Articaine Local Infiltration Vs Lidocaine IANB for Restoration of 
First Permanent Molars in Children

By

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<th>Description</th>
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<tbody>
<tr>
<td>AAPD</td>
<td>American Academy of Pediatric Dentistry</td>
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<tr>
<td>ADA</td>
<td>American Dental Association</td>
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<td>ASA</td>
<td>American Society of Anesthesiologists</td>
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<tr>
<td>CDC</td>
<td>Clinical Data Collection</td>
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<tr>
<td>COD</td>
<td>College of Dentistry</td>
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<tr>
<td>EHR</td>
<td>Electronic Health Record</td>
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<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
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<tr>
<td>HCL</td>
<td>Hydrochloride</td>
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<tr>
<td>IANB</td>
<td>Inferior Alveolar Nerve Block</td>
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<td>IDC</td>
<td>Initial Data Capture</td>
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<td>LA</td>
<td>Local Anesthesia</td>
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<td>MBPS</td>
<td>Modified Behavioral Pain Scale</td>
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<tr>
<td>PG</td>
<td>Post-graduate</td>
</tr>
<tr>
<td>PI</td>
<td>Principal Investigator</td>
</tr>
<tr>
<td>PIL</td>
<td>Patient Information Leaflet</td>
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<tr>
<td>PRS</td>
<td>Pain Response Scale</td>
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<tr>
<td>STS</td>
<td>Study Title Sheet</td>
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<tr>
<td>UIC</td>
<td>University of Illinois at Chicago</td>
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<tr>
<td>VAS</td>
<td>Visual Analogue Scale</td>
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SUMMARY

This was a randomized control clinical trial, which aimed to compare the effectiveness of articaine local infiltration versus lidocaine inferior alveolar nerve block for restoration of first permanent mandibular molars in patients 7 to 12 years of age. A total of 40 participants were recruited and randomly allocated, using a random digit table method, to either the lidocaine group (control) or the articaine group. One investigator/operator completed the local anesthesia administration for all subjects in both groups. Two types of examiners evaluated the participant’s observable behavior during the dental visit. An examiner A (dental assistant), observed the subject during the administration of local anesthesia and evaluated and scored the expression of pain by completing the validated rating scale (Modified Behavioral Rating Scale). An examiner B (pediatric dental resident), who was blinded to the type of anesthetic agent used, completed the planned restoration on first permanent molars. Examiner B evaluated and scored the expressed pain experienced by the subject during the actual treatment by also completing the Modified Behavioral Rating Scale. A total of 6 examiners A and 10 examiners B took part in the study. All examiners were trained and calibrated with regard to using the Modified Behavioral Rating Scale. At the end of the treatment visit, the participant was asked to subjectively evaluate their own perception of pain experienced throughout the appointment by completing the Wong Baker Pain Scale. For physiological parameters assessment, the blood pressure and pulse for each participant was recorded during the entire dental visit. The data gathered through all recordings was numerically coded and statistically analyzed.
INTRODUCTION

A. Background

Local anesthesia (LA) is used routinely in dentistry to inhibit temporary pain during operative care. It should always be administered in the safest and most effective way possible, which is particularly important when working on children. Pediatric patients can readily withdraw cooperation at the first sensation of discomfort or pain. LA may be applied with various agents and various techniques, depending on the properties of the local anesthetic and the innervation of the tooth requiring anesthesia. Dental providers should have good understanding of the advantages and limitations of the various LA agents available for dental use and be able to make the most appropriate choice of LA, based on the clinical care requirements.

LA can be either administered as a local infiltration or a nerve block.¹ Nerve blocks are technique sensitive interventions, requiring accurate needle positioning and localizing correctly anatomical structures in deeper body layers. Individual anatomy variations may further complicate the achievement of successful nerve block.² Local infiltration is a technique where the LA agent is administered in the immediate vicinity of the tooth. Generally, it is simpler, more comfortable, and has fewer complications.³ However, local infiltrations may not successfully anesthetize teeth in areas of high bone density. Although porous in early age, the cortical layer of the mandible increases its bone mineral density during growth and development as a response to increase in biomechanical loading.⁴

Currently, the gold standard for LA of mandibular molars is inferior alveolar nerve block (IANB) with 2 % lidocaine with 1:100,000 epinephrine. IANB anesthetizes all the mandibular teeth on the ipsilateral side of injection. Complications associated with IANB
include increased chances of needle breakage, nerve damage and hematoma. This technique has variable success rates as high as 92% and as low as 42%, due to difficulties in correct needle placement. IANB becomes increasingly challenging with poor cooperation from the patient.

Lidocaine is the most commonly used anesthetic agent in dentistry. However, it cannot penetrate through the denser cortical mandibular bone and therefore cannot achieve successful anesthesia when administered via local infiltration.

Articaine is a newer anesthetic agent that has gained popularity in recent years. Similar to lidocaine, articaine is an amide; however, it is derived from a thiophene instead of a benzene. This difference in chemical structure makes articaine lipophilic, thereby allowing diffusion through bone and soft tissues alike. The diffusion potential allows articaine to be administered as a local infiltration for mandibular teeth. Another advantage to the chemical structure of articaine is the presence of an ester group. Therefore, the agent is more rapidly metabolized due to the presence of esterase in the blood, thus reducing toxicity.

It has been shown that typical dental formulation of 4% articaine hydrochloride (HCL) is 1.5x as potent as 2% lidocaine HCL while it is less toxic (0.6x). Articaine has been documented for efficacy and safety in adults and children over 4. It has been approved by the FDA since 2000. Reports of paresthesia when administered as IANB have been made in the past; although these claims have weak evidence. Other reports confirm safe use of articaine administered as IANB without postoperative complications.

Few studies have compared lidocaine IANB to articaine local infiltration for treatment of mandibular molars in adults, and no study has compared a lidocaine IANB to articaine
local infiltration for treatment of mandibular first permanent molars in children. There is a need to provide evidence for safe and effective methods of anesthesia for pediatric patients in order to add to a clinician’s armamentarium.
REVIEW OF LITERATURE

A. **Lidocaine**

Lidocaine is a local anesthetic in the amide family. It has been available in the United States for about 70 years and has had proven success since its release.\(^\text{10}\) Currently, it is the most commonly used anesthetic in all of dentistry. Lidocaine is indicated for almost any dental injection. When administered, anesthesia of pulpal tissue can last for about 85 minutes and soft tissues can last for 190 minutes in children.\(^\text{8}\) In the maxilla, it may be used as a local infiltration; however, the density of the mandible makes the local infiltration technique inadequate when working on mandibular posterior teeth.

Lidocaine has multiple formulations, but 2% lidocaine is the most common. The formulation may or not have epinephrine, which constricts blood vessels for hemostasis and delays anesthetic absorption for prolonged duration of anesthetic effect.\(^\text{8}\) The concentration of epinephrine may vary from 1:50,000 to 1:100,000 to 1:200,000. Care must be taken to not give epinephrine intravascularly to a patient with a cardiac condition as it might increase heart contraction and systolic blood pressure.\(^\text{8}\)

B. **Articaine**

Articaine is a local anesthetic that is also in the amide family. It first became available in Europe in 1976, but did not receive FDA approval in the United States until 2000.\(^\text{11}\) Like lidocaine, it has many possible formulations but the most common is the 4% concentration. Articaine has unique chemical properties among the amide anesthetics, leading to increasing popularity among US providers.\(^\text{9}\) The amide in articaine is derived from a thiophene instead of a benzene like other amides. This property makes this anesthetic lipophilic, which increases diffusibility into hard and soft tissues.\(^\text{6}\) When
administered, pulpal anesthesia lasts for about 60 minutes and soft tissue anesthesia lasts for about 190 min. The increased diffusibility of articaine increases the potency; therefore smaller volumes of anesthetic solution may be utilized. Furthermore, the solubility of articaine allows it to diffuse through the dense mandibular bone making local infiltration for anesthesia of mandibular molars possible. Another unique chemical structure that articaine has in comparison to other amides is the presence of an ester group. This ester group allows articaine to be metabolized into an inactive form by esterases in the blood. It has been shown that 4% articaine HCl has a potency that's 1.5x greater than 2% lidocaine in addition to toxicity that is 0.6x that of lidocaine.

C. Local Anesthesia Techniques

The gold standard for LA of mandibular molars is IANB with 2% lidocaine with 1:100,000 epinephrine. This technique completely anesthetizes the entire quadrant of the side where the anesthesia was administered. It requires specific needle placement in an area posterior to all of the teeth, which cannot be directly visualized. This method is technique sensitive with variable reported success rates (42% to 92%).

Pogrel et al., (2009) conducted a retrospective case series reviewing 16 case reports of needle breakage. They discovered that 15 of the needle breaks occurred during IANB, with 5 of those cases occurring in children younger than age 10. All cases required the patients to be placed under general anesthesia in order to retrieve the needle fragment. They concluded that risk of needle breakage is higher with IANB and even more so with younger uncooperative children.

The technique for an IANB involves placement of anesthesia at a nerve branch near the mandibular canal. Direct visualization of anesthesia deposit location is not
possible. Providers must use anatomical landmarks to guide needle placement and estimate depth of penetration. Complications with this technique include blood vessel perforation, hematoma, and nerve paresthesia. This technique is further complicated by a potentially uncooperative pediatric patient thereby increasing chances of complications associated with IANB.

In contrast to IANB, local infiltration involves administration of anesthesia in the immediate vicinity of the tooth thereby giving direct visualization. This technique is simpler than IANB and has been associated with less pain.\textsuperscript{10} Local infiltration is limited by the density of bone surrounding the terminal nerve endings of the tooth. This is especially problematic in the mandible. The mandible increases bone mineral density during development due to the increases in biomechanical loading.\textsuperscript{4} The chemical properties of articaine allow this agent to diffuse through the mandible to reach adequate anesthesia, which is generally not possible with other agents.

D. Indications for Use

Local anesthesia aims to temporarily inhibit pain during restorative care. It is the aim of the provider to administer LA in the safest and most effective manner. This is particularly important when working with the pediatric population because a child will often withdraw cooperation at first sign of discomfort. The gold standard for anesthetizing the mandibular molars is the IANB. Generally speaking, local infiltration is simpler and more comfortable than an IANB. Lidocaine does not have the ability to penetrate the thick dense mandible; therefore, even a properly administered local infiltration with lidocaine is inadequate. Articaine is a newer agent with special chemical properties allowing diffusion through the thick mandible that make local infiltration in the mandible possible. Literature
has shown that 4% articaine HCL infiltration is as effective as 2% lidocaine HCL IANB for anesthesia of irreversible pulpitis in the mandibular teeth\(^{12-14}\). Articaine was approved by the FDA in 2000 for both simple and complex procedures. A systematic review conducted by Su et al., (2016) looked at the use of articaine versus lidocaine for irreversible pulpitis treatment. They concluded that articaine was as good as or superior to lidocaine for anesthesia of mandibular molars in treatment of irreversible pulpitis in adults.\(^{15}\) There are no available studies that included subjects under the age of 18.

Controversy regarding use of articaine as an IANB remains, due to claims of increased paresthesia risks.\(^{16}\) These reports were found to have weak scientific evidence; other research has found articaine to be safely used in IANB and in any other LA administration.\(^{7}\) A literature review conducted by Yapp et al., (2011) evaluated the neurotoxicity potential of articaine compared to other commonly used anesthetics. They concluded that articaine does not have increased neurotoxicity and that it is safe for clinical use.\(^{7}\)

E. **Use in Children**

The 4% articaine HCL is an FDA approved drug that has documented safety for use in both children and adults. The manufacturer, Septodont, indicates that it can be used for children over the age of four years. Studies have documented success in using articaine with children under the age of four years; however, the literature was insufficient to include the younger age group in permitted use.\(^{17}\) Table 1 summarizes the findings of the available randomized clinical trials that compared articaine infiltration to lidocaine IANB when used for restorative dentistry in mandibular teeth. There have only been three such clinical trials.\(^{12–14}\) These publications included only adult subjects with an age range
of 18-49 and a mean age of 33.5. In all three trials, articaine performed comparable or superior to lidocaine. There is a need for literature that tests the efficacy of articaine in children in addition to their pain perception with articaine.

Table I: SUMMARY OF LITERATURE

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of Participants</th>
<th>Age Range in Years</th>
<th>Intervention Allocation</th>
<th>Anesthesia Assessment</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| Corbett et al., 2008 | 31                     | 20-30              | Each participant received both interventions | Electronic pulp testing | • Efficacy of 4% Articaine with for first molar pulp anesthesia was similar to that of an IANB using lidocaine over a 30-minute study period  
|                    |                        |                    |                         |                       | • Subjective tooth numbness was more common after IANB than buccal infiltration  
|                    |                        |                    |                         |                       | • The discomfort of buccal infiltration with Articaine was volume dependent  
| Monteiro et al., 2015 | 50                    | 18-49              | Random allocation into 2 groups: 30 for Articaine and 20 for Lidocaine | Success of intervention: emergency root therapy | • A higher success (P = 0.03) was observed with Articaine (40%) than with Lidocaine (10%)  
|                    |                        |                    |                         |                       | • No significant difference was found when a single injection plus one supplemental injection was compared between groups  
|                    |                        |                    |                         |                       | • Supplemental injection increased the anesthetic success rates within groups  
| Zain et al., 2016  | 156                    | 22-43              | Random allocation into 2 groups: 30 for Articaine and 20 for Lidocaine | Success of intervention: emergency root therapy | • The success rate of 4% buccal infiltration was 76.9%; whereas the success rate of 2% Lidocaine IANB was 62.8% with no statistically significant difference between the groups  
|                    |                        |                    |                         |                       | • 4% articaine buccal infiltration can be considered a viable alternative for successful pulpal anesthesia for endodontic therapy  |

F. Behavior Rating Scales for Pain Perception in Children

1. Modified Behavioral Pain Scale

The modified behavioral pain scale form (MBPS) is a validated form that was utilized to rate the facial and bodily movements of children receiving vaccination. Taddio et al., (2009) verified the accuracy of the form by comparing infant reactions to vaccinations using the MBPS forms and compared it to a validated visual analog scale. This was a double blind randomized clinical trial with 120 subjects. Inter and intra reliability tests were completed to verify accuracy of examiners. The study showed that the MBPS form was acceptable to use to measure pain in children undergoing invasive procedures.
2. **Wong-Baker FACES® Pain Rating Scale**

The Wong-Baker FACES Pain Rating Scale (PRS) is a form designed for children to self-report their pain experienced. It is a visual analog scale that contains six different facial expressions ranging from laughing to crying. Each facial expression had an associated number for statistical analysis. The visual analog scale was determined to be acceptable for use in small children since it does not involve verbal communication.\(^{18}\)

This scale was validated by Garra et al., (2010) and was found to be useful for indicating the perception of pain in children. Their study looked at children in acute pain in a hospital and compared how they rated their pain using the FACES PRS compared to another validated visual scale. They found no statistical differences concluding that the Wong-Baker FACES PRS was acceptable to use as an assessing perception of pain for children.

G. **Gap in the Current Literature**

A very limited number of studies have compared lidocaine IANB to articaine local infiltration for treatment of mandibular molars in adults. Currently, there are no available studies comparing the two LA agents with the two techniques for restorative care of mandibular first permanent molars in children. There is a need to provide evidence for safe and effective methods of anesthesia for pediatric patients in order to add to a clinician’s armamentarium.
PURPOSE AND OBJECTIVES OF THE STUDY

The purpose of the study was to compare the effectiveness and the subjective pain perception of local infiltration with 4 % articaine HCL with 1:100,000 epinephrine versus inferior alveolar nerve block with 2 % lidocaine HCL with 1:100,000 epinephrine used for restorative care of mandibular first permanent molars (FPM) in pediatric patients.

The objectives of the study included:

- To compare the effectiveness of articaine infiltration to lidocaine IANB for successful anesthesia of mandibular FPM during restorative care in children between the ages of 7 and 12.
- To compare the reported self-pain perception of children (in the 7-12 years age group) between the articaine infiltration and lidocaine IANB for anesthesia.
HYPOTHESIS OF THE STUDY

The null hypotheses are:

• There is no statistical difference in the effectiveness of articaine local infiltration and lidocaine IANB for successful anesthesia of mandibular FPM during restorative care in children between the ages of 7 and 12.

• There is no statistical difference in the self-pain perception between the articaine infiltration and lidocaine IANB for anesthesia
MATERIALS AND METHODS

A. Overview

Approval for this study was granted by the Institutional Review Board (IRB) of UIC in November 2018 (IRB approval of protocol # 2018-0943).

This study had a design of a prospective randomized controlled clinical trial. The participants were recruited from patients attending the Department of Pediatric Dentistry, College of Dentistry (COD), University of Illinois at Chicago (UIC) and were selected using inclusion and exclusion criteria. Parents signed informed consents for each participant. In addition, verbal assents were obtained from participants between the ages of 7 and 11, and written assent was obtained from all 12-year-old participants. One designated operator, an experienced pediatric dentist, administered the local anesthesia (LA) to all participants. A trained and calibrated examiner A (dental assistant) recorded the patient’s reactions during the LA administration using the Modified Behavioral Pain Scale (MBPS). A second investigator/ examiner B, a resident in pediatric dentistry, who was blinded to the type of LA agent administered, completed the planned dental treatment. Examiner B used a second MBPS form to evaluate the patient’s reactions during dental treatment. A total of 6 examiners A and 10 examiners B took part in the study. All examiners were trained and calibrated with regard to using the MBRS. Each participant wore a pulse and blood pressure monitor to record physiological reactions to both the LA and the dental procedure throughout treatment. At the end of the dental visit the pediatric patient was asked to rate their experience using the Wong-Baker FACES® Pain Response Scale. The data, in all its various forms, was transferred into Microsoft® Excel 2016 and the statistical analysis was carried out using IBM SPSS Statistics.
B. **Study Site, Participants and Enrollment Process**

1. **Study Site**

   The study site was the Department of Pediatric Dentistry, COD, UIC. This site was chosen because there was a sufficient number of patients available that met the inclusion and exclusion criteria.

2. **Operator**

   One designated and trained investigator/operator performed the administration of LA for all participants. The operator was an experienced pediatric dentist who closely followed a step-by-step procedure guide for each of the LA type and technique (Appendices L and M). The training included reviewing the step by step study procedure guides. The operator administered LA to a dose calculated according to participant’s weight and the maximum dose recommended by the manufacturers for each anesthetic was never exceeded.

3. **Examiners**

   Two types of examiners, examiner A and examiner B, recorded the patient’s reaction to the LA using MBPS forms (Appendices I and J). Examiner A was a trained and calibrated dental assistant who recorded the patient’s reaction during administration of the anesthesia. A total of 6 examiners A took part in the study. Although the dental assistants were not formally blinded to the type of LA used (they were able to observe the patient/participant and the operator during LA administration), they were not explicitly informed of it either.

   Examiner B was a pediatric dental resident who completed the restoration on mandibular FPM after the operator administered the anesthesia. Examiner B was blinded
to the type of LA used. A total of 10 examiners B participated in the study. Each examiner B recorded the patient’s reaction during restoration of the first permanent molar (FPM). All of the 16 examiners (both A and B) were trained and calibrated with regard to using the MBRS.

Training of all examiners was achieved via a teaching program that demonstrated how to fill out the MBPS forms and provided a visual example of how to evaluate participant’s reactions using the MBPS form. The calibration process included the following steps. Each examiner was asked to watch a video of a pediatric patient receiving dental treatment. The examiners rated the reactions of the patient in the video using the MBPS form. The scores of the MBPS forms were then statistically analyzed for inter-rater reliability. Each examiner then watched the same video again at a later date, after the original training was completed, and instructed to rate the patient’s reactions using the MBPS form. The scores of these second MBPS forms were statistically analyzed for intra-rater reliability.

4. **Study Subjects**

The study subjects were selected from the pool of patients of the Department of Pediatric Dentistry, COD, UIC. Pre-screening of patients was based on a review of the axiUm® electronic health record system to find patients with cooperative behavior that also had a treatment plan for restoration of mandibular FPM. Inclusion and exclusion criteria were specified for the purposes of this study (summarized in table 2). Forty subjects (20 per group) were enrolled in this study.
5. **Inclusion Criteria**

- **Age** - patients between the ages of 7-12 years old. These patients are typically in the mixed dentition or early permanent dentition phase of their dental development and developmentally the cortical mandible is considered still porous. The lower limit was set based on when usually first permanent molars erupt, which is around age 6-7. The upper limit was set at 12 to only allow pre-adolescent patients to participate.

- **Health status** – Included were patients who were healthy or have had only mild health conditions. Patients were categorized according to the health status classification of the American Society of Anesthesiology (ASA). The participants must have been categorized as ASA I (healthy) or ASA II (mild, well-controlled illness) to have been included in the study. Classification was based on parent-reported medical history questionnaires that were completed during the patient's initial examination and stored on the axiUm® electronic health record system.

- **Mandibular FPM requiring restoration** - Patients that had been treatment planned for restorative treatment on mandibular first permanent molars and required local anesthesia. Only restorations limited to intra-coronal restorations and full coronal coverage restoration (stainless steel crown) were included in the study.

- **Dental patient cooperation** - Patients with documented cooperative behavior that did not require advance behavioral management techniques such as oral sedation or general anesthesia. Each patient's behavior record was obtained from previous clinical notes in axiUm® electronic health record system. Only patients who had previously demonstrated Frankl scores of 3 (positive) or 4 (definitely positive)
behavior, as determined by dental provider at the time of exam, were included in the study. These patients were determined to exhibit appropriate behavior, which would limit the number of external factors in the study.

- English language - Parent/guardians and patients who did not need assistance understanding English were only included in the study. All study documents were in English. Proficient English literacy of parents/guardians and patients was required for valid consents and to ensure a thorough understanding of the study.

6. **Exclusion Criteria**

- Patients younger than 7 and older than 12. Children under the age of 7 were excluded from the study because they may not have developed fully erupted FPM. Children older than 12 were excluded because they are approaching developmental phase when the cortical layer of the mandible typically becomes denser and may limit the effect of the studied infiltration technique LA.

- Patients with significant medical history. Patients were considered to have significant medical history if they were categorized as ASA III (severe systemic disease that is not life threatening) or ASA IV (severe systemic disease that is a constant threat to life). Classification was based on parent-reported medical history questionnaires that were completed at patient's initial examination and stored on the axiUm® electronic health record system.

- Patients that had not been treatment planned for restoration on mandibular FPM. Additionally, patients that had been treatment planned for restoration on mandibular FPM but did not require local anesthesia were excluded.
• Patients that required endodontic therapy or extractions for mandibular FPM. Reaching sufficient anesthesia for endodontic therapy or extraction may require supplemental anesthesia; therefore, these patients were excluded.
• Patients with documented uncooperative behavior whose treatment would require advanced behavioral management techniques such as oral sedation. Each patient's behavior record was obtained from previous clinical notes located in the axiUm® electronic health record system. Patients who have previously demonstrated Frankl scores of a 1 (definitively negative) or a 2 (negative), as determined by the dental provider at the time of the exam, were excluded.

Parent/guardian and patient who needed assistance understanding English. All study documents were in English. Proficient English literacy of parents/guardians and patients was required to obtain valid consents and to ensure a thorough understanding of the study.

Table II: INCLUSION AND EXCLUSION CRITERIA

<table>
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<tr>
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<th>Inclusion Criteria</th>
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| Patient | • Age range 7 - 12 years old  
• Medically Fit (ASA* I or II)  
• Cooperative behavior (Frankl 3 or 4)  
• English literacy | • Younger than 7 or older than 12  
• Medically compromised (ASA* III or IV)  
• Uncooperative behavior (Frankl 1 or 2)  
• Poor English literacy |
| Tooth  | • Mandibular FPM require restorative therapy that is limited to resin composite or stainless-steel crown  
• Require local anesthesia | • Tooth other than mandibular FPM  
• Tooth requiring endodontic therapy or extraction  
• Does not require local anesthesia |
C. **Subject Enrollment**

Study subjects were selected from the patient pool at the Department of Pediatric Dentistry, COD, UIC. The primary investigator (PI) searched for patients on the post-graduate (PG) clinic daily schedule that were in the required age range and had a treatment plan that involved restoration of the mandibular FPM. The PI then accessed the electronic health-record (EHR) system at UIC (axiUm) to review past notes about the potential subject. The notes determined if the patient met the inclusion/exclusion criteria (table 2) specified for the study.

After identifying the qualifying patients, the PI created a list of potential patients and their associated EHR patient numbers. At the beginning of each qualifying patient’s dental appointment for restoration of FPM, the PI approached the patient and their parents/guardians. The PI gave a verbal description of the study to both patient and parent/guardian and distributed a patient information leaflet (PIL). The PIL described the study and provided detailed information about the two types of anesthesia used for the study. Clear explanations of advantages and disadvantages, risks and benefits, and the study participation process were also included in the PIL (Appendix B).

Prior the formal subject enrolment, the PI clinically examined the patient to verify that all aspects of the inclusion criteria were satisfied. After successful identification of a qualifying participant, consents were obtained. An informed consent (Appendix C) was obtained from the parent/guardian. Verbal assent (Appendix E) was obtained from patients aged 7 to 11 years old. Written assent was obtained from all 12-year-old patients (Appendix F). The time that was taken to enroll the participants did not contribute to exceed the planned time of the dental appointment. For example, if the dental
appointment was scheduled to be an hour long, the time taken to screen and enroll subjects in addition to completing the dental treatment was finalized within that hour.

Once all appropriate documents were signed, each participant was given a study number. A master list kept record of all study numbers and associated EHR patient numbers. The master list was updated throughout enrollment of subjects and shredded at end of subject enrollment.

If enrollment of a particular patient into the study was unsuccessful for whatever reason (for example patient not satisfying inclusion criteria or an inability to obtain proper consents), the patient continued with their scheduled dental appointment as originally planned.

There was no financial benefit to patients or to the clinic gained as a result of conducting the study. All dental fees and clinic reimbursements remained the same. None of the subjects received any compensation, financial or other incentives associated to participation in the study. The cost of the dental treatment plan was the same regardless of the patient's research enrollment.

D. Armamentarium

The armamentarium for administering LA consists of a syringe, anesthetic cartridge and a needle. The two types of anesthetic cartridges were 4 % articaine HCL with epinephrine 1:100,000 and 2 % lidocaine HCL with epinephrine 1:100,000. Specific manufacturer details are described below. These cartridges were selected based on their availability in the PG clinic, Pediatric Dentistry Department, COD, UIC. These brands were the commonly used once in the clinical setting. No manufacturer was chosen specifically for the study.
1. **Articaine**

Septodont® is the manufacturer of 4 % articaine HCL with epinephrine 1:100,000. The chemical structure of articaine contains an amide group and an ester group; therefore, it is metabolized by both the liver and esterases in the blood. According to Septodont®, articaine cannot be used in children under the age of 4 years because there is a lack of evidence supporting safety for use in children under 4 years of age. Per the manufacturer, the maximum dosage for articaine is 7.0 mg/kg and is not to exceed 500 mg. The onset of articaine is rapid and occurs within minutes, but duration ranges from 60 to 190 minutes.

**Table III: SEPTOCAINE® BY SEPTODONT®**

<table>
<thead>
<tr>
<th>Brand</th>
<th>Manufacturer</th>
<th>Company Logo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Septocaine® (Articaine HCL 4% with Epinephrine 1:100,000)</td>
<td><em>Septodont P.O. Box 68 Cambridge, Ontario Canada N1R 5S9</em></td>
<td><img src="image" alt="septodont logo" /></td>
</tr>
</tbody>
</table>

**Figure 1 Septocaine® cartridge**
2. **Lidocaine**

Novocol® is the manufacturer of 2% lidocaine HCL with Epinephrine 1:100,000. The chemical structure of lidocaine contains an amide group and does not contain an ester group. Therefore, it is only metabolized in the liver. The manufacturer claims that the anesthesia can be safely administered to all children and adults, regardless of age. Per the manufacturer, the maximum dosage of lidocaine is 4.4 mg/kg and is not to exceed 300 mg. The onset of lidocaine is rapid and occurs within minutes, but duration ranges from 60 to 190 minutes.

<table>
<thead>
<tr>
<th>Brand</th>
<th>Manufacturer</th>
<th>Company Logo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Henry Schein®</strong></td>
<td>Novocol Pharmaceutical of Canada, Inc</td>
<td></td>
</tr>
<tr>
<td>Lidocaine HCL 2%</td>
<td>25 Wolseley Court, Cambridge, ON N1R6X3, Canada</td>
<td></td>
</tr>
<tr>
<td>Epinephrine 1:100,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table IV: LIDOCAINE HCL 2% EPINEPHRINE 1:100,000 by NOVOCOL®**

**Figure 2: Henry Schein® Lidocaine HCL 2% Epinephrine 1:100,000 cartridge**
3. **Regulatory Compliance**

Both 4% articaine HCL with epinephrine 1:100,000 and 2% lidocaine HCL with epinephrine 1:100,000 are FDA approved and have been successfully documented as effective and safe for children and adults. Both comply with U.S. and international regulations for product safety. The following regulatory information is listed on the material and safety data sheets for each product:

- **Septocaine® (articaine HCL 4% with epinephrine 1:100,000)**
  - Occupational Safety and Hazard Association (OSHA) regulatory status: epinephrine bitartrate is not listed as a hazardous product in the Resource Conservation and Recovery Act (RCRA) and Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) regulations.
  - Regulatory status: This product is exempt from current Workplace Hazardous Material Information System (WHMIS) legislation as a drug product.
  - FDA approval: approved in 2005 for infiltration or nerve block anesthesia in dentistry.

- **Lidocaine hydrochloride 2% with epinephrine 1:100,000**
  - OSHA regulatory status: Epinephrine bitartrate is not listed as a hazardous product in the RCRA and CERCLA regulations.
  - Regulatory status: This product is exempt from current WHMIS legislation as a drug product.
o FDA approval: approved in 1980 for infiltration or nerve block anesthesia in dentistry.

4. Needles

The type of needle used for the participants receiving infiltration LA with articaine in this study was a 30-gauge short needle. The specific dimensions of the short needles were 0.3112 mm in diameter and 20 mm in length. The type of needle used for the participants receiving the inferior alveolar nerve block was 27-gauge long needle. The specific dimensions of the long needles were 0.4126 mm in diameter and 32 mm in length. The manufacturer for the needles used in this study was Henry Schein®, because these were the needles available in the clinic. The needles were disposable; therefore, only one sterile needle was used per patient.

Figure 3: Henry Schein® 30 gauge short needle

The type of needle used for the participants receiving local infiltration with articaine in this study was a 30-gauge long needle. The specific dimensions of the needles were...
0.3112 mm in diameter and 20 mm in length. The manufacturer for the needles used in this study was Henry Schein®, because these were the needles available in the clinic. The needles were disposable; therefore, only one sterile needle was used per patient.

**Figure 4 Henry Schein® 27 gauge long needle**

The type of needle used for the participants receiving inferior alveolar nerve block with lidocaine in this study was a 27-gauge long needle. The specific dimensions of the needles were 0.4126 mm in diameter and 32 mm in length. The manufacturer for the needles used in this study was Henry Schein®, because these were the needles available in the clinic. The needles were disposable; therefore, only one sterile needle was used per patient.

5. **Syringe**

The syringe used for delivery of LA was a standard stainless-steel dental syringe. Prior to administration of LA, each syringe was sterilized in an autoclave.
machine. The anesthetic cartridge was placed in the center chamber of the syringe and the needle attached to the hub of the syringe. The plunger of the syringe would push the anesthesia out of the cartridge and through the needle.

**Figure 5: Dental syringe**

![Dental syringe](image)

**E. Injection Technique**

The specific details for the injection technique used for both inferior alveolar nerve block (IANB) and local infiltration are outlined in the step-by-step guide outlined in Appendices L and M. The textbook “*Dentistry for the Child and Adolescent*” by McDonald and Avery was used to develop the step-by-step guide.

**F. Initial Data Capture**

All study participants were evaluated, based on prior visits, to ensure they demonstrated the required behavior and cooperation levels. The Frankl behavioral rating scale (Frankl *et al.*, 1962) is the conventional behavior rating scale used for pediatric patients in the United States.¹⁹ At each visit, patients of the Pediatric Dental Clinics, COD, UIC are typically rated according to this scale and the rating is recorded in the day note located in their electronic health record. The Frankl Behavioral Rating Scale consists of
behaviors that are assigned to numerical values, such as: F1=Definitely negative; F2=Negative; F3=Positive; and F4=Definitely positive.19

All study participants’ relevant information was documented on an initial data capture form (IDC) (Appendix G) completed by the operator administering the LA. The form recorded the electronic health record number; patient’s ethnicity, age, and weight (for appropriate dosing). The amount and type of anesthesia used were also recorded in the IDC. This data was recorded to ensure the proper retention of pertinent information for each patient/participant.

G. Randomization Process

A random digit table method was used to allocate patients into either the articaine group or the lidocaine group. The study enrolled 40 participants in total; therefore, 20 were assigned to the articaine group and 20 were assigned to the lidocaine group. The random digit table generated 40 random numbers (equal odd and even numbers) in a random order. In the order of enrolment, each participant received a study number from the random digit table matching their order. An odd number placed the participant in the articaine group, and an even number placed the participant in the lidocaine group.

H. Clinical Outcome Data

Objective (observable behavior, physiological signs) and subjective (self-reported) methods were used in this study in order to evaluate participants’ reactions considered indicative for experiencing pain. Three rating systems were utilized: the Modified Behavioral Pain Scale (MBPS), the Wong-Baker FACES® Pain Rating Scale (PRS), and monitoring physiological responses (blood pressure and pulse).
1. **Participants’ Reaction to Injection (LA Administration)**

The MBPS is a validated scale that has been used in previous studies to rate the facial and body movements of pediatric patients during administration of vaccinations. Due to the similarities between the injection of vaccinations and local anesthesia, this form was adapted for this study. The MBPS form rates the behavior of the patient on three categories: facial expression, cry and body movement. Each category has a numerical score, which is then totaled to create an overall rating of the patient's pain during administration of the LA. A higher total score indicates that a higher level of pain was observed. Examiner A (the dental assistant) was trained and calibrated to use this form in order to rate the patient’s reaction to pain (MBPS #A). Examiner A was not formally blinded (since able to observe the participant and the operator at time of LA administration) however was not explicitly told which type LA was used. Examiner A completed the MBPS #A form accordingly.

2. **Participants’ Reaction to Dental Treatment**

Examiner B (pediatric dentistry resident) used an identical form to the form used by examiner A (MBPS #B) to record the patient's observable pain reaction during the actual dental treatment. Examiner B was blinded to the type of local anesthesia that had been randomly assigned. Since examiner B was a dental provider who could have personal preference towards certain type of LA, the blinding was very important to reduce the potential of opinion bias. After the operator completed the LA administration and verified that adequate anesthesia had been given, examiner B stepped in and completed the planned dental treatment. Examiner B completed the MBPS #B form at the end of the dental treatment. Each subcategory of the MBPS form was given a numerical score.
The scores were totaled to create an overall rating of the pain the patient experienced during dental treatment. A higher total score indicates that examiner B observed a higher level of pain in the patient.

3. **Basic Signs Recording**

Pulse and blood pressure were monitored throughout the appointment by Dre® monitors. These monitors are used by the clinic during moderate sedations; therefore, they are checked and calibrated regularly, thus validating their accuracy with measurement. The monitors were set to automatically record every 10 minutes during the participant’s entire dental visit. Three monitor units (both for blood pressure and pulse) were used for this study and were all calibrated by a medical device technician. The initial recordings were all at rest and used as a baseline measurement. All readings were transferred into the Basic Signs Form (Appendix H) by the PI. The readings recorded from both the lidocaine and the articaine groups were compared to one another. The baseline readings were used as a norm and were also checked that matched the normal range pulse and blood pressure values per age, based on the AAPD manual. Increased blood pressure or an elevated pulse typically indicate that the patient is experiencing increased level of stress. The increased level of stress was interpreted as an increased experience of pain, thus providing the PI with an potential objective sign of pain.

4. **Self-Reported Perception of Pain**

At the end of the visit, the Wong-Baker FACES® Pain Rating Scale (PRS) (Appendix K) was completed by the patient/participant to obtain the self-reported perception of pain. The PRS consists of a visual analog scale, which allows the patient to provide a personal subjective evaluation of the pain he or she experienced throughout
the dental appointment. The PRS visual scale contained different facial expressions that depicted different emotions, ranging from smiles, to neutral and to tears. The facial expressions represent a visual expression of pain and is therefore suitable for children to self-identity how they felt throughout the procedure.

I. **Flow Chart of the Study Process**

![Flow Chart of the Study Process](image)

J. **Criteria for Clinical Success**

The overall determinants for clinical success include:

- Successful completion of the planned restorative care without interruption or need for supplemental LA administration;
- Participants exhibiting cooperative behavior (Frankl 3 or 4) for the entire duration of the treatment;
- A lack of clinical complications such as medical/dental emergencies;
If any of these criteria were not satisfied, the case was considered a “failure” of LA for the purposes of this study and was not included for statistical analysis.

K. **Statistical Analysis**

The data collected throughout all study forms was compiled and organized on a Microsoft Excel Spreadsheet 2016. Statistical analysis was completed using the IBM SPSS statistical software program.

A prospective power analysis was carried out using numeric results for the Two-Sample T-Test, which allowed for an unequal variance. According to the power calculation, group sample sizes of 20 for both the articaine and lidocaine groups achieved 78% power to reject the first null hypothesis of equal means. The power would have been 98% if 40 participants were recruited into each group. Due to logistical limitations (the duration of the residency program, clinic schedule), a sample size of 40 total subjects was selected.

L. **Data Analysis**

Demographic information was described using univariate descriptive statistics including frequency, mean, median and standard deviation. Bivariate statistics including independent t-test and Mann Whitney-U were used to analyze pain rating scores (the MPBS #A and MBPS #B forms) and visual analog scores (FACES® PRS). A p-value of <0.05 was used to determine statistical significance for the Mann Whitney-U and t-tests. Objective clinical values such as blood pressure and pulse were analyzed using Repeated Measures ANOVA. Pillai’s Trace was used to determine significance for the multivariate test.
RESULTS

A. **Study Sample**

A total of 40 patients were recruited in the study. These 40 patients were randomly assigned to either the lidocaine group or the articaine group. The 20 subjects in the lidocaine group were administered 2% lidocaine HCL with 1:100,000 epinephrine via IANB. The 20 subjects in the articaine group were administered 4% articaine HCL with 1:100,000 epinephrine via local infiltration. Neither group had any post-operative complications. No supplemental anesthesia was required for any of the subjects. None of the cases were considered failures; hence, all subjects were included for the statistical analysis.

B. **Demographic Characteristics of Study Sample**

The demographics of all 40 subjects are summarized in table 3. The average age of the recruited subjects was 9.28 years with a standard deviation of 1.63. Of the 40 subjects, 21 were male, and 19 were female.

The racial and ethnic distribution of the subjects included 52.5% Hispanic (N=21), 17.5% African American (N=7), 15% White/ Caucasian (N=6), and 15% other (N=6). In the lidocaine group there were 9 males and 11 females. The racial and ethnic distribution of the lidocaine group included 22.5% Hispanic (N=9), 10% African American (N=4), 12.5% White/ Caucasian (N=5), and 5% other (N=2).

In the articaine group there were 12 males and 8 females. The racial distribution of the articaine group included 30% Hispanic (N=12), 7.5% African American (N=3), 2.5% White/ Caucasian (N=1), and 10% other (N=4).
Table V: DEMOGRAPHICS OF SUBJECTS

<table>
<thead>
<tr>
<th></th>
<th>Lidocaine N = 20</th>
<th>Articaine N = 20</th>
<th>Total N = 40</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (mean)</strong></td>
<td>8.20 ± 1.74</td>
<td>9.35 ± 1.69</td>
<td>9.28 ± 1.63</td>
</tr>
<tr>
<td><strong>Gender (count)</strong></td>
<td>Males = 9 Females = 11</td>
<td>Males = 12 Females = 8</td>
<td>Males = 21 Females = 19</td>
</tr>
<tr>
<td><strong>Race (count)</strong></td>
<td>Hispanic = 9 African American = 4 Caucasian = 5 Other = 2</td>
<td>Hispanic = 12 African American = 3 Caucasian = 1 Other = 4</td>
<td>Hispanic = 21 African American = 7 Caucasian = 6 Other = 6</td>
</tr>
</tbody>
</table>

C. Types of Restorative Treatment

The types of restorations completed for each group are summarized in table 4. Both intra-coronal restorations (resin composites and amalgam) and full crown coverage (stainless steel crowns) were used during this study. Mandibular FPM’s that required endo therapy or extractions were excluded from this study. In the lidocaine group, 14 resin composites and 6 stainless steel crowns were completed. In the articaine group, 15 resin composites and 5 stainless steel crowns were completed. No amalgam restorations were planned for either group.
### Table VI: TYPES OF RESTORATIONS FOR EACH GROUP

<table>
<thead>
<tr>
<th></th>
<th>Lidocaine Group</th>
<th>Articaine Group</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Resin Composite</strong></td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>(count)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Stainless Steel Crown</strong></td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>(count)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### D. Pain Rating Scales

The results of the pain rating scales are summarized in table 5. The pain rating scales were completed based on: the evaluations/ scores of observable behavior by examiners A (MBPS #A), the evaluations/ scores of observable behavior by examiners B (MBPS #B) and the self-evaluations/ scores by subjects post-treatment (Wong-Baker Faces).

The MBPS form consisted of three subcategories (facial expression, cry, and body movements). Each subcategory had a score that ranged from 1-4 with descriptions of each score. The lower the score, the less pain observed. The MBPS #A were completed by the examiners A (dental assistants) during LA administration. The median facial expression score was 3 for the lidocaine group and 2 for the articaine group. The median cry score was 3 for the lidocaine group and 2 for the articaine group. The median body movement score was 2 for the lidocaine group and 1 for the articaine group.

The MBPS #B forms were completed by the examiners B (dental residents) who did the restorative care. The median facial expression score was 2 for the lidocaine group and 2 for the articaine group. The median cry score was 2 for the lidocaine group and 2 for...
the articaine group. The median body movement score was 2 for the lidocaine group and 1 for the articaine group.

The data was analyzed by both Mann-Whitney U and an independent samples t-test. Both tests showed statistical significance (p<0.05) for all MBPS sub-categories and for the totaled MBPS scores (P=0.00 for total MBPS #A form; P=0.001 for total MBPS #B form). A summary of all p values is presented in table 5.

With regard to the Wong- Baker FACES PRS, the median score for the lidocaine group was double the median score for the articaine group (4 versus 2). The data was analyzed using an independent samples t test and shown to be statistically significant (p=0.011, p<0.05). The results obtained from the Wong-Baker FACES visual analog scale are also summarized in table 5.

Table VII: SUBJECTIVE PAIN SCORES

<table>
<thead>
<tr>
<th>Pain Scale</th>
<th>Type of Anesthetic</th>
<th>Median Score</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total MBPS #A</td>
<td>Lidocaine</td>
<td>8</td>
<td>P = 0.000</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Total MBPS #B</td>
<td>Lidocaine</td>
<td>6</td>
<td>P = 0.001</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Wong Baker FACES PRS</td>
<td>Lidocaine</td>
<td>4</td>
<td>P = 0.011</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>
E. **Blood Pressure and Pulse**

The subject's blood pressure and pulse were recorded every 10 minutes. The first measurement was at rest and used as a baseline. The second measurement was recorded during administration of the LA, and the third and fourth measurements were recorded during treatment. All treatment procedures were completed within 40 minutes. However, for those participants that had their restorations finished in 30 minutes only 3 measurements were obtained, while those that took slightly longer had 4 measurements recorded. Multivariate repeated measures ANOVA test was used to compare the blood pressure and pulse between the lidocaine and the articaine groups. Additionally, values measured were compared to normal values of a child of the same age to assure that no participant had any abnormal readings. Pilai’s test was used to compare the change in blood pressure and pulse over time for both the lidocaine and articaine group.

The systolic (p=0.941) and diastolic blood pressure (p=0.443) was not statistically significant in difference (p>0.05) between the lidocaine and the articaine group. Furthermore, the pulse measurements (p=0.615) were also found not statistically significant in difference (p>0.05) between the two groups. For both groups blood pressure was not statistically significant in difference when compared to baseline/normal values. However, both groups demonstrated a slightly increased pulse rates at baseline when compared to normal values of children of the same age group. Furthermore, Pilai’s test indicated that p=0.826, suggesting that there was no statistically significant difference in blood pressure or pulse over time between the lidocaine and the articaine groups (p>0.05). The results of the blood pressure and pulse monitoring are summarized in table 6.
Table VIII: PHYSIOLOGIC MEASURES

<table>
<thead>
<tr>
<th></th>
<th>Type of anesthetic</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>P -value (between groups)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Systolic BP</strong></td>
<td>Lidocaine</td>
<td>100.65</td>
<td>9.799</td>
<td>p = 0.941</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>105.90</td>
<td>10.052</td>
<td></td>
</tr>
<tr>
<td><strong>Diastolic BP</strong></td>
<td>Lidocaine</td>
<td>62.85</td>
<td>11.435</td>
<td>p = 0.443</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>64.05</td>
<td>9.047</td>
<td></td>
</tr>
<tr>
<td><strong>Pulse</strong></td>
<td>Lidocaine</td>
<td>89.50</td>
<td>14.734</td>
<td>p = 0.826</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>86.25</td>
<td>13.856</td>
<td></td>
</tr>
</tbody>
</table>

**F. Examiner Calibration**

The examiners / observers were trained and calibrated to fill out the MBPS forms. Intra and inter-examiner agreement analyses were run. The values were very close indicating excellent agreement; however, the results cannot be formally reported due to the small variation of the numerical categories (from 1 to 4).

There is a well-established difficulty of obtaining meaningful summary statistics indicating reliability in data with a restricted range, therefore a reliability analysis cannot be reported formally.
DISCUSSION

A. **Infiltration vs. IANB**

The 2% lidocaine with 1:100,000 epinephrine administered via inferior alveolar nerve block is considered the gold standard for LA used during restoration of mandibular FPM. Therefore, the lidocaine IANB served as the control group. In each subcategory of both MBPS forms, the median pain score reported for the articaine group was as good as, or better than, the lidocaine group’s median pain score. In addition, neither groups had any failures or post-operative complications.

In the totaled MBPS #A scale, the articaine group’s pain score was lower than the lidocaine group’s pain score. This finding was statistically significant (p=0.00, p<0.05). The MBPS #A form was completed by the examiner A (dental assistant) during administration of LA. Therefore, this study suggests that an observer detected less pain during LA administration when local anesthesia was administered via local infiltration with 4% articaine w/ 1:100,000 epinephrine. In the totaled MBPS #B scale, the articaine group’s pain score was again lower than the lidocaine group’s pain score. This finding was statistically significant (p=0.001, p<0.01). The MBPS #B form was completed by the examiner B (dental resident) after restoration of anesthetized mandibular FPM was completed. Therefore, this study suggests that an observer also detected less pain during treatment when anesthesia was admitted with 4% articaine w/ 1:100,000 epinephrine.

At the end of the procedure, the patient was asked to complete the Wong-Baker FACES pain rating scale (PRS) in order to document the subject’s self-perception of pain. The median pain scale score reported by the articaine group was half that of the lidocaine group (2 versus 4). This finding was statistically significant (p=0.011, P<0.05). The study
suggests that subjects perceived less pain when local anesthesia was performed via local infiltration with 4% articaine w/ 1:100,000 epinephrine. There was no difference between the two groups in regards to physiologic findings (BP/pulse), showing that IANB and infiltration have equivalent physiologic responses. Although pain can occur without changes in BP/pulse, the lack of physiologic changes does not indicate other results to be unreliable.

B. **Clinical Relevance**

The results of the study suggest that using articaine infiltration as opposed to lidocaine IANB can lead to increased comfort for the subject. Infiltration is a simpler technique compared to IANB. Local infiltration directly administers local anesthesia in the tissue immediately surrounding the tooth. IANB requires deeper needle penetration in a more posterior location than infiltration. IANB block is also technique sensitive, a prospect which can be further complicated if the administering dentist has difficulty seeing the penetration site, which is common for pre-adolescent children given their smaller size. These complications become increasingly difficult when paired with the fact that younger patients are also more likely to cooperate poorly by thrashing and moving around.

Furthermore, IANB anesthetizes all of the posterior mandibular teeth in addition to the ipsilateral side of the tongue because the lingual nerve is also anesthetized. This excess numbing may be overwhelming and upsetting for a pediatric patient. By contrast, local infiltration only anesthetizes the tooth of interest and the soft tissue immediately surrounding the tissue, reducing this risk of upsetting the patient. In some cases, there may be desire to localize the area that get anesthetized in order to minimize the area of numbing sensation.
Anesthesia techniques are particularly relevant when working with pediatric patients. Depending on the cooperation level of the patient, an easier injection may be more appropriate than a complete block. This study offers evidence that articaine local infiltration may be the easier injection technique for FPM restoration in children because it causes less discomfort in the patient while sufficiently accomplishing the same task as a more difficult injection technique, such as an IANB.

C. **Articaine Limitations**

The aim of this study was to determine if a local infiltration with articaine is a suitable alternative to IANB with lidocaine for the restorative care of mandibular FPM. This study is not meant to replace IANB with lidocaine as the gold standard for treatment of mandibular molars. Clinicians may find local infiltration to be more appropriate in certain cases than a nerve block. Articaine should be well understood to make it a more useful tool in a clinician’s armamentarium. Although articaine has advantages over lidocaine, there are some limitations that may make a lidocaine IANB a better option.

Patients may have multiple teeth in the lower quadrant that require restoration. In this situation an articaine local infiltration would require many insertions of the needle in order to administer adequate anesthesia. An IANB with lidocaine can provide anesthesia to all the teeth in the quadrant with one injection. Therefore, IANB may be the preferable choice.

Additionally, the concentration of articaine is 4%, as opposed to the 2% that is present in lidocaine. This means that articaine has a lower total volume in maximum dose, which may be a limiting factor depending on the extent of treatment indicated.
Also, administering articaine as local infiltration may not be the best option for invasive procedures, such as extractions. Extraction of a tooth involves manipulation of all tissues including tooth, gingiva and bone. Local infiltration with articaine may not be sufficient for adequate anesthesia of all tissues involved in an extraction.

Furthermore, age is an important consideration when choosing between lidocaine IANB and articaine infiltration for local anesthesia. According to the manufacturer, articaine should not be administered to patients below the age of 4 years. Additionally, FDA approval and AAPD guidelines advise against using articaine in children under the age of 4 years. Although there are clinical trials that document the safe use of articaine in children under 4 years old, the data available is insufficient to safely recommend articaine for this age group.

D. Pain Rating Scales

Validated pain rating scales were used in this study including the Modified Behavior Pain Scale (MBPS) and Wong-Baker FACES® PRS. The MBPS were completed by observers and the Wong-Baker FACES® PRS was completed by subjects, who reported their own perceptions of pain. The examiners / observers were trained and calibrated to fill out the MBPS forms. Intra and inter-examiner agreement analysis were run. The values were very close indicating excellent agreement, however the results cannot be formally reported due to the small variation of the numerical categories (from 1 to 4). Statistically, there is a well-established difficulty of obtaining meaningful summary indicating reliability in data with a restricted range, therefore a reliability analysis was not reported formally.
The FACES scale was an appropriate scale to gauge the patient's perception of pain because the scale provides visual depictions of pain. Children were able to easily understand the directions regarding circling the image that corresponds with their perception of pain. However, it should be noted that although the children were able to understand the directions, children are not always reliable reporters. The pain scale reported by the child did not always match the behavior observed by the examiners. Children may rate experiences according to what they think will please the authority figure or parental figure standing nearby. Therefore, the pain level they report may be lower than the pain level they are actually experiencing. For example, one child in the lidocaine group was visibly uncomfortable. The child was grimacing and quietly groaning during administration of anesthesia and during treatment. However, the child rated the experience as “no hurt”. Alternatively, children may also seek attention from authority figures by selecting a pain level that is greater than the actual pain they are experiencing. Children may also overrate their pain because of the inability of local anesthesia to take away the sensation of pressure. Children may perceive that pressure as pain because it feels unfamiliar and out of hyperawareness. For example, one child in the articaine group did not move during administration of anesthesia or during treatment. However, the child rated the experience as “hurts worst”. These potential complications aside, the FACES scale was the best way to capture the patients' perception of pain. The limitations of the child’s ability to accurately rate the pain was offset through use of the MBPS forms, along with the blood pressure and pulse monitors, which helped more accurately capture the pain the child was experiencing. Regardless of the issues of FACES scale, the median
PRS rated by the child in the articaine group was half the PRS rated by the child in the lidocaine group (2 vs 4).

E. Study Strengths

Previous studies have only investigated the use of 4% articaine local infiltration versus 2% lidocaine IANB for restorations of mandibular permanent molars in adults. No study has investigated the use of articaine in the pediatric population that is in the mixed or early permanent dentition stage. This study was designed as a randomized controlled clinical trial to evaluate treatment efficacy. The lidocaine group served as the control variable to compare the effectiveness of articaine as a local anesthesia. The anesthesia was randomly assigned to the patients. A randomized control study is the best way to evaluate effectiveness.

Another strength of this study is that one operator administered the local anesthesia to every participant that was recruited for the study. The operator was an experienced pediatric dentist who followed a step-by-step guide to minimize variability in local anesthesia administration. Allowing multiple providers to administer local anesthesia would have introduced additional confounding factors. Restricting the administration to one operator reduces this risk.

Observers could always introduce opinion bias, but all efforts were made in the study design to reduce the risk of subjective preference.

The participant’s observable behavior during entire dental visit was evaluated by two type of examiners. While examiner A did not have an explicit knowledge of the type LA, he/she was able to see the operator during LA administration. However, the dental assistants who took part in this study do not administer LA and are unlikely to have own
preference to a particular type of LA agent. Hence, it is less likely that the examiners B has an opinion bias towards articaine or lidocaine, while completing the evaluation forms.

On the other hand, it was much more important to blind the examiner B for the type of LA used. The pediatric dental residents of the COD, UIC would have had sufficient experience with both LA agents at the time of study conduction in order to develop personal preferences, therefore by introducing the study blinding the risk of opinion bias was reduced.

In order to accurately evaluate the pain experienced by the subjects, multiple methods of evaluation were utilized to minimize biases and strengthen the results of the study. Two types trained and calibrated observers, one type also blinded to the anesthesia being used in each instance, separately evaluated the pain utilizing validated rating scale and specifically designed evaluation forms. The subjective evaluation was captured by having the participants/patients fill out the FACES PRS, where they rated their own pain level. Additionally, blood pressure and pulse monitors were worn by the patient throughout the duration of the appointment, providing an objective measurement of pain. The combination of these various measurements led to more accurate assessment of each patient’s pain.

The sample size chosen for the study (N=40) showed that it had achieved a sufficient power since statistically significant differences between groups were established. The study design included 20 subjects assigned to the lidocaine group and 20 subjects assigned to the articaine group.
F. **Study Limitations**

While the sample size was adequate for the purposes of this study, future trials may enroll larger groups of participants to continue the evaluation on a bigger scale.

The use of a single clinic setting could be considered a study limitation. All subjects were recruited from the Department of Pediatric Dentistry, COD, UIC. Many patients seen at this clinic were referred due to poor cooperation or due to difficulty finding another clinic that accepts their insurance. Furthermore, patients often are previously seen by an outside provider who was unable to perform the treatment due to an inability to manage behavior. These patients have had a baseline anxiety with dentists due to an unsuccessful experience. Although the patients were cooperative (Frankl 3 or 4), they may have had underlying anxiety due to an anticipation of pain occurring. Additionally, the clinic at UIC has an open bay setting design. The treatment interventions as part of this study were not done in separate rooms but rather in dental cubicals. Participants may have had heightened anxiety and increased anticipation of pain due to surrounding patients who had more severe dental anxiety and cried throughout their appointments. Increased anxiety and increased anticipation of pain may alter the patient's perception of pain. To exclude this behavior bias, the study should have had treatments done in quiet rooms with participants who did not have a previous poor dental experience. However, due to logistics this was not possible to accommodate.

Another limitation to the study was the number of examiners utilized in the study. There was a total of 6 examiner A’s and 10 examiner B’s. Although all examiners were trained and calibrated, there remains chances of different examiners having different ratings of pain. Utilization of multiple examiners was due to constraints involving function
of clinic. The dental assistants (examiner A) rotate providers they work with thereby making having only one examiner A unreasonable. There was also a restraint of acquiring subjects for the study. For time efficiency of collecting data, multiple providers (examiner B) were utilized. Different providers have different non-pharmalogical behavior management techniques. Varying behavior management techniques adds a layer of confounding variables that serve as a limitation to the study.

G. Future Studies

This study only included the mandibular FPM of patients between the ages of 7 and 12. Future studies could further investigate the use of articaine local infiltration on teenagers, shedding light on whether articaine is effective for patients in later stages of development. As the child continues to grow and develop, the density of the mandible increases. This study design could be utilized at various age groups to allow insight into the effectiveness of articaine in different stages of development of the mandible and its bone density.

An inclusion criterion for this study required that all restorations be limited to intra-coronal restorations and full coverage crowns. Future studies could focus on the effectiveness of articaine local infiltration for more invasive procedures, such as endodontic therapy (i.e. direct pulp cap, pulpotomies, etc.) or extractions. These future studies would have clinical relevance because they would expand the dental field's knowledge about the effectiveness of articaine infiltration in a wider variety of cases.
CONCLUSIONS

This study determined that:

- Articaine local infiltration achieved as effective anesthesia as lidocaine IANB for restorative care of mandibular first permanent molars in children between the ages of 7-12 years old.
- There was less observable pain related behavior during LA administration and dental treatment when anesthesia was given with articaine local infiltration than it was for lidocaine IANB.
- There was less self-reported pain perception for the entire dental visit when anesthesia was given with articaine local infiltration than it was for lidocaine IANB.
- Articaine local infiltration is a suitable alternative to lidocaine IANB for restorative care in mandibular FPM in patients 7 to 12 years of age.
- The Null hypotheses of the study were rejected.
APPENDICES

APPENDIX A

Approval Notice
Initial Review (Response To Modifications)

November 16, 2018

Angelo Arce
Pediatric Dentistry

RE: Protocol # 2018-0943
"Randomized Controlled Clinical Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine for Restorative Care of First Permanent Molars in Pediatric Patients"

Dear Dr. Arce:

Your Initial Review (Response To Modifications) was reviewed and approved by the Expedited review process on November 16, 2018. You may now begin your research

Please note the following information about your approved research protocol:

Matthew Strumpf was not added as key research personnel, since there is no record of CITI IPS HIPAA training for him. He cannot participate in the study in any capacity until he has completed CITI IPS training, at which point he can be added to key research personnel in a separate amendment.

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<td>Additional Determinations for Research Involving Minors:</td>
<td>The Board determined that this research satisfies 45CFR46.405 and 21CFR50.52, research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects. Therefore, in accordance with 45CFR46.408 and 21CFR50.55, the IRB determined that only one parent's/legal guardian's permission/signature is needed. Wards of the State may not be enrolled unless the IRB grants specific approval and assures inclusion of additional protections in the research required under 45CFR46.409 and 21CFR50.56. If you wish to enroll Wards of the State contact OPRS and refer to the tip sheet.</td>
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APPENDIX A (continued)

Version 2, 09/19/2018

Recruitment Material:
   a) Patient Information Leaflet, Version 1, 07/19/2018

Informed Consent:
   a) Waiver of informed consent granted [45 CFR 46.116(d)] for the identification of potential subjects in the recruitment phase of the research.

Assents:
   a) Verbal Assent for children 7 to 11 years of age, Version 5; 11/6/2018
   b) Written Assent for children 12 years of age, Version 4; 11/1/2018

Parental Permissions:
   a) Parental Permission, Version 4, 11/1/2018

HIPAA Authorizations:
   a) HIPAA Authorization Version 1, 09/19/2018
   b) Review Preparatory to Research acknowledged [45 CFR 164.512(i)(1)(ii)]

Please note the Review History of this submission:

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Please remember to:

→ Use your research protocol number (2018-0943) on any documents or correspondence with the IRB concerning your research protocol.


Please note that the UIC IRB has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.
APPENDIX A (continued)

Please be aware that if the scope of work in the grant/project changes, the protocol must be amended and approved by the UIC IRB before the initiation of the change.

We wish you the best as you conduct your research. If you have any questions or need further help, please contact OPRS at (312) 996-1711 or me at (312) 413-2053. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,

Laura Litman, BA, CIP
IRB Coordinator, IRB # 3
Office for the Protection of Research Subjects

Uploaded Documents:
1. Assent Documents:
   a) Verbal Assent for children 7 to 11 years of age, Version 5; 11/6/2018
   b) Written Assent for children 12 years of age, Version 4; 11/1/2018
2. Parental Permission:
   a) Parental Permission, Version 4, 11/1/2018
3. Recruiting Material:
   a) Patient Information Leaflet, Version 1, 07/19/2018

cc: Marcio Da. Fonseca, Pediatric Dentistry, M/C 850
    Evelina Kratunova, Faculty Sponsor, M/C 850
APPENDIX B

Patient Information Leaflet

Research Project

Randomized Controlled Clinical Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine for Restorative Care of First Permanent Molars in Pediatric Patients

Introduction:

Your child requires dental treatment on his/her back teeth (molars). In order to fix the teeth, a medicine called local anesthetics is given to numb the teeth. Local anesthetic is an important part of dentistry because without it dental treatment would be very uncomfortable and painful. In order for local anesthetic to work, it needs to be given near the nerves of the teeth. Since the nerves are located under the gums and bone the only way this can be done is by giving an injection.

In this research project, we are evaluating two different methods of numbing teeth in the lower jaw. One of these methods is Articaine infiltration and the other is Lidocaine nerve block. Lidocaine and Articaine are two of the most common local anesthetic drugs used in dentistry to numb the teeth. The two main types of injections for numbing teeth are infiltration injection and nerve block. Infiltration injection is given near the area that will be treated while a nerve block is given in a different location than the area that will be treated. A nerve block is often necessary in areas where the bone is thick and infiltration injection will not be sufficient. Due to the thick bone in the lower jaw the most common method of numbing teeth in this area is giving a nerve block using lidocaine. An alternative method of numbing teeth in the lower jaw is using Articaine which is a newer local anesthetic that is FDA approved for use in children and adults. Articaine is a unique anesthetic because it is able to penetrate even thick bone allowing it to be given as an infiltration injection even in the lower jaw. There are many studies proving Articaine and lidocaine to be safe and effective and we want to see how well each method works on baby teeth.
Patient Information Leaflet

Figure 1: Articaine (Left), Lidocaine (Right)

Figure 2: Infiltration injection (Left), Nerve Block (Right)

What does this involve?

Monitors measuring blood pressure and heart rate will be placed on your child’s arm or leg. An experienced pediatric dentist will give your child the local anesthetic injection. The type of local anesthetic used will be randomly selected and only that dentist will know which one is used. The dental assistant will record your child’s response to receiving the local anesthetic injection. A second dentist (pediatric dental resident) will then complete the planned treatment. The treatment that has been planned by your child’s dentist will not change as a result of participating in this study. In other words, even if you do not participate the same treatment will be completed on your child. At the end of the visit, your child will be asked to rate their experience by pointing to a visual chart (see below).

Figure 2: Visual scale (Wong-Baker FACES Pain Rating Scale)

Wong-Baker FACES® Pain Rating Scale

0 2 4 6 8 10
No Hurt Hurts Little Bit Hurts Little More Hurts Even More Hurts Whole Lot Hurts Worst

VERSION 1 1 07/19/2018
APPENDIX B (continued)

**Patient Information Leaflet**

Where will this treatment take place?
This research trial will be performed at the Pediatric Dentistry Department, College of Dentistry, UIC (801 S Paulina St, Chicago, IL 60612).

How long will this take?
On average, treatment visits last about an hour.

Your child will only participate in this study for one of their dental visits. The number of dental visits your child needs depends on their treatment plan. The rest of the visits will be completed as normal in the UIC Pediatric Dentistry Department.

Do I have to take part?
No, you do not have to be a part of this study. If you decide that you do not want your child included in the study, we will still carry out treatment of your child’s back tooth. It will not affect your right to treatment.

Can I withdraw my child from the study?
Yes, you can decide to withdraw from the study at any point even if you have been involved at the start.

Confidentiality:
Your child’s identity will remain confidential. His/her name will not be published and will not be disclosed to anyone outside the study group.

Confidentiality of Information:
Your child will be identified on all records/data by a participant’s number. Access to your child’s records and data from this study will be limited to the dentists in the research group. Any computerised information will be stored on password-protected computers with restricted access. The study data will be kept for 5 years after the study is completed in a locked cabinet but will not be used for any future unrelated studies without your permission.

Access to Data:
The data collected regarding your child will be available for you to see at any point during the study by asking a team member.

Permission:
Study permission is granted by the UIC Institutional Review Board.

Use of the data:
The results from this study will be published in a suitable dental journal or can be presented in a lecture format so others can benefit from the information.
APPENDIX C

University of Illinois at Chicago
Authorization To Use And Disclose (Release) Health Information For a Research Study

Randomized Controlled Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine versus Inferior Alveolar Nerve Block with Lidocaine for Restorative Care of First Permanent Molars in Pediatric Patients

State and Federal laws, including the Health Insurance Portability and Accountability Act (HIPAA), require researchers to protect your child’s health information. This form describes how researchers, with your authorization (permission), may use and release (disclose or share) your child’s protected health information in this research study. Please read this form carefully.

Your child has been asked to take part in a research study. The study has already been described to you in a separate consent form. By signing this form you are permitting Dr. Angelo Arce, Pediatric Dentistry Department, COD, UIC and his research team to create, get, use, store, and share protected health information that identifies your child for the purposes of this research study.

Description of protected health information that may be used and released (disclosed or shared)
The health information includes all information created and/or collected during the research as described in the ‘Parental Permission for Participation in Research’ entitled Research Information and Parental Permission for Participation in Biomedical Research. Protected health information may include results of tests, procedures or surveys that are part of the research. Health information in your child dental record may be used and released if it is needed for the research; for example, past medical conditions or medications or information related to illness or hospitalizations that occur during your participation in the research.

The dental health information includes name, phone numbers, email addresses, date of birth and dental record number.

Research use of your protected health information:
During the conduct of the research, the researchers may use or share your health information:

Title: Randomized Controlled Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine for Restorative Care of First Permanent Molars in Pediatric Patients
Version: 1
Date: 09/19/2018
APPENDIX C (continued)

HIPAA Authorization Template V1, 08/29/18

- With each other and with other researchers involved with the study;
- With law enforcement or other agencies, when required by law;
- With representatives of government agencies: Food and Drug Administration, review boards including the University of Illinois at Chicago Institutional Review Board and other persons who watch over the conduct of research;

**Protection of your health information**

The researchers agree to protect your health information and will only share this information as described in this Authorization and the Parental Permission for Participation in Biomedical Research Form.

When your health information is given to people outside of the research study, those agencies that receive your health information may not be required by federal privacy laws (such as the Privacy Rule) to protect it. They may also share your information with others without your permission, if permitted by laws that they have to follow.

**Expiration of Authorization**

This Authorization expires at the end of the study but can be canceled sooner if you decide to withdraw your permission.

**Withdrawal or removal from the study**

You may change your mind and cancel this Authorization at any time. To cancel this Authorization, you must write to:

Angelo Aree, D.D.S.
Pediatric Dentistry Department, COD, UIC
801 S. Paulina Street,
Room 267 (MC850)
Chicago, IL 60612-7211
Phone 312 996-7532
Fax: 312 413-8006
Email: aarce4@uic.edu

If you cancel this Authorization, your child may no longer be allowed to take part in the research study. Even if you cancel this Authorization, the researchers may still use and disclose health information they have already obtained to maintain the integrity and reliability of the research and to report any adverse (bad) effects that may have happened to your child.

**Contact information for questions about my rights under HIPAA**

If you have questions or concerns regarding your privacy rights under HIPAA, you should contact the University of Illinois at Chicago Privacy Officer at Ph: (312) 996-2271.

If you have not already received a copy of the Notice of Privacy Practices, you should ask for one. **You will be given a copy** of this Authorization after it has been signed to keep for your records.

Title: Randomized Controlled Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine for Restorative Care of First Permanent Molars in Pediatric Patients
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Page 2 of 3
APPENDIX C (continued)

Right to Refuse to Sign this Authorization
You do not have to sign this Authorization. However, because your child’s dental health information is required for research participation, if you decide not to sign this Authorization form, it will only mean your child cannot take part in this research. Not signing this form will not affect your child’s non-research related treatment, payment or enrollment in any health plans or your child’s eligibility for other medical benefits.

Signature of Subject
I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions, and my questions have been answered to my satisfaction. I authorize the use and disclosure of my child’s protected health information for this research.

Printed name of Subject

Signature of Parent/Guardian or of Subject   Date (must be same as Subject’s)

Printed name of Parent / Guardian

Describe relationship to subject (Check one below)
☐ Parent
☐ Legal guardian
☐ Other; specify

Title: Randomized Controlled Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine for Restorative Care of First Permanent Molars in Pediatric Patients
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University of Illinois at Chicago

Research Information and Parental Permission for Participation in Biomedical Research

Randomized Controlled Clinical Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine for Restorative Care of First Permanent Molars in Pediatric Patients

Your child is being asked to participate in a research study. Researchers are required to provide a Parental Permission form such as this one to tell you about the research, to explain that taking part is voluntary, to describe the risks and benefits of participation, and to help you to make an informed decision. You should feel free to ask the researchers any questions you may have.

Principal Investigator Name and Title: Dr. Angelo Arce, DDS
Department and Institution: Pediatric Dentistry Department, University of Illinois at Chicago
Address and Contact Information:
Pediatric Dentistry Department
University of Illinois at Chicago
801 S. Paulina Street
(MC850)
Chicago, IL 60612-7211
Phone 312-996-1984
Fax: 312-413-1638
Email: aarce4@uic.edu

Emergency Contact Name and Information:
Dr. Evelina Kratunova, BDS, MDS, DChDent
Phone 312-996-1984
Fax: 312-413-1638
Email: evekrat@uic.edu

Conflict of Interest: Your child’s health care provider may be an investigator on this research protocol, and as an investigator, is interested in both your clinical welfare and in the conduct of this study. Before entering this study or at any time during the research, you may ask for a second opinion about your child’s care from a clinician who is not associated with this project. Your child is not obligated to participate in any research project offered by his/her clinician. Your child’s participation in this research study is voluntary and he/she does not have to participate. The decision to not participate will not affect your child’s clinical care now or in the future.

Why is my child being asked?
Randomized Clinical Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine versus Inferior Alveolar Nerve Block with Lidocaine for First Permanent Molars in Pediatric Patients

Date: 11/1/2018  Version 4
APPENDIX D (continued)

Your child requires dental treatment on his/her lower permanent back teeth (molars). Dental treatment on these back molars will typically involve the placement of white fillings or silver crowns. In order to comfortably complete the dental treatment, a medicine will be used to numb the teeth. This medicine is a type of drug that is injected to numb a particular area. The two main ways to numb teeth are giving the injection near the tooth (infiltration injection) or giving the injection further back in the mouth which numbs the whole section (nerve block). Infiltration injection is less complicated because the injection site is easier to see, and the injection is given near the area that will be treated. A nerve block is more complicated because the injection is given further back in the mouth in a different location than the area that will be treated. A nerve block is often needed in areas where the bone is thick and infiltration injection will not go deep enough through the bone. Due to the thick bone in the lower jaw the most common method of numbing teeth in this area is giving a nerve block using a medicine called lidocaine. An alternative method of numbing teeth in the lower jaw is using a medicine called articaine which is a newer numbing medication that is approved by the U.S. Government for use in children and adults. Articaine is a unique numbing medication because it is able to go through thick bone allowing it to be given as an infiltration injection even in the lower jaw.

We are asking your permission for your child to be a participant in a research study that investigates the effectiveness of two types of numbing medications for lower molar teeth: 2% lidocaine with epinephrine and 4% articaine with epinephrine. We recruit participants who are children between 7 to 12 years of age, who need dental treatment on lower back teeth, and are believed to be cooperative for dental treatment. Participation in this study does not affect your child’s dental treatment needs. Your child will receive the same dental treatment as planned and be given either lidocaine or articaine to numb their teeth. Your child’s participation in this research is voluntary. Your decision whether or not your child should participate will not affect your child's current or future dealings with the University of Illinois at Chicago. If you decide to let your child participate, your child will be free to withdraw at any time without affecting that relationship. Approximately 60 subjects will be involved in this research at the UIC.

What is the purpose of this research?
The study is being done to test how well the two types of medications work in a child’s mouth to numb the teeth. Our goal is to examine how good these medications are for back teeth in children. A number of items including blood pressure, any discomfort during injection, any discomfort during the procedure, and the child’s perception of the procedure will be examined. These numbing medications have been available on the dental market for a number of years and many pediatric dentists are using them in their clinics. Both types of medications are FDA approved and are safe and effective for use in children and adults. The use of both anesthetics are considered standard of care treatment at UIC. We hope to find out if there is any difference between the two medication types and if articaine can be routinely used instead of lidocaine.

What procedures are involved?
This research trial will be performed at the Pediatric Dentistry Department, College of Dentistry, UIC (801 S Paulina St, Chicago, IL 60612).

Your child will only participate in this study for one dental visit regardless of the number of visits your child needs. In other words, if your child requires 4 dental visits, they will only participate in the study for one of those visits. The remainder of the treatment will still be Randomized Clinical Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine versus Inferior Alveolar Nerve Block with Lidocaine for First Permanent Molars in Pediatric Patients

Date: 11/1/2018 Version 4
completed as planned. On average, treatment visits last about an hour. Two different dentists will be involved. The first dentist will use the medication to numb the back tooth. The second dentist will complete the dental treatment (fillings or crowns).

Since we want the type of medication to be random, the dentist will use a random method to determine which medication will be used. Only the doctor giving the numbing injection will know which medicine will be used. You, your child, and the doctor completing the dental work will not know which numbing medicine is used.

At the time of the numbing medication injection the dental assistant will look at the child’s response and fill out a special scoring sheet. Then the second dentist will complete the dental treatment. At the end of the procedure your child will be asked to rate their dental experience using a chart (visual face scale) to tell us how they felt. This is a visual chart with pictures and your child will simply point to the picture that best shows how they feel.

**What are the potential risks and discomforts?**
There is a risk of loss of confidence. Risks to local anesthesia include toxicity, allergic reaction, paresthesia, and postoperative soft tissue injury. Additionally, there is risk that being assigned to one arm of the study could result in more pain and discomfort than being assigned to the other arm of the study. Should any problems arise, including your child experiencing pain or discomfort during the procedure, steps will be taken to alleviate their pain and standard of care treatment will continue. If your child needs to receive more medication during the procedure, the person administering the drugs will know what dosage of what drug was given initially so they can administer the correct dose of whatever drug is then used. Your child will receive supplemental local anesthesia (LA) to assure successful treatment completion.

**Will I be told about new information that may affect my decision to participate?**
During the course of the study, you and your child will be informed of any significant new research findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation, that might cause you to change your mind about continuing in the study. If new information is provided to you and your child, your parental permission to continue participating in this study may be re-obtained.

**Are there benefits to taking part in the research?**
There may be no direct benefits to your child by participating in the study. It is hoped that knowledge gained from this research may benefit others that will require treatment with these two type local anesthetics in the future.

**What other options are there?**
If you decide that you do not want your child included in the study, he/she will receive the dental care as originally planned.

**What about privacy and confidentiality?**
The people who will know that your child is a research participant are only the members of the research team. No information about your child, or provided by you, during the research, will be disclosed to others without your written permission, except if necessary to protect your child’s

Randomized Clinical Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine versus Inferior Alveolar Nerve Block with Lidocaine for First Permanent Molars in Pediatric Patients

Date: 11/1/2018 Version 4
rights or welfare or if required by law. Study information which identifies your child and the parental permission form signed by you can be looked at and/or copied for examining the research by the U.S. Food and Drug Administration (FDA). A possible risk of the research is that your child’s participation in this study or information about your child and his/her dental health might become known to individuals outside the research. However, every effort will be made by the research team to prevent this to happen. Participants will be identified by a study number, which is allocated to them at the time of study enrolment. All study data will be coded using only the participants’ study numbers and not including any other personal identifiers. The key to the code (personal information matching participants ‘study numbers) along with all participants’ personal information and records will be kept confidential at all times. Only the research team will have access to the study documentation. Hard copy files, parental permission forms, assent forms and data collection sheets will be stored in a locked cabinet in the room 269- D at the Pediatric Dentistry Department of the College of Dentistry, UIC. All computerized records, including the key to the data coding, will be protected in an encrypted folder on a password protected UIC computer. When the results of the research are published, or discussed in conferences, no information will be included that would reveal your child’s identity. All research records will be kept for 5 years after study completion and then will be destroyed. The discarding of all electronic and paper documentation will follow strictly the policy of the Pediatric Dentistry Department, College of Dentistry, UIC for confidential information disposal. If you and/or your child disclose actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult, the researcher or any member of the study staff must, and will, report this to Child Protective Services (i.e. Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

What if your child is injured as a result of his/her participation?
If your child gets ill or injured from being in the study, UIC will help your child get medical treatment. You should let the study doctor know right away that your child is ill or injured. If you believe your child has become ill or injured from this study, you should contact Dr Arce at telephone number (312) 996-7532.

You should let any health care provider who treats your child know that your child was in a research study. If your child does seek medical treatment, please take a copy of this document with you because it may help the doctors where your child seeks treatment to treat him/her. It will also provide the doctors where your child seeks treatment with information they may need if they want to contact the research doctors.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

UIC has not set aside any money to pay you or to pay for your child’s treatment if your child gets ill or injured from being in the study. There are no plans for the University to provide other forms of compensation (such as lost wages or pain and suffering) to your child for research related illnesses or injuries. The only exception to this policy is if it is proven that your child’s injury or illness is directly caused by the negligence of an UIC employee.

Randomized Clinical Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine versus Inferior Alveolar Nerve Block with Lidocaine for First Permanent Molars in Pediatric Patients

Date: 11/1/2018  Version 4
APPENDIX D (continued)

By signing this form, you and your child are not giving up any legal rights to seek compensation of injury.

What are the costs for participating in this research?
There is no cost to the participants associated with their taking part in this study.

Will I be reimbursed for any of my expenses or paid for my participation in this research?
Your child will not be offered any payment for being in this study.

Can I withdraw or be removed from the study?
If you decide to enroll your child in this study, you are free to withdraw your parental permission and discontinue your child’s participation at any time without affecting your child’s future care at UIC. However, you should understand that if you choose to withdraw your parental permission after the procedures have been performed the results from the research procedures will be irreversible and cannot be undone. Your child has the right to leave the study at any time without a penalty. For your child’s safety, however, you should consider the investigator’s advice about how to leave the study.

Who should I contact if I have questions?
Contact the researchers:

Dr. Angelo Arce  
Phone: 312 996 7532  
Email: aarce4@uic.edu

Dr. Evelina Krasnova  
Phone 312 996-1984  
Email: evekrat@uic.edu

If you have any questions about this study or your child’s part in it, if you feel your child has had a research-related injury (or a bad reaction to the study treatment), and/or if you have questions, concerns or complaints about the research you can contact the following as they maintain quality assurance in the Department of Pediatric Dentistry:

Dr. Marcio da Fonseca  
Pediatric Dentistry Department Head  
Email: marcio@uic.edu

Dr. David Avenetti  
Post-Graduate Program Director  
Email: avenetti@uic.edu

What are my child’s rights as a research subject?
If you have questions about your child’s rights as a research subject or concerns, complaints, or to offer input you may call the Office for the Protection of Research Subjects (OPRS) at 312-996-1711 or 1-866-789-6215 (toll-free) or e-mail OPRS at uicirb@uic.edu.

Randomized Clinical Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine versus Inferior Alveolar Nerve Block with Lidocaine for First Permanent Molars in Pediatric Patients

Date: 11/1/2018 Version 4
Remember:
Your child’s participation in this research is voluntary. Your decision whether or not to permit your child to participate will not affect your child’s current or future relations with the University. If you decide to permit your child’s participation, your child is free to withdraw at any time without affecting that relationship.

Signature of Subject:
I have read (or someone has read to me) the above information. I have been given an opportunity to ask questions and my questions have been answered to my satisfaction. I agree to my child to participate in this research. I will be given a copy of this signed and dated form.

___________________________  __________________________
Signature                                      Date

___________________________
Printed Name

___________________________  __________________________
Signature of Person Obtaining Consent          Date (must be same as subject’s)

___________________________
Printed Name of Person Obtaining Consent

Randomized Clinical Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine versus Inferior Alveolar Nerve Block with Lidocaine for First Permanent Molars in Pediatric Patients

Date: 11/1/2018  Version 4
APPENDIX E

VERBAL ASSENT TO PARTICIPATE IN RESEARCH
For children 7 to 11 years of age

Title: Randomized Controlled Clinical Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine for Restorative Care of First Permanent Molars in Pediatric Patients

Dialogue to be used for verbal assent:

1. My name is Dr. Angelo Arce.

2. We are asking you to take part in a research study because we are trying to learn more about medicines used to numb teeth.
   ✓ Numbing means that you can’t feel something. Numbing your teeth means that the dentist can fix what is wrong with your teeth and you don’t feel any pain. You will get medicine today while we fix your teeth.
   ✓ We are testing two different types of medicine to see if one will work better than the other. One is called articaine and the other is called lidocaine.

3. If you say yes to be in this study:
   ✓ You will get one of these medicines, either lidocaine or articaine, for one side of your bottom back teeth.
   ✓ We will be checking your blood pressure and heart rate with a special machine the whole time you are here.
   ✓ At the end of the visit we will show you a chart with pictures of different faces and you will pick the face that is most like how you felt when you got the medicine.

4. The numbing usually lasts 2-3 hours so you need to be careful not to accidentally bite your cheek, lip, or tongue:
   ✓ Do not bite or chew on hard or sticky foods until the numbing goes away.

Randomized Controlled Clinical Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine for First Permanent Molars in Pediatric Patients
Version 5; Date: 11/6/2018

University of Illinois at Chicago
The numbing can feel strange but do not play with or bite your cheek, lip, or tongue. If you accidentally bite yourself, it will hurt after the numbing goes away and can last for 7 to 10 days.

6. Please talk with your parents before you decide to say yes or no. We will also ask your parents if it is okay for you to be in this study. Even if your parents say “yes” you can still decide to say no and it will be okay.

7. If you don’t want to be in this study, you can say no. Being in this study is up to you and no one will be upset if you don’t want to be in it or even if you say yes then change your mind later and want to stop.

8. You can ask any questions that you have about the study. If you have a question later that you didn’t think of now, your parents can call me at phone number: 312 996 1984 or you can ask me next time.

9. Saying yes means that you agree to be in this study. You will still get medicine and your dentist will still fix your teeth whether you say yes or no to be in this study. You and your parents will be given a copy of this paper.
University of Illinois at Chicago

APPENDIX F

ASSENT TO PARTICIPATE IN RESEARCH
For children 12 years of age

Title: Randomized Controlled Clinical Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine for Restorative Care of First Permanent Molars in Pediatric Patients

1. My name is Dr. Angelo Arce.

2. We are asking you to take part in a research study because we are trying to learn more about medicines called local anesthetics used to numb teeth.
   ✓ A local anesthetic is a medicine that is given by the dentist to numb the teeth for dental procedures.
   ✓ The teeth are numbed so that it is not painful when we fix the teeth.
   ✓ We are testing two different types of medicine to see if one will work better than the other. One is called articaine and the other is called lidocaine.
   ✓ Even if you decide not to be in this study, you will still need this medicine to fix your teeth.

3. If you agree to be in this study:
   ✓ You will get one of these medicines, either lidocaine or articaine, for one side of your bottom back teeth.
   ✓ We will be checking your blood pressure and heart rate with a special machine the whole time you are here.
   ✓ At the end of the visit you will be asked if you have had any pain from the procedure by showing how it felt when the medicine was given by pointing on a chart that has different faces.

4. The numbing usually lasts 2-3 hours so you need to be careful not to accidentally bite your cheek, lip, or tongue:
   ✓ Do not bite or chew on hard or sticky foods until the numbing goes away.

Randomized Controlled Clinical Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine for First Permanent Molars in Pediatric Patients
Version 4; Date: 11/1/2018
The numbing can feel strange but do not play with or bite your cheek, lip, or tongue. If you accidentally bite yourself it will hurt after the numbing goes away and can last for 7 to 10 days.

5. By taking part of our study you will get to have your teeth fixed with one type of numbing medicine but you or the doctor fixing your teeth will not know which one.

6. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say “yes” you can still decide not to do this.

7. If you don’t want to be in this study, you don’t have to participate. Remember, being in this study is up to you and no one will be upset if you don’t want to participate or even if you change your mind later and want to stop.

8. You can ask any questions that you have about the study. If you have a question later that you didn’t think of now, you can call me on phone number: 312 996 1984 or ask me next time.

9. Signing your name at the bottom means that you agree to be in this study. Your dentist will continue to treat you whether or not you participate in this study. You and your parents will be given a copy of this form after you have signed it.

Name of Subject

Date

Signature

Age

Grade in School

Randomized Controlled Clinical Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine for First Permanent Molars in Pediatric Patients

Version 4;

Date: 11/1/2018
APPENDIX G

Randomized Controlled Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine in Pediatric Patients

Initial Data Capture Form

Date of procedure:

<table>
<thead>
<tr>
<th>Participant’s Study Number</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Participant’s age</td>
<td></td>
</tr>
<tr>
<td>Participant’s age</td>
<td></td>
</tr>
<tr>
<td>Type of LA used</td>
<td></td>
</tr>
<tr>
<td>Total volume LA used</td>
<td></td>
</tr>
<tr>
<td>Type injection used</td>
<td></td>
</tr>
<tr>
<td>Type of planned treatment</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX H

Randomized Controlled Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine in Pediatric Patients

Basic Signs Form

Date:

Participant’s Number:

Pulse and Blood Pressure recordings:

<table>
<thead>
<tr>
<th>Time</th>
<th>Pulse</th>
<th>Blood Pressure</th>
</tr>
</thead>
</table>
### Modified Behavioral Pain Scale #A

#### LA Administration

**Participant's Number:**

**Date:**

<table>
<thead>
<tr>
<th>Behavior Observed</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facial Expression</td>
<td></td>
</tr>
<tr>
<td>• Definite positive (i.e., smiling)</td>
<td></td>
</tr>
<tr>
<td>• Neutral Expression</td>
<td></td>
</tr>
<tr>
<td>• Slightly Negative Expression (i.e. grimace)</td>
<td></td>
</tr>
<tr>
<td>• Definite Negative</td>
<td></td>
</tr>
<tr>
<td>Cry</td>
<td></td>
</tr>
<tr>
<td>• Laughing or giggling</td>
<td></td>
</tr>
<tr>
<td>• Not crying</td>
<td></td>
</tr>
<tr>
<td>• Moaning, quiet vocalizing or gentle or whimpering cry</td>
<td></td>
</tr>
<tr>
<td>• Full-lunged cry or sobbing</td>
<td></td>
</tr>
<tr>
<td>• Full-lunged cry, clearly more than baseline full-lunged cry</td>
<td></td>
</tr>
<tr>
<td>Movements</td>
<td></td>
</tr>
<tr>
<td>• Usual movement and activity</td>
<td></td>
</tr>
<tr>
<td>• Resting and relaxed</td>
<td></td>
</tr>
<tr>
<td>• Partial movement or attempt to avoid pain by moving</td>
<td></td>
</tr>
<tr>
<td>• Agitation with complex movements involving the head, torso or other limbs, or rigidity</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX J

Randomized Controlled Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine in Pediatric Patients

**Modified Behavioral Pain Scale #B**

*Dental treatment*

Participant’s Number: 

Date: 

<table>
<thead>
<tr>
<th>Behavior Observed</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Facial Expression</strong></td>
<td></td>
</tr>
<tr>
<td>• Definite positive (i.e., smiling)</td>
<td></td>
</tr>
<tr>
<td>• Neutral Expression</td>
<td></td>
</tr>
<tr>
<td>• Slightly Negative Expression (i.e. grimace)</td>
<td></td>
</tr>
<tr>
<td>• Definite Negative</td>
<td></td>
</tr>
<tr>
<td><strong>Cry</strong></td>
<td></td>
</tr>
<tr>
<td>• Laughing or giggling</td>
<td></td>
</tr>
<tr>
<td>• Not crying</td>
<td></td>
</tr>
<tr>
<td>• Moaning, quiet vocalizing or gentle or whimpering cry</td>
<td></td>
</tr>
<tr>
<td>• Full-lunged cry or sobbing</td>
<td></td>
</tr>
<tr>
<td>• Full-lunged cry, clearly more than baseline full-lunged cry</td>
<td></td>
</tr>
<tr>
<td><strong>Movements</strong></td>
<td></td>
</tr>
<tr>
<td>• Usual movement and activity</td>
<td></td>
</tr>
<tr>
<td>• Resting and relaxed</td>
<td></td>
</tr>
<tr>
<td>• Partial movement or attempt to avoid pain by moving</td>
<td></td>
</tr>
<tr>
<td>• Agitation with complex movements involving the head, torso or other limbs, or rigidity</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX K

Randomized Controlled Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine in Pediatric Patients

Self-reported Pain Rating Scale Form

Date of procedure:

Participant’s Number:

Wong-Baker FACES® Pain Rating Scale

0 2 4 6 8 10
No Hurt Hurts Little Bit Hurts Little More Hurts Even More Hurts Whole Lot Hurts Worst
APPENDIX L

Guide for inferior alveolar nerve block in a pediatric patient

- Dry injection site with gauze and apply small amount of topical anesthetic with cotton-tipped applicator
- The location of the mandibular foramen is situated below the occlusal plane in the pediatric patient, therefore, the injection must be made slightly lower and more posteriorly than for an adult patient

- Thumb is laid on the occlusal surface of the molars, with the tip of the thumb resting on the internal oblique ridge and the ball of the thumb resting in the retromolar fossa. Firm support during the injection procedure can be given when the ball of the middle finger is resting on the posterior border of the mandible.

- The barrel of the syringe should be directed on a plane between the two primary molars on the opposite side of the arch. It is advisable to inject a small amount of the solution as soon as the tissue is penetrated and to continue to inject minute quantities as the needle is directed toward the mandibular foramen.

- The depth of insertion averages about 15 mm but varies with the size of the mandible and its changing proportion. Insert to the depth that is adjacent to bone.
- Aspirate
- Slowly inject bolus of anesthetic
- Remove needle
Guide for infiltration anesthesia

Please note images depict infiltration of maxillary arch, however, the same technique will be applied to the mandibular arch.

Dry injection site with gauze and apply small amount of topical anesthetic with cotton-tipped applicator

Reflect tissue to expose injection site
Orient bevel of the needle to be parallel to the bone and insert needle into mucobuccal fold

Proceed to the depth that approximates the apices of the buccal roots of the primary molars
Aspirate
Deposit bolus of anesthetic slowly
Remove needle
CITED LITERATURE


VITA

Angelo M. Arce, D.D.S.

EDUCATION

UNIVERSITY OF ILLINOIS AT CHICAGO COLLEGE OF DENTISTRY, Chicago, IL

Pediatric Dentistry Resident

Candidate for Masters of Oral Science

Expected Graduation Date: June 2019

COLUMBIA UNIVERSITY COLLEGE OF DENTAL MEDICINE, New York, NY

Graduated: May 2017

FRANKLIN & MARSHALL COLLEGE, Lancaster, PA

Graduated: May 2013

PEDiatric CLINICal EXPERIENCE

Apple Dental Care, Chicago, IL

Dentist

July 2018 - Present

KIDS Philippines Dental Mission, Taguig City, Philippines

Student Team Leader

February 2016

Columbia Dental Mobile Van, New York, NY

Student Dentist

March 2016 - May 2017

RESEARCH EXPERIENCE

University of Illinois at Chicago, Chicago, IL

Principal Investigator Master’s Thesis

September 2017 - Present

• “Randomized Controlled Clinical Trial Comparing the Effectiveness of Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine for Restorative Care of First Permanent Molars in Pediatric Patients”

PROFESSIONAL DEVELOPMENT

Memberships

American Dental Association

May 2013 - Present

American Academy of Pediatric Dentistry

July 2017 - Present

Illinois Society of Pediatric Dentistry

July 2017 - Present

Chicago Dental Society

July 2017 - Present