A PROSPECTIVE, RANDOMIZED, SINGLE BLIND STUDY OF INTRALIGAMENTARY ANESTHESIA AS AN ADJUNCT FOR ANESTHETIZING THE PALATAL MUCOSA OF THE MAXILLARY FIRST MOLAR

A Thesis

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Abstract

Introduction: Palatal anesthesia is considered to be one of the most painful dental injections. The purpose of this prospective, randomized, single-blind study was to compare injection pain ratings of a mid-palatal intraligamentary injection (PDL) plus palatal infiltration versus a standard palatal infiltration to anesthetize the palatal mucosa of a maxillary first molar.

Methods: One hundred thirty-three adults received both a PDL/palatal injection and mock PDL/palatal injection at two separate appointments in a random order. The PDL injection consisted of 0.4 mL of 2% lidocaine with 1:100,000 epinephrine into the mid-palatal gingival sulcus of the maxillary first molar. The mock PDL injection consisted of needle insertion but no anesthetic delivery. After one minute, all subjects received 0.9 mL of 2% lidocaine with 1:100,000 epinephrine as a palatal infiltration. Subjects recorded pain of needle insertion and solution deposition for all injections on a 170 mm visual analog scale. Soft tissue mapping of palatal anesthesia was conducted over a period of 30 minutes.

Results: The PDL/palatal treatment technique demonstrated significant less pain compared to the mock PDL/palatal technique for the palatal infiltration ($p < 0.0001$). The PDL injection was significantly less painful than the palatal injection ($p < 0.0001$). Females demonstrated higher pain ratings for palatal injections than males in both

techniques. The area of soft tissue anesthesia peaked at 10 minutes in both techniques followed by a steady decline over 30 minutes.

Conclusion: Administering a less painful mid-palatal PDL injection prior to palatal infiltration significantly reduced palatal injection pain.

Dedication

To my wife, Rupa, for your endless love and support, and unending service and dedication to our family. You've sacrificed so much of your life over these past two years while I'm out chasing my dreams. Thank you for the love you keep pouring into our family and I am so fortunate we have shared this awesome journey together!

To my little Benny boy and Hannah Banana, I hope you remember the long nights of daddy working downstairs after you went to bed and know I did this hard work for you. Never give up on your dreams. I love you both; now we can go play!

To Mom and Dad, thank you for all the love and support and for being the role model of what hard work and perseverance look like.

I thank God for His provision and perfect timing, in all things and in all seasons of life. What a testimony to see His grace and goodness, and fulfillment of Isaiah 55:10-11 played out in my life.

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Chapter 1. INTRODUCTION

Dental anxiety and fear of pain from anesthetic injections can have a crippling effect on some patients, causing avoidance of necessary dental care. As a result, the patient's quality of life can be negatively impacted as patients experience uncontrolled pulpitis pain rather than receive professional intervention to address their problem (1). This global problem does not discriminate between different ethnic groups (2, 3) or socioeconomic status as the anticipated pain and fear of dental injections may cause cancelations or constant rescheduling of dental appointments (4). These highly anxious patients suffer not only from odontogenic issues, but delaying treatment can alter their overall quality of life by affecting sleep patterns and their psychosocial well-being (1, 5-7). Another component of dental anxiety and pain responses are related to the age and gender of the patient, with females and younger patients experiencing higher anxiety to dental treatment compared to men and older individuals. (8-12). The underlying symptoms of a patient's anxiety can be rooted in past negative dental experiences in youth or as an adult, as well as shaped through parental fears projected onto the patient, witnessing traumatic dental appointments, and media bias perpetuating the negative stereotype associated with dentistry (2, 13-17).

One aspect of significant anxiety is related to pain of dental injections (4). Efforts have been made to minimize intra-operative discomfort through the use of different

needle sizes (18-21), bevel design (22), adjusting the speed of injection (23-26); different formulations of dental anesthetics (27, 28) distraction techniques (29-31), and topical anesthetics (32-47). However, these practices still have not completely eliminated pain during anesthetic injections.

Within dentistry, specifically, palatal anesthesia is considered or perceived to be a very painful injection (48). One area of focus to alleviate the discomfort of this injection is placing topical anesthetic on intraoral tissue prior to administration of anesthetic. There is a plethora of topical anesthetic literature published across multi-disciplinary fields of dentistry and medicine evaluating its efficacy in reducing pain; however, there is not a general consensus on its effectiveness as some studies (43, 49-51) have stated there is no significant decrease in the pain of injection after topical anesthetic application while other studies (44, 52) have demonstrated its usefulness in reducing the pain of injection. Bhalla and coauthors (42) found that topical 5% lidocaine reduced the pain of needle insertion if left on the palatal mucosa for 2, 5, or 10 minutes, but it had no effect on clinical pain relief for local anesthetic solution deposition. The pain experienced by the patient during solution deposition may be due to expansion of the tissue rather than needle insertion (18). The volume of anesthetic administered (53), or pressure of the anesthetic being delivered into the non-compliant palatal tissue (54, 55) may also be a factor.

While topical 20% benzocaine has been the traditional gel used prior to local anesthesia administration, other topical products have been developed in an attempt to reduce or eliminate pain from injections. A eutectic mixture of 2.5% lidocaine and 2.5%

prilocaine (EMLA) was initially used in medicine as a topical cream for dermal anesthesia (56) but has transitioned to dentistry in hopes it can provide intraoral mucosal surface anesthesia. Meechan et al (57) compared 5% EMLA to 5% lidocaine as an intraoral topical anesthetic in kids and found there was no significant difference between the two products for maxillary buccal infiltrations. In another study, Meechan and Thomason (58) later discovered that when applying EMLA cream to buccal mucosa for 5 minutes, there was a significant decrease in injection pain compared to topical 5% lidocaine. Holst and Evers (59) found that 2 minutes of EMLA on buccal mucosa provided surface anesthesia in the buccal fold and needed 5 minutes for a higher degree of anesthesia on the palatal tissue. The success of EMLA has been shown in other studies for palatal anesthesia (38, 39). Primosch reported that EMLA was equally effective as Orabase-B (sodium carboxymethylcellulose oral adhesive with 20% benzocaine gel) and 20% benzocaine gel on palatal tissue in kids when placed for 5 minutes. However, Al-Melh et al found that EMLA cream and Oraqix (2.5% lidocaine and 2.5% prilocaine thermosetting topical anesthetic gel) are significantly more effective at reducing pain of needle insertion on palatal tissue in adults compared to 20% benzocaine.

Longer-acting agents have been explored as topical anesthetics to reduce pain in both medicine (60) and in dentistry (35, 37, 61). A gel of 20 mg 1% ropivacaine was placed in the buccal fold of the maxillary right canine for 2 minutes and was compared against 60 mg of 1% ropivacaine, 60 mg of EMLA, and 20 mg of 20% benzocaine in the same location. There was no significant difference in the mean visual analogue scale

(VAS) pain scores among groups and 60 mg of EMLA had a significantly longer soft tissue anesthetic duration compared to the other agents (61). Liposomal encased anesthetic is another proposed longer acting agent that can be applied to intraoral tissue prior to injection. Franz-Montan et al (62) evaluated various concentrations of ropivacaine in a liposomal-encapsulated form compared to EMLA. There was no significant difference in success of pain reduction among the groups when the dental needle was inserted into the palatal tissue. Paphangkorakit's et al (35) used an ultrasonic dental scaler to create a liposome-encapsulated 2% lignocaine solution and 0.2 ml of the solution was placed on a cotton pellet and applied to the palatal tissue for 4 minutes. This was compared against 0.3 g of 18% benzocaine/2% tetracaine anesthetic gel (OneTouch, Hager, USA) applied to the palatal tissue for 1 minute on the contralateral side. The liposomal agent had significantly reduced VAS pain ratings during anesthetic injection compared to the control group. Franz-Montan et al (37) also evaluated various combinations of liposome-lidocaine, EMLA, and a lidocaine ointment applied to the palatal mucosa. The authors found that liposome-lidocaine 5% and 2.5% EMLA were both equally effective in reducing pain of dental needle insertion and anesthetic solution deposition compared to the other groups (Liposome-lidocaine 2.5% and Xylocania, 5% lidocaine ointment) and are suitable to use as topical agents prior to injection.

Adhesive patches may facilitate delivery of topical anesthesia prior to injection. DentiPatch®, an adhesive patch delivering 20% lidocaine when adhered to gingival tissue, significantly reduced the pain of injection on both maxillary and mandibular when compared to topical lidocaine gel in kids (42). Kreider et al (32) also studied the effects

of the DentiPatch® when left on the palatal tissue for 15 minutes compared to topical anesthetic gel applied for 1 minute (20% benzocaine). DentiPatch® showed a statistically significant decrease in injection pain when evaluating verbal indicators but there was no difference in VAS scores. Kishimoto et al (33) studied if there is a difference between amide and ester topical anesthetics for reduced pain from topical application. An adhesive patch with 0.06 mL of 2% lidocaine hydrochloride with 12.5µg/mL epinephrine was placed on the maxillary canine alveolar mucosa for 5 minutes. This was compared against 0.06 g of 20% benzocaine topical gel. Results showed the VAS pain scores for the lidocaine group was lower than the benzocaine group, although there was no significant difference between the two. A natural, plant-based approach for creating an adhesive patch was investigated by Santana de Freitas-Blanco et al (34). Jambu is a food spice that is used for homeopathic purposes and attains its analgesic effect from a bioactive compound named spilanthol. The vehicle to deliver this compound is through chitosan. The authors determined that the "oral mucoadhesive film patch based on chitosan is a good vehicle to deliver topical anesthetic based on jambu extract." This novel approach is an effective topical agent for intraoral use.

One idea to reduce pain of injections is to control the rate of anesthetic deposition. Various computer-controlled devices have been developed to standardize the flow rate of anesthetic. Numerous studies have been performed to evaluate the effectiveness of providing painless injections using these devices (63-73). For palatal injections, using a computer controlled local anesthesia system (CCLAD), Johnson and Primosch (74) compared infiltration pain using a 20% benzocaine topical anesthetic gel (HurriCane®)

held at the injection site for 2 minutes, pressure anesthesia using a cotton tip applicator that was pressed firmly against the tissue causing blanching for 30 seconds and held in place during the injection, a combination of both methods, and use of neither method. They found no difference in injection pain among the various site preparation methods used. However, Jälevik and coauthors (75) found that the pain of a palatal injection in children was significantly lower with the CCLAD system compared with conventional syringe injection. Nusstein and coauthors (65) studied the pain of the anterior middle superior alveolar (AMSA) injection. Comparison of the CCLAD system and the conventional syringe technique resulted in the following respective pain ratings: 38% and 32% moderate pain and 0% and 2% severe pain on needle insertion; 25% and 40% moderate pain and 0% and 2% severe pain on solution deposition, respectively. The AMSA injection using the CCLAD system resulted in statistically lower pain ratings during anesthetic solution deposition. Yenisey and coauthors (67) also found lower pain scores for needle insertion and solution deposition using a CCLAD system for the AMSA technique compared with conventional injections. However, the AMSA injection, whether using the CCLAD system or a conventional syringe, has the potential to still be a painful injection.

In medicine, vapocoolant sprays have been studied to anesthetize skin prior to medical procedures to reduce pain associated with the expected procedure. Hijazi and coauthors (76) found that topical vapocoolant COLD spray (a mixture of propane, butane, and pentane) (DIFA Chemical Industries for Alpha First Aid Supplies) reduced pain before venous cannulation. Robinson and coauthors (77) reported that intradermal

lidocaine was more effective at pain reduction before venous cannulation than ethyl chloride topical spray. Hartstein and Barry (78) failed to find a topical skin coolant beneficial in venous cannulation. Hogan and co-authors (79) also failed to find a significant pain reduction in kids who received a vapocoolant spray prior to venous cannulation compared to placebo. Engel (80) discovered that, for those receiving botulinum toxin injection, using a topical skin refrigerant (Pain Ease®) significantly reduced the pain when sprayed on the skin for 5 seconds prior to injection.

Pre-cooling soft tissues can also apply for dental treatment. In pediatric dental patients requiring local anesthetic injections, precooling the soft tissues with ice helped to reduce the pain of local anesthetic injection with IANB (81). Harbert et al (82) also described a technique utilizing topical ice to reduce the pain of palatal injections by using an ice stick created from an empty local anesthetic carpule. The ice stick was removed from the carpule and placed at the palatal injection site for 45 seconds before needle insertion. Kosaraju and Vandewalle (83) compared injection pain of a 5-second application of a cold refrigerant (Pain Ease®, Gebauer, Cleveland, OH) versus a 2-minute application of 20% benzocaine gel in the posterior palate. While the cold refrigerant was better at reducing the pain of injections, there was no postoperative follow-up to determine if tissue damage occurred from the application of cold. Wiswall and coauthors (84) found that the pain of a palatal injection over the greater palatine foramen was no different using 4 different techniques, three of which involved pressure using a cotton tip applicator and a control of injection and deposition of anesthetic. The study analyzed the effect of pressure with the cotton tip applicator alone, pressure and 20% benzocaine, and

pressure and a skin refrigerant (Hygenic® Endo-Ice®). All techniques were applied for 10 seconds each. They reported that the pain of needle insertion was less than that of solution deposition. However, over 80% of the subjects reported post-operative side effects, mainly resulting in a palatal ulceration at the Hygenic® Endo-Ice® application site occurring 2 to 48 hours after cold application and persisting for 1 to 10 days. The manufacturers of Endo-Ice caution that it should not be applied to mucosal tissues because of freezing of the tissue and soft tissue damage. Therefore, using Endo-Ice® or prolonged cold application to the palatal mucosa should not be used clinically to achieve anesthesia. Jayasuriya et al (85) proposed that placing a frozen cotton bud on the palatal injection site for 1 minute prior to administering anesthesia will reduce pain. In this study, after the one-minute application of frozen cotton bud on the palatal tissue, local anesthesia is delivered directly next to the cotton bud with the cotton still in place, applying pressure onto the palatal surface. All patients in this study had a VAS pain score of 0 while receiving this procedure with no reported gingival tissue side effects or complications.

Previous studies have attempted other means to reduce the pain associated with a palatal infiltration. Preemptive application of lasers have been studied. For a palatal injection of lidocaine, no difference in pain was found between the application of a 790 nm low-intensity laser with a continuous wave at an applied energy of 3.6 J, and a 0.13 cm^2 focal spot, 20% benzocaine topical anesthetic, or pressure from a customized laser probe all applied for 2 minutes prior to injection (86). Other adjunct techniques involve pressure anesthesia. The palatal press and roll technique creates pressure anesthesia by

applying topical anesthetic on palatal tissue for 2 minutes and then the blunt end of the mirror handle adjacent to the topical. The mirror handle is depressed onto the tissue and rolled towards the needle while injecting a few drops of anesthesia. After waiting for 1 minute, any remaining local anesthesia required can be re-administered. The authors report this is a predictable technique that provides adequate palatal anesthesia (31). Wiswall et al (84) compared four techniques for reducing pain for anesthetic injections, three of which involved pressure using a cotton tip applicator and a control of injection and deposition of anesthetic. A pressure of 3.00 Newtons (N) was established in the study that would create pain on the palatal tissue greater than the mild pain descriptor. A cotton tip applicator was placed in a calibrated mechanical gauge (Chatilion, AMETEK Measurement & Calibration Technologies Division, Largo, FL) and this device depressed the palatal tissue in the area of the greater palatine foramen, adjacent to the maxillary second molar. Different agents (20% benzocaine and Endo-Ice® cold refrigerant spray) were added onto the cotton tip applicator and then pressure was generated on the palatal tissue to evaluate the effectiveness of pressure and the various agents in pain reduction to needle insertion and anesthetic solution deposition. As a result, there was no significant difference in any of the agents used on the cotton tip applicator and pressure applied to the palatal tissue for needle insertion and solution deposition. Adding sodium bicarbonate as another adjunct technique for painless palatal anesthesia was investigated by Gupta et al (87). The addition of 7.4% sodium bicarbonate to 2% lignocaine with 1: 80,000 adrenaline reduced the pain of local anesthetic injection at the palatal site

compared to 2% lignocaine with 1: 80,000 adrenaline. This method also decreased the onset time and created a longer lasting anesthetic site on palatal tissue.

The Periodontal Ligament Injection (PDL), intraligamentary injection was first described by Cassamani (88). This technique has been used both as a primary method of anesthesia and secondary means to provide local anesthesia when the primary method fails. (89-91). The onset of anesthesia is immediate after delivering the PDL injection (63, 90, 91) and depending if it was given as primary or supplemental technique, the pulpal anesthesia lasts for approximately 10 minutes (27, 92, 93) to 23 minutes (94), respectively. Creating strong back pressure is essential in attaining successful anesthesia with the intraligamentary technique (90). The technique is performed with a short or ultra-short needle and placed parallel to the long axis of the tooth. The needle is inserted to the most apical part of the gingival sulcus, until firm resistance is met and the needle should be wedged between the root surface of the tooth and the alveolar crestal bone (95). Approximately 0.2 mL of anesthetic solution is deposited along the mesial and/or distal root of the tooth with a conventional syringe or high pressure syringe. The mechanism of action of the intraligamentary injection is considered to be an intraosseous route because the anesthetic passes through the cribriform plate and bone spaces and into the surrounding tissues and vasculature (93, 95). The literature reports that in asymptomatic teeth only 3% of subjects reported moderate to severe pain for needle insertion and solution deposition, so the PDL injection has the potential to not be a painful injection. (94). Conversely, other studies (89, 93, 96) reflect that patients feel discomfort during and after the injection, particularly if administered within the anterior region. The pulp is

unaffected by the intraligamentary injection and there was no effect on pulp vitality (89, 97) and PDL injection appears to cause only minimal damage to the periodontium (98, 99). Post-operatively, while Khedari (100) reports the PDL injection is less painful than a local infiltration, most other studies (27, 65, 68, 92, 93, 95, 101, 102) report a higher incidence of post-operative complications and pain and occasional periodontal abscess, gingival pocketing after the PDL injection, and the sensation the tooth feels "high" once anesthesia wears off.

Studies have looked at reducing the pain of the PDL injection. Berlin et al (63) compared the pain of the intraligamentary injection of 1.4 mL 4% articaine with 1:100,000 epinephrine and 1.4 mL 2% lidocaine with 1:100,000 epinephrine administered with the computer-controlled local anesthetic delivery (CCLAD) system. Results demonstrated the incidence of moderate pain (14% to 27%) and 4% severe pain with needle insertion. For solution deposition, moderate pain was reported 8% to 18% of the time, with no reports of severe pain. An added benefit of the intraligament injection is seen in Froum et al's study (103) where intraligamentary injections given with CCLAD produced minimal damage to the injected site from a histological perspective, thus allowing better healing capacity from the reduced trauma caused by the PDL injection.

Palatal injections continue to be painful, and further studies are needed to reduce pain of these injections. Since the intraligamentary injection is less painful than a palatal infiltration, we propose that enough local anesthetic solution can be delivered with the intraligamentary technique to anesthetize the palatal gingival collar of the tooth, thus

allowing a relatively painless infiltration to this area. Therefore, the purpose of this prospective, randomized, single blind study is to use intraligamentary anesthesia as an adjunct to anesthetizing the palatal mucosa of the maxillary first molar.

Chapter 2. METHODS AND MATERIALS

One hundred and thirty-three adult patients participated in this study. All were in good health as determined by a health history and oral questioning. Inclusion criteria included adults 18-65 years old and ASA classification I or II. Exclusion criteria consisted of - allergy to local anesthetics or epinephrine, history of significant medical problem (ASA classification III or greater), recently taken central nervous system (CNS) depressants (including alcohol or any analgesic medications, tranquilizers, sedatives, or hypnotics), pregnancy, lactating, or inability to give informed consent. The Ohio State University Human Subjects Review Committee approved this study (2018H0014). Written informed consent, HIPAA authorization, and medical history were obtained from each subject. Patients completed a Corah dental anxiety scale (104) to rate their level of anxiety prior to commencement of the study. (See Appendix E).

The test area was the mucosal tissue of the palatal root of the maxillary first molar. Clinical examinations insured the test tooth was free of caries, large restorations, and periodontal disease. A Williams Periodontal probe (Hu-Friedy, Chicago, IL) was used along the entire aspect of the palatal gingival sulcus, confirming a healthy periodontium. The sulcus probing depths at the mesiopalatal, mid-palatal and distopalatal aspects of the first molar were recorded.

Before the experiment, each patient was randomly assigned two different six-digit numbers from a random number table (www.random.org). One number was designated for the mock treatment and the other random number signified the actual treatment. One hundred and thirty-three subjects randomly received two types of palatal anesthetic administrations, at two appointments, spaced at least two weeks apart. The order of the two sets of anesthetic administration delivered and the side (right or left) were randomly determined using the 2 different six-digit random numbers.

Prior to each appointment, the anesthetic was pre-measured by the investigator to provide 0.4 mL of 2% lidocaine 1:100,000 epinephrine (Xylocaine, AstraZeneca LP, Dentsply, York, PA) as the intraligament injection and 0.9 mL of 2% lidocaine with 1:100,000 epinephrine as the anesthetic amount deposited into the palatal mucosa after the intraligament or mock-intraligament injection. A black marker was used to draw a singular black line around the cartridge at each anesthetic level, indicating the appropriate amount of solution to be deposited for each injection. The cartridges were pre-loaded into a standard syringe prior to the subject arriving and covered with a paper napkin so the syringe was not visible to the subject.

A 170 mm Heft-Parker visual analog scale (VAS) (105) (Appendix G) was used to rate the subject's pain of needle insertion and solution deposition for the palatal infiltration as well as the needle insertion, solution deposition, or mock solution deposition for the intraligament injection. Prior to the injection, subjects were trained on how to rate the pain of each injection phase (needle insertion and solution deposition), which was reinforced during the injection, using two separate Heft-Parker VAS forms.

At the first appointment, the subject would receive either the mock intraligament treatment or actual treatment based on the randomized number assigned to them. Whatever treatment was rendered at the first appointment (i.e mock vs. treatment), the subject was provided the opposite treatment at the second appointment which was 2 weeks later. The injections were administered as follows; the patient was placed in a supine position. If the subject was receiving treatment, an intraligament injection of 0.4 mL of 2% lidocaine with 1:100,000 epinephrine using a standard syringe and a Stabident® 27-gauge ultra-short needle (8 mm, Fairfax Dental Inc., Miami, FL) was administered in the mid-palatal gingival sulcus of the maxillary first molar (needle insertion phase) with firm apical pressure. The bevel of the needle faced outward toward the palatal aspect of the mouth and 0.4 mL of the anesthetic solution was deposited slowly under back-pressure (solution deposition phase) over 30 seconds. The investigator (BC) had direct vision to monitor if anesthetic solution was expressed from the gingival sulcus. If notable solution escaped, the needle was rotated clockwise with further firm apical pressure applied into the sulcus and the injection was continued as outlined above. A saliva ejector was placed just distal to the ultra-short needle during the intraligament injection to suction any excess anesthetic that may have escaped during the injection sequence to ensure the subject remained blinded as to which intraligament technique they were receiving. Immediately after the completion of the intraligament injection, a water syringe was used to rinse out the patient's mouth and was suctioned up with the saliva injector. The subject was asked to rate the pain of needle insertion and solution deposition using two separate VAS sheets. Subjects were also asked to re-rate

their initial pain of the injection 5 minutes post injection sequence to determine if their memory of the pain during the injection were similar.

If the subject received the mock intraligament injection, a 27-gauge ultra-short needle (8 mm, Monoject; Sherwood Services, Mansfield, MA) attached to a standard syringe was placed into the sulcus at the same site listed above but no anesthetic solution was delivered. The portion of the needle which penetrates the anesthetic cartridge inside of the syringe was pre-bent prior to the subject arriving so no solution could be expressed from the needle. The needle was held in place for 30 seconds, the same amount of time as during the actual injection. Firm apical pressure was provided to also mimic the apical pressure provided during the actual intraligament injection. Just like in the treatment group, a saliva ejector was placed just distal to the intraligament injection site for mock treatment and the area was rinsed with water for standardization purposes. The subject was then asked to rate the pain of needle insertion and solution deposition using two separate VAS sheets. Subjects were also asked to re-rate their memory of the pain 5 minutes post injection sequence on new VAS sheets.

At one minute post intraligament injection (mock or treatment), a palatal infiltration of 0.9 mL of 2% lidocaine with 1:100,000 epinephrine was administered. For the intraligament treatment group, the palatal infiltration was given in the blanched, alveolar mucosa within the gingival collar of the maxillary first molar's palatal root using a standard aspirating syringe equipped with a 27-gauge, ½ inch needle over 1 minute. This anesthetic volume was pre-measured by the investigator and the cartridge marked with a black marker to indicate the level of anesthetic administered into the palatal

mucosa. Like with the intraligament injections, a saliva ejector was placed just distal to the dental needle to prevent any anesthetic run-off and the patient's mouth was rinsed at the completion of anesthetic deposition and suctioned with the saliva ejector.

If the patient received the mock intraligament injection, a palatal infiltration of 0.9 mL of 2% lidocaine with 1:100,000 epinephrine using a standard aspirating syringe equipped with a 27-gauge ½ inch needle was given superior (or palatal) to the gingival sulcus of the palatal root over 1 minute. The anesthetic was administered in the alveolar mucosa of the maxillary test tooth's palatal root 7 mm palatally from the attached gingival margin one minute post-mock intraligament injection. This distance was pre-measured right before needle insertion with the Williams Periodontal probe and a small indentation was placed into the palatal mucosa at the 7 mm distance with the tip of the periodontal probe. The subject was instructed to rate the pain of needle insertion and solution deposition for the palatal infiltration by marking a singular line on two separate VAS sheets following the injection. Subjects were also asked to re-rate their memory of the initial pain 5 minutes post injection sequence on new VAS sheets.

The extent of the anesthetized area of the palatal soft tissue was evaluated using a dental explorer following the completion of pain ratings for the palatal infiltration. The mapping was performed at 1, 5, 10, 15, 20, 25, and 30 minutes. A stopwatch was used to monitor all timing sequences (Google stopwatch, Mountain View, CA). The explorer was gently placed on the palatal mucosa starting at the needle insertion site (second injection) and moved mesial until painful sensation was felt by the patient. This distance was measured with a periodontal probe and then recorded. This same procedure was

conducted in distal, superior and inferior directions from the needle insertion site and also recorded. At the completion of the initial and second appointment, the subject was instructed each time to recognize any post-operative pain or tenderness after the anesthetic wore off and to compare any difference in post-operative pain experiences between appointments. It was explained to the subjects they would need to distinguish post-operative pain differences between each appointment for the purpose of completing a pain questionnaire at the follow-up evaluation.

The subjects were scheduled for a follow-up evaluation one month after the final set of injections to evaluate soft tissue healing using gingival probing. The sulcus probing depths at the mesiopalatal, mid-palatal and distopalatal aspects of the subject's test tooth were measured using a Williams Periodontal probe and recorded. The subjects also indicated on a follow-up pain questionnaire if they experienced more pain after the first appointment, second appointment, or neither appointment (indicating either they had no post-operative pain after both appointment or the post-operative pain after each appointment was the same).

Differences in pain of injection for the intraligamentary and palatal infiltration techniques was analyzed using paired t-tests. Additional within treatment group comparisons between intraligament/palatal and mock intraligament/palatal with respect to gender and order of appointment were performed using two sample independent t-tests. The spread of palatal soft tissue anesthesia was analyzed repeated measures ANOVA including gender, treatment type, Corah Dental Anxiety level, and order of technique as covariants. With a non-directional alpha risk of 0.05 and assuming a standard deviation

of 27.4 and a correlation of 0.4, a sample size of 133 subjects provided a power of 0.95 to demonstrate a difference ± 10 points on the visual analogue scale.

Chapter 3. RESULTS

One hundred thirty-three overall subjects participated in this study. Sixty-seven were males and sixty-six were females, ranging from ages 19 to 43 years with an average age of 25 years old. (Table 1). The Corah Dental Anxiety scores for each subject was calculated. Corah Dental Anxiety scores ranged from 4 (low dental anxiety) to 14 as the maximum score (high dental anxiety). The overall median Corah Dental Anxiety score was 5, which corresponds to a low dental anxiety range. Male and female Corah Dental Anxiety scores were both calculated to be 5 as well (Table 1). There was no significant difference between male and female dental anxiety scores ($p < 0.1455$). All biographical information is found in Appendix A.

The 170 mm Visual Analog Scale (VAS) with subjective descriptors (Appendix G) was used to express the subject's experienced pain at different points of the appointment. Each subject was advised at the beginning of the appointment how to properly fill out each form and this was re-enforced chairside during each phase. A new VAS sheet was utilized for each PDL and palatal needle insertion event and solution deposition within the appointment and also at the second appointment. The overall mean VAS pain ratings for needle insertion and solution deposition were calculated (Table 2) and plotted (Figure 1 and Figure 2) for the mock and treatment PDL and palatal techniques. Subjects rated the mock PDL treatment experienced an overall average pain

rating of 41 mm when the needle was placed into the PDL space, which corresponds to a subjective pain rating between mild and moderate pain. The overall mean mock PDL solution deposition pain was also classified between mild to moderate pain with a calculated pain rating at 35 mm. Following the mock PDL treatment, the overall mean palatal needle insertion pain was calculated to be 71 mm and classified between moderate to severe pain. The same range was seen with the overall mean palatal solution deposition phase of the study, with a calculated pain rating score at 76 mm also categorized as moderate to severe pain (Table 2; Figure 2).

When the subjects received the PDL treatment, the overall mean PDL needle insertion and solution deposition scores were similar to the mock technique, with mild pain ratings calculated as 38 mm and 31 mm, respectively (Table 2; Figure 1). However, there was a noticeable decline for the palatal needle insertion and solution deposition pain ratings after the subjects received the treatment PDL sequence first. Overall, mean pain ratings for the palatal needle insertion was 6 mm and the palatal solution deposition was 8.0 mm, falling within the no pain to mild pain range. There was a statistically significant difference in pain responses, with subjects reporting significantly lower pain for palatal needle insertion and palatal solution deposition with the treatment technique ($p < 0.0001$).

The mean VAS pain ratings for the PDL and palatal mock and treatment techniques were calculated for the first appointment and second appointment (Table 3 and Table 4) and plotted (Figures 3-6). For those subjects who received the mock appointment first, the PDL needle insertion for the first appointment had a pain ratings

calculated to be 40 mm and the mock deposition pain was 33 mm, both categorized as mild pain (Table 3). Subsequently, for the mock PDL treatment group at the first appointment, the palatal insertion pain ratings were calculated to be 68 mm and solution deposition pain to be 70 mm and categorized as moderate pain (Table 4). Those who were in the mock technique at the first appointment then experienced the treatment group at the second appointment. The PDL and deposition mean pain ratings for the second appointment were considered as mild pain with scores rated 35 mm and 27 mm, respectively (Table 3). Interestingly, the mock PDL deposition pain ratings (33 mm) were higher than the actual solution being administered into the PDL (27 mm). After subjects received the treatment PDL, the average pain ratings calculated at the second appointment for palatal needle insertion was 5 mm and 9 mm for solution deposition, categorized as faint pain in the mild descriptor category (Table 4).

Those subjects who received the treatment group at the first appointment, the mean PDL needle insertion at this appointment was calculated to be 42 mm and 35 mm for the PDL deposition categorized as mild pain (Table 3). As a result of the PDL treatment, the palatal insertion pain rating was 8 mm and the solution deposition was 7 mm categorized as faint pain with the mild category (Table 4). At the second appointment, these subjects received the mock PDL treatment and experienced a pain rating of 41 mm for PDL needle insertion and 37 mm for mock solution deposition (mild pain) (Table 3). The palatal needle insertion pain ratings for this group is 74 mm and 82 mm for solution deposition into the palate signifying moderate pain. The order of the treatment was marginally significant as those who received the palatal solution deposition

after the mock PDL at the second appointment had an overall higher pain rating score (82 mm) than the group who experienced the palatal solution deposition after the mock PDL at the first appointment (70 mm) (Table 4).

Gender differences were evaluated for the mock and treatment techniques for all 4 phases. There were no significant differences between males and females for any phase of the mock treatment (Table 5). For the mock technique, both males and females rated the mean pain scores for PDL needle insertion and solution deposition as mild pain and the palatal needle insertion and solution deposition as moderate pain. For the treatment technique (Table 6), there was no significant differences in mean pain ratings between males and females for PDL needle insertion or solution deposition. However, there was a statistically significant difference between males and females for the palatal needle insertion for the treatment technique ($p = 0.0148$) (Table 6). This difference may not be clinically significant though as both males and females reported such low pain ratings overall (3 mm and 9 mm, respectively). There was a marginally significant difference for the palatal solution deposition as females experienced more pain than males ($p = 0.0711$) (Table 6). Females reported the mean pain rating for the palatal solution deposition as 10 mm while males reported the mean pain score as 6 mm. Both are considered faint pain under the mild category. There may not be a clinical significance here as well due to such low pain ratings.

The Paired t-test was utilized to compare pain ratings of the treatment PDL to the mock palatal technique for both needle insertion and solution deposition (Table 7 and 8; Figure 9 and 10). The palatal needle insertion when subjects receive the mock PDL was

significantly more painful than the PDL treatment needle insertion (Table 7) (Figure 9). The mean palatal pain rating for the needle insertion for the mock technique was moderate pain (71 mm) while the needle insertion pain rating for the PDL was mild pain (38 mm). There is a significant difference when comparing the pain values for PDL and palatal needle insertion ($p < 0.0001$). The same is true for solution deposition, in that the palatal solution deposition is significantly more painful than the treatment PDL (Table 8) (Figure 10). The mean palatal pain rating for the solution deposition in the mock technique was 76 mm (moderate pain) compared to the mean PDL deposition pain, which was 31 mm (mild pain). There was a significant difference in pain ratings ($p < 0.0001$).

Tables 9 and 10 demonstrate the groupings of the VAS pain categories for both the mock and treatment techniques. The majority of subjects in the mock technique rated the PDL needle insertion and solution deposition as mild pain (75% and 71%, respectively) (Table 9). This is consistent for PDL needle insertion and solution deposition for the treatment technique as subjects rated mild pain 80% and 78% of the time, respectively (Table 10). For the mock technique, 65% of subjects rated the palatal needle insertion as moderate to strong pain (Table 9). Conversely, for the treatment technique, subjects rated moderate to strong pain for palatal needle insertion 1% of the time. This drastic difference was also seen for the solution deposition into the palate in which subjects rated moderate to strong pain for the treatment technique 2% of the time, while they rated moderate to strong pain for palatal solution deposition 65% of the time for the mock technique.

After the injections were fully completed, soft tissue mapping of the anaesthetized palatal soft tissue was tracked over time, starting 1 minute after the completion of the palatal anesthetic deposition and re-evaluated every 5 minutes up to 30 minutes. The mean volume of the area was calculated for each time point and the treatment versus the mock spread over time was compared. (Table 11) and (Figure 11). For the mock and treatment techniques, the anesthetized area on the palatal tissue increased up to the 10-minute mark at 813 mm^2 and 526 mm^2, respectively. The area of anesthetized tissue for both techniques started to decrease by the next evaluation time point and continued to decrease until the final evaluation mark at 30 minutes. There was a significant difference in the volume of anesthetized area between the two techniques, with the palatal deposition from the mock PDL technique having a greater volume of area anesthetized compared to the palatal deposition with the PDL treatment technique. Soft tissue anesthesia did not resolve completely by the 30 minute time frame when testing was stopped.

After the second appointment was completed, all subjects were brought back for a one-month soft tissue evaluation and were provided a post-operative pain questionnaire. A chi-squared analysis was performed to analyze the results. All 133 subjects followed up for the one-month post-operative evaluation. Table 12 reflects the results to the post-operative pain felt by each subject. Twenty subjects (15%) in the mock technique and 20 subjects (15%) in the treatment technique reported more post-operative pain after the first appointment compared to their experience after the second appointment. Twenty subjects (15%) in the mock technique and 27 subjects (20%) in the treatment technique reported

more post-operative pain after the second appointment compared to their experience after the first appointment. Forty-six subjects (34.5%) reported no difference in pain experienced after the first or second appointment, or no post-operative pain at all whether they experienced mock or treatment first or second. There is no statistical relationship in pain identification by appointment ($p = 0.2972$). There was no difference in the periodontal status of all subjects when comparing the one-month re-evaluation to the baseline periodontal probing.

Chapter 4. DISCUSSION

Palatal anesthesia continues to be a painful dental injection (48, 106) despite advances in materials and techniques to reduce pain. The multi-factorial nature of the fear and anxiety of dental needles and the process of receiving local anesthesia can be rooted in negative childhood experiences (4, 13, 17, 107, 108), fear from other people's experiences projected onto the patient (16, 109, 110), undesirable dental appointments as an adult with insufficient pulpal anesthesia and subsequent painful treatment and the expectation of pain at future appointments (111, 112), or from the negative connotations society associates with dentistry (111). As a result of this expectant discomfort, patients tend to delay or avoid dental care, prolonging treatment that can alleviate them from their malady (113). The anxiety and fear of receiving anesthesia is often too much to overcome as the patient unnecessarily suffers and this high level of anxiety may progress into a phobia of dentistry (6). Efforts have been made to improve the patient's experience at the dentist from the use of surface anesthesia (32-47) prior to injection to devices that control the speed of delivery of the anesthetic solution (63-73). Despite these improvements, the palatal injection still hurts.

Palatal anesthesia can be a painful experience compared to receiving local anesthesia in other intraoral areas and is generally considered to be a painful injection (114). Aminabadi et al (81) studied site specificity of pain sensitivity to intraoral

anesthetic injections in children. Intraoral injections were delivered to eight different locations in children ages 5-6 years old with a 27-gauge conventional syringe. Their results show that the anatomic location where anesthetic is administered is important for the amount of pain one experiences, with the most painful injections being the nasopalatine nerve block and the greater palatine nerve block. Meechan et al (18) also demonstrated a difference in pain responses based on injection location, evaluating only needle insertion pain. Palatal needle insertion was more painful than buccal needle insertion, with anterior palatal needle insertion being the most painful location. Wahl et al (54) evaluated pain differences of anesthetic injections of bupivacaine with epinephrine compared to plain prilocaine and whether there was a difference in pain response based on these different formulations as well as different injection locations. Patients reported significantly more pain for palatal injections regardless of anesthetic type used and also higher palatal pain ratings compared to maxillary buccal infiltrations or inferior alveolar nerve blocks.

The use of a computer controlled device (CCLAD) for palatal injections has also been evaluated. Nusstein et al (68) demonstrated that injecting either 2% lidocaine with 1:100,000 epinephrine or 3% mepivacaine as the palatal-anterior superior alveolar (P-ASA) injection with the Wand Plus® (Milestone Scientific) was a painful injection. Needle insertion pain (27-gauge needle was used) categorized as moderate/severe ranged from 30-43% and the needle placement pain responses for the same pain descriptor category ranged from 54-58%. Moderate/severe solution deposition pain ratings ranged from 8-12%, indicating that palatal injections are still very uncomfortable, even with the

CCLAD unit. A similar study performed by Nusstein et al (65) evaluated the injection pain ratings when using the Wand® or a conventional syringe at the anterior middle superior alveolar block (AMSA) injection site. The CCLAD unit used a pen-like hand-held plastic wand attached to a Leur-Lok needle (Becton Dickinson and Co). The Wand® demonstrated moderate/severe pain of 38% for needle insertion and 32% of subjects reported moderate/severe pain for conventional syringe needle insertion. The Wand® caused less pain for solution deposition into the palate. However, it still was a painful injection as 25% of subjects rated the solution deposition pain as moderate/severe and 42% of subjects rated the anesthetic deposition using the conventional syringe injection as moderate/severe pain.

The palatal soft tissue anatomy is different from the maxillary buccal anatomy and may be the reason patients experience higher palatal injection pain. The palatal tissue is relatively non-compliant and bound more tightly to the periosteum. As a result, there is a larger amount of pressure created by the injection and from the anesthetic displacing the palatal tissue creating more pain relative to the loose, submucosal buccal tissue (115). An additional palatal anatomical landmark to consider is the longitudinal palatal groove. Dave et al (116) reported the potential complications of administering local anesthesia into the palate due to the presence of bony crests and ridges in proximity to where the longitudinal groove is. Zivanovic (117) also reported the presence of ridges at the location of the longitudinal palatal groove with compounded problems of bony spines present, protruding from the palate as much as 4 mm high. These bony eminences

can interfere with pathways of anesthetic travel and the ability to effectively deliver anesthesia in this area.

The intraligamentary injection (PDL) pain experience has been reported to be comparable to the inferior alveolar nerve block (101). The injection technique involves placing a short or ultra-short needle into the gingival sulcus parallel to the long axis of the root of the tooth until resistance is met, and administering a small amount of anesthetic under high pressure. This forces the anesthetic solution through the cribriform plate and into the cancellous bone to anesthetize the tooth (91, 93). The PDL anesthetic technique has been used as a primary injection (63, 90) as well as supplemental anesthesia when the primary route of local anesthesia failed (91). Mansour et al (118) found that 96% of the patients reported the PDL injection resulted in less pain compared to other injection techniques. Since the intraligamentary injection is considered to be less painful than other methods (118, 119), one purpose of our study was to evaluate the pain of the palatal injection after administering a small amount of local anesthesia into the periodontal ligament (PDL) space and subsequent pain of palatal needle insertion and solution deposition around the same tooth.

As previously described in our methods and materials section, one hundred and thirty-three subjects randomly received two types of palatal anesthetic injection techniques, at two appointments, spaced at least two weeks apart. The random numbers assigned to each subject were determined using www.random.org. The order of appointment in whether they received the mock or treatment group first was determined by this same method. Suresh (120) explained the importance of having randomization

within experiments was to minimize selection and accidental bias. As a result, randomization allows for the investigator to test how effective the treatment may be since some confounding factors of bias are eliminated. There is confidence that the findings from experiments with randomization incorporated are accurately reflecting the effects of the intervention being studied and the results are not due to some other variable. Gender was also balanced in distribution of the participants (Table 1). This was done to remove potential gender bias ratings of pain (8, 9, 12).

A medical questionnaire was filled out by each participant to confirm they qualified for the study and there were no contraindications in receiving the anesthetic solution. As mentioned in our methods and materials section, exclusion criteria consisted of an allergy to local anesthetics or epinephrine in order to avoid a potential anaphylactic reaction; history of significant medical problem (ASA classification III or greater) to avoid potential adverse effects due to the epinephrine within the local anesthetic; and taken a central nervous system (CNS) depressants (including alcohol or any analgesic medications, tranquilizers, sedatives, or hypnotics) within the past 12 hours. CNS depressants have the ability to block or reduce peripheral nerve transmission from reaching the brain so subjects who have taken any kind of CNS depressant within 12 hours of the appointment may have an altered perception of pain and may not be able to react to pain like they normally would without taking any depressant. Subjects who were younger than the age of 18 years old were excluded as they could not legally give informed consent due to being a minor and those over the age of 65 were excluded as pain reactivity and thresholds are diminished in older individuals compared to younger

individuals hence older subjects may not report as much pain, potentially skewing the results (121, 122).

As previously mentioned in the methods and materials section, each subject filled out a Corah Dental Anxiety score sheet (see Appendix E) and the median anxiety score for males and females were calculated (see Table 1). This questionnaire is an accepted tool and gold standard in research studies to evaluate a patient's dental anxiety in a simple, highly valid, and a reliable way (104). Each of the four questions are answered on a five-point scale (a-e) with "a" equaling 1 point, "b" equaling 2 points, and so on. Total anxiety scores range from 4-20, with a cumulative score less than 8 indicating the subject has low anxiety, scores between 9-12 reflecting moderate anxiety, scores between 13-14 signifying high anxiety, and 15-20 indicating severe anxiety. The dental anxiety scores are an important component when measuring pain since anxiety has been shown to be related to pain reporting (7, 123-125). It is critical to ensure there were no outliers within the data points that could skew the anxiety score results.

Table 1 demonstrates the median Corah Dental Anxiety scores results for males and females in our study. Females reported slightly higher anxiety scores than males; however, there was no significant difference in anxiety scores between genders ($p = 0.1455$). Both males and females reported low anxiety scores with the median score for each gender being 5. Literature has demonstrated that women have a higher prevalence of fear and anxiety compared to men (8-11, 112, 126). Dental anxiety and its relationship to gender was reported by Locker and Liddell (9) in which women and younger participants demonstrated higher levels of dental anxiety than men and older

subjects. Van Wijk and Hoogstraten (125) and Humphris and King (112) confirmed females had a higher anxiety rating and reported more dental pain experience than males. The anxiety women face may also have a personal component attached to the emotion as Humphris and King (112) noted that those who experienced sexual assault had an increased likelihood of having dental anxiety. Anxiety and fear of pain may also have a biologic component as Wabnegger et al (126) pointed out. In that study, the grey matter volume of dental phobic patients was analyzed using MRI and compared to non-phobic people. The results of that study demonstrated that women had a higher grey matter volume in specific areas of the brain that are known to be related to pain processing and anticipation of fear and pain (dorsolateral and dorsomedial prefontal cortex). Since these areas, which deal with emotion regulation, were more pronounced in women who experienced dental anxiety, it is practical to draw from the conclusion that females have higher dental anxiety and fear of pain. Similar MRI studies evaluated the same concept and came to similar conclusions (127, 128). Our results could not support the conclusions in studies that reported women having higher anxiety and fear of dental appointments as women and men had equally low anxiety scores as reported in Table 1.

The participants in the current study were primarily dental students, family members/significant others of these students, and employees of the College of Dentistry. As a result, the majority of subjects may have more dental awareness and more regular dental attendance than the average person. It is reasonable to consider that the individuals in our study may not represent a fearful population with dental anxiety who avoid dental care, as reflected by the low Corah Dental Anxiety scores for both males and

females in the current study (Table 1). Furthermore, the demographic breakdown in Table 1 shows the average participant age was 25 years old. The ages ranged from 19-43 years old. It is worth noting that the great majority of subjects were in the 24-26 year range, with one subject at 43 years of age. Removing this single individual from the overall range may lower the average participant age. Previous studies have reported that younger patients tend to report more anxiety and pain responses compared to older individuals (9). However, in the current study the predominately young population reported a mean overall low anxiety. This younger age suggests that the subjects in the current study may not be indicative of the overall patient population and our results may not fully translate to responses from all patient groups.

The project was broken down into two different phases: mock and treatment. The mock technique was used as a baseline to compare the treatment technique to. Since the main difference between each group was whether anesthetic was deposited (treatment) into the PDL or not (mock), with all other major treatment parameters staying the same, this allowed for a direct comparison to see if the treatment technique was effective at reducing the pain of palatal injections.

Subjects were trained, at the beginning of the study, on how to fill out the 170 mm Heft-Parker visual analog scale (VAS) and this concept was re-enforced chairside when it came time for the subjects to rate their pain. Participants rated the pain of needle insertion into the PDL space and solution deposition, on two different VAS forms, followed by pain ratings for palatal needle insertion and solution deposition, also on two different VAS forms. As previously described in our methods and materials section, four

different descriptive categories comprised the form, with 0 mm corresponding to no pain and mild pain defined as greater than 0 mm but less than or equal to 54 mm. The descriptive words "faint" and "weak" were incorporated into the mild category. Moderate pain was categorized as greater than 54 mm but less than or equal to 114 mm. From 114 mm to 170 mm, severe pain was labeled, with the words "strong", "intense", and "maximum" pain encompassing the severe category. The Heft-Parker VAS was selected to quantify pain ratings because of its higher sensitivity over other scales, as it is commonly used with other subjective pain rating studies, and it is easy for subjects to understand and mark correctly (105). Briggs and Closs (129) compared the VAS to a verbal rating scale (VRS) and found a higher sensitivity and specificity for the VAS as a result of more response categories to choose from. Therefore, the VAS was an appropriate measurement to evaluate pain with.

The PDL needle was placed in the mid-palatal gingival sulcus for both the mock and treatment techniques for this study despite the traditional PDL injection site being mesial and/or distal to the tooth that's being anesthetized. The mid-palatal site was chosen because we were not evaluating pulpal anesthetic success like in other PDL injection studies (63, 91, 93). Rather, our study focused on determining if soft tissue could be comfortably anesthetized and if enough of the gingival collar was anesthetized so when the palatal injection was performed in the blanched tissue, the palatal injection would be painless. The standard palatal injection is normally given over the projected location of the palatal root, so it is important to have tissue anesthesia over the midline of this root. By giving traditional interproximal PDL anesthesia, there would be uncertainty

as to whether anesthesia will spread to the mid-palatal area. Therefore, the mid-palatal site was selected.

In terms of the PDL injection, Malamed (101) recommends using a 25-gauge or 27-gauge short needle. A 30-gauge short needle could bend upon placement into the sulcus for the PDL injection, thus not allowing for the proper back pressure needed for the injection technique. In the current study, we used a Stabident® (8 mm, Fairfax Dental Inc., Miami, FL) 27-gauge ultra-short needle to allow for better control of the needle during the PDL injection. This is due to its increased stiffness compared to a standard short needle, reducing the chance of the needle bending during anesthetic administration under high pressure. The bevel of the needle faced outward toward the palatal tissue in our study which is opposite of what Malamed (101) and Smith and Walton (95) recommend. They recommend having the bevel directed toward the root to allow better needle penetration in the sulcus. Their technique is intended to achieve pulpal anesthesia. However, our aim was not to address pulpal anesthesia, but to provide soft tissue anesthesia, so the bevel faced the palatal mucosa for maximum penetration of the anesthetic into the soft tissue.

The PDL injection was delivered with strong back pressure over a period of 30 seconds, in which 0.4 mL of 2% lidocaine with 1:100,000 epinephrine was delivered into the mid-palatal gingival sulcus. Having strong back pressure has been reported to be essential for the success of the technique (90, 95, 101). If back pressure was not present, the anesthetic solution would flow out of the sulcus and into the patient's mouth, not anesthetizing the soft tissue. The investigator had direct visualization as to whether any

anesthetic escaped from the gingival tissue. If the solution was not being administered correctly, the syringe was re-oriented by turning it in a clockwise motion with more apical pressure being applied and then continued injection of the anesthetic with the attained back pressure. Herod (130) provided a review of the literature for the intraligamentary injection. The literature review reported that 0.2 mL of anesthetic should be given over a period of 15-20 seconds. In the current study, 0.4 mL of local anesthesia was deposited into the PDL space, so it is reasonable to extrapolate that 30 seconds is a sufficient timeframe to use for the intraligamentary injection of that volume.

Two percent lidocaine was the anesthetic used in the current study. D'Souza et al (96) compared 2% lidocaine with saline and needle penetration alone to evaluate the extent of anesthesia and found there is a significant difference in the incidence of anesthesia when using the anesthetic solution compared to saline solution and needle insertion ($p < 0.001$). The results demonstrated the PDL injection does not anesthetize pulpal anesthesia by pressure anesthesia, but requires a local anesthetic solution. The importance of using an anesthetic for the PDL injection was also demonstrated by Kim (131) who showed that injecting saline under high back pressure into the PDL had no effect on success for anesthesia. Moore et al (92) confirmed this finding that injecting saline into the PDL of mandibular premolars did not provide pulpal anesthesia but when injecting 2% lidocaine with 1:100,000 epinephrine there was a high level of pulpal anesthesia based on EPT readings. Utilizing an anesthetic with epinephrine is important since the vasoconstriction that occurs with the injections "holds" the anesthetic solution in place. Clinically, this can be important for clamp placement in endodontic therapy due

to the length of time the clamp will be in place as well as to supplement or attain supplemental pulpal anesthesia. It has been shown that 3% mepivicaine, which does not have epinephrine, has a pulpal anesthesia duration of 20 minutes, with soft tissue anesthesia being shorter (48) so this anesthetic would not be an ideal solution to use for the purpose of soft tissue anesthesia. Berlin et al (63) and Nusstein et al (132) showed there was no difference in anesthetic success (pulpal anesthesia) between articaine and lidocaine for primary PDL injections. Since lidocaine is safe and an often-studied anesthetic, using other anesthetics may not have made an impact on our results. Future studies could compare other anesthetics to lidocaine for this technique.

A mock PDL technique was also used to compare the palatal needle insertion and solution deposition pain to the treatment group needle insertion and solution deposition pain ratings. For the mock PDL injection, the cartridge penetrating end of the Stabident® needle was pre-bent prior to the subject arriving so no anesthetic solution was expressed from the needle during the mock technique. The subjects filled out the VAS forms the same way for both techniques. For standardization purposes, the same phrases were used in each technique as the subject was informed of needle placement and solution deposition. In the mock PDL technique, the Stabident® 27-gauge, ultra-short needle was placed into the mid-palatal sulcus of the maxillary first molar with the bevel pointing towards to palatal mucosa. No anesthetic was administered even though the subject was informed it could be. Apical pressure was provided for 30 seconds, in the same manner and timeframe for the PDL treatment technique. Subjects rated the pain of needle insertion and solution deposition on two different VAS sheets. All procedures for the

mock PDL technique were performed identical to the treatment PDL technique with the exception of anesthetic being administered into the PDL sulcus. This standardization was important so to keep the patient blinded as to which technique they received at the particular appointment and to reduce the chance of bias by the subject. Having the subject being unaware of which technique they received through blinding gives a more accurate baseline of how well the treatment technique worked compared to the mock technique and allowed for a more precise statistical comparison to demonstrate if there were any differences between techniques.

Palatal injections were administered 1 minute after the PDL injection sequence. For the treatment technique, the palatal injection was performed in the blanched alveolar mucosa 3 mm apical from the palatal gingival margin. The palatal injection for the mock PDL technique was 7 mm apical from the gingival margin. The difference in palatal injection site was the result of focusing on the purpose of our study, which was soft tissue anesthesia rather than pulpal anesthesia. In order to demonstrate a painless palatal injection, it was important for the solution to be injected near the location of the PDL solution administration. Since a small amount of anesthetic was deposited into the gingival sulcus, there was not a large apical spread of blanching tissue. As a result, it was reasonable to keep the palatal injection closer to the PDL injection site. The palatal injection for the mock PDL technique was located 7 mm from the gingival margin as this is the recommended position by Malamed (133). A standard 27-gauge short needle was used as it was convenient for a palatal infiltration to administer 0.9 mL of 2% lidocaine with 1:100,000 epinephrine over 1 minute as this is a clinically acceptable amount of

local anesthetic and a suitable flow rate of anesthetic into the palatal soft tissue. After the palatal infiltration was completed, subjects rated the pain of palatal needle placement and solution deposition on two different VAS sheets.

The second appointment was conducted at least 2 weeks after the first appointment to allow for the gingival tissue to heal should there had been any serious damage to the PDL space or palatal injection site after the first appointment. Previous studies have indicated that the intraligamentary and palatal injection can cause potential post-operative periodontal problems and sequelae. White et al (93) found that 86% of subjects reported mild or moderate pain within the first 24 hours after a PDL injection. This abated by post-injection day 3. One serious complication occurring in White's study involved previously healthy periodontal tissue at the start of the study which broke down, leading to the need for root canal therapy. It was presumed that the PDL injection caused the tissue breakdown. Childers et al (94) reported, at a one-month follow-up evaluation following PDL injection, one subject had developed 6-8 mm periodontal pocketing, requiring subgingival scaling and curettage. By 18 months, the pocketing had resolved. Nusstein et al (68) had two participants experience palatal ulcerations adjacent to the incisive papilla injection site, manifesting within 3-4 days after injection which resolved in 7-10 days. Palatal swelling was observed after AMSA injections in Nusstein et al's (65) study, which resolved by the third post-injection day. Zaman et al (134) presented a case report of a palatal necrotic ulcer following local anesthesia administration into the hard palate for tooth extraction. The ulcer was managed with an oral topical ointment and chlorhexidine mouthwash and fully healed after 3 weeks. The authors hypothesized

the reason for the ulcer could have been from ischemia of soft tissue at the injection site leading to necrosis from vasoconstriction of the epinephrine within the local anesthetic and a rapid and pressurized injection into the soft tissue. Another possibility was a viral component, with the reactivation of herpes simplex virus as a result of the soft tissue trauma. Nusstein et al (132) demonstrated that 35% of participants experienced swelling at the injection site following the intraligamentary injection of the mandibular first molar. Eight percent of subjects developed an ulcer on the gingival tissue following the intraligamentary injection.

In the current study, one subject reported a traumatic ulcer developed one day after receiving the palatal injection from the treatment technique at the first visit. The ulceration was located at the palatal attached gingiva of the maxillary first molar. Two weeks later when the subject came back for the second appointment, the ulcer had fully resolved and there were no residual periodontal defects present. All subjects had a periodontal evaluation around the test tooth at each appointment, and at the one-month follow-up evaluation and no other subjects experienced or reported any tissue problems nor was any abnormal periodontal pocketing discovered. A one-month follow-up after the second appointment was chosen as the appropriate periodontal re-evaluation period as other published studies (93, 94) used the same time parameter to evaluate for any post-operative complications following the periodontal ligament injection. Any transient periodontal breakdown or issues should be resolved by the 4-week mark and if true periodontal damage occurred, this would still be present at the one-month follow up and distinguished from temporary periodontal injury which would have resolved.

The results of the current study can be found in Tables 2-12 in Appendix A. The mean values for the pain of needle insertion and solution deposition can be found in Table 2. The results show there was a significant difference in pain between the mock and treatment techniques for the palatal needle insertion pain and solution deposition pain ($p < 0.0001$ for each phase). This demonstrates that when anesthesia was first deposited via the PDL injection for the treatment technique, very little pain, if any, was felt by subjects when the needle was inserted into the palatal tissue and minor discomfort or no discomfort was noted when lidocaine was injected into the palatal tissue. The overall mean pain scores of palatal insertion and solution deposition for the treatment technique were in the mild pain descriptor category when compared to the palatal injection sequence from the mock PDL technique (moderate pain). Interestingly, the mock PDL solution deposition technique reported higher pain scores compared to the treatment PDL solution deposition technique despite no anesthetic being administered in the mock PDL deposition group. One explanation for this finding could be related to the nocebo effect. The subject expected a painful injection so their reaction to the anticipated painful injection of a solution caused the subject to report more pain than one would normally feel. The operator (BC) verbally informed the subjects, "Now I'm going to deposit the anesthesia in the PDL" whether it was the mock or treatment group. The simple suggestion that a solution was going to be administered with possible pain may have increased the negative side effects for the subject. Another explanation could be related to the calibrated procedure the operator followed for standardization and ensuring the participant remained blinded as to which technique they were receiving. After

verbalizing that anesthetic will be deposited into the PDL in both techniques, apical pressure was applied in the mock PDL injection technique, simulating the apical pressure needed to administer the anesthesia in the treatment PDL injection technique. Since the literature has established the onset of anesthesia in intraligamentary injections is immediate (89, 96), it is possible the subjects during the treatment technique would already feel some numbness within the 30 seconds of anesthetic administration. So when the needle was removed from the sulcus in the treatment PDL technique, their memory of the pain may not have been as strong as compared to the mock technique of having the needle placed with apical pressure for 30 seconds and removing the needle from un-anesthetized tissue. As a result of experiencing trauma and irritation to gingival tissue for the mock PDL technique for the duration of the sequence, the subjects may have been more aware of the discomfort compared to the treatment PDL technique.

The order of appointment was evaluated to determine if there was a difference in VAS pain ratings between receiving an injection technique at either the first or second appointment for each technique (Table 3). There was a significant difference between the first versus second appointment PDL mock needle insertion pain ratings, with the second appointment being statistically much less painful than the first appointment. For the PDL solution deposition in the mock technique, there was no statistically significant difference in order between the first and second appointment; however, the pain ratings for the second appointment in the mock PDL solution deposition decreased. These findings suggest that for the mock PDL insertion phase, since most of the subjects had never received a PDL injection prior to participating in this study, once they experienced the

needle entering the sulcus the first time they understood or anticipated what to expect for the second appointment and were more prepared for the needle entering again. In regards to the differences between the first (mock) and second (treatment) appointments for PDL solution deposition, the nocebo effect could have applied as previously discussed. For those participants who had the treatment technique as their first appointment and mock as the second, there was no statistically significant difference in the pain of PDL insertion nor solution deposition (mock deposition) between the appointments. When analyzing the differences between appointments for the palatal insertion and solution deposition, there was a statistically significant difference whether it was the mock or treatment technique (all p values are < 0.0001). This supports the previously stated findings (48, 106) that the mock PDL technique results in much more painful palatal injection sequences compared to the palatal anesthesia administration when local anesthesia is first deposited via the treatment PDL technique. The mock PDL group received a straight palatal injection.

The differences in gender pain ratings for both the mock and treatment appointments were evaluated and reported in Tables 4 and 5. There was a significant difference in pain ratings between males and females for needle insertion into the palatal tissue after receiving anesthesia in the PDL treatment technique, with females reporting more pain than males ($p = 0.0148$). Both genders described the palatal insertion pain in the treatment technique as mild pain, with the mean male VAS scores reported as 3 mm and female VAS scores as 9 mm. This difference in VAS values may not be clinically significant. Females also reported higher pain ratings than males for the solution

deposition into the palate for the PDL treatment technique as well with pain ratings as 10 mm versus 6 mm, respectively; although, the difference between males and females was not significantly different. ($p = 0.0711$). The differences seen with women reporting higher pain responses than males, even with the treatment technique might be related to gender operator bias. Perry et al (135) reported that females reported higher pain on solution deposition when a male operator delivered the anesthesia compared to when a female operator did. When assessing the data from the mock group between males and females, females reported higher pain ratings in all 4 categories of needle placement into the PDL and palatal tissue as well as the mock solution deposition into the PDL and solution deposition into the palatal tissue. However, the differences between male and female pain ratings were not significantly different. This is not a surprising result as there is ample established literature indicating that women have higher pain and anxiety ratings compared to males. As previously mentioned in the introduction of the current study, Fredrikson et al (11) demonstrated that women, overall, have a higher prevalence of phobias and anxiety compared to men, thus re-enforcing Marks' study (136). Fillingim et al (8) showed that women will experience higher experimental pain and more pain sites than males. Thermal testing was performed with a thermal sensory analyzer which demonstrated females having a lower pain threshold for the stimulus than males and tolerated the stimulus better than females. A study by Keogh et al (10) reported similar findings, in which women were less tolerant to cold pain than males and women self-reported higher pain levels when focusing on the pain they did experience.

By adding a PDL injection prior to administering local anesthesia in the palatal tissue, it is important to ensure we are not trading one painful injection for another. To be effective in providing painless anesthesia, there has to be an obvious benefit and justification for delivering the PDL injection first. Table 5 reviews the differences in the mean pain scores between the treatment PDL technique needle insertion pain compared to the needle insertion into the palate from the mock PDL technique, where no anesthesia was provided into the PDL space first. There is a strongly significant difference in the level of pain ($p < 0.0001$) for the PDL insertion pain rating relative to the amount of pain subjects felt when the needle was inserted into the un-anesthetized palatal tissue. This shows that there is significantly more pain for the needle insertion into the palatal tissue (mock technique) compared to the needle insertion into the PDL (treatment technique). Table 6 focuses on the solution deposition pain differences between the treatment PDL technique (anesthetic delivered into the PDL space) compared to the pain experienced by the palatal anesthetic deposition from the mock PDL technique (no anesthetic was administered into the PDL space prior to deposition into the palate). The data also confirms a strongly significant difference ($p < 0.0001$) in the amount of pain patients experienced when local anesthesia was delivered into the un-anesthetized palatal tissue relative to the low amount of pain participants felt when delivering anesthesia into the PDL space for the PDL treatment technique. There was significantly more pain upon solution deposition into the palatal soft tissue in the mock PDL technique compared to the pain of solution deposition into the PDL sulcus. Since the data in this study establishes the PDL injection is not a painful injection, as confirmed by a previous study

(118), there is a clear clinical relevance and validation that by providing a small amount of anesthetic into the PDL space prior to giving the palatal injection, one can drastically reduce the pain patients may experience during palatal anesthesia.

Table 7 summarizes the percentage breakdown of participants and how they rated pain on four-point descriptor scale. There is a noticeable difference in pain ratings when comparing the mock technique to treatment technique. This confirms that PDL needle insertion and solution deposition (treatment technique) was much less painful than the same variables in the local infiltration of the palate (mock treatment technique). Sixty-five percent of subjects rated moderate to severe pain for needle insertion into the palate when receiving the mock PDL. This is compared to 1% of subjects rating moderate to severe pain for palatal needle insertion after receiving the PDL first. For solution deposition pain ratings 65% of people reported moderate to severe pain for the palatal injection in the mock PDL technique compared to 2% of subjects reporting the same amount of pain when anesthetic was delivered into the palate after receiving a PDL injection first. The data shows the PDL injection is a relatively painless procedure. For both the mock and treatment PDL techniques, subjects rated the pain of needle insertion as none to mild pain 79% and 83% of the time, respectively, and pain of solution deposition as none to mild pain in the PDL mock and treatment techniques 82% and 89% of the time, respectively. This level of pain for the intraligamentary injection is similar to those reported in Nusstein et al (132). In that study, the investigators used a CCLAD device for injection into the PDL of mandibular posterior teeth. Nusstein reported 14-27% moderate pain for needle insertion and severe pain ratings for needle insertion were

0-4% (132). In the current study, the mock PDL technique needle insertion was reported as 21% moderate pain in the mock PDL technique and 16% moderate pain in the treatment technique. One percent of subjects in the current study reported severe pain within the treatment technique for needle insertion and 0% in the mock PDL technique. For solution deposition, the pain rating scores are comparable between studies. In our study, 11% of subjects rated solution deposition within the treatment group as moderately painful with 0% rating severe pain. Nusstein reported comparable results with 8-18% moderate pain for deposition and 0% severe pain for the category (132).

After the palatal injection was completed, the extent of anesthetic spread within the palatal soft tissue was determined by placing the tip of the dental explorer lightly into the palatal tissue along a vertical and horizontal line from the palatal injection site until pain was reported. The area was measured in four directions: mesial, distal, inferior, and superior from the palatal injection location using a delineated periodontal probe. The area was calculated in mm^2 by adding the mesial and distal distances and multiplying this by the sum of the inferior and superior distance measured at each time interval (Table 8). The injection location within the palatal tissue was evident as there was a small pinpoint area of hemorrhage at the needle insertion site. The degree of anesthetic coverage was assessed starting 1 minute after the palatal injection, and was measured every 5 minutes until the 30 minute mark. Table 8 and Figure 15 summarizes the area of soft tissue anesthesia for both the mock and treatment techniques. The maximum spread of anesthesia for both the mock and treatment techniques peaked at 10 minutes post-injection and a steady decline in area for both techniques was observed until the 30

minute mark. No subject experienced complete soft tissue anesthetic reversal by the 30 minute mark. The treatment technique had a smaller area of anesthetized soft tissue at all time points compared to the palatal deposition of lidocaine in the mock PDL technique despite the PDL treatment having an overall greater volume of anesthetic dispensed due to the added solution from the PDL deposition (1.3 mL vs. 0.9 mL). The findings can be explained by the location of each technique's injection site. For the treatment technique, the palatal injection site was within the blanched gingival collar of the maxillary first molar, approximately 3-4 mm from the gingival margin. This area is attached tissue and bound tightly to the bone, not allowing for an easy spread of solution (115). The palatal injection site for the mock PDL technique was at Malamed's recommended site (133), 7 mm from the gingival margin. This area is a transition from tightly bound tissue to bone to a loose, flexible tissue. As a result, anesthetic solution could more easily spread, thus allowing for a greater capacity and extent of soft tissue numbness, anesthetizing the terminal nerve endings of the greater palatine nerve.

The difference in palatal injection sites in this study was due to the attempt to re-produce a typical clinical palatal injection for the mock PDL technique. In the mock PDL technique, the palatal needle insertion and solution deposition site was the conventional site of injection a patient would normally receive during treatment. We wanted to standardize this process and replicate a process to a clinical application and demonstrate the pain patients normally feel. The palatal injection site after receiving the treatment PDL technique first was slightly different since the gingival collar could attain predictable anesthesia. As a result of anesthesia in this location, the probability of a

painless subsequent palatal injection was high. As the purpose of our study was to evaluate pain, we wanted to keep the palatal injection site closer to the PDL location and demonstrate a reliable and consistent place to attain painless palatal anesthesia. The clinical application for treatment technique was to provide a painless palatal injection for clamp placement and soft tissue management during dental procedures. Since our study did not analyze pulpal anesthesia, we cannot confirm or deny that anesthetic molecules still penetrate through the bone in the treatment technique and provide pulpal anesthesia to the palatal root. Future studies can analyze the effect of the treatment technique on pulpal anesthesia for single rooted teeth. Other studies can evaluate if the area of palatal anesthesia with the treatment technique would be sufficient for minor soft tissue surgical procedures or if further palatal injections would be needed.

Studies have indicated that the intraligamentary injection may cause post-operative pain and complications at the site of injection (27, 63, 93, 96, 132). In our study, we only evaluated whether post-operative complications occurred once anesthesia resolved. We also asked if subjects remembered any post-operative pain after each appointment. Table 9 reviews the one-month follow-up evaluation data from the participants in this study. Subjects were asked to identify whether they felt more pain when the anesthesia wore off after the first appointment, second appointment, or had no pain after either appointment or the pain experienced after the first and second appointment were of the same magnitude. There was an even distribution in data demonstrating that there was no significant difference in subjects experiencing more or less post-operative pain after one appointment versus the other ($p = 0.2972$). While 35%

of subjects reported no difference in pain after either appointment or the same amount of pain after each appointment, this could be attributed to the subject failing to recall if there was a true difference or not and selecting the "neither" category by default, or this could be an accurate representation that they either felt no pain after each appointment or the pain was comparable whether the mock or treatment technique was performed. Should the latter be true, this suggests there was minimal periodontal disruption and damage when using this technique despite the PDL being traumatized twice within a two-week period. This differs from previous studies (93) which reported higher post-operative pain after PDL injections, with 86% of subjects reporting mild/moderate pain post-operatively. In the current study, a questionnaire was given to subject to mark any post-operative sequelae and pain from injection. The self-evaluation period was 72 hours after the appointment and the subjects were re-evaluated 30 days after the second appointment to assess periodontal health.

This was a single-blinded study in which the operator was aware if the mock or treatment technique was being administered, allowing the potential for some degree of bias. However, creating a double-blinded study would have been difficult since the operator had direct visual access to the field when delivering the anesthesia and seeing if anesthetic escaped from the PDL space or not during the treatment technique PDL injection.

The results of the current study are promising in providing a technique for a painless or nearly painless palatal injection. Future studies could re-create this work to see if there are similar results with patients requiring dental treatment or for symptomatic

patients needing endodontic therapy, more closely representing a clinical environment. Pain can add another dimension into the subjective evaluation patient's may report. Since there was a confounding variable in our study with placing the needle into the palatal tissue at two different sites, an alternative study could examine if one can achieve predictable supplemental pulpal anesthesia 3-4 mm from the free gingival margin using our PDL technique. Another study might even evaluate whether the palatal injection is needed to supplement a buccal infiltration for pulpal anesthesia if the PDL injection alone is insufficient.

Chapter 5: SUMMARY AND CONCLUSION

Dental anxiety and fear of injections can have a debilitating effect on anxious patients, leading to negative oral health outcomes from cancelling dental appointments. When a nervous patient has a dental need, the fear of dental injections may be too great, causing the person to suffer from avoiding treatment. Palatal anesthesia is particularly painful. Despite attempts to alleviate the pain of injection, palatal infiltrations still hurt. Intraligamentary injections are useful for providing primary or supplemental anesthesia and have the potential to be a mildly painful injection compared to the palatal injection. The purpose of this prospective, randomized, single-blind study was to compare injection pain ratings of a pre-emptive intraligamentary injection (PDL) plus palatal infiltration versus a standard palatal infiltration to anesthetize the palatal mucosa of the maxillary first molar.

One hundred thirty-three subjects participated in this research experiment. Participants were appointed two consecutive appointments, spaced at least two weeks apart. The order in which technique they would encounter at the first appointment and which maxillary first molar would receive the technique was randomized. Whatever technique they received at the first appointment (mock or treatment), they received the opposite technique at the second appointment. The PDL treatment technique consisted of using an ultra-short 27-gauge needle and delivering 0.4 mL of 2% lidocaine with

1:100,000 epinephrine into the mid-palatal sulcus of the maxillary first molar over a 30 second period. Then, a standard 27-gauge short needle was used to deliver 0.9 mL of 2% lidocaine with 1:100,000 epinephrine into the gingival collar of the palatal mucosa, 3 to 4 mm from the gingival sulcus over a 1 minute period. Subjects were asked to rate the pain of needle insertion and solution deposition for each phase of the injections on two separate VAS sheets.

The mock technique consisted of inserting a 27-gauge ultra-short needle into the mid-palatal sulcus of the maxillary molar, but no anesthetic solution was deposited. After 30 seconds of mock solution deposition into the PDL, 0.9 mL of 2% lidocaine with 1:100,000 epinephrine was deposited into the un-anesthetized palatal mucosa 7 mm from the gingival margin over a 1 minute period. Subjects also rated the pain of needle insertion and solution deposition for each sequence on two separate VAS sheets. For each technique, 30 minutes of palatal soft tissue mapping occurred every 5 minutes to track the extent of soft tissue anesthesia over time. Subjects returned 1 month after the second appointment to re-evaluate their periodontal status and record post-operative pain differences between appointments.

The results of the study demonstrated there was a significant difference in pain reduction for subjects who received the treatment technique compared to the mock technique ($p < 0.0001$). The subjects who experienced the mock PDL technique reported moderate pain for the palatal needle insertion and solution deposition compared to mild pain reporting for the PDL treatment for needle insertion and solution deposition. Pain differences were noted between genders, with females reporting higher pain ratings than

males for palatal needle placement and solution deposition for both the mock and treatment techniques. However, this difference may not be clinically significant since the pain ratings were close to no pain.

There was a significant difference when comparing the pain of the mock PDL needle insertion to the palatal needle insertion for the mock technique ($p < 0.0001$). The same was true for the solution deposition in which there was a significant difference between the pain of receiving anesthesia into the PDL compared to the pain of palatal solution deposition ($p < 0.0001$). These results show that the PDL injection is significantly less painful than a standard palatal injection. Soft tissue evaluation for each technique revealed a peak spread at the 10 minute mark and gradually declined over the 30 minute evaluation period. The mock technique had a much greater spread of anesthesia compared to the treatment technique, likely due to the difference in location of palatal solution deposition for each technique.

There was no significant difference in post-operative pain ratings for one appointment or the other at the one-month evaluation.

In conclusion, providing an intraligamentary injection into the mid-palatal sulcus of the maxillary first molar prior to administering a palatal injection significantly reduced the pain of needle insertion and solution deposition into the palate. Inserting an ultra-short 27-gauge needle into the PDL and delivering 0.4 mL of lidocaine solution was significantly less painful compared to the local infiltration of the un-anesthetized palatal tissue when using a short 27-gauge needle. Gender differences were noted within the study, with females reporting higher pain ratings than males overall. Widespread soft

tissue numbness was evident for 30 minutes post-palatal injection, with the maximum area noted at 10 minutes. No significant post-operative side effects were noted and no difference in the amount of pain experienced after each appointment was reported.

Appendix A: Tables

Table 1: Biographical data.

Variable	N	Mean	SD	Min - Max
Age (Yrs)	133	25.0	3.3	19 - 43
Females	66	-------	-------	-------
Males	67	-------	-------	-------
Corah Dental Anxiety Score (CDAS)	133	5	1.6	4 - 14
CDAS for Females	66	5	1.6	4 - 14
CDAS for Males	67	5	1.6	4 - 10
				p = 0.1455

Table 2: Pain of injection: mean values for needle insertion and solution deposition.

Group	N	Needle PDL Insertion (mm)	Solution PDL Deposition (mm)	Needle Palate Insertion (mm)	Solution Palate Deposition (mm)
MOCK	133	41	35	71	76
TX	133	38	31	6	8
P-value		0.3400	0.0800	**<0.0001**	**<0.0001**

Table 3: Mean PDL VAS pain ratings for 1st and 2nd appointment.

Group (1st appt)	N	PDL Needle Insertion 1st appt (mm)	PDL Needle Insertion 2nd appt (mm)	**P value**	PDL Solution Deposition 1st appt (mm)	PDL Solution Deposition 2nd appt (mm)	P value
Mock	67	40	35	**0.0045**	33	27	0.0604
Treatment	66	42	41	0.7440	35	37	0.5109

Table 4: Mean palate VAS pain ratings for 1st and 2nd appointment.

Group (1st appt)	N	Palate Needle Insertion 1st appt (mm)	Palate Needle Insertion 2nd Appt (mm)	**P value**	Palate Solution Deposition 1st appt (mm)	Palate Solution Deposition 2nd Appt (mm)	**P value**
Mock	67	68	5	**< 0.0001**	70	9	**< 0.0001**
Treatment	66	8	74	**< 0.0001**	7	82	**< 0.0001**

Table 5: Mean VAS pain ratings by gender--mock technique.

Mock Group	Count	PDL Needle Insertion (mm)	PDL Solution Deposition (mm)	Palate Needle Insertion (mm)	Palate Solution Deposition (mm)
Male	67	41	37	67	71
Female	66	40	33	75	81
P-value		0.9378	0.3882	0.1867	0.0765

Table 6: Mean VAS pain ratings by gender--treatment technique.

TX Group	Count	Needle PDL Insertion (mm)	Solution PDL Deposition (mm)	Palate Needle Insertion (mm)	Palate Solution Deposition (mm)
Male	67	40	31	3	6
Female	66	37	30	9	10
P-value		0.4769	0.8107	**0.0148**	0.0711

Table 7: Pain rating comparison of PDL insertion to palate insertion--mock technique.

Group	N	Mean PDL Insertion Pain (mm)	Mean Palate Insertion Pain (mm)
MOCK	133	-------	71
TX	133	38	-------
P-value	**< 0.0001**	-------	-------

Table 8: Pain rating comparison of PDL solution deposition to palate solution deposition.

Group	N	Mean PDL Deposition Pain (mm)	Mean Palate Deposition Pain (mm)
MOCK	133	-------	76
TX	133	31	-------
P-value	**< 0.0001**	-------	-------

Table 9: Grouping of VAS pain categories for mock technique.

Mock	% VAS PDL Insertion	% VAS PDL Deposition	% VAS Palate Insertion	% VAS Palate Deposition
None	4%	11%	3%	1%
Mild	75%	71%	32%	35%
Moderate	21%	17%	59%	49%
Strong	0%	1%	6%	16%

Table 10: Grouping of VAS pain categories for treatment technique.

Treatment	% VAS PDL Insertion	% VAS PDL Deposition	% VAS Palate Insertion	% VAS Palate Deposition
None	3%	11%	61%	44%
Mild	80%	78%	38%	54%
Moderate	16%	11%	0%	2%
Strong	1%	0%	1%	0%

Table 11: Area of soft tissue spread over time.

Technique	Time (min)	Area spread (mm^2)	P-value
Mock	1	677	**< 0.0001**
Treatment	1	384	
Mock	5	797	**< 0.0001**
Treatment	5	508	
Mock	10	813	**< 0.0001**
Treatment	10	526	
Mock	15	805	**< 0.0001**
Treatment	15	518	
Mock	20	791	**< 0.0001**
Treatment	20	505	
Mock	25	776	**< 0.0001**
Treatment	25	481	
Mock	30	765	**< 0.0001**
Treatment	30	465	

Table 12: One month follow-up regarding pain after each appointment.

Technique type	First appt worse	Second appt worse	Neither
Mock	20	20	27
Treatment	20	27	19

Appendix B: Figures

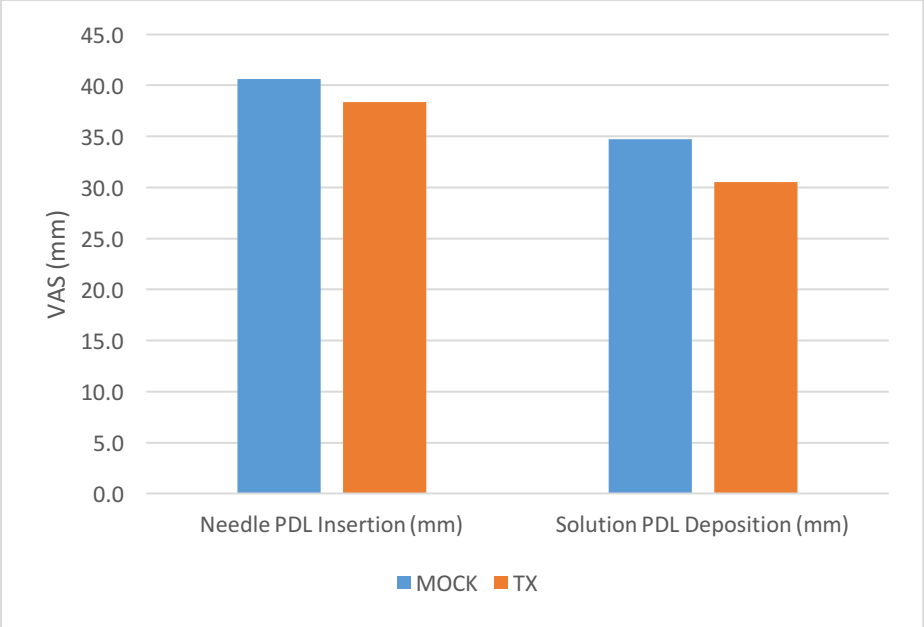


Figure 1: Overall mean pain values for the PDL injections.

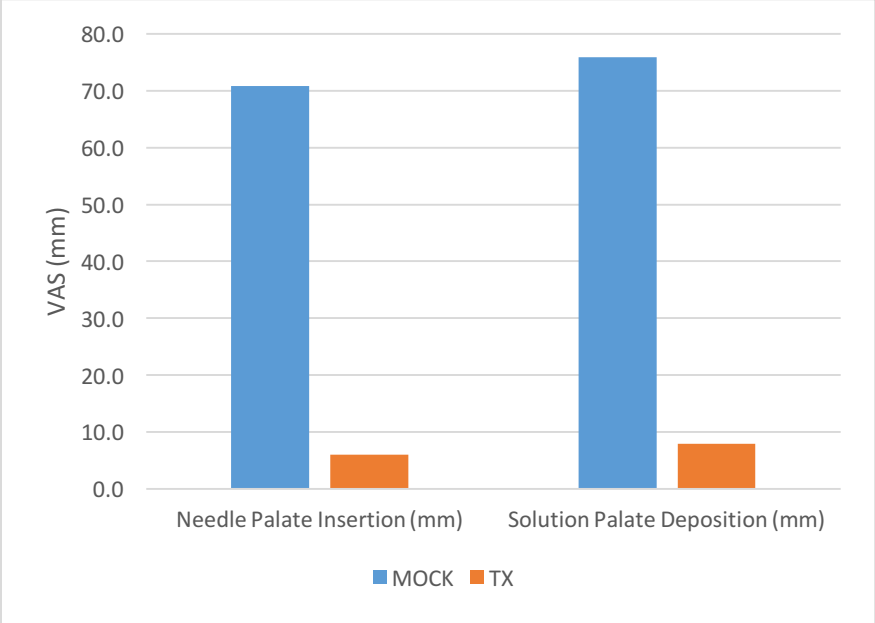


Figure 2: Overall mean pain values for palate injections.

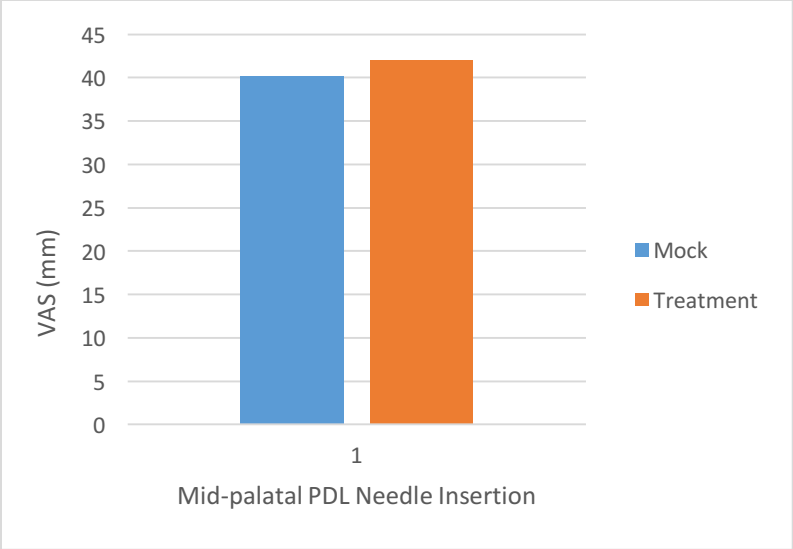


Figure 3: Mean VAS pain ratings for PDL needle insertion pain--1st appointment.

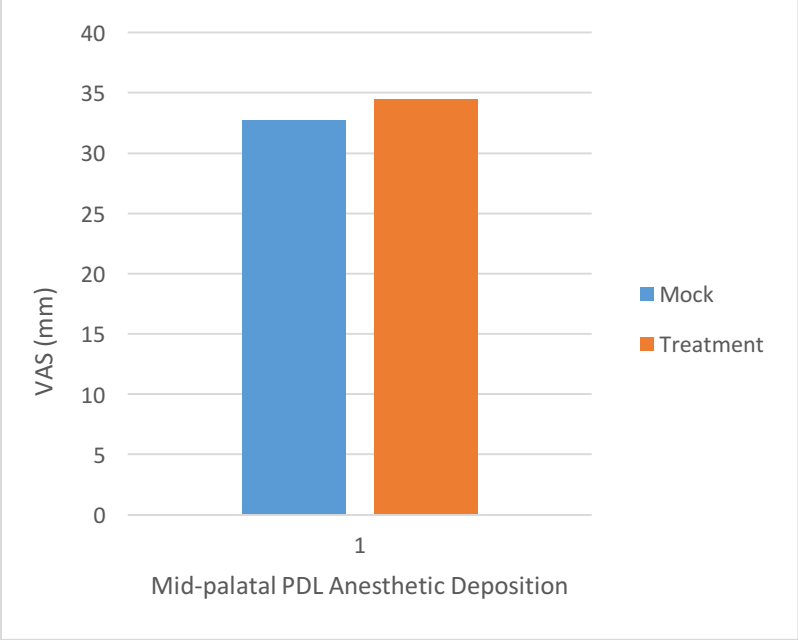


Figure 4: Mean VAS pain ratings for PDL solution deposition pain--1st appointment.

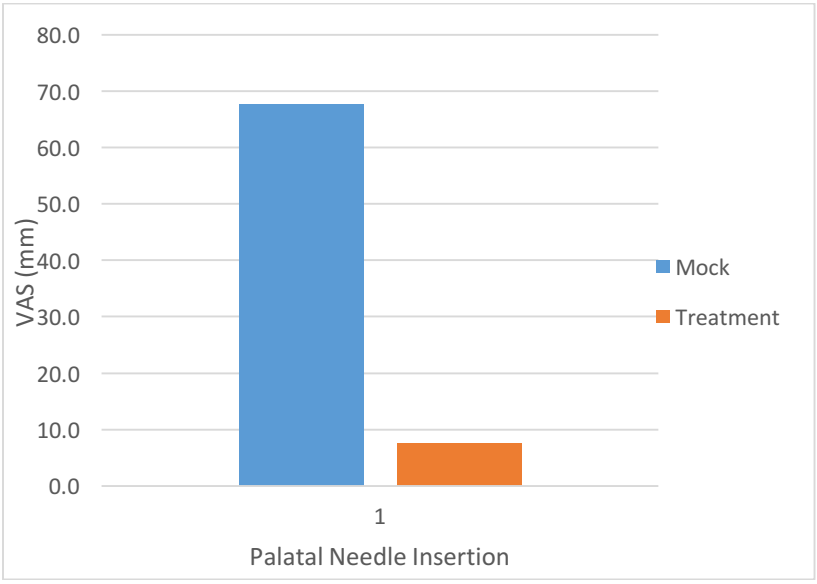


Figure 5: Mean VAS pain ratings for palatal needle insertion pain--1st appointment.

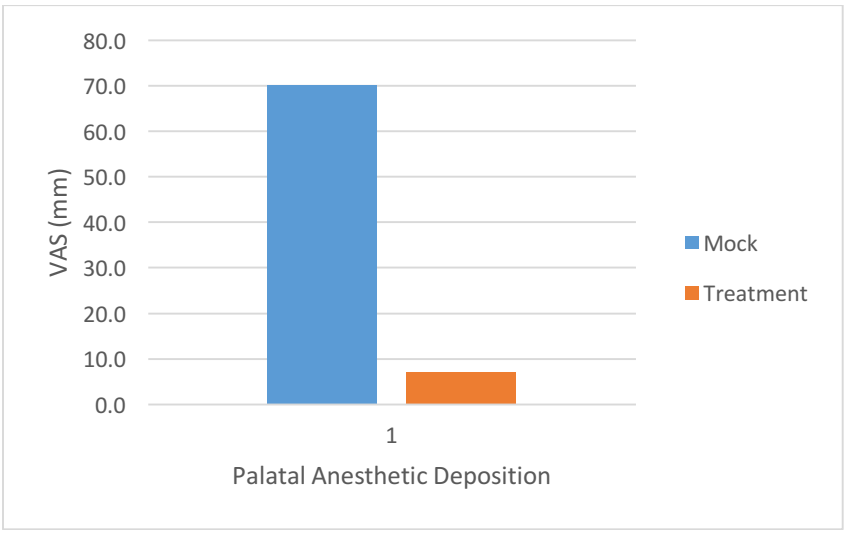


Figure 6: Mean VAS pain ratings for palatal solution deposition-- 1st appointment.

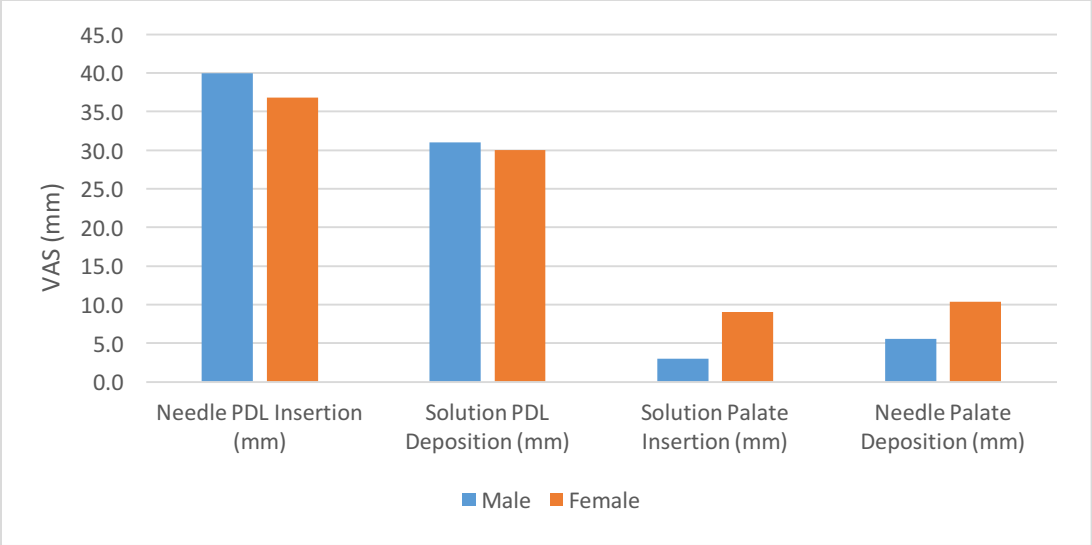


Figure 7: Mean pain by gender for treatment technique.

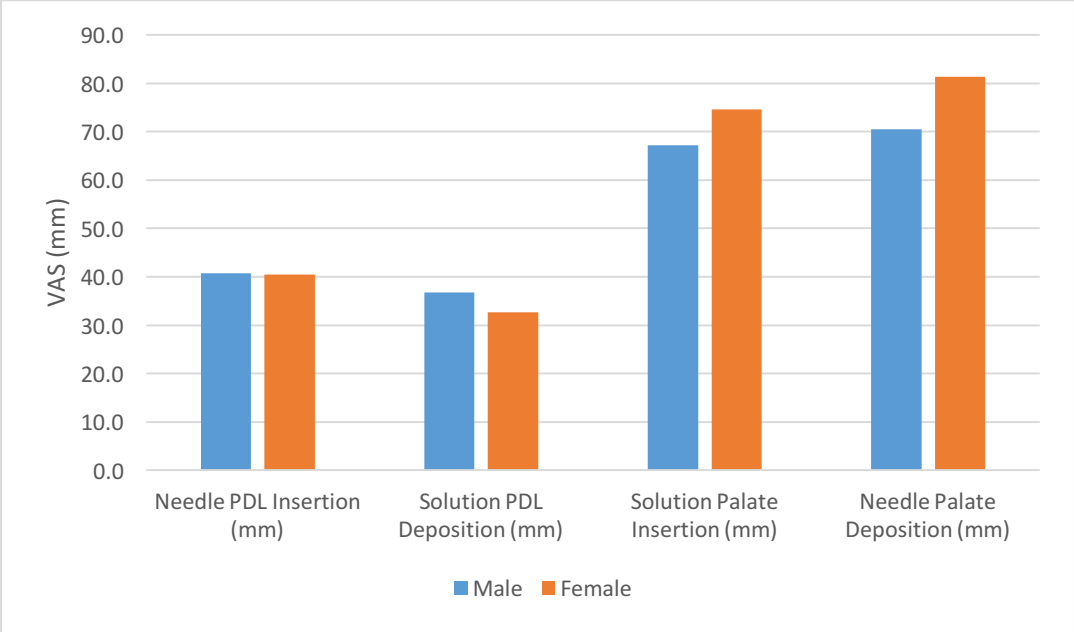


Figure 8: Mean pain by gender for mock technique.

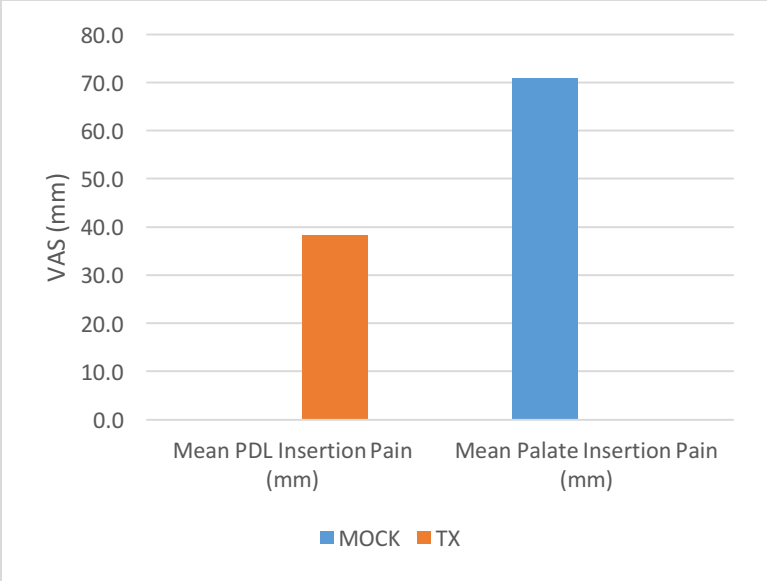


Figure 9: Treatment PDL vs. mock palatal needle insertion pain rating.

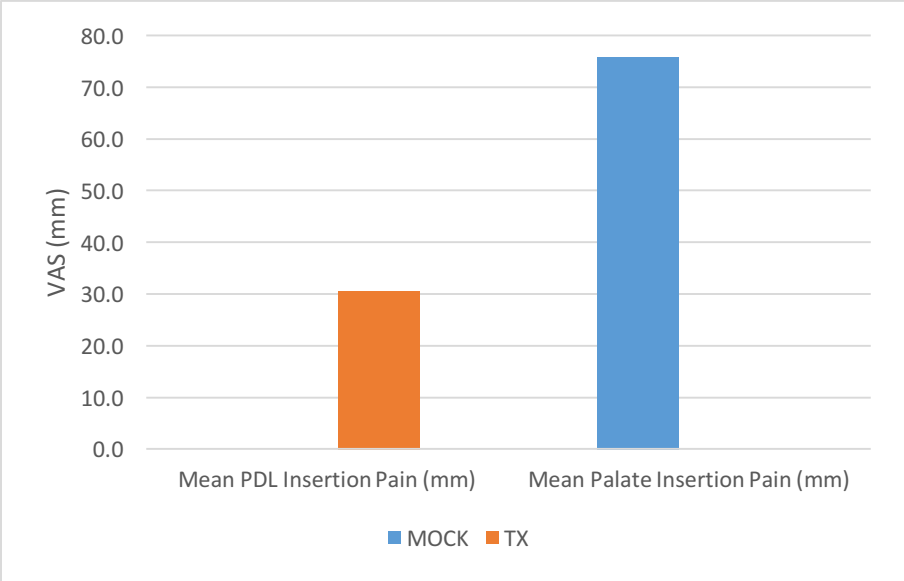


Figure 10: Treatment PDL solution deposition vs. mock palatal solution deposition pain rating.

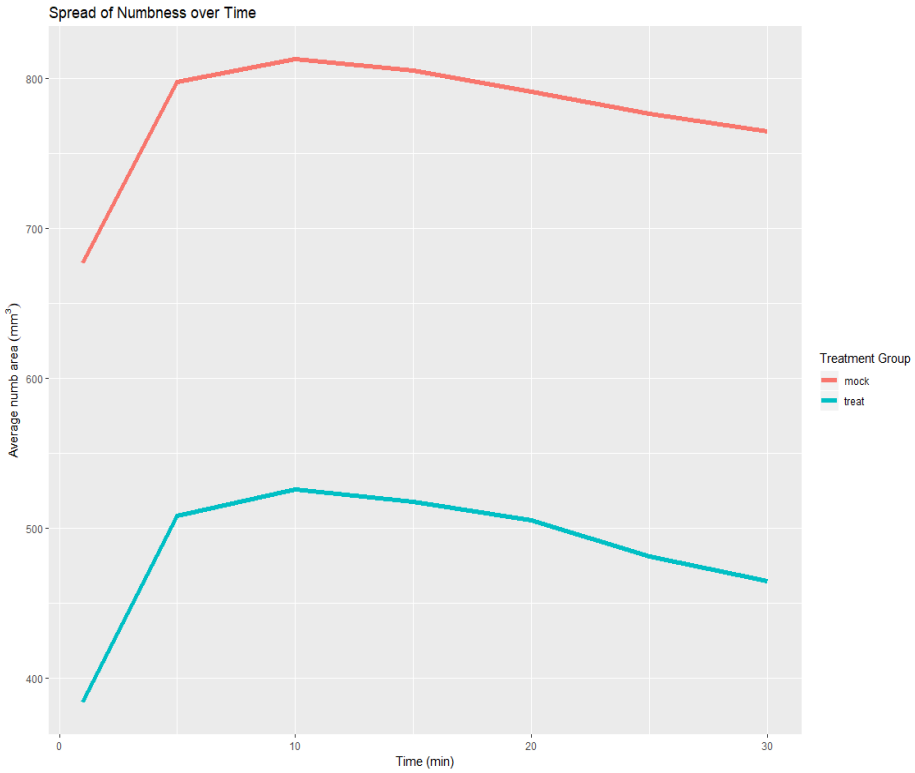


Figure 11: Soft tissue anesthetic spread over time.

Place a mark on the line below to show the amount of pain that you feel.

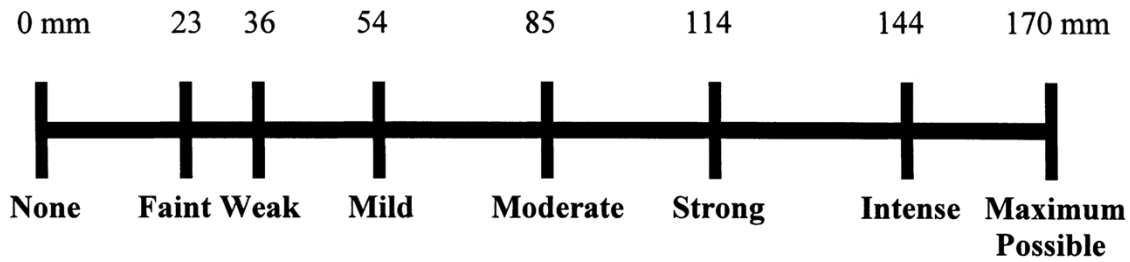


Figure 12: Heft-Parker VAS used for assessment of pain.

Appendix C: Medical History Form

THE OHIO STATE UNIVERSITY
COLLEGE OF DENTISTRY

Patient Name _____
Date _____
Date of Birth _____

Medical History

1. Do you have or have you had any of the following?

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

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

3. Have you ever been hospitalized? NO YES

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

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

6. Have you recently taken any central nervous system (CNS) depressants? NO YES
   (Including alcohol or any analgesic medications, tranquilizers, sedatives, or hypnotics)

7. 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_____

8. Are you pregnant or nursing? Estimated date of delivery_____ NO YES

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

10. How often do you have dental check ups? _____ Date of last Exam_____

11. Do you have any lumps or sores in your mouth now? NO YES

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

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

Current Medications

Trade Name	Generic Name	Dose/Frequency	Reason

Summary of Patient's Medical Status:_____
_____
_____

Medical Risk Assessment

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

Medical Consultation Required

- ☐ No (healthy and/or stabilized disease)
- ☐ Yes (ASA III or IV; cardiac murmur; vague hx; recent major disease; recent diagnosis/operation; uncontrolled disease; blood pressure; etc.)

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

_____ _____
Patient's Signature Date

Appendix D: Consent Form

The Ohio State University Combined Consent to Participate in Research and HIPAA Research Authorization

Study Title:	**A prospective, randomized, single blind study of intraligamentary anesthesia as an adjunct for anesthetizing the palatal mucosa of the maxillary first molar**
Principal Investigator:	**Dr. John Nusstein, DDS, MS**
Sponsor:	**The Ohio State University Division of Endodontics**

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.
- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.
- **You may or may not benefit as a result of participating in this study.** Also, as explained below, your participation may result in unintended or harmful effects for you that may be minor or may be serious depending on the nature of the research.
- **You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate.** If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. Why is this study being done?

The purpose of this study is to see if an intraligamentary injection (shot under the gum tissue next to the tooth or "gum" shot) prior to a palatal injection (shot on the roof of your mouth) reduces the pain of the palatal injection as compared to a palatal injection alone. We propose that enough local anesthetic solution (numbing solution) can be delivered with the intraligamentary technique ("gum" shot) to anesthetize the gingival collar of the tooth (the tissue on the roof of your mouth next to the tooth), thus allowing a relatively painless shot on the roof of your mouth (palatal injection).

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

One hundred thirty three (133) people will take part in this study.

3. What will happen if I take part in this study?

If you choose to participate in this study, you will receive a "gum" shot and a shot on the roof of your mouth or a mock (fake) "gum" shot and a shot on the roof of your mouth to assess if the "gum" shot prior to palatal anesthesia reduces the pain of the shot on the roof of your mouth. After you consent to participate and sign a privacy form, you will be required to complete a medical history questionnaire and a Corah dental anxiety questionnaire.

You will then be randomly assigned to one of two groups to determine whether you will receive the "gum" shot and a shot on the roof of your mouth or mock "gum" shot and a shot on the roof of your mouth at the first appointment. You will then receive the other injection combination at a second appointment. You will not know which procedure you are receiving. The doctor will know which procedure you are receiving at each appointment.

Intraligamentary and palatal injection or mock intraligamentary and palatal injection: 2% Lidocaine w/ 1:100,000 epinephrine (numbing solution) will be the local anesthetic used for both the "gum" shot and the shot on the roof of your mouth. Following each injection, you will be asked to rate the amount of pain you feel when the needle is placed and when the numbing solution is deposited. You will do this by marking your pain experience on a line graph with a pen. This will be done for all shots (real or fake). A secondary form will be filled out 5 minutes afterwards to re-evaluate your pain experience by marking another set of line graphs. The palatal mucosa (tissue on the roof of your mouth) will be evaluated with a dental explorer for anesthesia (numbness) at 1, 5, 10, 15, 20, 25, and 30 minute intervals.

You will be asked to come back one month after the second appointment to evaluate tissue healing by periodontally probing the site (checking the gum tissue around the tooth on the roof of the mouth). A final post-operative form will be completed at this follow up appointment. This will conclude your study participation. Any additional treatment will be performed outside of the study.

4. How long will I be in the study?

You will have two treatment appointments at two week intervals. You will either receive a "gum" shot and a shot on the roof of your mouth at one appointment and a fake "gum" shot and a shot on the roof of your mouth at the second appointment. If you receive the fake injection at the first appointment, then you will receive the actual injection at the next appointment and vice versa. The order is randomized (up to chance) so you will not know which set of injections you will receive first. Each appointment will last

approximately 45 minutes. You will return no sooner than one month after the second appointment for evaluation and that appointment should take approximately 5 minutes.

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 to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University. If you are a student or staff member at OSU and choose not to participate in this study, your grades and/or employment will not be affected. You may withdraw from the study by emailing crump.47@osu.edu

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 injections, you may have swelling (hematoma-a collection of blood in my mouth) or a bruise may develop. The injection site may ulcerate. 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 or a possible altered sensation to the roof of your mouth that may last up to a few weeks. Your tooth may feel sore to bite on for a few days.

If you are a woman able to have children, you will be questioned regarding pregnancy or suspected pregnancy and will not be allowed to participate if pregnant, suspect a pregnancy, trying to become pregnant, or nursing. Additionally, you will be offered to take a urine pregnancy test before you can start this study. The reason for excluding pregnant or potentially pregnant women is an attempt to minimize this population in the study because the potential risks to the fetus and nursing baby are unknown. This test will be paid for by the investigator.

7. What benefits can I expect from being in the study?

You will not directly benefit from this study. Society may benefit from determining if the "gum" shot followed by a shot on the roof of your mouth is less painful than the shot on the roof of your mouth alone.

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. There are no other choices other than to participate or not participate in the study.

9. What are the costs of taking part in this study?
The study will pay for the cost of the study drug (Lidocaine) and the urine pregnancy test.

10. Will I be paid for taking part in this study?
Yes, you will be paid $80 cash for your participation. You will receive $80.00 cash immediately after completing all aspects (3 sessions) of the study. If you are unable or unwilling to complete all sessions of the study, you will be paid a pro-rated $30.00 cash for one completed session after notifying the investigator and $70 cash for two completed sessions after notifying the investigator. Payment is to compensate you for time and travel expenses. By law, payments to subjects are considered taxable income.

11. 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.

12. 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.

13. 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).

An Institutional Review Board responsible for human subject 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. HIPAA AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

I. What information may be used and given to others?

- Past and present medical records;
- Research records;
- Records about your study visits;
- Information that includes personal identifiers, such as your name, or a number associated with you as an individual;
- Information gathered for this research about:
  Physical exams
  Laboratory, x-ray, and other test results
  Diaries and questionnaires

II. Who may use and give out information about you?

Researchers and study staff.

III. Who might get this information?

- The sponsor of this research. "Sponsor" means any persons or companies that are:
  - working for or with the sponsor; or
  - owned by the sponsor.

- 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 record;

IV. Your information <u>may</u> be given to:

- The U.S. Food and Drug Administration (FDA), Department of Health and Human Services (DHHS) agencies, and other federal and state entities;
- Governmental agencies in other countries;
- Governmental agencies to whom certain diseases (reportable diseases) must be reported; and
- The Ohio State University units involved in managing and approving the research study including the Office of Research and the Office of Responsible Research Practices.

V. Why will this information be used and/or given to others?

- To do the research;
- To study the results; and
- To make sure that the research was done right.

VI. When will my permission end?

There is no date at which your permission ends. Your information will be used indefinitely. 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.

VII. May I withdraw or revoke (cancel) my permission?

Yes. Your authorization will be good for the time period indicated above unless you change your mind and revoke it in writing. You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the researchers. If you withdraw your permission, you will not be able to stay in this study. When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

VIII. What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study and receive research-related treatment. However, if you are being treated as a patient here, you will still be able to receive care.

IX. Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission. Any information that is shared may no longer be protected by federal privacy rules.

X. May I review or copy my information?

Signing this authorization also means that you may not be able to see or copy your study-related information until the study is completed.

15. Who can answer my questions about the study?

For questions, concerns, or complaints about the study, or if you feel you have been harmed as a result of study participation, you may contact Dr. John Nusstein or Dr. Brian Crump at 614-292-5399.

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

For questions related to your privacy rights under HIPAA or related to this research authorization, please contact Dr. Henry Fischbach at the Ohio State College of Dentistry; 305 W. 12th Ave, 1130-B Postle Hall Columbus, OH 43210. Phone: 614-292-3265.

If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. John Nusstein or Dr. Brian Crump at 614-292-5399.

Signing the consent form

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

I am not giving up any legal rights by signing this form. I will be given a copy of this combined consent and HIPAA research authorization 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)
Relationship to the subject	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.

Printed name of person obtaining consent	Signature of person obtaining consent
	AM/PM Date and time

Witness(es) - *May be left blank if not required by the IRB*

Printed name of witness	Signature of witness
	AM/PM Date and time
Printed name of witness	Signature of witness
	AM/PM Date and time

Appendix E: Corah Dental Anxiety Scale Form

CORAH'S DENTAL ANXIETY SCALE

Code_____

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 F: Periodontal Probing Forms

Periodontal Probing—Pre-Study

Code:_____
Subject:_____
Date: _____

Tooth #_____

Mesiopalatal:_____

Mid-Palatal: _____

Distopalatal: _____

Periodontal Probing—Post Study

Code:_____
Subject:_____
Date: _____

Tooth #_____

Mesiopalatal:_____

Mid-Palatal: _____

Distopalatal: _____

Appendix G: 170 mm Heft-Parker VAS Pain Forms

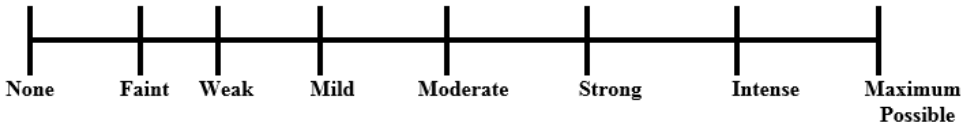
Intraligamentary Pain Rating

Code:_____
Subject:_____
Date: _____ Side: _____

Palatal Injection Test Tooth Rating

Placement

Mark an "x" on the point on the line that best describes your pain.



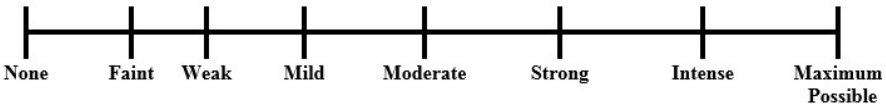
Intraligamentary Pain Rating

Code:_____
Subject:_____
Date: _____ Side: _____

Palatal Injection Test Tooth Rating

Deposition

Mark an "x" on the point on the line that best describes your pain.



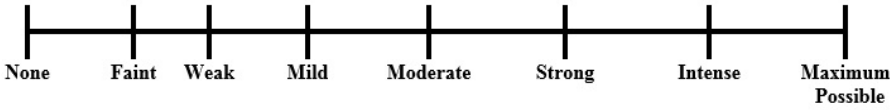
Palatal Infiltration Pain Rating

Code:_____
Subject:_____
Date: _____ Side: _____

Palatal Injection Test Tooth Rating

Placement

Mark an "x" on the point on the line that best describes your pain.



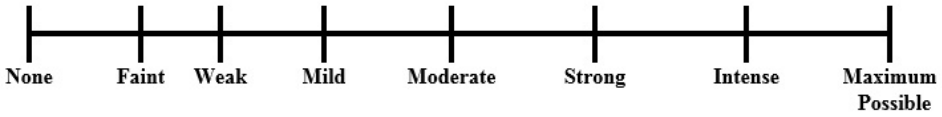
Palatal Infiltration Pain Rating

Code:_____
Subject:_____
Date: _____ Side: _____

Palatal Injection Test Tooth Rating

Deposition

Mark an "x" on the point on the line that best describes your pain.



Appendix H: Soft Tissue Anesthesia Measurement

Soft Tissue Anesthesia Measurements (mm)

Code:_____
Subject:_____ Visit ____1 _____2
Date: _____

Tooth #_____

1 Minute

Mesial	Distal	Superior	Inferior

5 Minute

Mesial	Distal	Superior	Inferior

10 Minute

Mesial	Distal	Superior	Inferior

15 Minute

Mesial	Distal	Superior	Inferior

20 Minute

Mesial	Distal	Superior	Inferior

25 Minute

Mesial	Distal	Superior	Inferior

30 Minute

Mesial	Distal	Superior	Inferior

Appendix I: Follow-Up Pain Survey Form

Follow-up Care Palatal Anesthesia Study

Code:_____
Subject:_____
Date: _____

Please circle the best answer for your experience:

1.) Which appointment did you experience the most pain afterwards?

First Appointment Second Appointment Neither Appointment

(Both were same)

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