Participant Information Sheet

Study title:	Should ankle syndesmosis screws be removed? Medium term follow up of a randomised controlled trial comparing screw retention with screw removal following ankle fracture fixation	
Locality:	**Counties Manukau & Waitemata District Health Boards**	Ethics committee ref.:
Lead investigator:	**Dr. Ryan Gao**	Contact phone number: **021-024-222-13**

You are invited to take part in a study investigating whether removal of ankle screws after healing of an ankle injury improves patient outcomes after a minimum of five years following surgery. Your participation is entirely voluntary (your choice). You do not have to take part in this study, and if you choose not to take part you will receive the standard treatment available.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is six pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

You are invited to take part in this study because we would like to find out how you are doing following your ankle fracture fixation more than five years ago. The reason you have been identified to participate in this study is because you have previously participated in a randomised controlled study investigating whether there was any benefit in routinely removing the syndesmosis screw used to treat your ankle fracture. Using the valuable information we gathered from the initial study, we demonstrated that there was no clinical or radiological difference in removing or retaining the syndesmosis screws one year after surgery. The findings from the initial study have influenced the way orthopaedic surgeons practice around the world. Now, more than five years after surgery, we would like to find out whether there are any clinical or radiological differences in removing the syndesmosis screws.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

This study will involve completion of standardised, validated questionnaires designed to explore your ankle function. In addition, you will have two X-Rays of your ankles so the investigators can assess how your ankle is doing radiologically.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

This study will provide a significant benefit to medical knowledge and will help orthopaedic surgeons to decide if it is better to remove syndesmosis screws after the ankle injury has healed, or to leave them in place.

The study has ethics approval from the Health and Disability Ethics Committee.

WHO PAYS FOR THE STUDY?

You will not incur any costs during the trial.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT ARE MY RIGHTS?

Your participation in this trial is completely voluntary. You are free to decline to participate or to withdraw from the trial at any time and this will have no effect on your clinical care or your future clinical care or right to health care. With your consent, your General Practitioner will be informed of your participation in this trial.

You have the right to access any medical information collected about you as part of the study.

You will be informed of any new information about adverse or beneficial effects related to the study that becomes available during the study that may have an impact on your health

All information about you will be collected and stored securely within hospital databases and any data analysis will only be performed by the investigators involved in the study. All other medical data relevant to your surgery will only be accessed by health practitioners involved in your clinical care.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

The study data will be stored securely on hospital grounds by the investigators for no longer than 10 years at which point will be destroyed according to standard hospital protocols.

The study findings will be communicated back to participants in summary form and also published in the appropriate research journals in its entirety. We would expect that this may take approximately three years.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr. Ryan Gao
Counties Manukau District Health Board Switch Board
ryan.gao@middlemore.govt.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

If you require Maori cultural support, talk to your whanau in the first instance. Alternatively you may contact the Maori Orthopaedic Surgical Registrar Dr. Ailsa Te Rina Kari Wilson via Counties Manukau District Health Board Switch Board.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Consent Form

Ankle Syndesmosis Screw Extended Term (ASSET) Study

If you need an INTERPRETER, please tell us.
If you are unable to provide interpreters for the study, please clearly state this in the Participant Information Sheet

Please tick to indicate you consent to the following
I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
I have been given sufficient time to consider whether or not to participate in this study.
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
I consent to the research staff collecting and processing my information, including information about my health.
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
I understand the compensation provisions in case of injury during the study.

I know who to contact if I have any questions about the study in general.	
I understand my responsibilities as a study participant.	
I wish to receive a summary of the results from the study.	Yes ☐ No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date: