VAS values determined in each group. A Pearson Chi-square test was used to evaluate the effect of injection technique on the need for rescue anesthesia and the profoundness of anesthesia (alpha = 0.05).
RESULTS

The participant pool was made up of 12 men and 3 women whose ages ranged from 19 to 87 years (average age, 39 years). The participants rated the Numbee with topical anesthetic a median VAS score of 33 mm and interquartile range of 39.9 mm. Participants rated the IAN block with topical anesthetic a median VAS score of 44 mm and interquartile range of 34.6 mm. The Wilcoxon Signed Rank Test found no significant difference in VAS scores with pain upon injection between the Numbee and IAN block (p=0.078).

The Numbee required rescue anesthesia with 60% of procedures and the IAN block required rescue anesthesia with 20% of procedures. Local anesthesia administered with the Numbee was never determined to be profound (two consecutive pulp test readings of 80). The IAN block was determined to be profound in 46% of procedures. Of those with profound anesthesia from the IAN block, 71% demonstrated profound anesthesia for > 30 minutes, 57% for > 45 minutes, 43% for > 60 minutes. The Pearson Chi-Square Test found a significant difference in the need for rescue anesthesia between the two injection techniques (p=0.025). The use of the Numbee injection resulted in significantly more subjects reporting the need for rescue anesthesia than the use of the IAN injection. The Pearson Chi-Square Test found a significant difference in profound anesthesia between the two injection techniques (p=0.003). The use of the IAN injection resulted in significantly more subjects reporting profound anesthesia (i.e., 80 EPT score) than the use of the Numbee.

Of the patients that stated a preference, 50% of patients stated they preferred the Numbee injection while the other 50% stated preference for the IAN block. One patient stated no preference and rated discomfort the same for each injection.

DISCUSSION

The manufacturer of the Numbee makes the claim that the device will “eliminate your patient’s injection anxiety and discomfort.” Utilizing a proven dental anesthetic technique of an intraligamentary style injection, the Numbee substitutes a needle with a
small silicone-coved cannula. If the manufacturer’s claims held true, this device could be very beneficial for both patients and providers.

Investigators in this study selected the treatment of the mandibular dentition. Compared to the maxilla, the greater bone density of the mandible may provide a better assessment of the capability of intraligamentary deposition by the Numbee. Also, the IAN has previously been rated as the dental injection that causes the greatest pain response.[22] Researchers thought comparing the Numbee to the IAN would be a good test to determine if any reduction in discomfort was achieved when using the Numbee.

Similar to a study by Kaufman et al., subjects in this study reported greater pain upon injection with an IAN injection compared to an intraligamentary injection (Numbee).[22] However, no significant difference was found in VAS scores between the Numbee and IAN block in this split-mouth study. Therefore, the first null hypothesis was not rejected. Despite a majority (60%) of participants rating the IAN injection with the higher VAS scores, subjectively, half of the participants preferred the IAN injection and half preferred the Numbee.

A common theme among patients who preferred the IAN injection stated the injection was overall faster (57% of participants that preferred the IAN injection). As previously stated, per manufacturer’s instructions, the Numbee injection typically requires two, slow 10-15 second squeezes of the BioDent intraligamentary syringe handle per injection site with 3-6 injection sites per tooth.[13] Therefore, a Numbee injection for one tooth may take 1-2 minutes to administer while the IAN injection in this study was administered within 30 seconds. Other participants reported that soft-tissue regional anesthesia associated with the IAN injection was reassuring or that they felt more completely numb (43% of participants that preferred the IAN injection). Twenty percent of participants reported that the IAN injection had greater pain upon injection but preferred the IAN injection because they experienced less pain during the procedure and did not have to be injected a second time (i.e. rescue anesthesia).

Patients that preferred the Numbee commonly stated less pain upon injection as the primary reason (100% of participants that preferred the Numbee). Forty-three percent of the participants that preferred the Numbee gave a secondary reason that they enjoyed
not having the regional soft-tissue anesthesia sensation on the side of the Numbee injection.

The second null hypothesis was rejected. There was a difference in efficacy between the Numbee and IAN block in achieving pulpal anesthesia for sufficient duration. As previously stated, the IAN block is reported to achieve an 80-85% success rate.[10, 21] Of the 15 subjects treated, 80% achieved successful anesthesia with one IAN Block that allowed pain-free restorative procedures of dentinal caries and did not require rescue anesthesia. The Numbee was only 40% successful in this regard and required rescue anesthesia for the majority (60%) of its restorative procedures. This needle-less intraligamentary injection device, Numbee, falls short of the previously stated 60-100% success rate of traditional intraligamentary (or periodontal ligament, PDL) injection that utilizes a needle.[16-18] The Numbee, while classified as an intraligamentary type of injection, is not advanced to the PDL because its tip is only inserted to the base of the gingival sulcus per manufacturer's instructions. Investigators in this study believe that without advancement of a needle into the PDL, achieved during a traditional intraligamentary injection, anesthetic is not as readily available to be deposited into the cancellous bone surrounding the ligament. The Numbee relies on the pressure form the syringe to “infuse tissue” coronal to the PDL with local anesthetic. Instead of puncturing the epithelium and connective tissue located between base of the gingival sulcus and the PDL, the Numbee forces local anesthetic through this tissue. As a result there may be less local anesthetic reaching the bone surrounding the teeth when compared to the traditional intraligamentary syringe. After all, it is the marrow spaces of the bone surrounding the teeth that allows the local anesthetic to reach the periapical tissues of the teeth and gives the intraligamentary injection the same mechanism of action as the intraosseous injection.[10]

The EPT was used to assess profound anesthesia because randomized clinical trials have demonstrated a 96.88% accuracy in determining pulpal anesthesia.[25] The EPT was used for purposes of comparing pulpal anesthesia duration between the Numbee and IAN injection. The rate of profound anesthesia achieved with an IAN Block was 46% compared to the 0% profound anesthesia rate with the Numbee. Comparing profound anesthesia rates with the Numbee to a traditional intraligamentary injection
(utilizing a needle) might have provided an explanation as to whether or not a suspected less intraosseous deposition of anesthetic was a likely etiology of the Numbee’s shortcomings. Investigators in this study were surprised to see such a difference when comparing the rates of successful anesthesia to profound anesthesia among the same type of injection. The deposition of secondary or tertiary dentin that would also allow for asymptomatic caries excavation of an un-anesthetized tooth may have played a factor in a higher successful anesthesia rate than a profound anesthesia rate. Perhaps secondary innervation of those teeth anesthetized with an IAN played a factor in a lower profound anesthesia rate than a successful anesthesia rate. A Long Buccal injection or other supplemental nerve blocks were not administered during this study because investigators wanted to compare the Numbee injection to a single local anesthesia injection method. Supplemental injections were only administered for the purpose of rescue anesthesia.

Limitations of this study include the inability to control confounding variables such as rate of injection administration, size and depth of caries or secondary (recurrent caries) caries on contralateral sides of the mouth and the possible placebo effect from the use of a needle-less device. Moreover, this randomized, controlled clinical trial was not blinded to patient or provider. Participants were informed of use of the Numbee and standard dental anesthetic syringe during the informed consent process, however, investigators of this study intentionally attempted to conceal the identity of the device at time of injection and subject’s rated pain and preference based on which side of the mouth and not by the device name. Regardless, an observant subject would most likely differentiate the two injection techniques prior to or during the injection. Future studies evaluating the needle-less device should include subjects of the pediatric age. Another dataset not collected that would have benefited this study would have been overall pain (VAS score) experienced during each restorative procedure instead of just the pain upon injection. We suspect restorative procedures that were completed with anesthesia administered by the Numbee would have experienced more overall pain (higher VAS score) during the procedure due to fact that 60% of the subjects injected with the Numbee had to be supplemented with rescue anesthesia. Also, future studies should evaluate or include the subjects’ overall apprehension toward needles. Perhaps the greatest benefit of a needle-less device is not significantly reducing injection discomfort, that this study demonstrated,
but more so reducing a dental-phobic patient’s anxiety by having the patient witness “no needle” prior to injection.

**CONCLUSIONS**

Pain upon injection with the needle-less injection device, Numbee, was not significantly different in pain perception from an IAN injection. The Numbee was found to be significantly different than the IAN injection in achieving pulpal anesthesia. The Numbee did not achieve profound anesthesia and often had to be supplemented with additional local anesthetic techniques to complete caries restorative procedures on the mandibular dentition.

**Disclaimer:** The voluntary, fully informed consent of the subjects used in this research was obtained as required by 32 CFR 219 and DODI 3216.02_AFI 40-402. The views expressed are those of the authors and do not reflect the official views or policy of the Uniformed Services University, Department of Defense, or its Components. The views of Henry Schein, Covidien AG, Sybron Endo, Sultan Dental Products, Biodent, Gismart, or Empire are not necessarily the official views of, or endorsed by, the U.S. Government, the Department of Defense, or the Department of the Air Force. No Federal endorsement of Henry Schein, Covidien AG, Sybron Endo, Sultan Dental Products, Biodent, Gismart, or Empire is intended.

**REFERENCES**

11. Nusstein, J.B., Jeffrey; Reader, Al; Beck, Mike; Weaver, Joel, Comparison of Injection Pain, Heart Rate Increase, and Postinjection Pain of Articaine and Lidocaine in a Primary Intraligamentary Injection Administered With a Computer-Controlled Local Anesthetic Delivery System. American Dental Association of Anesthesiology, 2004. 51: p. 126-133.