

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

Submission date 13/09/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 21/09/2022	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 08/12/2022	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 stemless humeral component in total reverse shoulder arthroplasty (one of the replacement parts for the bony ball and socket joint of the shoulder). The stability of this component will be evaluated using radiostereometric 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 years with concentric glenohumeral (shoulder) osteoarthritis

What does the study involve?

All participants will have surgery with a LIMA reverse glenoid and the stemless humeral component which are part of the Shoulder Modular System (LIMA Corporate, Italy). At the time of listing for surgery, if the surgeon considers the use of this type of shoulder replacement clinically appropriate, the patient will be invited to participate in this study. If the patient is willing to consider participation, a participation information sheet will be provided and the patient is given the opportunity to discuss this and ask questions with the research staff. During the clinical visit, pre-operative information, including clinical and patient-reported data, will be collected as part of routine care. Written consent to participate in the study will then be sought in person at either a follow-up clinic visit or at a pre-op assessment. Final confirmation of willingness to participate in the RSA study will be affirmed by the surgeon on the ward during the booking in process. The research team will be available to address any further questions and complete any study documentation. 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 (usually while the patient is still an in-patient) and the patient will be followed up with RSA images and data collection at 3 months, 6 months, 12 months and 2 years.

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 include preservation of host bone stock and prevention of stress shielding.

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?
Lindsay Cunningham, Lindsay.J.Cunningham@wwl.nhs.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

299318

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 50609, IRAS 299318

Study information

Scientific Title

A study of the performance of the novel LIMA stemless reverse humeral replacement; a prospective radio-stereometric analysis study of the magnitude and pattern of migration of humeral components

Study objectives

In patients over the age of 60, with painful rotator cuff arthropathy of the glenohumeral joint, the LIMA stemless humeral component has acceptable short-term stability.

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

Participants will be invited to participate at the time of listing for surgery and pre-operative information, including clinical and patient-reported 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 and the patient will be followed up with RSA images and data collection at 3 months, 6 months, 12 months and 2 years.

Intervention Type

Other

Primary outcome measure

The magnitude and pattern of migration of the LIMA hybrid anatomic glenoid component measured using model-based RSA over a minimum period of 2 years

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. 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 for imaging and required assessment (due to the need to access specialist equipment at Wrightington for the RSA imaging)

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

Wigan

United Kingdom

WN6 9EP

Sponsor information**Organisation**

Wrightington, Wigan and Leigh NHS Foundation Trust

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.wwl.nhs.uk/>

ROR

<https://ror.org/028mrx52>

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