

# Patient reported clinical outcomes and imaging study for a new all-ceramic hip resurfacing device

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| <b>Submission date</b><br>05/10/2020   | <b>Recruitment status</b><br>No longer recruiting     | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>15/10/2020 | <b>Overall study status</b><br>Ongoing                | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>12/12/2024       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan   |
|  |   | <input type="checkbox"/> Results                     |
|  |   | <input type="checkbox"/> Individual participant data |
|  |   | <input type="checkbox"/> Record updated in last year |

## Plain English summary of protocol

### Background and study aims

Hip replacement is a successful medical intervention that treats diseased or damaged joints. There are two options for hip replacement implants and this is total hip replacement or hip resurfacing replacement. A total hip replacement removes the entire head of the bone for replacement whereas hip resurfacing as it suggests removes just the damaged surface of the joint. Hip resurfacing is therefore a more bone-conserving operation and may offer benefits to younger/active patients.

Currently hip resurfacing is manufactured using all-metal (cobalt chromium). A small proportion of patients can have an adverse reaction to metal debris leading to early failure of the implant. Therefore more benign materials such as ceramics commonly used in total hip replacement are of interest and BIOLOX® delta ceramic (CeramTec) has clinical use. MatOrtho's ReCerf is an all-ceramic hip resurfacing device manufactured from this clinically successful BIOLOX® delta ceramic. The aim of this study is to demonstrate the performance of ReCerf Hip Resurfacing is comparable to clinical data from existing hip implants and this data will support regulatory applications in the future.

### Who can participate?

Adults eligible for hip resurfacing.

### What does the study involve?

All patients would complete questionnaires about their hip before surgery and then at 6, 12 and 24 months post-surgery. Adverse events and revision would be reported over 24 months. Standard radiographs would be collected. Patients recruited at Oxford would be assessed by RSA after surgery (within 5 days) and at 6, 12 and 24 months post-surgery.

### What are the possible benefits and risks of participating?

#### Benefits:

The information collected in this programme will be used to increase medical community knowledge on Hip Resurfacing implants. This could influence future thinking on the best treatment routes. The Hip Resurfacing itself should provide the patient with relief from their

symptoms. Collecting data does not intervene in any way with the patients normal treatment and rehabilitation programme.

#### Risks:

There are general risks of surgery and receiving a hip implant. There are risks to receiving a new device. The clinical performance and longevity of the ReCerf device are not proven and residual risks are possible. Unknown or unexpected failure modes can occur for new devices.

X-rays used to assess the positioning of a hip replacement expose you to a small amount of radiation.

Patients taking part in RSA migration study will have very small tantalum beads placed in the bone near to the Investigational Device. The insertion of beads takes an additional 5 to 10 minutes during surgery. Although this increases surgical time, there is no increase incidence of infection, bleeding, or blood clotting. The beads get stably integrated into the bone, however, the beads could move or become loose, eventually embedding in adjacent tissue. This risk is considered very small; over 300,000 beads have been implanted worldwide with no adverse effects related to bead movement or loosening.

Where is the study run from?

MatOrtho Limited (UK) and hospitals in the UK

When is the study starting and how long is it expected to run for?

June 2019 to April 2027

Who is funding the study?

MatOrtho Limited (UK)

Who is the main contact?

MatOrtho Limited, [info@matortho.com](mailto:info@matortho.com)

Andrew Manktelow, Nottingham University Hospital Trust

James Holland, Freeman Hospital, Newcastle Upon Tyne Hospital Trust

Sarah Muirhead-Allwood, Princess Grace Hospital

Dominic Meek, NHS Greater Glasgow and Clyde Trust

Ben Kendrick, Oxford University Hospitals

## Contact information

### Type(s)

Scientific

### Contact name

Dr Study Contact

### Contact details

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

277975

### ClinicalTrials.gov (NCT)

Nil known

### Protocol serial number

ST-010320-CI, IRAS 277975

## Study information

### Scientific Title

ReCerf Hip Resurfacing Clinical Investigation

### Study objectives

There are two hypotheses: The clinical trial will assess that the amount of migration of components over time as compared to the surrounding bone (reference) is acceptable; and patient reported outcome using an Oxford Hip Score questionnaire will not be worse than the National average reported in the UK National Joint Registry for similar devices.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Approved 02/04/2020, London-Stanmore Research Ethics Committee (Health Research Authority, Skipton House, 80 London Road, London, SE1 6LH, UK; +44 (0)20 7972 2561, stanmore.rec@hra.nhs.uk), ref: 20/LO/0279

### Study design

Prospective observational non-randomized multicentre

### Primary study design

Observational

### Study type(s)

Treatment

### Health condition(s) or problem(s) studied

End-stage joint disease e.g. osteoarthritis, requiring hip joint replacement

### Interventions

All patients taking part in the study would receive a Patient Information Sheet from their consultant if they are eligible for hip resurfacing. Following consent the patient would be asked to answer a series of questionnaires on their hip (baseline, pre-op data). Information on pre-op

health and demographics would be recorded prior to surgery. The data collected would not include personal information and would not identify the patient. The patient would only be identified with the study ID number throughout. Intra-operatively, surgical details would be collected including component details. Post-operatively patients would complete questionnaires at 6, 12 and 24 months. Standard radiographs would be taken and collected for the study. Throughout, adverse events including readmissions and revisions would be collected.

In addition, patients recruited at Oxford would be invited to take part in a migration ('RSA') study. The patients would complete all of the same methods above but would also have RSA imaging. RSA stands for radiostereometric analysis and it is a highly accurate method to measure small movements over time between the implant components and the bone. RSA uses a dual set of stereo x-rays. The RSA assessment is taken immediately post-surgery (within 5 days) and at 6, 12 and 24 months.

The total duration of follow-up for all patients is 24 months post-surgery. The observations will take around 20-30 minutes for patient reported scores. The RSA assessment would take 40-60 minutes.

## **Intervention Type**

Device

## **Phase**

Not Specified

## **Drug/device/biological/vaccine name(s)**

ReCerf Hip Resurfacing

## **Primary outcome(s)**

1. Proximal migration measured by RSA at 12 months
2. Hip function measured using the Oxford Hip Score at 6 months

## **Key secondary outcome(s)**

1. Migration measured by RSA at 6 and 24 months
2. Hip function measured using the Oxford Hip Score at 12 and 24 months
3. Rate of adverse events collected by research team as they occur (all times to 24 month)
4. Revision rate (i.e device failure rate) measured by research team as they occur (all times to 24 month)
5. Additional PROMs (pre-op, 6, 12 and 24 months):
  - 5.1. Hip function (Oxford Hip Score)
  - 5.2. Quality of life (EQ5D)
  - 5.3. Hip symptoms (HOOS)
  - 5.4. Activity (UCLA Activity Scale)
  - 5.5. Satisfaction score (using a novel 4 item questionnaire)
  - 5.6. Single question on joint awareness

## **Completion date**

30/04/2027

## **Eligibility**

### **Key inclusion criteria**

1. Patient suitable for hip resurfacing arthroplasty
2. Patient able to give informed consent
3. Patient willing and able to take part in the study for the prescribed length of the study
4. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the study
5. Minimum age of 18 years

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patient deemed unsuitable for hip resurfacing arthroplasty by the surgeon
2. Patient has significant contraindications when following the manufacturer's Instruction For Use of the product
3. Patient likely to become incapacitated during the study
4. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study

**Date of first enrolment**

30/06/2020

**Date of final enrolment**

31/03/2025

**Locations****Countries of recruitment**

United Kingdom

England

Scotland

**Study participating centre**

Freeman Hospital

James Holland

Newcastle Upon Tyne Hospital Trust  
Freeman Road  
High Heaton  
Newcastle  
United Kingdom  
NE7 7DN

## Sponsor information

### Organisation

MatOrtho Limited

## Funder(s)

### Funder type

Industry

### Funder Name

MatOrtho Limited

## Results and Publications

### Individual participant data (IPD) sharing plan

All data generated or analysed during this study will be included in the subsequent results publication.

### IPD sharing plan summary

Other

### Study outputs

| Output type                          | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |