AOANJRR | Australian Orthopaedic Association National Joint Replacement Registry

Protocol

DISTINCT: Dual Mobility Versus Standard Total Hip Arthroplasty In Femoral Neck Fractures, A Registry-Nested, Cluster-randomised Trial

Prepared by AOANJRR

Version 4.1

Contents

DISTINCT: Dual Mobility Versus Standard Total Hip Arthroplasty In Femoral Neck Fractures, A Registry-Nested, Cluster-randomised Trial

Methodology	• A pragmatic, multicentre, cluster-randomised, crossover, superiority trial with a primary endpoint of hip dislocation within one year integrated with Registry data collection. • In addition to usual registry data, the outcome will be determined by data linkage between the AOANJRR and hospital level data acquired through state governments or the Australian Institute for Health and Welfare.

1. Introduction

1.1 About the AOANJRR

The AOANJRR was established in 1999 to improve outcomes for patients undergoing joint replacement surgery in Australia. The AOANJRR is federally funded and operates as a Federal Quality Assurance Activity. It has almost complete data on all hip and knee replacement procedures performed since it achieved full national implementation in mid-2002 (with over 1.5 million procedures now captured). In 2004 the AOANJRR extended to collecting all other joint replacements including shoulders, elbows, wrists, ankles and spines and full national data collection was implemented by 2008. Using revision, reason for revision and death as its principal end points, it has identified best practice with respect to prostheses choice, surgical technique, and patient selection. Making this information available to relevant stakeholders, including surgeons, has reduced post-operative complications and subsequent revision surgery.

1.2 Background

Hip fracture is the most serious and costly fall-related injury suffered by older people, affecting more than 25,000 Australians each year at a cost of more than $1 billion in 2018.[1] Despite a reduction in the age-specific incidence of hip fractures secondary to effective preventive measures, the absolute number of hip fractures is increasing in Australia due to population growth and ageing.[2] Elderly patients with hip fracture are likely to experience significant functional impairment, decreased mobility and reduced quality of life that may necessitate the transition from independent living to a residential aged care facility.[3] The one-year mortality following a fractured neck of femur is approximately 25%,[4-6] and is associated with an increased risk of death that persists for several years after injury.[7] International treatment guidelines therefore focus on reducing morbidity and mortality, as well as maximising functional independence post-fracture.

Nearly half of hip fractures are in the 'subcapital' (femoral neck) region, of which the majority are displaced.[1] These fractures are normally treated with arthroplasty, which involves either partial or complete replacement of the hip joint with a prosthesis. Traditionally, subcapital fractures have been treated with *hemi*arthroplasty (HA), which involves replacing the femoral head only, leaving the patient's acetabulum (socket) intact. An alternative form of arthroplasty is total hip arthroplasty (THA) which involves replacing the femoral head and the acetabulum (socket). Recent research has demonstrated improved pain and functional outcomes following THA for patients that can independently mobilise, and have greater than five years life expectancy.[8,9] These findings have been incorporated into international practice guidelines,[10-12] and consequently, the use of THR for femoral neck fractures in Australia is increasing.[1,13] Despite improved functional independence and quality of life, the rate of dislocation after THA for hip fracture is more than double that of HA, and approximately

five times higher than the rate after THA for osteoarthritis. Dislocation involves separation of the prosthetic femoral head and acetabular cup and requires closed reduction of the prothesis under sedation or general anaesthetic to restore a patient's ability to ambulate. For irreducible or recurrent cases, a revision THA may be required. Treatment of recurrent instability is associated with significant costs and decreased patient quality of life.[14,15] Closed reduction and revision THA incur additional hospital costs of 19% and 148% of an otherwise uncomplicated THA, respectively.[15] Currently, patients undergoing a THR are routinely informed about the risk of dislocation prior to their surgery. Medical and allied health staff often provide "hip precautions" which require patients to restrict their post-operative activity to minimise the risk of dislocation.[16] These restrictions (not flexing beyond 90 degrees, not sitting in deep chairs, not crossing legs) are disruptive to usual activity and are a source of anxiety during recovery as patients are constantly reminded of the risk of dislocation.[17]

Dual mobility cup (DMC) has been proposed as an alternative, novel design for THA that is purported to reduce the risk of dislocation in high-risk populations such as femoral neck fractures. The DMC theoretically increases stability by providing an additional articulating surface ('ball-within-ball') compared to traditional THA designs (Figures 1-3).[18] This is achieved by use of a larger head-to-neck ratio and jump distance (i.e. vertical or inferior head displacement required for dislocation) that approximates the size of the natural femoral head (and the size of a hemiarthroplasty) allowing an increased range of motion in all directions before dislocation occurs. In standard THA, impingement of the neck against the polyethylene liner at a single articulation creates a lever effect, increasing the risk of dislocation. In the setting of elective THA performed for osteoarthritis, use of DMC is associated with a significantly decreased risk of dislocation compared to conventional THA in the first post-operative year for both primary and revision THR procedures.[19]

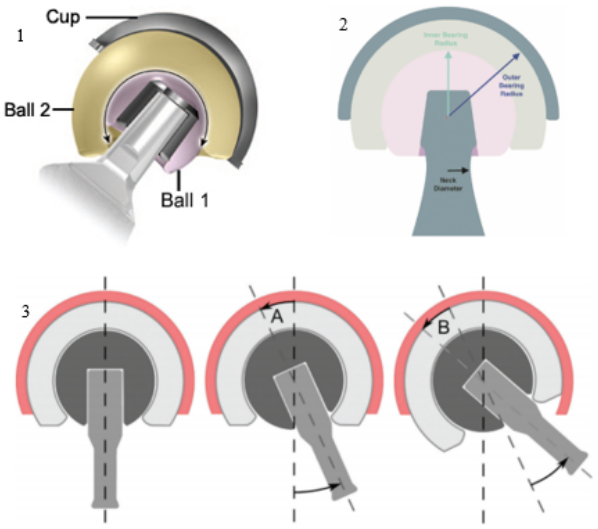

Figure: 1. 'Ball-within-ball' concept of dual mobility THA; 2. Head-to-neck ratio and jump distance, dual mobility versus standard single-bearing total hip arthroplasty; 3. Articular motion of the dual mobility THA, the femoral head rotates within the liner until contact is made at A, at which point the liner then rotates within the acetabular shell B, increasing the range of motion 10-15°.

There is evidence that the use of DMC in the fracture neck of femur population reduces risk of dislocation. A prospective multicentre case series of 214 patients with a mean age of 83 years demonstrated a dislocation rate of 1.4% at 9 months post-operatively.[20] A Danish before-and-after case series comparing DMC to bipolar HA in a similar patient demographic reported a slightly higher dislocation rate of 4.6% and 14.6%, respectively. The use of DMC was associated with a significantly

lower incidence of re-operation for dislocation.[21] A similar before-and-after case series comparing DMC to conventional THA reported dislocations and revision surgery only in the latter group.[22] A prospective, randomised feasibility trial in the UK was abandoned due to poor recruitment and results for the sample of 20 patients were not analysed.[23] The most recent systematic review reporting 554 DMC performed for fractured neck of femur found a relatively low dislocation rate of 2.3%.[24] Registry data from the Nordic Arthroplasty Register Association (NARA) database demonstrates a greater than 50% reduction in the risk of revision for dislocation using propensity score matching to compare DMC to conventional THA in the fractured neck of femur population.[25] Australian registry data, however, does not show a difference in the risk of revision surgery for dislocation, but this may be due to confounding by indication.[13] For example, DMC may be preferentially used in patients with conditions associated with a higher risk of dislocation such as revision procedures, tumours and hip fractures.

On November 15, 2018, we conducted a focus group with a convenience sample of five patients who had recently had a THA (three for fracture, two elective) at two participating hospitals (St. George and Sutherland). While the main concern patients had during their recovery was the risk of an infection, all patients specifically recalled the risk of dislocation and the recommended precautions, and all reported it as a major source of anxiety. Patients were "particularly careful" and most thought their hip was "going to pop out" if they performed normal activities, such as gardening, cutting their toenails, or driving. Two patients mentioned they were "chastised frequently" by hospital staff for "doing the wrong thing". Most patients voluntarily opted to use walking aids or held handrails to specifically mitigate dislocation risk and not "upset" the joint. All patients agreed dislocation following hip replacement was an important issue and supported an experimental trial to reduce that risk. The issue of prosthesis novelty was specifically raised, with a single patient expressing concern about having a prosthesis with a shorter track record than "standard" THA. Patients wanted to "move forward with innovations" and did not express concern when asked about consent, with most considering it unnecessary, particularly given that dual mobility THA is approved and is used routinely in many centres (without any specific consent).

Cost-benefit analyses have demonstrated significant savings associated with a reduced incidence of dislocation for primary THA performed for osteoarthritis. Economic modelling of a French cohort assuming a relative risk of dislocation of 0.4 for DMC compared to conventional THA reported 3,283 less dislocations and 882 less revision surgeries at a cost saving of €28.3 million per 100,000 THA procedures.[26] Similarly, analysis of direct and indirect costs using administrative and registry databases from the United States demonstrated net cost savings per dislocation saved at a cost difference threshold of $1,023 (2013 USD) more for DMC implants.[27] The DMC design of THA therefore has the potential to reduce the cost burden associated with closed reductions and revision THA performed for instability in a high risk population. A recent editorial from a leading orthopaedic journal called for a high quality, adequately powered trial to determine if routine use of DMC can address the problem of the high rate of dislocation associated with the use of THA in people with fractured neck of femur.[28]

1.3 Choice of comparators

Both prostheses (DMC and conventional THA) are currently used in usual care for the treatment of femoral neck fractures (FNF). DMC will be labelled the intervention and conventional THA as the comparator.

The trial will allow DMC of any brand. All DMC are similar in design and surgeons / hospitals will be allowed to choose the implant brand of their preference.

Conventional THA will use a polyethylene head size of at least 32 mm unless anatomy does not allow (e.g. unusually small patient).

Each participating surgeon will use the same femoral stem, fixation method and surgical approach for both the intervention (DMC) and control (THA) groups.

1.4 Hypotheses

In patients treated with hip replacement surgery for a recent femoral neck fracture, DMC reduces the risk of dislocation in the first year after surgery compared to conventional THA.

1.5 Primary Aim

To compare the effectiveness of DMC to conventional THA for femoral neck fracture in reducing the risk of hip dislocation in the first post-operative year.

1.6 Secondary Aim

- To compare the revision rates (for dislocation and for any reason) at one, two and five years post-operatively.
- To determine the cost-effectiveness of using DMC compared to conventional THA in reducing the risk of hip dislocation in a hip fracture population.
- To compare the mortality between groups at 30 days, 120 days, and then at one, two and five years post-operatively.

1.7 Primary Outcome Measure

The primary outcome is hip dislocation within one year.

1.8 Secondary Outcomes Measures

1.8.1 Revision surgery for dislocation at 1,2 and 5 years

1.8.2 Revision surgery for any reason at 1, 2 and 5 years

1.8.3 Death at 1, 2 and 5 years

1.8.4 Complications: any unplanned reoperation or readmission related to the surgery within 1 year (see below)

1.8.5 Costs: if DMC is found to be superior to conventional THA, the cost-effectiveness will be analysed (see list below).

Complications will be classified into the following groups:

- Readmission related to the original surgery or associated treatment (yes/no)
- Reason for admission: infection, dislocation, stiffness, fracture, wound dehiscence, implant loosening, migration or failure, wound bleeding, other (non-joint) surgery.
- Reoperation on the same joint (yes/no)
- Reason for reoperation: infection, dislocation, fracture, wound dehiscence, implant loosening, migration or failure.
- Death

2. Methods

2.1 Setting

Eligible hospitals (public and private) performing THA for fractured neck of femur in Australia. The study will be nested within the AOANJRR Clinical Trials Platform, an electronic platform for recruitment and data collection for patients undergoing joint replacement surgery.

2.2 Eligibility

2.2.1 Hospital (Site) Level

- Departmental (or surgeon group) agreement to participate in the study and adhere to study protocols.
- No other changes to practices or protocols relevant to the care of patients with fractured neck of femur over the course of the study.
- All listed investigators will complete Good Clinical Practice (GCP) training prior to commencement of the study if not completed within the past three years.

2.2.2 Patient Level

2.2.2.1 *Inclusion Criteria*

1. Displaced femoral neck fracture suitable for standard THA (e.g. no pre-existing deformity requiring custom or non-standard protheses)
2. Aged 50 years or older
3. Patient meets Australia New Zealand Hip Fracture Guidelines[10] for management of a displaced intracapsular hip fracture with a total hip replacement:
4. Able to walk independently out of doors with no more than use of a stick prior to the fracture
5. Not cognitively impaired
6. Medically fit for anaesthesia and the procedure

2.2.2.2 *Exclusion Criteria*

- For the primary analysis, the following exclusions will apply at a patient level:
- Dementia or other significant cognitive impairment
- Resident of a permanent residential aged care facility
- Pathological fracture due to tumour

2.3 Sample Size

A recent large randomised controlled trial of 1495 patients from 80 institutions in 10 countries demonstrated a 4.7% incidence of dislocation in the two years following THA for fractured neck of femur in patients aged greater than 50 years.[29] This compared to a 2.7% dislocation incidence for patients that received hemiarthroplasty in the same study. A systematic review and meta-analysis of randomised controlled trials comparing hemiarthroplasty to THA that included outcomes from five studies reported a 3.3% incidence of dislocation for hemiarthroplasty and 8.5% for THA.[9] The cumulative percent revision of primary conventional total hip replacement performed for fractured neck of femur in Australia is 3.0%, 5.3% and 7.9% at 1, 5 and 10 years respectively, of which prosthesis dislocation (32.5%) is the most common indication.[13]

For the sample size for the DISTINCT study, we anticipate an overall dislocation rate of 4-5% at one year based on the above data. A recent systematic review of DMC performed for FNF reported an incidence of dislocation of 2.5% and an overall revision of 2.3% at a mean follow-up of 1.3 years.[24] A matched-pair analysis from the Nordic Arthroplasty Registry Association (NARA) reported approximately half the revision rate for dislocation for DMC compared to conventional THA.[25] With targets of 6% and 3% for conventional THR and DMC, respectively (halving the revision rate as previously reported using Nordic registry data[25]), a cluster-randomised trial using at least 48 clusters would require 16 patients per

group, per cluster (n = 1,536) with 80% power and a significance level of 5% (ICC = 0.01, IPC = 0.008). As the outcome is cumulative incidence (regardless of mortality) and achieved through data linkage, no adjustment for death or loss to follow up has been made. The study will recruit a minimum of 16 patients per group (32 total) per cluster. This sample size would provide 90% power for a higher event rate of 8% and 4% for the two groups.

2.4 Recruitment

Hospitals will be approached individually by the lead CI and the study team, based on high usage of THA for hip fractures. A site will be considered eligible if they perform 15 THA for hip fracture within 12 months, allowing recruitment with 24 months. Departmental (or surgeon group) agreement with the study protocol and the individual treatment protocols (for each group) will be required. Sites where a subgroup of attending surgeons agree to participate will be included if the number of eligible patients for that group of surgeons per year is at least 15. A site investigator will be nominated for each site.

2.5 Blinding

Sites will not be blinded to group allocation. Patients will be informed of a study comparing two different but common types of THA used for fractured neck of femur

The statistical analysis will be blinded. The Writing Committee will be blinded and will prepare two separate manuscripts based on the possible group allocations.

2.6 Randomisation

Each site will be randomised with a 1:1 allocation with a computer-generated random sequence. Simple randomisation will be used (no use of blocks, no stratification). The allocation will refer to the first intervention.

2.7 Intervention

Each site will be allocated to two consecutive periods of standard protocol of DMC and standard protocol of conventional THA for management of FNF in eligible patients with the order of the two periods determined by randomisation at a 1:1 ratio on an open label basis. Allocation will occur one month (3 – 6 weeks) prior to site commencement to allow introduction of local protocols and supply of implants.

Each site will adhere to the initially randomised protocol for a time period based on surgical volume aiming for 16 patients eligible for the primary analysis per group (32 total per site).

Patients will be informed of the trial during initial data entry. Patients will be specifically asked at the time of study for consent to follow up, for use of their data in research, and use of linked data to measure and verify surgical outcomes. Patients will not be individually consenting to be randomised to either DMC or conventional THA, as both surgical implants represent standard practice and randomisation is not at the patient level. Further details on the consent process is listed in the protocol (section 4.3).

Patients will be followed by the AOANJRR by recording and matching revision procedures and mortality, as per usual practice. There will be no change to usual medical follow up (clinic attendance, investigations etc.). The outcome (dislocation) will be determine by data linkage between the AOANJRR and hospital level data acquired through state governments or the Australian Institute for Health and Welfare.

Total hip arthroplasty using both conventional and dual mobility design will be performed as per standard surgical technique according to surgeon preference, using the same surgical approach for

both treatment groups. Patients who have a contraindication to either implant design will be treated as per local protocols.

2.8 Adherence

Adherence to study protocol will be determined using standard AOANJRR data (prosthesis details)

2.9 Concomitant Care

Standardisation of surgery and post-operative treatment will be required as follows:

- Surgical approach can vary by surgeon, but individual surgeons must maintain the same approach criteria for both study groups
- If a posterior approach is used, a capsule repair will be performed
- Weight bearing without restriction post-operatively
- Splinting will not be used routinely
- Education and information around hip precautions will be consistent across groups
- Each site will provide the same rehabilitation approach for both treatment arms

2.10 Additional Care

As both interventions are standard, recommended practice, no additional treatment will be provided for participants.

2.11 Data Collection/Schedule

Data collection for baseline data and follow-up at 1 year, 2 years and 5 years will be via standard (currently routine) forms submitted to the AOANJRR for revision total hip arthroplasty and through data linkage.

Time Point	Data Collection Questions and Instruments
Pre-operative	Age Sex Joint (hip) Side Unilateral vs bilateral Primary or revision ASA grade BMI
1 year	Dislocation (via linked data) Revision surgery (via AOANJRR) Complications (via linked data)
2 years, 5 years	Revision surgery (via AOANJRR) Death (via linked data)

The AOANJRR already collects data on almost all joint replacement procedures performed in Australia. The operative data are completed at the time of surgery on a Registry form. These forms are collated each month by the hospital and sent to the Registry for data entry into the secure Registry database. This process will remain unchanged.
The Registry currently stores identified patient data for several reasons;

1. Procedures for the same patient need to be linked together in the Registry using patient identifiers to track the joint history.
2. The Registry links to the NDI twice a year in order to flag if a patient has died.

Furthermore, identified information is required for this registry-nested study because the Registry data needs to be linked to hospital level data acquired through state governments or the Australian Institute for Health and Welfare using patient identifiers.

2.12 Data Monitoring and Cleaning

A separate Data Quality Committee will be established to monitor data management and quality.
A separate safety monitoring committee will not be established, and no stopping rules will be used as both interventions are commonly used and recommended treatments. No interim analysis will be performed; this will reduce the chance of early stopping due to spurious findings. Adverse events (separate to complications listed under secondary outcomes) will be monitored by the Trial Management Committee.

2.13 Auditing and Data Validation

Revision surgeries recorded by the AOANJRR are validated by cross-referencing with hospital-level data and unmatched revisions are verified by contacting individual sites.

The AOANJRR Data Linkage project will be used to measure readmission and reoperation. The AOANJRR also links to the National Death Index (NDI) twice per year (February and September) to measure mortality.

2.14 Statistical analysis

The analysis for the primary aim will test between-group difference in the proportion of cases sustaining a dislocation of the affected hip within one year post-operatively.
The primary analysis will use cluster summary methods. These methods estimate the treatment effect using cluster level differences and have been shown to be appropriate for cluster randomised crossover trials with rare outcomes and the intracluster and interperiod correlation coefficients expected in this trial. Multiple imputation will be used to account for missing outcome data, using auxiliary variables gathered from routine AOANJRR data (including age, sex, baseline health, pain and function, diagnosis and surgical factors).

Secondary analyses will be performed for the primary outcome, to test for differences in treatment effect between subgroups of patients: surgical approach, ASA grade, BMI grade and gender.
The analysis method will be the same as the primary outcome and will include an interaction term between subgroup and treatment group.

Secondary analyses will include an analysis of all-cause revision, revision for dislocation, and other complications (death, re-operation and readmission rates). Cluster summary methods will be used for all secondary analyses.

If DMC are found to be superior to conventional THA, a cost effectiveness analysis of DMC compared to conventional THA will be performed from a health system perspective, calculating the cost per dislocation saved. The only difference in input costs will be the difference in implant costs, as all other care costs will be equal.

2.15 Operative Record

As above no standard processes will change regarding the operative record collected by the AOANJRR.

2.16 Data Access

All principal investigators involved in data analysis will have access to deidentified datasets. All principal investigators involved in subcommittees will have access to relevant deidentified data necessary for undertaking their specific role (e.g. outcome validation).

3. Study Approvals and Dissemination

3.1 Ethics & Site Approvals

All ethics and site approvals will be obtained prior to commencing patient recruitment at participating sites. Ethics approval will be obtained through an institutional Human Research Ethics Committee (HREC) or through a central HREC if the site accepts approvals through National Mutual Acceptance. Following approval, the study will be submitted to local ethics committees and Research Governance Offices as required for each site.

3.2 Amendments

Any modifications to the protocol which may impact on the conduct of the study, potential benefit of the patient or may affect patient safety, including changes of study objectives, study design, patient population, sample sizes, study procedures, or significant administrative aspects will require a formal amendment to the protocol. Such amendment will be agreed upon by the Steering Committee and approved by the Ethics Committee prior to implementation and site notification.

Administrative changes of the protocol are minor corrections and/or clarifications that have no effect on the way the study is to be conducted. These administrative changes will be agreed upon by Trial Management Committee and will be documented in a memorandum. The Ethics Committee may be notified of administrative changes at the discretion of Trial Management Committee.

3.3 Consent

Individual consent is not being sought for randomisation. This is because randomisation is not occurring at the patient level and because both treatments represent current standard practice. Patients are not usually consented or informed regarding the specific type of THA used in hip fracture surgery (e.g. type of articulation, bearing surface, implant fixation method or use of DMC). The DISTINCT study will use the same waiver of consent process as the CRISTAL study which has received ethics approval (Reference: X18-0424 & HREC/18/RPAH/603). Participants will be consented for surgery as per usual practice.

3.4 Governance (Coordinating Centre)

The day to day management of the trial will be the responsibility of the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) and South Australian Health and Medical Research Institute (SAHMRI).

Other expert subgroups may be established throughout the project to advise on specific elements and make recommendations should the need arise. SAHMRI is already contracted by the AOA to provide data entry, data management, IT and statistical analysis services to the AOANJRR.

3.5 Risks to Patients

As patients will be treated with the standard protocol for both conventional THA and DMC, this study poses no foreseeable risk, harm or discomfort to patients.

3.6 Data Confidentiality, Privacy and Security

SAHMRI will provide IT, data management and statistical analysis services for this registry-nested study. SAHMRI is contracted by the AOA to provide similar services for the AOANJRR. This collaboration has been very successful at maintaining a high level of data security and data quality for the AOANJRR.

3.6.1 South Australian Health and Medical Research Institute

SAHMRI is South Australia's first independent flagship health and medical research institute. The SAHMRI team working on the AOANJRR consists of a project manager, data managers, statisticians, IT resources and data entry staff. The SAHMRI team contribute crucial data management and analysis expertise to the AOANJRR which will be transferred to the DISTINCT study. This collaboration has been very successful at maintaining a high level of data security and data quality for the AOANJRR. See SAHMRI ICT Security Summary.

3.6.2 Protection and confidentiality

The AOANJRR is required to have highly secure data protection systems to secure the identified information which it currently holds as this is an absolute requirement under its Federal Quality Assurance Activity.
SAHMRI has existing security systems, policies and procedures in place as well as software barriers to protect personal information and ensure confidentiality (Appendix A).

3.6.3 Restrictions to use of data

The data collected as part of standard Registry data collection will continue to be used for Registry activities, any additional data collected specifically for this study will only be used by the AOANJRR for the purposes of this study.

Any data published in reports, papers and publications will be de-identified. Access to identifiable information is limited to authorised AOANJRR and SAHMRI staff.

3.6.4 Patient confidentiality

All patient data will be managed in accordance with the Guidelines for the Protection of Privacy in the Conduct of Medical Research. Patient contact details will only be used for the purpose for which they were collected and will be stored securely and confidentially. Patients will not be identified in any reports, manuscripts or presentations derived from the DISTINCT project.
https://www.oaic.gov.au/privacy/the-privacy-act/rules-and-guidelines/medical-research/

3.6.5 Surgeon and Hospital confidentiality

No individual surgeons or hospitals will be identified in any reports manuscripts.

3.7 Data Storage and Record Retention

The SAHMRI Data Management Staff have established security systems which limit access to SAHMRI Data Management and Registry staff only.
There are policies and procedures in place as well as software barriers to protect personal information. These include the use of codes, passwords and encryption.

The proforma used for data collection are stored in a secure locked room at SAHMRI. After a period of two years the forms stored will be optically scanned and electronically stored in the secure SAHMRI database. All data will be retained in accordance with good scientific practice.
All electronic data collected will be held for a minimum of 15 years after publication of any final reports and manuscripts. Data quality will be checked monthly under the supervision of the Data Quality Committee.

3.8 Reporting and Dissemination

3.8.1 Reporting

Although identifying information is stored no patient is identified in any Registry reports or publications. AOANJRR Registry reports will only contain deidentified data. This includes any ad hoc reports prepared by the Registry.
There is a requirement to meet standard AOANJRR publication policy requirements which includes having clinical oversight from the AOANJRR and the Statistician involved in the analyses included as authors on the paper). A writing committee will be established to write the principal papers (primary and secondary outcomes).

3.8.2 Dissemination

Dissemination will be by peer reviewed journal publication, conference presentation and through media. All study findings will be reported, regardless of statistical significance or the size or direction of effect.
Study findings will be released to participating sites and investigators.
Input will be sought into guideline development by state and national bodies (e.g. ACSQHC).
The results of the study are expected to be published in a journal with high impact and to be of interest to a wide audience (beyond orthopaedics and geriatricians, including hospitalists and public health). They are expected to have clinical importance and statistical power that will enable the results to influence practice, which currently lacks studies on this size and quality.

3.8.3 Authorship

Authorship for principal papers will be by the members of the writing committee and the DISTINCT Study Group (consisting of all investigators according to the authorship guidelines of the ICMJE).

3.9 Implementation

Following the study, practice change at departmental and surgeon level will be measured for each surgeon and each site using routine AOANJRR data. Implementation of practice change based on study results is expected to be facilitated by widespread surgeon involvement in the trial and the uncertainty around the superiority of either method.

3.10 Statement for Compliance with NHMRC National Statement on Ethical Conduct of Research Involving Humans

This study will be conducted in accordance with the ethical principles that have their origin from the Declaration of Helsinki and are consistent with ICH/GCP. This study will comply with the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Research Involving Humans.
https://www.nhmrc.gov.au/guidelines-publications/e72

4. Administrative Information

4.1 Registration

DISTINCT will be registered with the Australian and New Zealand Clinical Trials Registry (anzctr.org.au).

4.2 Funding

This study is funded by an Australian Orthopaedic Association Research Foundation (AOARF) grant awarded in October 2019. The funding source had no role in the design of this study and will not have any role in execution, analyses, interpretation of the data, dissemination or decision to publish. The study is also funded by the Whitlam Orthopaedic Research Centre.

4.3 Sponsor

Whitlam Orthopaedic Research Centre, Level 2, Ingham Institute, 1 Campbell St, Liverpool NSW, 2170.

4.4 Declaration of interests

Ian Harris (IH), Stephen Graves (SG), Richard de Steiger (RdS) and Michelle Lorimer are employed by the AOANJRR.

4.5 Contributors

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Consumer

4.6 Study Coordination

Committee	Members	Responsibilities
Writing Committee	IAH, SA, JEF, LK	Protocol development and publication Preparation of principal publications (primary and secondary outcomes)
Steering Committee	All investigators listed above (contributors)	Final protocol approval Study oversight Principal publication approval
Trial Management Committee	IAH, SEG, JEF AOANJRR Registry Manager, AOANJRR Clinical Trials Manager, LK, ML, Project Manager	Integration with AOANJRR Ethics approval Site liaison (recruitment and maintenance)

Data Quality Committee	IAH, JEF, LK, ML, Project Manager	Data management Data quality audits

4.7 Abbreviations

AOANJRR	Australian Orthopaedic Association National Joint Replacement Registry
AAOS	American Academy of Orthopaedic Surgeons
ANZHFR	Australian and New Zealand Hip Fracture Registry
DMC	Dual Mobility Cup
FNF	Femoral Neck Fracture
ICJME	International Committee of Medical Journal Editors
NICE	National Institute of Health and Care Excellence
THA	Total Hip Arthroplasty

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Appendix A - SAHMRI ICT Security Summary

Confidentiality

• SAHMRI staff have confidentiality clauses in their employment contracts that prohibit the disclosure of confidential information – even after the termination of the agreement in question
• Access to SAHMRI information is revoked on termination of employment
• SAHMRI staff are directed to have a "clean desk" policy to ensure that confidential information is properly secured. These measures mitigate the risk of confidential data being disclosed to unauthorised people, as well as ensuring that conversations about confidential data can take place in a secure location.

Software Patching
• SAHMRI endpoints and infrastructure undergo regular patching activities, as recommended by the applicable vendor (e.g. Microsoft).

Network Security
• SAHMRI employs an endpoint security solution that is deployed to all endpoints providing on-access scanning, application monitoring, as well as regular scheduled scans
• The endpoint security system alerts the SAHMRI ICT team when suspicious activity within the SAHMRI network occurs, and can automatically take appropriate action to mitigate adverse consequences
• Access to the ICT infrastructure is granted to a select group of ICT personnel for the necessary administration of the environment
• Documents and data relating to the AOANJRR project are stored on network file shares to which access is granted to authorized personnel on a least privilege basis
• Access controls are enforced using groups in Active Directory
• Group membership is approved by data owners
• General SAHMRI staff do not have administrator access to desktop machines
• SAHMRI's network is protected by security appliances that actively monitor the environment for suspicious activities
• SAHMRI's email server provides spam filtering and malware protection

Physical Security
• SAHMRI staff, as well as IT administration staff are located at SAHMRI's North Terrace facility in secure areas with multiple levels of swipe card access and no publicly visible windows
• Data is housed in SAHMRI's main server room in its North Terrace site which is physically accessible to a select group of authorised personnel only via card swipe access
• Tape backups of the data are stored securely offsite https://www.timg.com/service/backup-media-storage

Appendix B – Primary Investigators

Table 1: List of Sites for Ethics Approval by Sydney Local Health District (RPAH Zone)

State	Hospital	Primary Investigator Details

ACT	Canberra Hospital	Dr Alexander Burns
NSW	Albury Base Hospital	Dr Jeremy Kolt
	Blacktown Hospital	Dr Bijoy Thomas
	Coffs Harbour Hospital	Dr Peter Summersell
	Concord Repatriation General Hospital	Dr Peter Walker
	Gosford Hospital	Prof. Ian Incoll
	Hornsby & Ku-Ring-Gai Hospital	Dr David Hale
	John Hunter Hospital	Dr Zsolt Balogh
	Liverpool Health Service	Dr David Lieu
	Northern Beaches Hospital	Dr Rob Sew Hoy
	Royal North Shore Hospital	Dr Joseph Isaacs
	Royal Prince Alfred Hospital	Dr Mark Horsley
	St George Hospital	Dr Rob Molnar
	St Vincents Hospital (Sydney)	Dr John Rooney
	Sutherland Hospital	Dr Rob Molnar
	Sydney Adventist Hospital	Dr Louis Shidiak
	Prince of Wales Hospital	Dr Michael Solomon
	Wagga Wagga Base Hospital	Dr Andrew Clout
	Westmead Hospital	Dr Buddhika Bulalla

	Wollongong Hospital	Dr Aziz Bhimani
QLD	Cairns Base Hospital	Ben Parkinson
	Gold Coast Hospital Health Service (Robina and University Hospitals)	Dr Will Talbot
	Greenslopes Private Hospital	Dr Lorenzo Calabro
	Ipswich Hospital	Dr Daniel Bopf
	Logan Hospital	Dr Julian Nusem
	Mater Hospital Brisbane	Dr John Radivanovic
	Mater Private Hospital Brisbane	Dr John Radivanovic
	Prince Charles Hospital	Dr Catherine McDougall
	Princess Alexandra Hospital	Dr Cameron Cooke
	Queen Elizabeth II Jubilee Hospital	Dr Chris Bell
	Redcliffe Hospital	Dr Anthony Houston
	Sunshine Coast University Hospital	Dr James Tunggal
	Townsville Hospital	Dr Kaushik Hazratwalla
	Wesley Hospital Brisbane*	Dr Rohan Brunello
SA	Calvary Adelaide Hospital*	Dr Luke Mooney
	Flinders Medical Centre	Dr Chris Wilson
	Lyell McEwin Hospital	Dr Andrew Kurmis
	Royal Adelaide Hospital	Dr Lucian Bogdan Solomon

TAS	Launceston General Hospital**	Dr Jonathan Mulford
	Royal Hobart Hospital**	Dr Stephen Hutchinson
VIC	Box Hill Hospital	Dr Raphael Hau
	Cabrini Hospital	Dr Marinis Pirpiris
	Frankston Hospital	Dr Peter McCombe
	Maroondah Hospital	Dr Parminder Singh
	Latrobe Regional Hospital	Peter Rehfisch
	St Vincents Hospital (Melbourne)	Dr Roger Bingham
	The Alfred Hospital	Dr Elton Edwards
	The Royal Melbourne Hospital	A/Prof Andrew Bucknill
	University Hospital Geelong Barwon Health	Prof. Richard Page
	Western Health – Footscray, Williamstown	Dr Phong Tran
WA	Fiona Stanley Hospital	Prof Piers Yates and Dr Chris Jones
	Joondalup Health Campus	Dr Arash Taheri
	Royal Perth Hospital	Dr Sam Young
	Sir Charles Gairdner Hospital	Dr David Wysocki

* Non-RPAH Zone Ethics Application
** Tasmanian ERM Application