A randomized controlled trial comparing free-hand versus distal targeting jig-based for distal interlock screw placement

NCT05613257

10/25/2023

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CONSENT FORM FOR RESEARCH

Study title: A randomized controlled trial comparing free-hand versus distal targeting jig-based for distal interlock screw placement

Study support provided by: Stryker
Cedars-Sinai Principal Investigator: Carol Lin, MD, Charles Moon, MD

Study contact phone number at Cedars-Sinai:

Goran Stankovic, Study Coordinator (310) 423-1620

After-hours emergency contact (24 hours): Dr. Carol Lin (310) 210-7558

1. Key Information

We are asking for your consent to take part in this research study. This section provides key information about the study. The rest of this form has more detailed information.

- **Voluntary:** Taking part in this research study is your choice. You can also stop taking part at any time. You will not lose any services, benefits or rights you would normally have if you choose not to take part or stop taking part.

- **Purpose:** The purpose the research is to compare an orthopaedic medical device with free-hand techniques for screw placement in lower extremity orthopaedic nailing.

- **Procedures:** The main thing that will happen in this study is that we will use a jig-based distal targeter for your lower extremity nailing orthopedic surgery procedure.

- **Duration:**. We expect your participation will last up to a week for consent, randomization, and surgery. Follow up data will be collected for two years.

- **Risks:** All research studies involve some risk. Risks or discomforts from this study are the same as those that would be inherent to the procedures itself, such as bleeding, infection, nonunion after 6 months and reoperation at a later date.

- **Benefits:** You are not likely to be helped from taking part in this research study. But the information learned from this study may help others in the future.

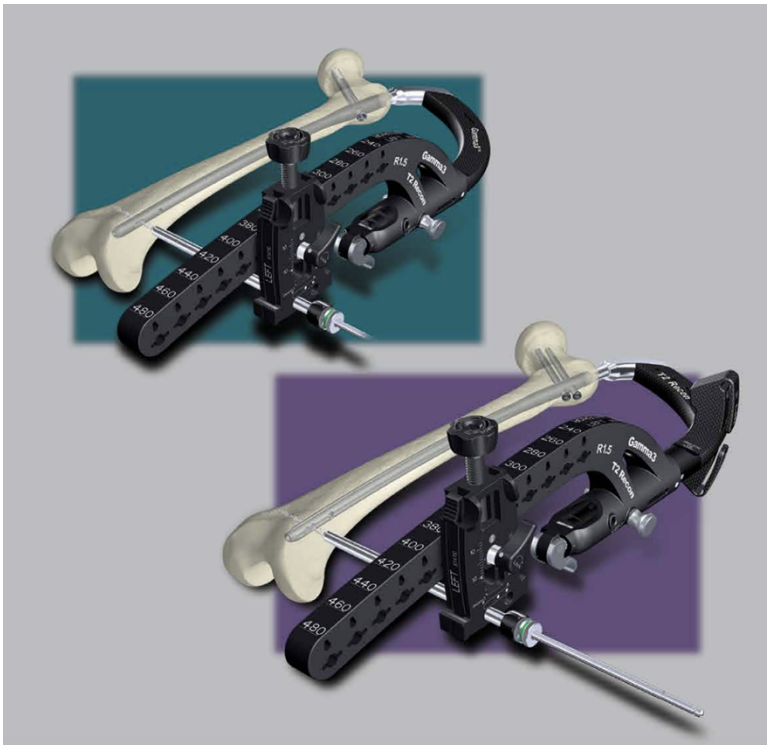
- **Alternatives:** You can choose not to take part. There may be other choices for you. Some other choices may be not participating in this study. Please talk about these choices with the study team.

Please take time to read this entire form. You should ask questions before deciding whether to take part in this study. You can talk with family, friends and/or healthcare providers before you decide.

During the study, we may find out new information about this research study. We will tell you about any important changes or new findings that may impact whether you want to continue taking part in the study.

2. Purpose of the Study

We are doing this study to compare the use of a specific method of interlocking screw insertion during fractures of the tibia and femur. One method uses a specialized attachment to the femoral or tibial rod that helps with screw placement and may reduce the amount of intraoperative xrays needed (jig-based locking, picture below). The other method is the traditional method which uses only xrays during surgery and does not use this attachment (free-hand locking). Both methods are commonly used for these surgeries



The U.S. Food and Drug Administration (FDA) has approved the Stryker distal targeter device as it is being used in this study. It has been shown to reduce fluoroscopy time in prior studies.

You are being asked to take part in this research study because you have sustained an orthopedic injury that is eligible for the use of this device.

Even if you are randomized to the jig-based technique, there is a chance your surgeon may decide during your surgery to place the screws with the freehand technique. This is because of the jig's construction, there may be instances where its use is not possible due to interference with other surgical instrumentation. If this happens, you will remain enrolled in the study and considered a 'crossover' into the other study group.

The study will include up to 66 people in total.

3. Main Study Procedures

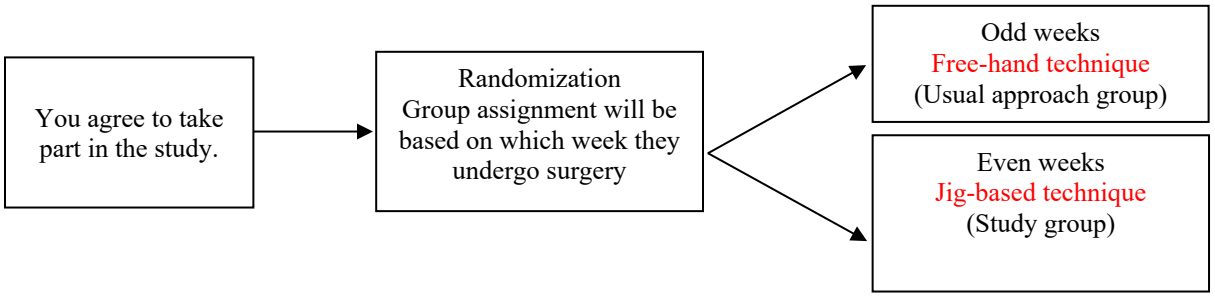
Description of main research procedures:
All patients undergoing femoral or tibial nailing will undergo one method of interlock placement starting on the first of the month starting with free-hand locking. The method of interlocking screw placement will then switch to jig-based screw placement at the first of the following month. The method of screw placement will alternate each month until enrollment is complete.

This study has 2 study groups:

- The first group is those getting free-hand locking method.
- The second group is those getting jig-based screw placement.

This is a randomized, single-blind research study.

- **Randomized**: Whether subjects are placed in the free-hand technique (control) group or the distal targeter (experimental) group will depend on the date of injury. The orthopaedic trauma team will alternate which techniques they are going to use each week. Since both methods of screw insertion are commonly used, the method of screw insertion will change each month and be applied to all patients who have surgery to fix a femur fracture or tibia fracture that month. The results could be better, the same or worse than the results in other groups. Once you are put in one group, you cannot switch to another group. You and your doctor cannot choose the group you are in.
- **Single-blind:** This means that the researchers will know which group you are in. They will not tell you which group you are in.



If you receive the free-hand locking) technique treatment, your care will be the same as if you were not in the study, we will just collect information from your standard of care follow up appointments.

How long will you be in the study ?
We think you will be in this study for the length of your surgery, and any injury-related follow up appointments.

4. Possible Risks and Discomforts of the Main Research Procedures

The risks subjects may undergo for this study are the same as those in standard of care of this procedure, such as bleeding, infection, nonunion and reoperation at a later date.

5. Common Medical Procedures Performed for Research Purposes and Risks

All procedures subjects may undergo are only those that would be performed in standard of care.

6. Benefits From Taking Part in the Study

You should not expect to benefit from taking part in this research study.

7. Whether Research Results Will Be Shared

The imaging procedure(s) in this study are being done for research purposes. However, they will be done following standard clinical imaging techniques. The imaging results may be shared with you. They may be placed in your Cedars-Sinai medical record.

8. Reasons Participation May Be Stopped

Your participation in this study may be stopped at any time. The researcher or the sponsor can stop your participation without your consent for any reason. Some reasons for stopping your participation include:

- The study is stopped or suspended.
- Funding for the study is reduced, stopped or withdrawn.
- It is in your best interest.
- You do not follow the study procedures.

9. Choosing to Take Part and Other Options

Participating in this study involves allowing researchers to collect data from your medical chart and imaging. Taking part in research is voluntary. You have the right to choose not to take part. You can stop taking part in this research study at any time. You can do this without any penalty or loss of benefits to which you would be entitled outside of the study. Your choice not to take part or to stop taking part will not affect the care you get at Cedars-Sinai.

If you decide to stop taking part, we will keep any data collected on you up to the time you choose to stop. Also, if you stop taking part, the study team may ask you whether you want to give further data from your routine medical care.

You can decide not to take part in this study. You have other choices. For example, you may choose:

- To be treated following the usual clinical approach

- To take part in a different study at Cedars-Sinai or elsewhere, if one is available.
- To not be treated.

The study team will discuss these options and their risks and benefits with you. You may also choose to discuss these with your treating physician.

10. Confidentiality Protections

We will do our best to keep your personal information collected as part of this study private. But we cannot guarantee total privacy. We may put a copy of your research consent and authorization forms in your electronic medical record at Cedars-Sinai. Your personal information may be given out if required by law. Publications or presentations about this study at scientific meetings will not use your name and other identifiable personal information.

Organizations that may look at and/or copy your medical records for research oversight, quality assurance and data analysis include:

- Accrediting agencies (agencies that grant official certifications to educational institutions)
- Government and regulatory groups, such as the Food and Drug Administration (FDA) and Office for Human Research Protections (OHRP)
- The Institutional Review Board (IRB), which reviews research to protect people taking part in studies
- Safety monitors, which monitors the safety of individual participants and the overall safety of the study
- Companies that sponsor the study and authorized representatives of the sponsor

Attached to this consent form is an Authorization Form. It outlines with whom your information may be shared for this research and under what circumstances.

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

11. Research-Related Illness or Injury

Contact your study doctor at once if you feel that you are ill or have been injured because of taking part in this study. As needed, your study doctor will treat you or refer you for treatment. If it is a medical emergency, call 911 or go to an emergency room. Promptly notify your study doctor of your situation at the phone number listed on page 1 of this consent form.

Who pays for my research-related illness or injury?
A research-related injury or illness is a direct result of either the study device or a procedure performed only as a part of this study and that is not part of your standard clinical medical treatment. Injury or illness related to your underlying medical condition or caused by non-research-related activities (such as treatment generally provided outside of this study) would not be considered research-related. If you are being treated for a research-related injury or illness, you will not pay for

the costs of your appropriate medical or emergency room care. Cedars-Sinai and the sponsor have no plans to pay for losses such as lost wages or pain and suffering. You do not waive any of your legal rights by signing this form.

12. Financial Considerations

Costs of Participation
The attached flowchart lists items, drugs and services that will be billed to you and/or your insurance and those that will be covered by the Study Sponsor. Review the flowchart for details.

Standard of care procedures and the cost of the study device, implant procedure, and related items, drugs and procedures will be charged to you or your insurance company. You remain responsible for all deductibles, copays and balances under your health benefit plan.

The research staff will seek pre-authorization from your insurance company for the procedures in this study. Before any study procedures are performed, pre-authorization must be received from your insurance company. If your insurance company denies coverage, you may decline to take part in this study or you may choose to pay out of pocket. If you have questions or concerns about your insurance coverage, you should ask your health benefit plan.

Payment

You will not be paid for taking part in this research study.

Financial Interest in the Research

The principal investigator and institution have no potential financial conflict of interest with this study.

13. Contact for Questions or Problems

Please contact the investigator for questions, problems or concerns about the research. Their contact information is on page 1 of this form.

You might have feedback, questions, problems, concerns or want to obtain more information about this study. If so, you can talk with someone who is not part of this study by contacting:

Cedars-Sinai Human Research Protection Program (HRPP)
Phone: 310-423-3783
Email: ResearchConcerns@cshs.org
Website: cedars-sinai.org/research/administration/office-of-research-compliance/review-board.html

The Cedars-Sinai HRPP protects the rights and welfare of research participants.

Experimental Subject's Bill of Rights

In accordance with California Health and Safety Code 24172, any person who is required to consent to participate as a subject in a research study involving a medical experiment or who is requested to consent on behalf of another has the right to:

1. Be informed of the nature and purpose of the experiment.

2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

3. Be given a description of any attendant discomforts and risks to the subject reasonably to be expected from the experiment.

4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

7. Be given an opportunity to ask any questions concerning the experiment or the procedure involved.

8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

9. Be given a copy of any signed and dated written consent form used in relation to the experiment.

10. Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

AUTHORIZATION FOR USE AND DISCLOSURE OF IDENTIFIABLE HEALTH INFORMATION FOR RESEARCH

1. USE AND DISCLOSURE OF HEALTH INFORMATION

If you agree to this Authorization, you give permission to the Sponsor, Principal Investigator, other investigators and their research team described in the Consent Form for Research ("Research Team") to use or disclose your identifiable health information ("private information") for the research study titled "**A randomized controlled trial comparing free-hand versus distal targeting jig-based for distal interlock screw placement**" which is described in the Consent Form for Research ("Consent Form") to which this Authorization is attached. In particular, you authorize the research team acting under the direction of the Principal Investigator to review your medical records and collect your private information from the following sources:

- ☐ Laboratory tests
- ☐ Pathology reports
- ☒ Imaging reports (e.g., x-rays or scans)
- ☐ Photographs or videos of your image
- ☒ Doctor/clinic records
- ☒ Hospital/medical records
- ☐ Mental health records
- ☐ Billing records
- ☒ Demographics, which may include age, gender identity, race, ethnicity, and/or sexual orientation
- ☐ Other tests or other types of medical information: N/A

2. WHO WILL HAVE ACCESS TO YOUR PRIVATE INFORMATION?

Your private information will be used by and/or shared with the Research Team.

In addition to the research team, if applicable, the following parties may receive your private information and inspect your records:

- The reviewing Institutional Review Boards and Cedars-Sinai offices with authority to oversee research compliance.
- U.S. government agencies, such as the Food and Drug Administration and the Department of Health and Human Services.
- Researchers at other organizations who are participating in this research study.
- The Study Sponsor, its business partners, and Cedars-Sinai's business partners for matters related to research study oversight, conduct of the research, data analysis, use of research results in product development, and payment or reimbursement.

- Representatives from regulatory agencies in other countries may join in the review of your research records, including research-related medical reports and information, with the Sponsor and/or the FDA.

Cedars-Sinai takes steps to protect your private information when sharing it with the recipients described above. Though these steps and applicable law are meant to protect your private information, there is a risk that a recipient could share your private information without your permission.

3. WHEN WILL MY AUTHORIZATION EXPIRE?

By signing this document, you authorize the use and sharing of your private information until the end of the research study and any related optional sub-study you choose to participate in.

4. REVOKING AUTHORIZATION

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the research team may still use or disclose private information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to the Principal Investigator of the research study by writing to the Office of Research Compliance and Quality Improvement, 6500 Wilshire Blvd, Suite 1800, Los Angeles, Calif. 90048 and/or emailing to ResearchConcerns@cshs.org.

5. NOTICE OF RIGHTS AND OTHER INFORMATION

You do not have to agree to this Authorization, but if you do not agree, you may not participate in the research study. Cedars-Sinai may not condition (withhold or refuse) the provision of standard of care treatment for you on whether you agree to this Authorization.

If you agree to this Authorization, please sign on the appropriate signature line on the Signature Page. You will receive a copy of this Authorization.

Signature Page

Consent Form for Research and Authorization
for Use and Disclosure of Identifiable Health Information (Research)

If you agree to take part in this study, you should sign and date on the signature lines below. You will be given a signed and dated copy of this form. This includes the "Experimental Subject's Bill of Rights," "Authorization for Use and Disclosure of Identifiable Health Information (Research)" and any optional sub-study descriptions, when applicable.

Signature by the Participant
Main Research Study: *I agree to take part in the research study described to me during the informed consent process and described in this informed consent form. My questions have been answered to my satisfaction.*

You will be given a signed and dated copy of this form.

Participant name (please print)	Signature	Date

Authorization for Use and Disclosure of Identifiable Health Information (Research): *I hereby agree that my identifiable health information may be used and/or disclosed in accordance with the "Authorization for Use and Disclosure of Identifiable Health Information (Research)."*

Participant name (please print)	Signature	Date

Signature by the Investigator
I attest that all the elements of informed consent described in this form have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Investigator name (please print)	Signature	Date

Signature by the Interpreter/Witness
(Signature of an interpreter is only required when enrolling a non-English-speaking subject with the assistance of an interpreter and IRB-approved "short form" consent processes. The witness may be any person who is conversant in both English and the language of the non-English-speaking subject, such as a certified hospital interpreter, study staff, a family member or other person. The witness signs the consent forms to confirm that the oral interpretation occurred.

Signature of a witness is required when an English-speaking subject who has been determined to have capacity to consent is unable to read or physically sign the consent form but chooses to indicate via a "mark" or verbally that he/she agrees to participate. The witness signs the consent form to confirm that an oral consent process occurred and that the individual verbally consented to participate in the research.)

_____

Interpreter/Witness name (please print) Signature Date of signature

To be marked at time of signature:
Consent obtained:
☐ *From non-English speaking individual with assistance of interpreter*
☐ *From English-speaking individual who is not physically able to sign the consent document*