**Reverse Shoulder Arthroplasty with Metallic Augments to Restore Joint Line Anatomy in Patients with Glenoid Bone Loss (RESHAPING): A Prospective Self Controlled Case Series**

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**Funding Source:**

Northland Orthopaedics Research Trust

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**Conflicts of Interest:**

None.

**STUDY SUMMARY**

**Title:**

Reverse Shoulder Arthroplasty with Augments to Restore Joint Line Anatomy in Patients with Glenoid Bone Loss (RESHAPING): A Prospective Self Controlled Case Series

**Methodology:**

Prospective, consecutive, self controlled case series

**Study Duration:**

Estimated duration to undertake all the post-operative computed tomography (CT) scans and analyse the data is 4-6 months from time of recruitment.

**Study Centre(s):**

Multi -centre – Whangarei Hospital, Northland District Health Board and Kensington Hospital, Whangarei

**Objectives:**

Primary outcome is to quantify the restoration of the glenohumeral joint line with metallic augments in comparison to pre-surgery anatomy.

Secondary outcomes are assessing correction of glenoid version, inclination of the implant, osseous integration of the implant, scapular notching, and patient reported outcome measures (PROMs) following surgery.

**Number of Subjects:**

Approximately 20 patients, based on pre-study power calculations with reference to anatomic values in a similar paper by Italia et al., 2020 (1).

**Main Inclusion/Exclusion Criteria:**

Inclusion criteria

* All patients who have had reverse shoulder arthroplasty (RSA) with glenoid bone loss corrected with metallic augments
* Age over 18 years
* RSA surgery performed at Whangarei Hospital
* Consent and compliance with all aspects of the study protocol, methods, providing data during following up

Exclusion criteria

* Age younger than 18 years
* Use of bone graft in the RSA procedure
* Previous augment or bone graft use on the ipsilateral shoulder
* Involvement with any other ongoing studies

See methods section for full list of inclusion/exclusion criteria.

**Study Variable of Interest**

Use of metallic augments (without bone graft) in RSA

**Comparison Groups**

This is a self controlled case series. The pre-surgery CT scan will provide reference information for the patient’s glenohumeral joint line anatomy. The post-surgery CT scan in the same patient will allow the investigators to measure whether the joint line anatomy has been restored following RSA with metallic augments.

**Statistics Methodology**

Primary endpoint

* Variation in post-surgery joint line in comparison to pre-surgery joint line (millimetres) on CT imaging

Secondary endpoints

* Glenoid version on post-surgery CT imaging (degrees)
* Inclination of the implant on post-surgery CT imaging (degrees)
* Nerot-Sirveaux classification for scapular notching on post-surgery CT imaging (2)
* Osseous integration of the implant
* Oxford Shoulder Score (OSS) and Quick Disabilities of the Arm, Shoulder, and Hand (qDASH) score for PROMs

Glenoid bone loss on pre-surgery CT scan was classified using the Gupta-Seebauer classification (3)

**Purpose:**

The primary objective of this study is to evaluate whether use of metallic augments in RSA is an effective and reliable technique to restore glenohumeral joint line anatomy in patients who have glenoid bone loss.

**Background:**

RSA is a procedure used to address a variety of different shoulder pathologies. It was originally designed with the intent of treating shoulder arthritis with severe rotator cuff destruction (4). However, the indications for RSA are expanding. RSA in addition to being performed for cuff tear arthropathy, has been indicated in patients with massive cuff tear without arthritis, proximal humerus fractures, inflammatory arthritis, osteoarthritis, and revision following failed total or hemiarthroplasty (5–10). Consequently, the prevalence of RSA is increasing significantly (11).

One of the challenges with RSA surgical technique is correctly positioning and adequately fixing the base plate to the glenoid (12). In patients with glenoid bone loss, these crucial aspects of the procedure are much more difficult to achieve satisfactorily. Commonly, medialisation of the glenohumeral joint line occurs with glenoid bone loss.

Medialisation of the glenohumeral joint line is associated with unsatisfactory outcomes in shoulder arthroplasty (13). Excessive medialisation of the construct reduces the functional tension of the deltoid muscle and other soft tissues, both of which can lead to prosthetic instability. Malpositioning of the implant as a result of joint line medialisation can cause limited range of motion and impingement post-operatively. Longer term, repeated impingement can lead to scapular notching (1).

To address glenoid bone loss, several techniques have been described in the literature. Eccentric reaming of the glenoid has been reported to have good outcomes in patients with RSA (14–16). However, it’s success is limited to mild glenoid erosions with retroversion less than 15 degrees (17). Larger defects cannot be treated with eccentric reaming due to the medialisation effect of the joint line. Bone grafting is another option to glenoid bone loss. This technique restores the biological bone stock of the glenoid and consequently restores the joint line anatomy (1). Autologous bone blocks can be placed between the reamed glenoid and the base plate in the concept of bony increased-offset RSA (BIO-RSA) to correct glenoid version and inclination (18). However, as with use of bone graft anywhere around the body, there is an additional morbidity associated with harvesting the graft from the donor site. Furthermore, there is also a risk of non-union and missed bone graft resorption adjacent to the base plate (1,19).

Metallic augments used alongside the glenoid base plate is a relatively new alternative for addressing glenoid bone loss (20). Based on pre-operative CT scans and intra-operative findings, the defect in the glenoid can be filled with the metallic augment whilst minimising the need for further bone removal. Good results have been reported in use of metallic augments with regards to patient satisfaction and shoulder range of motion (16). However, to date no study has demonstrated that metallic augments restore the anatomic joint line of the shoulder.

With consideration of the detrimental effects of joint line medialisation, we believe it is critical for the joint line to be restored. Using CT scans to compare the joint line both before and after surgery, our primary aim is to quantitatively describe the effects of metallic augments in RSA surgery. Secondary aims of the study are to assess glenoid version and inclination correction, describe the incidence of scapular notching, and assess symptoms and function through patient reported outcome measures (PROMs).

**Goals of the Study:**

1. To investigate the effectiveness and accuracy of using metallic augments to restore joint line anatomy in patients who have glenoid bone loss undergoing reverse shoulder arthroplasty surgery.
2. To measure the incidence of radiographic complications in the same patient cohort e.g. glenoid version, inclination, and scapular notching.
3. To assess the functional outcomes in the same patient cohort using PROMs.

**Duration of the Study:**

The study is estimated to take 2 months for enrolment and a further 2 months to complete all the post-operative CT scans. Statistical analysis will be outsourced to a qualified Biostatistician, with aim of completing the entire project including write-up and publication within 6 months from recruitment.

**Product Description:**

In RSA, metallic augments are additional modular components which complement the standard glenoid baseplate to fill in glenoid bone defects. They come in a variety of shapes and sizes. Commonly, they are wedge shaped and are used to address a particular aspect of the glenoid that is deficient. Examples include posterior and superior wedge augments which are placed between the baseplate and the reamed glenoid itself (21,22). Full wedge augments are also available to address larger glenoid defects where reaming has reached its limitations (23).

For this particular study, we have included only patients who underwent RSA with the Zimmer Biomet Comprehensive® Reverse Shoulder System Augmented Baseplate. More information on this product can be found on their website referenced below (24).

**Product Intended Use:**

Metallic augments in all of our patients have been used to address glenoid bone loss in RSA.

**Product Acquisition:**

Patients included in this study have already had their surgery performed prior to recruitment for a clinically appropriate indication. The funding for the product have been either from the District Health Board if performed in the public sector, or other personal source if performed in the private sector.

**Post-operative CT Scan:**

The additional intervention that patients who are enrolled in this study are exposed to is a post-operative CT scan. This is a non-contrast scan limited to the affected shoulder region. The obvious risk with any exposure to radiation is subsequent development of cancer. In a large cross sectional study investigating radiation exposure to cancer development, the risk is dependent on radiation dosage, location of exposure, and age of the patient (25).

The overall risk following a single phase non-contrast shoulder CT scan for patients in our study is low. We expect the average age of the patients in our study to be greater than 65. All patients will be counselled on the full risks of CT scan radiation exposure, and informed consent will be gained prior to enrolment.

**Methods:**

*Study Design*

This is a single blinded self-controlled case series involving approximately 20 participants who have had RSA surgery with metallic augments for glenoid bone loss. All participants would have undertaken a pre-operative CT scan. The self-controlled aspect of the study occurs when these same patients received a post-operative CT scan after enrolment. The two CT scans will be compared to evaluate the restoration of the glenohumeral joint line. Following the post-operative CT scan, patients will be asked to complete the OSS and qDASH questionnaires to evaluate functional outcomes. Blinding will occur with respect to the researchers involved in measuring the radiographic joint line anatomy. The participants cannot be blinded. Each participant will contacted by research staff at each follow up point.

*Data Collection and Storage*

Measurement of the joint line anatomy will be based on 3D rendering of the shoulder from the two CT scans. Standard reference points such as the coracoid will be used to measure the glenoid defects and the joint line anatomy, and compare the anatomy before and after surgery. Validated classification tools will be used to measure radiographic complications, such as the Nerot-Sirveaux classification for scapular notching (2). All PROM tools used have been externally validated (26–29).

Data will be stored on a password encrypted spreadsheet. Data will be maintained for two (2) years after the date the investigation is completed, terminated or until the records are no longer required to support the protocol, whichever date is later. Custody of the records may be transferred in accordance with the Privacy Act 2020, New Zealand. Patient records and data are eligible for inspection and/or copying by applicable regulatory authorities in accordance with the Privacy Act 2020, New Zealand.

*Study Population and Selection Criteria*

All aspects of the study and consent forms will be approved by the HDEC Ethics Committee prior to implementation. All participants will require full informed consent, be willing and able to comply with all study requirements, and will meet the following selection criteria:

Inclusion criteria

* All patients who have had reverse shoulder arthroplasty (RSA) with glenoid bone loss corrected with metallic augments
* Age over 18 years
* RSA surgery performed at Whangarei Hospital and Kensington Hospital
* Consent and compliance with all aspects of the study protocol, methods, providing data during following up

Exclusion criteria

* Age younger than 18 years
* Concurrent use of bone graft in the most recent RSA procedure
* Previous augment or bone graft use on the ipsilateral shoulder
* Involvement with any other ongoing studies
* No pre-operative CT scan images available
* Unable to fill in questionnaire form for any reason

*Recruitment Methods*

Participants have been identified from hospital procurement records for Zimmer Biomet metallic augment use. The Investigators YZ and SK will contact the patients, provide a participant information sheet (PIS), study protocol on request, and discuss the full benefits and risks of the study to the participant. If he/she is happy to continue with the study, they will sign a consent form and be enrolled in the study.

The study is in process of being registered with the Australian New Zealand Clinical Trials Registry (ANZCTR). Registration number TBC.

*Variables*

Primary endpoint

* Variation in post-surgery joint line in comparison to pre-surgery joint line (millimetres) on CT imaging

Secondary endpoints

* Glenoid version on post-surgery CT imaging (degrees)
* Inclination of the implant on post-surgery CT imaging (degrees)
* Nerot-Sirveaux classification for scapular notching on post-surgery CT imaging (2)
* Osseous integration of the implant
* Oxford Shoulder Score (OSS) and Quick Disabilities of the Arm, Shoulder, and Hand (qDASH) score for PROMs

All analyses will be performed using per-protocol population only.

*Expected Outcomes*

Based on preliminary New Zealand Joint Registry data, we expect the overall outcomes of patients who undergo metallic augmented RSA to perform well. To date, there has not been a study investigating joint line anatomy restoration following this procedure. However, there has been a recent paper investigating joint line anatomy restoration following bone graft augments in RSA (1). We expect our patients to have similar outcomes both radiographically and functionally compared to patients who undergo RSA with bone graft.

*Adverse Outcomes*

There is no expectation for adverse outcomes given the surgery has been performed prior to the beginning of this study. However, there is the possibility that following the post-operative CT scan, complications of the surgery may be discovered. In that case, the two fellowship trained Orthopaedic Surgeons MH and MVN will make referral to the appropriate services for clinical assessment and follow up. All participants will be notified of their CT scan results as soon as this is available, including incidental findings and complications. All participants will be given access to contact information of the Principal Investigator and Co-investigators so that any adverse reactions can be reported immediately.

**Reasons for Withdrawal or Termination**

A subject may be discontinued from the study at any time if the subject, the Investigator, or the Sponsor feels that it is not in the subject’s best interest to continue. The following is a list of *possible* reasons for study treatment discontinuation:

* Screening Failure
* Subject withdrawal of consent
* Subject is not compliant with study procedures
* Adverse Event that in the opinion of the Investigator would be in the best interest

of the subject to discontinue study participation

* Protocol violation requiring discontinuation
* Lost to follow-up
* Sponsor request for early termination of study
* Subject death

All subjects are free to withdraw from participation at any time, for any reason, specified or unspecified, and without prejudice. Reasonable attempts will be made by the Principal Investigator to provide a reason for subject withdrawals. The reason for the subject’s withdrawal from the study will be specified in the subject’s source documents and the Case Report Form (CRF). If a subject is withdrawn from treatment due to an adverse event, the subject will be followed and treated by the Investigators until the abnormal parameter or symptom has resolved or stabilized. The Investigators must make every effort to contact subjects who are lost to follow-up. Attempts to contact such subjects must be documented in the subject’s records (e.g., times and dates of attempted telephone contact, receipt for sending a registered letter, etc.).

**Handling of Participant Withdrawals or Termination**

Although subjects may withdraw from the study at any time and for any reason, (or may be withdrawn at the Investigator’s discretion), subject withdrawal should be avoided as much as reasonably possible. In any case, appropriate follow-up for endpoints should be continued. Subjects who prematurely discontinue are not to be replaced. For subjects considered lost to follow-up, the CRF must be completed up to the last visit performed.

**Premature Termination or Suspension of Study**

This study may be temporarily suspended or prematurely terminated if there is sufficient reasonable cause. Written notification, documenting the reason for study suspension or termination, will be provided by the suspending or terminating party to the Investigators, the Sponsor, the Institutional Review Board (IRB) and the Ethics Committee as appropriate. If the study is prematurely terminated or suspended, the Investigators will promptly inform the IRB and will provide the reason(s) for the termination or suspension. Circumstances that may warrant termination or suspension include, but are not limited to:

* Determination of unexpected, significant, or unacceptable risk to participants
* Demonstration of efficacy that would warrant stopping
* Insufficient compliance to protocol requirements
* Data that are not sufficiently complete and/or evaluable
* Determination of futility

The study may resume once concerns about safety, protocol compliance, data quality are

addressed and satisfy the Sponsor and/or the IRB.

**Study Schedule**

1. Registration with ANZCTR
2. Ethics Committee approval
3. Hospital procurement records searched for list of patients who meet the selection criteria
	1. Manual exploration of potential participant list to ensure they meet the selection criteria
4. Potential participants contacted by Investigators and provided PIS, study protocol on request, and discussion around the risks and benefits of the study
5. Participant signs consent form and are formally enrolled in the study
6. Appointment arranged for participant to undergo a limited CT scan, funded by the study Sponsor
7. Following CT scan, participants meet in person with the Investigators to complete PROM questionnaires and to discuss CT scan results
	1. This also provides a final opportunity for participants to ask questions about their surgery, scan, and the study itself
8. Blinded radiographic measurements using the CT scans from at least two fellowship trained Orthopaedic Surgeons
9. Data analysis
	1. Statistics analysis will be outsourced to a qualified Biostatistician
10. Manuscript write-up for publication in a reputable open-access indexed journal

All participants will have the opportunity to arrange unscheduled appointments with the Investigators to discuss any concerns or questions.

**Sample Size Justification**

The following parameters were used for the sample size calculation:

* Primary outcome is joint line anatomy restoration
* α=0.05
* 1-β=0.8
* Enrolment ratio 1:1
* Italia et al., 2020 paper was used for the anticipated effect size

From our sample size calculation, we require 12 participants to achieve statistical significance. We aim to approach 20 patients with the expectation that some may decline or not be able to be contacted. In the unlikely event that we over-recruit, a random sample of 20 participants will be selected to continue with the study.

**Assessment of Safety**

Adverse events (AE) will be monitored and collected by the study team from the point of signed consent until 7 (for non-serious AEs) or 30 days (for serious AEs) after the last day of study participation. For each AE, a detailed explanation will be obtained from the subject and subject’s medical record. All AEs will be recorded on the CRFs.

*Definition of Adverse Event*

An AE is defined as any unanticipated medical occurrence regardless to relationship of the investigative arm of the trial. An AE can be any unintended sign, lab abnormality, symptom, or disease associated with the trial. Any abnormality that presents during a medical test are to be defined as an AE if it produces clinical signs and/or symptoms, requires intervention, or deemed clinically significant by the Investigators.

*Definition of Serious Adverse Event (SAE)*
An adverse event is considered serious if it results in any of the following:

1. Death
2. A life-threatening AE
3. Requires inpatient hospitalization or prolongs existing hospitalization
4. Persistent disability/incapacity
5. Medically important event by the Investigators

*Definition of Unanticipated Adverse Device Effect (UADE)*
Unanticipated adverse device effect is any serious adverse effect on health or safety, any life-threatening problem or death caused by, or associated with a device, if that effect, problem, or death was not previously identified in nature, severity, or degree of incidence in the application; or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects.

*UADE Reporting*

In the case of a UADE, the study Investigator shall notify the Sponsor and the reviewing IRB as soon as possible, but in no event later than 10 working days after the Investigator first learns of the effect. The study Sponsor is responsible for conducting an evaluation of an UADE and shall report the results of such evaluation to the reviewing IRB and the Investigator within 10 working days after the Sponsor first receives notice of the effect.

*Severity of Adverse Event*
The Investigators will be asked to assess the severity of the AE using the following categories:

* 1. **Mild** – Events requiring minimal or no treatment and do not interfere with the participant’s daily activities
	2. **Moderate** – Events result in a low level of inconvenience or concern with the therapeutic measures. Moderate events may cause some interference with functioning.
	3. **Severe** - Events interrupt a participant’s usual daily activity and may require systemic drug therapy or other treatment. Severe events are usually potentially life-threatening or incapacitating.

*Data Safety Monitoring*
As the treatments and surgical techniques are currently being used as standard of care, the study team does not anticipate subjects experiencing any adverse events solely due to being in the study. This is simply a proposal to formally randomize and follow subjects undergoing two commonly performed procedures, both of which have been shown to be safe and approved. Therefore, a formal Data Safety Monitoring Board will not be needed for this study.

**Data Monitoring**

The Principal Investigator will be responsible to ensure the study is conducted in accordance with the protocol, Good Clinical Practice (GCP), applicable regulatory requirements, and that the data recorded is valid. To achieve this objective, the study will be continuously monitored and reviewed on a monthly basis by the study team.

Clinical site monitoring is conducted to ensure that the rights and well-being of human subjects are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirement(s).

A Clinical Monitoring Plan will be created by the Sponsor and describe in detail who will conduct the monitoring, at what frequency monitoring will be done, at what level of detail monitoring will be performed, and the distribution of monitoring reports.

**Data Handling and Record Keeping**

The collection of personal patient information will be limited to the amount necessary to achieve the aims of the research, so that no unneeded sensitive information is being collected.

Only study personnel will collect data. Hard copy documents will be retained for the duration of the study until data entry. These will primarily be limited to qualitative study notes, questionnaire forms, and results of CT scans. All hard copy documents will be kept in a locked cabinet in the research coordinator’s office. Data entry will be completed on a password encrypted and secured Excel spreadsheet which will then be used for data analysis. Only de-identified data will be used for data analysis. All hard copy documents will be shredded within five years after completion of the study upon Sponsor approval.

**Institutional Review Board**

The protocol, informed consent form(s), and all participant materials will be submitted to the IRB for review and approval. The Institutional Review Board will be based at Northland District Health Board and is chaired by Dr. Michael Roberts. Contact details of the IRB can be found on the HDEC website, or alternatively directly emailed at research@northlanddhb.org.nz. Approval of both the protocol and the consent form must be obtained before any participant is enrolled. Any amendment to the protocol will require review and approval by the IRB before the changes are implemented to the study. All changes to the consent form will be IRB approved; a determination will be made regarding whether previously consented participants need to be re-consented.

**Consent Process**

Each potential participant must provide written consent with full knowledge of the procedures involved. The informed consent, approved by the IRB and in accordance with regulatory guidelines, must be fully explained by the Investigators or member of the study staff including the study aims, methods, benefits and risks, and signed by the subject before enrolment into the study. Potential participants will be informed that study participation is voluntary and that they may withdraw at any time. The subjects will be told that choosing against participation will not affect the care received for treatment. The subjects will be informed that they will be authorizing access of investigational staff to confidential medical records. The subject will be given sufficient time to read the consent and ask any questions. Once the informed consent is signed, the subject will be given a copy of the document.

**Study Protocol Deviation**

A protocol deviation is any noncompliance with the clinical trial protocol or GCP requirements. The noncompliance may be either on the part of the participant, the Investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

All protocol deviations/violations should be documented using the Protocol Deviations/Violations CRF and submitted to the IRB according to their reporting guidelines.

**Laws and Regulations**

This clinical study will be conducted in compliance with all national laws and regulations of the countries in which the clinical trial is performed, as well as any applicable guidelines. The trial will be registered on the ANZCTR website.

**Publication and Data Sharing Policy**

The preparation and submittal for publication of manuscripts containing the study results shall be in accordance with a process determined by mutual written agreement among the study Sponsor and participating institutions. The publication and presentation of any study results shall comply with all applicable privacy laws.

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