The Role of Biodentine in Class V Dental Lesions on Oral Health Related Quality of Life

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SPECIFIC AIMS

More than 45 million adults suffer from overly sensitive teeth in the United States [1] which affects women more than men [2]. Tooth sensitivity leads sufferers to avoid many of their favorite foods because the temperature of the food can lead to a sharp intense pain. Even cold atmospheric air can trigger extreme pain [3]. Tooth sensitivity can be chronic causing a disruption in daily activities of the affected individuals, thereby seriously impacting their oral health related quality of life [4].

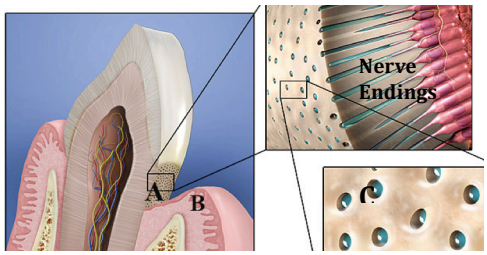

Figure 1: Tooth diagram. Enamel is in white and dentin is in pink. **A)** Shows the exposed region of dentin on a tooth where nerve endings can be exposed; **B)** is the recessed gingiva created by excess tooth brushing; **C)** Dentin tubules containing the nerves.

Tooth sensitivity occurs when the dentin and dentin tubules that contain fluid along with nerve endings are exposed due to the removal of a protective layer surrounding dentin called cementum. This process of cementum removal is frequently associated with gingival recession caused by aggressive tooth brushing. Improper tooth brushing techniques can cause the toothbrush bristles to act like a saw at the gumline. The saw-like action creates a V shaped lesion thereby exposing dentin [5] (Fig. 1), which is frequently associated with tooth sensitivity [6]. Once the dentin is exposed, the fluid inside the dentin tubules can move by changes in osmotic pressure (Fig. 1C) [7]. This movement leads to perceived pain via activation of nocioceptors. For the purposes of this study, we will be referring to tooth sensitivity as tooth pain because of the activation of nocioceptors within the pulp [8]. Commonly, patients that suffer from extreme tooth pain associated with V shaped lesions are treated with non-restorative and restorative treatments that include the use of over-the-counter fluoride, prescription fluoride, sensitivity reducing medicaments, toothpastes containing potassium nitrates and restorations with dental materials that cover the affected area [9, 10]. *Despite numerous ways to treat tooth pain associated with V shaped lesions, most of them are unsuccessful at reducing the discomfort permanently* [11].

For very symptomatic V shaped lesions, a resin-modified glass ionomer restoration may be the preferred treatment [9, 10, 12]. This material covers and seals the dentin tubules, providing a protective layer where the cementum has worn away. However, resin-modified glass ionomer restorations do not always reduce or diminish the tooth pain because the chemical makeup of resin-modified glass ionomers themselves may trigger tooth irritation through an inflammatory response in the pulp [13]. Therefore, it is important to evaluate new dental materials that may be more effective in treating the pain associated with tooth sensitivity with fewer negative sequelae. A new biocompatible and bioactive material (Biodentine™) is available. Biodentine™ has a wide range of clinical applications because of its similarity to the dentin and its mechanisms of dentin adherence. Furthermore, Biodentine™ has been successfully used as a safe dentin substitute in clinical studies[14]. However, the effect of Biodentine™ to reduce tooth pain in V shaped lesions is unknown.

We propose to investigate the effect of Biodentine™ as a restorative dental material on V shaped lesions with a randomized single blind controlled study. Specifically, we will investigate how Biodentine™ treatment affects oral health related quality of life. Because Biodentine™ is a biocompatible and a bioactive material, which is considered a dentin substitute material, we hypothesize that Biodentine™ is a more effective way of treating tooth pain associated with V shaped lesions compared to traditional resin-modified glass ionomer restorations. To evaluate the effects of Biodentine™ as a dental restorative material, we will compare the treatment with Biodentine™ to the resin modified glass ionomer, which is a dental material widely used to restore V shaped lesions. In addition, we will evaluate the impact on oral health via patient self-reporting of pain and daily activities with an oral health related quality of life questionnaire before and after treatment at multiple time points.

Specific Aims (SA):

SA1: Investigate whether Biodentine™ is more effective compared to resin-modified glass ionomer in reducing tooth pain in V shaped lesions

SA 2: Investigate whether Biodentine™ is more effective compared to glass resin-modified ionomer in improving general oral health-related quality of life in patients with V shaped lesions.

In the mission of the PORT grant, these data will help identify a new material to effectively treat patients suffering from tooth pain in V shaped lesions, which may lead to improve oral health related quality of life.

RESEARCH STRATEGY

Significance

Pain associated with tooth sensitivity is highly prevalent among the US adult population [1]. Considering the adult population, women and men aged 30-40 years old are both affected by tooth sensitivity and women tend to show a slightly higher prevalence than men. In addition, as the population ages, tooth sensitivity is frequently caused by V shaped lesions and by intensified brushing activity after gum disease [2, 15]. Despite the large number of affected individuals with tooth sensitivity associated pain [16, 17], the impact of tooth pain from V shaped lesions in the oral health related quality of life (OHRQL) is still unknown. Surprisingly, no evidence-based guidelines to treat tooth pain from V shaped lesions exist and the condition is merely managed with two basic approaches without any concern for OHRQL outcomes [18]. The first approach uses chemical agents to temporarily reduce tooth pain by plugging dentin tubules[19]. The second approach uses the placement of a dental restoration. However, both approaches are not always effective and require periodic reevaluations. In addition, the majority of studies evaluating tooth pain related to V shaped lesions did not assess the psychological component of pain from these lesions [20, 21]. There is a current gap in knowledge characterizing the patient OHRQL in individuals suffering from pain in V shaped lesions before and after treatment. Consequently, the assessment of OHRQL in affected patients may help identify better treatment strategies. Furthermore, it is difficult to estimate the impact of tooth pain in the patients' quality of life because many patients fail to inform their clinician of sensitivity issues they experience [22]. Therefore, this study expects to contribute to the knowledge of the impact of tooth pain associated with V shaped lesions in OHRQL.

Given the restraints of the current approaches to treat tooth pain on OHRQL, our study proposes to investigate the impact of tooth pain associated with V shaped lesions with a widely used OHRQL questionnaire, the Oral Health Impact Profile-49 (OHIP-49). The OHIP-49 questionnaire has been extensively validated to evaluate the impacts of oral health in people's ability to function psycho-socially in regards to dental health and perceived health prior to treatment and at multiple time points after treatment [23]. Lastly, in summary, our study will contribute to the knowledge of the treatment of V shaped sensitive lesions and will assess the impact of tooth pain in the quality of life before and after treatment on V shaped lesions.

Innovation

Despite the millions of patients suffering from tooth sensitivity, a treatment that effectively eliminates tooth pain associated with V shaped lesions near the gumline does not exist. More importantly, dental materials in the market are highly sensitive to placement under damp conditions. Placing restorations near the gum tissue, which is the primary location for the V shaped lesions, poses a challenge even for a talented clinician. The main reason for failure of dental restorations is contamination from saliva, which results in microleakage at the margins of the restoration. This leakage can cause fluctuations in the fluid in the dentin tubules and leads to pain, even when the restoration is present. Moreover, some of the materials placed in these lesions can cause an increased inflammatory response because they are placed on the dentin which contains tubules that lead directly to the pulp (Fig. 1) and cause more irritation in the pulp and perceived pain [24].

Therefore, this study is innovative because it proposes to evaluate a new bioactive and biocompatible dental material as it relates to diminishing tooth pain. More specifically, our study includes four important innovative aspects: 1) Biodentine™ is biocompatible and bioactive, which may suppress inflammatory pulp responses and promote better marginal seal [25-28]; 2) Biodentine™ relies on the presence of biofluids to form hydroxyapatite crystals [24] [25]; 3) Biodentine™ derived hydroxyapatite crystals (naturally present in the tooth structure) may result in more long-lasting effects on tooth pain [29]. More importantly, 4) we propose to evaluate the impact of V shaped lesions associated tooth pain in our patients' quality of life before and after the proposed alternative treatments.

The lack of guidelines to treat tooth pain associated with V shaped lesions is an important area of study [30, 31]. In addition, despite the many treatments used by clinicians to treat pain in V shaped lesions there is little evidence of their effectiveness [27]. The results of our study will provide evidence to fulfill an enormous lack of

knowledge in the dentistry, which will ultimately help clinicians make appropriate treatment decisions to treat tooth pain associated with V shaped lesions. More importantly our study may contribute to the knowledge of the impact of pain associated with V shaped lesions in the patients' overall quality of life.

Approach

Study Design

The proposed study is a two-year single blind study with blinded assessors to evaluate participant responses about chronic pain from V shaped tooth lesions. The participants will be recruited from the University of Michigan School of Dentistry and will be treated with a traditional dental material and with a new dental material. Participants will fill out screening questions to determine eligibility. Once enrolled they will either receive the traditional treatment for a sensitive V shaped lesion or will be treated with the new material Biodentine™. Participants will be evaluated prior to treatment and post treatment at 1 week, 2 weeks, and 3 months to determine the effects of the two different treatment modalities on OHRQL.

Table 1. Study Inclusion and Exclusion Criteria

Inclusion Criteria
• Males and females age 18-64 • Chief complaint associated with pain from cold or hot • Chronic sensitivity associated with supragingival lesions • Pain not associated with decay • Fluent in English and able to read English at a 6th grade level • Pulpal response <40 via pulp tester • Active salivary flow from palpation of parotid and submandibular glands • Patients self reporting pain over 6/10 in the past week and/or the past 2 months
Exclusion Criteria
• Pregnant women • Patients taking benzodiazepines, narcotics and multiple antidepressants for pain management not associated with the oral cavity • Unexplained xerostomia • Patients taking two or more medications associated with dry mouth • Pulpal response >40 via pulp tester • Patients requiring treatment for more than 5 decayed sites, periodontal disease and root canal therapy • Complicated medical history (>4 concurrent treatment for systemic diseases) • Lesion >1mm below the gumline

Participants

Men and women from the ages of 18-64 years old will be recruited from the University of Michigan School of Dentistry because of their prevalence of pain associated with V shaped lesions. Additionally, the study will be capped at the age of 64 because of the pathologic changes occurring within the pulp due to the natural aging of a tooth by the addition of secondary dentin within the pulp. This can lead to inconclusive pulp testing results in older individuals [15, 32]. Participants enrolled will be limited to those whose chief complaint is chronic tooth pain associated with V shaped lesions and that the lesion is non-carious and located near or at the gumline (Table 1). Participants will be on limited medications to avoid the effects of polypharmacy, more specifically the effects on reducing saliva flow which enhances the risk for caries development. The affected teeth will have the pulp vitality evaluated with an electronic pulp tester, which is a device that can assess the vitality of the tooth with a quantifiable number. Pulp test readings must be below 40 to be considered for the study. Participants will also be asked what their average pain is when the tooth pain is triggered and must register over a 6 point in the self-report brief pain inventory index for each question asked to the patient. All participants will have tooth-associated pain for more than 2 months to meet inclusion criteria. Both of these short assessments will be measured on a 1-10 Likert scale. See Table 1 for inclusions and exclusions. If a participant has two or more teeth in the associated quadrant that have associated chronic pain, we will fill up to two sites that are innervated by the same nerve. Participants must be fluent in English in order to fill out the surveys and have at home access to a computer or the ability to come to the school of dentistry to fill out the survey on a supplied iPad®.

Participants will be excluded from the study if their dental health requires treatment from multiple disciplines of dentistry, including endodontics (root canals) and periodontics (active periodontal disease). Participants with extensive systemic health problems will also be excluded. Participants with low saliva flow (Xerostomia) will be excluded – typically if the participant is on more than 2 medications that reduce salivary flow. The baseline

evaluation for salivary flow will be milking of the parotid gland and submandibular glands to evaluate flow. We will need to visualize the induction of salivary flow with physical stimulation for inclusion. Patient reported mouth dryness will be considered as an exclusion criteria. Pregnant women will also be excluded from the study. Participants suffering from chronic pain in other areas of the body and participants with prescription of narcotics to treat pain on a regular basis will be excluded because these characteristics may alter that data on pain associated from a V shaped lesion. Lesions that extend more than 1mm below the gumline will be excluded.

Study procedures

Participants will be recruited via flyers at the University of Michigan School of Dentistry and from emails of the flyer to the student providers operating in the dental undergraduate clinics. Participants will be initially screened in the undergraduate clinics by updating participants health history, completion of an exam, dental cleaning and by answering five questions from the Brief Pain Index about pain in the last 24 hours, week and month and right now. It is the standard of care the UMSoD for all patients to have a current exam and up to date cleaning. Exams and cleanings are not part of our study but must be up to date (within the past six months or year based on the recommendations of the American Dental Association and UMSoD protocol) in order for participants to take the 5 question pre-screen test modified from the Brief Pain Index. The 5 questions are: 1) Do you have any tooth pain? 2) Rate this pain at its worst over the past week. 3) Does this pain originate near the ditch in your tooth near the gum line? 4) Does this pain occur when you eat or drink something cold, like cold water or ice cream? 5) Can you point to the area that causes you the most pain? This pre-screen questionnaire will allow us to check participants prior to the enrollment process because of the large numbers of patients seen at the school and ensure that patient's dental oral health is being adequately addressed based on the guidelines of the UMSoD prior to enrollment in the study.

Once participants show interest in the study and meet the criteria in the pre-screening step, the participants will be then screened for inclusion and exclusion in the study with assessment of the Oral Health Impact Profile-49 (OHIP-49) and complete the pain assessment modified from brief pain inventory (BPI) to assess oral pain. The OHIP-49 questionnaire was selected due to its validation in oral health research in multiple population groups as well as evaluating the general oral health knowledge in participants[33]. Participants will also assess their level of pain on a specific tooth when pain is triggered with numerical pain scale based on questions relating to oral health modified from the BPI (See above for questions). This scale is highly validated in multiple age groups when assessing pain [34]. Because it is challenging to recapitulate tooth pain in a dental setting, we will use the scale based on triggers the participants experience in daily life from a modified BPI. Lastly, at every time point after the first appointment, we will include an additional survey- Patient's global impression of change (PGIC) scale. This measure has been highly validated in intervention studies and will add an extra evaluation of patient observed changed after the intervention.

Study Team

Study team personal that will conduct the initial screening for eligibility and complete the restoration will include the PIs, Elizabeth Van Tubergen and Elisabeta Karl and trained third year and fourth year dental students at the University of Michigan School of Dentistry. Blinded assessors will be different third and fourth year students that will be trained on how to implement the study. The dental students will be selected from students enrolled in the Health Advocacy arm of the Pathways program at the UMSoD, which is a graduation requirement. Typically students must show interest in a project prior to selecting a project. Research monies are also associated with each student of $500 to support the research project. We anticipate 2-4 dental students to be involved in the PORT clinical study, but they have not been identified at this time.

Study Procedures

Once enrolled, the participants will be randomly assigned to control or treatment group. The control group participants will receive the gold standard treatment for V shaped lesions - a resin modified glass ionomer (Photac-fil®). Treatment group participants will receive their V shaped lesion restoration with Biodentine™. When they receive the restoration, all treatments will follow the standard of care for their placement and polishing at the UMSoD. Participants will be assigned a random number to identify them and will be blinded as to which treatment they will receive. Participants will fill out the same OHIP-49 and BPI questionnaire via a

survey link at 1 week, 2 weeks, and 3 months post treatment. If participants complete the survey, they will receive a monetary compensation of $10 dollars/group of surveys completed for a potential of $40 dollars to ensure participant compliance with the survey. Surveys will be completed at recall appointments on a secure survey system maintained by the UM medical school, REDCap and data will be stored on REDCap and backed-up to a secured University of Michigan Server. Expert assessors collecting patient information will be blinded as to the treatment the participant receives. At 3 months, the patients will receive a follow up evaluation of the filling, and an evaluation of the restoration placed at the V shaped lesion. Table 1 gives a visual breakdown of the study design. The restorative materials used in this study will be placed following manufacturer's instructions.

Table 2: Study Design

Timeline	Control Group (group size: 20) Study enrollment **assigned random number**	Treatment Group (group size: 20) Study enrollment **assigned random number**
Prescreen	Oral exam, dental prophylaxis, (Part of standard of care at UMSoD) pre-screen questionnaires modified from BPI	Oral exam, dental prophylaxis, (Part of standard of care at UMSoD) pre-screen questionnaire modified from BPI
Day 1 – Baseline	OHIP-49 BPI questionnaire	OHIP-49 BPI questionnaire
Day 1 - Baseline	Treatment: PHOTACFIL®	Treatment: BIODENTINE™
Week 1 - Follow-up (survey will be emailed and should be completed within 7 days)	OHIP-49 BPI questionnaire PGIC Scale	OHIP-49 BPI questionnaire PGIC Scale
Week 2 - Follow-up (survey will be emailed and should be completed within 7 days)	OHIP-49 BPI questionnaire PGIC Scale	OHIP-49 BPI questionnaire PGIC Scale
3 months (+/- three weeks)- Follow-up	OHIP-49 BPI questionnaire PGIC Scale Rationale: We expect an immediate elimination of pain but the impact on OHRQL will be more quantifiable if assessed over time.	OHIP-49 BPI questionnaire PGIC Scale Rationale: We expect an immediate elimination of pain but the impact on OHRQL will be more quantifiable if assessed over time.

Data Collection Procedures

Initially patients will be consented for enrollment and treatment in the study. Data for the clinical study will be collected multiple times during the study including prior to treatment, and 1 week, 2 weeks, and 3 months post treatment. Patients will receive an OHIP-49 questionnaire and a modified BPI and the third survey (PGIC scale) to relate to overall oral health via electronic emails. The surveys will be emailed to the participants via a secure survey source (REDCap) and completed electronically by the participants after their initial visit for the restoration placement. Patients will have 7 days to complete the email surveys and email reminders will be sent daily until the surveys are completed. If patients are unable to complete an emailed survey, they have the opportunity to return to the school to complete the surveys. The UMSoD has a supply of iPads® available for research purposes and will be used to collect data at the initial enrollment and if patients come to the school to fill out follow up surveys. There will be a 3-week window for subjects to return to the school for the 3-month follow-up visit.

Data management

All scanned data that goes to a digital form and acquired digital data will be kept on a secure server at the University of Michigan School of Dentistry that is password protected. A secure patient treatment record will be created with the patients assigned participant number, all paper materials returned from patients and participant consent materials will be kept in a locked cabinet in a locked office at the University of Michigan School of Dentistry..

Statistical Analysis Plan

Prior to testing primary study aims, we will examine data distribution characteristics to identify outliers and determine suitability of the data for parametric testing. Bivariate correlations will be conducted to identify important covariates for inclusion in main statistical models (e.g. age). Assuming underlying assumptions are met, we will use repeated measures of general linear models (GLM) to test for significant differences between the control and treatment groups in terms of changes in pain (specific aim 1) and oral health related quality of life (specific aim 2) over the course of the study. Significant group versus time effects will be examined graphically to determine the nature of the interaction and to qualify how pain and oral health related quality of life changed over time for each group.

Power Analyses

Currently, we do not have input data available to do an adequate sample size analysis or the study. For this small pilot study, we planned for a sample of 40 participants (20 subjects in control group and 20 in the experimental group) to generate some preliminary data for conducting a rigorous sample size analysis for a larger clinical trial

Potential Problems and Alternatives Strategies

In the event that we do not recruit enough patients to fulfill project timeline, we can recruit patients from the graduate clinic at the University of Michigan School of Dentistry and the emergency clinics.

In the event that either the control or treatment restoration falls off we will offer to replace the restoration and we will continue the measurement procedures. Due to the locations of the class V lesions, the stresses of the restoration during mastication may promote debonding of the restorations however, Biodentine has an increased risk of debonding. According to the manufacturer, Biodentine bonds well with dentin; however, no studies exist evaluating its bond strength in class V cervical lesions. If the Biodentine debonds, we will place a base layer of Biodentine to cover and seal the dentin and place Photac-fil® over top of that for added retention. This will allow Biodentine to remain in contact with the dentin but be more retentive. If a Biodentine restoration is placed in a shallow lesion that does not have a lot of natural retention, we will automatically place a Biodentine layer that is covered by Photac-fil®. Loss of restorative material will be covered under the grant for up to six months after initial placement of the restoration and will be noted in the patients record. If a participant has a restoration replaced, a new time line will be started for post-treatment evaluations just like a newly placed restoration. Additionally, Biodentine™ is not offered in multiple shades and patients may request that it is covered with a more esthetic restoration after the study is completed at the University of Michigan School of Dentistry (UMSoD).

Project feasibility

The undergraduate clinics have over 5,000 male and female patient visits per month for treatment of patients aged between18-60. New patients are screened daily at the school and are continuously added to the patient population at the UMSoD. We plan to recruit from the dental undergraduate clinic. While we do not foresee enrollment issues, we can also access over 3,000 more patients in other clinics at the UMSoD by including the graduate clinics and faculty clinic. Given the high numbers of patients seen at the school of dentistry, we do not anticipate any difficulties in recruiting patients to meet enrollment numbers for the study.

Project Management and Project Timeline

The project principal investigator is Dr. Elizabeth Van Tubergen and co-investigator is Dr. Elisabeta Karl. We will train and calibrate dental students to apply the materials as well as collect participant assessments as

blinded assessors that are part of the Health Advocacy Pathway for their education. Andrea Frantz will be the study coordinator, and a graduate resident will assist with the students, which will be identified at a later date.

Table 3 estimates the project time line.

Table 3: Project Timeline

Comprehensive Activities	2017				2018			
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
Project approval	X	X						
IRB approval		X	X					
Pre-screening/Recruitment			X	X	X	X		
Enrollment (#)			10	10	10	10		
Intervention			X	X	X	X	X	
Data Collection			X	X	X	X	X	X
Manuscript completion								X

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PROTECTION OF HUMAN SUBJECTS

1. Risks to Human Subjects

1.1. Human Subjects Involvement, Characteristics and Design. Participants in this study will be healthy male and female volunteers, current patients at the University of Michigan health system and aged 18-64 years. The population to be studied will receive a free restorative treatment in the area associated with chronic pain. The recruitment will be made by the use of flyers and emails to undergraduate dental students at the University of Michigan school of Dentistry (UMSoD). Subjects will be required to meet the following selection criteria: (1) male and female patients between 18 to 64 years old; (2) Patients whose only and chief complaint is tooth sensitivity (pain) associated with V shaped sensitivity non-carious lesions and (3) patients with limited polypharmacy and no significant medical history. Please see Table 1 for all inclusions.

1.2. Sources of Materials

1.3. Data collection methods. The data obtained will be used specifically for research purposes, including: a modified Brief Pain Inventory (BPI) to reflect oral pain, OHIP-49 questionnaire and the Patient Global Impression of Change (PGIC) Scale identified only by the enrollment number that will be given to the patients. Participants will take the BPI, OHIP-49 at their first appointment, one week later, 2 weeks after the placement of the restoration and 3 months after the placement of the restoration. The PGIC survey will be given in addition to the other surveys one week after the placement of the restoration, 2 weeks after the placement of the restoration and 3 months after the placement of the restoration. Surveys will be generated on REDCap and emailed to participants to complete the survey. Daily email reminders to complete the surveys will continue until the surveys are completed.

1.4. Potential risks. Overall, potential risks associated with the participation in the study are low risk. The proposed treatments, more specifically the dental restorations, will not involve either a tooth preparation.

1.4.1. Physical. There is little likelihood of any physical risk as a result of participation in this research project. The participants will be not exposed to any physical harm. The study will be conduct at the UMSoD clinics in appropriated dental settings.

1.4.1.1 Management. Also, given the pain the patients may experience prior to the placement of the restorative material, patients may require local anesthetic during the application and finishing of the restoration. Topical anesthetic will be first applied to the gingiva and if necessary, patients may receive a carpule of 2% lidocaine HCl containing 1:100,000 epinephrine which is the standard anesthetic used in patients at the University of Michigan School of Dentistry to manage pain. The use of the local anesthesia will be limited to two carpules, 3.6ccs. This dosage is well tolerated and within the dosing considerations for patients with some associated risks with epinephrine. This amount of local anesthesia is also considered the standard of care at UMSoD. Participants will understand the minor discomfort that can be associated with EPT testing and palpation of the salivary glands.

1.4.2. Psychological. Participants will be asked to provide information about their self-reported pain associated with tooth sensitivity and to answer the OHIP-49 questionnaire, BPI survey and PGIC survey. These questions have a small likelihood of low psychological risk. If participants demonstrate to be uncomfortable or emotionally disturbed by the questionnaires, they will be reminded that there is absolutely no obligation to fulfill the questionnaires. In these cases, the patients will still receive the dental care proposed in this study.

2. Protection Against Risks

2.1. Recruitment and informed consent. For recruitment, we will distribute flyers at the UMSoD and we will send emails to the dental students (dental providers) about information on the study. Volunteers who are

interested in an alternative treatment for tooth sensitivity will be examined per the guidelines of the UMSoD, informed about the study and take a pre-screen questionnaire. After selecting the volunteers under the inclusion and exclusion criteria, patients will receive a random number at the study enrollment session. From this point on, we will only identify the patients by the given enrollment random number and age. A well-trained team of third and fourth-year dental students will deliver the dental care including the restorations in the Foundations Clinic at the UMSoD and will be supervised by Dr. Karl and Dr. Van Tubergen. The dental care treatments proposed in this study are part of the second year dental students competency requirement. We strongly believe that the third and fourth year dental students are entirely competent to delivery such treatments based on the competencies they passed in their first and second years of their dental training. A second team of dental students that are blinded to the treatment will collect and analyze the data at the designated time points. Prior to conducting any treatment and assessing the self-perceived outcomes, all participants will be given a formal Statement of Consent Form to read. The interviewer will verbally explain the form by the following study team members: Dr. Karl or Dr. Van Tubergen and the study coordinator, Andrea Frantz, if necessary. Participants will sign the form indicating that they understand that they are being asked to participate in a research study, that they understand the risks involved in participating, that they can refuse to answer any question that they are not comfortable with, and that the information they provide will be kept strictly confidential. The informed consent form will also provide assurances that their participation in the research aspect of this project will in no way affect their patient status either positively or negatively.

2.2. Protection against risks

2.2.1. Minimizing physical and psychological risks. Participants are free to refuse to respond to any question that may result in psychological disturbance. Written information collected is for research purposes only and will not become part of their personnel chart records. Individual responses to our questionnaires will not be linked to identifying information, except for age, and will not at all influence current or future delivery of dental care at the UMSoD. These precautions are expected to effectively eliminate risks associated with the study participation. Management of complications of epinephrine and systemic medications, such as propranolol, will be mitigated by allowing participants to receive a maximum of two carpules of 2% lidocaine HCl containing 1:100,000 of epinephrine which is well within the recommended dose for epinephrine and patients with cardiovascular complications.

2.2.2. Minimizing risks to confidentiality. Identifying information from any of the participants in the study will be kept separately from the forms on which they record their responses to the questions. The participants identifying information will be safely stored at the University of Michigan Mident Axium system as any other patient assisted at the UMSoD. Records will be linked to individuals only through the enrollment number and the information used to link records with identifying information will be kept in a securely file drawer in a locked room only accessible to project principal investigators. Names and any other identifying information collected will be kept in a locked file drawer in a locked room only accessible to the project principal investigators and study coordinator. References to names or other identifying information will be eliminated from the written transcript of the interview in preparation for analysis of qualitative data. Names and any other identifying information will be eliminated in preparation for analysis of these records. These are precautions that we expect to be completely effective in eliminating risks to confidentiality. Email identifiers in the surveys will also be eliminated during analysis of the study.

3.Potential Benefits

The benefits to the participant are that they will receive at least one free dental restoration, which will potentially reduce or eliminate the tooth sensitivity associated pain. Furthermore, all other patients suffering from tooth pain may also benefit from an alternative, long-lasting and effective solution for tooth pain associated with V shaped lesions. Participants will also be compensated monetarily for the time after completing of each survey time point.

4. Gained Knowledge.

The information gained in this study may improve the treatment and the management of tooth-sensitivity associated dental pain. Additionally, the information gained with this research will specifically enhance the

knowledge of the impact of tooth pain associated with V shaped lesions and patients' oral health related quality of life.

5.Inclusion of Women and Minorities

We anticipate that the participants in this study will come from all counties in Michigan. The participants in this study will be men and women. We expect a very diverse population of Latinos, African-Americans, and Asians in our study as well. The UMSoD receives daily a very diverse population of patients, with different social-economical backgrounds as well. The participants in this study are likely to follow the diverse population of the UMSoD.