THE EFFECT OF OPERATOR AND SUBJECT GENDER ON INJECTION PAIN IN MAXILLARY ANTERIOR INFILTRATIONS

Thesis
Presented in Partial Fulfillment of the Requirements for
the Degree of Master of Science in the
Graduate School of The Ohio State University

By

Shayne Perry D.D.S.

Graduate Program in Dentistry

The Ohio State University
2013

Master’s Thesis Committee:
Melissa Drum D.D.S., M.S., Advisor
Al Reader D.D.S., M.S.
John Nusstein D.D.S., M.S
F. Michael Beck D.D.S., M.A.
ABSTRACT

The purpose of this randomized, double-blind investigation was to evaluate operator gender and its influence on subject gender pain in maxillary anterior infiltrations.

Two hundred subjects participated in this study. Each subject was seen at two appointments separated by at least 2 weeks. Each subject was randomly assigned to receive an injection over the right or left maxillary lateral incisor. At each appointment, each subject randomly received an initial injection of 2% lidocaine with 1:100,000 epinephrine by one of twenty, individually calibrated operators. At the second appointment, each subject received the same injection by a different operator of the opposite gender. Immediately after each injection, subjects rated pain of needle insertion, needle placement, and solution deposition on 170-mm visual analog scales. Dental anxiety was determined by each subject, at each appointment, using the Corah’s Dental Anxiety Scale.

No significant differences were detected between male or female participants on the Corah’s Dental Anxiety Scale. In addition, no significant differences were found for the needle insertion or needle placement phases of the injections. A significant difference
(p=0.0357) was only found during the solution deposition phase of the injection as female subjects reported higher pain scores when receiving injections from male operators.

In conclusion, gender did not have a statistically significant effect on injection pain for most phases of the maxillary infiltration injection. While gender did show a statistical difference for solution deposition pain, it was only when a male operator administered the injection to female subjects.
DEDICATION

To my loving wife Sherri who has been unconditionally supportive. I would not be where I am today without your help. I am lucky to have you.

To my wonderful children, Brielle and Jaxon, you have brought more joy into my life than you will ever know.

To my loving parents Lora and Lindsay, thank you for always encouraging me in all of my pursuits. Everything I am, I owe to you.

I love you all very much.
ACKNOWLEDGEMENTS

Dr. Drum – I would like to extend my sincerest thanks and appreciation for your tremendous dedication, effort, and patience along this difficult process. Your expertise, understanding, and passion for teaching were pivotal to my graduate experience. You are such an inspiration to me, and I could not have asked for a better advisor and mentor.

Dr. Reader – It has been my great honor to train under such a renowned individual in the field of endodontics. I feel so incredibly fortunate to have learned under one of the great minds of endodontics and local anesthesia. You are one of the funniest and smartest people I know. Thank you for your tireless drive in laying a foundation for us to succeed in our careers and life.

Dr. Nusstein – I am eternally grateful to have learned so much about endodontics and critical thinking from you. I owe a debt of gratitude to you for your time and careful attention to detail. Thank you for all your hard work, dedication, and sacrifice for your residents.

Dr. Beck – Your knowledge and instruction were extremely fundamental during this process. I am incredibly grateful for your hard work and meticulous contribution. Everything I know about statistics is thanks to you.

Brett, Emily, and Vivian – What a ride these last two years have been! You have all made this experience extremely enjoyable and I thank you for your friendships. I wish you all the best in your future endeavors.

A special thanks to everyone who sacrificed their time to give injections to innocent people for the good of research.
VITA

August 24th, 1981…………………………………..Born: Salt Lake City, Utah

June 2007……………………………………………Bachelor of Science,
Business Management
The University of Utah
Salt Lake City, Utah

June 2011……………………………………………Doctor of Dental Surgery,
The Ohio State University
College of Dentistry
Columbus, Ohio

August 2013………………………………………..Specialization in Endodontics
Post-Doctoral Certificate,
The Ohio State University
College of Dentistry,
Columbus, Ohio

FIELD OF STUDY

Major Field: Dentistry

Specialization: Endodontics
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstract</td>
<td>ii</td>
</tr>
<tr>
<td>Dedication</td>
<td>iv</td>
</tr>
<tr>
<td>Acknowledgments</td>
<td>v</td>
</tr>
<tr>
<td>Vita</td>
<td>vi</td>
</tr>
<tr>
<td>Table of Contents</td>
<td>vii</td>
</tr>
<tr>
<td>List of Tables</td>
<td>ix</td>
</tr>
<tr>
<td>List of Figures</td>
<td>xi</td>
</tr>
<tr>
<td>Chapters:</td>
<td></td>
</tr>
<tr>
<td>1. Introduction</td>
<td>1</td>
</tr>
<tr>
<td>2. Materials and Methods</td>
<td>39</td>
</tr>
<tr>
<td>3. Results</td>
<td>47</td>
</tr>
<tr>
<td>4. Discussion</td>
<td>52</td>
</tr>
<tr>
<td>5. Summary and Conclusions</td>
<td>99</td>
</tr>
<tr>
<td>List of References</td>
<td>101</td>
</tr>
<tr>
<td>Appendices:</td>
<td></td>
</tr>
<tr>
<td>A. Tables</td>
<td>111</td>
</tr>
<tr>
<td>B. Figures</td>
<td>128</td>
</tr>
<tr>
<td>C. Consent Form</td>
<td>131</td>
</tr>
<tr>
<td>D. Privacy Form</td>
<td>138</td>
</tr>
<tr>
<td>E. Medical History Form</td>
<td>143</td>
</tr>
</tbody>
</table>
F. Corah’s Dental Anxiety Scale .................................................. 146
G. Heft-Parker Visual Analog Scale ............................................. 148
H. Injection Pain Survey ............................................................... 150
I. Pain Coping Ability Survey ....................................................... 152
J. Operator Calibration Sheet ....................................................... 154
K. Subject Debriefing Script ......................................................... 157
## LIST OF TABLES

<table>
<thead>
<tr>
<th>Table</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Study Participants and Injection Side</td>
<td>112</td>
</tr>
<tr>
<td>2. Biographical Data</td>
<td>112</td>
</tr>
<tr>
<td>3. Operator Experience by Gender</td>
<td>113</td>
</tr>
<tr>
<td>4. Operator Experience Level by Gender</td>
<td>114</td>
</tr>
<tr>
<td>5. Groups by Gender of Subject and Operator</td>
<td>115</td>
</tr>
<tr>
<td>6. Corah’s Dental Anxiety Scale Ratings</td>
<td>116</td>
</tr>
<tr>
<td>7. Corah’s Dental Anxiety Scale Ratings by Category</td>
<td>117</td>
</tr>
<tr>
<td>8. Injection Sequence by Subject Gender</td>
<td>118</td>
</tr>
<tr>
<td>9. Between Group Comparisons for Operator and Subject Gender (VAS mm)</td>
<td>119</td>
</tr>
<tr>
<td>10. Pain Ratings by Injection Phase for Maxillary Infiltration Injection</td>
<td>121</td>
</tr>
<tr>
<td>11. Pain Ratings by Subject Gender, Operator Gender, and Injection Phase</td>
<td>122</td>
</tr>
<tr>
<td>12. Subject Injection Preference by Gender</td>
<td>123</td>
</tr>
<tr>
<td>13. Subject Injection Preference by Gender</td>
<td>124</td>
</tr>
<tr>
<td>14. Injection Preference by Subject Gender</td>
<td>125</td>
</tr>
<tr>
<td>15. Pain Coping Ability Score by Subject Gender</td>
<td>126</td>
</tr>
</tbody>
</table>
16. Pain Coping Ability Score by Subject Gender..............................127
## LIST OF FIGURES

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Overall Study Flowchart</td>
<td>129</td>
</tr>
<tr>
<td>2.</td>
<td>Injection Pain Ratings by Subject Gender, Operator Gender, and Injection Phase</td>
<td>130</td>
</tr>
</tbody>
</table>
CHAPTER 1

INTRODUCTION

A common phobia many people have is fear of the dentist. Fiset and co-authors (1) surveyed 1,019 residents of Seattle, WA and found that dental fear was repeatedly ranked as either the first or second most common fear, with a prevalence estimated between 183 and 226 persons per 1000. Their findings showed that more than 66% of people had a fear of going to the dentist since childhood. Dental fear was associated with fears of heights, flying, and enclosed spaces. They also found that patients who are afraid of the dentist reported that they are more likely to delay or cancel dental appointments, report a longer period since their last visit to the dentist, and report poorer oral health and less satisfaction with oral appearance. Results showed that females were 1.8 times more likely than males to report higher fear of the dentist.

Crafts-Barnes (2) and co-authors showed a link between dental anxiety, general anxiety, and quality of life. Twenty-four phobic and 19 non-phobic patients were compared using four different questionnaires over a six day period regarding anxiety, quality of life, and feelings toward dentistry. The experimental group showed higher total mean anxiety scores and a poorer quality of life when compared with the control group.
Samorodnitzky and Levin (3) studied dental anxiety at a military dental clinic. Dental anxiety questionnaires were administered to 393 young adults and voluntarily returned. The results showed that women reported higher levels of dental fear than males. They also concluded that anxious patients typically rate his/her own dental needs much higher than those with lower dental anxiety scores. This leads to the notion that those who fear the dentist also avoid dental treatment.

A large portion of patients consider dental treatment to be associated with pain and discomfort. Using a variety of questionnaires to analyze anxiety, pain, and discomfort with regard to dental treatment experience, Vassend (4) used questionnaires and interviews to assess people’s feelings on past dental experiences. Over 3500 people were used in the study and they found that between 20-30% of people rated their last dental treatment as moderately painful or worse, with a similar percentage expecting their next appointment to be at least moderately painful. It was also shown that approximately 60% of respondents reported having had at least one dental experience as very painful and 5-6% experienced dental treatment in general to be painful.

Fear of injection plays a major role in evaluating one’s fear of the dentist. However, other variables may also contribute. Vika et al. (5) compared the perceived fear, pain, and anxiety among a large sample (n=1385) of young adolescents when comparing dental and medical visits. The data was collected by using visual analog scales (VAS) to assess pain and anxiety questionnaires in a classroom setting. They found much higher mean VAS scores for dental injections than medical injections for fear, 22.6 ± 26.0 mm vs. 19.7 ± 27.0 mm; for pain, 24.7 ± 23.5 mm vs. 15.6 ± 21.5 mm; and for unpleasantness, 32.4 ± 27.5 mm vs. 21.0 ± 26.7 mm. The authors stated that the higher
VAS scores for dental injections, compared to typical medical injections, could be that dental injections are frequently used in settings where other painful procedures such as root canals and tooth extractions are being performed, while this is not usually the case with medical injections. This difference in pain could also be influenced by location of injection as most medical injections are administered in the arm or leg in comparison to dental injections administered intraorally. This same study also showed that females were significantly more frequently categorized in the high fear groups and reported higher frequencies of fainting, and near fainting, experiences compared with males.

Milgrom and coauthors (6) surveyed 350 University of Washington students and staff regarding avoidance of dental care and fear of dental injections. They found the most common reason for avoiding dental appointments was a general fear, including pain of injection, followed by a fear of bodily injury from injection. They also reported that patients who have high dental fear of dental injections have higher dental anxiety scores than those with low fear of injections.

**Maxillary Infiltration Injection Pain**

Most procedures performed by a dentist require an injection of local anesthetic. Injection pain has the possibility of causing anxiety for both the practitioner and patient alike. The pain associated with different types of injections in different areas of the mouth can be variable. Kaufman and co-authors (7) studied pain of injection in patients presenting for routine dental treatment. Two hundred forty-seven patients (90 males and 157 females) were given injections by either of two male dentists. They measured pain, pressure, and discomfort of 4 different local anesthetic injections. These injections were
as follows: local infiltration of maxillary and mandibular molars and incisors, mental nerve block, inferior alveolar nerve block, and mandibular molar and premolar periodontal ligament injections. Patients rated pain, discomfort, and pressure on a 100-mm visual analog scale (VAS) on needle insertion and pressure of injection. They found the inferior alveolar nerve block resulted in more discomfort than infiltration, PDL injection, and mental nerve block. No significant difference was found between subject age, subject gender, or the tooth being anesthetized (premolars, canines, incisors and molars). While local infiltration injections were found to be the least painful injections overall, local infiltration injections in the maxillary anterior region yielded the highest discomfort scores.

Aminabadi and co-authors (8) studied children’s pain reaction during several common injection techniques, namely maxillary and mandibular infiltration anesthesia, middle superior alveolar nerve block, posterior superior alveolar nerve block, greater palatine nerve block, nasopalatine nerve block, and inferior alveolar nerve block. Four hundred fifty-five children (242 boys and 213 girls) aged 5-6 years old were used in the study. All injections were given by a single pediatric dentist. The operator used a counterstimulation technique using the thumb to create vibration as a distraction technique for all injections. Patient’s responses were recorded by a second dentist using the sound, eye and motor (SEM) scale. The SEM scale is a test to assess children’s sounds, eye signs, and body movements on a scale from 1-4, with 1 showing the lowest pain response and 4 displaying the highest pain response for each of the categories. When the values for sounds, eye movement, and body movements are totaled, each patient rating is recorded as a single value ranging from 3-12, with 12 being the most painful.
The researchers found that maxillary anterior infiltrations had higher pain scores (median = 8) than inferior alveolar nerve blocks (median = 4), mandibular posterior infiltrations (median = 5), and mandibular anterior infiltrations (median = 6). Maxillary anterior local infiltrations injections were shown to be equally as painful as greater palatine nerve block injections (median = 8), with only the nasopalatine nerve blocks averaging higher pain scores (median = 10).

Meechan and co-authors (9) compared needle penetration pain in different parts of the palatal mucosa. Twenty-four patients received a needle insertion down to the periosteum in the palatal mucosa using a 27-gauge short needle and were asked to rate their pain using a 100 mm visual analogue scale (VAS). Their findings showed that infiltration was more uncomfortable in the anterior palate (46 ± 16 mm) than the posterior palate (28 ± 16 mm). It was also noted that although men could not make a distinction between new and previously used needles (24 ± 21 mm vs. 16 ± 13 mm) for a second buccal mucosal penetration, women reported a considerable increase in discomfort with previously used needles (29 ± 18 mm vs. 41 ± 23 mm).

Authors have previously studied injection pain for infiltration injections in the maxillary anterior. Nusstein et al. (10) studied injection pain along with the effects of topical anesthesia (20% benzocaine) on the pain of injection. Seven hundred sixteen patients were given maxillary anterior infiltration injections and instructed to rate their pain on a scale of 0-3, with 0 = no pain; 1 = mild pain (pain that was recognizable but not discomforting), 2 = moderate pain (pain that was discomforting but bearable), and 3 = severe pain (pain that caused considerable discomfort and was difficult to bear). They
found moderate-to-severe pain ratings for ranging from 18 % (using topical anesthetic) to 21% (no topical anesthetic) in the maxillary lateral incisor region.

**Pain for Needle Insertion**

Various studies have looked at pain experienced during maxillary infiltration injections during three separate phases of a typical local anesthetic injection. These three phases are: 1) needle insertion, which is the moment when the needle first penetrates mucosal tissue, 2) needle placement, which is the movement of the injection needle through mucosal tissue to the area where anesthetic will be injected, and 3) solution deposition, which is the actual administration of the local anesthetic to the intended injection site.

Gross (11) administered 1.8 mL of 2% lidocaine with 1:100,000 epinephrine and 1.8 mL of 0.5% bupivicaine with 1:100,000 epinephrine in human maxillary anterior infiltration injections given over the lateral incisor. Participants were given one of each injection spaced 1 week apart. In the study, some patients were given 0.2 mL of HurriCaine® topical anesthetic while others were given Vaseline® as a placebo. Afterwards, each patient was asked to rate the pain felt during needle insertion using the following scale: zero, indicating no pain; one, indicating mild pain which was recognizable but not discomforting; two, indicating moderate pain which was discomforting but bearable; and three, indicating severe pain which caused considerable discomfort and was difficult to bear. They found that, in maxillary lateral incisors, bupivacaine displayed a significantly lower anesthetic success rate of 78%, in contrast to a 97% success rate for lidocaine (12). The needle insertion pain ratings for both groups
(2% lidocaine and 0.5% bupivacaine) that received topical anesthetic, 59.5 % of participants reported zero-to-mild pain while 40.5% reported moderate-to-severe pain. In the placebo group, 39.0% of participants reported zero-to-mild pain while 61.0% reported moderate-to-severe pain. There was no significant difference found between the topical anesthetic and placebo groups.

In a similar study design to Gross (11), Mikesell (13) studied anesthetic efficacy of 1.8 mL and 3.6 mL of 2% lidocaine with 1:100,000 epinephrine for maxillary infiltration injections. Ninety-six patients (74 male and 22 female) received one of the two injections over the maxillary lateral incisor spaced 1 week apart. They found that while the anesthetic success for both volumes of anesthetic ranged from 97% to 100%, the 3.6 mL volume provided a statistically longer duration of pulpal anesthesia (14). For the topical anesthetic group, they found that 81% of participants reported zero-to-mild pain and 19% reported moderate pain. In the placebo group (Vaseline®), 66% of participants reported zero-to-mild pain while 34% reported moderate pain. No participants reported severe pain during needle insertion. There was no significant difference found between the topical anesthetic and placebo groups.

In a similar study design to Gross (11), and Mikesell (13), Mason (15) compared the analgesic efficacy of 2% lidocaine with 1:100,000 epinephrine, 2% lidocaine with 1:50,000 epinephrine, and 3% mepivacaine in maxillary lateral incisors and first molars. Their results showed slightly lower pain ratings than previous studies. Sixty participants received a maxillary lateral incisor and molar infiltration injection in a double-blind manner spaced at least 1 week apart. They found that the anesthetic success of pulpal anesthesia was not significantly different between 2% lidocaine with either 1:100,000 or
1:50,000 epinephrine, and 3% mepivacaine, for the lateral incisor (16). For both the placebo and topical anesthetic groups, they found that 97% of participants experienced zero-to-mild pain and 4% experienced moderate pain. No patients reported severe pain for needle insertion in any of the groups.

Katz (17) studied the anesthetic efficacy of 4% prilocaine with and without 1:200,000 epinephrine and 2% lidocaine with 1:100,000 epinephrine in maxillary lateral incisor buccal infiltrations. In addition to the 4-point injection pain scale previously described, patients were also asked to mark their pain on a 100-mm VAS. Anesthetic success was not significantly different between 2% lidocaine with 1:100,000 epinephrine, 4% prilocaine with 1:200,000 epinephrine, and 4% prilocaine for the lateral incisor and first molar (18). For both the placebo and topical anesthesia group, 93.3% reported zero-to-mild pain while 6.7% reported moderate pain. When neither placebo nor topical anesthesia was administered, 90.0% of patients reported no-to-mild pain while 10% reported moderate pain. No participants reported severe pain. The following mean values were reported for needle insertion pain using a 100 mm VAS: 6.5 mm for the topical group, 9.0 mm for the placebo group, and 3.5 mm for the placebo or topical group. In an effort to compare these results with those found in our studies, these VAS pain ratings would be equivalent to the approximate values on a 170 mm VAS scale: 11.0 mm for the topical group, 15.3 mm for the placebo group, and 6.0 mm for the placebo or topical group. No significant difference was found between the three groups.

Scott (19) also reported on maxillary anterior injection pain. Their study had 40 subjects, (28 men and 12 women) who were given repeated maxillary infiltration injections given in two separate appointments. At one of the appointments, they
administered an initial infiltration of 1.8 mL of 2% lidocaine with 1:100,000 epinephrine followed by an additional infiltration of the same anesthetic and dose given 30 minutes after the initial infiltration. At the other appointment, subjects received an initial infiltration of 1.8 mL of 2% lidocaine with 1:100,000 epinephrine followed by a mock repeated infiltration given 30 minutes after the initial infiltration. The focus of the study was pulpal anesthesia. The repeated infiltration improved pulpal anesthesia significantly in the maxillary lateral incisor from 37 to 90 minutes (20). Afterwards, each patient was asked to rate the pain felt during needle insertion using the following scale: zero, indicating no pain; one, indicating mild pain which was recognizable but not discomforting; two, indicating moderate pain which was discomforting but bearable; three, indicating severe pain which caused considerable discomfort and was difficult to bear. For the initial infiltration, they found that 78% of patients had no-to-mild pain and 22% reported moderate-to-severe pain for needle insertion pain.

Evans (21) studied the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine versus 2% lidocaine with 1:100,000 epinephrine in maxillary infiltrations. Forty adult patients (25 men and 15 women) were used in the study. All patients received 20% benzocaine for 60 seconds prior to each injection. Patients rated their pain on a 170-mm VAS after each injection. They found that articaine had a significantly higher anesthetic success rate (88%) when compared with that of lidocaine (62%) for maxillary lateral incisor infiltrations (22). They also found increased injection pain levels in the anterior versus the posterior maxilla with both lidocaine and articaine solutions. For needle insertion, the mean pain ratings were 24.0 ± 29.0 mm for the articaine group and
23.0 ± 24.0 mm for the lidocaine group. No significant difference was found between the groups.

Hobeich and co-authors (23) studied injection pain and anesthetic success of 2% lidocaine with 1:100,000 epinephrine buffered with 5% and 10% sodium bicarbonate in maxillary infiltrations. Thirty subjects (12 men and 18 women) received a single maxillary canine infiltration of 1.8 mL 2% lidocaine with 1:100,000 epinephrine or 2% lidocaine with 1:100,000 epinephrine buffered with 5% or 10% sodium bicarbonate. They studied injection pain for needle insertion and pain scores were recorded on a 170-mm VAS. Not only did the study find that buffering the anesthetic did not have a significant effect on anesthesia, it also did not have a statistically significant effect on injection pain. For the non-buffered anesthetic, 5% and 10% buffered solutions, needle insertion pain mean VAS values were 34.0 ± 24.0 mm, 40.0 ± 24.0 mm, and 40.0 ± 23.0 mm, respectively.

**Pain for Needle Placement**

Many studies only record needle insertion pain and solution deposition pain while ignoring needle placement pain in their studies. Several studies, however, have included this observation in their studies. Scott (19) reported on maxillary anterior injection pain. Their study had 40 subjects, (28 men and 12 women) who were given repeated maxillary infiltration injections in two separate appointments. At one of the appointments, they administered an initial infiltration of 1.8 mL of 2% lidocaine with 1:100,000 epinephrine followed by an additional infiltration of the same anesthetic and dose given 30 minutes after the initial infiltration. In the group where an initial infiltration injection followed by
a mock injection was given, they found that 70% of patients had zero-to-mild pain and 30% reported moderate-to-severe pain for needle placement pain. In the group where an initial infiltration injection followed by a lidocaine injection was given, 78% of patients had zero-to-mild pain and 22% reported moderate-to-severe pain for needle placement pain.

Evans (21) studied the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine versus 2% lidocaine with 1:100,000 epinephrine in maxillary infiltrations. They found increased injection pain levels in the anterior versus the posterior maxilla with both lidocaine and articaine solutions. For needle placement pain, the mean pain ratings were 26.0 ± 22.0 mm for the articaine group and 25.0 ± 23.0 mm for the lidocaine group. No significant difference was found between the groups.

**Pain for solution deposition**

Gross (11) administered 1.8 mL of 2% lidocaine with 1:100,000 epinephrine and 1.8 mL of 0.5% bupivicaine with 1:100,000 epinephrine in human maxillary anterior infiltration injections given over the lateral incisor. Participants were given one of each injection spaced 1 week apart. Afterwards, each participant was asked to rate the pain felt during solution deposition using the following scale: zero, indicating no pain; one, indicating mild pain which was recognizable but not discomforting; two, indicating moderate pain which was discomforting but bearable; three, indicating severe pain which caused considerable discomfort and was difficult to bear. Participants in the lidocaine group reported zero-to-mild pain 40% of the time while 60% reported moderate-to-severe pain.
Mikesell (13) studied anesthetic efficacy of 1.8 mL and 3.6 mL of 2% lidocaine with 1:100,000 epinephrine for maxillary infiltration injections. Ninety-six participants (74 male and 22 female) received one of the two injections over the maxillary lateral incisor spaced 1 week apart. In a similar study design to Gross (11), pain was reported on a 4-point scale. For the group receiving 3.6 mL of anesthetic, they found that 72% of participants reported zero-to-mild pain and 28% reported moderate-to-severe pain. For the group receiving 3.6mL of anesthetic, 63% of participants reported zero-to-mild pain while 37% reported moderate-to-severe pain.

Mason (15) compared the analgesic efficacy of 2% lidocaine with 1:100,000 epinephrine, 2% lidocaine with 1:50,000 epinephrine, and 3% mepivacaine in maxillary lateral incisors and first molars. Their results showed slightly lower pain ratings than previous studies. In a similar study design to Gross (11) and Mikesell (13), pain was reported on a 4-point scale. For the group receiving 2% lidocaine with 1:100,000 epinephrine, they found that 100% of participants experienced no-to-mild pain. For the group receiving 2% lidocaine with 1:50,000 epinephrine, they found that 93% of participants experienced no-to-mild pain and 7% experienced moderate pain. For the group receiving 3% mepivacaine, they found that 93% of participants experienced no-to-mild pain and 7% experienced moderate pain. No participants reported severe pain for solution deposition in any of the groups.

Katz (17) studied the anesthetic efficacy of 4% prilocaine with and without 1:200,000 epinephrine and 2% lidocaine with 1:100,000 epinephrine in maxillary lateral incisor buccal infiltration injections. In a similar study design to Gross (11), Mikesell (13), and Mason (15), pain was reported on a 4-point scale. Participants were also asked
to mark their pain on a 100-mm VAS. In the 4% prilocaine group, 100% reported no-to-mild pain. In the 4% prilocaine group with 1:200,000 epinephrine group, 100% reported no-to-mild pain. In the 2% lidocaine with 1:100,000 epinephrine group, 86.7% reported no-to-mild pain while 13.3% reported moderate-to-severe pain. No significant difference was found between the three groups.

Scott (19) also reported on maxillary anterior injection pain. Their study had 40 subjects, (28 men and 12 women) who were given repeated maxillary infiltration injections given at two separate appointments. At one of the appointments, they administered an initial infiltration of 1.8 mL of 2% lidocaine with 1:100,000 epinephrine followed by an additional infiltration of the same anesthetic and dose given 30 minutes after the initial infiltration. At the other appointment subjects received an initial infiltration of 1.8 mL of 2% lidocaine with 1:100,000 epinephrine followed by a mock repeated infiltration given 30 minutes after the initial infiltration. The focus of the study was pulpal anesthesia. Afterwards, each participant was asked to rate the pain felt during solution deposition using the following scale: zero, indicating no pain; one, indicating mild pain which was recognizable but not discomforting; two, indicating moderate pain which was discomforting but bearable; three, indicating severe pain which caused considerable discomfort and was difficult to bear. In the group where an infiltration initial injection followed by a mock injection was given, they found that 68% of participants had no-to-mild pain and 32% reported moderate-to-severe pain for solution deposition pain. In the group where an infiltration initial injection followed by a lidocaine injection was given, they found that 69% of participants had no-to-mild pain and 31% reported moderate-to-severe pain for solution deposition pain.
Evans (21) studied the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine versus 2% lidocaine with 1:100,000 epinephrine in maxillary infiltrations. Forty adult participants (25 men and 15 women) were used in the study. Participants rated their pain on a 170-mm VAS after each injection. For solution deposition pain, the mean pain ratings were 59.0 ± 33.0 mm for the articaine group and 51.0 ± 33.0 mm for the lidocaine group. No significant difference was found between the groups.

Hobeich and co-authors (23) studied injection pain and anesthetic success of 2% lidocaine with 1:100,000 epinephrine buffered with 5% and 10% sodium bicarbonate in maxillary infiltrations. Thirty subjects (12 men and 18 women) in their study received a single maxillary canine infiltration injection of 1.8 mL 2% lidocaine with 1:100,000 epinephrine, 2% lidocaine with 1:100,000 epinephrine buffered at 5% or 10% sodium bicarbonate. They studied injection pain for solution deposition pain which were recorded on a 100 mm VAS. All anesthetics were deposited over 60 seconds. Buffering the anesthetic did not have a significant effect on solution deposition pain. For the non-buffered anesthetic, 5% and 10% buffered solutions, solution deposition mean VAS values were 39.0 ± 24.0 mm, 45.0 ± 21.0 mm, and 42.0 ± 26.0 mm, respectively.

Counterstimulation and Anesthetic Volume

A counter stimulation (using finger vibration of oral tissue) is a common practice to help reduce pain and anxiety in dental patients. Aminabadi et al. (24) showed a decrease in pain felt among pediatric patients. Their study was based on a dentist’s response of pediatric patients receiving injections while the dentist performing the injection used counter stimulation using the thumb and having the patient raise the right
and left legs in order to aid in distraction efforts. Nanitsos and coauthors (25) found similar results using vibration of tissue in order to decrease the pain of local anesthetic administration. Patients were given either an inferior alveolar nerve block, maxillary infiltration, or mandibular infiltration injection, and asked to rate the pain of injection on a 100 mm VAS. On average, all injections types were found to be more painful when tissue vibration was not used (mean = 22.2 mm) vs. injections when tissue stimulation was used (mean = 12.9 mm).

**Injection Volume and Solution**

One important variable that could affect injection pain is the volume of anesthetic used in maxillary infiltration injections. Brunetto and co-authors (26) compared 3 different volumes of 2% lidocaine with 1:100,000 epinephrine in a double-blind, crossover study. Twenty five recruited volunteers (13 women and 12 men) received injections of 0.6, 0.9, and 1.2 mL deposited into the buccal sulcus in the upper lateral incisor, canine, and premolar regions. Pain scores were recorded on a 100-mm VAS. The 0.6 mL group had an average overall pain rating of 7.4 mm, the 0.9 mL group had an average of 7.4 mm, and the 1.2 mL group had an average VAS score of 7.3 mm. No significant difference in pain was experienced when each of the different volumes were used.

Different solutions of anesthetic could also play a role in pain felt during maxillary infiltrations. Kramp and colleagues (27) studied the efficacy of 4% prilocaine for minimizing pain of local anesthesia injections. One-hundred fifty adults were randomly injected with one of three solutions: 2% mepivacaine with 1:20,000
levonordefrin, 2% lidocaine with 1:100,000 epinephrine, and 4% prilocaine without vasoconstrictor. The following injections were administered: inferior alveolar nerve block, maxillary and mandibular premolar and molar buccal infiltrations, maxillary and mandibular incisor and canine labial infiltration, and molar and premolar palatal infiltrations. Participants were asked to rate the pain of injection felt on a VAS numbered 1-10, with 1= no pain on injection, and 10= severe sharp pain. For the labial infiltration group, the average pain score was 4.00 mm for 2% mepivacaine with levonordefrin, 2.31 mm for 2% lidocaine with epinephrine, and 2.65 mm for 4% prilocaine (plain). They found no significant difference with regard to injection site. They also found that while prilocaine resulted in less perceived pain than both lidocaine and mepivacaine, the difference was statistically insignificant.

Wahl and co-authors (28) compared the injection pain of bupivacaine with epinephrine and prilocaine plain. Their study consisted of 681 maxillary buccal infiltration and inferior alveolar nerve block injections administered by 2 separate dentists. Participants were asked to rate their pain on a scale from 0-5, with 5 being the most painful. Their results showed a lower injection pain of prilocaine plain in maxillary anterior infiltration injections (1.75 vs. 0.75), posterior maxillary infiltrations (1.59 vs. 0.64) and inferior alveolar nerve blocks (1.41 vs. 0.74). The differences were believed to be due to the difference in pH of the solutions as lidocaine with epinephrine and bupivacaine have pH’s of approximately 4.5 and 3.3-5.5, respectively, while prilocaine plain has a pH of 6.0-7.0. These studies only had participants rate injection pain after the injection was given and did not differentiate phases of the injection into needle insertion, placement and solution deposition.
Topical Anesthesia

Topical anesthesia is a commonly used method of decreasing the pain of injection. Numerous studies support the use of topical anesthetics in order to reduce perceived local anesthetic injection pain (29-31), while others have shown minimal efficacy (32, 33).

Nusstein and Beck (10) studied the effectiveness of 20% benzocaine on 2336 injections on a total of 1080 adult patients. Their results showed that topical anesthesia using (20%) benzocaine significantly increased the odds of patients experiencing no needle insertion pain during maxillary anterior infiltration injections. Rosivack and co-authors (29) investigated the effectiveness of both 20% benzocaine and 5% lidocaine on 60 adult volunteers. Their results indicated that both anesthetics were able to significantly reduce pain caused by needle insertion when compared to placebo, although the difference between the two topical anesthetics was insignificant. Hutchins and coauthors (31) had similar findings when testing the effect 20% benzocaine used before maxillary buccal premolar injections. They also showed that while cheek vibration alone did not significantly lower injection pain values, lowest pain values were experienced using the cheek vibration method along with topical anesthesia.

Martin and co-authors (32) conducted a placebo study regarding topical anesthesia. Thirty-three male subjects and 31 female subjects were told they were going to receive either a placebo or active topical anesthetic. Participants rated his/her pain on a 100-mm VAS. In reality, all participants received a placebo injection and a topical anesthetic injection. Results found a placebo effect in that subjects who believed they
were receiving topical anesthetic reported less pain (22.8 ± 17.5 mm) than those who thought they were receiving a placebo (33.1 ± 20.4 mm).

Other studies have not found topical anesthetic to be of clinical significance. Parirokh et al. (33) studied the effect of topical anesthesia used before giving one cartridge of 3% prilocaine for maxillary central incisor buccal infiltration. Twenty-five people participated in their double-blind study. Each subject received two injections in 2 separate appointments during a period of 2 weeks. At one appointment, the participant would receive a topical anesthetic using 20% benzocaine. At the other appointment, a placebo was used for the topical anesthetic which was a topical gel with the same appearance, smell, and color. The mean pain scores during needle insertion after using topical anesthetic and placebo were 1.5 ± 0.8 and 1.6 ± 0.8, respectively. Participants were asked to rate their pain as follows: 0, no pain; 1-3, mild pain; 7-9, severe pain. They recorded pain for both needle penetration and anesthetic deposition. The mean scores for solution deposition pain after using topical anesthesia and placebo were 1.6 ± 0.8 and 1.4 ± 0.6, respectively. They did not find a significant difference regarding pain of needle penetration or anesthetic injection.

**Anxiety and Pain**

Anxiety and pain have been shown to have a clinical correlation. Van Wijk and Hoogstraten (34) studied the relationship between anxiety felt in the dental setting and pain felt during anesthetic injection. Two hundred fifty two patients (115 males and 137 females) in a dental setting were instructed to rate their anxiety on a scale of 1-10 (0=not anxious to 10=extremely anxious) prior to a dental procedure. Patients were subsequently
asked to raise their hand when feeling pain as result of the injection, continue raising their hand as long as they felt pain, and to lower the hand as soon as the pain was gone. While the study did give varying amounts and types of local anesthetic in different areas of the mouth, a significant difference was determined. Results showed that anxious patients feel more pain and of longer duration than less anxious patients. They also showed that fear of dental pain was the best predictor for duration of pain. This was shown using a fear of dental pain questionnaire where patients were asked to rate 5 items related to pain on a 5-point scale ranging from 1 (no fear at all), to 5 (extreme fear). They also showed that dental anxiety was the best predictor of intensity of pain as patients with higher dental anxiety scores reported a higher pain intensity score on the Numerical Rating Scale (NRS) ranging from 0 (no pain) to 10 (worst pain possible).

Other studies have shown a link in pain experienced and pretreatment anxiety. Ulusoy and coauthors (35) surveyed patients undergoing extraction or root canal treatment and asked them to rate anxiety and pain after treatment. Patients rated their fear using a Corah’s Dental Anxiety Scale where they rated their fear in four dental situations on a five-point scale. They also rated pain experienced using the Pain Experience Scale (PES) which determines pain on a four-point scale. A (PES) was measured on a 120-mm scale ranging from 0 (no pain) to 120 (worst pain imaginable). While many patients reported that they felt less pain than they had anticipated, patients who reported higher anxiety scores before treatment experienced more pain (70.4 ± 17.0 mm) than those with lower dental anxiety scores (40.5 ± 21.39 mm).

Crofts-Barnes and coauthors (2) studied the quality of life of 43 patients leading up to their individual dental appointments. Patients took a Corah’s Dental Anxiety Scale
questionnaire, Minor Symptom Evaluation Profile questionnaire, and a Psychological General Well-being Scale during the pre-operative period before their dental exam. They found that patients who report high levels of anxiety during dental visits also experienced a significantly lower quality of life leading up to a dental appointment than those who are less anxious. Altering anxiety levels may be an important adjunct in lowering pain thresholds for patients.

**Injection Sequence/Order Effect**

One important aspect to consider when patients and/or research participants receive injections at multiple appointments is a phenomena called “order effect”. This refers to the idea that a patient’s pain perception may be influenced by the effect that the order of injection has on pain. Bartfield and co-authors (36) have found contrasting results that order effect has on injection pain. In one study, 91 adult patients with simple linear lacerations were injected with either buffered or plain lidocaine. In one group, the first wound edge was injected with the buffered anesthetic while the second wound edge was injected with the non-buffered anesthetic. In another group, the first wound edge was injected with the non-buffered anesthetic while the second wound edge was injected with the buffered anesthetic. Their results found that the second injection was significantly less painful than the first injection for both groups. The authors concluded the difference in pain scores “was attributed to either a diffusion of local anesthetic from one wound wedge to the other, or to patients feeling more comfortable and less anxious if pain felt was less than had been previously perceived before the first injection.”
Other studies have found results opposite to those found by Bartfield and co-authors (36). A similar study comparing buffered and non-buffered local anesthetic injections in wound edges was done by Orlinsky and coauthors (37). They found that patients preferred the first injection to the second injection, regardless of the anesthetic used. They attributed this to the fact that, “Such a psychological reaction might be explained by the difference in the expectation of pain and the actual level of pain produced by the stimulus. If the patient was told that the injection would be painful or if the patient did not know what to expect, the patient’s anticipation of pain would usually be heightened and the actual pain produced by the stimulus relatively diminished. On the second injection, however, the patient has already experienced the pain and the anticipation of pain would be very close to what would actually happen.”

In a separate study done by Bartfield’s group (38) participants received a 0.5 mL intradermal injection in each forearm and were told the injection would be lidocaine with or without a buffering agent, to which they would be blinded. In reality, all patients received buffered lidocaine for both injections. Their results found that the second injection was significantly more painful than the first. Fitton (39) found similar results when comparing injection. Pain scores were significantly lower for the initial injection in comparison to the second. It is difficult to determine the effect injection sequence has on pain perception. Several other studies (40-44) have failed to find a significant difference between pain experienced during first or second injections among patients.
Speed of Injection

Several studies have studied the effect rate of injection have on pain and anxiety. Hochman and coauthors (45) studied the interstitial tissue pressure associated with several injections (intraligamentary or PDL, palatal, anterior middle superior alveolar nerve block, and IAN block). Interstitial tissue pressure varied greatly depending on the site of injection (mean psi values ranging from 9.76 for an IAN block to 293.92 psi for the PDL injection). Studies have shown a significant correlation between intensity of pain and injection pressure. Kudo et al. (46) studied injection pain based on lower canine injection pain using 2% lidocaine with 1:80,000 epinephrine. The anesthetic was injected submucosally at a speed of either 30 or 160 mL/sec. Injection pressure was measured using an invasive sphygmomanometer and analytic software. Participants subsequently filled out a 100-mm VAS and a standard faces anxiety scale. They found a significant correlation between injection pressure and pain (p<0.05). The authors recommend giving injections at a slower rate in order to decrease injection pressure and pain.

Kanaa and co-authors (47) confirmed these results when comparing injection speeds in inferior alveolar nerve blocks. Not only were inferior alveolar nerve blocks more successful when administered slowly (60 seconds vs. 15 seconds), injections were found to be much more painful when given at a faster rate. Injection pain was recorded on a 100-mm VAS. Participants recorded an average of 20.9 mm when the injection was given slowly vs. 30.5 mm when it was given rapidly.

Scarfone et al. (48) studied injection pain between buffered and non-buffered 1% lidocaine. Each participant’s pain was rated on a 100-mm visual analog scale comparing rapid (5 seconds) vs. slow (30 seconds) injections. They found that participants who
received slower injections had significantly lower pain scores than those who received faster injections with and without the presence of a buffer. Other authors who have also concluded that speed of injection plays a significant role in pain felt during anesthetic injections (49, 50).

**Gender influences on Anxiety and Pain**

It is a common belief that gender may play a role in anxiety and perception of pain. Many conditions have been shown to be much more prevalent in women including migraine headaches (51), irritable bowel syndrome (52), and fibromyalgia (53) while others such as cluster headaches (54) are more prevalent among males. Ruau et al. (55) conducted a cohort study that compared sex differences found in electronic medical charts of 11,000 patients and 47 diagnoses. Data collected consisted of reported pain scores in various disorders including musculoskeletal, circulatory, respiratory, and digestive systems. They found that on average, women scored higher than men in the majority of categories. In fact, several diagnostic sections exhibited greater than 20% higher pain level experienced by women compared to men.

One study compared sex differences in dental and orofacial pain. Orofacial pain is a common problem in dentistry ranging from mouth sores to jaw pain. In a Florida dental care study, Riley and Gilbert (56) recruited 724 participants to take part in a standardized telephone interview. They were asked to rate pain prevalence of jaw joint pain, face pain, toothache pain, painful mouth sores, and burning mouth. Females reported a higher prevalence in each of these categories except burning mouth, which did not show a statistical difference. This could be due to the relatively small sample size as burning
mouth was only reported by 1.6% of the respondents, the lowest reported of the 5 categories.

In a study evaluating anticipated and experienced pain associated with endodontic therapy, females were shown to anticipate greater pain and unpleasantness than males (57). Two hundred three females and 130 males evaluated his/her pain before and after treatment of scheduled root canals using a 100-mm VAS. All of the dentists in the study were endodontic faculty members or residents. All participants filled out a VAS before and after the treatment. The pre-treatment VAS asked the subject to rate the pain they anticipated having prior to the dental appointment while the post-treatment VAS asked how painful the procedure actually was. They found that females anticipated much greater pain preceding the appointment. They also reported higher experienced pain scores, although these findings were not statistically significant. Segura-Egea (58) also studied the role gender plays in pain felt during root canal treatment. One hundred and seventy-six patients (68 men and 108 women) completed a 100-mm visual analog scale after root canal treatment. Teeth of all pulpal and periodontal diagnoses were used. They did not find a significant difference in average pain scores felt between men and women. They did however find that men were much more likely to report “zero” pain than women, while women were more likely to report slight-moderate pain than men. In a related study that determined the prevalence of persistent pain after endodontic treatment, Polycarpou et al. (59) found gender to be an important factor in reporting pain prevalence. One hundred and seventy-five patients who received surgical or non-surgical endodontic therapy participated in the study. Patients were asked whether or not they had pain at a recall appointment of 12-59 months after treatment. The results were as follows,
“Among patients (N=103) with complete healing after endodontic treatment, women (18/21) were more likely to report pain at follow-up (12-59 months post-tx) than men (3/21).”

Ryan et al. (60) studied sex differences in analgesia in endodontic pain. Forty-eight patients who had a pulpal diagnosis of irreversible pulpitis or pulpal necrosis, with a periradicular diagnosis of normal, acute, or chronic periradicular periodontitis were used in the study. Patients were given placebo, ibuprofen 600 mg, or pentazocine 50 mg/0.5 mg naloxone in a randomized, double-blinded study. Following endodontic treatment, patients took their assigned medication every 6 hours for 24 hours and recorded their degrees of discomfort on a 100-mm visual analog scale. Females who took the pentazocine/naloxone medication experienced significantly greater analgesia than did their male counterparts while analgesia from placebo was relatively the same.

In a Norwegian study, Eggen (61) showed that women report using analgesic medication more frequently than men. In a cross-sectional survey of 19,137 men and women aged 12-56 years of the general population in Norway, 28% of women had used analgesics as opposed to just 13% of men. It was noted that while analgesic use during menstruation was a strong predictor in the 15-24 year age group. Depression was the most significant predictor in women overall.

Morin and co-authors (62) studied post-op pain after titanium implant placement in the anterior mandible. Forty-eight edentulous subjects (27 female and 21 male) received two implants in the anterior mandible under local anesthesia. Afterwards they were asked to complete a Pain Rating Index (PRI) which evaluates pain scores in four categories (sensory, affective, evaluative, and miscellaneous). They were also asked to
complete a pain diary to be filled out 3 times a day for 14 days. They found that women have much higher PRI values for each of the categories than males. Women also reported more intense post-surgical pain than males. It was noted that men reported a higher disturbance of a specific type of pain, namely low levels of pain that lasts several days.

Hittner and Hemmo (63) conducted a study on the psychosocial predictors of dental anxiety and made a few important conclusions using dental anxiety scales. Forty-eight males and 96 females, of which 89 were recruited from the waiting room of a dental practice and 55 were college undergraduate students, participated in the study. Participants were asked to feel out several questionnaires, one of which was a Modified Dental Anxiety Scale (MDAS) which is a revised version of the Corah’s Dental Anxiety Scale that adds an extra question about local anesthesia injections. Dental anxiety was linked to several variables including increased age, reduced income, and female gender. The dental anxiety experienced by females was significantly higher than males (p=.033).

Liddel and Locker (64) conducted a study on how men and women typically feel regarding dental visits. Questionnaires were sent to randomly selected subjects selected from the voters’ list in Toronto, Canada. Two thousand six hundred nine respondents (1481 women and 1128 men) whose survey had sufficient information were used in the study. The average age of respondents was 48.7 years for women and 48.7 years for men. Each participant filled out two surveys: 1) Corah’s Dental Anxiety Scale questionnaire, and 2) The Pain Anxiety Symptoms Scale (PASS) which is used to measure avoidance of pain, acceptance of pain, and fear of pain using 10 self-analyzing questions. For the Corah’s Dental Anxiety Scale, they found that women were significantly more anxious
than men and that dental anxiety increased significantly with age. The results were as follows; 1) Age <50, Male: 8.03 vs. 8.91 female 50-64, 2) Age 50-64: 7.72 male vs. 8.95 female, and 3) 6.66 male vs. 8.15 female. The results for the PASS questionnaire showed a significant overall gender difference with women being more affected by pain than men at all ages. Their results showed that women were generally more anxious in the dental setting than men (p<0.001). As stated by the authors, “In other words, women said they try to avoid pain more than men, accept it less and fear it more than men.” It was also noted that men and women did not differ in their reports of past painful dental experiences. This leads to the notion that gender differences in dental anxiety are likely due to differences in the perception and meaning of the painful experiences.

Several studies have shown strong evidence that men and women have very different abilities to tolerate pain. Dougher and Glodstein (65) studied focal pressure pain as it relates to gender. Eighty participants (40 male and 40 female) were used in the study. A focal pain stimulator was applied to the phalanx of the participants’ fingers until a throbbing pain was produced. Participants were asked every five seconds to report their sensations by giving a number on a 7 point rating scale (1=slight pressure, 2=moderate pressure, 3=slight discomfort, 4=moderate discomfort, 5=slight pain, 6=moderate pain, 7=pain tolerance). Women were shown to have a statistically significant lower pain threshold (time taken to report a “5”) and lower pain threshold (time taken to report a “7) when compared to men.

Clark and Goodman (66) showed similar results using a 100-watt projector bulb as a radiant heat stimulus. A radiant-heat stimuli housing a 100-watt projector bulb was applied to the forearm skin of 40 paid college students (equal male/female). Participants
were then asked to rate their pain using a thermal experience scale ranging from no stimulus felt to very painful and withdrawal. The results showed that women had higher pain ratings and a lower pain tolerance (p<0.001).

In a study conducted by Woodrow and co-authors (67), pain tolerance was conducted by applying mechanical pressure on the Achilles tendon. This test was included in the routine health examination of 41,119 subjects. The participant placed his/her heel on the floor with the Achilles tendon positioned between two motor-driven rods. The subject was then given the following set of instructions, “This is a pressure tolerance test. This test is to determine the amount of pressure which you can take on your ankle tendon. I will increase the pressure and stop it as soon as you tell me to. The test cannot injury you in any way. Try to stand it as long as you can”. They found both age and gender to play major roles in pain tolerance. Pain tolerance decreased with increasing age (range from ~18-80) for both genders. Also, men tolerated pain more than women. In fact, even the oldest men (70+) had a higher average pain tolerance than the youngest women (<20). Men had a mean tolerance nearly double that of women (28.7 psi for men vs. 15.9 psi for women). It should be noted that societal norms and expectations may have played a role considering this study was done in 1966.

Kindler et al. (68) studied thermal sensitivity in patients with chronic lower back pain. Fifty nine subjects (24 women, 35 men) seeking operative treatment for shoulder pain participated in the study. Each participant completed a self-report questionnaire to assess clinical pain and underwent a series of experimental pain tests consisting of pressure and thermal pain. The thermal pain threshold was determined by applying a computer controlled Medoc Neurosensory Analyzer to the uninvolved volar forearms.
Temperature was increased at a rate of 0.5ºC per second until the patient reported their first sensation of pain (threshold). Tolerance was determined by having subjects say “stop” when the pain became intolerable. Their findings showed that women had greater clinical pain (p=0.005), experienced a lower pain tolerance (p<.001), and had lower pain thresholds (p<.001) when compared to their male counterparts.

Robinson and coauthors (69) reported similar pain tolerance findings using heat stimulation. Sixty-seven subjects (30 women, 37 men) were asked to rate pain based on temporal summation of heat pulse stimulus. A contact thermode was applied to the thenar surface of the right hand using a computer-controlled thermal sensory analyzer. Each pulsed was applied from a baseline temperature of 39ºC with a peak temperature of 51ºC. Subjects were then asked to record pain intensity ratings on a 100-mm VAS. Results showed that women reported a statistically higher average pain intensity (p<0.05) in pain rating than men.

Several studies have shown women to report more pain than men (70). Five hundred forty-three subjects participated in the study. They were classified into four major ancestral groups: Asian (N=96), African American (N=65), European (N=296), and Latino (N=88). Of the 543 participants, 301 were women and 242 were men. Patients rated their pain using a 100-mm VAS following the extraction of at least two third molars, one of which had to be bony impacted. Overall, gender played a significant role in reporting pain following third molar extractions. The average VAS scores were as follows; Asian men 32.5 mm vs. Asian women 44.5 mm. African American men 46.8 mm vs. African American women 50.1 mm, European men 27.2 mm vs. European
women 34.3 mm, and Latino men 31.7 mm vs. women 48.5 mm. Overall, men reported less pain than women regardless of ethnic background.

Von Korff and co-authors (71) conducted a pain report studying the prevalence of chronic pain. Questionnaires were completed by 1016 adult enrollees of the Group Cooperative Maintenance Organization in western Washington. Patients were asked a set of questions about the frequency of pain as it relates to headaches, abdominal pain, and temporomandibular disorder pain over a 6 month period. Nearly two-thirds of people with recurrent pain were female (63.9%) and nearly three-fourths of respondents with severe persistent pain disability days due to pain were female (72.2%).

Many anxiety and pain scales have been used in dentistry, with the Corah’s Dental Anxiety Scale being the most widely used questionnaire that measures anxiety (72). Self-reporting pain and anxiety appears to differ between men and women. Heaton and coauthors (73) studied dental fear and general anxiety before dental treatment. One hundred eight adult patients (58 women and 50 men) seeking treatment at the graduate periodontology clinic at the University of Kentucky College of Dentistry participated in the study. Each patient filled out a five-item modification of Corah’s Anxiety Scale along with the Gatchel’s Scale (a 10-point single-item dental anxiety scale). Overall, women reported more anxiety on both dental anxiety scales than men (p<0.05). The study also consisted of providing dentists’ observations of patient behavior during each dental procedure. Each dentist would rate his/her patient’s anxiety using a 100-mm visual anxiety scale in 10 different behavior categories as they related to anxiety. Among these behaviors were perspiration, showing muscle tension, increased respiration rate, trembling/shaking, showing facial signs of anxiety (such as the patient become flushed or
pale), showing vocal signs (yelling, crying), informing the dentist of anxiety, asking questions regarding the nature or need of treatment, and interrupting treatment. Of the 10 categories, women rated higher than men in 8 of them. The highest discrepancy of the 10 categories were the number of women who informed the dentist that she was nervous, anxious or scared (21.3 for women vs. 14.2 for men). It was also noted that previous dental experience, specific treatment scheduled for that day, or the treating physician did not significantly alter anxiety perception as there was not a significant difference in pain scores between among the dentists. Unfortunately, anxiety ratings for patients were not analyzed according to dentist gender. Since both male and female dentists were used in the study, it would have been interesting to see if operator gender played a role in perceived patient anxiety.

Blitz and Dinnerstein (74) studied the effects of how males and females respond to experimentally induced pain. A cold pressor pain test was used by having participants place their hand in ice water and fill out appropriate pain rating scales. Thirty-six people (18 male and 18 female) participated in the study. The temperature measured before each trial was maintained at 0.5°C. Participants would first place his/her hand in a warm water bath of 35°C for 2 minutes and then immediately switch to the cold water bath. Each participant did this twice with a different set of instructions each time. The first time they were asked to tolerate the pain as long as they could while the second time they were to imagine it was a very hot day in attempt to make the feeling as “pleasant” as possible. The results of the study showed that males have a significantly higher tolerance for cold presser pain regardless of the scenario.
Keogh et al. (75) also studied the effects on how males and females respond to experimentally induced pain. One hundred students (50 female, 50 male) were recruited from the University of London. A cold pressor pain test was used by having participants place their hand in ice water, followed by reporting pain using the McGill Pain Questionnaire. Participants were instructed to their non-dominant hand in a warm water bath (37°C) followed by the immediate transfer in to an ice-water bath that was maintained at 3°C. Participants were instructed to indicate at what point they felt pain (pain tolerance) and at what point they could no longer tolerate the pain (pain threshold). The results of the study showed that males have significantly higher pain tolerance levels than females (93.6 seconds for males vs. 65.5 seconds for females). Men also had a higher pain threshold (26.2 seconds) when compared to women (16.8 seconds).

Pain tolerance between genders has also been compared by various studies. Wittmer et al. (76) showed that women had significantly lower warmth detection thresholds, thermal pain thresholds, and thermal pain tolerances than males. Thirty-three patients with lower back pain reporting for a pain rehabilitation program in Jacksonville, Florida were used in the study. This study consisted of two parts. First, the participants’ arms were hooked up to a continuous heat stimulus. The stimulus started at 35°C and increased at a rate of 0.05°C/second. This process continued until the subject indicated that his/her pain threshold had been met. Male participants had a statistically higher threshold than did their female counterparts (mean 49.4 vs. 45.7). Second, subjects were administered 10 consecutive heat impulses of <1 second of 0.33 Hz. The temperature of the heat impulses fluctuated between 35°C and 47°C and patients were asked to rate their pain using a 100-mm VAS. Women with chronic lower back pain showed a significantly
greater temporal summation in response to thermal stimuli than men (p<0.013). It was also noted by the authors that the mechanisms underlying sex differences in the experimental pain response have yet to be established, but suggested that a variety of factors may contribute, including hormonal alteration, resting blood pressure and psychological factors.

One explanation as to why a discrepancy in pain tolerance exists between men and women is a result of social expectations. This reasoning suggests men are expected to behave in a more “stoic” manner (66). Otto and Dougher (77) studied traditional masculine beliefs and their correlation with higher pain threshold and tolerance when compared to women. Eighty undergraduate volunteers (40 male, 40 female) from an introductory psychology class at the University of New Mexico participated in the study. Two male and two female students in an advanced psychology were the experimenters. All subjects completed a Bern Sex-role Inventory Higher scores on measures of masculinity which is a sex-role inventory questionnaire designed to characterize a person as masculine, feminine, or “androgynous”. The scale is based on a 7-point scale on how each of 60 masculine, feminine, and neutral personality traits describes one’s self (78). After the Bern sex-role inventory scale was completed, subjects were asked to place the middle finger of their non-dominant hand in a focal pain simulator consisting of a dull Lucite edge weight with a continuous pressure of 640 gm. The device produces a dull pain that gradually increases in intensity. The results of the study yielded two important conclusions. The first conclusion regarding the effect of the experimenters’ sex was stated as follows’ “Analysis of factorial design, crossing experimenters’ sex with subjects’ sex, with 20 subjects in each of the four cells yielded a significant effect for
subjects’ sex but no main effect or interaction for experimenter’s’ sex. Therefore, the experimenter’s’ sex was ignored for subsequent analysis.” The results showed that men scored much higher on the “masculinity” portion of the Bern Sex-role Inventory scale as women scored much higher on the “feminity” portion. In addition, the male subjects displayed a much higher pain threshold (64.1 seconds for men vs. 32.5 seconds for women) and overall pain tolerance (172.6 seconds for men vs. 98.9 seconds for women) when compared to their female counterparts.

Due to the fact that many studies use questionnaires to assess dental pain, some researchers have looked at tendencies in survey response rates among genders. In an online survey designed to compare demographic data among respondents (79), gender trends of respondents was compared. They examined university faculty members of a large research university with a full-time faculty of approximately 1000. This population was selected for examination since they were comparable in parameters such as, “education level, internet access, geographic location, occupation, and income.” They found that female faculty members were much more likely to respond to questionnaires than their male counterparts.

The evidence that women are more likely to respond to surveys and questionnaires was supported in a separate study done by Sax and co-authors (80). A large number of college students (4,416) at 14 institutions nationwide compared response rates for paper and web-based surveys. The two surveys administered were the 2000 Cooperative Institutional Research Program (CIRP) Freshman Survey and the 2001 Your First College Year (YFCY) survey. They found that response rates were higher among
women for both written surveys (26.6%, vs. 13.4% among men) and web-based surveys (24.6% and 12.3%).

Robinson et al. (81) conducted an analysis regarding sex differences in expectations of pain. Participants consisted of 156 male and 235 females who were asked to complete the Gender Role Expectations of Pain questionnaire which is used to measure sex-related stereotypic attributions of pain sensitivity, endurance, and willingness to report pain. Women rated men as having greater endurance, less willingness to report pain, and slightly less sensitivity to pain. In contrast, men rated women as having less endurance and more willingness to report pain. The majority of men (65.7%) rated their own endurance as higher than the typical pain, lending to the notion that many men often try and live up to a societal “stoic” expectation. These reports concluded that men are expected by both sexes to have higher pain endurance and lower pain sensitivity than women.

It has been hypothesized that biological mechanisms may play a role in explaining the gender pain disparity. The monoamine neurotransmitter serotonin (5HT) is a vasoactive mediator that causes vasoconstriction and is present in nerve terminals, endothelial cells, and platelets (82). It has also been shown to be a nociceptive mediator that has the ability to evoke hyperalgesia when injected in to human tissues (83). Fehrenbacher and co-authors (84) studied Capsaicin-evoked Calcitonin gene related peptide (CGRP) release from the human dental pulp. This study evaluated the responsiveness of isolated human nociceptors by measuring stimulated release of neuropeptides from collected dental pulp biopsies. They found that gender did not play a role in the amount of CGRP released from human dental pulp. However, gender did play
a role on the inhibitory effect of DAMGO (D-Ala2, N-MePhe4, Gly-ol-enkephalin), a synthetic opioid peptide used in experimental settings for the possibility of reducing opiate tolerance for patients under the treatment of opioids. DAMGO, in the presence of prostaglandin E2 (PGE2), had a greater ability to reduce the CGRP in male human dental pulps when compared with female human dental pulps. These results suggest a biologic mechanism in which men may have higher pain thresholds than women.

Lloyd et al. (85) studied the role gender played when comparing capsaicin and serotonin pain pathways. Pulpal tissue was collected from 140 extracted molar teeth from men and women. These pulps were treated with 5HT and capsaicin followed by quantification using an enzyme immunoassay. Capsaicin alone was shown to evoke concentration-dependent CGRP release from the dental pulp. Serotonin, however, enhanced capsaicin-stimulated CGRP release from the female but not the male human dental pulp. This difference was believed to be due to a sexually dimorphic effect of the effect serotonin has on CGRP concentrations or the level of capsaicin receptors transient receptor potential cation channel subfamily V member 1 (TrpV1). It was also noted that serotonin-enhanced CGRP release was lowest in the female dental pulp in the week during menses (days 1-7) but highest in the week before menses (days 22-28). This evidence suggests certain hormone and pain pathways may play a key role in the difference in pain sensitivity among genders.

Fillingim et al. (86) observed pain sensitivity among females during different phases of the menstrual cycle. Female participants were instructed to respond to thermal pain onset and thermal pain tolerance using a thermal probe to the left volar. They were also asked to rate ischemic arm pain using a blood pressure cuff used as a tourniquet.
Their findings showed that while thermal pain sensitivity did not vary across the menstrual cycle, ischemic pain did show a significant difference. Ischemic pain tolerance was marginally higher during the ovulatory phase and significantly higher when compared to the mid-to-late luteal phase.

One interesting aspect of studying gender, as it relates to pain and anxiety, is the relationship between gender interaction of patients and dentist. Wahl et al. (87) showed a difference in injection pain when using prilocaine plain vs. articaine with 1:100,000 epinephrine, lidocaine with 1:100,000 epinephrine, and mepivacaine plain. Their double-blind study involved 1,391 adult patients who received injections from one of the four aforementioned anesthetics via a maxillary buccal infiltration, palatal infiltration, or inferior alveolar block injection from one of 2 dentists (one female and one male). Patients reported his/her pain using a 10-point scale, with “1” indicating no pain and “10” indicating unbearable pain. It was shown that male patients reported more pain to the male dentist than the female dentist, whereas female patients reported more pain to the female dentists than to the male dentists. While gender could have played an important role in determining the outcome of this study, it should be noted that there were only two dentists administering injections. Since neither dentist was calibrated to use the same injection technique or say the same thing to each patient, operator personality and technique may have played a role in the observed outcome.

Levine and De Simone (88) also found that the sex of the experimenter had a differential effect on the degree of pain reported by male and female participants in a cold presser study. Male participants reported significantly lower pain levels to a female than a male. Female participants reported higher levels of pain to a male experimenter than a
female but the difference was not statistically significant. This result is hypothesized to be a result of a societal gender role requirement of men wanting to appear “macho”, according to the study.

It would be important to determine the influence gender plays on perceived pain from one of the most painful injections in dentistry. It is also important to add to the literature the pain felt from maxillary infiltration injections using 2% lidocaine with 1:100,000 epinephrine. The purpose of this prospective study was to compare pain and anxiety experienced by participants of each gender when receiving a maxillary infiltration injection, and if the operators’ gender is influential in this perceived pain.
CHAPTER 2

MATERIALS AND METHODS

Two hundred adult subjects, 100 male and 100 female, participated in this study. All subjects were in good health (ASA classification I or II), and not taking any medication that would alter pain perception (non-steroidal anti-inflammatory drugs, opioids, alcohol) as determined by a written health history (Appendix E) and oral questioning. Criteria for exclusion were as follows: younger than 18 years of age, allergies to local anesthetics or sulfites; pregnant or nursing; history of significant medical conditions (ASA classification of III or higher); taking any medications which may affect pain assessment (NSAIDs, opioids, alcohol); active sites of pathosis in area of injection; or inability to give informed consent. The Ohio State University Human Subjects Review Committee approved the study, and written informed consent (Appendix C) was obtained from each subject. Each participant completed the following forms: informed consent (Appendix C), HIPAA (Appendix D), medical history (Appendix E), and a Corah’s Dental Anxiety Scale (Appendix F, 8-10) at the beginning and end of each appointment.

Ten male and ten female operators administered the infiltration injections in this study. The operators were current endodontic residents (11), endodontic faculty (1), and
dental students (8). All dental students were in good class standing, had a desire to participate in research, and were selected by the predoctoral endodontic director for their ability and patient management skills. Prior to the study, each operator was individually calibrated to ensure that all injections were given in the same manner. Calibration was confirmed as follows: Each cubicle was set up by the same individual (SP) with: one cartridge of 2% lidocaine with 1:100,000 epinephrine in a standard syringe and a 27-gauge 1½ inch needle. Each cubicle was also equipped with a timer and napkin/bib concealing the anesthetic syringe. Before each injection, the primary investigator (SP) spoke with each subject individually to obtain consent (Appendix C), deliver the participant privacy form (Appendix D), and explain the Corah’s Dental Anxiety Scale (Appendix F), VAS (Appendix G), and overall injection process (needle insertion, placement and solution deposition). Each operator was given written instructions in a step-by-step format. These instructions were outlined as follows:

1. The doctor will introduce him/herself and say: “I will be giving you your injection today.”

2. Lay subject back in the chair with their head parallel to the floor.

3. Check recording form to see which side you will be giving injection. Set timer.

4. Remove cap off of needle behind subject (out of the subject’s sight of vision).

5. Lift lip with the other hand, pulling the tissue taught. This will be done with the thumb and index finger with just enough pressure to hold the lip. The operator will not shake the lip during the procedure.

6. Hold the syringe parallel with the long axis of the lateral incisor.
7. Insert the needle into the mucosa at the height of the mucobuccal fold (deepest part of vestibule). The subject will be informed that this is “needle insertion.”

8. Advance the needle until it is at the apical region of the tooth (this is only around 3-5 millimeters in depth). The subject will be informed that this is “needle placement.”

9. Aspirate. If aspiration is positive (blood introduced into the anesthetic carpule), withdraw the needle and re-insert the needle. Aspirate. Operators were instructed to mark any positive aspirations on the VAS under “needle placement”. Only one positive aspiration was noted in the study. This was noted in Group 2 (female subject/male operator).

10. If aspiration is negative, start timer and deposit the entire cartridge over the 60 seconds. The subject will be informed that this is “anesthetic deposition.”
   a. In order to keep a steady flow, make sure you have deposited ¼ of the cartridge at 15 seconds, half at 30 seconds, etc.

11. Slowly withdraw the needle.

12. Place the needle back in the protective cap (out of the sight of the subject).

13. Subjects are then brought back to an up-right position. The VAS is filled out at this time.

Anesthetic was not given as the needle was advanced during the needle placement phase of the injection. After each participant had confirmed they had read and understood the directions, they were instructed to meet with the primary investigator (SP) to ensure calibration. Each operator went through a “mock injection” in which they would demonstrate step-by-step how he/she would be administering injections. Any necessary
corrections were made on an individual basis. Each operator was also instructed not to
deviate from the written script in any way. Any conversation was prohibited and all
questions during the procedure were directed to the primary investigator (SP). This was
done to eliminate any personality biases.

Using a crossover design, 100 male subjects received two maxillary lateral incisor
infiltrations, administered by a male and a female operator. One hundred female subjects
also received two maxillary lateral incisor infiltrations, administered by a male and a
female operator. Each male and female group received the two maxillary infiltration
injections administered at two separate appointments spaced at least 2 weeks apart. Each
male and female operator administered two infiltrations, one to a male subject and one to
a female subject at the two separate appointments. Figure depicts the overall flochart of
the study. The groups were balanced between the right and left sides. The same side
chosen for the first infiltration was used for the second infiltration. A visual and clinical
examination was conducted to ensure that all injection sites were free of inflammation,
infection or pathosis. At the end of each injection, the subjects were given final
instructions and surveys by the primary investigator (SP). It was at this time any
unanswered questions were answered and subjects were dismissed.

Before and after each injection, subjects were shown a Corah’s Dental Anxiety
Scale (Appendix F) which is a four question survey designed to evaluate one’s overall
anxiety regarding dental visits. After each injection, subjects filled out a Heft-Parker
VAS (Appendix G, 105) and were asked to rate the pain for each phase of the
injection: needle insertion, needle placement and deposition of solution. The VAS is a
170-mm line with various descriptive terms. The subjects placed a mark on the scale
where it best described their pain level. To interpret the data, the VAS was divided into the following four categories. No pain corresponded to 0 mm on the scale. Mild pain was defined as greater than 0 mm and less than or equal to 54 mm. Mild pain included the descriptors of faint, weak, and mild pain. Moderate pain was defined as greater than 54 mm and less than 114 mm. Severe pain was defined as equal to or greater than 114 mm. Severe pain included the descriptors of strong, intense and maximum possible.

A standard maxillary infiltration injection was administered with the a 27-gauge 1½ inch needle (Sherwood Medical Co., St. Louis, MO) using a standard aspirating syringe and a cartridge of 2% lidocaine with 1:100,000 epinephrine (Xylocaine, AstraZeneca LP, Dentsply, York, PA). No topical anesthetic was used in order to help ensure calibration and allow the investigators to evaluate if gender plays a role in needle insertion pain. In other words, the purpose was not to try to reduce injection pain. Following the second injection, each subject was given instructions on the final two questionnaires and dismissed. The first questionnaire was an injection sequence questionnaire (Appendix H) where each subject was asked to rate which injection, if any, was more painful. This question was written as follows: Which injection was more painful? Please circle one answer.

1) The injection at the first appointment
2) The injection at the second appointment
3) Neither. There was no difference in the injection pain between both appointments.
In the final questionnaire, each subject was asked to rate his/her ability to cope with pain (Appendix I). This was done by drawing a vertical line on a 100 mm linear scale. This question was written as follows:

Please mark a vertical line “│” on the line below to rank your ability to cope with pain.

I have no problem coping with pain I have extreme difficulty coping with pain

The target site was centered over the root apex of the maxillary lateral incisor. The needle was gently placed into the alveolar mucosa (needle insertion phase). The needle was advanced until the needle was estimated to be at or just above the apex of the lateral incisor (needle placement phase). The anesthetic solution was then deposited over a period of one minute (solution deposition phase). Each operator was calibrated on the exact technique of administering the infiltration.

Before the experiment, the male and female subjects were each randomly assigned six-digit numbers from a random number table. The random numbers were assigned to each of the 100 male and 100 female subjects to designate which gender (male or female) of the operator was used to administer the two injections at each of the two appointments. Therefore, the choice of who administered the first injection (male or female) was randomly determined. At the second appointment, the other gender
administered the second infiltration. Operators and subjects were unaware of the overall aim of the study as to try to prevent any biases. Operators and subjects were told the objective of the study was to get an overall baseline for pain experienced during maxillary anterior injections. Each subject was unaware we were studying gender. This design was approved by IRB with the stipulation that all subjects be informed of the deception at the conclusion of the study. Subjects were each given a debriefing script after the study explaining the true nature of the experiment and reason for deception. The debriefing script stated the following:

We would like to thank you for your participation in our research on pain felt during upper front tooth shots. A pain scale questionnaire was used to rate the pain you felt during 3 parts of a typical dental numbing shot. We evaluated the pain of this shot but we also analyzed the gender (male/female) of the person giving and receiving the shot to determine if there were any differences by gender. It has been hypothesized that gender may influence pain. Our study was aimed at testing the validity of this hypothesis. You were not informed of the gender part of the study in order to achieve unbiased results. Final results are now available from the investigator (Shayne Perry). You may contact me at (shayneperry@yahoo.com) to receive the results of the study. All results will be grouped together; therefore individual results are not available. Your participation, including your name and contact information, will remain absolutely confidential, even if the report is published. If you have any additional questions regarding this research please don’t hesitate to contact me. Again, thank you for your participation.
Statistical analysis was performed to interpret the results. Differences in injection sequence were analyzed using the chi-square test and differences in subject age and coping score were assessed using the randomization test. The Mann-Whitney-Wilcoxon test was used to evaluate differences in subject anxiety and operator experience level. Injection preference was analyzed using multiple McNemar tests and the step-down Bonferroni method of Holm. Injection pain was evaluated using factorial, repeated-measures analysis of variance with operator gender, subject gender, and injection phase as the factors. Post hoc analysis was done using the Tukey-Kramer procedure. With a nondirectional alpha risk of 0.05 and assuming a standard deviation of 32.9, a sample size of 200 subjects was required to demonstrate a difference of ± 10 points on the VAS with a power of 0.95.
CHAPTER 3

RESULTS

One hundred female subjects received two maxillary lateral incisor infiltrations, one administered by a male operator and one administered by a female operator. Twenty operators, 10 adult males and 10 adult females, administered 20 injections overall, 10 to male subjects and 10 to female subjects. One hundred injections were administered over the left lateral incisor and 100 injections were administered over the right lateral incisor (Table 1).

Table 2 shows the age breakdown for both operators and subjects. The 10 female operators had a range of 25-33 years old, with an average age of 27.3 ± 2.5 years. The 10 male operators had a range of 25-32 years old, with an average age of 28.6 ± 2.1 years. No significant difference was found between average operator age of female verses males. Table 2 also shows the average age of research participants. The 100 female subjects had a range of 20-63 years old, with an average age of 25.8 ± 7.9 years. The 100 male subjects had a range of 21-52 years old, with an average age of 26.0 ± 4.0 years. There was no significant difference between subject age (years) by gender.
Experience level of the operators was categorized into 3 main categories: dental student, endodontic resident, and endodontic department faculty. Tables 3 and 4 give the overview of operator experience level by gender. Of the 10 female operators, 4 were dental students, 5 were endodontic residents, and 1 was a faculty member of the endodontic department. Of the 10 male operators, 4 were dental students and 6 were endodontic residents (Table 3). There was no significant difference found in experience level in female operators when compared to male operators (Table 4).

There were four possible subject/operator groups used in the study, which are demonstrated in Table 5. In group 1, female subjects received injections by female operators. In group 2, female subjects received injections by male operators. In group 3, male subjects received injections by female operators. In group 4, male subjects received injections by male operators.

The questionnaire used to analyze dental anxiety was the Corah’s Dental Anxiety Scale (Tables 6 and 7). Scores are categorized as follows: 4-8 mild anxiety, 9-12 moderate anxiety, 13-14 high anxiety, and 15-20 severe anxiety. As shown in Tables 5 and 6, the mean levels of anxiety were 5.6 ± 1.3 for females before each injection, and 5.7 ± 1.4 after the injection. For male participants, the mean levels of anxiety were 5.7 ± 1.6 before each injection, and 5.7 ± 1.7 after the injection. Zero participants reported high or severe anxiety in the study (Table 7). Most of the subjects fell in the mild anxiety range both pre- and post-injection (Table 7).

The injection sequence according to subject and operator gender was analyzed and is shown in Table 8. Fifty-four female and 45 male subjects had a female operator for appointment 1 and male operator for appointment 2. The remaining subjects (46
female and 55 male) received their injection from a male operator at the first appointment and a female operator at the second appointment. No significant difference was found between these groups.

Each participant rated his/her injection pain of needle insertion, needle placement, and solution deposition based on a 170-mm VAS. Tables 9 illustrates the values of pain reported on the VAS in millimeters. Group 2 (female subject/male operator) showed a significantly higher pain rating for solution deposition pain (mean of 68.0 ± 38.1 mm) as compared to group 1 (female subject/female operator) with mean VAS values of 54.4 ± 34.9 mm, group 3 (male subject/female operator) with mean VAS values of 46.8 ± 32.4 mm, and group 4 (male subject/male operator) with mean VAS values of 49.9 ± 32.2 mm. In general, solution deposition was the most painful phase of injection for all the groups (Tables 9-11). There was no significant difference in pain ratings between groups 1, 3, and 4 for solution deposition pain. For all groups, no significant difference was found in reported pain for needle insertion or needle placement.

Tables 10 and 11 show pain ratings by category. A greater proportion of subjects in group 2 (female subject/male operator) reported severe pain during solution deposition in comparison to the other 3 groups. In group 2, 33% of females reported zero-to-mild pain, 53% reported moderate pain, and 14% reported severe pain. These results were significantly different from the other 3 groups. In group 1 (female subject/female operator), 45% females reported zero-to-mild pain, 48% reported moderate pain, and 7% reported severe pain. In Group 3 (male subject/female operator), 61% of males reported zero-to-mild pain, 35% reported moderate pain, and
4% reported severe pain. In group 4 (male subject/male operator), 59% reported zero to mild pain, 37% reported moderate pain, and 4% reported severe pain. There was no significant difference for solution deposition pain between groups 1, 3, and 4. There was also no significant difference found when comparing needle insertion pain, or needle placement pain, between any of the four groups.

At the end of the second injection, participants were asked to fill out a questionnaire regarding which injection, if any, they perceived as more painful. They were able to respond one of 3 ways; 1=the first injection was more painful, 2=the second injection was more painful, or 3=neither injection was more painful than the other. These results were further analyzed to determine if the subject gender played a role in injection preference (Tables 12-14). No significant difference in preference was found among female participants between the first or second injection (Tables 13 and 14). However, there was a significant difference found in preference of both the first injection (p=0.00016) and second injection (p=0.00002) as compared to no preference between the two injections. While females did not perceive one injection to be more painful than the other, most of the respondents (88%) chose either the first or second injection as opposed to no difference in injection pain (option 3). Among the three options (1=the first injection was more painful, 2=the second injection was more painful, or 3=neither injection was more painful than the other), no significant difference in preference was found among male participants (Tables 12-14).

All participants were asked to rate his/her own ability to cope with pain based on a 100-mm rating scale with higher numbers illustrating more difficulty coping with pain (Tables 15 and 16). Female participants were found to show a statistically lower
pain coping ability (mean 27.1 ± 17.4mm) than their male counterparts (22.2 ± 17.1mm) (Table 15). Of the 100 female participants, 9 reported no difficulty coping with pain, 74 reported mild difficulty, 15 reported moderate difficulty, and 2 reported severe difficulty. Of the 100 male participants, 10 reported no difficulty coping with pain, 79 reported mild difficulty, 10 reported moderate difficulty, and 1 individual reported severe difficulty. Overall, women rated themselves as having more difficulty coping with pain than males (Table 16).
CHAPTER 4

DISCUSSION

The purpose of this prospective, randomized, study was to evaluate gender differences in injection pain between operators and subjects for maxillary anterior infiltrations. Two hundred adult subjects, 100 male and 100 female, completed the study. Injections were administered by 20 operators, 10 female and 10 male. This equality in gender distribution was important to adequately interpret the results. Studies have shown women to have a lower acceptance of pain, a greater fear of pain, and avoid pain more than males (62, 64, 65, 89). Women have also been shown to have lower pain thresholds and tolerance levels than their male counterparts (89). Therefore, it was important to have an equal number of males and female subjects participate in the study in order to prevent a skew in the results. In order to balance operator gender, 10 female and 10 male operators were used in the study. It was our aim to determine if the operator’s gender would play a role in the pain experienced by male and female subjects. Thus, an equal number of operators of each gender were used.
In order to try to eliminate chairside manner and personality as potential distractions or biases, all operators in our study were instructed to follow strict protocol for administering injections. They were given written and oral instructions on how to introduce him/herself and things that could and could not be said. All operators wore mandatory personal protective equipment (PPE), which consisted of a blue gown, mask, goggles, and gloves. This also helped to make personal appearance among operators relatively uniform. Any questions from participants were directed to the research investigator. The main question asked was the purpose of the experiment. All subjects were told that we were getting a baseline evaluation for maxillary infiltration injection pain. Participants were not informed that gender would be an evaluative factor. This was done in order to protect the integrity of the study, and also facilitate unbiased results. Operators were given both written and hands-on, detailed instructions on how to administer the injections. This was done in order to try to have gender be the only difference between male and female operators and to try to eliminate personality as a possible influence.

All anesthetic cartridges were checked to ensure their expiration date was after the projected end of the study. A letter code, R or L, was assigned to each participant’s packet at the beginning of the study in order to designate whether the injection was to be given apical to the subject’s left or right maxillary lateral incisor. This ensured that an equal number of injections were administered to each side. Both injections were given on the same side with each subject. This was done to remove the side of injection as a potential variable. It was also important to maintain consistency by having the injection placed over the same tooth and in the same location for each participant. One hundred
subjects received injections on his/her left side, and 100 received injections on his/her right side (Table 1).

The mean age for all female participants in our study was 25.8 ± 7.9 years with a range from 20 years of age to 63 years of age (Table 2). The mean age for all male participants in our study was 26.0 ± 4.0 years with a range from 20 years of age to 63 years of age. No significant difference was found between the average ages between both groups (P=0.85). All subjects were healthy which was assessed using a medical history given to each subject to complete (Appendix E). This medical history was checked by the research investigator. Some authors (90, 91) have suggested a physiologic basis for differences in pain perception in older subjects. They have found that these subjects could possibly have an increase in pain sensitivity to intense stimuli when compared to subjects of a younger age. Other authors (92) have found that elderly patients are less likely than younger patients to report noxious stimuli as painful. In our study, no significant difference was found with regard to age. However, because of the younger age group of the subjects (approximately 26 years old), the results of this study may not apply to adolescents or older adults.

Experience level of the operators was categorized into 3 main categories: dental student, endodontic resident, and endodontic department faculty. Tables 3 and 4 give the overview of operator experience level by gender. There was no significant difference found in experience level in female operators when compared to male operators (Table 3). All dental students were in good class standing, had a desire to participate in research, and were selected by the predoctoral endodontic director for their ability and patient
management skills. Of the 8 dental student operators, 7 (3 males and 4 females) were in their fourth year of dental school while one (male) was a third year dental student. The dental residents included 5 (3 males and 2 females) first year residents, 3 (1 male and 2 females) second year residents, and 3 (2 male and 1 female) third year residents. One operator (female) was a current faculty member that had approximately 3 years of post-graduate experience. Prior to the study, each operator was individually calibrated to ensure that all injections were given in the same manner. Experience level was not believed to play a significant role due to two main reasons. First, all operators were given specific step-by-step written instructions on how to administer each injection. No verbal interaction was allowed except for self-introduction and informing the participant of each phase of the injection (needle insertion, needle placement, solution deposition). This was done to eliminate any operator personality and bedside manner as potential variables that would create a statistical bias in pain ratings. Second, we used the maxillary infiltration injection, in part, due to its low technical sensitivity. The maxillary infiltration injection is a relatively simple injection to administer in comparison to many other injection techniques (i.e. IAN block and Vazirani-Akinosi).

In this study, each subject was seen at two separate appointments spaced at least two weeks apart. In order to balance out the influence that an operator’s gender could potentially have on the perception of pain, each subject received one of the injections by a male operator, and the other by a female operator. This created four possible groupings in the study (Table 5). In Group 1, female subjects received their injection by a female operator. In Group 2, female subjects received an injection by a male operator. In Group 3, male subjects received an injection by a female operator. In Group 4, male subjects
received the injection by a male operator. Although all subjects received injections from both a female and male operator at separate appointments, subjects were not informed that gender was being studied in order to try to prevent any biases.

**Dental Anxiety**

As shown in Tables 6 and 7, no significant difference was found between male and female participants in the study regarding Corah’s Dental Anxiety Scale ratings. The scale ranges from a score of 4 to 20, with high scores representing higher anxiety. Scores were classified as follows: 4-8 as having no-to-mild anxiety, 9-12 as having moderate anxiety, 13-14 as having high anxiety, and 15-20 as having severe anxiety. In each of the four groups, all participants rated his/her anxiety level as mild-moderate. No statistical difference was found between male and female subjects (Table 6). There was also no significant difference found between pre-injection and post-injection surveys. The mean levels of anxiety were 5.6 ± 1.3 for females before each injection, and 5.7 ± 1.4 after the injection. For male participants, the mean levels of anxiety were 5.7 ± 1.6 before each injection, and 5.7 ± 1.7 after the injection. No participants reported high or severe anxiety in the study (Table 7). These low reports could be due to the fact that most of the participants were dental students at The Ohio State University and could potentially have less anxiety towards dental appointments and dental injections in comparison to the general public. Most of the subjects fell in the mild anxiety range both pre- and post-injection (Table 7). We felt it was important to collect anxiety ratings before and after each appointment for several reasons. For some of the participants, the first appointment
would be the first time they would receive a maxillary infiltration injection. We wanted to determine if ratings would change between the pre-injection surveys when injection pain was imminent, and the post-injection surveys when the injection was completed. We also wanted to see if anxiety ratings would fluctuate between the first injection, when the injection was relatively unfamiliar, and the second when the injection was more familiar. Pre-injection and post-injection scores were not significantly different for males or females. This could be due to the fact that the overall anxiety scores were low. In addition, these ratings were consistent and reproducible as an identical questionnaire was used before and after each injection. Overall, our Corah’s Dental Anxiety Scale ratings were slightly lower than those found in other studies (2, 63-65). It should be noted that other studies that have used the Corah’s Dental Anxiety Scale tested the general population before dental appointments. Our study consisted of dental students who may be more familiar in the dental setting than the general population. Also, other studies evaluated patients before undergoing a dental procedure while our study consisted of participants who were receiving a maxillary infiltration injection only. These parameters may have contributed to the overall lower anxiety ratings.

Other studies have also failed to show a difference in anxiety levels between males and females. Bertrand and co-authors (109) conducted a study to detect the influence of gender on anxiety and pain response using pupillometry. Ninety-six participants (48 female and 48 male) participated in the study. Each participant filled out a Beck questionnaire to determine his/her level of anxiety. Afterwards, they were divided into groups based on his/her anxiety ratings. Pupil diameters were recorded as each participant underwent a painful pressure stimulus using a digital pressure algometer.
applied to the right middle finger up to 1,500 kPa of pressure. They had several interesting findings. First, pupil diameter increased in response to pain for all participants. Second, participants with moderate-to-severe anxiety had higher pupil diameters than those with no or mild anxiety. They did not find a significant difference between females and males with regard to pupil diameter or anxiety levels. This could be due to the fact that the anxiety levels of men were relatively low in comparison to the females.

Ellermeier and Westphal (110) found contrasting results in a pupil dilation study. In the first group, 20 participants (10 male and 10 female) rated pain of tonic pressure, using a metal rod, applied to the subjects middle finger. They did not find a difference between genders during low pressure levels. They did, however, find that females reported higher pain scores than males at higher pressures. In a second experiment, 16 participants underwent tonic pressure to their fingers while measuring their pupil reactions using “infrared video pupillometry”. They found that female subjects demonstrated more pupil dilation at high pressure. These findings suggest females not only report more pain at higher pain intensities, but they may also be more sensitive to a painful stimulus as demonstrated by the pupil dilation experiment.

The Corah’s Dental Anxiety Scale has been used in other studies. Liddell and Locker (64) found that women were significantly more anxious with regard to dental treatment than males. A sample of 2069 adults, aged 18 years and over, living in Toronto were randomly selected from the local voters’ list. Participants were asked to take a Corah’s Dental Anxiety Scale and mail them back in to the investigators. They found that
men reported an overall mean of $8.03 \pm 2.98$ while women reported an overall mean of $8.91 \pm 3.59$. This study was comparable to ours in that the participants were not undergoing any dental treatment prior to the questionnaire. Their results were much higher than those found in our study, likely due to the fact the majority of our participants were dental students volunteering to receive dental injections.

Crofts-Barnes and coauthors (2) studied the quality of life of 43 patients leading up to their individual dental appointments. Patients took a Corah’s Dental Anxiety Scale questionnaire before the dental appointment. Their participants had an average Corah’s Dental Anxiety Scale rating of 16.2 in the group labeled as “phobic” and 8.3 in the control groups of seemingly average patients. They found that patients who report high levels of anxiety during dental visits also experienced a significantly lower quality of life leading up to a dental appointment than those who were less anxious. Our study reported lower anxiety values than both of these groups, likely due to differences in the sample populations being tested.

Ulusoy and coauthors (35) surveyed 97 patients undergoing extraction or root canal treatment and asked them to rate anxiety and pain after treatment. Patients rated their fear using a Corah’s Dental Anxiety Scale where they rated their fear in four dental situations on a five-point scale. Overall, they found no significant difference between subject genders with regard to pain ratings. They found Corah’s Dental Anxiety Scale scores were much higher than our study with a mean value of $10.21 \pm 4.54$. This higher number was likely due to the fact participants were going to have a root canal or
extraction after filling out the survey while our study compromised dental students, who were not undergoing subsequent painful dental procedures.

Heaton and coauthors (73) studied dental fear and general anxiety before dental treatment. One hundred eight adult patients (58 women and 50 men) seeking treatment at the graduate periodontology clinic at the University of Kentucky College of Dentistry participated in the study. Each patient filled out a Corah’s Dental Anxiety Scale. Overall, women reported more anxiety than men (p<0.05). Men reported a mean score of $9.0 \pm 3.5$ compared to $10.8 \pm 4.4$ for females. These scores were higher for both men and women than those in our study. Our study likely had lower anxiety scores as the participants in our study knew they were receiving an injection only, and no other dental procedures would be performed. Also, our participants were mostly dental students who may have lower anxiety toward dental injections. Lastly, it would be expected that these individuals would have lower anxiety scores as they all volunteered to receive a dental injection. Due to these factors, it was not surprising that our sample population reported relatively low anxiety scores. This may also help explain why we failed to show a statistically significant difference between male and female anxiety scores. It is difficult to detect a difference between two relatively non-anxious groups.

Hittner and Hemmo (63) conducted a study on the psychosocial predictors of dental anxiety and made a few important conclusions using dental anxiety scales. Forty-eight males and 96 females, of which 89 were recruited from the waiting room of a dental practice and 55 were college undergraduate students, participated in the study. Participants were asked to fill out several questionnaires, one of which was a Modified
Dental Anxiety Scale (MDAS). Dental anxiety was linked to several variables including increased age, reduced income, and female gender. The dental anxiety experienced by females was significantly higher than males (p=0.033). The Modified Dental Anxiety Scale (MDAS) used in this study is a revised version of the Corah’s Dental Anxiety Scale that adds an extra question about local anesthesia injections. The question states: “If you were about to have a LOCAL ANAESTHETIC INJECTION in your gum, above an upper back tooth, how would you feel? Not Anxious □ Slightly Anxious □ Fairly Anxious □ Very Anxious □ Extremely Anxious □”.

We did not use the Modified Dental Anxiety Scale (MDAS) as all participants were aware that they would be receiving an injection as part of the study while the question suggests a hypothetical injection. Also, the injection being administered in our study was the maxillary lateral incisor infiltration, not a maxillary molar.

**Injection Sequence**

The injection sequence according to subject and operator gender was analyzed and is shown in Table 8. At the onset of the study, it was designed to have an equal number of participants receive his/her first injection by a female operator as a male operator. Fifty-four female and 45 male subjects had a female operator for appointment 1 and male operator for appointment 2. The remaining subjects (46 female and 55 male) received their injection from a male operator at the first appointment and a female operator at the second appointment. This small difference between the groups was due to
the fact that some subjects were unable to attend certain appointments. In attempt to accommodate subject and operator schedules, a slightly larger number of female subjects (54 vs. 46) were injected by a female operator at the first appointment, and a male operator at the second appointment. In contrast, a slightly smaller number of female subjects (45 vs. 55) were injected by a female operator at the first appointment and a male operator at the second appointment. These differences were very small and were not found to be significantly different (p=0.2031). It was important to have these groups be similar in order to evaluate injection sequence and its overall effect on reporting injection pain.

**Topical anesthetic**

Topical anesthesia is a commonly used method of decreasing the pain of injection. Numerous studies support the use of topical anesthetics in order to reduce perceived local anesthetic injection pain (26-31) while others have shown minimal efficacy (32, 33).

Nusstein and Beck (10) studied the effectiveness of 20% benzocaine on 2336 injections on a total of 1080 adult patients. Their results showed that topical anesthesia using (20%) benzocaine significantly increased the odds of patients experiencing no needle insertion pain during maxillary anterior infiltration injections. Rosivack and co-authors (29) investigated the effectiveness of both (20 %) benzocaine and (5%) lidocaine on 60 adult volunteers. Their results showed that both anesthetics were able to significantly reduce pain caused by needle insertion when compared to placebo, although
the difference between the two topical anesthetics was not significant. Hutchins and coauthors (31) had similar findings when testing the effect of (20%) benzocaine used before maxillary buccal premolar injections. They found that while cheek vibration alone did not significantly lower injection pain values, lowest pain values were experienced using cheek vibration method in addition to using topical anesthesia.

Other studies have not found topical anesthetic to be of clinical significance. Parirokh et al. (33) studied the effect of 20% benzocaine topical anesthetic used before prilocaine for maxillary central incisor buccal infiltration. Twenty-five people participated in their double-blind study. They did not find a significant difference regarding pain of needle penetration or anesthetic injection.

Martin and co-authors (22) conducted a placebo study regarding topical anesthesia. Thirty-three male subjects and 31 female subjects were told they were going to receive either a placebo or active topical anesthetic. In actuality, all participants received a placebo injection and a topical anesthetic injection. Results found a placebo effect in that subjects who believed they were receiving topical anesthetic experienced less pain than those who thought they were receiving a placebo. Therefore, the use of topical anesthetic could possibly have its largest effect due to its psychological influence on patients who believe the dental practitioner is doing something to try to prevent injection pain.

Topical anesthetic was not used in this study as the purpose of the study was not to prevent pain. Instead, injections were to be given in a standardized manner and an overall baseline of injection pain was desired. We believed that an injection with lower
pain levels would prove more difficult in detecting differences in injection pain. Our desire was to have high enough pain ratings to determine if gender would play a significant role in altering these reported levels.

Maxillary Anterior Infiltration Injection

In our study, each subject was administered one cartridge of 2% lidocaine with 1:100,000 epinephrine using a 27-gauge 1½-inch needle. The 27-gauge needles used in this study were consistent with those of previous studies conducted by the Division of Endodontics allowing comparisons to be made.

Maxillary infiltrations were given around the apex of the lateral incisor. This injection was used for several reasons. First, it is a relatively simple injection to administer when compared to other injections such as the inferior alveolar nerve block. Also, other studies have shown this injection to be one of the more painful injections used in dentistry (7, 8). It was our intent to use a more painful injection in order to have a broader range in pain ratings to detect any differences between subjects.

Injections were given at least 2 weeks apart. This amount of time was allowed to pass so that all tissues would have adequate time to heal and so the subsequent injection would not have an altered pain recording due to residual effects. The injections were given over 60 seconds in order to help standardize the injection for each operator. Several studies have determined the effect tissue pressure and rate of injection have on pain and anxiety. Hochman and coauthors (45) studied the interstitial tissue pressure associated
with several injections (intraligamentary or PDL, palatal, anterior middle superior alveolar nerve block, and inferior alveolar nerve block). Interstitial tissue pressure varied greatly depending on the site of injection (mean psi values ranging from 9.76 for an IAN block to 293.9 psi for the PDL injection). Studies have shown a significant correlation between intensity of pain and injection pressure. Kudo et al. (46) studied injection pain based on lower canine injection pain using 2% lidocaine with 1:80,000 epinephrine. The anesthetic was injected submucosally at a speed of either 30 or 160 mL/s. Injection pressure was measured using an invasive sphygmomanometer and analytic software. Participants subsequently filled out a 100-mm VAS and a standard faces anxiety scale. They found a significant correlation between injection pressure and pain (p<0.05). The authors recommend giving injections at a slower rate in order to decrease injection pressure and pain.

Kanaa and co-authors (47) confirmed these results when comparing injection speeds in inferior alveolar nerve blocks. Not only were inferior alveolar nerve blocks more successful when administered slowly (60 seconds vs. 15 seconds), injections were found to be much more painful when given at a faster rate. VAS scores had an average of 20.9 mm when given slowly vs. 30.5 mm when given rapidly.

Aggarwal and co-authors (108) also evaluated the effect injection speed has on injection pain. In their study, 59 patients were randomly divided into 2 groups and received either a slow or rapid inferior alveolar nerve block injection using 3.6 mL of 2% lidocaine with 1:200,000 epinephrine. Pain was recorded using a 170-mm Heft-Parker
VAS. They found that injections given at a slower rate (120 seconds) were much less painful than those given at a rapid rate (30 seconds).

Scarfone et al. (48) studied injection pain between buffered and non-buffered 1% lidocaine. Each participant’s pain was rated on a 100-mm visual analog scale comparing rapid (5 seconds) vs. slow (30 seconds) injections. They found that patients who received slower injections had significantly lower pain scores than those who received faster injections, regardless if a buffer was present or not. Other authors who have studied the anesthetic buffering effect on injection pain have also concluded that speed of injection can significantly alter injection pain (49, 50).

One technological advancement that aids in administering slow injections at a consistent rate is the Computer-Controlled Local Anesthetic Delivery (C-CLAD™) system, rebranded from the The Wand®. This device administers anesthetic solution of 1.4 mL at a consistent solution deposition rate, with the slowest rate of 4 minutes and 45 seconds. Numerous studies have shown that the CompuDent CCLAD™ unit can decrease dental injection pain (93-98). This device helps to give consistent injection pressure and speed. While this device would have helped to give injections over a standard rate and pressure in our study, our intent was not to reduce overall pain. We wanted high enough pain ratings to determine if our study variable (gender) would play a role in perceived pain. We believed that injections with low pain levels would prove difficult in detecting any difference in injection pain. In addition, the majority of maxillary infiltration studies have been performed using a conventional syringe. In order to have a direct comparison to other studied regarding injection pain, we chose not to change this variable.
In our study, all injections were administered over 60 seconds. This was done in order to help ensure all injections were given at the same rate. We chose 60 seconds since it would ensure all operators had enough time to deposit a full cartridge of anesthetic. Also, we wanted to have a direct comparison to other studies that have reported maxillary infiltration pain levels given over 60 seconds (11-23).

**Pain for Needle Insertion**

A summary of pain ratings for needle insertion, placement, and deposition using a 170-mm VAS can be seen in Table 9. When comparing needle insertion pain, no significant difference was found between any of the four groups. Group 1 (female operator/female subject) had an average pain rating of 53.2 ± 30.0 mm, Group 2 (female subject/male operator) had an average pain rating of 46.2 ± 30.5 mm, Group 3 (male subject/female operator) had an average pain rating of 41.6 ± 28.3 mm, and Group 4 (male subject/male operator) had an average pain rating of 39.5 ± 30.1 mm.

Overall, 61.5% of respondents reported needle insertion for all anesthetics in the no-to-mild pain category, while 38.5% of subjects reported pain in the moderate-to-severe group (Table 10). In Group 1, 68 subjects (68.0%) reported no-to-mild pain and 32 subjects (32.0%) reported moderate-to-severe pain. For Group 2, 56 subjects (56.0%) reported no-to-mild pain and 44 subjects (44.0%) reported moderate-to-severe pain. For Group 3, 54 subjects (54.0%) reported no-to-mild pain and 46 subjects (46.0%) reported moderate-to-severe pain. For Group 4, 68 subjects (68.0%) reported no-to-mild pain and 32 subjects (32.0%) reported moderate-to-severe pain (Table 10).
No significant difference was found between any of the groups for needle insertion pain. This finding may be due to the fact that our insertion pain ratings were relatively low in contrast to solution deposition pain for all groups. Overall, a large portion (38.5%) of subjects rated his/her pain as moderate or severe. However, these pain levels were not high enough to detect significant differences in pain ratings between men and women. We felt that our overall needle insertion pain ratings were reliable as all operators giving injections were calibrated to ensure proper technique. Also, pain ratings for maxillary infiltration injections from this study can be compared to studies that have also reported pain ratings using this injection. It should be noted that our study is the only maxillary infiltration injection study where the participant was aware that they were not receiving topical anesthetic before the injection. Other studies that report injection pain without using topical anesthetic were done in a single- or double-blind study design. We hypothesized this may lead to slightly higher needle insertion pain ratings as subjects were aware they would not be receiving any topical anesthetic prior to each injection. It should also be noted that the other studies listed which have reported needle insertion pain, needle placement pain, and solution deposition pain did not analyze the pain ratings according to gender. These studies can be compared to our results as a group; however, statistical comparisons between male and female participants is not possible.

Various studies have looked at needle insertion pain experienced during maxillary infiltration injections. Gross et al. (11) administered 1.8 mL of 2% lidocaine with 1:100,000 epinephrine and 1.8 mL of 0.5% bupivacaine with 1:100,000 epinephrine in human maxillary anterior infiltration injections given over the lateral incisor using a 27-gauge 1½-inch needle. They found that, in maxillary lateral incisors, bupivacaine
displayed a significantly lower anesthetic success rate of 78%, in contrast to a 97% success rate for lidocaine (12). Overall, of the group that received topical anesthetic, 59.5% of participants reported zero-to-mild pain while 40.5% reported moderate-to-severe pain. In the placebo group, 39.0% of participants reported zero-to-mild pain while 61.0% reported moderate-to-severe pain. While the group that received topical anesthetic reported similar needle insertion pain ratings as our study, the results of the placebo group were higher.

Other studies have found similar needle insertion pain ratings as those reported in our study. In a similar study design as Gross (11), Mikesell (13) studied anesthetic efficacy of 1.8 mL and 3.6 mL of 2% lidocaine with 1:100,000 epinephrine for maxillary infiltration injections using a 27-gauge 1-inch needle. They found that while the anesthetic success for both volumes of anesthetic ranged from 97% to 100%, the 3.6 mL volume provided a statistically longer duration of pulpal anesthesia (14). For the topical anesthetic group, they found that 81% of participants reported zero-to-mild pain and 19% reported moderate pain. In the placebo group (Vaseline®), 66% of participants reported zero-to-mild pain while 34% reported moderate pain. No participants reported severe pain during needle insertion. The placebo group pain ratings were very similar to those found in our study. These findings are expected considering both studies evaluated injections using 2% lidocaine and neither their placebo nor our study used topical anesthetic. It should be noted that the pain ratings reported by their group in the topical anesthetic group were lower than those in our study, suggesting the efficacy of topical anesthetic (10).
Some studies have found lower overall needle insertion ratings than those found in our study. In a similar study design as Gross (11) and Mikesell (12), Mason (15) compared the analgesic efficacy of 2% lidocaine with 1:100,000 epinephrine, 2% lidocaine with 1:50,000 epinephrine, and 3% mepivacaine in maxillary lateral incisors and first molars using a 27-gauge 1-inch needle. They found that the anesthetic success of pulpal anesthesia was not significantly different between 2% lidocaine with either 1:100,000 or 1:50,000 epinephrine, and 3% mepivacaine, for the lateral incisor (16). For both the placebo and topical anesthetic groups, they found that 97% of participants experienced zero-to-mild pain and 3% experienced moderate pain. No participants reported severe pain for needle insertion in any of the groups.

Katz (17) found similar pain ratings to Mason (15). In a similar study designed to the previous 3 studies, Katz et al. (17) studied the anesthetic efficacy of 4% prilocaine with and without 1:200,000 epinephrine and 2% lidocaine with 1:100,000 epinephrine in maxillary lateral incisor labial infiltrations using a 27-gauge 1-inch needle. In addition to the 4-point injection pain scale, participants were also asked to mark their pain on a 100-mm VAS. Anesthetic success was not significantly different between 2% lidocaine with 1:100,000 epinephrine, 4% prilocaine with 1:200,000 epinephrine, and 4% prilocaine for the lateral incisor and first molar (18). For both the placebo and topical anesthesia group, 93.3% reported zero-to-mild pain while 6.7% reported moderate pain. When neither placebo nor topical anesthesia was administered, 90.0% of participants reported mild-to-moderate pain while 10% reported moderate pain. No participants reported severe pain. The following mean values were reported for needle insertion pain using a 100-mm VAS: 6.5 mm for the topical group, 9.0 mm for the placebo group, 3.5 mm for the placebo or
topical group. In an effort to compare these results with those found in our studies, these VAS pain ratings would be equivalent to the approximate values on a 170 mm VAS: 11.0 mm for the topical group, 15.3 mm for the placebo group, 6.0 mm for the placebo or topical group. No significant difference was found between the three groups. Similar to Mason (15), these needle insertion ratings were lower than those found in our study. It is difficult to assess if personality played a role as the calibration protocol was less strict than our study. These results could be a reflection on the operator as all injections were administered by the same individual. This is due to the fact that they were primarily studying anesthesia and it is likely that more interaction between operator and subject was allowed in their study. Also, both of these studies evaluated injection pain in 60 volunteers while ours looked at a larger population of 200 subjects. This may have allowed us to see a larger number of individuals reporting a broader range of pain ratings.

Scott (19) also reported on maxillary anterior injection pain. Their study had 40 subjects, (28 men and 12 women) who were given repeat maxillary infiltration injections using a 27-gauge 1½-inch needle administered at two separate appointments. The repeated infiltration improved pulpal anesthesia significantly in the maxillary lateral incisor from 37 to 90 minutes (20). They also found that 78% of participants had zero-to-mild pain and 22% reported moderate-to-severe pain for needle insertion pain. These ratings for moderate-to-severe pain were lower than those found in our study.

Evans et al. (21) studied the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine versus 2% lidocaine with 1:100,000 epinephrine in maxillary infiltrations using a 27-gauge 1½-inch needle. Forty subjects (25 men and 15 women) were given a
maxillary infiltration injection over the lateral incisor. Participants received 20% benzocaine for 60 seconds prior to each injection. Participants rated their pain on a 170-mm VAS after each injection. They found that articaine had a significantly higher anesthetic success rate (88%) when compared with that of lidocaine (62%) for maxillary lateral incisor infiltrations (22). They also found increased injection pain levels in the anterior versus the posterior maxilla with both lidocaine and articaine solutions. For needle insertion, the mean pain ratings were 24.0 ± 29.0 mm for the articaine group and 23.0 ± 24.0 mm for the lidocaine group. No significant difference was found between the groups. While our findings were slightly higher for needle insertion pain, this could be due to the fact we did not use topical anesthetic in our study. Also, operator personality and personal interaction with each subject may have influenced reported pain ratings.

Hobeich and co-authors (23) studied injection pain and anesthetic success of 2% lidocaine with 1:100,000 epinephrine buffered with 5% and 10% sodium bicarbonate in maxillary infiltrations using a 30-gauge 1¼-inch needle. They found that for the non-buffered anesthetic, 5% and 10% buffered solutions, needle insertion mean VAS values were 34.0 ± 24.0 mm, 40.0 ± 24.0 mm, and 40.0 ± 23.0 mm, respectively. Our values ranged from approximately 42 – 53 mm (Tables 8A and 8B). These differences may be due to infiltrations placed over the maxillary canine vs. lateral incisor or the smaller number of subjects used in the study by Hobeich (23).

Overall, our needle insertion pain ratings were higher than some studies (15, 17) and lower than other studies, but were within a comparative range (11, 13, 19, 21, 23). Comparative studies did not analyze gender to detect the role operator or subject gender
has on perceived pain. We did not find that gender made a significant difference for needle insertion pain. It is likely that we were unable to detect these differences for needle insertion pain due to the fact that our study used a non-inflammatory model where none of the participants were in pain and no treatment subsequent to the injection was to be performed. Other studies have detected gender differences regarding pain perception. It is important to note that the subjects in these studies were exposed to seemingly more painful stimuli than the needle insertion pain experienced in our study. Some examples of studies where gender differences in pain were reported are 1) cold pressor pain studies where subjects were instructed to hold his/her hand in a cold water bath for several minutes or until the pain was too painful to bear (74, 75, 88), 2) mechanical pressure studies where participant placed his/her heel on the floor with the Achilles tendon positioned between two motor-driven rods. Pressure was increased until the subject signaled that the pain was too much to bear (67), and 3) heat stimulation studies where a contact thermode was applied to the thenar surface of the right hand using a computer-controlled thermal sensory analyzer. Each pulsed was applied from a baseline temperature of 39°C with a peak temperature of 51°C (66). Our study was not designed to maximize pain nor was it intended to determine pain thresholds. Needle insertion may be lower in contrast to other comparative gender pain discrimination tests which may explain why no difference in pain ratings was observed.
Pain for Needle Placement

When comparing needle placement pain, no significant difference was found between any of the four groups. We did not find that operator or subject gender had a statistically significant difference on needle placement pain. We found that Group 1 (female operator/female subject) had an average pain rating of 46.8 ± 28.0 mm, Group 2 (female subject/male operator) had an average pain rating of 49.7 ± 34.0 mm, Group 3 (male subject/female operator) had an average pain rating of 37.4 ± 28.4 mm, and Group 4 (male subject/male operator) had an average pain rating of 36.8 ± 25.0 mm (Table 9).

Overall, 60.0% of respondents reported needle placement for all groups in the no-to-mild pain category, while 40.0% of subjects reported pain in the moderate-to-severe group (Table 10). In Group 1 (female operator/female subject), 75 subjects (75.0%) reported no-to-mild pain and 25 subjects (25.0%) reported moderate-to-severe pain. For Group 2 (female subject/male operator), 58 subjects (58.0%) reported no-to-mild pain and 42 subjects (42.0%) reported moderate-to-severe pain. For Group 3 (male subject/female operator), 54 subjects (54.0%) reported no-to-mild pain and 46 subjects (46.0%) reported moderate-to-severe pain. For Group 4 (male subject/male operator), 73 subjects (73.0%) reported no-to-mild pain and 27 subjects (27.0%) reported moderate-to-severe pain (Table 10).

Pain ratings for maxillary infiltration injections from this study can be compared to studies that also investigated the pain felt during this injection. Many studies only recorded needle insertion pain and solution deposition pain while ignoring needle placement pain in their studies.
Scott (19) studied maxillary anterior needle placement pain. In the group where an infiltration initial injection followed by a mock injection was given, they found that 70% of participants had zero-to-mild pain and 30% reported moderate-to-severe pain for needle placement pain. In the group where an infiltration initial injection followed by a lidocaine injection was given, 78% of participants had zero-to-mild pain and 22% reported moderate-to-severe pain for needle placement pain. Overall, these pain ratings were similar to those found in our study.

Evans (21) studied the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine versus 2% lidocaine with 1:100,000 epinephrine in maxillary infiltrations. She found increased injection pain levels in the anterior versus the posterior maxilla with both lidocaine and articaine solutions. For needle placement pain, the mean pain ratings were 26.0 ± 22.0 mm for the articaine group and 25.0 ± 23.0 mm for the lidocaine group. No significant difference was found between the groups. These ratings were lower than those found in our study (37 - 50 mm – Table 9). However, as with our study, their pain ratings for needle insertion and needle placement were very similar. Also, having only one individual operator and an overall smaller sample size could have played a role in the recorded pain ratings.

Overall, our needle placement pain ratings were similar to other studies. Comparative studies did not analyze gender to detect the role operator or subject gender had on perceived pain. No significant difference was found between any of the groups for needle placement pain. This finding may be due to the fact that our needle placement pain ratings were relatively low in contrast to solution deposition pain for all groups. Overall,
a large portion (40.0%) of subjects rated his/her pain as moderate or severe. However, these pain levels were not high enough to detect significant differences in pain ratings between men and women. Some studies have reported needle placement pain as the most painful phase of the inferior alveolar nerve injection (93, 99) while others have shown that needle placement pain is less painful than solution deposition in mandibular supplemental buccal infiltration injections (100). It has also been shown to be the most painful phase of the palatal-anterior superior alveolar injection (101). For maxillary infiltration injections, needle pain is likely lower since the needle only penetrates the mucosal tissue a few millimeters since we were injecting over the lateral incisor, which is a relatively short tooth. Also, other injections, such as the inferior alveolar nerve injection, may penetrate muscle tissue which can further increase needle placement pain. Lastly, it is also likely that we were unable to detect these differences for needle insertion pain due to the fact that our study used a non-inflammatory model as discussed previously for needle insertion pain.

Pain for solution deposition

When comparing solution deposition pain, we found that Group 2 reported a significantly higher deposition pain than Group 1 (p=0.0357), Group 3 (p=0.0012) and Group 4 (p=0.0172). Group 2 (female subject/male operator) had an average pain rating of 68.0 ± 38.1 mm. Group 1 (female operator/female subject) had an average pain rating of 54.4 ± 34.9 mm, Group 3 (male subject/female operator) had an average pain rating of 46.8 ± 32.4 mm, and Group 4 (male subject/male operator) had an average pain rating of
49.9 ± 32.2 mm (Table 9). Overall, 49.5% of respondents reported solution deposition pain for all anesthetics in the no-to-mild pain category, while 50.5% of subjects reported pain in the moderate-to-severe group (Table 10). In Group 2 (female subject/male operator), 33 subjects (33.0%) reported no-to-mild pain and 67 subjects (67.0%) reported moderate-to-severe pain. In Group 1 (female operator/female subject), 45 subjects (45.0%) reported no-to-mild pain and 55 subjects (55.0%) reported moderate-to-severe pain. For Group 3 (male subject/female operator), 61 subjects (61.0%) reported no-to-mild pain and 39 subjects (39.0%) reported moderate-to-severe pain. For Group 4 (male subject/male operator), 59 subjects (59.0%) reported no-to-mild pain and 41 subjects (41.0%) reported moderate-to-severe pain. When standard deviations are taken into account, all groups had ranges into the moderate or severe categories (Tables 9, 10).

Overall, these findings showed that solution deposition pain was the most painful phase of injection in each of the four groups. This difference is to be expected for several reasons. Needle deposition pain is a direct reflection on physical tissue displacement. Our study used mainly dental students who volunteered to participate in a dental injection study. It was expected that they would feel relatively comfortable with dental injections, thus leading to low anxiety and needle insertion pain ratings. In addition, needle insertion and placement happens over just a few seconds, while solution placement pain was of longer duration (60 seconds). This contrast may have played a role in why subjects rated this to be more painful than needle insertion and placement pain.

While solution deposition pain was the most painful phase of the injection, it was only shown to be statistically significant by gender of subject and operator (Group 2).
This can be explained, in part, by the cumulative effect of 2 important aspects of this group. First, the subjects reporting pain in this group are females who have been shown in other studies to report more pain than men (66, 67, 74, 75). Second, other studies have shown this phase of maxillary infiltration injections to be the most painful, which would explain the high pain ratings in this group (24-26). While these theories help explain our results, it is interesting to point out that females in Group 2 (female subject/male operator) showed significantly higher pain ratings than females in Group 1 (female subject/female operator). These findings suggest that the interaction of female subjects receiving injections from male operators was responsible for the higher pain ratings, which has been shown in other studies where participants in a cold presser study showed male participants reported significantly lower pain levels to a female than to a male (88). However, this was only evident during solution deposition and not needle insertion or placement. These observations suggest that gender interaction is only significant during the most painful phase of the injection. It should be noted that although these results showed a statistically significant difference, the results were not so dramatic that one would necessarily expect a clinically significant difference.

Our solution deposition pain can be compared to those in other studies who also administered maxillary infiltration injections over a 60 second time frame. While the results between the studies are similar, the pain scales used were not identical. Slight differences may be due to the fact that we used a 170-mm VAS which may allow for an easier discrimination between small differences in pain reporting than does the 4-point scale and 100-mm scales used in the comparable studies.
Some authors have reported lower pain levels than those found in our study. Mason (15) compared the analgesic efficacy of 2% lidocaine with 1:100,000 epinephrine, 2% lidocaine with 1:50,000 epinephrine, and 3% mepivacaine in maxillary lateral incisors and first molars administered over 60 seconds. Sixty subjects participated in the study. In a similar study design to Gross (11) and Mikesell (13), pain was reported on a 4-point scale. For the group receiving 2% lidocaine with 1:100,000 epinephrine, they found that 100% of participants experienced zero-to-mild pain. For the group receiving 2% lidocaine with 1:50,000 epinephrine, they found that 93% of participants experienced zero-to-mild pain and 7% experienced moderate pain. For the group receiving 3% mepivacaine, they found that 93% of participants experienced zero-to-mild pain and 7% experienced moderate pain. Zero participants reported severe pain for solution deposition in any of the groups. Katz et al. (17), found similar results. They studied the anesthetic efficacy of 1.8 mL of 4% prilocaine with and without 1:200,000 epinephrine and 2% lidocaine with 1:100,000 epinephrine in maxillary lateral incisor buccal infiltration injections given over 60 seconds. Sixty subjects participated in the study. In a similar study design to other studies (11-18), pain was reported on a 4-point scale. Participants were also asked to mark their pain on a 100-mm VAS scale. In the 4% prilocaine group, 100% reported no-to-mild pain. In the 4% prilocaine group with 1:200,000 epinephrine group, 100% reported no-to-mild pain. In the 2% lidocaine with 1:100,000 epinephrine group, 86.7% reported no-to-mild pain while 13.3% reported moderate-to-severe pain. No significant difference was found between the three groups. Similar to Mason (15), these ratings were lower than those found in our group. This difference could be attributed to several differences in study design. First, differences could be related to each
administering operator, lack of operator calibration, and the influence of personal interaction with participants. Our study did not allow personal interaction, aside from a scripted personal introduction. The aforementioned studies were studying local anesthesia and were not as focused on limiting personal interaction between operators and subjects. This interaction has the potential to influence the reported pain ratings of the participants. Also, both of these studies included much smaller sample sizes (60 subjects in each) in comparison to ours (200 subjects). This larger sample population may be a better representation of true deposition pain ratings as more people were included in our study. Lastly, these studies used different pain rating scales than those used in our study. Our pain ratings were recorded on a 170-mm VAS scale which is a much broader scale than a 4-point questionnaire. This difference may have allowed us to better differentiate between mild, moderate, and severe pain.

Several studies have reported similar solution deposition ratings to our findings. Gross (11) administered 1.8 mL of 2% lidocaine with 1:100,000 epinephrine and 1.8 mL of 0.5% bupivacaine with 1:100,000 epinephrine in human maxillary anterior infiltration injections given over the lateral incisor over 60 seconds. Participants in the lidocaine group reported zero-to-mild pain 40% of the time while 60% reported moderate-to-severe pain. These findings were very similar to those found in our study for solution deposition pain using lidocaine with 1:100,000 epinephrine. Mikesell (13) studied anesthetic efficacy of 1.8 mL and 3.6 mL of 2% lidocaine with 1:100,000 epinephrine for maxillary infiltration injections. In a similar study design to Gross (11), pain was reported on a 4-point scale. For the group receiving 1.8 mL of anesthetic, 63% of participants reported
zero-to-mild pain while 37% reported moderate-to-severe pain. As with Gross (11), these pain scores were very similar to those found in our study.

Scott and co-authors (19) also reported on maxillary anterior injection pain. Their study had 40 subjects, (28 men and 12 women) who were given repeat maxillary infiltration injections given in two separate appointments. In the group where an initial infiltration followed by a mock injection was given, they found that 68% of participants had no-to-mild pain and 32% reported moderate-to-severe pain for solution deposition pain. In the group where an infiltration initial injection followed by a lidocaine injection was given, they found that 69% of participants had no-to-mild pain and 31% reported moderate-to-severe pain for solution deposition pain. These findings were similar to the values found in our study.

Evans (21) studied the anesthetic efficacy of 4% articaine with 1:100,000 epinephrine versus 2% lidocaine with 1:100,000 epinephrine in maxillary infiltrations. Forty adult participants (25 men and 15 women) were used in the study. Participants rated their pain on a 170-mm VAS after each injection. For solution deposition pain, the mean pain ratings were 59.0 ± 33.0 mm for the articaine group and 51.0 ± 33.0 mm for the lidocaine group. No significant difference was found between the groups. The 170-mm pain scale used in this study was identical to the one used in our study. This helps to have the most direct comparison amongst all of the comparative studies. Overall, our solution deposition pain was similar to those reported in the 2% lidocaine with 1:100,000 epinephrine group (47 – 68 mm) (Table 9)
Hobeich and co-authors (23) studied injection pain and anesthetic success of 2% lidocaine with 1:100,000 epinephrine buffered with 5% and 10% sodium bicarbonate in maxillary infiltrations. Thirty subjects (12 men and 18 women) in their study received a single maxillary canine infiltration injection of 1.8 mL 2% lidocaine with 1:100,000 epinephrine, 2% lidocaine with 1:100,000 epinephrine buffered with 5% or 10% sodium bicarbonate. They found that for the non-buffered anesthetic, 5% and 10% buffered solutions, solution deposition mean VAS values were 39.0 ± 24.0 mm, 45.0 ± 21.0 mm, and 42.0 ± 26.0 mm, respectively. These values were lower than those recorded in the current study.

Overall, several studies found similar results for solution deposition pain (11-14, 19-23). While none of the comparative studies evaluated the role gender had on reported pain, we found that females reported the highest pain when receiving injections from a male operator. Many studies have found that females report higher pain levels than men, which is discussed in greater detail later.

Injection Preference

At the end of the second injection, participants were asked to fill out a questionnaire regarding which injection, if any, they perceived as more painful. They were able to respond one of 3 ways; 1=the first injection was more painful, 2=the second injection was more painful, or 3=neither injection was more painful than the other. These results were further analyzed to determine if the subject gender played a role in injection preference (Tables 12-14). No significant difference in preference was found among
female participants between the first or second injection (Table 14). However, there was a significant difference found in preference of both the first injection (p=0.00016) and second injection (p=0.00002) as compared to no preference between the two injections. While females did not perceive one injection to be more painful than the other, most of the respondents (88%) chose either the first or second injection as opposed to no difference in injection pain (option 3). Among the three options (1=the first injection was more painful, 2=the second injection was more painful, or 3=neither injection was more painful than the other), no significant difference in preference was found among male participants (Tables 12-14).

Segura-Egea (58) studied the role gender plays in pain felt during root canal treatment. One hundred and seventy-six patients (68 men and 108 women) completed a 100 mm VAS after root canal treatment. Teeth of all pulpal and periodontal diagnosis were used. They did not find a significant difference in average pain scores felt between men and women. They did however find that men were much more likely to report “zero” pain than women, while women were more likely to report slight-moderate pain than men. This finding is interesting as our study showed that males did not tend to find a difference in injection pain between appointments while females were more likely to choose one appointment being more painful than the other.

The differences found could be due to something called an order effect. This refers to the idea that a patient’s pain perception may be influenced by the effect that the order of injection has on pain. Bartfield and co-authors (36) have found contrasting results that order effect has on injection pain. In one study, 91 adult patients with simple
linear lacerations were injected with either buffered or plain lidocaine. In one group, the first wound edge was injected with the buffered anesthetic while the second wound edge was injected with the non-buffered anesthetic. In another group, the first wound edge was injected with the non-buffered anesthetic while the second wound edge was injected with the buffered anesthetic. Patients recorded pain on a 100-mm VAS. Their results found that the second injection was significantly less painful than the first injection for both groups. The authors concluded the difference in pain scores “was attributed to either a diffusion of local anesthetic from one wound wedge to the other, or to patients feeling more comfortable and less anxious if pain felt was less than had been previously perceived before the first injection.”

Other studies have found results opposite to those found by Bartfield and co-authors (36). A similar study comparing buffered and non-buffered local anesthetic injections in wound edges was later done by Orlinksky and coauthors (37). They found that patients preferred the first injection to the second injection, regardless of the anesthetic used. They attributed this to the fact that, “Such a psychological reaction might be explained by the difference in the expectation of pain and the actual level of pain produced by the stimulus. If the patient was told that the injection would be painful or if the patient did not know what to expect, the patient’s anticipation of pain would usually be heightened and the actual pain produced by the stimulus relatively diminished. On the second injection, however, the patient has already experienced the pain and the anticipation of pain would be very close to what would actually happen.”
In a separate study done by Bartfield’s group (38), participants received a 0.5 mL intradermal injection in each forearm and were told the injection would be lidocaine with or without a buffering agent, to which they would be blinded. In reality, all patients received buffered lidocaine for both injections. Each participant rated his/her pain on a 100-mm VAS. Their results found that the second injection was significantly more painful than the first. Fitton (39) found similar results when comparing injection pain. Pain scores were significantly lower for the initial injection in comparison to the second. It is difficult to determine the effect injection sequence has on pain perception. Several other studies (40-44) have failed to find a significant difference between pain experienced during first or second injections among patients. It was important to take elapsed time between injections into account. Other studies have hypothesized that patient perception of pain may change over time (66, 102). In a study conducted by Kent (102), dental patients' reports of dental pain given 3 months after an appointment were often different from reports given immediately after the appointment. It was noted that anxious patients reported a higher level of pain at the 3 month mark than they had reported after the dental appointment. He suggested that, “A patient's memory of pain is remodeled over time to become consistent with the existing level of anxiety”.

While our study did not find one injection to be more painful than the other, females were less likely than males to actually choose the option that the two injections were equally as painful. This could be due to the fact that many female participants assumed we were studying something and tried to choose one of the options since having two of the same injection seemed unlikely. It is possible that females may have been more thorough in answering the question and gave a more earnest effort in providing a
conclusive answer, while men may have been less enthused about taking the survey. This would be consistent with other studies that have shown females to have a higher response and participation rate with regard to taking surveys (79, 80). Also, since at least two weeks passed between each injection, it may have been difficult for participants to remember how painful their last injection was.

**Pain coping ability**

All participants were asked to rate his/her own ability to cope with pain based on a 100-mm pain rating scale with higher numbers illustrating more difficulty coping with pain (Tables 15 and 16). This scale was used as it is very similar to a commonly used 100-mm VAS pain rating scale that has been shown to be reliable and has consistent interpretation values (103). In a traditional 100-mm VAS, individuals mark, using a vertical line, any point on a pre-measured 100-mm horizontal line with zero representing no pain and 100 representing maximum pain possible. Results are interpreted as follows; 0-4 mm equals no pain, 5-44 mm equals mild pain, 45-74 mm equals moderate pain, and 75-100 mm equals severe pain. Our modifications to a pain coping ability were as follows; 0-4 mm signified no difficulty coping with pain, 5-44 mm signified mild difficulty coping with pain, 45-74 mm signified moderate difficulty coping with pain, and 75-100 mm signified severe difficulty coping with pain. Our results found that female participants showed a statistically lower pain coping ability (mean 27.1 ± 17.4 mm) than their male counterparts (22.2 ± 17.1 mm) (Table 15). Of the 100 female participants (Table 16), 9 reported no difficulty coping with pain, 74 reported mild difficulty, 15
reported moderate difficulty, and 2 reported severe difficulty. Of the 100 male participants, 10 reported no difficulty coping with pain, 79 reported mild difficulty, 10 reported moderate difficulty, and 1 individual reported severe difficulty. Overall, women rated themselves as having more difficulty coping with pain than males (Tables 15, 16). As previously stated, studies have shown women to have a lower acceptance of pain, a greater fear of pain, and to avoid pain more than males (64). Pain-coping ability was studied in order to detect if the perception of oneself to tolerate pain would relate to experienced pain. Although females rated themselves as less able to tolerate pain, they only reported higher pain during the anesthetic deposition phase of the injection when administered by a male operator.

**Gender and pain**

In this study, the only significant difference found was among female subjects. This is consistent with many other studies that have shown women to report more pain than men. Many conditions have been shown to be much more prevalent in women including migraine headaches (51), irritable bowel syndrome (52), and fibromyalgia (53) while others such as cluster headaches (54) are more prevalent among males. Ruau et al. (55) conducted a cohort study that compared sex differences found in electronic medical records of 11,000 patients. Data collected consisted of reported pain scores in various disorders including musculoskeletal, circulatory, respiratory, and digestive systems. They found that on average, women scored higher than men in the majority of categories. In fact, several diagnostic sections exhibited greater than 20% higher pain level experienced
by women compared to men. It was no surprise to us that the female groups reported more pain than males. However, a significant part of our study was that females only reported a statistically higher pain rating when receiving an injection by a male operator and only during the solution deposition phase of the injection. Our findings showed that women and men reported similar pain ratings during the other two phases (needle insertion and needle placement) of the injection regardless of the operator. Also, females who received an injection by a female operator reported similar pain ratings to the male group.

Several studies have shown strong evidence that men and women have very different abilities to tolerate pain. (65, 66, 67, 70, 75, 76). These studies revealed that overall, women report higher pain and have much lower pain tolerance ratings than males. Each of these studies is discussed in greater detail in the introduction. However, this was only evident in the male operator and female subject group. These findings suggest that the interaction of female subjects receiving injections from male operators was responsible for the higher pain ratings, which has been shown in another study by Levine and DeSimone (88). Their study was a cold pressor study where each subject would place his/her hand in a cold water bath and the operator would record findings and temperatures. Male participants reported significantly lower pain levels to a female than a male. In addition, female participants reported higher levels of pain to a male experimenter than a female, but the difference was not statistically significant.

**Operator gender as a variable**
It is difficult to conclusively state why females who receive injections from males felt more pain during solution deposition. Due to the large number of studies that report higher pain values for females in comparison to males, we believe this could have played some role in the results. One explanation as to why a discrepancy in pain tolerance exists between men and women is a result of social expectations. This reasoning suggests men are expected to behave in a more “stoic” manner (66). Otto and Dougher (77) studied traditional masculine beliefs and their correlation with higher pain threshold and tolerance when compared to women. Eighty undergraduate volunteers (40 male, 40 female) from an introductory psychology class at the University of New Mexico participated in the study. Two male and two female students in an advanced psychology class were the experimenters. All subjects completed a Bern Sex-Role Inventory Questionnaire, which is a sex-role inventory questionnaire designed to characterize a person as masculine, feminine, or “androgynous”. The scale is based on a 7-point scale on how each of 60 masculine, feminine, and neutral personality traits describes one’s self (78). After the Bern Sex-Role Inventory scale was completed, subjects were asked to place his/her middle finger in a focal pain simulator consisting of a dull Lucite edge weight with a continuous pressure of 640 gm. The device produced a dull pain that gradually increased in intensity. The results of the study showed two important conclusions. The first conclusion regarding the effect of the experimenter’s sex was stated as follows’ “Analysis of factorial design, crossing experimenter’s sex with subject’s sex, with 20 subjects in each of the four cells yielded a significant effect for subject’s sex but no main effect or interaction for experimenter’s sex. Therefore, the experimenter’s sex was ignored for subsequent analysis.” This differs from our study
where operator gender was used for statistical analysis; however, they only had 2 female and 2 male experimenters. The results showed that men scored much higher on the masculinity portion of the Bern Sex-Role Inventory scale and women scored much higher on the femininity portion. In addition, the male subjects displayed a much higher pain threshold (64.1 seconds for men vs. 32.5 seconds for women) and overall pain tolerance (172.6 seconds for men vs. 98.9 seconds for women) when compared to females. It is possible that the men in our study were attempting to show more stoic behavior during the most painful part of the injection, solution deposition and that their female counterparts were less inclined to display this stoic characteristic. It is possible that in our study, men were trying to be more stoic regardless of the gender of the operator. In contrast, it is possible that females showed more stoic attributes when receiving injections from a female operator but were less inclined to do so when receiving an injection from a male operator.

Robinson et al. (81) conducted an analysis regarding sex differences in expectations of pain. Participants consisted of 156 male and 235 females who were asked to complete the Gender Role Expectations of Pain questionnaire which is used to measure sex-related stereotypic attributions of pain sensitivity, endurance, and willingness to report pain. Women rated men as having greater endurance, less willingness to report pain, and slightly less sensitivity to pain. In contrast, men rated women as having less endurance and more willingness to report pain. The majority of men (65.7%) rated their own endurance as higher than the typical pain, lending to the notion that many men often try and live up to a societal “stoic” expectation. These reports conclude that men are expected by both sexes to have higher pain endurance and lower pain sensitivity than
women. Females may have been more inclined to report vulnerability to their male counterparts. This may have been reflected in our study with regard to females reporting higher pain levels after receiving injections from a male operator.

Another explanation as to why women in our study reported more pain when the operator was a male could be a reflection on gender personality tendencies. Men are often viewed as more forceful and aggressive while females are viewed as caring and nurturing. It would be plausible that the male participants in our study showed an overall stoic tendency by reporting low pain scores for solution deposition, shown to be the most painful part in maxillary infiltration injections, regardless of the operator gender. However, females may have been attempted to give pain ratings closer to the reality of pain felt from the solution deposition phase of maxillary infiltration injections. The fact that they reported much higher pain ratings to a male operator in comparison to a female operator could be a reflection that they perceived female operators to be more gentle clinicians than males during painful procedures. This would be consistent with other studies that have found that many people perceive female dentists to be more gentle than male dentists. In a survey regarding pain in dentistry (106), 106 students and 54 non-college students completed a one-page survey on traits displayed by male and female dentists. They found that, “female dentists were viewed as significantly more likely to make patients feel relaxed and to take time to discuss ailments with them, perceptions found most frequently among those respondents who expressed a preference for a female dentist. Male dentists were perceived as significantly more likely to expect a patient to endure pain without complaints, more devoted to career than family, and more likely to seem to be in charge and to be attracted to the power of their profession”. However, it is
possible that these perceptions could have been a factor as to why females perceived more pain during solution deposition when the operator giving the injection was a male.

Other studies have evaluated operator gender and its relationship to pain and anxiety. Wahl et al. (87) showed a difference in injection pain when using prilocaine plain vs. mepivacaine plain, articaine with 1:100,000 epinephrine, and lidocaine with 1:100,000 epinephrine using a 25-gauge 1-inch needle. Their double-blind study involved 1,391 adult patients receiving dental treatment. The subjects received injections of one of the four aforementioned anesthetics via a maxillary buccal infiltration, palatal infiltration, or inferior alveolar block injection from one of 2 dentists (one female and one male). Patients reported his/her pain using a 10-point scale, with “1” indicating no pain and “10” indicating unbearable pain. Their study showed two significant conclusions. First, prilocaine plain produced significantly lower pain scores than lidocaine with epinephrine, mepivacaine plain, or articaine with epinephrine. Also, it was shown that male patients reported more pain to the male dentist (mean=2.98 ± 1.82) than the female dentist (mean=2.66 ± 1.78), whereas female patients reported more pain to the female dentist (mean=3.51 ± 2.24) than to the male dentist (mean=3.29 ± 1.85). While gender could have played an important role in determining the outcome of this study, it should be noted that there were only two dentists administering injections. Since neither dentist was calibrated to use the same injection technique or say the same thing to each patient, operator personality and technique may have played a role in the observed outcome. This study was also unique from ours as individual subjects were not able to directly compare the operators. Each patient received an injection from either the male or female operator, but not from both. Our study was unique in that each individual subject received
injections by both a male and a female operator, thus allowing for direct comparisons of operators by the same subject.

Levine and De Simone (88) also found that the sex of the experimenter had an effect on the degree of pain reported by male and female participants in a cold presser study. As part of a psychology course requirement, the subjects were 35 male and 33 female undergraduate students with an age range of 17-29 years. In a double blind study, subjects were randomly assigned to either a male or female experimenter. The cold pressor test consisted of having subjects place his/her hand in a bucket filled with ice water where the temperature was 0-1°C. Pain reports were given on a scale from 1-32, with 32 being the most painful. Pain levels were recorded every 15 seconds, and continued until the 12 minute mark or when the subject withdrew his/her hand from the ice water bath. The experimenters were encouraged to dress in accordance with stereotypical gender characteristics of masculinity and femininity. The male experimenter wore sleeveless t-shirts. The female wore sweaters, A-line skirts and heels. Both of the experimenters followed a written script. Their results were slightly different than the previous study. Males reported an average pain rating of 19 ± 2.50 when the experimenter was a male, versus 10.0 ± 2.70 when the experimenter was a female. Females however reported an average of 24 ± 2.0 when the experimenter was a female versus 29 ± 2.90 when the experimenter was a male. Statistical analysis showed that male participants reported significantly lower pain levels to a female than to a male, while female participants reported higher levels of pain to a male experimenter than a female. This result is hypothesized to be a result of a “societal gender role requirement of men wanting to appear macho”, according to the study. While our study did not find a
difference in pain reports among male subjects, our results were similar to the female pain ratings in that we also found females to report higher pain to male operators.

The last hypothesis as to why women in our study reported more pain to male operators than females could be that the men in our study did, in fact, give more painful injections than their female counterparts. It is possible that male subjects were less likely to be honest about the true pain felt in attempt to appear tough or macho while women were more honest in true injection pain from the male operators. This would be consistent in another study by Cunningham and Kelsey (104) who found that, “while women had more musculoskeletal complaints than men, musculoskeletal disorder was equally prevalent in the 2 groups on physical examination.” Our findings may be a reflection on gender differences in reporting pain as opposed to actual pain experienced. While we did not find males to give more painful injections overall, this could have been statistically skewed if males underreported their pain.

**Biological differences for pain differences**

It has been hypothesized that biological mechanisms may play a role in explaining the gender pain disparity. The monoamine neurotransmitter serotonin (5HT) is a vasoactive mediator that causes vasoconstriction and is present in nerve terminals, endothelial cells, and platelets (82). It has also been shown to be a nociceptive mediator that has the ability to evoke hyperalgesia when injected in to human tissues (83). Fehrenbacher and co-authors (84) studied capsaicin-evoked calcitonin gene related peptide (CGRP) release from the human dental pulp. This study evaluated the
responsiveness of isolated human nociceptors by measuring stimulated release of neuropeptides from collected dental pulp biopsies. They found that gender did not play a role in the amount of CGRP released from human dental pulp. However, gender did play a role on the inhibitory effect of DAMGO (D-Ala2, N-MePhe4, Gly-ol-enkephalin), a synthetic opioid peptide used in experimental settings for the possibility of reducing opiate tolerance for patients under the treatment of opioids. DAMGO, in the presence of PGE2, had a greater ability to reduce the CGRP in male human dental pulps when compared with female human dental pulps. These results suggest a biologic mechanism in which many men have naturally higher pain thresholds than women.

Several studies have attempted to evaluate the role hormonal levels and menstrual cycle phases may play a role in pain levels among females. We did not include this information in our study, although it could have been a potential factor as to why a certain groups of female participants recorded higher pain ratings. While the following studies discuss pain experienced along different phases of the menstrual cycle, further studies would be important in determining whether or not it has a significant effect on injection pain, as well as many basic dental procedures. Also, it is important to note that the participants in each of these studies only observed females under relatively normal, non-emergent conditions. It is possible that these ratings could be altered during times of painful inflammatory conditions, i.e. symptomatic irreversible pulpitis.

Lloyd et al. (85) studied the role gender plays when comparing capsaicin and serotonin pain pathways. Pulpal tissue was collected from 140 extracted molar teeth from men and women. These pulps were treated with 5HT and capsaicin followed by
quantification using an enzyme immunoassay. Capsaicin alone was shown to evoke concentration-dependent CGRP release from the dental pulp. Serotonin, however, enhanced capsaicin-stimulated CGRP release from the female but not the male human dental pulp. This difference was believed to be due to a sexually dimorphic effect of serotonin effect on CGRP concentrations or the level of capsaicin receptors (TRPV1). It was also noted that serotonin-enhanced CGRP release was lowest in the female dental pulp in the week during menses (days 1-7) but highest in the week before menses (days 22-28). This evidence suggests certain hormone and pain pathways may play a key role in the difference in pain sensitivity among genders.

Fillingim et al. (86) observed pain sensitivity among females during different phases of the menstrual cycle. Female participants were instructed to respond to thermal pain onset and thermal pain tolerance using a thermal probe to the left volar forearm. They were also asked to rate ischemic arm pain using a blood pressure cuff used as a tourniquet. Their findings showed that while thermal pain sensitivity did not vary across the menstrual cycle, ischemic pain did show a significant difference. Ischemic pain tolerance was marginally higher during the ovulatory phase and significantly higher when compared to the mid-to-late luteal phase.

In a meta-analysis of 16 published articles examining the relationship between experimentally induced pain and the menstrual phase among healthy adult females, pain was found to vary during different parts of the ovulation cycle (107). They found that during the follicular phase where progesterone levels are particularly low, females had
highest pain thresholds and highest tolerances to pain. Therefore, hormone levels and menstrual cycles can affect pain tolerance levels of women.

While these studies have shown a biological model as to why women may experience higher levels of pain than males, it was not likely a factor in our study. While the injections in our study caused pain, they were only administered for a short duration of time. Therefore, these injections did not likely cause a large amount of CGRP release by participants. This study was a non-inflammatory model where participants did not initially present with pain. Future studies may be focused on exploring differences in pain reports on patients presenting with pain who are about to undergo a perceived painful procedure, such as a root canal or extraction.

Overall other studies have detected gender differences regarding pain perception. As previously stated, it is important to note that the subjects in these studies were exposed to seemingly more painful stimuli than maxillary infiltrations. Several experimental studies that have shown a significant difference in pain ratings between female and male participants include: cold pressor pain studies where subjects were instructed to hold his/her hand in a cold water bath for several minutes or until the pain was too painful to bear (74, 75, 88), mechanical pressure studies where participant placed his/her heel on the floor with the Achilles tendon positioned between two motor-driven rods and pressure was increased until the subject signaled that the pain was too much to bear (67), and heat stimulation studies where a contact thermode was applied to the thenar surface of the right hand using a computer-controlled thermal sensory analyzer (66). While these studies were able to detect pain rating differences between female and
male participants, these studies were designed to evoke extremely painful stimuli in order to reach maximum pain thresholds. This may not be applicable to common dental procedures, such as maxillary anterior infiltrations.

Our study is the first to evaluate gender of the operator and its influence on gender of the subject in a dental setting using maxillary anterior infiltrations. We found that, in asymptomatic participants, operator and subject gender may influence perceived pain in a common dental setting of a maxillary anterior infiltration. Our findings showed that female subjects reported significantly higher pain levels during the solution deposition phase of maxillary infiltrations when the operator was a male. This finding was statistically significant.
CHAPTER 5

SUMMARY AND CONCLUSIONS

The purpose of this investigation was to evaluate for gender differences on injection pain of maxillary infiltration injections using 2% lidocaine with 1:100,000 epinephrine. Two-hundred healthy (100 male and 100 female) adult subjects participated in this study. Each subject received an injection by two (one female and one male) of twenty different calibrated operators spaced 2 weeks apart. Each subject completed a Corah’s Dental Anxiety Scale to rate his/her level of anxiety before and after each injection. Each subject subsequently rated the pain for each phase of each injection: needle insertion, needle placement, and deposition of anesthetic solution using a Heft-Parker visual analogue scale (VAS).

No significant difference in anxiety was found between male and female participants according to the Corah’s Dental Anxiety Scale questionnaire. Also, no significant difference was found in pre-injection or post-injection questionnaires. This leads to the notion that, in a noninflammatory model, male and female participants may not differ with regard to dental anxiety.

Female participants reported having greater pain during solution deposition (p<0.05) in comparison to male subjects, but there were no significant differences in
reported pain during the needle insertion or needle placement phases of the injection. However, this finding was only evident when the injection was administered by a male operator, and not when the operator was female. Male subjects did not show a difference in injection pain regardless of the phase of the injection or the gender of the operator. It appears that subject and operator gender may play a role in the solution deposition phase of maxillary infiltration pain.

Overall, operator and subject genders were not a critical factor in altering pain perception of maxillary infiltration injections. Further research should be done to see if gender plays a significant role in an inflammatory model where subjects present with pain and subsequently undergo a dental procedure.
LIST OF REFERENCES


13. Mikesell A. Anesthetic efficacy of 1.8 mL and 3.6 mL of 2% lidocaine with 1:100,000 epinephrine for maxillary infiltrations. The Ohio State University, 1986. Masters thesis.


APPENDIX A

TABLES
<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Male</td>
<td>10</td>
<td>50</td>
</tr>
<tr>
<td>Subject Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>100</td>
<td>50</td>
</tr>
<tr>
<td>Male</td>
<td>100</td>
<td>50</td>
</tr>
<tr>
<td>Number of Injections Per Side</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male Left</td>
<td>100</td>
<td>50</td>
</tr>
<tr>
<td>Male Right</td>
<td>100</td>
<td>50</td>
</tr>
<tr>
<td>Female Left</td>
<td>100</td>
<td>50</td>
</tr>
<tr>
<td>Female Right</td>
<td>100</td>
<td>50</td>
</tr>
</tbody>
</table>

Table 1. Study Participants and Injection Side.

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Age Range (years)</th>
<th>Mean Age (years)</th>
<th>Standard Deviation</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operator</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>10</td>
<td>25-33</td>
<td>27.3</td>
<td>2.5</td>
<td>&gt;.05*</td>
</tr>
<tr>
<td>Male</td>
<td>10</td>
<td>25-32</td>
<td>28.6</td>
<td>2.1</td>
<td></td>
</tr>
<tr>
<td>Subject</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>100</td>
<td>20-63</td>
<td>25.8</td>
<td>7.9</td>
<td>&gt;.05*</td>
</tr>
<tr>
<td>Male</td>
<td>100</td>
<td>21-52</td>
<td>26.0</td>
<td>4.0</td>
<td></td>
</tr>
</tbody>
</table>

* Randomization test.

Table 2. Biographical Data.
<table>
<thead>
<tr>
<th>Experience</th>
<th>Female (N)</th>
<th>Male (N)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental Student</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Endodontic Resident</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>Endodontic Faculty</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 3. Operator Experience by Gender.
<table>
<thead>
<tr>
<th>Gender</th>
<th>Variable</th>
<th>N</th>
<th>Median</th>
<th>Interquartile Range</th>
<th>Range</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>*Experience Level</td>
<td>10</td>
<td>2</td>
<td>1</td>
<td>1-3</td>
<td>&gt;0.05**</td>
</tr>
<tr>
<td>Male</td>
<td>*Experience Level</td>
<td>10</td>
<td>2</td>
<td>1</td>
<td>1-2</td>
<td></td>
</tr>
</tbody>
</table>

*1=Dental student 2=Endodontic Resident 3=Faculty
** Mann-Whitney-Wilcoxon test.

Table 4. Operator Experience Level by Gender.
<table>
<thead>
<tr>
<th>Group</th>
<th>Subject</th>
<th>Operator</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Female</td>
<td>Female</td>
</tr>
<tr>
<td>2</td>
<td>Female</td>
<td>Male</td>
</tr>
<tr>
<td>3</td>
<td>Male</td>
<td>Female</td>
</tr>
<tr>
<td>4</td>
<td>Male</td>
<td>Male</td>
</tr>
</tbody>
</table>

Table 5. Groups by Gender of Subject and Operator.
<table>
<thead>
<tr>
<th>Gender</th>
<th>Variable</th>
<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Median</th>
<th>Quartile Range</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>Corah’s Dental Anxiety (Pre-Injection)</td>
<td>100</td>
<td>5.6</td>
<td>1.3</td>
<td>5</td>
<td>1</td>
<td>&gt;0.05*</td>
</tr>
<tr>
<td>Male</td>
<td>Corah’s Dental Anxiety (Pre-Injection)</td>
<td>100</td>
<td>5.7</td>
<td>1.6</td>
<td>5</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>Corah’s Dental Anxiety (Post-Injection)</td>
<td>100</td>
<td>5.7</td>
<td>1.4</td>
<td>5</td>
<td>1</td>
<td>&gt;0.05*</td>
</tr>
<tr>
<td>Male</td>
<td>Corah’s Dental Anxiety (Post-Injection)</td>
<td>100</td>
<td>5.7</td>
<td>1.7</td>
<td>5</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

* Mann-Whitney-Wilcoxon test.

Table 6. Corah’s Dental Anxiety Scale Ratings.
<table>
<thead>
<tr>
<th>Subject/Operator</th>
<th>4-8</th>
<th>9-12</th>
<th>13-14</th>
<th>15-20</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mild Anxiety</td>
<td>Moderate Anxiety</td>
<td>High Anxiety</td>
<td>Severe Anxiety</td>
</tr>
<tr>
<td>Female/Female</td>
<td>96</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>96</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Female/Male</td>
<td>93</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>92</td>
<td>8</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Male/Female</td>
<td>96</td>
<td>4</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>93</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Male/Male</td>
<td>93</td>
<td>7</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>91</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 7. Corah’s Dental Anxiety Scale Ratings by Category.
<table>
<thead>
<tr>
<th>Subject Gender</th>
<th>Operator Sequence</th>
<th>N (%)</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>Female/Male</td>
<td>54/200 (27.0)</td>
<td>&gt;.05</td>
</tr>
<tr>
<td>Female</td>
<td>Male/Female</td>
<td>46/200 (23.0)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>Female/Male</td>
<td>45/200 (22.5)</td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>Male/Female</td>
<td>55/200 (27.5)</td>
<td></td>
</tr>
</tbody>
</table>

*Values analyzed using Chi-square test.

Table 8. Injection Sequence by Subject Gender.
<table>
<thead>
<tr>
<th>Group (Subject/Operator)</th>
<th>Stage</th>
<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Group (Subject/Operator)</th>
<th>Stage</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Delta</th>
<th>P(adj)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female/Female</td>
<td>INS</td>
<td>100</td>
<td>53.2</td>
<td>30.0</td>
<td>Female/Male</td>
<td>INS</td>
<td>46.2</td>
<td>30.5</td>
<td>7.0</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>PLC</td>
<td>100</td>
<td>46.8</td>
<td>28.0</td>
<td></td>
<td>PLC</td>
<td>49.7</td>
<td>34.0</td>
<td>-2.9</td>
<td>&gt;0.05</td>
<td></td>
</tr>
<tr>
<td>DEP</td>
<td>100</td>
<td>54.4</td>
<td>34.9</td>
<td></td>
<td>DEP</td>
<td>68.0</td>
<td>38.1</td>
<td>-13.6</td>
<td>0.0357*</td>
<td></td>
</tr>
<tr>
<td>Female/Female</td>
<td>INS</td>
<td>100</td>
<td>53.2</td>
<td>30.0</td>
<td>Male/Female</td>
<td>INS</td>
<td>41.6</td>
<td>28.3</td>
<td>11.6</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>PLC</td>
<td>100</td>
<td>46.8</td>
<td>28.0</td>
<td></td>
<td>PLC</td>
<td>37.4</td>
<td>28.4</td>
<td>9.4</td>
<td>&gt;0.05</td>
<td></td>
</tr>
<tr>
<td>DEP</td>
<td>100</td>
<td>54.4</td>
<td>34.9</td>
<td></td>
<td>DEP</td>
<td>46.8</td>
<td>32.4</td>
<td>7.6</td>
<td>&gt;0.05</td>
<td></td>
</tr>
<tr>
<td>Female/Female</td>
<td>INS</td>
<td>100</td>
<td>53.2</td>
<td>30.0</td>
<td>Male/Male</td>
<td>INS</td>
<td>39.5</td>
<td>30.1</td>
<td>13.7</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>PLC</td>
<td>100</td>
<td>46.8</td>
<td>28.0</td>
<td></td>
<td>PLC</td>
<td>36.8</td>
<td>25.0</td>
<td>10.1</td>
<td>&gt;0.05</td>
<td></td>
</tr>
<tr>
<td>DEP</td>
<td>100</td>
<td>54.4</td>
<td>34.9</td>
<td></td>
<td>DEP</td>
<td>49.9</td>
<td>32.2</td>
<td>4.5</td>
<td>&gt;0.05</td>
<td></td>
</tr>
</tbody>
</table>

*Significantly different. Values analyzed using ANOVA and Tukey-Kramer tests

Table 9. Between Group Comparisons for Subject and Operator Gender (VAS mm).
Table 9 Continued

<table>
<thead>
<tr>
<th>Group (Subject/Operator)</th>
<th>Stage</th>
<th>N</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Group (Subject/Operator)</th>
<th>Stage</th>
<th>Mean</th>
<th>Standard Deviation</th>
<th>Delta</th>
<th>p(adj)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female/Male</td>
<td>INS</td>
<td>100</td>
<td>46.2</td>
<td>30.5</td>
<td>Male/Female</td>
<td>INS</td>
<td>41.6</td>
<td>28.3</td>
<td>4.6</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td>PLC</td>
<td>100</td>
<td>49.7</td>
<td>34.0</td>
<td>PLC</td>
<td>37.4</td>
<td>28.4</td>
<td>12.3</td>
<td>&gt;0.05</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DEP</td>
<td>100</td>
<td>68.0</td>
<td>38.1</td>
<td>DEP</td>
<td>46.8</td>
<td>32.4</td>
<td>21.2</td>
<td>0.0012*</td>
<td></td>
</tr>
<tr>
<td>Female/Male</td>
<td>INS</td>
<td>100</td>
<td>46.2</td>
<td>30.5</td>
<td>Male/Male</td>
<td>INS</td>
<td>39.5</td>
<td>30.1</td>
<td>6.7</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td>PLC</td>
<td>100</td>
<td>49.7</td>
<td>34.0</td>
<td>PLC</td>
<td>36.8</td>
<td>25.0</td>
<td>12.9</td>
<td>&gt;0.05</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DEP</td>
<td>100</td>
<td>68.0</td>
<td>38.1</td>
<td>DEP</td>
<td>49.9</td>
<td>32.2</td>
<td>18.1</td>
<td>0.0172*</td>
<td></td>
</tr>
<tr>
<td>Male/Female</td>
<td>INS</td>
<td>100</td>
<td>41.6</td>
<td>28.3</td>
<td>Male/Male</td>
<td>INS</td>
<td>39.5</td>
<td>30.1</td>
<td>2.1</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td>PLC</td>
<td>100</td>
<td>37.4</td>
<td>28.4</td>
<td>PLC</td>
<td>36.8</td>
<td>25.0</td>
<td>0.7</td>
<td>&gt;0.05</td>
<td></td>
</tr>
<tr>
<td></td>
<td>DEP</td>
<td>100</td>
<td>46.8</td>
<td>32.4</td>
<td>DEP</td>
<td>49.9</td>
<td>32.2</td>
<td>-3.1</td>
<td>&gt;0.05</td>
<td></td>
</tr>
</tbody>
</table>

*Significantly different. Values analyzed using ANOVA and Tukey-Kramer tests.
<table>
<thead>
<tr>
<th>Injection Phase</th>
<th>No – Mild (%)</th>
<th>Moderate – Severe (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insertion</td>
<td>61.5</td>
<td>38.5</td>
</tr>
<tr>
<td>Placement</td>
<td>60.0</td>
<td>40.0</td>
</tr>
<tr>
<td>Deposition</td>
<td>49.5</td>
<td>50.5</td>
</tr>
</tbody>
</table>

Table 10. Pain Ratings by Injection Phase for Maxillary Infiltration Injection.
<table>
<thead>
<tr>
<th>Group (Subject/Operator)</th>
<th>N</th>
<th>None 0 mm</th>
<th>Mild 1-54 mm</th>
<th>Moderate 55-113 mm</th>
<th>Severe 114-170 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Needle Insertion</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female/Female</td>
<td>100</td>
<td>1</td>
<td>67</td>
<td>30</td>
<td>2</td>
</tr>
<tr>
<td>Female/Male</td>
<td>100</td>
<td>8</td>
<td>48</td>
<td>41</td>
<td>3</td>
</tr>
<tr>
<td>Male/Female</td>
<td>100</td>
<td>4</td>
<td>50</td>
<td>42</td>
<td>4</td>
</tr>
<tr>
<td>Male/Male</td>
<td>100</td>
<td>9</td>
<td>59</td>
<td>30</td>
<td>2</td>
</tr>
<tr>
<td><strong>Needle Placement</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female/Female</td>
<td>100</td>
<td>3</td>
<td>72</td>
<td>25</td>
<td>0</td>
</tr>
<tr>
<td>Female/Male</td>
<td>100</td>
<td>8</td>
<td>50</td>
<td>37</td>
<td>5</td>
</tr>
<tr>
<td>Male/Female</td>
<td>100</td>
<td>6</td>
<td>48</td>
<td>44</td>
<td>2</td>
</tr>
<tr>
<td>Male/Male</td>
<td>100</td>
<td>7</td>
<td>66</td>
<td>27</td>
<td>0</td>
</tr>
<tr>
<td><strong>Deposition</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female/Female</td>
<td>100</td>
<td>5</td>
<td>40</td>
<td>48</td>
<td>7</td>
</tr>
<tr>
<td><strong>Female/Male</strong></td>
<td>100</td>
<td>4</td>
<td>29</td>
<td>53</td>
<td>14</td>
</tr>
<tr>
<td>Male/Female</td>
<td>100</td>
<td>1</td>
<td>60</td>
<td>35</td>
<td>4</td>
</tr>
<tr>
<td>Male/Male</td>
<td>100</td>
<td>3</td>
<td>56</td>
<td>37</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 11. Pain Ratings by Subject Gender, Operator Gender, and Injection Phase.
<table>
<thead>
<tr>
<th>Subjects</th>
<th>Preference (%)</th>
<th>Lower Class Boundary (0.95)</th>
<th>Upper Class Boundary (0.95)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Injection</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>41/100 (41)</td>
<td>31.3</td>
<td>51.3</td>
</tr>
<tr>
<td>Male</td>
<td>31/100 (31)</td>
<td>22.1</td>
<td>41.0</td>
</tr>
<tr>
<td>All</td>
<td>72/200 (36)</td>
<td>29.4</td>
<td>43.1</td>
</tr>
<tr>
<td><strong>Second Injection</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>47/100 (47)</td>
<td>36.9</td>
<td>52.2</td>
</tr>
<tr>
<td>Male</td>
<td>44/100 (44)</td>
<td>34.1</td>
<td>54.3</td>
</tr>
<tr>
<td>All</td>
<td>91/200 (46)</td>
<td>38.5</td>
<td>52.7</td>
</tr>
<tr>
<td><strong>No Preference</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>12/100 (12)</td>
<td>6.4</td>
<td>20.0</td>
</tr>
<tr>
<td>Male</td>
<td>25/100 (25)</td>
<td>16.9</td>
<td>34.7</td>
</tr>
<tr>
<td>All</td>
<td>37/200 (19)</td>
<td>13.4</td>
<td>29.6</td>
</tr>
</tbody>
</table>

Table 12. Subject Injection Preference by Gender.
<table>
<thead>
<tr>
<th>Subject Gender</th>
<th>First Injection (%)</th>
<th>Second Injection (%)</th>
<th>No Preference (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>41*</td>
<td>47**</td>
<td>12</td>
</tr>
<tr>
<td>Male</td>
<td>31</td>
<td>44</td>
<td>25</td>
</tr>
<tr>
<td>All</td>
<td>36*</td>
<td>46**</td>
<td>19</td>
</tr>
</tbody>
</table>

* First injection vs. no preference between injections (p<0.05).  
** Second injection vs. no preference between injections (p<0.05).

Table 13. Subject Injection Preference by Subject Gender.
**Table 14. Injection Preference by Subject Gender.**

<table>
<thead>
<tr>
<th>Subjects</th>
<th>N</th>
<th>Comparison</th>
<th>p-value**</th>
</tr>
</thead>
<tbody>
<tr>
<td>All</td>
<td>200</td>
<td>First vs. Second</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>First vs. None</td>
<td>0.00207*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Second vs. None</td>
<td>0.00001*</td>
</tr>
<tr>
<td>Female</td>
<td>100</td>
<td>First vs. Second</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>First vs. None</td>
<td>0.00016*</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Second vs. None</td>
<td>0.00002*</td>
</tr>
<tr>
<td>Male</td>
<td>100</td>
<td>First vs. Second</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>First vs. None</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Second vs. None</td>
<td>&gt;0.05</td>
</tr>
</tbody>
</table>

*Significantly different.

**Values analyzed using McNemar test and step down Bonferroni method of Holm.
<table>
<thead>
<tr>
<th>Subject</th>
<th>N</th>
<th>Mean</th>
<th>Std Dev</th>
<th>Min</th>
<th>Max</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>100</td>
<td>27.1</td>
<td>17.4</td>
<td>0</td>
<td>76</td>
<td>0.0459</td>
</tr>
<tr>
<td>Male</td>
<td>100</td>
<td>22.2</td>
<td>17.1</td>
<td>0</td>
<td>85</td>
<td></td>
</tr>
</tbody>
</table>

*Values analyzed using Randomization test. Scale is based on a 100-point scale.

Table 15. Pain Coping Ability Score by Gender.
<table>
<thead>
<tr>
<th>Gender</th>
<th>No Difficulty 0-4 mm</th>
<th>Mild Difficulty 5-44 mm</th>
<th>Moderate Difficulty 45-74mm</th>
<th>Severe Difficulty 75 to 100 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>9</td>
<td>74</td>
<td>15</td>
<td>2</td>
</tr>
<tr>
<td>Male</td>
<td>10</td>
<td>79</td>
<td>10</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 16. Pain Coping Ability Score by Gender.
Figure 1. Overall Study Flowchart.
Figure 2. Injection Pain Ratings by Subject Gender, Operator Gender, and Injection Phase.
APPENDIX C

GENERAL CONSENT FORM
A prospective, randomized study evaluating injection pain in maxillary anterior infiltrations

Principal Investigator:  Dr. Melissa Drum

Sponsor:

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

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

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

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

1. **Why is this study being done?**

   The purpose of this study is to evaluate injection pain in maxillary anterior infiltration injections.

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

   Two hundred fifteen (215) people will take part in this study.
3. **What will happen if I take part in this study?**

You will be randomly assigned (by chance, like flipping a coin) to one of 20 different operators at each of your 2 appointments.

You will receive a numbing injection into the soft tissue of the gums next to one of your upper front teeth. This upper front tooth shot will be administered using a numbing solution of 2% lidocaine with 1:100,000 epinephrine. You will return in 2 weeks to receive the same injection. You will complete a questionnaire regarding your dental anxiety before each appointment. This questionnaire will be used to assess how nervous you are before each appointment. You will also be asked to fill out a survey to rate the injection pain at the end of each appointment. Two additional questionnaires regarding pain will be given at the end of the second appointment.

4. **How long will I be in the study?**

You are aware that you will have two appointments, which will last approximately 15 minutes each (Time to fill out paper work and a 60 second injection).

5. **Can I stop being in the study?**

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty and you will be paid a pro-rated $12 per session. Your decision will not affect your future relationship with The Ohio State University.

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

You may have pain associated with the local anesthetic (numbing solution) or soreness at the site of the injections (shots) for approximately two days. Where you receive the injection, you may have swelling (hematoma—a collection of blood in your mouth) or a bruise may develop. You may experience a feeling of anxiety, lightheadedness or fainting, and or a temporary increase in your heart rate. You may have an allergic reaction to the local anesthetic (itching or hives, very rare), or have an unexpected infection (rare) which could result in permanent nerve damage. You may have soreness of your gum tissue for a few days after the injection.

If you are a woman able to have children, you will be questioned regarding pregnancy or suspected pregnancy and will not be allowed to participate if pregnant, suspect a pregnancy, trying to become pregnant, or nursing. Additionally, you will be required to take a urine pregnancy test before you can start this study. The reason for excluding pregnant or potentially pregnant women is an attempt to minimize this population in the study because of the unnecessary administration of anesthesia (numbing solution) during pregnancy.
7. **What benefits can I expect from being in the study?**

You will not directly benefit from this study. Society may ultimately benefit by decreasing pain in persons undergoing dental procedures.

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

You may choose not to participate without penalty or loss of benefits to which you are otherwise entitled. No dental treatment will be done, so no other choices are available.

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

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

Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- U.S. Food and Drug Administration;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor supporting the study, their agents or study monitors; and
- Your insurance company (if charges are billed to insurance).

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

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

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search the website at any time.
10. What are the costs of taking part in this study?
The study will pay for the cost of the study drug (lidocaine) and urine pregnancy test. You may need to pay for parking while participating in the study.

11. Will I be paid for taking part in this study?
You will be paid $25 for completing all aspects of the study. If you are unable to complete the study, you will be paid a pro-rated amount of $12 per session. You will be paid $25 in cash at the end of the second injection, or $12 after the first injection should you decide not to complete the second session. By law, payments to subjects are considered taxable income.

12. What happens if I am injured because I took part in this study?
If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center.

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

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

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

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

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

For questions, concerns, or complaints about the study you may contact Dr. Melissa Drum or Dr. Shayne Perry at 614 292-3596.

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

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Melissa Drum or Dr. Shayne Perry at 614 292-3596.

Signing the consent form

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

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

Printed name of subject ___________________________ Signature of subject ___________________________ AM/PM
Date and time ___________________________

Printed name of person authorized to consent for subject (when applicable) ___________________________
Signature of person authorized to consent for subject (when applicable) ___________________________
AM/PM
Date and time ___________________________

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

<table>
<thead>
<tr>
<th>Printed name of person obtaining consent</th>
<th>Signature of person obtaining consent</th>
<th>AM/PM</th>
<th>Date and time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Witness(es) - <em>May be left blank if not required by the IRB</em></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Printed name of witness</td>
<td>Signature of witness</td>
<td>AM/PM</td>
<td>Date and time</td>
</tr>
<tr>
<td>Printed name of witness</td>
<td>Signature of witness</td>
<td>AM/PM</td>
<td>Date and time</td>
</tr>
</tbody>
</table>
APPENDIX D

PRIVACY FORM
THE OHIO STATE UNIVERSITY
AUTHORIZATION TO USE
PERSONAL HEALTH INFORMATION IN RESEARCH

Title of the Study: A prospective, randomized study evaluating injection pain in maxillary anterior infiltrations

OSU Protocol Number:

Principal Investigator: Dr. Melissa Drum DDS, MS

Subject Name__________________________________________________________

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

• The Ohio State University and its hospitals, clinics, health-care providers and researchers are required to protect the privacy of your health information.

• You should have received a Notice of Privacy Practices when you received health care services here. If not, let us know and a copy will be given to you. Please carefully review this information. Ask if you have any questions or do not understand any parts of this notice.

• If you agree to take part in this study your health information will be used and shared with others involved in this study. Also, any new health information about you that comes from tests or other parts of this study will be shared with those involved in this study.

• Health information about you that will be used or shared with others involved in this study may include your research record and any health care records at the Ohio State University. For example, this may include your medical records, x-ray or laboratory results. Psychotherapy notes in your health records (if any) will not, however, be shared or used. Use of these notes requires a separate, signed authorization.

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

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

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

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

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

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

- None

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

Initials/Date: _____________________
Authorization Period

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

Signing the Authorization

• You have the right to refuse to sign this authorization. Your health care outside of the study, payment for your health care, and your health care benefits will not be affected if you choose not to sign this form.

• You will not be able to take part in this study and will not receive any study treatments if you do not sign this form.

• If you sign this authorization, you may change your mind at any time. Researchers may continue to use information collected up until the time that you formally changed your mind. If you change your mind, your authorization must be revoked in writing. To revoke your authorization, please write to:

Dr. Melissa Drum at the College of Dentistry, 305 W. 12th Avenue, The Ohio State University, Columbus, Ohio 43210 or Dr. Henry Fischbach at the College of Dentistry, 305 W. 12th Avenue, The Ohio State University, Columbus, Ohio 43210

• Signing this authorization also means that you will not be able to see or copy your study-related information until the study is completed. This includes any portion of your medical records that describes study treatment.

Contacts for Questions

• If you have any questions relating to your privacy rights, please contact Dr. Henry Fischbach at the College of Dentistry, 305 W. 12th Avenue, The Ohio State University, Columbus, Ohio 43210.

• If you have any questions relating to the research, please contact Dr. Melissa Drum at the College of Dentistry, 305 W. 12th Avenue, The Ohio State University, Columbus, Ohio 43210.
Signature

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

Signature __________________________________________________________
(Subject or Legally Authorized Representative)

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

Date___________ Time __________ AM / PM
Medical History

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

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

3. Have you ever been hospitalized? NO YES

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

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

6. Are you currently under the care of a physician (M.D., D.O.)? NO YES
   When were you last seen by a physician?_________________________
   Name of Physician___________________________________________
   Street address_____________________________________________
   City, State, and Zip Code____________________________________
   Phone____________________________________________________

7. Are you pregnant or nursing? Estimated date of delivery___________ NO YES

8. Have you had any trouble associated with previous dental treatment? NO YES

9. How often do you have dental check ups? ___________ Date of last Exam___________
10. Do you have any lumps or sores in your mouth now? NO YES

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

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

**Current Medications**

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

**Summary of Patient’s Medical Status:**

______________________________________________________________________________

______________________________________________________________________________

**Medical Risk Assessment**

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

**Medical Consultation Required**

No (healthy and/or stabilized disease)

Yes (ASA III or IV; cardiac murmur; vague hx; recent major disease; recent diagnosis/operation; uncontrolled disease; blood pressure; etc.)

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

Patient’s Signature ___________________________ Date ___________________________
APPENDIX F

CORAH’S DENTAL ANXIETY SCALE
PLEASE ANSWER THE FOLLOWING QUESTIONS BY CIRCLING THE ANSWER THAT BEST DESCRIBES HOW YOU FEEL.

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

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

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

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

HEFT-PARKER VISUAL ANALOG SCALE
Injection Pain Rating

Date: __________

Code #: __________

During each injection you will be verbally informed during needle 1) Insertion and 2) placement, followed by 3) solution deposition. There will be a pause between each instruction in order to allow you to differentiate between each step.

Needle Insertion

1. Please mark a vertical line “|” on the line below to rank the level of pain felt during needle insertion.

   None    Faint      Weak      Mild      Moderate      Strong      Intense      Maximum Possible

Needle Placement

2. Please mark a vertical line “|” on the line below to rank the level of pain felt during needle placement.

   None    Faint      Weak      Mild      Moderate      Strong      Intense      Maximum Possible

Solution Deposition

3. Please mark a vertical line “|” on the line below to rank the level of pain felt during solution deposition.

   None    Faint      Weak      Mild      Moderate      Strong      Intense      Maximum Possible

Note: Visual Analog Scales here are for representation purposes only and are not drawn to scale.
APPENDIX H

INJECTION PAIN SURVEY
Date: __________

Code #: __________

Injection Pain Survey

Which injection was more painful? Please circle one answer.

1) The injection at the first appointment
2) The injection at the second appointment
3) Neither. There was no difference in the injection pain between both appointments.
APPENDIX I

PAIN-COPING ABILITY SURVEY
Please mark a vertical line “│” on the line below to rank your ability to cope with pain.

I have no problem coping with pain

I have extreme difficulty coping with pain
APPENDIX J

OPERATOR CALIBRATION SHEET
Operator Calibration Sheet

Prior to subject assignment, Dr. Perry will have training sessions with operators to calibrate injection technique and protocol. Dr. Perry will discuss paperwork with each subject. At the end of the appointment, Dr. Perry will dismiss the subject.

The doctor will then introduce him/herself and say: “I will be giving you your injection today.”

The operatory will already be set up with:

- 27 gauge needle.
- 1 carpule of 2% lidocaine with 1:100,000 epinephrine.
- Timer
- Napkin/bib concealing anesthetic solution.

Patient will be given anesthetic injection. Instructions for maxillary infiltration:

1. The doctor will introduce him/herself and say: “I will be giving you your injection today.”

2. Lay subject back in the chair with their head parallel to the floor.

3. Check recording form to see which side you will be giving injection. Set timer.

4. Remove cap off of needle behind subject (out of the subject’s sight of vision).

5. Lift lip with the other hand, pulling the tissue taught. This will be done with the thumb and index finger with just enough pressure to hold the lip. The operator will not shake the lip during the procedure.

6. Hold the syringe parallel with the long axis of the lateral incisor.

7. Insert the needle into the mucosa at the height of the mucobuccal fold (deepest part of vestibule). The subject will be informed that this is “needle insertion.”
8. Advance the needle until it is at the apical region of the tooth (this is only around 3-5 millimeters in depth). The subject will be informed that this is “needle placement.”

9. Aspirate. If aspiration is positive (blood introduced into the anesthetic carpule), withdraw the needle and re-insert the needle. Aspirate.

10. If aspiration is negative, start timer and deposit the entire cartridge over the 60 seconds. The subject will be informed that this is “anesthetic deposition.”

   a. In order to keep a steady flow, make sure you have deposited \( \frac{1}{4} \) of the cartridge at 15 seconds, \( \frac{1}{2} \) at 30 seconds, \( \frac{3}{4} \) at 45 seconds, and the entire cartridge at 60 seconds.

11. Slowly withdraw the needle.

12. Place the needle back in the protective cap (out of the sight of the subject).

13. Subjects are then brought back to an up-right position. The VAS is filled out at this time.

After the injection is administered, each operator will immediately leave the cubicle.
APPENDIX K

SUBJECT DEBRIEFING SCRIPT
Subject Debriefing Script

We would like to thank you for your participation in our research on pain felt during upper front tooth shots. A pain scale questionnaire was used to rate the pain you felt during 3 parts of a typical dental numbing shot. We evaluated the pain of this shot; however, we also analyzed the gender (male/female) of the person giving and receiving the shot to determine if there were any differences by gender. It has been hypothesized that gender may influence pain. Our study was aimed at testing the validity of this hypothesis. You were not informed of the gender part of the study in order to achieve an unbiased results.

Final results are now available from the investigator (Shayne Perry). You may contact him at (shayneperry@yahoo.com) to receive the results of the study. All results will be grouped together; therefore individual results are not available. Your participation, including your name and contact information, will remain absolutely confidential, even if the report is published.

If you have any additional questions regarding this research please don’t hesitate to contact our department. Again, thank you for your participation.