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Early stability and clinical outcomes of the LIMA Hybrid Shoulder Replacement assessed using x-ray analysis, clinical follow-up and patient-reported outcomes

Submission date
13/09/2022

Recruitment status
No longer recruiting

Registration date
21/09/2022

Overall study status
Completed

Last Edited
19/10/2022

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
This study will be the first known study to investigate the stability and outcomes of the LIMA hybrid glenoid component and stemless humeral component in total anatomic shoulder arthroplasty (the replacement parts for the bony ball and socket joint of the shoulder). The stability of the components will be evaluated using radio stereometric analysis (RSA), a special x-ray technique which allows observation and measurement of very small movements (migrations) over a 2-year postoperative period.

Who can participate?
Patients over the age of 55 with concentric glenohumeral (shoulder) osteoarthritis

What does the study involve?
Participants suitable for the study will be identified preoperatively in outpatient clinics as part of standard care. Informed consent will be taken following detailed explanations of the intervention shared within the patient information literature and discussions with the study team. Validated questionnaires will be completed before the operation to provide a measure of pain and functional ability. The range of movement of the shoulder will also be measured by a member of the research team. The operation will be undertaken by a senior orthopaedic consultant. Following the operation, the clinical follow-up care and physiotherapy will be the standard milestone-driven pathway of rehabilitation for patients who have had a total shoulder replacement. The RSA images and validated questionnaires assessing pain and function will continue to be collected at 3, 6, 12 and 24 months after the operation to assess changes over time. The range of movement of the shoulder will also be re-measured at these timepoints to assess functional changes in the range of movement. A CT scan will be done 3 months after the operation to check the position of the new Hybrid glenoid. The researchers will record any adverse events at every follow-up visit and these will be monitored until the event has either resolved or reaches a time until no further intervention is required.

What are the possible benefits and risks of participating?
Risks include some increase in radiation dose to the patient. Standard surgical risks apply. All implants to be used are approved for human use in the UK. Potential benefits to the patient may be found although the study will primarily benefit future users of the product. Patients in the study can be reassured that they are being followed up closely.

Where is the study run from?
Wrightington, Wigan & Leigh Teaching Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
August 2021 to February 2025

Who is funding the study?
LimaCorporate (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
295411

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50648, IRAS 295411

Study information

Scientific Title
A study of the performance of the novel LIMA hybrid anatomic replacement; a prospective radio-stereometric analysis study of the magnitude and pattern of migration of the glenoid and humeral components

Study objectives
The study hypothesis is that the new Hybrid glenoid component (as part of the LIMA modular shoulder replacement system), is stable bone and does not significantly migrate within the first 2 years postoperatively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/12/2021, West Midlands - Solihull Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 (0)207 104 8191, +44 (0)207 104 8269; solihull.rec@hra.nhs.uk), ref: 21/WM/0227

Study design
Non-randomized; Interventional; Design type: Treatment, Imaging, Surgery

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Concentric glenohumeral osteoarthritis

Interventions
Having obtained ethical approval, 20 patients will be invited to participate at the time of listing for surgery. Pre-operative information, including clinical and PROM data, will be obtained after fully informed consent is given. Plain x-ray and CT scanning are routinely used preoperatively in patients being assessed for shoulder arthroplasty. The first postoperative RSA image will be obtained within 1 week of implantation. RSA images and PROM data collection will continue at 3 months, 6 months, 12 months and 2 years. A further CT scan will be obtained as part of this study at 3 months; primarily to investigate the accuracy of the SmartSpace planning software by measuring the post-operative component position. The CT scan will also be used to observe and comment on the status of bony osteointegration of all components.

Intervention Type
Other

Primary outcome measure
The magnitude and pattern of migration (how far in which direction) of the LIMA Hybrid Anatomic glenoid component, measured using radiostereometric analysis (RSA) involving special x-ray imaging and model-based RSA computer analysis. Imaging takes place over a period of 2 years; immediately post-op, and at 3, 6, 12 & 24 months post-op.

Secondary outcome measures
1. Clinical and patient-reported outcomes collected using the Shoulder Pain and Disability Index (SPADI) questionnaire from pre-op to 2 years
2. The accuracy of SmartSpace software (used for pre-operative planning) monitored by checking implant positioning by means of metal artefact reduction (MARS) CT scans at 3 months
3. Adverse events, implant survival and need for surgical revision", collected by the direct care team at clinical visits and by the research team at follow-up visits if this does not coincide with a clinical visit, monitored over a minimum of 2 years

Overall study start date
12/08/2021

Completion date
28/02/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/10/2022:
1. Male and female patients
2. Concentric glenohumeral osteoarthritis

3. Glenoid suitable for non-augmented anatomical component (Walch A or B1)
4. Intact rotator cuff

Previous inclusion criteria:
1. Male and female patients over the age of 55 years
2. Concentric glenohumeral osteoarthritis
3. Glenoid suitable for non-augmented anatomical component (Walch A or B1)
4. Intact rotator cuff

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 20; UK Sample Size: 20

Key exclusion criteria
1. Inability to consent
2. Inflammatory arthropathy
3. Sequelae of trauma
4. Patients who are unable to attend follow-up and required assessment

Date of first enrolment
14/06/2022

Date of final enrolment
14/06/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wrightington Hospital
Hall Lane
Appley Bridge
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United Kingdom
WN6 9EP

Sponsor information

Organisation
Wrightington, Wigan and Leigh NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

Website
http://www.wwl.nhs.uk/

ROR
https://ror.org/028mrxf52

Funder(s)

Funder type
Industry

Funder Name
LimaCorporate spa

Results and Publications

Publication and dissemination plan
The information gathered in the study will be published and peer-reviewed in scientific research journals and discussed at scientific conferences. Preliminary results will be available after 2 years and final results are expected within 4 years.

Intention to publish date

28/02/2027

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No