PALATAL ANESTHESIA: COMPARISON OF FOUR TECHNIQUES FOR DECREASING INJECTION DISCOMFORT

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ANDREW T. WISWALL

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Introduction

Dental procedures involving the maxillary posterior teeth frequently require local anesthesia for the palate in addition to buccal anesthesia. For many patients, palatal injections may be a painfully traumatic experience (Harbert, 1989). A traumatic experience in the dental chair can cause dental phobia that can last an average of 24 years (Öst, 1987). These phobias can lead to difficulty in patient management and in turn can be barriers to good dental care and specifically, fear of dental injections is associated with avoidance of dental care in almost one in twenty people. (Corah et al., 1985; Milgrom et al., 1997; O'Shea et al., 1984). Due to the patients' negative reactions to palatal anesthesia, many dentists attempt to avoid this injection if at all possible. The aim of this study was to identify a method to administer a less painful greater palatine injection.

Review of the Literature

The Development and Neural Anatomy of the Hard Palate

The oral cavity is lined by epithelium derived from both ectoderm and endoderm and the palatal epithelium is ectodermal in origin. The palatal shelves and the epithelium are formed and complete by eight to eleven gestational weeks (Stark, 1973).

A rich innervation allows the palatal mucosa to maintain a variety of voluntary and reflexive activities. The afferent nerves that supply the posterior hard palate arise from the second division of the trigeminal nerve, the maxillary nerve (Cohn, 1986). The sensory nerves in this region terminate in free and organized nerve endings that are found in the lamina propria and within the epithelium. The sensation of pain is understood poorly and appears to be initiated by noxious stimuli, which causes tissue damage. This damage activates the release of histamine, bradykinin and various neuropeptides such as substance P and calcitonin gene related protein (CGRP), adenosine triphosphate (ATP), 5-hydroxytryptamine (5-HT), prostaglandins and leukotrienes in the interstitial fluid that then act on free nerve endings of unmyelinated C-fibers and myelinated Aβ and Aδ fibers (Presland & Dale, 2000).

A noxious stimulus can produce an action potential in nerve fibers within the posterior hard palate. The first neurons carrying information from the palate are the primary afferent neurons whose cell bodies are located in the trigeminal ganglion. These impulses enter directly into the brain stem at the region of the pons and synapse with the

second order neurons in the trigeminal spinal tract nucleus. The trigeminal spinal tract nucleus is divided into three regions: the subnucleus oralis, the subnucleus interpolaris and the subnucleus caudalis. It is presumed that the subnucleus caudalis predominates in trigeminal nociception (Maixner et al., 1989; Sessle et al., 1986). The excitatory neurotransmitters in the subnucleus caudalis are substance P and glutamate, while inhibitory neurotransmitters such as GABA can also be released. Continuing across to the contralateral side of the brain stem in the anertolateral spinothlamic tract, the impulse ascends through the reticular formation to the thalamus where a synapse occurs with the third-order neuron (Hill, 2000). Finally the impulse ascends to the cortex for interpretation and evaluation and is perceived here as pain (Okeson & Bell, 1995).

Pain Theory

As discussed previously, pain is a very complex summation of variables that is still not fully understood. In 1664, Descartes proposed the first theory of pain, named the specificity theory, in which pain was a specific sensation, with its own sensory apparatus, independent of touch and other senses (Descartes, 1649). Throughout the course of pain history this theory has been disproved with advances in science and experimentation. Since Descartes' original work, many theories of pain have emerged and include the pattern theory, intensive (summation) theory, central summation theory, sensory interaction theory and finally the gate control theory (Okeson & Bell, 1995).

Melzak and Wall first published the gate control theory in 1965. The original theory stated that action potentials from the periphery are transmitted to three spinal cord

systems: the cells of the substantia gelatinosa in the dorsal horn, the dorsal-column fibers that project towards the brain, and the first central transmission (T) cells in the dorsal horn.

Figure 1: Gate Control Theory 1965

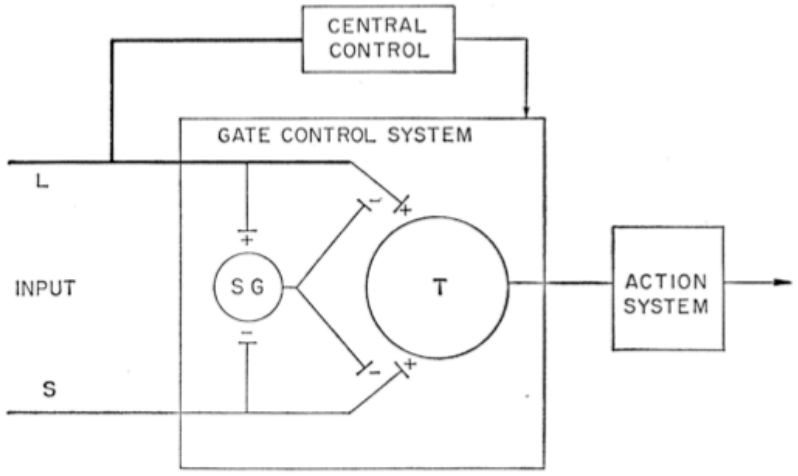


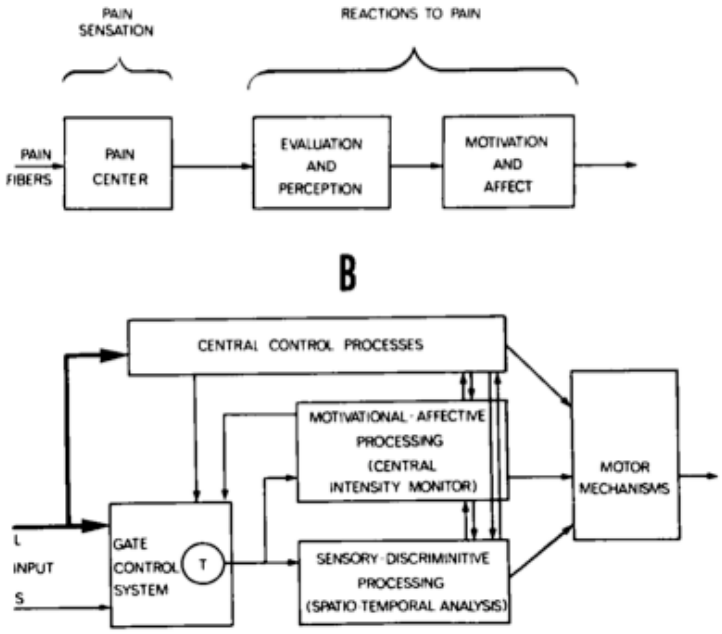
Fig. 4. Schematic diagram of the gate control theory of pain mechanisms: *L*, the large-diameter fibers; *S*, the small-diameter fibers. The fibers project to the substantia gelatinosa (*SG*) and first central transmission (*T*) cells. The inhibitory effect exerted by *SG* on the afferent fiber terminals is increased by activity in *L* fibers and decreased by activity in *S* fibers. The central control trigger is represented by a line running from the large-fiber system to the central control mechanisms; these mechanisms, in turn, project back to the gate control system. The T cells project to the entry cells of the action system. +, Excitation; −, inhibition (see text).

Melzak and Wall, 1965

The substantia gelatinosa functions as a gate control system that modulates the afferent patterns before they influence the T Cells. The afferent patterns in the dorsal column system act, in part, as a central control trigger which activates selective brain processes that influence the modulating properties of the gate control system, and the T cells activate neural mechanisms which comprise the action system responsible for the response and perception (Melzack & Wall, 1965).

In 1970, Mezack and Wall revised the gate control theory due to the laminar organization of the dorsal horn being better understood, indicating a convergence of visceral afferent impulses into the T cells. The stimulation of the brain activates descending efferent fibers, which can influence afferent conduction at the earliest synaptic levels of the somethetic system. Physiologic and behavioral studies emphasized the motivational, affective and cognitive aspects of the pain experience evidenced by the interaction of the neospinothalamic and paleospinothalamic projecting systems and the neocortical processes. The neospinothalamic projecting system in the brain serves to process sensory discriminative information about the location, intensity, and duration of the stimulus. Impulses passing through the paleospinothalamic tract and paramedical ascending system activate reticular and limbic structures that provoke the powerful motivational and aversive drive and unpleasant effect that triggers the organism into action. Finally, the neocortical higher central nervous system processes the input in terms of past experience, which exerts control over both discriminative and motivational systems (Melzack & Wall, 1970).

Figure 2: Gate Control Theory 1970



Mezack and Wall, 1970

Melzack and Wall revised the gate control theory to its current form from examination of 138 patients who presented with acute pain to the emergency clinic. Of the 138 patients, 51 (37%) indicated that they did not feel pain at the time of injury, most reported pain within an hour of the injury, however some delays were as long as 9 hours or more (Melzack et al., 1982). This further study led to Melzack and Wall's revision of the gate control theory to its current form. The new model accounts for excitatory and inhibitory links from the substantia gelatinosa to the transmission of T cells and includes the descending inhibitory control from the brainstem (Melzack, 2005).

Quantification of Pain

Pain is an unpleasant feeling that is conveyed to the brain by sensory neurons. The discomfort signals actual or potential injury to the body. However, pain is more than a sensation, or the physical awareness of pain; it also includes perception, the subjective interpretation of the discomfort. Perception gives information on the pain's location, intensity, and something about its nature. The various conscious and unconscious responses to both sensation and perception, including the emotional response, add further definition to the overall concept of pain. Traditional approaches to the measurement of pain include numerical and self-rating scales, behavioral observation scales, and psychological responses. The complex nature of pain suggests that measurements from these domains may not always show high concordance. However, the Heft-Parker scale (which combines features of both the categorical and VAS scales) has shown consistent assay sensitivity and correlation in clinical pain trials over the past 25 years (Coll et al., 2004; Downie et al., 1978).

The Heft-Parker VAS scale incorporates the irregular spacing of descriptive words commonly used in categorical scales on a horizontal graphic rating scale. Heft and Parker state that subjects make category judgments on the basis of word meanings and the categorical ratings are not merely an ordinal index. Their scale incorporates subjects' common understanding of six pain descriptive words that are irregularly spaced upon a 170mm line (Heft & Parker, 1984).

Gender and Pain

Pain from topical capsaicin, periodontal debridements, evoked masseter muscle stimulation, NiTi archwire adjustments, root canals and injections have all been studied in the dental literature. These studies have all included gender as a variable in an attempt to answer the question to whether or not gender plays a role in pain response.

The topical application of 5% capsaicin to the gingiva produces an unpleasant response. Fifty-four healthy volunteers rated the pain evoked by this topical application of capsacin on a VAS scale. Minor sex differences on the VAS scale were noted to the noxious stimuli, however they were not statistically significant (Baad-Hansen et al., 2005).

Guzeldemir et al. evaluated patients' dental pain perception during scaling using the VAS scale. One hundred thirteen patients (72 women and 41 men) participated in the study. In regard to pain perception, no gender differences were found (Guzeldemir et al., 2008).

Goddard et al. tested the reproducibility of VAS pain scores to measure changes in masseter muscle pain evoked by maximally tolerable mechanical stimulation over a short period of time in healthy subjects. They determined that the VAS pain scores were reproducible and that gender differences were not statistically significant (Goddard et al., 2004).

Following the adjustment of NiTi archwires in orthodontic patients, Fernandes et al. compared the pain patients experience during the initial phase of tooth movement. One hundred and twenty-eight patients rated the pain by means of the VAS scale over a

7-day period. They concluded there were no significant gender-specific differences (Fernandes et al., 1998).

Segura-Egea et al. evaluated the pain experienced by patients during root canal treatment correlated with age and gender, pulpal diagnosis, previous periapical status, dental characteristics and length of treatment. One hundred and seventy-six patients (68 men and 108 women) with ages ranging from 6 to 83 years were randomly recruited and asked to complete a VAS scale that ranked the level of pain experienced during root canal therapy. The mean levels of experienced pain did not differ by gender (Segura‐Egea et al., 2009).

In patients with irreversible pulpitis, one hundred twelve (53 men and 59 women) long buccal nerve block injections were administered and patients rated their pain on the Heft-Parker VAS scale. Results from the mean VAS ratings showed no statistical difference between the pain for males or females with respect to needle insertion pain (Drum et al., 2011). Rosa et al. evaluated twenty subjects (10 men and 10 women) VAS ratings of palatal injections with a 27-gauge needle following a 5% lidocaine or 20% benzocaine topical application. The results showed no significant difference related to gender (Rosa et al., 1999).

Interestingly, the gender of the person administering the experiment does have a significant influence on the pain perceptions of males and females. Levine and De Simone evaluated VNRS (verbal numeric rating scale) results from 35 male and 33 female subjects testing to cold pain and reported that males reported significantly lower pain to a member of the opposite sex than to another male. Females tended to report

higher pain to opposite sex experimenters, however this was not statistically significant (Levine & De Simone, 1991).

Needles Gauge

Many dentists prefer to use smaller gauge needles (30-guage) for local anesthetic injection, believing that these needles with a smaller diameter result in less injection pain than wider diameter needles. Malamed does not recommend the 30-gauge needle for any injection (Malamed, 2004).

In 1972, Hamburg demonstrated that patients could not differentiate among 23-, 25-, 27-, and 30-gauge needles (Hamburg, 1972). Since the publication by Hamburg, Fuller and Flanagan have completed similar studies that agreed, indicating no correlation between needle size and the patients perceived pain response (Flanagan et al., 2007; Fuller et al., 1979)

Injection Pain Reduction Strategies

Topical Anesthetic

The role of topical anesthetics is to relieve pain and abolish reflex activity arising in epithelial tissues covering the body and lining the hollow viscera. Local anesthetics pass into the subcutaneous or submucosal tissues and into the underlying plexuses of venules and lymphatics acting on the source where discomfort usually arises. Topical anesthetics do not reach the pain receptors beneath the epithelium and function to relieve

the pain that arises from the skin or mucous membranes. Skin functions as a barrier that protects the environment but the role of the mucosa is to act as a protective lining, as well as to secrete and absorb. This absorption is accomplished by finger-like projections on mucosal cells intertwining with the similar projections on adjacent cells, thus forming a large surface that function in the absorption process, hence allowing the topical anesthetic to be readily absorbed (Adriani et al., 1985)

Topical benzocaine is an ester derivative of para-aminobenzoic acid (PABA) with the base (vehicle) of polyethylene glycol. Benzocaine does not exist in cationic form and thus is termed a Class C anesthetic that acts by a receptor-independent physico-chemical mechanism (Yaacob et al., 1981). This mechanism involves the PABA molecules diffusing to hydrophobic regions of excitable membranes, producing a general disturbance of the bulk membrane structure, expanding some critical regions of the membrane, and preventing an increase in the permeability to sodium ions by decreasing the diameter of the sodium channels (Lee, 1976). The lack of sodium movement inhibits the nerve from being depolarized causing a conduction block (Hodgkin, 1954).

Several studies have investigated the efficacy of topical anesthetics in eliminating the discomfort of needle penetration in palatal tissue. The following studies found a reduction in discomfort following application of topical anesthetics to needle penetration. Yaacob et al. evaluated a 30 second application of 5% lignocaine compared with a placebo on the discomfort of a 27 gauge needle penetration palatal to the second molar tooth in volunteers. Results from this study indicated a significant reduction in discomfort with the active agent (Yaacob et al., 1981). Vongsavan and Vonsavan reported that a 2

minute application of 20% benzocaine was more effective than placebo treatment in reducing the discomfort of palatal injections in 14 human volunteers (Vongsavan & Vongsavan, 1996). Holst and Evers examined the effects of 2 minute and 5 minute applications of 5% lignocaine and EMLA (2.5% Lidocaine/ 2.5% Prilocaine) on the palatal mucosa opposite the upper canine in 10 healthy female volunteers. They found that there was less discomfort on needle penetration with a 30 gauge needle after a 5 min application of both topical anesthetics (Holst & Evers, 1985). Meechan and Winter compared the efficacy of placebo, transcutaneous electronic nerve stimulation (TENS) and a 5 minute application of EMLA on the palatal mucosa. They found that EMLA was significantly more effective than either the placebo or TENS in reducing the discomfort of palatal injections in adult patients having maxillary teeth extracted (J G Meechan & Winter, 1996). Rosa et al. investigated the effectiveness of 5% lidocaine and 20% benzocaine on 27 gauge needle penetration to the palate following a 1 minute application of each anesthetic and found that the 20 subjects evaluated rated both benzocaine and lidocaine significantly better for reducing the pain felt on injection versus placebo (Rosa et al., 1999)

The following studies found no difference to discomfort felt on injection whether a topical anesthetic was applied or not. Gill and Orr conducted a double-blind split-mouth investigation into the effects of the topical applications of 22% benzocaine, 2% amethocaine with 18% benzocaine, 5% lignocaine or placebo placed for 30 seconds on reducing discomfort felt from penetration of a 25 gauge needle into the palatal mucosa and found no significant differences between any of the active agents and placebo (Gill &

Orr, 1979). Martin et al. examined the effects of a 3-minute 20% benzocaine application versus placebo and failed to find any significant differences in pain perceived to the injection with a 25 gauge needle (Martin et al., 1994). Hutchins et al. investigated the topical application of 20% benzocaine and placebo for 1 min in alleviating the discomfort of buccal and palatal injections in volunteers using 27 gauge needles. They showed that the topical anesthetic reduced injection discomfort on the buccal side but not palatally (Hutchins et al., 1997).

Pressure

An important component of the gate control theory is that stimulation of the larger diameter Aβ fibers can close a neural "gate" to nociceptive signals and consequently reduce the perception of pain. Pressure will stimulate the mechanoreceptors, such as Pacinian corpuscles and the primary free nerve endings in the palate (Johansson et al., 1988). It has been suggested that it is the large diameter fibers within the area directly affected by pain that, when stimulated, will prevent maximum pain sensation (Lundeberg et al., 1984). This neural gate is proposed to lie within the spinal cord/brainstem and inhibits transmission of nociceptive action potentials to higher centers in the nervous system (Wall, 1978).

The utilization of this theory may be important especially in the very sensitive oral region where more than a third of the cells in the somatosensory cortex of the brain are devoted to sensory inputs from the mouth (Nanci & Cate, 2008). It has also been

suggested that pain reduction is greatest in the orofacial region if the source of pressure is applied not only within the area directly affected by pain, but when the firmness of pressure application stimulates the underlying bone on the same side as the pain (Melzack & Wall, 1965).

Pressure applications to sites of injections have been studied in the medical literature as precursors for immunization injections. The ShotBlocker is a plastic device, shaped like a 'u', which is placed on the skin prior to immunization injections in the deltoid. Cobb and Cohen investigated this technique and found a lack of significant findings at reducing the discomfort felt with immunization injections (Cobb & Cohen, 2009). Taddio et al. evaluated injection pain reduction strategies in adults undergoing immunization. They found that liposomal lidocaine was more effective than a distraction technique, but not different from either vapocoolant spray or tactile pressure stimulation (Taddio et al., 2010).

The dental literature on pressure is limited to anecdotal reports from textbooks and case series (Hutchins et al., 1997; Malamed, 2004).

Cold

The use of cold to test the sensibility of teeth has been used in dentistry for many years. Today, the use of a refrigerant spray is the most common method employed for the cold test. The spray is 1,1,1,2 –tetrafluoroethane (TFE, HFC-134a) and has a temperature of -

18.5 ± 7.0°C when applied to a cotton tip applicator from a distance of 5mm for 3 seconds (De Morais et al., 2008).

One concern with hydrofluorocarbons is that the haloalkane refrigerant exits the storage container as a vapor and is inhaled. Hydrofluorocarbons have been extensively studied in animal and human studies to evaluate the inhalation effects on reproductive performance, maturation, pulse, blood pressure and lung function. Alexander et al. evaluated HFC-134a inhalation in rats and found no adverse effects on reproductive performance of treated animals (Alexander et al., 1996). Ellis et al. determined the metabolic fate and disposition of HFC-134a in rats and found no evidence for a specific uptake or a metabolite into any organ or tissue analyzed (Ellis et al., 1993). Emmen et al examined the effects of HFC-134a exposure on eight healthy human volunteers and at exposure levels up to 8000 ppm no adverse effects on pulse, blood pressure, electrocardiogram, or lung function were observed (Emmen et al., 2000).

The use of a refrigerant to decrease injection discomfort has been described in technique articles and in the dental literature. Harbert described a techniqe of placing a -4°C ice stick on the palatal tissue for 5 minutes prior to injection into the palatal tissues (Harbert, 1989). Duncan et al. described a technique of spraying a cotton pellet with Frigi-Dent (Dichlorodifluoromethane) and holding it on the palatal injection site for 5 seconds prior to needle penetration into the palate (Duncan et al., 1992). One dental research study has been conducted using an FDA approved refrigerant spray for the oral mucosa. Kosaraju et al. evaluated the refrigerant Pain Ease (1,1,1,3,3-pentafluoropropane/1,1,1,2-tetrafluoroethane) applied to the palatal tissue for five

seconds prior to injection with a 30-gauge short needle against 20 percent benzocaine applied for two minutes. The results indicated that the use of the refrigerant spray significantly reduced the pain experienced during administration of palatal anesthetic versus 20 percent benzocaine according to VAS measurements (Kosaraju & Vandewalle, 2009).

Hypothesis

Null Hypothesis: Concurrent stimulation with mechanical (pressure) and chemical (20% Benzocaine, TFE) means during palatal anesthesia has no effect on the patients perceived pain experience versus injection alone according to Heft-Parker VAS measurements.

Hypothesis: Concurrent stimulation with mechanical (pressure) and chemical (20% Benzocaine, TFE) means during palatal anesthesia decreases the patients perceived pain experience versus injection alone according to Heft-Parker VAS measurements.

Specific Aims

The aim of this study was to evaluate the patient's perceived pain response to the injection and anesthetic deposition for the greater palatine nerve block. Heft-Parker VAS measurements were used to compare the following techniques for the injection: 1) Control (No concurrent stimulation), 2) Pressure, 3) Pressure and Cold (TFE), 4) Pressure and Topical Anesthetic (20% Benzocaine).

Materials and Methods

Approval for this study was obtained from the University of Minnesota Institutional Review Board. After approval, volunteer subjects were recruited through an email sent to the undergraduate dental students. Inclusion and exclusion criteria were set as the following:

Inclusion Criteria:

1. Patient is American Society of Anesthesiologists (ASA) I or II.
2. Patient is 18 years or older.
3. Patient must be able to read and sign the informed consent.

Exclusion Criteria:

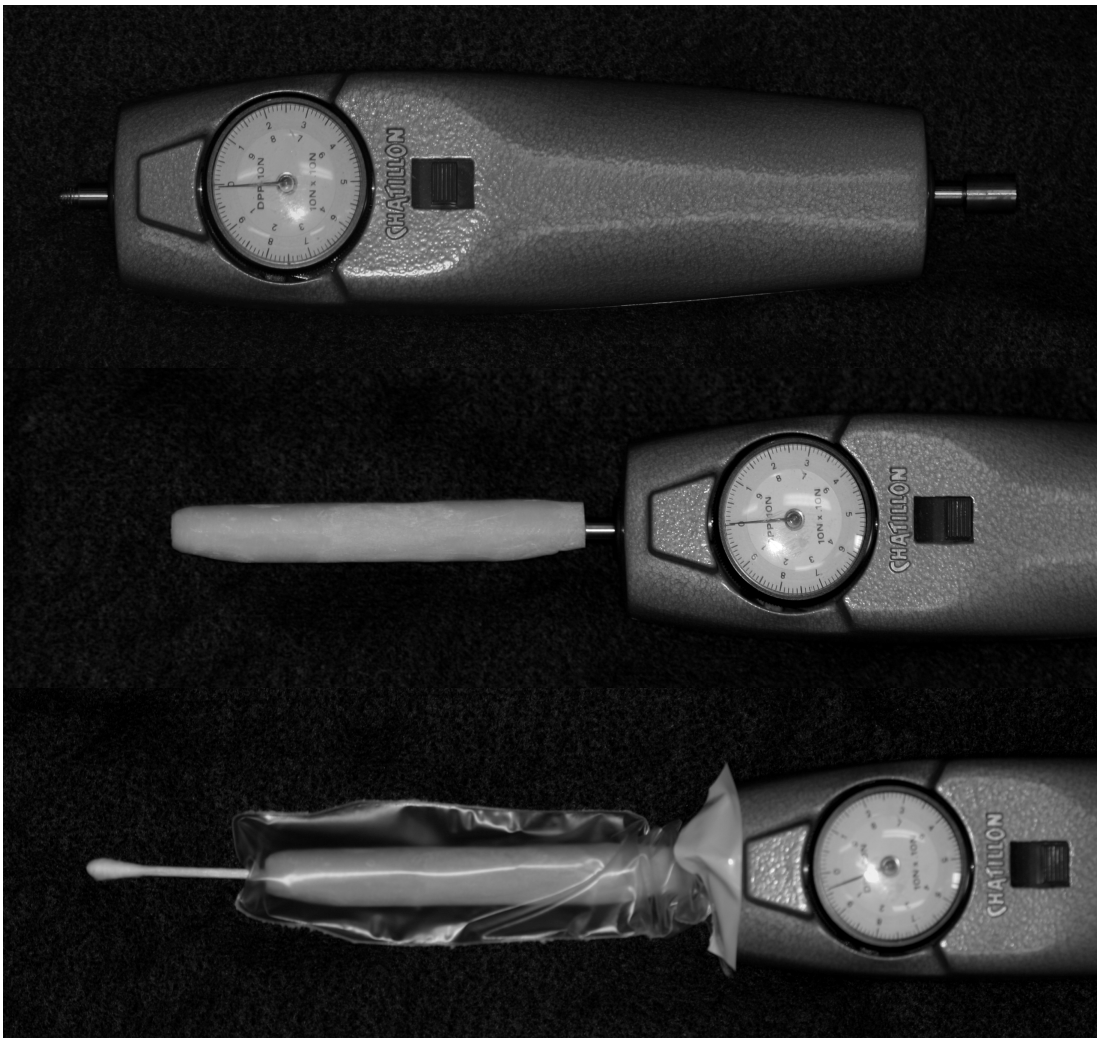
1. Patient has known allergies or intolerance to the test medication.
2. Patient is pregnant.
3. Patient is taking pain medication for an unrelated condition.
4. Patient unable or unwilling to complete the pain questionnaires.
5. Patient unwilling to sign informed consent

Research Design

Testing devices were fabricated and calibrated prior to testing. A Chatilion™ mechanical push/pull strain gauge (AMETEK® Measurement & Calibration Technologies Division; Largo, FL) was calibrated using a 100g Zieis™ (Zieis; Apple Valley, MN) calibration weight. The strain gauge measures force in Newtons and 100g = 0.9806 N. Following force calibration; a custom holder for a 6" cotton tip applicator (Crosstex®; Hauppauge, NY) was fabricated using Trim® (Bosworth Company; Skokie,

IL) to allow the cotton tip applicator to be used with the strain gauge.

Figure 3 Modified Chatilion™ Strain Gauge



To determine the Newton pressure applied to the palate, six volunteer subjects were chosen (3 male, 3 female). The volunteers were instructed to raise their right arm when the discomfort felt on the palate elevated past the descriptor of minimal pain (greater than 54mm) shown with a Heft-Parker VAS scale. The cotton tip applicator was applied to the posterior palate adjacent to the maxillary second molar, in the soft tissue depression associated with the greater palatine foramen. Pressure was increased until the

subjects indicated, by raising their right hand that the pain had past the threshold for minimal pain. The average of the six results was used to determine the Newton pressure applied during the experiment (Table 1).

Table 1. Palatal Pressure

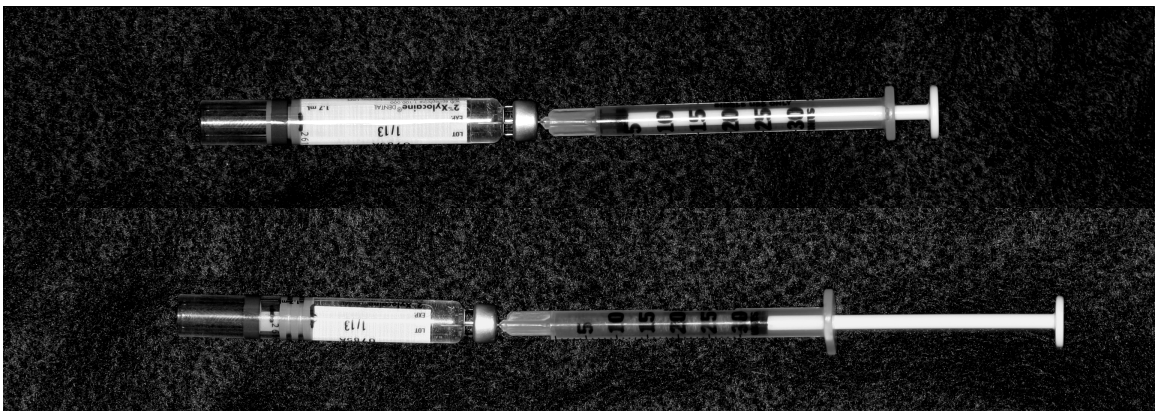
Sex	Pressure (N)
M	6
M	2
M	3
F	4
F	2
F	1
Average	**3.00**

The volume of local anesthetic to be delivered was calibrated using the average of 5 samples. A 3/10ml insulin syringe (Tyco Healthcare; Mansfield, MA) was used for calibration. The needle of the insulin syringe was inserted through the diaphragm of a 1.7ml 2% Xylocaine HCL cartridge with 1:100,000 epinephrine (Dentsply® Pharmacuetical; York, PA). A line was drawn on the outer surface of the anesthetic cartridge in conjunction with the stopper prior to drawing the solution into the insulin syringe. Following the uptake of local anesthetic into the insulin syringe another line was drawn in conjunction with the stopper, indicating the amount of movement the stopper completed. The lines were measured using a digital caliper (S-T Industries; St James, MN) accurate to 0.01mm and the results were recorded. Following the completion of 5 trials, the average was calculated (Table 2).

Table 2. Stopper movement for 0.3 ml of anesthetic solution

Trial	Distance (mm)
1	8.65
2	8.40
3	8.57
4	8.70
5	8.49
Average	**8.56**

Figure 4 Anesthetic Volume Calibration



Prior to testing, patients meeting criteria and willing and able to participate in the study signed a consent for study participation (Appendix 1) and their HIPPA rights (Appendix 2).

A bilateral model was used on each patient at two separate appointments separated by at least 2 weeks. A randomization table was used to randomize left and right injection order (Appendix 3). The 4 techniques for greater palatine anesthesia used for assessment included:

1) Control (Injection and Deposition)

2) Pressure with cotton tip applicator for 10 seconds prior to injection and continued throughout duration of anesthetic deposition.

3) Pressure with cotton tip applicator (10 seconds prior to injection and continued throughout duration of anesthetic deposition) impregnated with 20% benzocaine (HandiCane®, Sultan Healthcare Inc; Englewood, NJ)

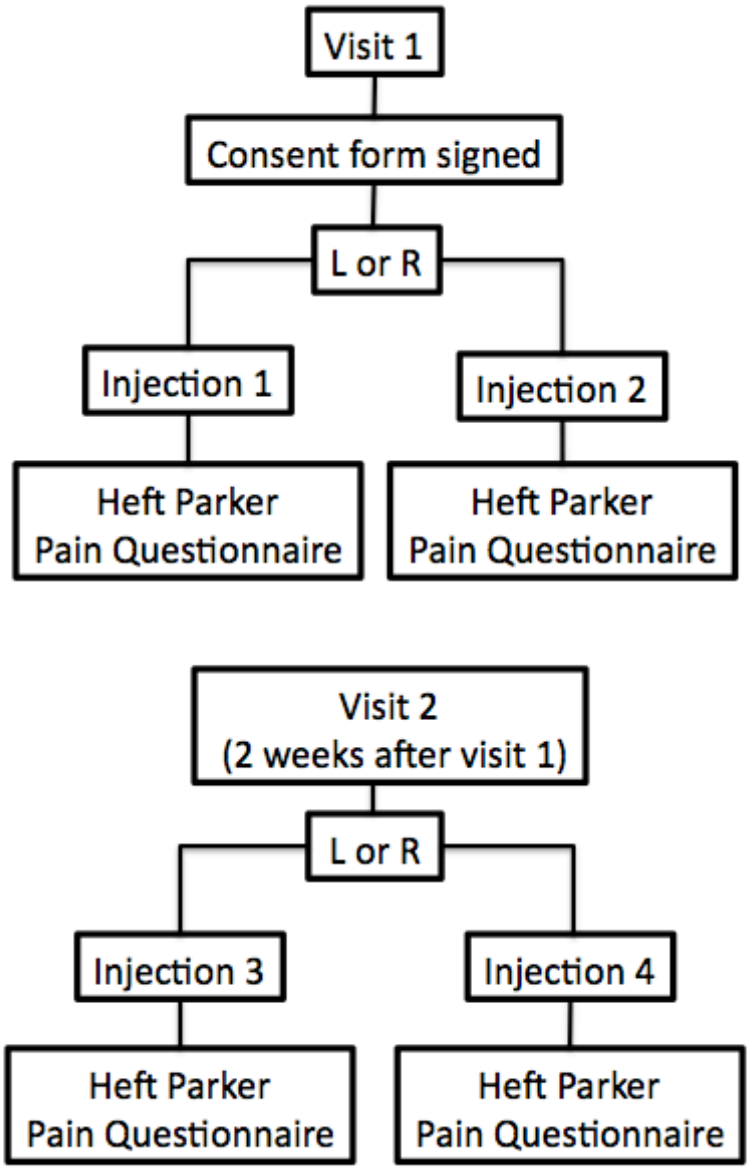
4) Pressure with cotton tip applicator (10 seconds prior to injection and continued throughout duration of deposition) impregnated with a 3 second sprayed application of Endo-Ice® (Coltene Whaledent®; Cuyahoga Falls, OH).

The order of each injection was randomized by a true randomization technique via drawing 4 colored uniform disks from a bag prior to injection, each color indicating the specific technique. The representative disk was removed following completion of each technique. A constant force of 3 N was applied to the greater palatine foramen (indicated by the soft tissue depression lingual to maxillary second molar indicating the greater palatine foramen) and measured using the modified Chatilion™ mechanical push/pull strain gauge attached to the cotton tip applicator. The 0.3ml of anesthetic (2% Xylocaine with 1:100,000 epi) was deposited with a 27-gauge long anesthetic needle (Patterson Dental; St. Paul, MN) inserted approximately 1 to 2 mm. The volume of 0.3ml was standardized by using the digital caliper to demarcate (line drawn on cartridge) 8.56mm, the distance the stopper needed to move in order to deposit this volume of solution. The anesthetic was injected at a rate of 0.3ml/10 seconds verified by the operator in accordance with a digital stopwatch.

Before the injections, patients were verbally instructed to rate the pain experienced during each phase of the greater palatine injection that was separated by verbal cues of “number 1” and “number 2” and correlated with the following: 1) Initial

needle insertion into the alveolar mucosa and 2) deposition of the anesthetic solution at the target site. Following injection given in the supine position, the patients were returned to an upright position and rated their pain on a 170-mm Heft-Parker visual analog scale (Appendix 4). The VAS was divided into 4 categories: no pain corresponds to 0mm; mild pain is defined as greater than 0mm and less than or equal to 54mm and included descriptors of faint, weak and mild pain; moderate pain is defined as greater than 54mm and less than 114mm and includes descriptors of moderate; severe pain was defined as equal to or greater than 114mm and includes descriptors of strong, intense, and maximum possible. The patients were instructed to make a vertical line indicating the pain experienced during the 2 phases denoted by the two separate Heft-Parker VAS scales. Following each trial the color (injection type), order (1^{st}, 2^{nd}, 3^{rd}, or 4^{th}) and the side (R or L) were written on the back of the paper for verification following testing and calculation. A supplemental pain questionnaire was given following injection with Endo-Ice (Appendix 5) to record any pain or tissue damage following this injection type. Following completion of data collection the lines indicated on the Heft-Parker VAS scale were measured using a digital caliper (S-T Industries; St James, MN) accurate to 0.01mm and the results were recorded.

Figure 5 Study Design Flow Diagrams



Statistical Analysis

Following conclusion of the clinical trial, all collected data were tabulated upon a spreadsheet (Appendix 6) and submitted for statistical analysis in conjunction with a key for the technique codes (Appendix 7) used during the randomization process labeled on the spreadsheet.

Descriptive statistics (means and standard deviations) were calculated for the Heft-Parker VAS scores at each time point for the three techniques and the control. Generalized estimating equations (GEE models), a method to analyze correlated data, were used to compare the means of the Heft-Parker VAS scores between the 3 techniques and the control. Technique, visit, procedure order, side, and a visit by order interaction were included in the models as independent variables. An unstructured correlation structure was used to model potential within-in subject correlation. P-values less than 0.05 were deemed statistically significant. SAS V9.1.3 (SAS Institute, Cary, NC) was used for the analysis.

Results

A total of forty two patients were enrolled in this investigation of which twenty one were male and twenty one were female.

The effectiveness of the true randomization technique that was employed in this study was evaluated first. Table 3a summarizes the technique allocation by side (right or

left) and Table 3b summarizes the technique allocation by order (first or second). Ideally, the percent allocation would have been as close to 25% as possible.

Table 3a. Count and Percent of Technique Allocation (by side)

	Visit 1		Visit 2	
	Left	**Right**	**Left**	**Right**
Control [R]	14 (33)	7 (17)	7 (17)	14 (33)
Press [G]	12 (29)	9 (21)	12 (29)	9 (21)
Press + Topical [B]	6 (14)	10 (24)	15 (36)	11 (26)
Press + Endo Ice [W]	10 (24)	16 (38)	8 (19)	8 (19)

Table 3b. Count and Percent of Technique Allocation (by order)

	Visit 1		Visit 2	
	First	**Second**	**First**	**Second**
Control [R]	10 (24)	11 (26)	5 (12)	16 (38)
Press [G]	12 (29)	9 (21)	9 (21)	12 (29)
Press + Topical [B]	12 (29)	4 (10)	18 (43)	8 (19)
Press + Endo Ice [W]	8 (19)	18 (43)	10 (24)	6 (14)
Left	20 (48)	22 (52)	19 (45)	23 (55)
Right	22 (52)	20 (48)	23 (55)	19 (45)

The statistical analysis focused on the effects attributable to individual treatment groups, specifically the Heft-Parker VAS measurements from the three injection techniques and the control (Table 4). The results indicate that the pain on needle insertion was less than that of deposition of anesthetic. Gender was not found to be statistically significant for all four techniques. Figure 5 depicts the raw mean Heft-Parker VAS measurements during the injection (Time 1) and anesthetic deposition (Time 2).

Table 4. Mean (SD) of Each Technique (n=42)

	VAS at Time 1	VAS at Time 2
Control [R]	50.0 (26.9)	70.7 (30.0)
Press [G]	46.8 (25.1)	77.7 (31.1)
Press + Topical [B]	44.2 (30.6)	79.9 (28.3)
Press + Endo Ice [W]	42.3 (28.0)	71.1 (28.6)

Figure 6

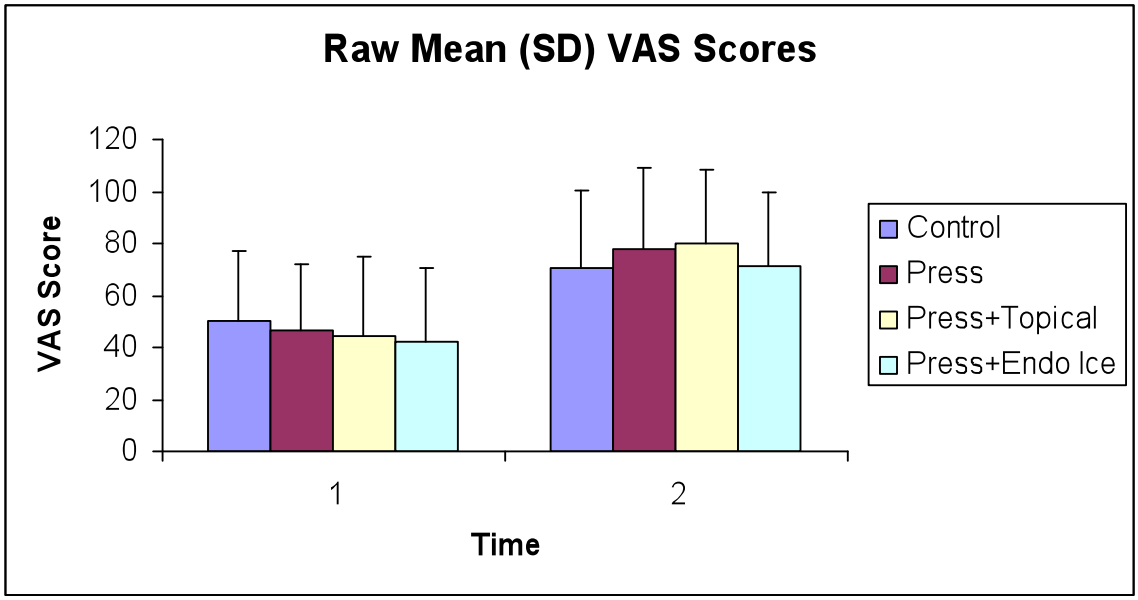


Table 5. P-values at time point 1 and 2

	P-value†	P-value‡
Technique (R, G, B, W)	0.8717	0.5164
Visit (1 or 2)	0.7559	0.7966
Order (1 or 2)	0.2585	0.0189*
Side (L or R)	0.5812	0.6733
Visit by Order interaction	0.0332*	0.0116*

† Analysis of VAS scores at time point 1. Gender was not significant when added to the model (p=0.6611).
‡ Analysis of VAS scores at time point 2. Gender was not significant when added to the model (p=0.7312).
* $p<0.05$

There was no statistically significant difference in perceived pain response between the 4 techniques, the visit, the order, the side or gender at both time points

(Table 5). However, there were significant visit by order interactions at each time point. For time point 1, the estimated VAS score mean was higher for the first procedure (mean=50.7, SE=4.1) compared to the second procedure (mean=39.8, SE=3.6) at visit 1 ($p < 0.05$). At visit 2, the estimated VAS score means were lower for the first procedure (mean=44.5, SE=4.0) compared to the second procedure (mean=48.3, SE=5.0) ($p < 0.05$).

For time point 2, the estimated VAS score mean was higher for the first procedure (mean=81.3, SE=4.3) compared to the second procedure (mean=67.3, SE=4.0) at visit 1. At visit 2, the estimated VAS scores were lower for the first procedure (mean=75.1, SE=4.7) compared to the second procedure (mean=75.7, SE=4.8).

Secondary Findings

Following the application of Endo Ice, volunteers received a post-injection survey (Appendix 5). It was recognized that assessment of clinical efficacy is only one aspect of injection pain reduction strategies and one must also evaluate the incidence of adverse effects. The results (Table 6) indicated that 81% of the volunteers reported a sore on their palate from 2 to 48 hours post cold application that lasted from 1 to 10 days and had a mean VAS rating of 51.4. There were no reported incidences of adverse effects from the remaining three treatment strategies.

Table 6. Summary of Post-Injection Survey Data

	N=42
Sore, n (%)	
Yes	34 (81)
No	8 (19)
First noted in hours	
Mean (SD)	19.6 (14.6)
Median	18.0
Min, Max	2.0, 48.0
Duration in days	
Mean (SD)	3.7 (1.7)
Median	4.0
Min, Max	1.0, 10.0
VAS, Mean (SD)	51.4 (33.9)

Discussion

This study examined techniques to reduce the discomfort of posterior palatal injections with materials that are generally available in a majority of dental offices and methods that are clinically relevant. Upon examination of forty two volunteers, the null hypothesis was accepted. The use of three pain reduction techniques was not effective in reducing the pain experienced by participants on needle penetration or deposition of anesthetic compared to the controls.

The constant in the three techniques used was pressure that was standardized in Newtons with a strain gauge. Pressure has been shown to reduce injection pain during immunizations in adults, while in children, it was shown to not be significant (Cobb & Cohen, 2009; Taddio et al., 2010). Dental injections involving pressure is limited to case series and anecdotal reports (Hutchins et al., 1997; Malamed, 2004). The use of vibration within the anesthetic syringe to reduce injection pain is currently being studied (Saijo et

al., 2005). In accordance with this study, the gate control theory explains why the pressure does not reduce injection pain.

When gentle pressure is applied to the mucosa of the palate, production of a disproportionate relative increase in large-fiber activity over small-fiber activity occurs and shortens the barrage generated by the T cells, thus a neural gate is partially closed resulting in less pain. If the pressure increases, more receptor-fiber units are recruited and the firing frequency of active units increases. The resultant negative effects of the large-fibers counteract the positive effects of the small-fiber inputs. The output of T cells rise producing more nerve impulses perceived as pain (Melzack & Wall, 1965). A pressure of 3 Newtons applied to the palate may have cancelled the neural gate closure and thus did not decrease the pain associated with subsequent firing of Aβ and Aδ fibers when the anesthetic needle pierces the tissue (Melzack, 2005).

In an attempt to evaluate clinically relevant pain reduction strategies, a ten second application of topical benzocaine was used. The use of topical anesthetic in dentistry has mixed reviews. When comparing applications of topical 20% benzocaine in the vestibule for three minutes, Rosavick et al. demonstrated a significant reduction in pain (Rosivack et al., 1990). However, others have shown that an application of 20% benzocaine for a duration of 3 minutes to 20 minutes had no significant reduction in the pain perceived (Fukayama et al., 2002; Kincheloe et al., 1991; Martin et al., 1994). When examining the palatal application of topical benzocaine and pain reduction, a 1 minute to 10 minute application has been demonstrated to significantly reduce pain (Bhalla et al., 2009; Holst & Evers, 1985; Rosa et al., 1999). On the other side to that argument, Gill & Orr showed

no reduction to pain after topical application to the palate (Gill & Orr, 1979). The 10 second duration of benzocaine topical anesthetic application in this study is less than the application times demonstrated in other studies. The time that it takes for the PABA molecule to diffuse to hydrophobic regions of the excitable membranes and cause expansion inhibiting the sodium ion permeability is not known. It appears that a 10 second application does not allow the PABA molecule to reach the critical regions of the membrane and may account for the lack of reduction in VAS scores when compared to the above-mentioned studies.

The application of cold prior to injections has been shown to reduce the VAS measurements of injection pain (Armstrong et al., 1990; Cohen et al., 1997; Kosaraju & Vandewalle, 2009). The mean VAS measurements for time period 1 were the least with the application of pressure and cold, though not statistically significant. The off-label use of Endo Ice (1,1,1,2-tetrafluoroethane) on the oral mucosa caused ulceration in 81% of the participants. Initially, a painful vesicle formed at the application site that quickly ruptured leaving a cratered ulceration on the palate that lasted from one to ten days.

The temperature of 1,1,1,2-tetrafluoroethane applied to a cotton tip applicator from a distance of 5mm for 3 seconds is 18.5 ± 7.0°C (De Morais et al., 2008). On application of the cryogen, the initial event is extracellular ice formation. This commences at -10°C to -15°C. The transformation of water into ice leads to loss of water from the extracellular compartment. This concentrates solutes and sets up an osmotic gradient across the cellular membrane. The movement of water across membranes is exacerbated by mechanical compression from extracellular ice crystals that damages the

cell membrane. The movement of water out of the cell leads to an intracellular concentration of solutes and the damage is reversible (Arikan & Gürkan, 2007). The cold temperature also leads to vasoconstriction and endothelial cell damage. Following application of -15°C to oral tissues, inflammation develops over the next 24 hours and there is separation at the dermo-epidermal junction resulting in blister formation (Thai & Sinclair, 1999). For this reason, the use of Endo Ice with pressure of 3 N should not be used as a pain reduction strategy for palatal injections, even though the VAS pain (Mean=51.4) measurements were considered mild to moderate.

The Heft-Parker VAS measurements were similar between male and female patients at most time points, however the male patients showed a higher threshold for needle injection at the first visit. Tófoli et al. also found male patients had a higher pain threshold for needle injection, and additionally showed that phases of the menstrual cycle and the use of oral contraceptives did not affect injection discomfort between female subjects (Tófoli et al., 2007). Although our subjects were of similar ages, it has been shown that older patients are less responsive to similar levels of pain. Looking at the ages of females, Carr et al. found that elderly female subjects tended to rate pain in the oral mucosa by needle-sticks with and without anesthetic injection less painful than younger female subjects, though no significant differences between injection and anesthetic deliver pain were found (Carr et al., 2002)

The limitations of this study include the inability to control confounding variables such as the needle penetration depth or the rate of injection. The results indicate that

posterior palatal injections produce discomfort and the ability to decrease pain may not be achievable.

Conclusion

In conclusion, this prospective, single blind study evaluating three injection techniques to reduce posterior palatal injection pain showed no significant reduction in pain compared to the control. Furthermore, 1,1,1,2-tetrafluoroethane placed with pressure should not be applied to the oral mucosa to prevent a painful ulceration.

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APPENDIX 1

Consent Form

CONSENT FORM
Palatal Anesthesia: Comparison of Four Techniques for Decreasing Injection Discomfort
Consent Form

You are invited to participate in a research study of injection discomfort of palatal (area located in the mouth where the top of your tongue touches the roof of your mouth) anesthetic given by 4 different techniques. You were selected as a possible participant because of your interest in volunteering based on your email response from our posted flyer. The study will take place in the Endodontic Clinic at the University of Minnesota School of Dentistry. We ask that you read this form and ask any questions you may have before agreeing to be in the study.

This study is being conducted by Dr. Andrew Wiswall DDS, University of Minnesota Department of Endodontics. It is funded by the Department of Endodontics Research Fund

Study Purpose

The purpose of the study is to assess the level of discomfort of palatal injections by using 4 techniques to attempt to diminish the discomfort felt. Injections into the palate are a routine part of dental procedures that involve the upper jaw. Scientifically evaluating which method will provide the least discomfort for patients receiving palatal injections is the aim of this study.

Study Procedures

If you agree to participate in this study, we would ask you to do the following: The procedure involved will be to have four injections with each of the 4 different techniques: 1. Pressure with a cotton tip applicator on the palate and subsequent injection of anesthetic; 2. Pressure with a cotton tip applicator infused with 20% benzocaine (topical anesthetic) on the palate and subsequent injection of anesthetic; 3. Pressure with a cotton tip applicator infused with a refrigerant (Endo-Ice) that will make your palate cold and subsequent injection of anesthetic; 4. Injection of the palate without any manipulation of the palate prior to injection. The pressure that will be applied to the wooden tip applicator will be monitored by a digital force transducer, which is a device that allows the exact pressure to be recorded in Newtons (a measurement of pressure applied to your palate) You will only receive 2 injections each session, one on the left side of the palate and one on your right side of your palate. The injection order will be based on a randomized selection process. All 4 injections will be written on separate cards and prior to each injection a card will be drawn to designate which injection is to be given. After your first session we will wait at least 2 weeks and then test the remaining 2 techniques that were not used in the first session, again this will be randomly selected by a drawing. After the two testing sessions you will have received all 4 techniques listed above given to the palate (at 2 sessions) and to rate the discomfort perceived by marking a line with a pen on a pain scale for pain felt on needle insertion as well as when the anesthetic is given. The 2 sessions will be spaced out at least two weeks apart and each test should take approximately 5 minutes.

Risks of Study Participation

By participating in this study the risks are no greater than those associated with routine dental anesthesia. The risk of trauma to the palate following the injection is a risk that needs to be considered. Caution should be exercised in eating and drinking following the procedure to prevent injury to the numbed area.
The following are potential side effects to the following injection techniques:

- Topical Anesthetic (20% Benzocaine) – can cause irritation, pain and redness at the site of placement.
- Endo Ice (Refrigerant Spray) – can cause irritation, pain and redness at the site of placement.
- The palate may be sore for a short duration once the numbness goes away.

The following severe side effects are extremely rare and occur in less than 0.1% of the patients injected.

- Lidocaine (1:100,000 epinephrine) injection – can cause serious reactions including seizures, respiratory arrest, arrhythmias, status asmaticus, heart block, coma, injection site pain, lightheadedness, tremor, confusion, hypotension, blurred vision, tinnitus (ringing in the ears), anxiety, dizziness, drowsiness, lethargy, nausea, vomiting, agitation and hallucinations.

Benefits of Study Participation

There will be no direct benefit to you for any of the four injection techniques, however the data collected will benefit others by decreasing injection pain to the palate for future dental patients.

Alternatives to Study Participation

The alternative to study participation is to not participate.

Study Compensation

A $10.00 gift card to ITunes will compensate participation in this study if the study is completed in full. If after participating in the first test the subject wishes to withdraw, a $5.00 gift card to ITunes will be given

Research Related Injury

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner to you or your insurance company. If you think that you have suffered a research related injury, let the study physicians know right away.

Confidentiality

The records of this study will be kept private. In any publications or presentations, we will not include any information that will make it possible to identify you as a subject. Your record for the study may, however, be reviewed by the University of Minnesota Institutional Review Board, which oversees research involving human subjects. To these extents, confidentiality is not absolute.

Protected Health Information (PHI)

Your PHI created or received for the purposes of this study is protected under the federal regulation known as HIPAA. Refer to the attached HIPAA authorization for details concerning the use of this information.

Voluntary Nature of the Study

Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future relations with the University or the School of Dentistry. If you decide to participate, you are free to withdraw at any time without affecting those relationships.

Contacts and Questions

The researcher conducting this study is Dr. Andrew Wiswall. You may ask any questions you have now, or if you have questions later, **you are encouraged to** contact them at 612-208-7458 or to the advisor of this study Dr. Walter Bowles at 612-624-9900.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researcher(s), you are encouraged to contact the Fairview Research Helpline at telephone number 612-672-7692 or toll free at 866-508-6961. You may also contact this office in writing or in person at University of Minnesota Medical Center, Fairview-Riverside Campus, 2200 Riverside Avenue, Minneapolis, MN 55454.

You will be given a copy of this form to keep for your records.

Statement of Consent

I have read the above information. I have asked questions and have received answers. I consent to participate in the study.

Signature of Subject_____
Date_____

Signature of Investigator_____
Date_____

APPENDIX 2

HIPPA Rights

HIPAA[1] AUTHORIZATION TO USE AND DISCLOSE
INDIVIDUAL HEALTH INFORMATION FOR RESEARCH PURPOSES

1. Purpose. As a research participant, I authorize Dr. Andrew Wiswall DDS and the researcher's staff to use and disclose my individual health information for the purpose of conducting the research project entitled Palatal Anesthesia: Comparison of Three Techniques for Decreasing Injection Discomfort, (1102M96493).

2. Individual Health Information to be Used or Disclosed. My individual health information that may be used or disclosed to conduct this research includes: Medical History and Gender.

3. Parties Who May Disclose My Individual Health Information.
The researcher and the researcher's staff may obtain my individual health information from other healthcare providers, such as laboratories, which are a part of this research, as well as healthcare providers that are not part of this research (other doctors, hospitals and/or clinics) for the purposes of carrying out this research study. I authorize these parties to disclose my individual health information to the researcher and the researcher's staff for the purposes of carrying out this research study.

4. Parties Who May Receive or Use My Individual Health Information. The individual health information disclosed by parties in item 3 and information disclosed by me during the course of the research may be received and used by Dr. Andrew Wiswall DDS and the researcher's staff.

5. Right to Refuse to Sign this Authorization. I do not have to sign this Authorization. If I decide not to sign the Authorization, I may not be allowed to participate in this study or receive any research related treatment that is provided through the study. However, my decision not to sign this authorization will not affect any other treatment, payment, or enrollment in health plans or eligibility for benefits.

6. Right to Revoke. I can change my mind and withdraw this authorization at any time by sending a written notice to Dr. Andrew Wiswall DDS 515 Delaware St SE 8-166, Minneapolis, MN 55455 to inform the researcher of my decision. If I withdraw this authorization, the researcher may only use and disclose the protected health information already collected for this research study. No further health information about me will be collected by or disclosed to the researcher for this study.

7. Potential for Re-disclosure. Once my health information is disclosed under this authorization, there is a potential that it will be re-disclosed outside this study and no longer covered by this authorization. However, the research team and the University's Institutional Review Board (the committee that reviews studies to be sure that the rights and safety of study participants are protected) are very careful to protect your privacy and limit the disclosure of identifying information about you.

7A. Also, there are other laws that may require my individual health information to be disclosed for public purposes. Examples include potential disclosures if required for mandated reporting of abuse or neglect, judicial proceedings, health oversight activities and public health measures.

[1] HIPAA is the Health Insurance Portability and Accountability Act of 1996, a federal law related to privacy of health information.

8. Suspension of Access. I may not be allowed to review the information collected for this study, including information recorded in my medical record, until after the study is completed. When the study is over, I will have the right to access the information again.

This authorization does not have an expiration date.

I am the research participant or personal representative authorized to act on behalf of the participant.

I have read this information, and I will receive a copy of this authorization form after it is signed.

_____	_____
signature of research participant or research participant's personal representative	date
_____	_____
printed name of research participant or research participant's personal representative	description of personal representative's authority to act on behalf of the research participant

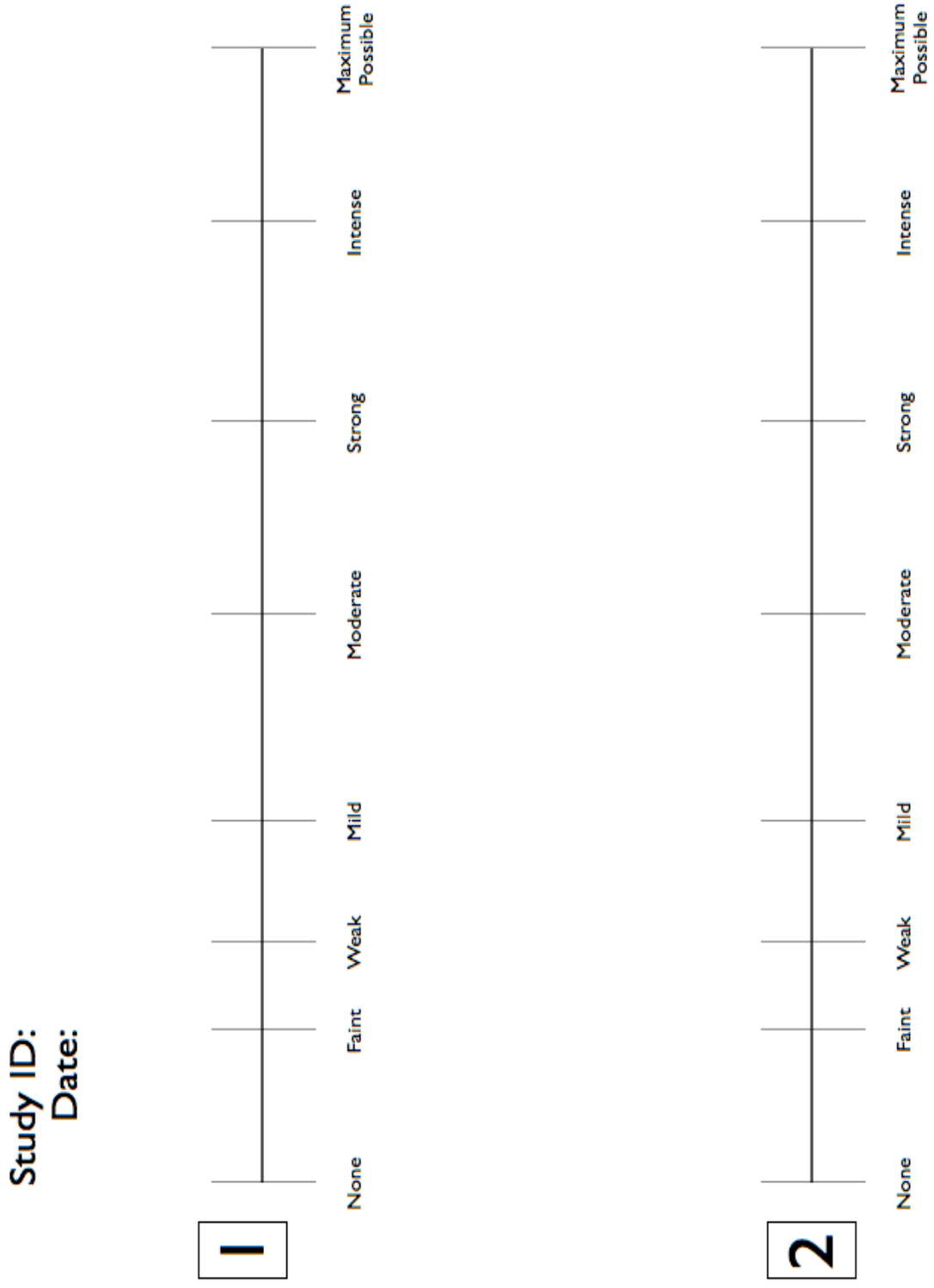
APPENDIX 3

Randomization Table (R and L)

Volunteer	1st	2nd	3rd	4th
1	L	R	L	R
2	R	L	L	R
3	L	R	R	L
4	R	L	L	R
5	R	L	R	L
6	L	R	R	L
7	L	R	R	L
8	R	L	L	R
9	R	L	R	L
10	R	L	L	R
11	L	R	R	L
12	R	L	R	L
13	L	R	R	L
14	L	R	L	R
15	R	L	L	R
16	R	L	R	L
17	L	R	L	R
18	L	R	L	R
19	R	L	R	L
20	L	R	L	R
21	L	R	R	L
22	L	R	R	L
23	R	L	L	R
24	L	R	L	R
25	R	L	L	R
26	R	L	R	L
27	R	L	R	L
28	R	L	L	R
29	L	R	R	L
30	L	R	L	R
31	R	L	L	R
32	L	R	R	L
33	R	L	R	L
34	L	R	L	R
35	L	R	R	L
36	L	R	R	L
37	R	L	R	L
38	R	L	L	R
39	R	L	R	L
40	L	R	L	R
41	R	L	R	L
42	R	L	R	L

APPENDIX 4

Heft-Parker VAS Scale



APPENDIX 5

Post Injection Pain Questionnaire

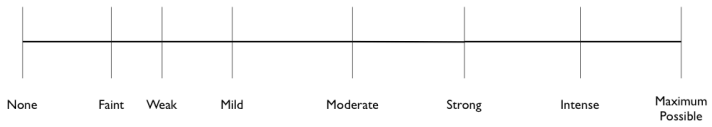
Study ID:

Did you get a sore on the palate after the application of cold? Yes No

If yes when did you first notice the sore? ____ hrs

If yes how long did it last? ____ days

What is the maximum discomfort you felt during the above time period



APPENDIX 6

Final Data Spreadsheet

ID #	Gender	Tech	R/L	mm 1	mm 2	Tech	R/L	mm 1	mm 2	Tech	R/L	mm 1	mm 2	Tech	R/L	mm 1	mm 2
		1				2				3				4			
1200	M	G	L	54.88	85.59	W	R	54.79	48.98	B	L	73.12	95.83	R	R	60.33	78.74
1210	F	B	R	105.46	111.82	W	L	58.83	79.01	G	L	56.72	89.11	R	R	88.32	66.91
1220	M	R	L	48.67	54.29	B	R	53.91	61.25	W	R	54.62	70.40	G	L	54.33	83.43
1230	F	G	R	69.67	85.74	B	L	53.61	68.89	W	L	45.82	85.10	R	R	69.88	85.06
1240	F	G	R	81.96	107.88	R	L	72.76	50.49	B	R	81.33	118.82	W	L	77.96	109.73
1250	M	R	L	44.61	89.44	G	R	53.74	64.63	B	R	20.04	32.46	W	L	30.74	58.08
1260	M	G	L	45.97	140.93	W	R	70.84	110.44	B	R	53.82	84.14	R	L	114.68	144.59
1270	F	B	R	34.67	113.71	R	L	14.60	65.24	W	L	0.00	54.34	G	R	22.14	69.12
1280	M	G	R	36.11	85.12	R	L	54.04	85.14	W	R	54.28	54.39	B	L	85.20	85.23
1290	F	W	R	87.56	110.47	G	L	44.65	70.91	B	L	29.38	88.37	R	R	27.24	57.05
1300	M	G	L	58.76	82.43	W	R	50.35	87.62	B	R	48.94	56.81	R	L	63.45	81.89
1310	F	B	R	24.51	68.93	W	L	24.46	33.31	G	R	22.70	50.49	R	L	23.48	23.21
1320	M	B	L	0.89	54.22	W	R	0.69	84.51	R	R	36.18	54.12	G	L	23.16	53.88
1330	F	G	L	55.75	132.87	W	R	58.96	107.14	B	L	55.20	87.36	R	R	0.60	92.38
1340	M	B	R	78.22	49.75	R	L	29.46	51.11	W	L	20.72	79.77	G	R	2.36	106.87
1350	M	R	R	62.37	54.52	G	L	88.56	102.77	W	R	59.84	83.74	B	L	38.24	69.19
1360	F	R	L	38.66	36.73	G	R	47.18	47.51	B	L	16.58	46.10	W	R	25.69	24.27
1370	F	B	L	25.03	96.79	W	R	3.71	87.91	G	L	60.05	82.37	R	R	2.23	108.61
1380	M	R	R	85.45	114.32	B	L	35.48	85.24	G	R	87.58	95.62	W	L	19.10	58.90
1390	M	W	L	3.86	91.13	B	R	12.27	75.05	G	L	17.54	14.62	R	R	69.23	4.65
1400	M	G	L	24.85	80.93	W	R	40.83	69.35	R	R	78.43	84.95	B	L	64.41	55.50
1410	F	R	L	53.96	77.35	W	R	5.61	36.41	G	R	88.98	111.93	B	L	120.81	97.31
1420	F	B	R	69.84	83.02	G	L	28.85	44.77	W	L	43.85	57.66	R	R	31.61	50.97
1430	M	W	L	41.82	107.89	G	R	47.27	80.96	B	L	4.60	104.30	R	R	0.39	84.15
1440	F	G	R	37.87	83.09	W	L	24.09	41.54	B	L	1.60	109.89	R	R	56.26	123.86
1450	M	B	R	0.00	35.80	G	L	0.00	35.90	W	R	53.93	71.28	R	L	36.31	45.82
1460	M	B	R	67.28	89.49	G	L	25.40	32.76	W	R	56.08	60.88	R	L	88.48	106.43
1470	F	B	R	26.01	84.16	G	L	22.97	54.20	R	L	8.01	19.28	W	R	11.69	27.17
1480	F	W	L	7.10	14.62	R	R	12.24	11.26	B	R	1.02	4.77	G	L	3.22	10.59
1490	M	R	L	53.55	84.63	W	R	40.54	70.69	B	L	33.76	94.88	G	R	29.06	85.84
1500	M	G	R	42.88	88.65	W	L	11.74	62.11	R	L	58.90	90.32	B	R	30.31	70.29
1510	F	B	L	77.04	58.64	R	R	60.69	70.16	W	R	58.77	80.25	G	L	66.90	92.10
1520	M	G	R	53.76	54.53	R	L	23.12	53.55	B	R	22.57	83.39	W	L	83.92	81.91
1530	F	G	L	49.19	63.81	W	R	21.98	39.60	B	L	25.36	77.95	R	R	44.80	82.36
1540	M	B	L	19.43	98.13	W	R	27.08	108.25	R	R	71.75	60.00	G	L	53.95	95.58
1550	M	W	L	72.51	79.90	R	R	75.96	92.58	B	R	14.38	108.07	G	L	73.38	110.36
1560	F	R	R	84.02	103.87	W	L	69.20	83.69	B	R	53.69	112.59	G	L	38.72	53.37
1570	F	W	R	71.17	68.73	R	L	50.27	65.64	B	L	80.21	58.25	G	R	91.56	94.76
1580	M	W	R	0.00	22.85	R	L	22.96	22.88	G	R	0.00	49.60	B	L	19.53	82.52
1590	F	R	L	68.33	67.94	W	R	35.96	35.84	G	L	78.44	30.54	B	R	47.35	29.70
1600	F	W	R	109.39	132.70	R	L	60.90	86.33	G	R	70.72	111.48	B	L	98.75	124.49
1610	F	R	R	54.17	85.08	W	L	85.26	114.03	B	R	53.69	143.90	G	L	54.05	143.80

ID #	Sore	1st Notice (hrs)	Duration (days)	mm
1200	Yes	3	2	44.55
1210	Yes	15	4	54.41
1220	Yes	4	6	85.14
1230	Yes	36	3	84.64
1240	Yes	5	5	24.36
1250	Yes	48	2	0.00
1260	Yes	12	6	114.46
1270	Yes	18	5	0.00
1280	No			
1290	Yes	12	5	97.61
1300	No			
1310	Yes	24	3	55.01
1320	Yes	24	10	36.15
1330	Yes	48	4	0.00
1340	Yes	20	5	87.87
1350	Yes	5	2	24.18
1360	Yes	24	3	36.56
1370	Yes	2	4	69.60
1380	Yes	48	4	78.02
1390	No			
1400	No			
1410	Yes	6	5	76.09
1420	Yes	9	4	65.65
1430	No			
1440	Yes	24	2	48.85
1450	Yes	18	5	91.67
1460	Yes	8	4	112.51
1470	Yes	14	2	19.03
1480	No			
1490	No			
1500	Yes	24	3	76.23
1510	Yes	24	4	85.06
1520	Yes	24	4	52.43
1530	Yes	3	3	25.65
1540	Yes	48	4	53.13
1550	Yes	12	2	0.60
1560	Yes	48	3	64.24
1570	Yes	18	2	22.27
1580	Yes	24	3	0.00
1590	Yes	3	3	46.53
1600	Yes	10	1	15.06
1610	No			

APPENDIX 7

Technique Key Code

Technique	Color
Control	R
Press	G
Press + Topical	B
Press + Endo Ice	W