A CLINICAL EVALUATION OF COMFORT FROM THE USE OF COOLING AS AN ADJUNCT TO THE TRADITIONAL USE OF PRESSURE FOR NASOPALATINE BLOCKS

A Thesis

by

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Submitted to the Office of Graduate and Professional Studies of
Texas A&M University
in partial fulfillment of the requirements for the degree of

MASTER OF SCIENCE

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August 2015

Major Subject: Oral Biology

ABSTRACT

Participants in this study received two treatments of 0.3 mL of 2% Lidocaine 1:100,000 epinephrine delivered as a nasopalatine injection, spaced 4 weeks apart. Each treatment was accompanied either by pressure alone or pressure with the adjunct of cooling through the use of refrigerant spray on a cotton tip applicator applied to the incisive papilla. Treatment modalities were randomized and participants were blinded as to which treatment they were experiencing at both appointments. After each treatment, participants completed a simple, visual analog scale to indicate comfort during injection. Four weeks after completion of the study, a survey was administered to assess preferences during treatment, complications with treatment and preferences post-treatment.

Forty-two students of the Texas A&M University Baylor College of Dentistry participated in the study. Forty students who had completed both treatments voluntarily participated in the survey. Wilcoxon Signed Ranks test was used to analyze data. Data showed a significant difference favoring the cold/pressure combination to pressure alone during injection (P=0.031). Results of the survey showed a significant number of the participants experienced mucosal sloughing associated with the use of the refrigerant spray.

It was concluded that cooling is an effective method to increase the comfort of nasopalatine injections in conjunction with pressure. Refrigerant spray is not

recommended for the coolant as it has been shown to cause tissue damage. More studies should be done to find a viable alternative.

ACKNOWLEDGEMENTS

I would like to thank multiple people involved with this study, most of all the students of the Texas A&M University Baylor College of Dentistry who volunteered their time, comfort and trust to my hands and a syringe. I would like to thank my co-residents who were flexible with their time and assisted me with my sample size. It is one thing to volunteer for a random study, it is quite another to do so when you intimately know the clinician and their faults and weaknesses.

I would like to give special thanks to my research assistant, Dominique Salas-Garfias, who kept me organized and efficient during clinical trials and kept a great attitude despite the monotony of the work. I truly appreciated her humility and willingness to help me with the work that would not be considered "sexy" by most people's standards. I hope this process will at least provide her with some background for a future research project I am sure she will undertake on her own.

Lastly, I would like to thank Drs. Kavitha Viswanathan and Carolyn Kerins for mentoring me through this process. They were always prompt with advice and willing to assist in whatever complication or question I had. I can't think of anything I would rather do less than edit the multitude of documents that I sent their way and for that I am extremely indebted. Thank you very much!

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CHAPTER I

INTRODUCTION

The injection is a key milestone in the restorative appointment for the pediatric dental population. This event can have the ability to end restorative treatment if a pediatric patient perceives the injection as painful and does not possess the coping mechanisms necessary to continue with treatment. It is therefore important for clinicians to develop the most comfortable techniques possible for delivery of local anesthetic so as to preserve the psyche of young dental patients and to move safely and efficiently past that milestone in order to complete the dental treatment necessary. Alternative techniques for reducing the pain associated with injections include: buffering of anesthetic[1], use of topical anesthetic, use of pressure, use of computer-controlled delivery[2], use of vibration[3] and use of cold[4, 5] as well as others. The use of cold for improving comfort during injections has been used in other disciplines, such as dermatology[6-8]. This use of cold is referred to as cryoanalgesia, and may present a safe, cheap and efficient way of providing analgesia associated with dental injections. This literature review focuses on the psychology behind the dental injection, the current methods by which cryoanalgesia is being used for treatments in a clinical setting and the potential mechanisms by which cryoanalgesia may be effective.

The dental injection is a concept that commonly elicits a negative reaction in many people who seek dental treatment. The injection has been shown to be the most anxiety inducing aspect of the dental visit for children[9]. This is often due to fear of the

pain associated with the injection or fear of the sensation of being numb[10]. Needle phobia appears to be somewhat inheritable[11]; however, there is also clear evidence that it may be a learned behavior[12]. Those who possess a needle phobia typically are able to trace their fear back to an adverse event or to witnessing a sibling experience an adverse event in childhood[13]. Although dental anxiety and fear tends to decrease with age[14], approximately one-fourth of the adult dental population experiences anxiety related to dental injections and half experience some anxiety to the feeling of numbness[9]. This trend in dental anxiety appears to have remained fairly consistent over the past 50 years[15]. It is important to decrease anxiety and phobias of the dental injection, as an increase in anxiety has been positively correlated with an increase in decayed, missing and filled teeth scores in children[16]. This fear has been shown to transfer into adulthood and can negatively affect the subsequent generation through impression of the parent's fear onto their child[17]. Dental anxiety and fear may lead to avoidance behavior which may lead to further progression of disease and more unfavorable outcomes long-term. It is important to make the dental injection as comfortable as possible, especially for the pediatric population, as the trauma associated with an adverse event may lead to further caries, progression of disease, anxiety later in life and have a negative effect on future generations of dental patients.

Currently, the use of cryoanalgesia has been described in the literature for use in dermatology, physical therapy and dentistry[1, 4-6, 8, 18-23]. Cryoanalgesia has been shown in dermatology to decrease the pain associated with local infiltration[7], botulinum injections[6, 18] and arterial puncture[8]. Within physical therapy it has

shown to decrease the amount of narcotic use and pain experienced by individuals post-surgery[24]. It has also been shown to be useful after multitudes of sports-related injuries and soft-tissue injuries as well[20, 21, 23, 25].

Within the dental literature, cryoanalgesia was first described as a method used for palatal anesthesia by Harbert in 1989[26]. In his case report, he described the use of a spent anesthetic carpule, filled with water and frozen in order to create a tube of ice that could then be used on the palatal mucosa prior to injection of local anesthetic. In 2009, Aminabadi looked at the use of cryoanalgesia with children for inferior-alveolar nerve injections[4]. This study helped to validate the claims by Hubert by providing a randomized control trial which compared the use of cryoanalgesia with topical anesthetic prior to inferior-alveolar injections and found a significant difference to be present. In 2013, Kosaraju found a significant difference to be present when a randomized control trial was performed comparing cryoanalgesia via endo-refrigerant spray with topical anesthetic use for greater palatine blocks[5].

Multiple theories exist regarding the mechanism by which cooling decreases nociceptive pain. Three theories by which cold may reduce pain during injection include:

1. Cold decreases ability of neurons to repolarize, thus decreasing conduction velocities, and frequency of action potentials when stimulated by noxious insult.
2. Cold decreases inflammation and release of inflammatory cytokines which activate signal propagation of sensory nerve

3. Cold sensation effectively competes with sensation of pain through activation of transient receptor potential channels specific to cold (Gates control theory)

To understand these three theories, it is important to first understand how the sensation of nociceptive pain is generated. Peripheral pain is a subjective experience for an individual brought about by an external stimulus[27]. Free nerve endings are stimulated by an irritant on the skin, causing a threshold to be reached which then propagates an action potential along the axon and into the central nervous system where it synapses with second and third order neurons in the brain stem and is eventually registered in the somatosensory area of the cerebrum as the stimulus[27]. Specialized somatosensory nerves within the body are specifically designed to register noxious stimuli, and they are called nociceptors[28]. These specialized nerve cells are designed to detect damage to tissue, extremes in cold and heat, pressure and damaging chemicals[27]. The basic mechanism by which stimuli is transmitted along the nerve relies on the extracellular concentration of electrolytes and the permeability of the nerve membrane to electrolytes, specifically sodium and potassium ions. At rest, a peripheral nerve has a resting potential of approximately -70 mV with a greater concentration of intracellular potassium and negatively charged chloride ions and a higher concentration of extracellular sodium ions. When a stimulus occurs to a free nerve ending of a peripheral sensory nerve, specific protein channels embedded within the membrane open, allowing the inflow of sodium through the cell membrane, thus depolarizing the cell. Once a specific threshold is met of approximately -50 to -60 mV, an action

potential is propagated. Once an action potential is propagated, protein channels along the membrane of the nerve's axon open in a wave like fashion that propagates the signal, sending the nerve impulse along the axon, to the brain and registering as a stimulus. Shortly after the nerve impulse is propagated, sodium channels close and potassium channels within the membrane open to selectively allow potassium to rush out of the nerve cell and into the extracellular space, thus terminating the action potential and repolarizing the cell.

There are different classifications of peripheral nerves which differ in their physical makeup, diameter and ultimately conduction velocity. Of the different types of nerve fibers, those which are important to nociception are the A-delta fibers and C fibers. A-delta fibers are myelinated and larger in diameter, which allows for greater conduction velocity, while C fibers are unmyelinated and smaller in diameter which results in relatively slower conduction velocity. This conduction velocity is important, because it explains the differences in pain we feel when we receive injury to a tissue. The relatively quick speed of the A-Delta fibers transmit the sharp, acute pain we feel at or near the time of insult, while the C fibers are responsible for the transient dull aching, throbbing and burning which accompanies the insult moments later. A-Delta fibers are able to transmit the initial sharp prickling pain within milliseconds of the injury, while the intensifying aching and burning transmitted by the c-fibers will typically not begin to be registered until a second or more after the injury. Within peripheral tissues, free-nerve endings from both types of fibers reside and are responsible for not only

nociception, but contain the capacity to transmit signals regarding temperature and touch as well.

In order to propagate an action potential, a sensory neuron must receive some form of chemical signal that causes a conformational change in the ion-pores of the neuronal cell membrane. This conformational change is what allows sodium ions into the neuron, thus depolarizing the cell past the critical threshold and propagating the action potential. Signal transduction occurs in nociception through chemical, thermal or mechanical insult to the tissue. A few different possibilities exist by which these stimuli can induce an action potential. Firstly, the mechanical, thermal or chemical stimuli itself may directly alter the cell-membrane of the free nerve endings to cause an influx of sodium ions and the propagation of the action potential. Secondly, it is postulated that damage to surrounding tissue during an insult of this nature releases intracellular components into the extracellular matrix which then bind to receptors located on the ion channels of the neuronal fibers. Lastly, inflammatory cytokines from a local injury may bind to the cell-membrane and either induce a signal themselves, or cause allodynia/hyperalgesia in the area. This is the basic background for how a stimulus such as thermal, mechanical or chemical insult creates the sensation that we register as pain in our brains. This basic explanation is important, because it will help to explain how an alternate sensation, such as cold, may decrease the sensation of pain during an injection. In summary, benefits of cold may include: decreasing the ability for neurons to repolarize, decreasing inflammation and release of inflammatory cytokines and competing with the sensation of injection pain.

1.) Cold decreases ability of neurons to repolarize, thus decreasing conduction velocities, and frequency of action potentials when stimulated by noxious insult.

One study investigated the role of temperature on nerve conduction velocities using dissected peripheral nerves in cats as a model. In this study, nerve impulses were propagated at the most peripheral portion of the feline nerve at room temperature as well progressively cooler temperatures[29]. It was demonstrated that as the temperature decreased, nerve impulses were propagated at much slower rates. Results of this study have been confirmed in the rat model while looking at similar constructs between peripheral afferent fibers and cooling [30]Studies on the cellular level have also demonstrated similar findings in non-CNS related human cell lines showing a decrease in the metabolic rate as temperature decreases [31]. It has also been shown that the Na+/K+ pump activity across neurons decreases with decreased temperatures [32-34]. This decrease in activity leads to increased depolarization of the cell, rendering it unable to repolarize and essentially creating a "nerve block" [32]. These results help to demonstrate that a decrease in temperature at the peripheral end of the nerves may help to decrease the metabolic rate of the nerve and thus decrease its ability to fire as intense and frequent action potentials. This could potentially explain one way in which cooling may increase comfort.

2.) Cold decreases inflammation and release of inflammatory cytokines which activate signal propagation of sensory nerve

Cold has been used as a therapeutic agent in physical therapy and general medicine as an effective tool in reducing inflammation due to injury and noxious stimuli [21, 23]. Cold can constrict capillaries and blood flow to an area via vasoconstriction, thus limiting edema as a result of local trauma and potential release of inflammatory cytokines that assist in sensitizing the nerve. This decrease in inflammation may help as well when local anesthetic is delivered into the tight, keratinized mucosa overlying the palate causing tissue damage and discomfort through the process of the sheer volume of liquid being deposited and the tissue's inability to expand as you might see in non-keratinized tissues.

3.) Cold sensation effectively competes with sensation of pain through activation of TRP channels specific to cold (Gates control theory)

This theory would postulate that the act of cooling the oral mucosa will cause activation of TRP channels that are present on the nociceptive A-delta and C fibers to open, thus causing the nerve to depolarize and send non-noxious impulses to the brain[35-38]. When the needle is inserted into the tissue and noxious stimuli is presented, the nerve is already propagating a non-noxious signal which competes through the process of these TRP channels to decrease the rate and ultimately the intensity with which the painful signal is able to be transmitted along the peripheral nerve[39].

Ultimately, the true answer to how cold can increase comfort of palatal injections may lie with all three explanations.

To date, only one randomized control trial exists which examines the use of cryoanalgesia in palatal injections. No studies have currently examined the use of cryoanalgesia for nasopalatine injections, and no studies have compared the use of cryoanalgesia to pressure alone for palatal injections. Therefore, the aim of this study was to examine the comfort felt during injection with the use of cryoanalgesia and pressure compared to pressure alone for nasopalatine blocks.

CHAPTER II

A CLINICAL EVALUATION OF COMFORT FROM THE USE OF COOLING AS AN ADJUNCT TO THE TRADITIONAL USE OF PRESSURE FOR NASOPALATINE BLOCKS

INTRODUCTION

The injection is a key milestone in the restorative appointment within pediatric dentistry and can help determine whether the procedure continues or fails. Nasopalatine nerve blocks have been shown to be the most painful injections experienced by the pediatric dental population[40]. This is quite likely due to the thickness of keratinized tissue overlying the periosteum which decreases the efficacy of topical anesthetic and requires an uncomfortable amount of pressure during the injection in order to deliver sufficient quantity of local anesthetic to the area. Previous studies have looked at different methods to increase comfort during these injections, including the use of vibration [3], controlled delivery of anesthetic [41] and successive injections through the interdental papilla [42]). An ideal topical anesthetic would be quick in onset, painless in delivery, non-irritating, cost effective, easily accepted by the patient and significantly decrease the discomfort felt during the injection of anesthetic. To date, no method has proven to be the best option for satisfying all criteria; the steps involved in the current method for delivering a nasopalatine injection are described as [43]:

1. Dry the tissue overlying the naso-palatine foramen with a clean and sterile gauze

2. Apply topical anesthetic for 2 minutes with cotton swab application (optional)
3. Move swab over the incisive papilla
4. Apply pressure for 30 seconds while slowly advancing needle and slowly depositing anesthetic
5. Once bone is contacted (approximately 5 mm), withdraw needle 1 mm.
6. Aspirate
7. If negative, deposit not more than ¼ carpule over a minimum of 15-30 seconds
8. withdraw needle

The use of pressure in this injection technique utilizes the gate-control theory of pain. In other injection techniques, the use of topical anesthetic is frequently recommended prior to the delivery of anesthetic. With regards to palatal injections however, research has shown that use of topical anesthetic is only effective after >2 minutes of direct application time to palatal tissues for needle insertion and made no difference with regards to pain felt during the actual injection of the anesthetic compared to controls [44]. This would lead one to believe that the effectiveness of topical anesthesia in naso-palatine injections is minimal at best and that the actual decrease in pain from injection in this area comes mainly from the action of pressure through gate-control theory.

The use of cold for anesthesia purposes, or cryoanalgesia, has been utilized in the field of dermatology for topical anesthesia in the use of various types of injections with great success [1, 6, 8, 45]. Cryoanalgesia has also been shown to be effective in pediatric patients with inferior alveolar nerve block injections [4]. The use of cryoanalgesia has

been shown to be more successful than benzocaine gel in reported pain levels for adults receiving greater palatine injections [5], however, no study has looked at whether or not there is a difference in discomfort for nasopalatine injections. There is only one published study that has looked at the use of refrigerant spray for this purpose [5]and this study would help to strengthen results found in their study which show the refrigerant spray as a convenient tool for its cooling purposes. Previous studies have shown it is safe to use with humans with no long-term systemic effects [46], but there are no reported studies documenting short term effects on tissues, particularly in the oral mucosa. While a study has been done to determine the effectiveness of cryoanalgesia as a suitable alternative to topical anesthetic for inferior alveolar nerve block and greater palatine nerve block injections, no study has been reported regarding its use in the traditionally more painful nasopalatine blocks.

This study explored a potentially viable alternative to the current standard of care for nasopalatine injections. If a significant difference is found, this could be an important addition to the technique armamentarium used to increase patient comfort during injections. Use of cryoanalgesia can potentially reduce costs, time in the chair for the patient, increase comfort of injection, eliminate temporary altered taste sensations and reduce the risk (albeit rare) of allergic reactions to topical anesthesia.

The specific aim of this study was to explore whether a significant difference exists between the use of pressure alone and pressure with the addition of cooling as well as whether dental refrigerant spray should be regarded as a good option for delivery of the cooling sensation.

MATERIALS AND METHODS

This study was approved by the Texas A&M University Baylor College of Dentistry Institutional Review Board. Power analysis was used to determine the number of subjects needed for significant results with an alpha level of 0.05 and a power level of 0.9 with an effect size of 0.5 due to lack of studies regarding this material and because we were looking for a moderate treatment effect. The G*Power 3.0.10 (Düsseldorf, Germany) software tool was used to calculate N given the previous parameters. A sample size of N=38 was calculated to satisfy the power analysis. Subjects for the study were recruited from the Texas A&M University Baylor College of Dentistry through emails to the general student body and fliers posted throughout the facility. Inclusion criteria included students of the Texas A&M Health Sciences Baylor College of Dentistry who were ASA 1 or 2. Exclusion criteria included those who are ASA 3 or 4, those who had active pathology in the nasopalatine area, history of diabetes, circulatory issues, true lidocaine allergy, skin sensitivity issues and those who could not commit to two visits. Participants received $20 after completion of both visits for their time and effort involved in participation. A total of 42 participants enrolled in and completed both visits of the study.

Each participant was required to attend two visits spaced 4 weeks apart. At the first visit, a coin (standard U.S. quarter) was flipped to determine the treatment order that the participant was going to receive. If a “heads” was flipped, the participant would receive the pressure and cold treatment at the first visit and if a “tails” was flipped, then he/she would receive the pressure alone treatment for their first visit. Participants were

unaware as to the order in which they would receive treatment. After determining the order sequence, participants would sit in the dental chair and be lowered back to an angle conducive for the operator to deliver a nasopalatine injection, typically just past horizontal. Standard laboratory safety goggles which were opaqued using duct-tape to protect the participants eyes while also "blinding" the participant to the treatment, were then placed over the participants eyes. Based upon the coin flip, patients received one of the following two treatments:

- Pressure and Cold: Cotton tip applicator was sprayed for 8 second using endo-refrigerant spray (1,1,1,2 Tetrafluoroethane spray, Patterson® Endo Refrigerant Spray – Fresh Vanilla Scent, 10 oz Spray Can).

  Or

- Pressure Alone: Cotton tip applicator was moistened using a 0.5 second submersion into a cup of water. The endo-refrigerant spray was discharged for 8 seconds, but was kept away from the cotton tip as to allow no contact between the spray and cotton tip applicator. Standard discharge between both treatments was used as a sound and smell blinding mechanism for the participants.

Injection Technique

The cotton tip applicator was then applied to the incisive papilla for 10 seconds with pressure to the tissue at an angle of approximately 80 degrees to a line following the midpalatal suture and 80 degrees to the left side of the operator, following the

patients intercanine line. After pressure was applied for ten seconds with clear blanching present, a standard anesthetic syringe loaded with 1 carpule of 2% lidocaine 1:100,000 epinephrine and 30 gauge short needle was used for deposition of 0.3 mL of solution over a minimal period of 30 seconds. Needle insertion was from the right side of the operator at a 45 degree angle to the papilla. The needle was slowly advanced as solution was deposited with firm pressure until bone was contacted, at which point needle was retracted approximately 1 mm and remaining solution deposited. Solution volume was determined by visualization of the rubber-stop within the carpule in relation to the "red-band" present on all carpules. It was determined prior to the initiation of the study that the red-band which is standardly present on all carpules of the local anesthetic used (Patterson® Lidocaine Anesthetic HCL 2% with 1:100,000 Epinephrine) corresponded with 0.33 mL of anesthetic. When the advancing end of the rubber stop had reached the top of the red-band, pressure on the syringe was relieved and needle was retracted. The patient was then allowed to rinse his/her mouth with water to remove any residual anesthetic that had been deposited into the oral environment. The patient was then allowed to remove the safety goggles and was presented with standard visual analog scale to mark his/her discomfort experienced during the injection process. Participants were not told what treatment modality they had received. After the patient had exited the appointment, his/her visual analog scale was marked in the upper right corner with a blue (signifying cold with pressure) or red (pressure alone) marker to signify their treatment for that day by the assistant or clinician. Four weeks after the initial visit, each subject returned to receive the second treatment consisting of the experimental condition

that was not received at the first visit. After completion of the second visit, the patient was given $20 compensation for participation.

Visual Analog Scales

Visual analog scales were identified solely by a unique number to each participant corresponding to the last four digits of their school number. The practitioner doing measurements was unaware of which participant each four digit number corresponded to in an effort to eliminate potential bias. A standard 30 cm ruler was used to measure markings on each participant's comfort scales. The visual analog scale was labeled such that the marking to the far left corresponded to "no discomfort" and 0, and the marking to the far right corresponded to "most discomfort possible" and 100. The visual analog scale was exactly 10 cm long. A marking 7.6 cm to the right of the "zero" hash corresponded to a "76" and a marking 3.2 cm to the right of the "zero" hash corresponded to a "32". Both visual analog scales from each participant were measured a total of three times for accuracy, and the consensus values were entered into Microsoft Excel 2010 (table 1). IBM SPSS Statistics 22 (Armonk, NY) was used to evaluate statistical significance of data using Wilcoxon Signed Ranks Test.

Post-study Survey

The research protocol and survey design was approved by Texas A&M Health Sciences IRB (IRB# 2014-0534-BCD-FB). The survey was then built using surveymonkey.com survey builder where a link was generated for the purposes of taking

the survey. The link was sent out to all participants of the study who completed both treatments. A second reminder email was sent out 2 days later to increase the response rate. *Figure 1* outlines the survey format and response sequence that was used.

RESULTS

The study group consisted of a total of 42 students from the Texas A&M University Baylor College of Dentistry. There were no dropouts in this study and all subjects who enrolled in the study completed both treatments. Table 1 shows recorded values for both treatment modalities of each patient as measured by self-reporting on the visual analog scale. A significant difference between the two treatments in favor of the pressure and cold over the pressure alone using the Wilcoxon Signed Ranks Test at the 95% CI (2-tailed, Z=-2.163, P = 0.031).

Forty of the forty-two participants who completed the study also chose to participate in the follow up survey. Of the 40 who responded, 28 were able to distinguish between the two treatments (Table 2). Of those 28, eighteen (64.29%) preferred the use of cooling with pressure to pressure alone, seven (25%) preferred pressure alone and three (10.71%) had no preference (Table 3). Of those same 28, nine people experienced no sloughing (32.1%), eighteen (64.3%) experienced sloughing with the use of cold and pressure only, no one experienced sloughing with pressure alone and one person (3.6%) experienced sloughing with both treatments (Table 4). Of those 19 (out of the 28 who were able to distinguish between treatment modalities) who experienced sloughing with either cold with the addition of pressure alone or with both

treatments, 5 (26.3%) experienced mild sloughing, nine (47.4%) experienced moderate sloughing and 5 (26.3%) experienced severe sloughing of the incisive papilla mucosa (Table 5).

Ten participants (25%) were: A.) able to distinguish between treatments, B.) preferred the use of cold and pressure to pressure alone and C.) Experienced sloughing associate with cold and pressure or with both treatments. Of those 10 participants, five (50%) would choose to use the cooling spray again despite the sloughing that presents after the use of the refrigerant spray, while the other 5 (50%) would consciously choose to use pressure alone due to the discomfort felt from the sloughing of their mucosa as a result of the refrigerant spray (Table 6).

Twelve participants (30%) were unable to determine the difference between the 2 treatment modalities (Table 3). Of those 12, five (41.7%) experienced no sloughing associated with either treatment, six (50%) experienced sloughing associated with one of the treatments and one (8.3%) experienced sloughing associated with both treatments (Table 7). Of those seven who experienced sloughing, six completed the last question of the survey. Three (50%) experienced mild sloughing, two (33.3%) experienced moderate sloughing and one (16.7%) experienced severe sloughing of their mucosa (Table 8)

CHAPTER III

DISCUSSION AND CONCLUSIONS

DISCUSSION

The aim of this study was to evaluate the use of cryoanalgesia on the palatal mucosa as an adjunct to the use of pressure for increasing comfort felt by patients during nasopalatine injections. In addition, this study also examined the use of 1,1,1,2 tetrafluoroethane on oral mucosa and the residual effects of its topical use.

The results of this study show that there is a significant difference between the use of pressure alone and pressure with the addition of cooling on the comfort felt during nasopalatine injections. The use of cooling, as shown in this study, can be an effective way to increase comfort of nasopalatine injections. These findings are similar to two other studies that have used cooling prior to intraoral injections which have both shown a significant difference in favor of cooling [4, 5], although this study differs in the site of injection and control treatment being rendered. The results are also consistent with dermatology studies that have shown significant differences in pain experience from the use of cooling prior to dermal injections with botulinum injections and laser therapy [1, 6, 8, 45]. The technique for cooling of palatal injections has been described before in the literature [26], however, to date there had been no studies that tested whether a benefit existed for the nasopalatine injection and none that had looked at cooling in comparison to pressure alone. The results also demonstrated through the follow-up survey that

1,1,1,2 tetrafluoroethane spray should not be a viable option for use as the cooling agent due to its propensity to cause thermal burns, resulting in the sloughing of the palatal mucosa. This result is ultimately unsurprising, as earlier studies have shown that under similar constructs, 1,1,1,2 tetrafluoroethane refrigerant spray can cool a cotton tip applicator to a temperature of -18.5 degrees Celsius [47]. It has been reported that frostbite can occur at temperatures between -2 and -10 degrees Celsius[48]. This result had not been previously mentioned in earlier published studies that had used refrigerant sprays for cooling [5] and may warrant future research to confirm results or to establish guideline for its safe use for topical application.

Limitations to this project include the inability to completely "blind' the participants to the treatment rendered due to the sensation of cold on the palate, degree of pressure not being standardized and controlled between patients and treatments, variations in anatomy of the participants and potential bias of the operator as a result of inability to double blind this study. Future studies may look at the effect of different temperatures on the comfort of injections and whether a threshold temperature exists at which there is no thermal burn induced but a strong clinical effect noted. It would also be valuable to study how the duration of application of cooling effects the degree of comfort felt and the addition of other known treatment modalities to add to cooling and pressure such as the use of vibration and controlled delivery syringes to see whether the addition of those other factors can improve the degree of comfort even further. Lastly, once a safe and effective manner is found in adults to utilize cooling for increasing

pressure, this method should also be researched in children to see if similar results are achieved.

Problems that developed during this study were all related to the extremely cold temperature to which the refrigerant spray was able to cool the cotton tip applicator. One incident which arose for the study practitioner was the actual freezing of saliva and moisture present on the surface of the incisive papilla of the patients receiving treatment. After application of the frozen cotton-tip applicator on the incisive papilla for the 8 seconds prior to injection, a layer of ice would sometimes form across the incisive papilla mucosa, creating a hard barrier which made visualization of the tissue difficult, as well as causing difficulty in penetrating into the tissue with a consistent pressure. This ultimately led to possibly uncomfortable penetrance of the needle into the tissue as well as premature deposition of anesthetic before the bevel was truly into tissue. The other problem that arose from the use of refrigerant spray was the self-reported sloughing that was occurring on patients of the study. After hearing multiple self-reports of the sloughing, it was decided to modify the study and include a voluntary survey of the study participants regarding the prevalence of this problem. Results indicated that the prevalence within the study population of sloughing related to the use of the refrigerant spray was great enough that we cannot in good conscience recommend its use for this purpose in the future.

Improving the comfort of injections for the pediatric patient helps to build trust between the patient and the practitioner, alleviates anxiety of injections and ultimately assists in progressing the restorative appointment and treatment of the present disease

process. With children, it is especially important to maximize their comfort so as to establish the dental office as a safe place where treatment can be rendered free from pain. Failure to acknowledge the comfort of this patient population can lead to phobia and future dental disease and pain due to avoidance behavior[10, 49, 50]. This study aimed to evaluate a relatively unexamined way to increase comfort felt during palatal injections and to evaluate whether the use of refrigerant spray is a viable tool for this method. Through the results of this study, it is hoped that future research can build on this information to establish a relatively painless method for local anesthetic delivery that is safe, cost effective for the practitioner, comfortable for the patient, quick in onset and does not lead to adverse sequelae (such as mucosal sloughing). Comfortable injections in the child population may lead to more positive experiences at the dentist, decreases in future avoidance behavior and ultimately a decrease in dental disease over time. The results of this study demonstrate that the addition of cooling may be a valuable tool in the development of painless palatal anesthesia delivery, but that refrigerant spray should likely be abandoned as a method of providing the cooling method to the oral mucosa.

CONCLUSIONS

The use of cooling in addition to pressure is more efficacious than the use of pressure alone for increasing comfort felt during nasopalatine injections. Also, the use of 1,1,1,2 tetrafluoroethane refrigerant spray can cause moderate tissue trauma after 8 seconds of use and is not recommended for use on palatal mucosa for this reason

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APPENDIX A

Table 1. Visual analog scale values

Subject	Pressure Alone	Pressure + Cold
1	39	9
2	59	19
3	32	9
4	30	15
5	46	36
6	36	41
7	14	24
8	26	65
9	16	15
10	24	7
11	39	12
12	38	31
13	16	31
14	44	25
15	49.5	31
16	25	24
17	10	14
18	30	14
19	12	28.5
20	59.5	20
21	73	24
22	64	29.5
23	19	30
24	28.5	19
25	16	13.5
26	17	24.5
27	45	34.5
28	57	10

Table 1. *Continued*

Subject	Pressure Alone	Pressure + Cold
29	22	40.5
30	37.5	82.5
31	86	77.5
32	83.5	35
33	76	16.5
34	12	66
35	31	11.5
36	21	68
37	10	27
38	52	42.5
39	29	27
40	65	39
41	15	6
42	47	25.5
	X= 36.94 +/- 3.23	X=29.05 +/- 2.90

Z= -2.163

P= 0.031

Table 2. Survey: Ability to distinguish treatment modalities

Response to question: Despite "blinding" to treatments, were you able to discern between the feeling of pressure alone and pressure with the use of cooling?

Answer Choices	**# Responses**
Yes, I could discern between the two treatments	28 (70%)
No, I was not able to discern between the two treatments	12 (30%)
Total	**N=40**

Table 3. Survey: Preferences for treatment modalities

Response to question: Which of the treatments was more comfortable during the injection Process?

Answer Choices	**# Responses**
Pressure Alone	7 (25%)
Cold and Pressure	18 (64.29%)
No Preference	3 (10.71%)
Total	**N=28**

Table 4. Survey: Mucosal sloughing

Response to question: Did you experience any mucosal sloughing associated with either of the treatments?

Answer Choices	**# Responses**
No	9 (32.1%)
Yes, with cold and pressure	18 (64.3%)
Yes, with pressure alone	0 (0%)
Yes, with both treatments	1 (3.6%)
Total	**N=28**

Table 5. Survey: Degree of sloughing

Response to question: Would you categorize the sloughing as "mild" (healing took 1-2 days), "moderate" (healing took 3-7 days) or "severe" (healing took more than 7 days)

Answer Choices	**# Responses**
Mild	5 (26.3%)
Moderate	9 (47.4%)
Severe	5 (26.3%)
Total	**N=19**

Table 6. Survey: Cold preference versus mucosal sloughing

Response to question: Based upon your experience with post treatment sloughing and healing, does your preference for treatment change?

Answer Choices	**# Responses**
No, I would choose pressure alone	5 (50%)
Yes, I would choose to use cold again	5 (50%)
Total	**N=10**

Table 7. Survey: Sloughing experience in those unable to distinguish treatments

Response to question: Did you experience any mucosal sloughing associated with either of the treatments?

Answer Choices	**# Responses**
No	5 (41.7%)
Yes, with one of the treatments	6 (50.0%)
yes, with both of the treatments	1 (8.3%)
Total	N=12

Table 8. Survey: Degree of sloughing in those unable to distinguish treatments

Response to question: Would you categorize the sloughing as "mild" (healing took 1-2 days), "moderate" (healing took 3-7 days) or "severe" (healing took more than 7 days)?

Answer Choices	**# Responses**
Mild	3 (50.0%)
Moderate	2 (33.3%)
Severe	1 (16.7%)
Total	N=6

APPENDIX B

Figure 1. Survey design

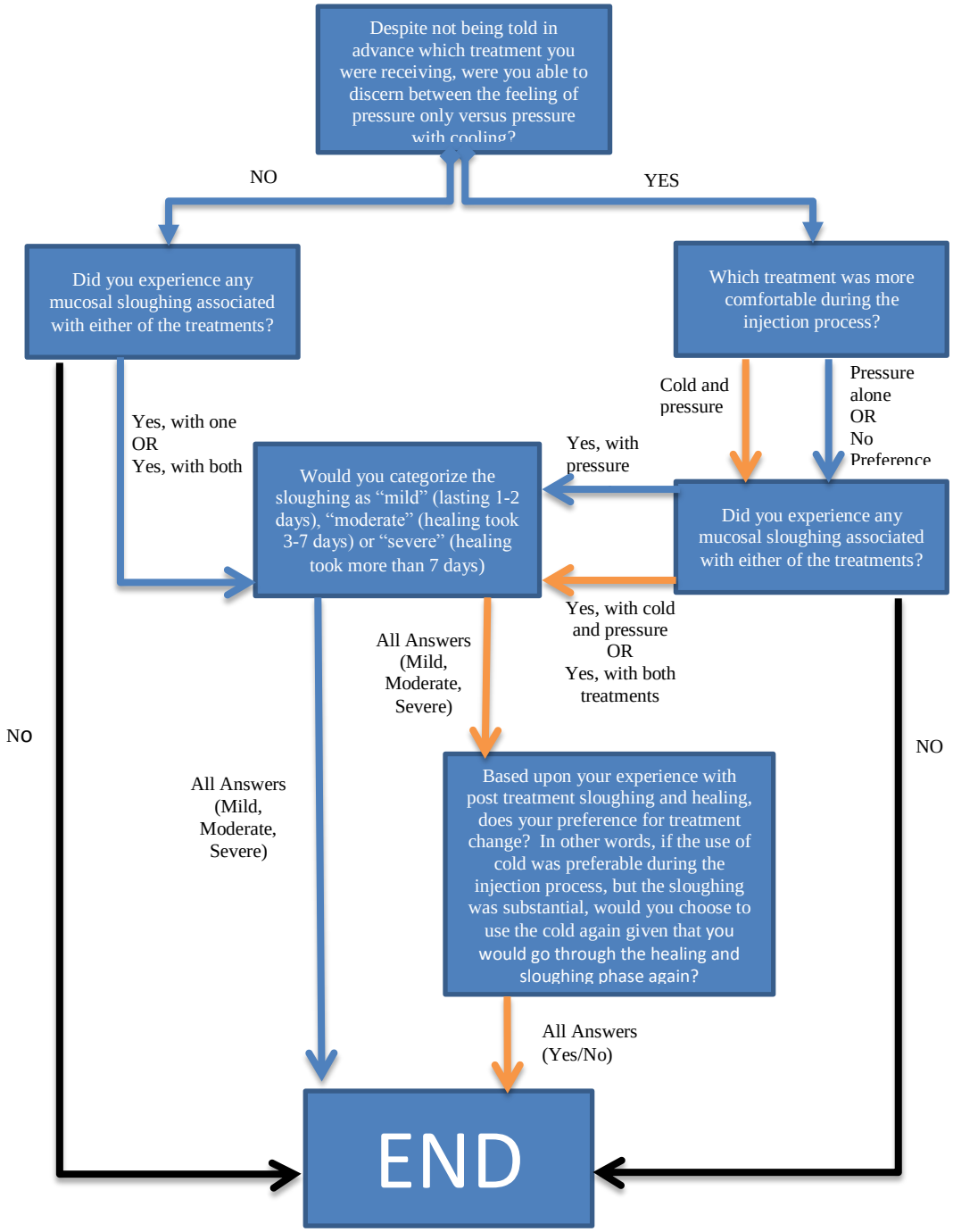

Figure 2. Example of mucosal sloughing