|  |  |
| --- | --- |
| Participant Information Sheet**RESHAPING Study** |  |
| Formal Study Title: Reverse Shoulder Arthroplasty with Metallic Augments to Restore Joint Line Anatomy in Patients with Glenoid Bone Loss (RESHAPING): A Prospective Self Controlled Case Series |  |
| Principal Investigator: Dr. Yushy Zhou (Registrar)Co-Investigators: Dr. Sanjeev Krishna (Registrar), Mr. Marc Hirner (Orthopaedic Surgeon), Mr. Mike van Niekerk (Orthopaedic Surgeon)Study Site: Whangarei HospitalContact phone number: +64 21 136 7637Contact email: yzho527@aucklanduni.ac.nzEthics committee ref.: TBC |  |  |  |
|  |  |  |  |

You are invited to take part in the RESHAPING Study. This study involves patients who have had reverse shoulder joint replacement surgery performed with metallic implants, and investigates whether their shoulder joint anatomy has been restored with the surgery. A 3D reconstructed CT scan helps us visualize the shoulder joint.

Whether or not you take part in this study is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

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 9 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

## Voluntary participation and withdrawal from this study

Participating in this study is entirely voluntary. You are under no obligation to be in the study, and declining will not have any impact on your medical/orthopaedic care in the future. We hope that after reading all the information, you will only agree to be in the study if you think you will be able to complete the follow up. However, if you want to withdraw from the study at any time, please let the research team know.

## What is the purpose of the study?

The shoulder joint is made up of two bones – the humerus and the glenoid. When replacing the shoulder joint, bone loss on the glenoid side can pose significant challenges and risks to the surgery. In patients with significant glenoid bone loss, this can be managed by either using the patient’s own bone from elsewhere in the body to plug the defect (bone grafting), or use of a metallic wedge (augment) to fill in the defect. There are also other options such as custom implants, but these are not yet readily available in the New Zealand health system.

One of the areas we are interested in is whether or not the original shoulder joint shape can be restored with metallic augments in patients who have had a reverse shoulder joint replacement and suffer from glenoid bone loss.

This study will use new 3D reconstructed CT scans taken after surgery, and compare them with the CT scans patients have had before their surgery to analyse the restoration of the shoulder joint anatomy. In addition, we will ask all our participants to fill in two short questionnaires to provide a better understanding of how patients are functioning following their shoulder surgery.

As a result of this study, we hope to better understand how effective metallic augments are in addressing glenoid bone loss, and our findings can be compared with other studies to ensure patients are getting the best possible treatment for their shoulder issues.

## How was this study designed?

This is a single-blinded self-controlled case series study.

All potential participants for this study were identified using hospital records that showed they received a reverse shoulder joint replacement with metallic augments. Participants will then be contacted to ask whether or not they would like to be enrolled in the study. Approximately 20 people in New Zealand will be asked to take part in the study.

Once a patient has enrolled for the study, they will offered an appointment for a CT scan of their shoulder. At the same time, they will be asked to complete two short questionnaires detailing the functional outcomes of their surgery. Questions may ask whether the participant can perform simple tasks, have pain, or require any assistance in day to day activities. No further appointments are required after the CT scan, unless the participant wishes to meet with the research team for any questions or concerns.

The results of the study will be communicated with the participants directly, and final results will be submitted for publication in Scientific Journals.

## Who can take part in the study?

You have been invited to take part in this study because you have:

* Had a reverse shoulder joint replacement in the past
* On pre-surgery CT scan, had some degree of glenoid bone loss that required use of metallic augments to correct the defect

You cannot participate in the study if you have any of the following:

* Age younger than 18 years old
* Have concurrent bone graft used in the same shoulder
* Had previous metallic augments or bone graft used in the same shoulder
* Did not receive a CT scan before your shoulder surgery
* On regular steroid treatment for any condition
* Unable to fill in the two short questionnaires for any reason
* Are currently involved in any other ongoing research studies

Prior to you beginning the study, we will ask you to provide a list of medications you are taking. This helps us see if there are any medications which may affect your bone health.

## What will my participation in the study involve?

Involvement in this study requires two meetings.

The first meeting will take approximately 15 minutes and can be either in person or via phone call / Zoom meeting. The purpose of this meeting is to provide all the relevant information regarding the study so you can make a fully informed decision as to whether or not you would like to participate. This meeting also serves as an opportunity for you to ask any questions about the study and/or the surgery you have had. If you meet the requirements to take part in the study, and give us your consent, we will arrange a time for you to get a CT scan. Please let us know before the CT scan if you have any concerns with your shoulder.

When you get your CT scan, a member of our research team will also provide you a questionnaire about your functional outcomes of the surgery. If there are any concerns with the CT scan which require further medical input, we will contact you and arrange an appointment to meet. If there are no concerns with the CT scan, no further appointments will be required.

## What will happen to my CT scan images?

Your CT scan images will be uploaded to your personal health records, and be associated with your National Health Index number. This means in future, if you have any concerns with your shoulder, your clinician can access your images just like any other medical investigation you have had.

The scan will not be reported by Radiologists. Instead, our Orthopaedic Surgeons involved in the study (Marc Hirner and Mike van Niekerk) will look through the images looking specifically at the shoulder joint.

At your request, we can provide you a copy of your CT scan images for your personal record keeping.

## What are the possible risks of this study?

The most obvious risk with this study is use of ionising radiation with CT scans. There is a known link to cancer with ionising radiation use, however, that risk is dependent on dose of radiation, location of exposure, and age. The lifetime risk of developing a fatal cancer from one abdominal CT scan is approximately 1 in 2000 (0.05%). The risk involved with a single CT scan of the shoulder is even less. To put this in perspective, the lifetime risk of developing a fatal cancer **not** related to radiation is approximately 1 in 5 (20%) and dying of a motor vehicle accident is approximately in 1 in 100 (1%).

You can find more information regarding the risks of radiation on the Harvard Medical School website at: <https://www.health.harvard.edu/staying-healthy/do-ct-scans-cause-cancer>.

Other risks to consider include finding incidental abnormalities as a result of the CT scan. These are conditions that show up on the CT scan which you otherwise may not have known existed and are usually asymptomatic. The majority of incidental findings do not require any intervention or follow-up. If an incidental abnormality is found on your CT scan, we will inform you promptly even if no further intervention is required. However, if there is an abnormality that requires further intervention or follow up, we will refer you to the appropriate Specialists for further consultation.

## What are the possible benefits of this study?

In patients who have any concerns with their shoulder, a CT scan is usually the standard of care investigation to perform. This study can fast track that process in getting a CT scan performed. As the images will be reviewed by fellowship trained Orthopaedic Surgeons, if there are any concerns regarding the shoulder, we can advise you of how to proceed in terms of management and treatment.

From the study perspective, the results of this study will benefit all patients who are considering shoulder joint replacement and have glenoid bone loss. The results of this study will contribute to our understanding of how best to manage patients in a similar situation.

## Will any costs be reimbursed?

The cost of the CT scan will be covered by our research grant. You do not need to pay for this. If there are any medical appointments that are required following the results of your CT scan, we will refer you to the appropriate service(s). If there are any concerns with costs of travel, please let the research team know and we can reimburse you with petrol vouchers.

## What if something goes wrong?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. 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 will happen to my information?

During this study the study doctors/researchers will record information about you and your study participation. This includes the results of any study assessments. If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). Only study doctors and the research assistant will have access to your identifiable information

Rarely, it may be necessary for the study doctors to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by the study doctor. Instead, you will be identified by a code. The study doctor will keep a list linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information, which may be sent and stored overseas:

* The sponsor, for the purposes of this study.
* People working with or for the sponsor, for the purposes of this study (this may include up to ten people such as
	+ Other doctors and nurses working on the study
	+ Scientists who help with the statistical analysis of the information from the study
* Regulatory or other governmental agencies worldwide.
* Zimmer Biomet, the company that makes the study augment

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information.

If you agree, your coded information may be used for future research related to the metallic augments for glenoid bone loss. If you agree, your coded information may also be used for other medical and/or scientific research that is unrelated to the current study.

This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.

You will not get reports or other information about some research that is done using your information.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

Security and Storage of Your Information.

Your identifiable information is held at Whangarei Hospital during the study. After the study it is transferred to a secure archiving site and stored for at least ten years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Your coded information may be sent overseas. Other countries may have lower levels of data protection than New Zealand. There may be no New Zealand representation on overseas organisations which make decisions about the use of your information. There is a risk that overseas researchers may work with information in a way that is not culturally appropriate for New Zealanders.

This research includes basic information such as your ethnic group, age range, and sex. It is possible that this research could one day help people in the same groups as you. However, it is also possible that research findings could be used inappropriately to support negative stereotypes, stigmatize, or discriminate against members of the same groups as you.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study’s scientific integrity.

If you have any questions about the collection and use of information about you, you should ask the study doctor or research assistant.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing your Study Doctor.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

If you agree, information collected up until your withdrawal from the study will continue to be used and included in the study. You may ask for it to be deleted when you withdraw, unless you withdraw after the study analyses have been undertaken.

## What happens after the study or if I change my mind?

If you wish to withdraw from the study at any time, you are free to do so. However, please inform our research team. Your decision to withdraw from the study will not impact your future healthcare provision.

After the study, we will provide you preliminary results of the study. You will also receive access to the published scientific paper when it becomes available.

The study is registered with the Australian and New Zealand Clinical Trials Registry. This can be found at [www.anzctr.org.au](http://www.anzctr.org.au) and search for the trial number XXXXXXX.

## Who is funding this study?

The funding for this study is provided by the Northland Orthopaedics Research Trust. This is a research fund managed by the Orthopaedic Surgeons in Northland. The study doctors all work at Whangarei Hospital in the Orthopaedics Department. The Orthopaedic Surgeons involved in the study also work at Northland Orthopaedic Centre (private sector).

## Who has approved this study?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The Central Health and Disability Ethics Committee has approved this study.

## 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. Yushy Zhou
Orthopaedic Registrar
Whangarei Hospital, NDHB*

*yzho527@aucklanduni.ac.nz* *+64 21 136 7637*

Alternatively, 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@advocacy.org.nz

Website: https://www.advocacy.org.nz/

For Maori health support, please contact:

 *Dr. Joy Panoho
Workforce Equity Manager
Te Poutokomanawa
Maori Health Directorate, NDHB*

*+64 21 881 4008
Joy.panoho@northlanddhb.org.nz*

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

Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

|  |
| --- |
| Consent Form**RESHAPING Study***An interpreter is available on request to help you understand this form* |

**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.  | Yes 🞏 | No 🞏 |
| I have been given sufficient time to consider whether or not to participate in this study. | Yes 🞏 | No 🞏 |
| 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. | Yes 🞏 | No 🞏 |
| 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. | Yes 🞏 | No 🞏 |
| 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. | Yes 🞏 | No 🞏 |
| I consent to the research staff collecting and processing my information, including information about my health. | Yes 🞏 | No 🞏 |
| I consent to my information being sent overseas. | Yes 🞏 | No 🞏 |
| 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. | Yes 🞏 | No 🞏 |
| 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. | Yes 🞏 | No 🞏 |
| I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics 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. | Yes 🞏 | No 🞏 |
| 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. | Yes 🞏 | No 🞏 |
| I understand the compensation provisions in case of injury during the study. | Yes 🞏 | No 🞏 |
| I know who to contact if I have any questions about the study in general. | Yes 🞏 | No 🞏 |
| I understand my responsibilities as a study participant. | Yes 🞏 | No 🞏 |
| 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: |