Comparing the Effectiveness of Articaine Mandibular Infiltration vs. Lidocaine IANB in Pediatric Patients

BY

AMY SHAH
B.S., University of Arizona, Tucson, 2007
D.D.S., University of Illinois at Chicago College of Dentistry, Chicago, 2011

THESIS

Submitted as partial fulfillment of the requirements for the degree of Master of Science in Oral Sciences in the Graduate College of the University of Illinois at Chicago, 2018

Chicago, Illinois

Thesis Committee

Dr. Evelina Kratunova, MDS, MFD, D.Ch.Dent., FFD, Department of Pediatric Dentistry, Thesis Committee Chair and Advisor
Dr. Ian Marion, DDS, MS, Department of Pediatric Dentistry
Dr. Sheela Raja, PhD, Department of Pediatric Dentistry
Dr. Anne Koerber, DDS, PhD, Department of Oral Medicine and Diagnostic Sciences
ACKNOWLEDGEMENTS

This study was conducted at the University of Illinois at Chicago Department of Pediatric Dentistry. I would like to thank the Department for their understanding and facilitation of this research study. I would like to thank the members of my committee: Dr. Ian Marion, Dr. Anne Koerber, and Dr. Sheela Raja for their continued guidance and support throughout this project. I would also like to express my deepest gratitude towards my mentor and committee chair Dr. Evelina Kratunova. She was instrumental in the completion of this project and her kindness and compassion is unparalleled. I am truly privileged and honored to be mentored by such a knowledgeable yet humble researcher, educator and clinician. I would also like to thank my family who always believed in me even when I doubted myself. Without my husband, parents, and siblings I would never have been able to pursue my professional aspirations while still being a mother to my daughter. Finally, I would like to thank my daughter Ellis who showed unconditional love and joy despite my absence. She may never know or remember her positive impact on this journey, but I will never forget.
TABLE OF CONTENTS

1. INTRODUCTION ........................................................................................................... 1
   1.1 Background Information ......................................................................................... 3
   1.2 Purpose of the Study ............................................................................................... 3
   1.3 Hypothesis of the Study ......................................................................................... 4

2. REVIEW OF LITERATURE .......................................................................................... 5
   2.1 Lidocaine .................................................................................................................. 5
   2.2 Articaine .................................................................................................................. 6
   2.3 Local Anesthesia Techniques ................................................................................. 7
   2.4 Indications for Use .................................................................................................. 8
   2.5 Use in Children ....................................................................................................... 9
   2.6 Behavioral Rating Scales for Pain Perception in Children ..................................... 10
       2.6.1 Modified Behavioral Pain Scale ..................................................................... 10
       2.6.2 Wong-Baker FACES® Pain Rating Scale ....................................................... 11

3. MATERIALS AND METHODS .................................................................................... 13
   3.1 Overview .................................................................................................................. 13
   3.2 Study Site, Participants, and Enrollment ................................................................. 14
       3.2.1 Study Site ........................................................................................................ 14
       3.2.2 Operator .......................................................................................................... 14
       3.2.3 Examiners ....................................................................................................... 14
       3.2.4 Study Subjects ............................................................................................... 15
       3.2.5 Inclusion Criteria ........................................................................................... 16
       3.2.6 Exclusion Criteria .......................................................................................... 18
   3.3 Subject Enrollment .................................................................................................. 19
   3.4 Armamentarium ..................................................................................................... 21
       3.4.1 Articaine .......................................................................................................... 22
       3.4.2 Lidocaine ........................................................................................................ 22
       3.4.3 Regulatory Compliance .................................................................................. 22
       3.4.4 Needles .......................................................................................................... 23
       3.4.5 Syringe ........................................................................................................... 24
   3.5 Injection Technique ................................................................................................. 24
   3.6 Initial Data Capture .................................................................................................. 24
   3.7 Randomization Process .......................................................................................... 25
   3.8 Clinical Outcome Data ........................................................................................... 25
       3.8.1 Participants’ Reaction to Injection ................................................................... 26
       3.8.2 Participants’ Reaction to Dental Treatment ...................................................... 26
       3.8.3 Basic Signs Recording .................................................................................... 27
       3.8.4 Self-Reported Perception of Pain .................................................................... 27
   3.9 Flow Chart of the Study Process ............................................................................. 28
   3.10 Criteria for Clinical Success .................................................................................. 28
   3.11 Statistical Analysis ................................................................................................. 29

4. Results ......................................................................................................................... 30
   4.1 Number of Subjects ............................................................................................... 30
   4.2 Demographics of Subjects ...................................................................................... 30
   4.3 Types of Restorative Treatment ............................................................................. 31
   4.4 Pain Rating Scales ................................................................................................... 32
4.5 Blood Pressure and Pulse ................................................................. 35

5. DISCUSSION .................................................................................. 36
  5.1 Infiltration vs. IANB ................................................................. 36
  5.2 Articaine Limitations .............................................................. 38
  5.3 Pain Rating Scales ................................................................. 39
  5.4 Comparisons to Past Studies .................................................. 40
  5.5 Study Strengths .................................................................. 41
  5.6 Study Limitations ............................................................... 42
  5.7 Future Studies ................................................................. 44

6. STUDY CONCLUSIONS ............................................................... 46

7. CITED LITERATURE .................................................................. 47

APPENDIX A ............................................................................... 50
APPENDIX B ............................................................................... 53
APPENDIX C ............................................................................... 56
APPENDIX D ............................................................................... 59
APPENDIX E ............................................................................... 64
APPENDIX F ............................................................................... 66
APPENDIX G ............................................................................... 67
APPENDIX H ............................................................................... 68
APPENDIX I ............................................................................... 69
APPENDIX J ............................................................................... 70
APPENDIX K ............................................................................... 71
APPENDIX L ............................................................................... 72
APPENDIX M ............................................................................... 74
VITA .......................................................................................... 75

LIST OF TABLES

Table 1 Summary of Literature ......................................................... 11
Table 2 Summary of Inclusion and Exclusion Criteria .................. 19
Table 3 Subject Demographics ......................................................... 31
Table 4 Treatment Types ................................................................ 32
Table 5 Anesthetic Volume .............................................................. 32
Table 6 MBPS Scores ..................................................................... 33
Table 7 Blood Pressure and Pulse Values ........................................ 36
LIST OF FIGURES

Figure 1 Subject Demographics ................................................................. 34
Figure 2 Treatment Types ................................................................. 34
Figure 3 Anesthetic Volume ................................................................. 34
**LIST OF ABBREVIATIONS**

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

1.1 Background Information

Local Anesthesia (LA) aims to provide temporary inhibition of pain during invasive dental treatment and is one of the most common procedures in dentistry. Achieving successful LA is particularly important in children as pediatric patients can easily withdraw cooperation at any sensation of pain or discomfort. Local anesthetic agents with different properties are available to accommodate requirements in various clinical situations. Different methods of local anesthetic administration are used with respect to the anatomy of tooth innervations.

LA is typically given either by infiltration or nerve block injection. Infiltration injection is generally simpler and associated with less discomfort and fewer complications. However, it has smaller operative field and may be ineffective in areas of dense bone. The Inferior Alveolar Nerve Block (IANB) is used to anesthetize unilaterally all mandibular teeth but requires increased depth of needle penetration. IANB is associated with higher incidence of adverse events such as needle breakage, nerve damage and hematoma. This method of injection is very technique sensitive and reported success rates vary from 92% to as low as 42%. IANB is associated with a higher incidence of needle breakage and more difficult retrieval often involving surgery. Furthermore, IANB is even more difficult when faced with an uncooperative patient.

Lidocaine is the current local anesthetic agent of choice in dentistry. Successful anesthesia for lower molars with lidocaine is achieved by blocking the Inferior Alveolar Nerve which is a branch of the Trigeminal Nerve. The cortical
bone in the mandible is dense, making it difficult for lidocaine to reach the terminal nerve endings.

In recent years, articaine has become an increasingly popular local anesthetic agent. It is approved by the Food and Drug Administration (FDA) as well as the AAPD for use in children ages four and older. Safety of use in pediatric patients younger than four has also been documented in a number of clinical trials. The chemical structure of articaine is unique amongst the group of amide anesthetics because it is derived from thiophene rather than benzene. This enables articaine to have higher lipo-solubility allowing larger amount of local anesthetic solution to be diffused into the teeth and the surrounding hard and soft tissues. The increased diffusion potential and potency permit a smaller volume of articaine to be used via local infiltration for anesthesia of mandibular molars. In addition, articaine is the only amide anesthetic to contain an ester group which enables more rapid breakdown into its inactive state, thus, reducing its systemic toxicity. It has been shown that 4% articaine hydrochloride (HCL) is 1.5 times as potent and 0.6 times as toxic as the current gold standard anesthetic 2% lidocaine HCL. Due to its unique chemical properties and ability to penetrate through areas of dense bone, articaine can be effectively used for mandibular molars with infiltration injection. The inflammation of the pulpal tissue within the tooth is known as pulpitis and is one of the most difficult conditions to anesthetize. Four percent articaine HLC has been shown to be as effective as 2% lidocaine HCL for the treatment of irreversible pulpitis. According to FDA, articaine is indicated for both simple and complex dental procedures. There is
controversy surrounding past reports of increased risk of paresthesia when used as an IANB. However, such claims have been shown to have weak scientific evidence and recent research confirmed the safety and efficacy of articaine administration including for IANB.²,⁹,¹⁰

A large body of evidence has confirmed the safety and efficacy of the use of articaine in adults. Fewer studies investigate its success in children. Since the search for safer ways of delivering LA to pediatric patients is continuing, there is a need of well-designed clinical trials assessing the effectiveness of infiltration anesthesia with articaine for primary mandibular molars in comparison to the established standard of IANB with lidocaine.

1.2 **Purpose of the Study**

This is a parallel design randomized controlled clinical trial that aims to evaluate the effectiveness of mandibular infiltration anesthesia with articaine (4% articaine HCL with 1:100,000 epinephrine) in comparison to IANB with lidocaine (2% lidocaine HCL with 1:100,000 epinephrine) in pediatric patients during restorative dental care of primary lower molars.

The objectives of the study are:

- To evaluate and compare infiltration anesthesia with articaine and IANB with lidocaine, for achieving successful LA for restorative dental care on primary mandibular molars in children between 4 and 10 years of age.
- To assess and compare a number of clinical and behavioral variables including blood pressure, pulse, physical movements, facial expression
and crying in pediatric patients during administration of each of the two LA agents and during the subsequent dental treatment.

• To evaluate and compare the subjective perception of discomfort/pain associated with each of the two local anesthetics.

• To establish whether infiltration anesthesia with articaine is a suitable alternative to IANB with lidocaine in achieving successful LA for restorative care of mandibular primary molars.

1.3 **Hypothesis of the Study**

The Null Hypotheses of the study are:

• There is no difference in the effectiveness of articaine mandibular infiltration and Lidocaine IANB for achieving successful LA for restorative care of primary lower molars.

• There is no difference in the subjective pain perception of articaine mandibular infiltration and lidocaine IANB for anesthesia of mandibular primary molars.

• There is no difference in the observed discomfort during LA administration and treatment between articaine mandibular infiltration and lidocaine IANB for anesthesia of mandibular primary molars.
2. REVIEW OF LITERATURE

This section reviews indications for the use of lidocaine and articaine, as well as comparison of established injection techniques to gain understanding of the clinical background of the gap in the literature and the need of the current study. Similar research trials aiming to find a safer alternative to the current standard of mandibular anesthesia by means of infiltration injection with suitable anesthetic agent are identified and discussed.

2.1 Lidocaine

Lidocaine is an amino-acid derived local anesthetic available in multiple formulations. Lidocaine has been available in the United States for nearly 70 years. Due to its long-standing availability and proven success, it is the most common local anesthetic used in dentistry. Lidocaine can be used for all types of dental injections including nerve block, local infiltration, and injection into the periodontal ligament space. Due to bone density and lipid solubility, lidocaine is typically given as an infiltration anesthetic in the maxilla and as a nerve block in the mandible. The average duration of anesthesia for pulpal tissue is approximately 85 minutes and 190 minutes for soft tissue in pediatric patients.

The most common formulation used in dentistry is 2% lidocaine HCL with 1:100,000 epinephrine. Lidocaine is typically pre-mixed with epinephrine, however, formulations that do not contain epinephrine are also available. Epinephrine is a vasopressor that constricts blood vessels aiding in hemostasis and delayed anesthetic absorption. The delay in anesthetic absorption functions to increase the duration of anesthesia and reduce systemic toxicity. The majority
of lidocaine preparations used in the dental setting contain epinephrine in varying concentrations such as 1:50,000, 1:100,000 or 1:200,000. However, epinephrine may be contraindicated in certain cardiac patients due to increased contractility of the heart and increased systolic blood pressure.\textsuperscript{5}

2.2 **Articaine**

4% articaine HCL is another amino-acid derived local anesthetic, widely used in the contemporary practice of dentistry. Articaine has been available in Europe since 1976 and was FDA approved in the United States in 2000.\textsuperscript{7} While it has been recognized that currently the most commonly used local anesthetic in the United States is 2% lidocaine HCL with 1:100,000 epinephrine, the 4% articaine HCL with 1:100,000 epinephrine is quickly gaining popularity due to its advantageous properties.\textsuperscript{9} The chemical structure of articaine is unique amongst all amide anesthetics because it is derived from thiophene rather than benzene. This enables articaine to have high lipid solubility allowing increased amount of anesthetic solution to be diffused into the teeth and the surrounding hard and soft tissues.\textsuperscript{2} The duration of anesthesia for pulpal tissue is approximately 60 minutes in pediatric patients. Soft tissue anesthesia duration is longer and can last up to 190 minutes.\textsuperscript{3} The increased diffusion potential of articaine and its better potency allow a smaller volume of anesthetic solution to be used via local infiltration for anesthesia of mandibular molars. Increased lipid solubility causes rapid diffusion into the cell membrane allowing faster onset of action.\textsuperscript{5} In addition, articaine is the only amide anesthetic to contain an ester group that enables the rapid breakdown into its inactive state reducing its systemic toxicity. 4% articaine
HCL solution is 1.5 times as potent and 0.6 times as toxic as the current gold standard anesthetic 2% lidocaine HCL.\textsuperscript{2,5} In essence, the pharmacological properties of articaine allow it to be more potent, have faster onset, and be less toxic in comparison to lidocaine.

2.3 **Local Anesthesia Techniques**

The traditional method of delivering LA for mandibular molars, both primary and permanent, involves IANB as a technique of administration and lidocaine as a choice of anesthetic agent This method of injection is very technique sensitive and reported success rates vary from 92\% to as low as 42\%.\textsuperscript{9} IANB is associated with a higher incidence of needle breakage and difficult retrieval often involving surgical intervention.\textsuperscript{1} A case series conducted by Pogrel \textit{et al.}, (2009) reviewed 16 cases of needle breakage. It was found that 15 of the 16 cases involved IANB and 5 of those were in children under the age of 10. All 16 of the cases required surgical intervention under general anesthesia often using radiographic guidance. Pogrel \textit{et al.}, (2009) concluded that most needle fractures occurred during administration of the IANB and children who were reported to move violently and suddenly during administration.\textsuperscript{1}

IANB is given at the nerve branch deep within the soft tissue near the mandibular canal. This area cannot be visualized directly so anatomical landmarks are used to help guide estimation of needle insertion and depth. Since needle insertion is approximated, there is an increased risk for incorrect insertion that can lead to blood vessel perforation, hematoma or nerve paresthesia.
Furthermore, IANB is even more difficult when faced with an uncooperative patient who may refuse to sit still or open their mouth.\textsuperscript{2,12}

The potency and aforementioned chemical properties of articaine allow this anesthetic to be used via infiltration injection rather than IANB. Infiltration anesthesia is simpler and less technique sensitive since the injection site is easier to visualize and the anesthetic solution is deposited directly in the area that will be treated. In addition to being a more simpler technique, it may also be associated with less pain on injection.\textsuperscript{13} Articaine infiltration has characteristics of a safer and less technique sensitive method for anesthetizing mandibular teeth.

2.4 \textbf{Indications for Use}

One of the most challenging, yet essential aspects of pediatric dentistry is the administration of local anesthetic. The purpose of LA is to provide temporary inhibition of pain during dental procedures. The inflammation of the pulpal tissue within the tooth is known as pulpitis and is one of the most difficult conditions to anesthetize. 4\% articaine HCL has been shown to be as effective as 2\% lidocaine HCL for treatment of irreversible pulpitis.\textsuperscript{6,7,14,15} According to the FDA, articaine is indicated for both simple and complex dental procedures. Su \textit{et al.}, (2016) conducted a systematic review comparing the effectiveness of articaine versus lidocaine for treatment of irreversible pulpitis. A total of twenty studies were included and it was concluded that articaine was superior to lidocaine for dental treatment of teeth with irreversible pulpitis.\textsuperscript{8}

There is some controversy surrounding reports of increased risk of paresthesia when articaine was administered for IANB, however, claims have
weak scientific evidence and recent research suggests safe use for all types of LA delivery including IANB.\textsuperscript{2,9,10} Yapp et al.,(2011) conducted a literature review which aimed to understand the current literature surrounding the use of articaine as a local anesthetic agent for dental treatment. They concluded that there was no conclusive evidence demonstrating increased neurotoxicity with the use of articaine compared to other local anesthetic agents. Articaine is confirmed to be a safe and effective choice for all ages and all aspects of clinical dentistry.\textsuperscript{10}

2.5 \textbf{Use in Children}

An FDA approved drug for use as a dental local anesthetic for both children and adults is 4\% articaine HCL. Manufacturer's (Septodont\textsuperscript{®}) recommendations along with the AAPD Guidelines commend use in children ages four and older.\textsuperscript{12} A number of studies have demonstrated that articaine is a safe anesthetic agent even for younger populations, however the evidence remains limited and insufficient to formulate clinical guidance.\textsuperscript{4} In Table 1, the findings from the available to date clinical trials comparing the efficacy of articaine versus lidocaine are summarized. It is evident that there are very few studies conducted in pediatric patients. Furthermore, the majority of those trials do not specifically compare articaine mandibular infiltration with lidocaine IANB.

4\% articaine HCL is a well-documented local anesthetic with proven safety and efficacy both in adults and children. However, there is a lack of well-designed randomized controlled clinical trials demonstrating the articaine use in children. This study aims to find a local anesthetic technique that is as effective yet safer
and simpler than the current gold standard. The proposed study design is unique and has not been utilized in past research.

2.6  **Behavior Rating Scales for Pain Perception in Children**

2.6.1  *Modified Behavioral Pain Scale*

   The method of using a Modified Behavioral Pain Scale (MBPS) for measuring facial and bodily movements, has been found to be a valuable indicator of pain perception in children. The MBPS has been validated by Taddio et. al., (2009). The purpose of their study was to test the validity and reliability of MBPS as an observer-based pain rating scale during vaccinations on infants and to compare it to the known and validated visual analog scale. Taddio et. al., (2009) conducted a double-blind randomized controlled trial including 120 participants who received immunization injections. Inter and intra-examiner reliability was assessed at baseline and during injection. The authors concluded the MBPS is an acceptable method of measuring procedural pain in children.
Table 1: Summary of Literature

<table>
<thead>
<tr>
<th>Study</th>
<th>Number</th>
<th>Age Range</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dudkiewicz et al., 1987</td>
<td>50</td>
<td>4-10</td>
<td>• Anesthesia successful in all cases&lt;br&gt;• No adverse effects reported</td>
</tr>
<tr>
<td>Wright et al., 1989</td>
<td>211</td>
<td>1-4</td>
<td>• No difference in pain control efficacy&lt;br&gt;• No adverse effects noted</td>
</tr>
<tr>
<td>Malamed et al., 2000a</td>
<td>1325</td>
<td>4-80</td>
<td>• No difference in pain control efficacy</td>
</tr>
<tr>
<td>Malamed et al., 2000b</td>
<td>50</td>
<td>4-13</td>
<td>• No significant difference in pain control during simple &amp; complex procedures&lt;br&gt;• No difference in pain relief&lt;br&gt;• No serious adverse events</td>
</tr>
<tr>
<td>Malamed et al., 2001</td>
<td>1325</td>
<td>4-80</td>
<td>• Adverse reactions similar&lt;br&gt;• Articaine 22%, Lidocaine 20%</td>
</tr>
<tr>
<td>Mikesell et al., 2005</td>
<td>57</td>
<td>4-80</td>
<td>• Articaine pulpal anesthesia: 4-54%&lt;br&gt;• Lidocaine pulpal anesthesia: 2-48%&lt;br&gt;• No significant difference</td>
</tr>
<tr>
<td>Ram et al., 2006</td>
<td>62</td>
<td>5-13</td>
<td>• Efficacy similar&lt;br&gt;• Longer soft tissue numbness with articaine&lt;br&gt;• Few adverse events with either</td>
</tr>
<tr>
<td>Chopra et al., 2016</td>
<td>30</td>
<td>4-8</td>
<td>• Pain Score showed significantly more movements with block as compared to infiltration&lt;br&gt;• Articaine infiltration can replace IANB for primary mandibular molars</td>
</tr>
</tbody>
</table>

2.6.2 Wong-Baker FACES® Pain Rating Scale

The Wong-Baker FACES® Pain Rating Scale (PRS) is a self-reported visual analog scale developed by Donna Wong and Connie Baker. It allows a subject to express their own evaluation of pain experience in relation to an intervention. The PRS contains six images of varying facial expression ranging from laughter to tears. Each image has an assigned numerical value for objective evaluation and statistical analysis facilitation. This PRS is considered suitable for young age group study populations as it does not require verbal communication.
The Wong-Baker FACES® PRS, as method of using facial expression images, has been found to be a useful indicator of perception of pain in children and has been validated by Garra et. al., (2010). In their study, PRS was compared to another well-known and previously validated visual analog scale. Their subjects were children in acute pain who presented to a hospital emergency room. Garra et. al., (2010). Found anagreement between the PRS and the control visual analog scale with no difference due to age, gender, or pain location with either pain scoring systems. The authors concluded that the Wong-Baker FACES® PRS is an acceptable tool for assessment of pain in children.
3. MATERIALS AND METHODS

3.1 Overview

Participants for this study were recruited from the pool of patients attending the Pediatric Dentistry Department of the College of Dentistry (COD), University of Illinois at Chicago (UIC). Inclusion and exclusion criteria were specified separately for the selected patients and for the teeth involved. Informed consent from the parents/guardians and assent from the pediatric participants (seven years of age and older) were obtained and signed. By design, the study is a prospective randomized controlled clinical trial utilizing a random digit table for participant allocation into either the articaine Group or lidocaine Group. A total of 40 participants (20 in each group) were recruited. The dosage of LA was determined by the child’s body weight and did not exceed the maximum recommended 4.4 mg/kg for lidocaine and 7 mg/kg for articaine. One designated operator, an experienced specialist pediatric dentist, conducted all LA injections to all subjects. Dental assistants were trained and calibrated for the study purposes (examiners A) and recorded the patients’ reactions during the LA administration using Modified Behavioral Pain Scale (MBPS), adapted by Taddio et al., (1994). This scale provided objective evaluation of pain using multiple criteria such as facial display, movement of extremities, movement of torso, and crying. Trained and calibrated investigators (examiners B), residents in pediatric dentistry, blinded to the type of LA agent used, completed the planned dental treatment for the primary mandibular molars. Examiners B also completed MBPS and evaluated the patients’ reactions during the invasive dental treatment.
procedure. In total, 7 examiners A and 9 examiners B took part in the study. All examiners underwent training and calibration with respect to the use of MBPS. As an objective evaluation of pain perception, during the entire treatment visit, each participant was observed with a pulse and blood pressure monitors and automatic recordings were collected every 10 minutes. At the end of the dental visit, all study subjects were asked to complete a Wong-Baker FACES® Pain Response Scale (PRS) for feedback of their own experience with the entire dental visit. All data was coded and captured on specifically designed for the purposes of the study evaluation forms. The data, gathered through all study forms was transferred into Microsoft® Excel 2016 and the statistical analysis was carried out with IBM SPSS Statistics.

3.2 Study Site, Participants and Enrollment Process

3.2.1 Study Site

This study was conducted at the UIC, COD, Pediatric Dental Department Clinics, which includes the Post-Graduate and the Pre-Doctoral Dental Clinics. The site selection was based on the high volume of patients that are treated for restorative care of primary molars.

3.2.2 Operator

One designated and trained operator, an experienced specialist pediatric dentist, administered all LA for the purposes of this study. The training consisted of close review of the local anesthetic techniques and studying the step-by-step procedure guide (Appendix L).

3.2.3 Examiners
Seven designated examiners A, all dental assistants, used MBPS #A, (Appendix I) to record and evaluate the participants’ reactions during the administration of LA. At this step of the study process, only the operator and an examiner A were in attendance on the study patient.

Nine other investigators, named for the study purposes examiners B, performed the restorative dental care on the primary mandibular molars. Examiners B were all pediatric dental residents with sufficient experience in dental care for children. They were not present at the patient’s site during the LA administration and were therefore blinded to the type of anesthetic used by the operator. Examiners B completed the MBPS #B (Appendix J) which evaluated the subjects’ reactions during restorative dental treatment.

All examiners, both A and B, were trained and calibrated. The training process included tutorial on the use the MBPS. Detailed explanation on how to visually evaluate the patient’s reactions and provide associated scoring on the MBPS forms was provided as part of the study training. A Microsoft® Office Power Point presentation was used for this purpose.

The accuracy and consistency of the MBPS scoring was completed was evaluated by the study calibration process. The examiners were shown videos of patients exhibiting various behaviors in a dental setting. For each case, the examiners completed MBPS forms. The same videos were shown to the examiners at different occasions and MBPS forms were completed again. The calibration scorings were used for statistical analysis of inter and intra examiner agreement.
3.2.4 **Study Subjects**

Study subjects were recruited from the UIC, Pediatric Dental Clinics including the Post-Graduate and the Pre-Doctoral clinics. Subjects were pre-screened by the principal investigator (PI) through the axiUm® electronic health record system, and selected based on co-operative behavior and need for restorative treatment of primary mandibular molars. Inclusion and exclusion criteria were specified for the purposes of this study separately for the selected patients and for the teeth involved. The target number for the study sample size was 40 subjects.

3.2.5 **Inclusion Criteria**

The inclusion criteria for the participants are summarized in Table 2 were as follows:

1) Males and females, between the ages of 4 and 10 years old. The lower limit of the selected age group reflects the articaine’s manufacturer recommendation of minimum patient’s age of four years at LA agent administration. The upper limit of the age group was determined in consideration to the required restorative care of mandibular molars. Typically, primary lower molars start to exfoliate after age 10 years and are no longer indicated for dental rehabilitation.

2) In accordance to the widely recognized health status classification of the American Society of Anesthesiology (ASA), the participants were categorized as ASA I (healthy) or ASA II (mild, well-controlled systemic illness) for inclusion in
this trial. The subjects were either healthy or have had mild systemic conditions as self-reported on the medical history questionnaire completed by the parent at examination.

3) Subjects were chosen from those planned for restorative dental procedure of their deciduous lower molars requiring use of local anesthetic. With regard to the treatment teeth, included were only primary mandibular molars indicated for restorative dental care, such as intra-coronal restoration or full coronal coverage restoration (pediatric crown) due to developmental defects, caries or tooth surface loss (erosion/attrition).

4) Children were chosen from those known to be co-operative for the required dental intervention and not in need of any advanced behavior management modalities, such as inhalation (Nitrous Oxide and Oxygen) or oral sedation. The evaluation of the patient compliance was based on the Frankl Behavior Rating Scale. Patients demonstrated Frankl scores 3 or 4 were included in the study since they were considered of appropriate positive compliance to dental care. The Frankl rating was determined by the regular patient’s dental provider and recorded in the electronic health record at the initial examination or prior operative treatment.

5) English literacy of the parent/guardian and the patient was required. The study documentation including the consent, assent forms and the patient information leaflet were available only in English language. Patients with insufficient knowledge of the language were considered having significant
disadvantage in understanding of the study purpose and unable give a valid consent.

3.2.6 **Exclusion Criteria:**

The list of the exclusion criteria for this study included:

1) Children younger than 4 years of age and older than 10 years of age. Children younger than 4 years of age were excluded from the study, as they may not yet have had a fully formed primary dentition and the manufacturer of articaine does not recommend it for younger age groups. Children older than 10 years of age typically would have primary molars close to exfoliation and would not benefit from the proposed restorative methods.

2) Patients with medical status categorized as ASA III to VI were excluded. Patients with significant medical history were excluded from study enrollment as the priority of their medical condition might limit their availability for participation.

3) Patients that required treatment on teeth other than primary mandibular molars.

4) Patients that required non-restorative dental procedures such as extraction or extensive pulp therapy (pulpectomy).

5) Patients that required restorative treatment not indicated for use of local anesthetic.

6) Child dental patients that were uncooperative for dental care (Frankl 1 and 2) or those that may have required advanced behavior management
modalities such as inhalation or oral sedation. This exclusion criteria were selected to prevent analgesic or sedative agents from distorting the subject’s perception of the procedure.

7) Non-English-speaking parents/guardians and patients were excluded as they were unable to adequately understand the research study materials and consent forms.

3.3 Subject Enrollment

Study participants were selected from the pool of patients attending the Pediatric Dentistry Department of the COD at UIC. The PI reviewed the daily schedule of the PG Pediatric Dental Clinic on the electronic health-record (EHR) system at UIC (axiUm) and accessed the past notes of the booked patients. The PI searched for potential study participants according to the specified inclusion criteria.

Table 2: Summary of Inclusion and Exclusion Criteria

<table>
<thead>
<tr>
<th>Patient</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Medically Fit (ASA* I or II)</td>
<td>• Medically Compromised (ASA*III to VI)</td>
<td></td>
</tr>
<tr>
<td>• Age range: 4 to 10 years of age</td>
<td>• Younger than 4 or older than 10 years of age</td>
<td></td>
</tr>
<tr>
<td>• Cooperative for dental treatment (Frankl 3 or 4)</td>
<td>• Uncooperative for dental treatment (Frankl 1 or 2)</td>
<td></td>
</tr>
<tr>
<td>• Obtained informed consent</td>
<td>• Informed consent not obtained</td>
<td></td>
</tr>
<tr>
<td>• English literacy</td>
<td>• Non-English speakers</td>
<td></td>
</tr>
<tr>
<td>Treatment Tooth</td>
<td>• Mandibular primary molar</td>
<td></td>
</tr>
<tr>
<td>• Restorative dental treatment indicated for:</td>
<td>• Tooth other than mandibular primary molar</td>
<td></td>
</tr>
<tr>
<td>• Caries</td>
<td>• Tooth requiring minor dental restoration for which local anesthesia is not indicated</td>
<td></td>
</tr>
<tr>
<td>• Pulp treatment including indirect pulp therapy or pulpotomy;</td>
<td>• Tooth requiring extraction</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Tooth requiring pulpectomy</td>
<td></td>
</tr>
</tbody>
</table>
Developmental defects
- Tooth surface loss (erosion/attrition)

*American Society of Anesthesiologists (ASA)*

The PI identified prospective subjects by tracking existing incomplete dental treatment plans or new dental treatment plans that met the eligibility requirements. Thus, a list of potential participants with their EHR patient numbers was generated.

Each of these patients and their parent/guardians, was approached by the PI at the time when they attended the dental clinic for their scheduled treatment appointment. A brief verbal description of the study and a patient information leaflet (PIL) was given to them. The PIL, aided with pictorial material, offered detailed information on the two anesthetic agents used in the study and a clear explanation of all advantages and disadvantages of the proposed LA. It also provided a description of the study participation process and associated risks and benefits.

Once a potential study participant was identified, the PI performed a brief dental exam to establish whether the patient truly fulfilled the inclusion criteria of the clinical trial. Those patients and parents/guardians, that were interested in research participation, were asked to complete and sign the consent (parental permission, Appendix D) and the assent form (Appendix E, for children 7 years of age and older) of the study. Time for consideration before enrollment was provided within the limit of the dental appointment duration and was no less than
30 minutes. The parent/guardian then signed the Study Parental Permission Form in order to document their agreement with the terms and conditions of the study. Study Assent Form was provided to obtain signature from the child participants who are in the 7 to 10 years age group.

Each participant received an individual study number. A master list of the participants’ study numbers with the respective patients’ EHR numbers was generated and kept until the subject enrollment was completed. This was necessary to avoid multiple patient enrollments. After participants’ recruitment had ended, the master list was permanently destroyed.

Patients who did not meet the study’s inclusion criteria or for whom an informed parental permission (consent) and assent (where applicable) could not have been obtained were not enrolled in the study and were advised to continue their dental care as previously planned.

With regard to reimbursement from dental insurance companies the American Dental Association (ADA) had established a set of standardized coding for dental procedures. Delivery of local anesthetic itself was not reimbursed but rather was inclusive in the restorative procedure code. Reimbursement for dental treatment was not altered by this study since the dental treatment plan remained unchanged.

None of the subjects received any financial incentives and the cost of the dental treatment plan remained the same regardless of participation in the study.

3.4 Armamentarium
Delivery of LA requires local anesthetic cartridge, syringe, and needle. The most common formulations of lidocaine and articaine for dental use are 2% lidocaine HCL with epinephrine 1:100,000 and 4% articaine HCL with epinephrine 1:100,000. Most of the supplies are available through many manufacturers. The specific manufacturers listed below have been chosen based on availability in the Pediatric Dental Department, UIC.

3.4.1 **Articaine**

Septodont® is the manufacturer of Septocaine® which is articaine HCL 4% with epinephrine 1:100,000. Septocaine® is indicated for local infiltration anesthesia for both simple and complex dental procedures. It is an amide type local anesthetic agent that is metabolized in the liver. Septodont® recommends its use in children 4 years and older as safety and effectiveness for younger children has not been well established. The manufacturer advises for maximum dosage of 7.0 mg/kg and not to exceed 500mg in total. Articaine has a rapid onset within minutes with a duration ranging from 60 to 190 minutes.

3.4.2 **Lidocaine**

Novocol® is the manufacturer of lidocaine HCL 2% with Epinephrine 1:100,000 which is distributed in the United States by Henry Schein®. The manufacturer claims indications for use include local anesthesia of dental procedures by nerve block or infiltration techniques. Lidocaine is also an amide type local anesthetic agent that is metabolized in the liver. Novocol® claims lidocaine HCL 2% with Epinephrine 1:100,000 can safely be used for adults and children with reduced dosages in children. The maximum pediatric dose is
4.4mg/kg, not to exceed 300mg total dosage. Lidocaine also has rapid onset within minutes with a total duration ranging from 60 to 170 minutes.

3.4.3 Regulatory Compliance

Both, 4% articaine HCL with epinephrine 1:100,000 and 2% lidocaine HCL 2% with epinephrine 1:100,000 fully comply with the 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)
  - OSHA regulatory status: epinephrine bitartrate is not listed as a hazardous product in the RCRA (EPA) and CERCLA (EPA) regulations.
  - Regulatory status: This product is exempt from current 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 listed as a hazardous product in the RCRA (EPA) and CERCLA (EPA) regulations.
  - Regulatory status: This product is exempt from current WHMIS legislation as a drug product.
  - FDA approval: approved in 1980 for infiltration or nerve block anesthesia in dentistry.

3.4.4 Needles
The most common size dental needle used in pediatric patients is a 30 gauge short needle. This needle was used for both the IANB and infiltration methods of local anesthetic delivery. The needles used in this study were manufactured by Henry Schein®, however, many other manufacturers of dental needles are available. These needles were sterile and disposable. They were only to be used for one patient during one dental visit but may be injected multiple times during the visit. The needs were hollow to allow fluid disbursement and contain a bevel to facilitate tissue penetration. The gauge of the needle refers to the thickness or diameter. A 30 gauge needle was used in this study which translates to an outer diameter of 0.3112mm. The length of the needle from hub to tip is 20mm.

3.4.5 Syringe

A standard stainless steel dental syringe was used for the LA delivery. The syringe was reusable and steam sterilized in an autoclave machine after each use. The disposable needle and anesthetic cartridge were attached to the syringe. The syringe contained a hub where the needle was attached, a chamber in the center for anesthetic cartridge placement, and a plunger to advance and retract fluid.

3.5 Injection Technique

Injection technique differs for both IANB and infiltration anesthesia. IANB is more technique sensitive due to location of injection site and reduced visibility. The step-by-step guides for both techniques is was developed specifically for the purposes of the study and is described in detail in the Appendix L. The reference source for the guides was the textbook of “Dentistry for the Child and Adolescent”
3.6 **Initial Data Capture**

Each study participant was evaluated for behavior and cooperation at prior visits. The Frankl behavioral rating scale (Frankl *et al.*, 1962) is the conventional behavior rating scale used for pediatric patients in the United States. Patients of the Pediatric Dental Clinics, COD, UIC are typically rated according to this scale at each attendance and the rating is recorded in the day note of 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; F4=Definitely positive.

For each study participant, an initial data capture (IDC) form (see Appendix F) was completed by the operator providing the LA. This form was designed to record pertinent information associated with the anesthesia delivery. The child’s age and weight were recorded to assure appropriate anesthetic dosing. The details of the type of local anesthetic agent used, the total volume and the nature of the planned dental treatment were also filled out as a baseline record.

3.7 **Randomization Process**

Each subject was assigned to either the articaine Group or the lidocaine Group using a random digit table. From a table of random numbers, a list of 20 odd and 20 even numbers in a random order was generated. In the order of study enrolment, each subject who received an odd number from the generated list
was assigned to the articaine Group. Those participants who received even numbers were assigned to the lidocaine Group respectively.

3.8 **Clinical Outcome Data**

The perception of pain was assessed on a number of criteria deemed important to determine the clinical outcome of each type of local anesthetic administration. Two rating systems were employed for the study: Modified Behavioral Pain Scale (MBPS) and the Wong-Baker FACES® Pain Rating Scale (PRS).

### 3.8.1 Participants’ Reaction to Injection (Local Anesthetic Administration)

The adapted MBPS was used to document the facial and bodily movements of the participant in response to the administration of local anesthetic. The MBPS #A form (see Appendix I) was specially designed for the purposes of this study and was completed by the trained and calibrated examiners A. Examiners A are dental assistants that observed the subjects’ reaction during the LA delivery done by the study’s operator. Behaviors were categorized into 3 subsections: Facial Expression, Cry, and Bodily Movement. Each applicable behavior was given an associated numerical score. The individual scores were added to formulate a total score. Higher total scores indicated increased perception of pain.

### 3.8.2 Participants’ Reaction to Dental Treatment

The MBPS #B (Appendix J) was used to document the facial and bodily movements of the participant in response to the dental treatment of the primary mandibular molars. The form was specially designed for the purposes of the study and was completed by the trained and calibrated examiners B. Examiners
B were residents in Pediatric Dentistry providing the operative care for the subjects. They were blinded for the type LA agent used. Each applicable behavior according to the MBRS was given an associated numerical score. The individual scores were added to formulate a total score. Higher total scores indicate increased perception of pain.

3.8.3 Basic Signs Recording

During the entire treatment visit, each participant wore a pulse and blood pressure monitor. The machine produced automatic recordings every 10 minutes. Patients experiencing distress and pain can exhibit increased pulse and blood pressure values outside of the considered normal range per age. The recordings from the machine were then transferred to the Basic Signs Form (Appendix H) by the PI. The readings for each participant were compared to the normal blood pressure and pulse rates per age as stated by the manual of the AAPD.

3.8.4 Self-Reported Perception of Pain

The Wong-Baker FACES® Pain Rating Scale (PRS) was completed by the participant at the end of the visit. The PRS is a self-reported visual analog scale allowing the participant to give a subjective evaluation of their pain experience with the dental visit. The PRS contains six images of varying facial expression ranging from laughter to tears. Each image was assigned a numerical value for objective evaluation and statistical analysis. The PRS is considered suitable for a young age group study population as it does not require verbal communication.
The scale was used in the study with the exclusive permission by the Wong-Baker FACES® Foundation. The Self-Reporting PRS form is illustrated in Appendix K.

3.9 Flow Chart of the Study Process

3.10 Criteria for Clinical Success

Determinants for clinical success were specifically identified for the study purposes to include:
1) Successful completion of the planned dental treatment without the need for supplemental LA administration.

2) Behavior for the entire dental visit of the subject consistent with the ratings of Frankl 3 or 4.

3) Lack of adverse events, such as medical (e.g. syncope), dental emergencies or associated with anesthesia delivery (e.g. paresthesia).

Failure in any of these criteria was considered as an item “failure” of the LA for the purposes of this study.

3.11 Statistical Analysis

Data gathered through all study forms were transferred into Microsoft Excel Spreadsheet (Microsoft Inc., Redmond, WA, USA). The data file was stored on a password-protected computer. The Excel data file was then transferred to the IBM SPSS statistical software program for statistical analysis. All data were assigned a numerical value in order to complete statistical analysis. A prospective power analysis was carried out using numeric results for the Two-Sample T-Test allowing unequal variance. According to the power calculation, group sample sizes of 20 and 20 achieved 78% power to reject the null hypothesis of equal means. The power would have been be 98% if 40 participants were recruited in each group.

The data analysis consisted of univariate descriptive statistics including frequency, mean, median, and standard deviation to describe demographic information. Bivariate statistics including independent t-test and Mann Whitney-U were used to analyze pain rating scores (MPBS #A and MBPS #B) 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.
4. RESULTS

4.1 Number of Subjects

The data collection period took approximately 5 months and in total 40 subjects participated in the study. Twenty subjects received LA by means of IANB with 2% lidocaine HCL, 1:100,000 epinephrine. Another 20 participants received LA by mandibular infiltration with 4% articaine HCL, 1:100,000 epinephrine. Post-operative adverse outcomes were identical for both groups with only one lip bite reported for each test group. No other adverse events related to the study occurred. All of the planned treatment was completed without the need for additional anesthetic hence no failures were noted for either group. Therefore, all subjects that participated in the study were used for statistical analysis.

4.2 Demographic Characteristics of Subjects

Table 3 summarizes the demographic characteristics of the study participants. The average age of the subjects was 6.15 years old for the lidocaine group and 6.25 years old for the articaine group. There were 10 male and 10 female subjects for the lidocaine group and 9 male and 11 female subjects for the articaine group. The total number of male and female participants was 47.5% and 52.5%, respectively. Reported racial information for all subjects in descending order was Hispanic (50%), African American (25%), Caucasian (7.5%), other (7.5%), declined to answer (7.5%), and Asian (2.5%). There was no statistical significance in age, gender, or race as p<0.05 for all demographic characteristics between the lidocaine and articaine groups.
Table 3: Subject Demographics

<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</strong> (mean in years)</td>
<td>6.15</td>
<td>6.25</td>
<td>6.20</td>
</tr>
<tr>
<td><strong>Gender</strong> (count and percentage)</td>
<td>M=10 (50%)</td>
<td>M=9 (45%)</td>
<td>M=19 (47.5%)</td>
</tr>
<tr>
<td></td>
<td>F= 10 (50%)</td>
<td>F=11 (55%)</td>
<td>F=21 (52.5%)</td>
</tr>
<tr>
<td><strong>Race</strong> (count and percentage)</td>
<td>Hispanic=9 (45%)</td>
<td>African American=5 (20%)</td>
<td></td>
</tr>
</tbody>
</table>

4.3 Types of Restorative Treatment

Table 4 summarizes the variety of restorative dental care performed for both groups. The type treatments of the mandibular molars included direct restorations (fillings) and stainless steel crowns. More than one treatment was possible to be completed for a single subject. A simple frequency analysis was conducted to determine the amounts of each type of treatment for each group.

For subjects receiving lidocaine IANB the following number of treatments were completed: fillings (8), stainless steel crowns (13). One subject also received a pulpotomy procedure on the tooth that was restored afterwards with a SSC (1).

For subjects receiving articaine mandibular infiltration the following treatments were completed: fillings (15), stainless steel crowns (8), pulpotomies (1).

The mean volume of local anesthetic used for the Lidocaine Group was approximately 2 mL and 1.2 mL for the articaine Group (Table 5).
Table 4: Treatment Types

<table>
<thead>
<tr>
<th></th>
<th>Lidocaine</th>
<th>Articaine</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=20</td>
<td>n=20</td>
<td>N=40</td>
</tr>
<tr>
<td>Fillings</td>
<td>8</td>
<td>15</td>
<td>23</td>
</tr>
<tr>
<td>Crowns</td>
<td>13</td>
<td>8</td>
<td>21</td>
</tr>
</tbody>
</table>

Table 5: Anesthetic Volume

<table>
<thead>
<tr>
<th></th>
<th>Mean Amount (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lidocaine</td>
<td>1.995</td>
</tr>
<tr>
<td>Articaine</td>
<td>1.200</td>
</tr>
</tbody>
</table>

4.4 Pain Rating Scales

Table 6 summarizes the results from the observable pain rating scale data obtained from the MBPS #A and MBPS #B. As previously described, the Modified Behavior Pain Scale is evaluated for injection administration (MBPS #A) and response to dental treatment (MBPS #B). The MBPS consists of 3 subcategories: Facial Expression, Cry, and Bodily Movement. Mean MBPS #A Facial Expression for Lidocaine is 1.9 vs. 0.6 for articaine. Mean MBPS #A Cry for lidocaine is 1.75 vs. 1.05 for articaine. Mean MBPS #A Bodily Movement for lidocaine is 1.3 vs. 0.5 for articaine. Mean MBPS #B Facial Expression for Lidocaine is 1.9 vs. 0.6 for articaine. Mean MBPS #B Cry for lidocaine is 1.3 vs. 0.65 for articaine. Mean MBPS #B Bodily Movement for lidocaine is 1.25 vs. 0.5 for articaine. Both Mann-Whitney U and Independent samples t-test show p<0.05, indicating statistical significance for all subcategories of the MBPS. It can be concluded that Lidocaine inferior alveolar nerve block is associated with
higher pain on administration and more discomfort during dental treatment in comparison to Articaine mandibular infiltration.

*Figures 1-3 summarize the results from the Wong-Baker FACES® visual analog scale for subjective evaluation of pain experience with the dental visit. The mean score for the lidocaine group was 3.1 vs. 1.4 for the articaine group. Independent samples t-test statistical analysis indicated p=0.057. This p-value is not statistically significant but was determined to be approaching statistical significance.*

*Table 6: MBPS Scores*

<table>
<thead>
<tr>
<th>MBPS Categories</th>
<th>Type of Anesthetic</th>
<th>N</th>
<th>Mean Score</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MBPS #A Facial</td>
<td>Lidocaine</td>
<td>20</td>
<td>1.90</td>
<td>.000</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>0.60</td>
<td></td>
</tr>
<tr>
<td>MBPS #A Cry</td>
<td>Lidocaine</td>
<td>20</td>
<td>1.75</td>
<td>.002</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>1.05</td>
<td></td>
</tr>
<tr>
<td>MBPS #A Movement</td>
<td>Lidocaine</td>
<td>20</td>
<td>1.75</td>
<td>.012</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>0.95</td>
<td></td>
</tr>
<tr>
<td>MBPS #B Facial</td>
<td>Lidocaine</td>
<td>20</td>
<td>1.30</td>
<td>.008</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>0.50</td>
<td></td>
</tr>
<tr>
<td>MBPS #B Cry</td>
<td>Lidocaine</td>
<td>20</td>
<td>1.30</td>
<td>.002</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>0.65</td>
<td></td>
</tr>
<tr>
<td>MBPS #B Movement</td>
<td>Lidocaine</td>
<td>20</td>
<td>1.25</td>
<td>.003</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>0.50</td>
<td></td>
</tr>
</tbody>
</table>
Figure 1: Mean FACES® pain scores for Lidocaine IANB vs. Articaine infiltration

![FACES® Pain Scores](image)

Figure 2: FACES® pain score frequency for Articaine infiltration

![FACES® Score Frequencies for Articaine](image)

Figure 3: FACES® pain score frequencies for Lidocaine IANB

![FACES® Score Frequencies for Lidocaine](image)
4.5 **Blood Pressure and Pulse**

*Table 7* summarizes the results of blood pressure and pulse data. Baseline values for blood pressure and pulse were obtained prior to treatment initiation and were recorded automatically every 10 minutes. Statistical analysis was conducted on blood pressure and pulse values at baseline, during local anesthetic injection, and during treatment. Duration of treatment variation was based on the restorative needs of the patient, therefore, an average treatment blood pressure and pulse was calculated and used for statistical analysis. Multivariate repeated measures ANOVA was used to analyze the data. Data analysis was conducted for systolic blood pressure, diastolic blood pressure, and pulse.

The systolic blood pressure results indicated $p=0.096$ for between-groups, therefore there is no statistical significance between the systolic blood pressures from use of lidocaine versus articaine. The diastolic blood pressure data yielded similar results with $p=0.38$ between-groups, indicating no statistical significance between diastolic blood pressures from the use of lidocaine versus articaine.

However, the difference in pulse between lidocaine and articaine was found to be statistically significant ($p=0.042$). Estimated marginal means of pulse values for the lidocaine Group were: baseline (93), injection (102), and treatment (92) versus articaine pulse values: baseline (92), injection (100), and treatment (99). As expected, injection caused the blood pressure to increase in both groups. The results suggested the pulse was likely to stay higher during the duration of treatment for articaine, whereas, the pulse was more likely to reduce
near baseline for the lidocaine group. It should be noted that although found to be statistically significant, this finding bears no clinical significance as all reported values are well within normal limits for typical pediatric pulse rates.

*Table 7: Blood pressure and pulse values*

<table>
<thead>
<tr>
<th></th>
<th>Type of Anesthetic</th>
<th>N</th>
<th>Mean</th>
<th>p-value (between groups)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>baseline systolic BP</strong></td>
<td>Lidocaine</td>
<td>20</td>
<td>102</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>102</td>
<td></td>
</tr>
<tr>
<td><strong>injection systolic BP</strong></td>
<td>Lidocaine</td>
<td>20</td>
<td>106</td>
<td>.096</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>102</td>
<td></td>
</tr>
<tr>
<td><strong>treatment systolic BP</strong></td>
<td>Lidocaine</td>
<td>20</td>
<td>101</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>104</td>
<td></td>
</tr>
<tr>
<td><strong>baseline diastolic BP</strong></td>
<td>Lidocaine</td>
<td>20</td>
<td>61</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td><strong>injection diastolic BP</strong></td>
<td>Lidocaine</td>
<td>20</td>
<td>64</td>
<td>.096</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>55</td>
<td></td>
</tr>
<tr>
<td><strong>treatment diastolic BP</strong></td>
<td>Lidocaine</td>
<td>20</td>
<td>62</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>61</td>
<td></td>
</tr>
<tr>
<td><strong>baseline pulse</strong></td>
<td>Lidocaine</td>
<td>20</td>
<td>93</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>92</td>
<td></td>
</tr>
<tr>
<td><strong>injection pulse</strong></td>
<td>Lidocaine</td>
<td>20</td>
<td>102</td>
<td>.042</td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>100</td>
<td></td>
</tr>
<tr>
<td><strong>treatment pulse</strong></td>
<td>Lidocaine</td>
<td>20</td>
<td>92</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Articaine</td>
<td>20</td>
<td>99</td>
<td></td>
</tr>
</tbody>
</table>

5. DISCUSSION
5.1 Infiltration vs. IANB

This study found that the use of 4% articaine HCL 1:100,000 Epinephrine infiltration is as effective as 2% Lidocaine HCL 1:100,000 Epinephrine IANB for anesthesia of mandibular primary molars. No anesthesia failures were noted for either group or all planned treatment was completed. Articaine performed as effective as Lidocaine for completion of restorative dental treatment including fillings, crowns, and pulpotomy procedures on lower primary molars.

The results indicate infiltration with articaine is associated with less overall discomfort in comparison to IANB with lidocaine. Infiltration anesthesia is a simpler technique that requires deposition of anesthesia in the immediate vicinity of the teeth to be restored. In contrast, IANB is more difficult to visualize, more technique sensitive, and requires deeper needle penetration. IANB can provide profound anesthesia of all posterior mandibular teeth and also the tongue since the lingual nerve is anesthetized upon removal of the needle from soft tissue. However, buccal soft tissues are often not anesthetized and require a supplemental long buccal nerve injection.

Ease of injection technique is particularly important in pediatric dentistry since young children and those with special needs are often fearful and uncooperative. Good needle placement for IANB can be very challenging on a patient who is trashing or requires forcible mouth opening. Safety is a concern as needle breakage is more common in IANB due to deeper needle penetration. The unique chemical properties of articaine appear to provide a suitable alternative to traditional local anesthesia techniques for areas of dense bone.
5.2 **Articaine Limitations**

This study does not aim to replace the current gold standard of anesthetizing mandibular teeth, but rather it aims to find an alternative that may be more comfortable for the patient. Many clinical situations where lidocaine IANB is used can be treated more effectively and comfortably with articaine infiltration. Clinicians should become more familiar with articaine and use it as another tool in their armamentarium. There are some situations where Lidocaine IANB may be preferred over mandibular infiltration with Articaine. One such instance would be treatment of 4 or more teeth in a single quadrant. An IANB may be more comfortable for the patients as such a long span would require several infiltration injections. Articaine is also formulated in a 4% solution rather than a 2% solution. Since it is more concentrated, less total volume can be used until maximum dose is reached which may be a limiting factor in the amount of treatment that can be completed in a single visit. Another clinical situation in which an IANB is preferable over articaine infiltration is with a more invasive procedure such as an extraction. An extraction involves manipulation of all types of oral tissues including tooth, gingiva, mucosa, and bone. Since this procedure is so invasive, infiltration injection may not provide sufficient anesthesia.

Furthermore, a limitation for the use of articaine is the patient’s age. The lower limit for age was determined to be four years old due to manufacturer recommendations, FDA approval, and AAPD guidelines. Safety of use in children younger than four has also been documented in a number of clinical trials,
however, not enough data is currently available for the manufacturer to reduce age recommendations.

5.3 Pain Rating Scales

Several pain rating indices were used in this study including the Modified Behavior Pain Scale (MBPS) for observable behavior and the Wong-Baker FACES® PRS for subjective evaluation of the participants own pain experience. All the examiners that completed MBPS were trained and calibrated in an effort to reduce any potential study biases.

The FACES® scale was selected for this study due to its simplicity and imagery. Even young children were able to understand how to use this scale with little explanation. However, children are not typically not reliable reporters and in some instances their own rating did not correlate well with the examiners’. Even though the pain scores were more than double for the lidocaine group (3.4 vs. 1.4) it was still not statistically significant due to the range of the self-reported scores. Children often aim to please authority figures and may choose an answer that they believe the examiner or parent wants to see. One subject in the lidocaine group was visibly anxious and seemingly uncomfortable, yet rated their dental experience as “no hurt”. Children also have difficulty distinguishing pain from pressure. Local anesthesia inhibits pain but it cannot remove the sensation of pressure. One subject in the articaine group was very relaxed and did extremely well for the invasive part of the procedure but did not like the sensation of the pressure from seating the stainless steel crown. This subject rated their experience as “hurts a little” only due to pressure from crown seating and not
actual pain. Another subject in the articaine group did extremely well for the procedure but rated their experience as “hurt worst” because they were bothered by the assistant rinsing with the air/water syringe. Due to children having limited understanding, their eagerness to please, and unreliable reporting, it is no surprise the FACES® scores are less consistent than the MBPS scores which were conducted by trained and calibrated adults. Nonetheless, the FACES® scale was the best available pain rating scale for the purposes of this study. Despite inconsistencies in reporting, the articaine group was still associated with a more comfortable dental visit in comparison to the lidocaine group.

5.4 Comparison to Past Studies

Several studies exist on the effectiveness of articaine in adults, however, few studies exist for use in children. A majority of articaine studies are in relation to extraction and pulp therapy of permanent teeth. Bartlett et. al., (2016) compared buccal infiltration with articaine and IANB with lidocaine in adult patients. The study results indicated both techniques were successful and there was no significant difference between the two. No children were included in this study, therefore, generalizations cannot be made concerning the pediatric population.

Oulis et al., (1996) describe the effectiveness of mandibular infiltration compared to mandibular block anesthesia for primary molars in children. The study demonstrated no statistically significant difference in the two techniques for either behavior or pain when performing amalgam or stainless steel crown procedures. Mandibular infiltration was less effective than IANB when performing
pulpotomy or extraction. Although this study is similar in terms of injection technique, Oulis et al., (1996) only used 2% lidocaine for all subjects.

Arali et al., (2015) studied the anesthetic efficacy of 4% articaine mandibular buccal infiltration compared to 2% Lidocaine IANB in children. The authors concluded that 4% articaine can be used in place of 2% Lidocaine IANB for irreversible pulpitis. Although this study was conducted on pediatric patients and compared articaine mandibular infiltration with lidocaine IANB, it was specific only to cases irreversible pulpitis rather than restorative treatment of mandibular primary molars.

Ram et al., (2006) conducted a study on pediatric patients comparing 4% articaine and 2% lidocaine. The study evaluated clinical properties, adverse outcomes, and reaction to pain for the two local anesthetic agents. The authors stated that articaine was as effective as lidocaine but the effect of soft tissues numbness was longer lasting with articaine. Although this study is similar in design, it was not specific to mandibular teeth and also did not specify what procedures were completed. articaine was used for both the maxilla and mandible and was also used for inferior alveolar nerve block.

To the best of our knowledge there are no studies available comparing articaine infiltration and Lidocaine IANB local anesthesia for routine restorative dental care of mandibular primary molars in pediatric patients.

5.5 Study Strengths

To date, there have been no studies investigating 4% articaine mandibular infiltration vs. 2% lidocaine IANB for restorative care of mandibular primary
molars. This study is a randomized controlled clinical trial, a high quality study design for evaluating treatment efficacy. Subject frequency, gender, age, and race were evenly distributed across both test groups minimizing confounding variables.

Another strength was the consistency in local anesthetic administration since a single designated operator, an experienced pediatric dental specialist, performed all local anesthetic injections. Having a designated operator solely for local anesthetic injection allowed the examiner performing the dental treatment to be blinded to the type of local anesthetic agent used. This eliminates examiner bias and strengthens the validity of the study.

Furthermore, all examiners were trained and calibrated. The research trial utilized well-documented and validated behavior rating scales.

To reduce bias, the pain perception was evaluated threefold: objectively, by measuring physiological responses; subjectively, by the participant’s own evaluation and from observers, trained and calibrated for the methods of the study.

5.6 Study Limitations

One limitation of this study is the sample size. A total of 40 subjects were included in this study, with 20 subjects in each test group. A power analysis was conducted prior to subject recruitment which determined group sample sizes of 20 and 20 achieve 78% power to reject the null hypothesis of equal means. A study sample size of 40 subjects in each group would yield better statistical power and more confidence in rejecting the null hypothesis.
Another limitation is the lack of variation in clinical setting. Patient population, caries risk, parental expectations and patient behavior can vary based on the type of dental setting. All data collection for this study was conducted in the Department of Pediatric Dentistry at the University of Illinois at Chicago (UIC). This particular dental clinic is one of the largest providers of Medicaid dental services in the state of Illinois and a majority of the patients receiving services have Medicaid insurance. Caries risk and extent of dental decay is typically greater in this particular population compared to a typical private practice or fee-for-service dental clinic. In addition, specialty dental services like the ones provided at this dental clinic can be difficult to obtain in Illinois when utilizing Medicaid insurance. Many patients seen at UIC have been to other dental offices that may have attempted dental treatment but were unsuccessful due to behavior or were limited by the type of dental services provided. This leads to children having several dental visits prior to receiving treatment in the UIC dental clinic. Children are less tolerant of dental treatment than adults and cooperation tends to decrease with each subsequent appointment. Patients with high cooperation (Frankl 3 or 4) were difficult to recruit due to the aforementioned circumstances of the typical pediatric patient at UIC. In addition UIC is a teaching institution causing the duration of treatment to be longer compared to a non-teaching clinical setting. The increased duration of treatment can potentially impact behavior, thereby affecting scoring of the observational and subjective pain rating scales.

The number of operators and examiners may also provide limitations to this
study. A single designated operator was used to anesthetize all subjects. This operator was an experienced specialist in pediatric dentistry and adhered closely to the step-by-step procedure guide outlined in the protocol. Despite minimizing confounding variables with detailed guidelines, different operators could potentially produce different results. In contrast, multiple examiners were utilized to perform restorative dental treatment and complete the MBPS #B pain rating scale. Different examiners may have different behavior management techniques that can alter the behavioral outcome of the procedure. For example, a child who may have experienced pain but had a good rapport with the treating dentist may be more inclined to self-report a lower pain score. The speed at which the operator completes the dental treatment also varies between examiners. As mentioned before, duration of treatment has the potential to negatively impact behavior and cooperation. An operator to who is less experienced may take longer to complete a procedure which can negatively affect patient behavior and cooperation.

To minimize the aforementioned limiting factors, the protocol was detailed and all attempts were made to adhere to these guidelines as best as possible. Examiner training and calibration techniques were also utilized to minimize variation in scoring of the pain rating scales.

5.7 **Future Studies**

An interesting future study would be to investigate first permanent molars with the same study design. First permanent molars typically erupt around age six and often require restorative treatment due to caries or hypoplasia. It would
be clinically relevant to see if articaine infiltration had similar success rates and less pain on administration compared to lidocaine in permanent molars of children. Furthermore, it would be valuable to compare the effectiveness of articaine for permanent teeth versus primary teeth in children.

Another consideration for a future study would be treatment of more invasive dental procedures with mandibular articaine infiltration. These treatments would include extraction, pulpotomy, and pulpectomy of mandibular primary teeth. It would be interesting to observe differences in the efficacy of articaine and Lidocaine when the nerve is directly manipulated in these types of procedures. One potential difficulty would be that children have difficulty distinguishing pressure from pain so perhaps the methodology would have to be adapted to account for this potential complication particularly in the case of dental extraction.
6. STUDY CONCLUSIONS

The following conclusions can be made based on the results of this study:

• Articaine infiltration local anesthesia is as effective as lidocaine inferior alveolar nerve block for restorative dental treatment of primary mandibular molars.

• Articaine infiltration is associated with less pain on administration compared to lidocaine inferior alveolar nerve block.

• Articaine infiltration can be routinely recommended for restorative care of primary mandibular molars.

The outcomes of the Null hypotheses are:

• We fail to reject the hypothesis that there is no difference in the effectiveness of articaine mandibular infiltration and lidocaine IANB for achieving successful LA for restorative care of primary lower molars.

• We fail to reject the hypothesis that there is no difference in the subjective pain perception of articaine mandibular infiltration and lidocaine IANB for anesthesia of mandibular primary molars is also accepted.

• We reject the hypothesis that there is no difference in the observed discomfort during LA administration and treatment between articaine mandibular infiltration and Lidocaine IANB for anesthesia of mandibular primary molars.
CITED LITERATURE


11. Brandt RG, Anderson PF, McDonald NJ, Sohn W, Peters MC. The pulpal


APPENDIX A

University of Illinois at Chicago

Office for the Protection of Research Subjects (OPRS)
Office of the Vice Chancellor for Research (MC 672)
203 Administrative Office Building
1737 West Polk Street
Chicago, Illinois 60612-7227

Approval Notice
Initial Review (Response To Modifications)

April 21, 2017

Amy Shah, DDS
Pediatric Dentistry
801 S. Paulina St
M/C 850
Chicago, IL 60612
Phone: (312) 996-7532 / Fax: (312) 413-8006

RE: Protocol # 2017-0184
“Randomized Controlled Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine in Pediatric Patients”

Dear Dr. Shah:

Your Initial Review (Response To Modifications) was reviewed and approved by the Expedited review process on April 19, 2017. You may now begin your research.

Please note the following information about your approved research protocol:

Appendix P: According to OPRS records, Risa Hurwich, Jasna McDonald, Hilary Habel and Shahad Alshamali have not completed the required Initial and/or HIPAA Investigator training. Both courses must be completed before these individuals may participate as a member of the research team. Please note that these individuals must be re-added via a separate amendment after the required training has been completed. For further information, please see the OPRS website: http://research.uic.edu/compliance/irb/education-training.

<table>
<thead>
<tr>
<th>Protocol Approval Period:</th>
<th>April 19, 2017 - April 19, 2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved Subject Enrollment #:</td>
<td>80 Total</td>
</tr>
<tr>
<td>Performance Sites:</td>
<td>UIC</td>
</tr>
<tr>
<td>Sponsor:</td>
<td>None</td>
</tr>
</tbody>
</table>

Research Protocol(s):

a) Randomized Controlled Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine in Pediatric Patients; Version 1, 02/14/2017

Recruitment Material(s):

Phone: 312-996-1711                  http://www.uic.edu/depts/ovcr/oprs/          FAX: 312-413-2929
a) Patient Information Leaflet as submitted to OPRS on February 15, 2017 (No footer)

**Informed Consent(s):**

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

**Assent(s):**

a) Assent To participate for children 7 to 10 years of age, Version 2, 04/03/2017

**Parental Permission(s):**

a) Parental Permission, Version 2, 03/16/2017

**HIPAA Authorization(s):**

a) HIPAA- Written Authorization; Version 1, 02/14/2017

b) Review Preparatory to Research acknowledged [45 CFR 164.512(i)(1)(ii)]

**Additional Determinations for Research Involving Minors:**

The Board determined that this research satisfies 45CFR46.404 'and 21CFR50.51 (include if FDA- regulated), research not involving greater than minimal risk. Therefore, in accordance with 45CFR46.408 'and 21CFR50.55 (include if FDA- regulated), 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 (include if FDA- regulated). If you wish to enroll Wards of the State contact OPRS and refer to the tip sheet.

Your research meets the criteria for expedited review as defined in 45 CFR 46.110(b)(1) under the following specific category:

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

**Please note the Review History of this submission:**

<table>
<thead>
<tr>
<th>Receipt Date</th>
<th>Submission Type</th>
<th>Review Process</th>
<th>Review Date</th>
<th>Review Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/15/2017</td>
<td>Initial Review</td>
<td>Convened</td>
<td>03/01/2017</td>
<td>Modifications Required</td>
</tr>
<tr>
<td>04/04/2017</td>
<td>Response To Modifications</td>
<td>Expedited</td>
<td>04/19/2017</td>
<td>Approved</td>
</tr>
</tbody>
</table>

Please remember to:

→ Use your research protocol number (2017-0184) on any documents or correspondence with the IRB concerning your research protocol.

→ Review and comply with all requirements on the guidance,

"UIC Investigator Responsibilities, Protection of Human Research Subjects"

(http://research.uic.edu/irb/investigators-research-staff/investigator-responsibilities)

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.

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) 413-0241. Please send any correspondence about this protocol to OPRS at 203 AOB, M/C 672.

Sincerely,
Ibraheem Oguntade
IRB Coordinator, IRB #1
Office for the Protection of Research Subjects

Enclosure(s) sent as attachment to a separate email:

Please note that stamped and approved .pdfs of all recruitment and consent documents will be forwarded as an attachment to a separate email. OPRS/IRB no longer issues paper letters and stamped/approved documents, so it will be necessary to retain these emailed documents for your files for auditing purposes.

1. Assent Document(s):
   a) Assent To participate for children 7 to 10 years of age, Version 2, 04/03/2017

2. Parental Permission(s):
   a) Parental Permission, Version 2, 03/16/2017

3. HIPAA Authorization(s):
   a) HIPAA- Written Authorization; Version 1, 02/14/2017

4. Recruiting Material(s):
   a) Patient Information Leaflet as submitted to OPRS on February 15, 2017 (No footer)

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

Patient Information Leaflet

Research Project

Randomized Controlled Trial Comparing the Effectiveness of Two Methods of Local Anesthesia: Mandibular Infiltration with Articaine and Nerve Block with Lidocaine

Introduction:

Your child requires dental treatment on his/her baby back teeth (molars). In order to fix the baby teeth, a medicine called local anesthetic 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 baby 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)

<table>
<thead>
<tr>
<th>Wong-Baker FACES® Pain Rating Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
</tr>
<tr>
<td>No Hurt</td>
</tr>
</tbody>
</table>

Where will this treatment take place?
Patient Information Leaflet

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

Randomized Controlled Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine 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. Amy Shah, 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:
• With each other and with other researchers involved with the study;
• With law enforcement or other agencies, when required by law;

Title: Randomized Controlled Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine in Pediatric Patients
Version: 1, Date: February, 14th 2017
• 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:

Amy Shah, D.M.D.
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: melanc4@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.

**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

Title: Randomized Controlled Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine Versus Inferior Alveolar Nerve Block with Lidocaine in Pediatric Patients
Version: 1, Date: February, 14th 2017
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 ________________________________

__________________________
University of Illinois at Chicago

Research Information and Parental Permission for Participation in Biomedical Research

Randomized Clinical Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine versus Inferior Alveolar Nerve Block with Lidocaine 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. Amy Shah, DDS
Department and Institution: Pediatric Dentistry Department, University of Illinois at Chicago
Address and Contact Information:
801 S. Paulina Street,
Room 267 (MC850)
Chicago, IL 60612-7211
Phone 312 996-7532
Fax: 312 413-8006
Email: ashah75@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 obliged 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?
Your child requires dental treatment on his/her lower baby (primary) back teeth (molars). It is important to hold on to the baby back teeth in order to have space for the adult teeth to grow/erupt. Dental treatment on these back molars will typically involve the placement of white

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

Date: 03/16/2017

Version 2
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 site 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 even 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 baby molar teeth: 2% lidocaine with epinephrine and 4% articaine with epinephrine. We recruit participants who are children between 4 to 10 years of age, who need dental treatment on lower baby 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 80 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 baby back teeth. 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 as safe and effective for use in children and adults. 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 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 baby 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. For example, a coin will be flipped to determine which numbing medication your child will receive. 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 confidentiality.

**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 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

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

Date: 03/16/2017

Version 2
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 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. Amy Shah
Phone: 312 996 7532
Email: ashah75@uic.edu

Dr. Evelina Krasnaya
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:

Randomized Clinical Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine versus Inferior Alveolar Nerve Block with Lidocaine in Pediatric Patients
Date: 03/16/2017

Version 2
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.

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
ASSENT TO PARTICIPATE IN RESEARCH
For children 7 to 10 years of age

Title: Randomized Clinical Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine versus Inferior Alveolar Nerve Block with Lidocaine in Pediatric Patients

1. My name is Dr. Amy Shah.

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 baby teeth.
   ✓ Your baby teeth that are ill, will be cleaned and and fixed with either a white filling or a silver crown. A crown is like a cap that is glued over your whole tooth.
   ✓ 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 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 Clinical Trial Comparing the Effectiveness of Mandibular Infiltration Local Anesthesia with Articaine versus Inferior Alveolar Nerve Block with Lidocaine in Pediatric Patients
Version 2; Date: 04/03/2017

65
✓ 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
APPENDIX F

Search of the daily book of the EHR to identify prospective participants

80 participants in total

Subject Recruitment

Randomization: Random Digit Table

Lidocaine Group

Articaine Group

LA administration

Restorative Dental Treatment on Primary Mandibular Molars

Subject completes the Self-reporting Pain Scale form to document subjective experience

Subject wears blood pressure and pulse monitor and recordings are made every 10 min to document physiological signs during the entire procedure

Behavior of Patient evaluated by Examiner A (dental assistant) and documented in the MBPS#A form

Behavior of Patient evaluated by Examiner B and documented in the MBPS#B form

Data Collection and Statistical Analysis

Performing by the Study Operator (Experienced Pediatric Dentist)

Performed by a pediatric dentistry resident (Examiner B), who is blinded to the type of LA used

• Confirming subject eligibility
• Patient Information Leaflet/Verbal Explanation
• Parental Permission (Consent)
• Assent
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>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX I

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 #A**

**LA Administration**

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 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

<p>| | | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>2</td>
<td>4</td>
<td>6</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>No Hurt</td>
<td>Hurts Little Bit</td>
<td>Hurts Little More</td>
<td>Hurts Even More</td>
<td>Hurts Whole Lot</td>
<td>Hurts Worst</td>
</tr>
</tbody>
</table>
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

![Image]

- 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.

![Image]

- 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
• Deposite bolus of anesthetic slowly
• Remove needle
VITA

Amy P. Shah, D.D.S.

Education:

2016 – Present  University of Illinois at Chicago – College of Dentistry
Pediatric Dentistry Residency, PGY2
Masters in Oral Sciences
Projected Completion: June 2018

2007 – 2011  University of Illinois at Chicago – College of Dentistry
Doctor of Dental Surgery

2003 – 2007  University of Arizona
Major: Psychology. Minor: Chemistry
Bachelor of Sciences
Honors: Graduation with Distinction

Board Examinations:

  NBDE Part I – Pass
  NDBE Part II – Pass

Licensure:

  CRDTS Licensure Exam – Pass
  Illinois State Dental License
  Illinois State Controlled Substance License
  Arizona State Dental License

Work Experiences:

2014 – 2016  Near North Health Service Corporation
Dental Director
Head of FQHC dental program consisting of 2 multi-doctor clinics
and a mobile unit
Chicago, IL

2013  Modern Dental
Associate Dentist
Adult restorative and cosmetic dentistry
Chicago, IL
2013  Ivanhoe Dental Group  
*Associate Dentist*  
Adult and pediatric dental care  
Riverdale, IL

2011 – 2013  General Dentistry 4 Kids  
*Managing Dentist*  
Supervised day-to-day operations of large group practice along with providing pediatric patient care including restorative treatment, nitrous oxide, and moderate sedation  
Tucson, IL

2005 – 2007  University of Arizona Department of Psychiatry  
*Assistant to the Research Grant Coordinator*  
Assisted in assembly of research grants applications, liaison between department and IRB, and data entry  
Tucson, IL

2000 – 2007  Russell E. Schneider, DDS  
*Dental Assistant*  
Assisted dentist with procedures, room assembly, sterilization, and front desk duties  
Gurnee, IL

**Presentations:**

2018  Randomized Controlled Trial Comparing the Effectiveness of Articaine Infiltration vs. Lidocaine IANB for Local Anesthesia of Mandibular Primary Molars  
*Presented at the UIC Clinic and Research Day, Chicago, IL*

2017  The Effectiveness of Articaine Mandibular Infiltration vs. Lidocaine IANB in Pediatric Patients: A Review of the Literature  
*Presented at the UIC Clinic and Research Day, Chicago IL*

2016  Understanding and Serving the Underserved: An Introduction to Community Health  
*Keynote Speaker at the IPHCA Community Health Engagement Event, Chicago, IL*

2016  Dental Health Focus: Get Your Grill in Order  
*Radio Appearance, WVON radio 1690AM, Chicago, IL*
Research:

20016 - 2018 Randomized Clinical Trial Comparing the Effectiveness of Lidocaine IANB vs. Articaine Infiltration in Primary Mandibular Molars
Mentor: Evelina Kratunova, MDS, MFD, D.Ch.Dent., FFD
University of Illinois at Chicago Department of Pediatric Dentistry Chicago, IL

2005 – 2007 Light Spectroscopy of Natural Phenomena
Mentor: William Bickel, PhD
University of Arizona Department of Physics
Tucson, AZ

2003 - 2005 Conditioned Place Preference Study of the CB2 Cannabinoid Receptor-Selective Agonist AM1241
Mentor: Philip Malan, MD, PhD
University of Arizona Department of Anesthesiology and Pharmacology
Tucson, AZ

Honors and Awards:

2017 Clinic and Research Day Award - 1st place
2016 Dedication to Community Health Award
2013 GD4K Dental Provider of the Year Award
2011 Ann Tschirley Gunatillike Scholarship Award for excellence in the field of Dentistry
2003-2007 University of Arizona Full Academic Scholarship
2003-2007 Clara Abbott Foundation Scholarship

Affiliations:

2016 – Present Illinois Society for Pediatric Dentists (ISPD)
2016 – Present American Academy of Pediatric Dentistry (AAPD)
2007 – Present American Dental Association (ADA)
2007 – Present Chicago Dental Society (CDS)

Additional Language Proficiencies:

Gujarati