Main Informed Consent Form for Participation in a Research Study

Study Title: *Early Versus Delayed Weight-Bearing After Operatively Managed Trimalleolar Ankle Fractures (EASY-Ankle): A Pilot Randomized Controlled Single-Center Trial*

OHSN-REB Number:

Study Doctor:
Dr. Bradley Meulenkamp, Orthopedic Surgery, 613-798-5555 x18596
Dr. Karl-André Lalonde, Orthopedic Surgery, 613-798-5555 x18596

Sponsor: Ottawa Hospital Research Institute

Funder(s): American Orthopedic Foot & Ankle Society (AOFAS)

Emergency Contact Number (24 hours / 7 days a week): 613-722-7000

Non-Emergency contact numbers are noted at the end of this document under the section heading "Contacts".

INTRODUCTION

You are being invited to participate in a clinical trial/study (a type of research study to help learn about a medical intervention, such as a procedure or therapy). You are invited to participate in this study because you have recently undergone Open Reduction and Internal Fixation (ORIF) surgery for an unstable trimalleolar ankle fracture. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study. If you would like to, you can talk about this study with other people (for example your family, your friends, and your usual doctor or health care provider).

The study staff will tell you about the study timelines for making your decision.

Taking part in this study is voluntary. You do not have to participate at all or you may choose to leave the study at any time. Whatever you choose, it will not affect the usual medical care that you receive. If you have any questions about this, you can ask the study team.

IS THERE A CONFLICT OF INTEREST?

The Ottawa Hospital Research Institute is receiving financial payment from the American Orthopedic Foot & Ankle Society to cover the cost of conducting this study.

There are no additional conflicts of interest to declare related to this study.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

A trimalleolar ankle fracture is a break involving three parts of the ankle: the medial malleolus, which is the inside portion of the tibia; the lateral malleolus, which is the end of the fibula; and the posterior malleolus, which is the back portion of the tibia. These structures help stabilize the ankle. Because all three areas are involved, trimalleolar ankle fractures are considered unstable and typically require surgery to restore alignment and help the bones heal properly.

The standard or usual treatment for an unstable trimalleolar ankle fracture is surgery called Open Reduction and Internal Fixation (ORIF). During ORIF surgery, the bones are repositioned and held in place using plates, screws, or wires while they heal.

The usual post-operative treatment following trimalleolar ankle fracture surgery is approximately six weeks of non-weight-bearing with immobilization in a cast or orthosis.

Previous research in other types of ankle fractures suggests that early weight-bearing after surgery may improve ankle motion and help patients return to work and daily activities sooner without increasing post-operative complications. However, trimalleolar fractures are more complex and have often been excluded from previous studies. More research is needed to better understand whether early weight-bearing is safe and feasible after surgery for unstable trimalleolar ankle fractures.

WHY IS THIS STUDY BEING DONE?

The purpose of this study, called a pilot study or a feasibility study, is to test the study plan and to find out whether enough participants will join a larger study and accept the study procedures. This type of study involves a smaller number of participants and so it is not expected to prove the safety or effectiveness of early weight-bearing after surgery for unstable trimalleolar ankle fractures.
The results may be used as a guide for larger studies, although there is no guarantee that they will be conducted. Participation in a pilot study does not mean that you will be eligible to participate in a future larger study.

The researchers hope to learn whether early weight-bearing after surgery is safe and feasible and whether it may lead to equal or improved ankle function and quality of life compared with delayed weight-bearing.

WHAT OTHER CHOICES ARE THERE?

You do not have to take part in this study in order to receive treatment or care. If you do not want to participate, you will receive the standard or usual treatment determined by your treating surgeon.

Please talk to your usual doctor or the study doctor about the known benefits and risks of your treatment options before you decide to take part in this study.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Participants will be recruited from The Ottawa Hospital over a period of approximately 12 months. There is no fixed sample size for this pilot study.

The study will continue only if certain feasibility criteria are met, such as recruitment of a sufficient number of participants and participant compliance with follow-up visits and weight-bearing instructions. This study is expected to take approximately 24 months to complete, and the results should be known in approximately 36 months.

WHAT IS THE STUDY INTERVENTION?

Group 1: Early Weight-Bearing (Experimental/Study-Specific Intervention)
If you are in this group, you will start weight-bearing as tolerated on your operated ankle beginning two (2) weeks after surgery. You will use walking aids as needed.

Group 2: Delayed Weight-Bearing (Standard/Usual Care Intervention)
If you are in this group, you will avoid weight-bearing on your operated ankle until six (6) weeks after surgery. You will continue to use walking aids as needed. After the six-week period, you may begin weight-bearing as tolerated.

All participants, regardless of group assignment, will begin standardized ankle range-of-motion exercises two weeks after surgery as instructed by the clinic physiotherapist. These exercises are part of the usual post-operative rehabilitation plan.

ASSIGNMENT TO A GROUP

If you decide to participate then you will be randomized into one of the groups described above. Randomization means that you are put into a group by chance, like flipping a coin. There is no way to predict which group you will be assigned to. You will have an equal chance of being placed in either group. No one can choose what group you will be in.
You will be told which group you are in. The research team members who collect your study outcome data during follow-up appointments will not know which group you are in.

WHAT ELSE DO I NEED TO KNOW ABOUT THE STUDY INTERVENTION?

If you have side effects or post-operative complications while you are on this study, the study doctor may make changes to the intervention. This may include changing your weight-bearing status if the study doctor feels this is needed for your safety or clinical care.

WHAT ARE THE STUDY PROCEDURES?

Study-Related Procedures

The following information and procedures will be collected or completed as part of this study. Some of these are part of your standard/usual care, in which case the results may be added to the study data. Some are being collected only for the purpose of this study.

- Collection of demographic information such as age, sex, occupation, height, and weight.
- Collection of your medical history, including prescribed and non-prescribed medications, allergies, other medical conditions, and other injuries.
- Collection of surgical and injury information, including fracture type, fracture location, date and time of injury, date and time of surgery, surgical fixation, surgical complications, and any re-operations.

- Review and monitoring of any side effects or complications you may experience.
- Review of routine follow-up X-rays collected as part of standard clinical care to assess fracture healing and loss of reduction.
- Completion of study questionnaires to assess ankle function, pain, and quality of life.

Study-Specific Procedures

The study-specific procedures are randomization and assignment to one of the two post-operative weight-bearing groups.

Participants will be randomized in a 1:1 ratio to either the early weight-bearing group or the delayed weight-bearing group. Aside from the assigned weight-bearing timeline and completion of study questionnaires, your post-operative clinical follow-up visits, physiotherapy/rehabilitation, and routine radiographs will be performed as part of standard clinical care.

Questionnaire(s)

You will be provided with questionnaires at approximately 6 weeks, 12 weeks, 26 weeks, and 52 weeks after surgery. The purpose of the questionnaires is to assess ankle function, pain, daily activities, and health-related quality of life.
The questionnaires include:

- Olerud and Molander Ankle Score (OMAS)
- Foot and Ankle Ability Measure (FAAM)
- EuroQol EQ-5D-5L
- Visual Analog Scale (VAS)
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These questionnaires will take approximately 20 minutes to complete in total at each questionnaire session.

The information you provide is for research purposes only. Some of the questions are personal. You can choose not to answer questions if you wish.

Even though you may have provided information on a questionnaire, these responses will not be reviewed promptly by your health care team. If you wish them to know this information, please bring it to their attention.

Radiological Review

The researchers doing this study need to review your X-rays to assess fracture healing and specific radiological outcomes, including loss of reduction. Loss of reduction means checking whether the bones in your ankle have moved out of the correct position after surgery.

The X-rays used for this study will be those routinely collected as part of your standard medical care during your follow-up appointments. You will not be asked to have any extra X-rays for research purposes.

To protect your identity, your X-rays and other study data will be coded using a unique study ID. Reports about the research assessment of your X-rays will be available to the study doctors. If you would like to learn the results of this research, please let them know.

A full schedule of activity of the study visits and assessments are outlined in the table below:

Assessment Type	Operative day	2 Weeks PO	6 Weeks PO	12 Weeks PO	26 Weeks PO	52 Weeks PO
Inclusion/Exclusion Criteria*	X	X				
Informed Consent*	X	X				
Randomization*	X	X				
Surgical Procedure	X					
Radiographs	X		X	X	X	X
Questionnaires			X	X	X	X

*The Inclusion/Exclusion criteria verification, as well as the Informed consent process and randomization could occur anytime between the Operative day and 2 weeks PO.

COLLECTING HEALTH INFORMATION FROM A DATABASE OR MEDICAL RECORD FOR RESEARCH USE

If you agree to participate in this study, the study team will collect the following health information from your Ottawa Hospital medical record:

- Demographic information such as age, sex, occupation, height, and weight.
- Relevant medical history, including other medical conditions, medications, allergies, and other injuries.
- Injury and fracture information, including fracture type, fracture location, and date/time of injury.
- Surgical information, including date/time of surgery, fixation details, surgical complications, and re-operations.
- Routine follow-up X-ray results.
- Information about complications or side effects, including wound complications, loss of reduction, non-union, malunion, infection, DVT, PE, and unplanned re-operation.

This information will be collected for the duration of your participation in the study, which is up to 52 weeks after surgery.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to:

- Follow the weight-bearing instructions for your randomized intervention group.
- Participate in the ankle range-of-motion exercises as instructed by the clinic physiotherapist or study doctor.
- Attend follow-up visits.
- Tell the study doctor about your current medical conditions.
- Tell the study doctor about all prescription and non-prescription medications and supplements, including vitamins and herbals.
- Tell the study doctor if you are thinking about participating in another research study.
- Return any questionnaires that you take home to complete.
- Tell the study doctor or study team about any complications or changes in your health.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

You may experience side effects from participating in this study. Some side effects are known and are listed below, but there may be other side effects that are not expected. You should discuss these with the study doctor.

The study doctor will watch you closely to see if you have any post-operative complications. If you experience serious complications that require treatment between regular clinic/hospital visits, it is important that you make every effort to return to the plaster clinic to be seen by your treating surgeon. If you need urgent medical care, call 911 or go to the nearest emergency department.

Risks and side effects related to the early and delayed weight-bearing protocols being studied include:

Very likely (21%–100%)

- Common, expected post-operative discomfort, pain, and swelling, which is generally reversible with recovery.

Less likely (5%–20%)

- Problems with ankle healing, such as wound complications or minor complications that may delay healing.

Rarely (1%–4%)

- Loss of reduction/fracture displacement, meaning the bone shifts out of position. This is serious and may require another surgery.
- Non-union or malunion, meaning the bone does not heal properly or heals in the wrong position. This may require re-operation.
- Severe infection, which may require hospitalization and prolonged antibiotic treatment.
- Blood clot in the leg, called deep vein thrombosis or DVT, or in the lungs, called pulmonary embolism or PE. These can be serious and life-threatening.
- Unplanned re-operation.

Risks of Study-Related Procedures

There are no additional research-specific medical tests, imaging procedures, bloodwork, ECGs, EEGs, or sample collections required as part of this study.

Study questionnaires may include personal questions. You may choose not to answer any questions you do not wish to answer.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

If you agree to take part in this study, the experimental intervention may or may not be of direct benefit to you.

There is a possibility that participants assigned to early weight-bearing may experience improved function or quality of life, but this is not known.

We hope the information learned from this study will help other people recovering from unstable trimalleolar ankle fractures in the future

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

The study intervention will last for about six (6) weeks.

You will be asked to return to the plaster clinic at approximately 6 weeks, 12 weeks, 26 weeks, and 52 weeks after surgery for your routine post-operative follow-up visits. During these visits, you will also complete study-related assessments.

You may be seen more often if the study doctor determines that this is necessary.

No matter which group you are randomized to, and even if you stop the study intervention early, we would like to keep track of your health until 52 weeks after surgery to assess your recovery and study outcomes. We would do this through your routine clinic visits and review of study data collected during the study period.

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time without having to provide a reason. If you choose to withdraw from the study, you are encouraged to contact the study doctor or study staff.

During the study, you can decide to withdraw from the intervention portion of this study but continue to participate in follow-up data collection activities and/or study visits. For example, you may stop following the assigned weight-bearing protocol but still allow the study team to collect follow-up questionnaire and medical record information.

If you decide to leave the study, you can ask that the information that was collected about you not be used for the study. Let the study doctor know if you choose this. Some records of your participation in this study must be retained, for example this signed consent form.

No samples are being collected as part of this study.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The study doctor may stop your participation in the study early, and without your consent, for reasons such as:

- Staying in the study may be harmful to you, for example if you experience serious side effects or complications.
- You are unable to tolerate the study intervention.
- You are unable to complete all required study procedures.
- New information shows that the study intervention is no longer in your best interest.
- The study doctor no longer feels this is the best option for you.
- You develop a post-operative complication that requires a change to your weight-bearing status.
- The Sponsor decides to stop the study.
- The Ottawa Health Science Network Research Ethics Board withdraws permission for this study to continue.

If this happens, it may mean that you would not receive the study intervention for the full period described in this consent form.

If you are removed from this study, the study doctor will discuss the reasons with you and plans will be made for your continued care outside of the study.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the study doctor and study staff will only collect the information they need for this study. This may include looking at information obtained from your records already located at this site.

Your data will be shared as described in this consent form and/or as required by law and/or applicable research regulations. Records identifying you at this centre will be kept confidential and, to the extent permitted by applicable laws, will not be disclosed, except as described in this consent document. Authorized representatives of the following organizations may come to the participating site or be given remote access to an electronic portal to look at your original identifiable medical, clinical, and study records at the site where these records are held. This is done to check that the information collected for the study is correct and follows proper laws and guidelines. These records identify you, but everyone involved is responsible for making sure that your privacy and the confidentiality and security of your records are maintained.

- The Ottawa Health Science Network Research Ethics Board, which oversees the ethical conduct of this study.
- The Ottawa Hospital Research Institute, which oversees the conduct of research at this location.

Information collected about you for the study, called study data, may also be sent to the organizations listed above. Your name, address, email, or other information that directly identifies you will not be used. The records received by these organizations may contain your participant code, sex, and partial date of birth.

Communication by email is not absolutely secure. We do not recommend that you communicate sensitive personal information by email.

If the results of this study are published, shared, or presented at scientific meetings, your identity will remain confidential. It is expected that the information collected during this study will be used for analyses and may be published or presented to the scientific community at meetings and in journals. Your data may also be used to help design a future larger multicenter trial.
Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study may be included in your health record/hospital chart.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your family doctor or health care provider will not be informed by the study team that you are taking part in this study. You can choose to let your family doctor or health care provider know, if you like.

WILL INFORMATION ABOUT THIS STUDY BE AVAILABLE ONLINE?

A description of this clinical study will be available on *http://www.ClinicalTrials.gov*. This website will not include information that can identify you. You can search this website at any time.

This research study can be found on the above listed registry by using the clinical trial registration number.

WHAT IS THE COST TO PARTICIPANTS?

The costs of your medical treatment will be paid for by your provincial medical plan to the extent that such coverage is available.

Taking part in this study may result in added costs to you. For example:

- Equipment such as Aircast boots and physiotherapy may not be covered by provincial insurance.
- There may be extra costs that are not covered by your medical plan, such as medications or treatments to manage complications or side effects.
- There may be costs associated with hospital visits, such as parking, transportation, snacks, or meals.
- You may miss work.

You can speak with the study team about any added costs. Everything possible will be done to help you access reimbursement from your insurance company or other third-party payer where applicable.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

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

WHAT WILL HAPPEN IF A PARTICIPANT IS INJURED DURING PARTICIPATION IN THE STUDY?

In the case of research-related side effects or injury, medical care will be provided by your treating surgeon, or you will be referred for appropriate medical care as required.

By signing this form, you do not give up any of your legal rights against the study doctor, sponsor, or involved institutions for compensation, nor does this form relieve the study doctor, sponsor, or their agents of their legal and professional responsibilities.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please contact the study doctor. The results of this study will also be available on the clinical trial registry.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form you do not give up any of your legal rights.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHAT IF RESEARCHERS DISCOVER SOMETHING ABOUT A RESEARCH PARTICIPANT?

During the study, the researchers may learn something about you that they did not expect. For example, through routine X-rays they may discover information about your ankle healing or another medical finding.

If any new clinically important information about your health is obtained as a result of your participation in this study, you will be given the opportunity to decide whether you wish to be made aware of that information

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you are experiencing a side effect or have a research related injury, please contact the study doctor or the 24h contact number listed on the first page. If it is an emergency, please call 911 or proceed to your nearest emergency room.

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor, or the doctor who oversees the study at this institution. That person is:

Dr. Bradley Meulenkamp	613-798-5555 x18596
Name	Telephone

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study. Please contact the Ottawa Health Science Network Research Ethics Board Chairperson at 613-798-5555 extension 16719.

SIGNATURES

Study Title Early Versus Delayed Weight-Bearing After Operatively Managed Trimalleolar Ankle Fractures (EASY-Ankle): A Pilot Randomized Controlled Single-Center Trial

CONSENT

- All my questions have been answered,
- I have read (or someone has read to me) all pages of the information within this consent form, including risks, benefits, alternatives to participation, and my rights as a participant,
- I allow access to my medical records and transfer of sample(s) and related personal health information as explained in this consent form,
- I do not give up any legal rights by signing this consent form,
- I recognize that my family doctor/health care provider may be informed of my participation in this study by the study team, or may learn of my participation when reviewing my electronic health record,
- I agree, or agree to allow the person I am responsible for, to take part in this study.
- I will be given a signed and dated copy of this consent form.

Signature of Participant	Printed Name	Date

If consent is provided by Substitute Decision Maker: _____ PRINTED NAME of Participant

Investigator or Delegate Statement

I have explained to the above-named participant/substitute decision maker the nature and purpose, the potential benefits, and possible risks of participation in this study. All questions that have been raised about this study have been answered.

Signature of Person Conducting the Consent Discussion	Printed Name and Role	Date

Study Title: Early Versus Delayed Weight-Bearing After Operatively Managed Trimalleolar Ankle Fractures (EASY-Ankle): A Pilot Randomized Controlled Single-Center Trial

Participant Assistance

Complete the following declaration only if the participant / Substitute Decision-Maker is <u>unable to read</u>:

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant / Substitute Decision-Maker, and any questions have been answered.

Signature of Impartial Witness	Printed Name	Date

Relationship to Participant

Complete the following declaration only if the participant / Substitute Decision-Maker has <u>limited proficiency in the language in which the consent form is written and interpretation was provided</u> as follows:

☐ The person signing below acted as an interpreter, and attests that this study as set out in the consent form is accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and in additional discussion arising from this process.

Signature of Interpreter	Printed Name	Date

SIGNATURES

Study Title: Early Versus Delayed Weight-Bearing After Operatively Managed Trimalleolar Ankle Fractures (EASY-Ankle): A Pilot Randomized Controlled Single-Center Trial

Participant's Acceptance of Substitute Decision Maker's Consent

Your illness or injury made it impossible for you to participate in the informed consent process, so your substitute decision maker's (SDM) consent was obtained on your behalf. Your SDM agreed to your participation in this research study. Now that your condition has improved we would like to inform you of the details of the study and obtain your personal decision. You may agree or disagree with the decision made by your SDM.

- I understand that I am being asked to continue my participation in this research study,
- All my questions have been answered,
- I have read, or someone has read to me, all pages of this participant informed consent form, including the risks, benefits, alternatives to participation and my rights as a participant, I allow access to my medical records and transfer of sample(s) and related personal health information as explained in this consent form,
- I do not give up any legal rights by signing this consent form,
- I recognize that my family doctor/health care provider may be informed of my participation in this study by the study team, or may learn of my participation when reviewing my electronic health record,
- I will be given a signed and dated copy of this consent form.

❑ I voluntarily agree with my SDM's decision and wish to continue my participation in this study
OR
❑ I do not agree with my SDM's decision and choose not to continue my participation in this study. However, I will allow the information collected about me to remain in the study and be used by the researchers.

Signature of Participant	Printed Name	Date

Investigator or Delegate Statement
I have explained to the above-named participant the nature and purpose, the potential benefits, and possible risks of participation in this study. All questions that have been raised about this study have been answered.

Signature of Person Conducting the Consent Discussion	Printed Name and Role	Date