

American College of Integrative Medicine and Dentistry
Dr. Mark Wisniewski, DDS
78 Country Club Road
Greenfield, MA 01301
EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

Any person who is requested to consent to participate as a subject in a research study involving a medical /dental experimental procedure, or who is requested to consent on behalf of another, has the right to:

1. Be informed of the nature and purpose of the experimental procedure.
2. Be given an explanation of the protocol to be followed in the medical/dental experimental procedure and information on the substance or device being evaluated.
3. Be given a description of any attendant discomforts and risks to be reasonably expected from the experimental procedure, when applicable.
4. Be given a disclosure of any appropriate alternative procedures, substances, drugs or devices that might be advantageous to the subject, and their relative risks and benefits, if known.
5. Be given an explanation of any benefits to the subject to be reasonably expected from the experimental procedure, if applicable.
6. Be informed of the courses of medical/dental treatment, if any, available to the subject after the experimental trial if complications should occur.
7. Be given the opportunity to ask any questions concerning the experimental trial or other associated procedures.
8. Be instructed that consent to participate in the medical/dental experimental procedure may be withdrawn at any time, and that the subject may discontinue participating in the medical/dental experiment without prejudice.
9. Be given a copy of the signed and dated written consent form when one is required.
10. Be given the opportunity to decide to consent or not to consent to a medical/dental experimental procedure without the intervention of any element of force, fraud, coercion, or undue influence on the subject's decision.

Patient or Legal Guardian

Date

Witness

Date

Patient IRB study Number _____

ACIMD-IRB Study Number 2003-003

I, _____, do voluntarily, knowingly, and willingly give my consent to the administration of medical/dental oxygen/ozone treatments. I seek this treatment at my own request.

I understand that medical/dental oxygen/ozone therapy involves the injection of a mixture of oxygen and ozone in the form of a gas with or without local anesthetic, into the skin, mucous membranes, muscles, joints, jawbones, and teeth of the head, neck and associated structures. Medical/dental oxygen/ozone therapy is defined as the creation of a therapeutic oxygen rich environment which induces a multi-factorial positive biochemical/physiologic change in the affected tissues. Medical/dental oxygen/ozone therapy has the following medical/dental relevant and useful properties: it kills bacteria, viruses and fungi. It is a circulatory stimulant, a wound-cleanser, an accelerant for wound healing, a hemostatic agent, and an immune activating agent. There may be other effects that at this time are unknown.

I understand that medical/dental oxygen/ozone therapy has not been approved for use by the Food and Drug Administration of the United States Department of Health and Human Services.

I understand that I should tell the doctor or staff if I have ever had an allergic reaction to any anesthetic, particularly dental anesthetics prior to any treatment involving injections with anesthetics.

There are potential side effects with all types of medical/dental treatments. Medical/dental oxygen/ozone therapy carries with it some risk of side effects, such as ; pain and/or discomfort at the injection site, soreness and temporary bruising. There may be a red, inflamed, blister-type area at the injection site. This area usually heals in a 1-5 day time period. All types of medications have some risk of allergic reactions. An allergic reaction to the mixture of oxygen/ozone would be unusual, and usually restricted to the injection site. The most common patient comment is that there is a warm to burning sensation at the site of the injection. Some patients may experience flu-like symptoms, which is described in the literature as a “healing crisis or Herxheimer reaction”. This response will subside in 2-5 days.

Patient/Legal Guardian

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Limitations of Treatment using Medical/Dental concentrations of Oxygen/Ozone for the
Treatment of the Head, Neck, Face, TMJ, Teeth, and Associated Structures

I understand with any treatment, there is no guarantee that I will obtain satisfactory results. I may achieve no results, satisfactory results, or unsatisfactory results. If I am currently under the care of a physician or dentist for a known or unknown condition(s), it is my responsibility to inform all practitioners that are providing treatment(s) for my condition(s), of ALL other courses of treatment that I am receiving. Dr. Mark has advised me that it is in my best interest to integrate all therapeutic modalities that are available to treat my health condition(s).

I understand that Dr. Mark is not my primary care physician. I understand that it is in my best interest to have a primary care physician for advising me in regard to any treatment(s) that I may choose to receive.

INFORMED CONSENT TO RECEIVE TREATMENT WITH DENTAL/MEDICAL
OXYGEN/OZONE MIXTURES

I hereby authorize treatment with medical/dental oxygen/ozone and certify that I understand the nature of this treatment, including risks of possible complications and other choices that may be available. I have had any questions concerning this type of treatment answered. I consider myself to be as completely informed as possible and hereby consent to treatment using medical/dental oxygen/ozone. I represent that I am seeking treatment in order to further my own health and for no other reason. I do not represent a third party. I am aware that I may withdraw this consent at any time.

Patient or Legal Guardian

Date

Witness

Date

American College of Integrative Medicine and Dentistry
Mark Wisniewski, DDS
Doctor of Integrative Medicine

NON-SURGICAL INTERVENTION FOR THE TREATMENT OF OSTEONECROSIS,
INFECTION, AND INFLAMMATION OF THE HARD AND SOFT TISSUES OF THE
HEAD, NECK AND ASSOCIATED STRUCTURES WITH MEDICAL/DENTAL
OXYGEN/OZONE

Participant's Name _____

Introduction: You are requesting to voluntarily participate in a study using medical/dental oxygen/ozone for the treatment of infection and inflammation of the facial bones, teeth, muscles, tendons, ligaments, and lymphatic tissues.

Purpose: The purpose of this open study is to evaluate the efficacy of medical/dental oxygen/ozone as an effective alternative procedure to surgical intervention for the treatment of osteonecrosis, infection, and inflammation. Previous clinical observations have demonstrated that direct infusion of medical/dental oxygen/ozone may decrease or eliminate symptoms associated with these pathologic conditions.

Duration of Participation and Procedures: The study length will be approximately one to five years. Following a comprehensive clinical examination and radiographic evaluation, an initial diagnostic impression will be established. The area to be treated may or may not receive epinephrine free anesthetic. After anesthesia has been obtained, procedures will be performed depending upon the location of the lesion. Treatment of the upper jaw (maxilla) utilizes the placement of medical/dental oxygen/ozone in the proximity of the lesion. Treatment of the lower jaw (mandible) will in most cases, require the placement of a small opening in the bone to allow the oxygen/ozone to be infused directly into the lesion. Treatment of soft tissues and the interior of root canal treated teeth will receive direct infusion.

As part of the study, you will be asked to complete a number of health history questionnaires, including the SF-36 Health Status Survey. The SF-36 survey is a gold standard on health assessment. In addition, periodic radiographs or other assessments will be necessary to evaluate treatment progress and any resolution of the area receiving treatment.

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Rationale for treatment using medical/dental oxygen/ozone

Medical/dental oxygen/ozone has been shown to be an effective anti-bacterial, anti-fungal and anti-viral treatment agent. It increases circulation and oxygenation to the treatment area. It increases the immune response and creates an environment for the production of anti-oxidants.

Additional information and explanation for participants in the clinical trial

1. Your disorder(s) may not respond to the treatment(s).
2. You may experience pain, discomfort, soreness and bruising at and around the site of the injection.
3. Transient small “bubble-like blisters” may occur at or around the site of the injection.
4. All medications and treatments have some risk of allergic reaction(s). This is an unusual event and is usually restricted to the local area of the injection site.
5. The most common side effect of medical/dental oxygen/ozone treatment is a warm to burning or stinging sensation at the injection site.
6. This treatment of your head, neck, face, TMJ’s, teeth, and associated structures, will on occasion produce flu-like symptoms which last on average 2-5 days.
7. Any new treatment technique may produce unanticipated effects. All known effects to date have been explained in this document. If you experience any reaction not described in this document, please Dr. Mark Wisniewski and/or his staff. The office phone number is: 413-774-5591.
8. You will be notified of any significant new findings, which are relevant to your treatment.

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Benefits of participation: A possible benefit for participating in this study is the potential for some improvement or relief from symptoms associated with the condition(s) for which you sought treatment. You may also experience relief or improvement in symptoms associated with the head, neck, face, TMJ, teeth, and associated structures.

Alternative forms of treatment for infections of the hard and soft tissues of the maxilla and mandible: The only currently available form of treatment in the United States is surgical removal of the infected and necrotic material.

Confidentiality: Medical records and information, which may reveal your identity, will remain confidential.

Compensation: If you experience any physical injury as a direct result of this treatment, please contact your treating dentist, Dr. Mark, who is participating in the study. He will provide appropriate treatment or refer you to a treatment facility that will evaluate and provide treatment. Dr. Mark is not aware of any compensation that is available for any such injury. This is a private unfunded study. Neither Dr. Mark nor any other entity connected with this study will assume any financial responsibility for medical treatment related to any such injury.

Voluntary Participation: Your participation in this study is voluntary. You are free to withdraw at any time without penalty or loss of benefits regarding your future care with Dr. Mark. Dr. Mark has the authority to terminate your participation in the study, without your consent, at any time. This may be required due to: 1. New information from other study participants. 2. A change in your medical condition. 3. A failure on your part to comply with study protocols. 4. Unforeseen changes in study protocols, or other reasons.

Direct costs of the study protocols: You will be required to pay for any necessary tests associated with your health condition. These tests would include. But not be limited to: radiographs, clinical examinations, blood tests, etc. There will also be charges for the medical/dental oxygen/ozone treatments. These direct study costs to the patient is expected to range from \$500.00 to \$3500.00 for 3-6 months of treatment

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Witnessing and Signatures: I _____
have read the information and consent forms before signing. I have been offered ample opportunity to ask questions and have received answers that are to my complete satisfaction. I voluntarily consent to participate in this study. I hereby agree to permit Dr. Mark to perform the investigational treatment described in this protocol. All responsibilities which accrue to me or the investigator are fully disclosed in this document and I have made my decision to participate based on the information contained in this document.

Patient/Legal Guardian

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