24-010877

ZTE MRI Pulse Sequence Use for Visualization of Bone Cement, Breast Biopsy Markers

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MAYO CLINIC

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: ZTE MRI Pulse Sequence Use for Visualization of Bone Cement, Breast Biopsy Markers

IRB#: 24-010877

Principal Investigator: Christine Lee, MD, PhD and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits, or rights you would normally have if you choose not to take part.
Research Purpose	Breast biopsy markers are generally placed when a breast biopsy is performed. The purpose of this research is to determine if a clinically available MRI sequence called ZTE imaging better visualizes breast biopsy markers made of bone cement compared to the currently used breast biopsy markers made of metal. You have been asked to take part in this research because you are a healthy person and can have a non-contrast enhanced breast MRI
What's Involved	This study includes one visit—the MRI; no intravenous contrast will be used. For this study, an ultrasound gel pad typically used in clinical ultrasound scans will be placed next to each breast for the non-contrast enhanced MRI scan. In each gel pad, either an experimental marker or a commercial breast biopsy marker will be inserted. A grid holder made be used to gently hold the gel pads in place against the breasts.

Key Information	The MRI machine makes loud knocking sounds when it is scanning. Because of this you will be asked to wear earplugs while getting your MRI scan. The earplugs minimize discomfort from noise and keep the MRI noise within the safety range. The sounds coming from the MRI scanner for this study are typical of those during a clinical breast MRI scan. The ZTE sequence is essentially silent, and you will be reminded that there is actually a scan going on so that you can minimize motion during the scan. You will be on your stomach for the breast MRI. There will be a head-holder for your head to rest on, and the setup will be the same for a standard-of-care clinical breast MRI scan. There is no radiation associated with MRI, but people who have metal devices like pacemakers cannot have an MRI and will not be able to participate in the study. Some people with claustrophobia may feel too closed in and may not tolerate MRI scanning. If you feel too confined in the MRI scanner you can inform the technologist, and the MRI scan will be stopped.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Christine Lee, MD, PhD **Phone:** (507) 266-1207 **Study Team Contact:** Fatima Zohra **Phone:** (507) 284-2511 **Institution Name and Address:** Mayo Clinic Department of Radiology 200 First St. SW Rochester, MN 55905
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
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.

Why are you being asked to take part in this research study?

You have been asked to take part in this research because you are a healthy person can receive a non-contrast enhanced breast MRI.

Approximately 20 people will participate in this research study.

Why is this research study being done?

The purpose of this research is to see if an MRI sequence called ZTE, which uses no ionizing radiation or intravenous contrast agent, can clearly identify markers made of bone cement compared to markers made of metal.

Information you should know

Who is Funding the Study?
The National Institutes of Health is funding this study.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

The study will take the time to complete a single MRI exam and will require 1 visit.

What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following:

An MRI technologist will position you using standard of care for a non-contrast enhanced breast MRI scan. Breast MRIs are performed with you on your stomach, your breasts in a breast coil, and your head supported by a head rest. You will be provided ear plugs and an emergency bulb to hold in your hand during the MRI exam. An ultrasound gel pad typically used in clinical ultrasound scans will be placed next to each breast using paper tape. A grid holder made be used to gently hold the gel pads in place against the breasts. In each gel pad, either an experimental marker or a commercial breast biopsy marker will be inserted. During the MRI, you will be asked to stay as still as comfortably possible.

The MR exam will appear in your medical record as well as a radiology report describing findings. Results of image analysis performed for research purposes will not be provided to you. In the rare event that a finding might affect your health, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

What are your responsibilities?

If you take part in this research, you will be expected to:

- Come to the MRI exam and follow the instructions you are given by the study doctor or other study staff.
- Tell your study doctor or study staff if you think you are experiencing a harmful effect from the study participation.

What are the possible risks or discomforts from being in this research study?

There is no radiation associated with MRI, but people who have metal devices like pacemakers cannot have an MRI and will not be able to participate in the study. Some people with claustrophobia may feel too closed in and may not tolerate MRI scanning. If for any reason, you cannot tolerate the MRI exam, you will have an emergency squeeze ball which you can squeeze at any time during the MRI exam to let the study team know to stop the MRI. The study steam will immediately enter the MRI suite to talk to you. You can choose to stop the MRI at any time.

The MRI machine typically makes loud knocking sounds when it is scanning. Because of this you will be asked to wear earplugs while getting your MRI scan. The earplugs minimize discomfort from noise and keep the MRI noise within the safety range.

Breast MRIs are well-tolerated by patients, and including ZTE imaging does not add any additional risk to the MRI exam. Discomforts are not anticipated, but if you should have any, do not hesitate to let the study team know.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance.

What are the possible benefits from being in this research study?

You will not benefit from being in this research study. Other patients with breast biopsy markers in the setting of breast cancer care may benefit in the future from what we learn in this research study.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- *Non-contrast enhanced breast MRI*

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You won't be paid for taking part in this study.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers at institutions and companies without your additional informed consent.

How will your privacy and the confidentiality of your records be protected?

General Protections
Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. The data related to this study are electronically stored on password-protected servers. Any other data are stored in locked cabinets.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Authorization to Use and Disclose Protected Health Information (HIPAA)
During this research, information about your health will be collected. Under Federal law called the Privacy Rule (also referred to as Health Insurance Portability and Accountability Act [HIPAA]), health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

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Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other healthcare providers involved in your clinical care.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and <u>not</u> employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

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Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private, and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building PL 3-02
200 First St. SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

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Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature