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

NCT03304184

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INSTRUCTIONS FOR EDITING THIS DOCUMENT

1. Turn on Track Changes.
2. Make necessary changes in consent, and update the footer intended for study team version control.
3. Upload the revised consent into Section 10-1, maintaining the IRBMED standard naming convention as follows:
   - **Consent - Tracked**
   - **Consent -** *Concise Subtitle* **– Tracked** (provide a subtitle when there are multiple consents associated with the study)
   - **Assent - Tracked**
   - **Parental Permission/Assent - Tracked**
   - **Parental Permission – Tracked**

NOTES:
Words identified above in bold must not be changed; words identified in italics may be modified by the study team. Informed consent subtitles should be a one or two word descriptor, such as**:** **Consent – *Genetic* – Tracked** or **Consent – *Blood Draw* - Tracked**.

Each subsequent track changes version should be stacked on the previously uploaded track changes version.

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DO NOT upload a clean version of the consent**.**

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UNIVERSITY OF MICHIGAN
CONSENT TO BE PART OF A RESEARCH STUDY

INFORMATION ABOUT THIS FORM

You may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of the study, and the risks and possible benefits of participating in the study.

Please take time to review this information carefully. After you have finished, you should talk to the researchers about the study and ask them any questions you have. You may also wish to talk to others (for example, your friends, family, or other doctors) about your participation in this study. If you decide to take part in the study, you will be asked to sign this form. Before you sign this form, be sure you understand what the study is about, including the risks and possible benefits to you.

1. GENERAL INFORMATION ABOUT THIS STUDY AND THE RESEARCHERS

1.1 Study title: The role of Biodentine in Class V dental lesions on oral health related quality of life

1.2 Company or agency sponsoring the study:
Funding for this study is provided by the Michigan Institute for Clinical Health Research (MICHR) and the department of Cariology, Restorative Sciences & Endodontics and School of Dentistry.

1.3 Names, degrees, and affiliations of the principal investigator and study coordinator (if applicable):
Principal Investigator: Elizabeth Van Tubergen DDS, PhD, Department of Cariology, Research Sciences & Endodontics, University of Michigan
Study Coordinator: Andrea Frantz, RDH, BSDH, CCRP, Office of Research – Human and Clinical Research Center

2. PURPOSE OF THIS STUDY

2.1 Study purpose:
Tooth pain can occur even when you don't have tooth decay. Aggressive tooth brushing can expose nerves by removing tooth structure leading to chronic pain. These lesions are typically found near the gumline. Because of their location, size and shape, some dental fillings do not always work to eliminate the pain. In this study, we want to compare the dental material, Biodentine, to a different dental material, Photac-fil, in dental lesions located near the gumline. Tooth pain can really affect your quality of life. In this study, we also want to know how much your tooth pain affects your daily life and how the different dental materials alter your oral health related quality of life.

3. INFORMATION ABOUT STUDY PARTICIPANTS (SUBJECTS)

Taking part in this study is completely **voluntary**. You do not have to participate if you don't want to. You may also leave the study at any time. If you leave the study before it is finished, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Taking part in this study will not affect your status as a dental patient in any way, positively or negatively. If you have any questions about it, please contact the principal investigator, Dr. Van Tubergen, and co-Investigator, Dr. Karl.

3.1 Who can take part in this study?

Inclusion Criteria
• Males and females age 18-64 • Chief complaint associated with pain from cold or hot • Chronic sensitivity associated with cavities above the gumline • Pain not associated with decay • Fluent in English reading and writing • Healthy teeth • Good saliva flow
Exclusion Criteria
• Pregnant women • Taking benzodiazepines, narcotics and multiple antidepressants for pain management not associated with your mouth • Taking two or more medications associated with dry mouth • Requiring other treatment • Medically compromised

3.2 How many people (subjects) are expected to take part in this study?

Forty (40) subjects are expected to participate in the study from the University of Michigan School of Dentistry that have chronic tooth pain associated with a lesion found near the gumline that typically occurs from aggressive tooth brushing.

4. INFORMATION ABOUT STUDY PARTICIPATION

4.1 What will happen to me in this study?

If you agree to take part in this study, you will be randomly selected to have one of the two dental materials placed by the research team (a filling). In both cases, the research team will place a filling in the tooth area that is causing you pain. You will be offered an application of topical anesthetic near the gumline and if needed, you may receive anesthetic to numb the tooth and surrounding gum tissue. The restoration will be placed and polished to make it smooth. The details of the study will be described below in more detail.

Prior to the placement of the restoration, we will evaluate how healthy the tooth is with the use of an electronic tooth tester (EPT). The tooth must be healthy to be accepted in to the study. The EPT is the standard of care in dentistry to determine tooth health. During the procedure, toothpaste will be covering the EPT wand tip and a metal U ring will hang from your lip. The wand and the U ring allow the machine to send a low stimulus to the tooth. The current may cause mild and temporary discomfort. We will record the lowest amount of stimulus needed to get a response from the tooth to minimize discomfort. The level at which you respond to the stimulus lets the team know if the tooth is healthy enough for the study.

Salivary flow will be tested at the initial appointment. We want to determine if you have salivary flow that can be stimulated by touch of individual salivary glands. Team members will rub the side of your cheek to activate a salivary gland in the check (the paratoid gland) and will massage underneath your lower jaw to stimulate the glands underneath the floor of the mouth (submandibular glands). Team members will be looking to see if we are able to stimulate flow of saliva with minor massaging. Discomfort, if any, should be minimal during this procedure and temporary.

During the study, we will need you to come to the dental school at least two times and fill out two or three surveys four different times. At the first appointment when you receive the filling, you will complete two surveys. One week later, you will receive an email containing a website survey link to complete three surveys. Two weeks

later after the placement of the filling, you will receive another email containing a website survey to complete three more surveys. Finally 3-months (+/- 3 weeks) after the placement of the filling, we will check your filling at the dental school and you will be asked to complete 3 more surveys. If you do not have access to the Internet, you will be able to return to the dental school to take the surveys at the proper time points at 1 week and 2 weeks after the placement of the filling. The emailed surveys should be completed 7 days after the initial email link is received. You will receive a daily email reminder to complete the surveys until they are completed.

In order to protect the outcomes of the study, you will not be told what dental material you receive during the study. The two materials that you could randomly be assigned to restore the area that is experiencing sensitivity are Photac-fil and Biodentine. Photac-fil is commonly used in dental treatment for the dental lesions in this study. It is tooth colored and is filled with a glass (silicate) type material that is supported with resin that is safe to use in the mouth. It can be manipulated to fit the contours of the dental lesion. Biodentine is a dentin substitute and it is white in color. The material is composed of a mixture of calcium, glass and other materials (calcium-silicate). It also can be moved to fit the contours of the dental lesion. There is an increased chance that the Biodentine fillings may fall out during normal chewing compared to Photac-fil. If this does happen then you will return to the dental school to have the filling replaced and covered with Photac-fil. If you are not satisfied with the color of the Biodentine restoration, the investigators will correct the shade at the end of the study period (3 months) by adding a layer of another material or replacing the filling with another material. This would require an additional visit to the dental school.

During the placement of the restoration, we will either place a jelly like material near the gumline that will numb the gum tissue or you will be offered local anesthesia that will be given to you by an injection with a needle. You should be very comfortable during the placement of the restoration. Next the area will be rinsed and dried with some water and some puffs of air. The assigned material will be applied with metal instruments and shaped into the defect on the tooth. The material will be allowed to cure (set) with either time or with a machine that produces a blue light that causes the material to set. Once completed, the restoration will be smoothed with a dental drill that can refine and polish the surface of the filling.

4.2 How much of my time will be needed to take part in this study?
You will need to come to the dental school two times during the study. At the first appointment, we will need 3 hours of your time where you will receive the filling and complete two surveys. At the second visit to the dental school, we will need one hour of your time where the research team will evaluate the filling and you will complete three surveys. The 2 groups of 3 surveys sent via email will take less than 30 minutes to complete. You will be able to complete them anywhere that you can get access to the internet and email. You may elect to return to the dental school to complete some or all of the surveys, and you will need less than 1 hour to complete each group of surveys at 1 week and 2 week time points. The team will provide an iPad to complete the surveys on these visits. If you lose the filling material in your tooth, additional visits will be necessary to replace the filling

4.3 When will my participation in the study be over?
If you decide to enroll in this study, your involvement will last about 15 weeks (3 months) for a single subject. Time enrolled in the study may lengthen if the restoration needs to be replaced during the study time period.

4.4 What will happen with my information and/or biospecimens used in this study?
With appropriate permissions, your biospecimens and collected information may also be shared with other researchers, here, around the world, and with companies.

Your identifiable private information or identifiable biospecimens may be stripped of identifiers and used for future research studies or distributed to another researcher for future research studies without additional informed consent.

5. INFORMATION ABOUT RISKS AND BENEFITS

5.1 What risks will I face by taking part in the study? What will the researchers do to protect me against these risks?

There are minimal risks associated with this research. The following risks will be described below.
The risks associated with the study are the possibility of minor discomfort after the procedure near the gumline, general inconveniences of coming to the dental school for treatment or risk to confidentiality. Both of the materials selected for the study are safe to use in the mouth. Patients will be randomly assigned to the test group and could have a filling that may not perfectly match the existing tooth structure as well as other dental materials do. Both groups have a risk of the filling falling out but, if you are assigned to the test group, there has been an increase of the filling material falling out in some people. If this happens you will return to the dental school to have it replace and the material will be covered with Photac-fil for the test group and replaced for the control group. Use of the electronic pulp testing (EPT-to check tooth health) uses an electric stimulus to determine if the tooth is healthy. Its application to the tooth may cause minor discomfort to the tooth that is temporary and brief.

If you elect to have an injection for anesthesia, you can expect mild discomfort at the site of the injection immediately during the injection and potentially for 1-3 days after the injection.

The researchers will try to minimize these risks by being very cautious during the finishing and polishing of the restoration near the gumline. The research team will also try to coordinate appointments that work best with your schedule. The team will also protect confidentiality by using secure storage material for all data collected. As in any research study, there may be additional risks that are unknown or unexpected. If have any questions or concern about the involved risks please ask the principal investigators.

5.2 What happens if I get hurt, become sick, or have other problems as a result of this research?

The researchers have taken steps to minimize the risks of this study. Even so, you may still have problems or side effects, even when the researchers are careful to avoid them. Please tell the researchers listed in Section 10 about any injuries, side effects, or other problems that you have during this study. You should also tell your regular doctors about your involvement in the study**.**

5.3 If I take part in this study, can I also participate in other studies?

Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study.

5.4 How could I benefit if I take part in this study? How could others benefit?

You may not receive any personal benefits from being in this study. This research may help us to understand how oral health related quality of life could be altered by the placement of different dental materials. You may see your quality of life improving by eliminating the pain associated with the previous painful area near your gumline, which will be restored during this study.

5.5 Will the researchers tell me if they learn of new information that could change my willingness to stay in this study?

Yes, the researchers will tell you if they learn any important or new information that may change your willingness to stay in this study. If new information is provided to you after you have joined the study, it is possible that you may be asked to sign a new consent form that includes the new information.

6. OTHER OPTIONS

6.1 If I decide not to take part in this study, what other options do I have?

If you choose not to take part in the study, you can continue to see a dental practitioner at the University of Michigan School of Dentistry, dental school. You can also see another dentist outside the dental school to try to alleviate your symptoms associated with the dental lesion.

7. ENDING THE STUDY

7.1 If I want to stop participating in the study, what should I do?

You are free to leave the study at any time. If you leave the study before it is finished, there will be no penalty to you. You will not lose any benefits to which you may otherwise be entitled. If you choose to tell the researchers why you are leaving the study, your reasons for leaving may be kept as part of the study record. If you decide to leave the study before it is finished, please tell one of the persons listed in Section 10 "Contact Information" (below).

The researchers may decide to stop your participation without your permission, if he or she thinks that being in the study may cause you harm and that the dental material is not adhering to the location of the dental lesion.

7.2 Could there be any harm to me if I decide to leave the study before it is finished?

If you elect to leave the study or terminate your participation in the study, there are no known associated dangers. However, you should be aware that you would be responsible for replacing the restoration if it falls out after the 3-month post-evaluation period.

7.3 Could the researchers take me out of the study even if I want to continue to participate?

Yes. There are many reasons why the researchers may need to end your participation in the study. Some examples are:

- ✓ The researcher believes that it is not in your best interest to stay in the study.
- ✓ You become ineligible to participate.
- ✓ Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- ✓ You do not follow instructions from the researchers.
- ✓ The study is suspended or canceled.

8. FINANCIAL INFORMATION

8.1 Who will pay for the costs of the study? Will I or my health plan be billed for any costs of the study?

There are no costs or billing for this study. The study will pay for research-related items or services that are provided only because you are in the study. If you are not sure what these are, see Section 4.1 above or ask the researchers for a list. If you get a bill you think is wrong, call the researchers' number listed in section 10.1.

You or your health plan will pay for all the things you would have paid for even if you were not in the study, like:

- Health care given during the study as part of your regular care
- Items or services needed to give you study drugs or devices
- Monitoring for side effects or other problems
- Deductibles or co-pays for these items or services.

If you do not have a health plan, or if you think your health plan may not cover these costs during the study, please talk to the researchers listed in Section 10 below or call your health plan's medical reviewer.

By signing this form, you do not give up your right to seek payment if you are harmed as a result of being in this study.

8.2 Will I be paid or given anything for taking part in this study?
You will be eligible to receive compensation of US$10.00 for each group of surveys completed. Surveys can be completed after they are sent to an email address that you provided to the research team and/or completed at the dental school if you do not have access to the internet. The total amount of compensation you may receive is US$40.00 during participation in this study.

8.3 Who could profit or financially benefit from the study results?
No person or organization has a financial interest in the outcome of the study.

Research can lead to new discoveries, such as new tests, drugs, or devices. Researchers, their organizations, and other entities, including companies, may potentially benefit from the use of the data or discoveries. You will not have rights to these discoveries or any proceeds from them.

9. CONFIDENTIALITY OF SUBJECT RECORDS AND AUTHORIZATION TO RELEASE YOUR PROTECTED HEALTH INFORMATION

The information below describes how your privacy and the confidentiality of your research records will be protected in this study.

9.1 How will the researchers protect my privacy?
Research records will be kept in a separate research file that does not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. If you are a patient at the University of Michigan School of Dentistry, a non-descriptive note will be added to your electronic record regarding your participation in the study and tooth number associated with the treatment.

9.2 What information about me could be seen by the researchers or by other people? Why? Who might see it?
The researchers will have access to all your dental records at the University of Michigan School of Dentistry, which also includes your health history and medications.
Signing this form gives the researchers your permission to obtain; use, and share information about you for this study, and is required in order for you to take part in the study.

There are many reasons why information about you may be used or seen by the researchers or others during or after this study. Examples include:

- The researchers may need the information to make sure you can take part in the study.
- The researchers may need the information to check your test results or look for side effects.
- University, Food and Drug Administration (FDA), and/or other government officials may need the information to make sure that the study is done in a safe and proper manner.
- Study sponsors or funders, or safety monitors or committees, may need the information to:
    - Make sure the study is done safely and properly
    - Learn more about side effects
    - Analyze the results of the study
- The researchers may need to use the information to create a databank of information about your condition or its treatment.

- Information about your study participation may be included in your regular UMHS medical record.
- If you receive any payments for taking part in this study, the University of Michigan accounting department may need your name, address, social security number, payment amount, and related information for tax reporting purposes.

The results of this study could be published in an article, but would not include any information that would let others know who you are.

A description of this clinical trial will be available on http://www.clinicaltrials.gov/, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

9.3 What happens to information about me after the study is over or if I cancel my permission?
As a rule, the researchers will not continue to use or disclose information about you, but will keep it secure until it is destroyed. Sometimes, it may be necessary for information about you to continue to be used or disclosed, even after you have canceled your permission or the study is over.

Examples of reasons for this include:
- To avoid losing study results that have already included your information
- To provide limited information for research, education, or other activities (This information would not include your name, social security number, or anything else that could let others know who you are.)
- To help University and government officials make sure that the study was conducted properly

As long as your information is kept within the University of Michigan Health System, it is protected by the Health System's privacy policies. For more information about these policies, ask for a copy of the University of Michigan "Notice of Privacy Practices". This information is also available on the web at http://www.uofmhealth.org/patient+and+visitor+guide/hipaa. Note that once your information has been shared with others as described under Question 9.2, it may no longer be protected by the privacy regulations of the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA).

9.4 When does my permission expire?
Your permission expires at the end of the study, unless you cancel it sooner. You may cancel your permission at any time by writing to the researchers listed in Section 10 "Contact Information" (below).

10. CONTACT INFORMATION

10.1 Who can I contact about this study?
Please contact the researchers listed below to:
- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Talk about study-related costs to you or your health plan
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator: Elizabeth Van Tubergen
Mailing Address: 1011 N. University, Ann Arbor, MI 48109, Rm. 1376F
Telephone: 734-647-6860

Co-Investigator: Elisabeta Karl
Mailing Address: 1011 N. University, Ann Arbor, MI 48109, Rm. G363D
Telephone: 734-647-3352

Study Coordinator: Andrea Frantz, RDH, BSDH, CCRP
Mailing Address: 1011 N. University Ave., Ann Arbor, MI 48109-1078
Email Address: acransto@umich.edu
Telephone: (734) 647-4595

You may also express a concern about a study by contacting the Institutional Review Board listed below.

University of Michigan Medical School Institutional Review Board (IRBMED)
2800 Plymouth Road
Building 520, Room 3214
Ann Arbor, MI 48109-2800
Telephone: 734-763-4768 (For International Studies: US Country Code: 001)
Fax: 734-763-1234
e-mail: irbmed@umich.edu

If you are concerned about a possible violation of your privacy or concerned about a study you may contact the University of Michigan Health System Compliance Help Line at 1-866-990-0111.

When you call or write about a concern, please provide as much information as possible, including the name of the researcher, the IRBMED number (at the top of this form), and details about the problem. This will help University officials to look into your concern. When reporting a concern, you do not have to give your name unless you want to.

11. RECORD OF INFORMATION PROVIDED

11.1 What documents will be given to me?

Your signature in the next section means that you have received copies of all of the following documents:

- This "Consent to be Part of a Research Study" document. (*Note: In addition to the copy you receive, copies of this document will be stored in a separate confidential research file and may be entered into your regular University of Michigan medical record.)*

- Other (specify):_____

12. SIGNATURES

Consent to Participate in the Research Study

I understand the information printed on this form. I have discussed this study, its risks and potential benefits, and my other choices with _____. My questions so far have been answered. I understand that if I have more questions or concerns about the study or my participation as a research subject, I may contact one of the people listed in Section 10 (above). I understand that I will receive a copy of this form at the time I sign it and later upon request. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Legal Name: _____

Signature: _____

Date of Signature (mm/dd/yy): _____

Principal Investigator or Designee

I have provided this participant and/or his/her legally authorized representative(s) with information about this study that I believe to be accurate and complete. The participant and/or his/her legally authorized representative(s) indicated that he or she understands the nature of the study, including risks and benefits of participating.

Legal Name: _____

Title: _____

Signature: _____

Date of Signature (mm/dd/yy): _____