Consent Form

Title of Research Study: Post-operative pain following treatment using the Gentlewave system

Investigator Team Contact Information: Ronald Ordinola-Zapata, DDS, PhD, MS
For questions about research appointments, the research study, research results, or other concerns, call the study team at:

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Supported By: This research is supported by the University of Minnesota School of Dentistry, Division of Endodontics.

Financial Interest Disclosure: There is no financial conflict of interest to report.

Key Information About This Research Study
The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?
Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Research and clinical care are often combined. One purpose of this informed consent document is to provide you clear information about the specific research activities of this study.

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Why am I being asked to take part in this research study?
You are being asked to participate in this study because you are already scheduled for a standard of care root canal.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?
This research is being done to better understand when pain occurs following root canal treatment. The Gentlewave system is a machine that uses that standard disinfection materials to continuously clean root canals for several minutes. The safety of this device has been studied for several years and has been reviewed and approved by the Food and Drug Administration (FDA). Only one other study has explicitly sought to determine whether or not there is any difference between pain felt following the standard of care root canal treatment and root canal treatment using the Gentlewave system. The benefit to you is that regardless of the treatment group for which you are chosen, your needed treatment will be completed to the highest standard. Potential benefits to others include doctors having a high level of confidence in knowing their patients will be pain-free following the use of the Gentlewave system.

How long will the research last?
We expect that you will be in this research study for the duration of your root canal treatment plus seven days beyond that. Treatment will be at least two 2-hour appointments. Following the first appointment of your treatment, the additional time will be spent rating your pain level on a visual analog scale which should take no more than five minutes per day for seven contiuous days prior to your second appointment.

What will I need to do to participate?
You will be asked to identify your level of pain in the 24 hours prior to treatment with a visual analog pain scale. You will then be randomly assigned to either receive treatment using the standard root canal therapy or treatment using the Gentlewave system. Following treatment, you will be given the same visual analog pain scale and asked to record your level of pain at 6, 24, 72, and 168 hours post-treatment. Those pain scale recordings will then be returned to the graduate endodontics clinic via prepaid postage.

More detailed information about the study procedures can be found under “What happens if I say yes, I want to be in this research?”

Is there any way that being in this study could be bad for me?
This study includes two standard of care treatment options. As such, risks common to both arms include: Post-operative discomfort or swelling, restrictive mouth opening, jaw muscle spasm or cramps, temporomandibular joint difficulty, non-healing of the tooth, damage to restorations, reaction to local anesthetic, uncontrollable bleeding, separation of instruments within root canals,

over-instrumentation or over-obturation of root canals, and numbness or paresthesia. Increased sensitivity due to backpressure is a risk specific to Gentlewave treatment.

Will being in this study help me in any way?
There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research.

What happens if I do not want to be in this research?
You do not have to participate in this research. Instead of being in this research study, your choices may include: Treatment with the standard root canal therapy protocol. There are no additional risks or benefits to this alternative because it is the treatment that all patients within the graduate endodontics clinic receive.

Detailed Information About This Research Study
The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?
We expect about 100 people here will participate in this research study.

What happens if I say "Yes, I want to be in this research"?
Once you have decided to participate in the research:

- You will be scheduled for your root canal treatment.
- Treatment will take place in the University of Minnesota School Of Dentistry graduate endodontics clinic.
- Prior to the start of treatment, you will be asked to record on a visual analog pain scale your highest pain level within the 24 hours prior to the start of your treatment.
- Next will be the treatment portion of the study. You will be chosen for 1 of 2 treatment groups. You will either receive treatment using the standard root canal treatment protocol or you will receive treatment using the Gentlewave system for root canal disinfection. You will be unaware of which treatment group you are a member of. Your treatment may will take multiple appointments. Following your first appointment your tooth will be treated with an intracanal interappointment medicament: Calcium hydroxide.
- Once your treatment has been completed, you will be given the same visual analog pain scale to record your pain levels at intervals of 6, 24, 72, and 168 hours (1, 3, and 7 days) following treatment.
- After the 7th day post-treatment, and all pain levels have been recorded, the visual analog pain scales will be returned to the graduate endodontics clinic via prepaid postage.

The treatment you receive will be chosen by chance, like flipping a coin. You will not be told which treatment you are getting, however your study doctor will know. You will have an equal chance of being given either treatment.

What are my responsibilities if I take part in this research?
If you take part in this research, you will be responsible for: Reporting to the clinic for treatment, recording your pain levels at the determined time intervals, and returning the recordings to the graduate endodontic clinic for evaluation

What happens if I say "Yes", but I change my mind later?
You can leave the research study at any time and no one will be upset by your decision. That decision will not be held against you. If you decide to leave the research study, contact the investigator so that the investigator can update your record to state removal from the study and plan your alternative treatment accordingly.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future dental care.

If you stop being in the research, information about you that has already been collected may not be removed from the study database. Data collected prior to the point of withdrawal will be maintained. Should you choose to withdraw after root canal treatment has been completed, you may be asked to continue with the data collection portion of the study.

What do I need to know about reproductive health and/or sexual activity if I am in this study?
Endodontic treatment is known to cause patients great anxiety and distress under even the most controlled circumstances. Additionally, treatment in the graduate endodontics clinic can take 2+ hours to complete. As such, it is our standard practice to not perform these procedures on women past their second trimester unless it is an emergency situation. We do this to not cause a situation that could place undue stress on the mother or fetus. Secondly, in the graduate endodontics clinic, our pain management protocol includes NSAIDs and acetaminophen. This combination has been shown to be superior to either ibuprofen or acetaminophen alone. NSAIDs have been shown to cause premature closure of fetal blood vessels. The exclusion of ibuprofen would limit our pain management options to acetaminophen alone, which may not be sufficient.

Will it cost me anything to participate in this research study?
Taking part in this research study will not lead to any additional costs to you. Standard care costs will still apply.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services are performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We

cannot promise complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

Data or Specimens Collected
Data collected for the purposes of this study may be used in future studies. Information will be stored on Academic Health Center – Information Systems secured servers. Data will be retained indefinitely. The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Will anyone besides the study team be at my consent meeting?
You may be asked by the study team for your permission for an auditor to observe your consent meeting (or a recording of your consent meeting). Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting (or a recording of your consent meeting) without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?
This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to https://research.umn.edu/units/hrpp/research-participants/questions-concerns. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?
The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact

the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research?
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include, but not limited to, the discovery of and crack or fracture that would deem the tooth non-restorable. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What happens if I am injured while participating in this research?

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

Use of Identifiable Health Information
We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Signature Block for Capable Adult:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____
Signature of Participant Date

_____
Printed Name of Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Printed Name of Person Obtaining Consent

Signature Block for Interpreter:

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

_____ _____
Signature of Witness to Consent Process Date

_____
Printed Name of Person Witnessing Consent Process