New Tools for Assessing Fracture Risk
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Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Jeffry S. Nyman, PhD **Revision Date: 9/15/2015**
Study Title: New Tools for Assessing Fracture Risk
Institution/Hospital: VUMC

This informed consent applies to adults with a distal radius fracture (with MRI)

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to take part in this research study because you have a wrist (distal radius) fracture that requires surgical intervention. This study is looking at new ways and devices that may predict a patient's fracture risk. We would like to determine the difference in bone material between healthy volunteers, patients with healthy bone that have had a wrist fracture, and patients with osteoporotic bone that have had a wrist fracture. This study will involve a device called an OsteoProbe. It is a hand-held device that is applied to bone and tests bone material strength (or the ability of bone to resist indentation).

Your participation in this study will include an MRI (Magnetic Resonance Imaging) scan of your non-fractured wrist and a DEXA (Dual X-ray Absorptiometry) scan of your spine, hips, and non-fractured wrist. An MRI scan uses strong magnetic fields and radiowaves to form images of your body. The MRI scan will be able to tell us how much bound water and pore water you have located in your arm bones. A DEXA scan is used to determine bone mineral density. The DEXA scan of your arm, spine, and hips will be used in this study to determine your T-score, which is a metric used by doctors to help ascertain whether a patient has osteoporosis.

In addition to the MRI and DEXA scan, your distal radius bone will be indented with the OsteoProbe instrument during surgery to test your bone material strength. The OsteoProbe instrument will be applied to your bone after you have been sedated, and the incision to your arm is made. It will also occur before the surgeon repairs your distal radius fracture using a plating system. Your surgeon will apply the instrument to your distal radius bone at up to 10 different locations about 2 mm apart (less than a tenth of an inch apart). Each indentation is smaller than the screws used to secure the plating system. Once all OsteoProbe measurements have been obtained the surgeon will continue on with routine surgery.

2. What will happen and how long will you be in the study?

As part of your routine care, you will have surgery to repair your wrist fracture. Your follow-up schedule is determined by your doctor, and based on what type of treatment you receive as part of your routine clinical care.

<u>Enrollment Visit/Before Surgery (30 minutes)</u>

- You will be asked to complete two surveys about yourself and your symptoms today
- You will be scheduled for a research MRI scan and a research DEXA scan (both to be done within a week of surgery, either before or after surgery)

<u>Surgery Visit (2 to 3 hours)</u>

- During your routine surgery, your surgeon will apply the OsteoProbe to your distal radius (wrist) bone at up to 10 different locations about 2 mm apart. The OsteoProbe will tell us your bone material strength.

<u>MRI Visit (1 to 1 ½ hours, 1 week before or after surgery)-</u>

You will undergo an MRI of your non-fractured wrist. The MRI will take place at the Vanderbilt Institute of Imaging Science Building.

DEXA Scan Visit (45 minutes to 2 hours, 1 week before or after surgery)-
You will undergo a DEXA scan of your spine, hips, and non-fractured wrist. This DEXA scan will tell us your bone mineral density. The DEXA scan will take place at the Vanderbilt Clinical Research Center. If you are a female of childbearing potential, a blood sample will be collected for pregnancy testing prior to your DEXA scan (takes up to 1 hour for test results). If you are found to be pregnant, you will not be allowed to take part in this study.

3 Weeks After Surgery (30 minutes to 1 hour)
- You will be asked to complete two surveys about yourself and your symptoms today

6 Weeks After Surgery (30 minutes to 1 hour)
- You will be asked to complete two surveys about yourself and your symptoms today
- Your doctor or a research coordinator will take measurements of your wrist

12 Weeks After Surgery (30 minutes to 1 hour)
- You will be asked to complete two surveys about yourself and your symptoms today
- Your doctor or a research coordinator will take measurements of your wrist

3. Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if you take part in this study:
Common (≥10%), uncommon (<10%) or rare (≤1%)

Infection Risk (Uncommon)
As with any surgical procedure there is a slight risk of infection. To minimize this risk, the OsteoProbe tip that is used to indent your wrist bone will be sterilized prior to surgery. In addition, a sterilized sleeve will cover the other portions of the Osteoprobe machine.

Radiation Risk from DEXA Scan (Rare)
You will undergo a DEXA scan, which will slightly increase your radiation exposure. This research study involves exposure to radiation from 1DEXA scan of your arm, spine, and hips. This radiation exposure is not necessary for your medical care and is for research purposes only. The total amount of radiation you will receive by participating in this study is equal to your body receiving 47 days of radiation from your natural surroundings.

Risks from MRI Scan (Rare)
You will undergo an MRI scan for this study. MRIs do not use ionizing radiation so there are no harmful side-effects associated with temporary exposure to the strong magnetic field using by MRI scanners. The known risks of MRIs include:

- objects brought into the room may be pulled toward the magnet (this risk will be reduced by standard operating procedures of MRI facilities)
- a person that has an implanted metal or medical device may experience abnormal torques or fail to function properly (please notify the research coordinator if this applies to you). Note that the wrist with the plating system will NOT be placed inside the magnet.
- a risk of tissue heating if there is an excessive power due to electromagnetic waves
- a risk of peripheral nerve stimulation
- subjects may experience a claustrophobic reaction when in the magnet (please notify the research coordinator if this applies to you)
- there are loud banging noises with MRIs that may make you uncomfortable

Breach of Confidentiality (Rare)
There is a rare chance that the confidentiality of the data we collect about you may be breached by taking part in this study. To lower this risk, all study documents will be kept in a secure location where only research staff will have access to them. All data that is recorded in an online Vanderbilt database will be password-protected, and will only be accessible by research personnel.

Inconvenience
The time and travel to your study visit(s) may be inconvenient for you. We will make our best effort to schedule the MRI and DEXA visits on one day, possibly in combination with a routine clinic visit.

5. Risks that are not known:

If we discover an unknown risk to this study not listed in Item# 4 we will let you know about it.

6. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study: This study is intended to determine if two new, non-X-ray techniques can tell the difference in bone quality among healthy volunteers, patients with healthy bone that have had a wrist fracture, and patients with osteoporotic bone that have had a wrist fracture. This study may lead to the ability to advance new techniques to predict fracture risk, determine how drug therapies affect bone, and assess whether these new techniques to determine bone quality are useful in surgery.

b) The benefits you might get from being in this study: There is no direct benefit to you by participating in this study. You may receive a certain psychological reward knowing that you are contributing to increased medical knowledge that may help improve anti-fracture therapies in future patient populations.

8. Other treatments you could get if you decide not to be in this study:

You can receive the same routine treatment without taking part in this study.

9. Payments for your time spent taking part in this study or expenses:

You will be reimbursed $100 for your time and travel. A check will be mailed to you following completion of your MRI and DEXA visits.

10. Reasons why the study doctor may take you out of this study:

You may be taken out of this study if it is determined that you no longer meet inclusion criteria. You may also be removed from the study if you are unable to follow study guidelines, like participating in the MRI and DEXA scan visits. If you are taken out of this study you will be told why.

11. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell the research investigator or research coordinator.

12. Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact **Dr. Jeff Nyman, Dr. Donald Lee, or Julie Daniels** at 6[redacted].

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the Vanderbilt University Institutional Review Board Office at ([redacted] or toll free at ([redacted].

13. Clinical Trials Registry.

A description of this clinical trial will be available on 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.

14. Confidentiality:

During this study every attempt will be made to keep your protected health information (PHI) private. To reduce the risk of a breach of confidentiality, most study data will be maintained in a password-protected Vanderbilt Redcap database. A Vanderbilt Redcap database is a secure, web-based application for building and managing online databases. The data obtained and stored in this database will only be accessible by research personnel. All Redcap data will be de-identified prior to statistical analysis. All OsteoProbe measurements taken will be relayed from the OsteoProbe to a laptop which his connected to the instrument during the surgical case. The imported data will be displayed in an excel spreadsheet. This excel spreadsheet will be saved on a password-protected computer(s) held by research personnel. In addition, some of this data will be transferred to the Redcap study database and deleted from the excel file. . Any physical study forms (ex. consent documents, screening forms, surveys) will be kept in a locked cabinet in the Vanderbilt Hand & Upper Extremity Center Administrative Offices for

6 years following completion of the study at which time they will be disposed of in a shred-it confidentiality bin provided by VUMC.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Nyman and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

15. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Dr. Nyman and his study team may share the results of your study, as well as parts of your medical record, to the groups named below. These groups may include people from the: Active Life Scientific, Inc, Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, and the National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Nyman in writing and let him know that you withdraw your consent. His mailing address *is* [redacted]. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature

Printed Name and Title _____ Time _____