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Measurement of the movement of shoulder replacements in bone

Submission date
17/11/2015

Recruitment status
No longer recruiting

Registration date
04/07/2020

Overall study status
Completed

Last Edited
07/08/2020

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
Although shoulder replacement is a well-accepted procedure for patients with pain due to arthritis, one of the common problems is loosening of the replacement part from the bone. This loosening is often seen on x-ray as a line between the bone and replacement component.
One problem of using x-ray to identify the loosening is that such lines are often seen on the first x-ray taken after the operation and their significance, therefore, remains uncertain. In addition measurements of such lines is very difficult and subjective.
A recently developed method of recording bone changes after replacement surgery involves implanting metal beads (tantalum beads) into bony areas during surgery that can later be seen using x-ray (known as radiostereometry). The 3 dimensional pattern of the beads is used to define each bone segment on radiographs, with far more accuracy than is achievable using bone outline. Using x-rays taken over time, 3-dimensional measurement of the movement of the different parts of the joint replacement relative to the bone is possible. Radiosterometry is now routinely used in early testing of hip and knee replacements with normal movement patterns identified for both successful and failing implants.
There are only a few studies of shoulder replacement using radiostereometry and we wish to expand current knowledge and begin to define normal movement in bone for the components of shoulder replacement. The aim of this study is to use radiostereometry to examine the fixation and any movement that occurs of a shoulder replacement and compare this with standard x-ray measures and clinical success.

Who can participate?
All patients undergoing shoulder replacement for primary osteoarthritis who fulfil inclusion and exclusion criteria

What does the study involve?
Patients undergoing Shoulder replacement will have tantalum beads inserted into their humerus and scapula at the time of their surgery. These beads when visualised on stereo radiographs using a technique called Radiostereometry (RSA) allow the movement of the implant in the bead marked bone over time or under load to be measured. Postoperatively in addition to routine review and completion of measures at one and two years, they will undergo a series of RSA examinations of the shoulder at fixed time points. In addition to static RSA examinations from

the time of surgery, loaded examinations will be carried out in the later stages of recovery to examine motion of the bone and replacement components.

What are the possible benefits and risks of participating?
Possible benefits: Symptomatic patients post shoulder replacement will have RSA migration data available to their surgeons which may help in diagnosis of any problems
Risks:
1. Implantation of Beads: Implantation of tantalum beads during joint replacement is a well-established technique with no reported complications despite their use for almost 40 years. The additional operative time is short and tantalum is biologically inert.
2. Additional radiation exposure: These patients will require additional radiation exposure for RSA radiographs. The exposure is relatively small and a risk assessment has been performed as minor.

Where is the study run from?
Aberdeen Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
June 2010 to February 2021

Who is funding the study?
Mathys Orthopaedics Ltd (UK)

Who is the main contact?
Mr G. Patrick Ashcroft, g.p.ashcroft@abdn.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr George Ashcroft

Contact details
Aberdeen University Medical School
Polwarth Building
Foresterhill
Aberdeen
United Kingdom
AB25 2ZD
+44 (0)1224 556357
g.p.ashcroft@abdn.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

085853

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
3/068/11, IRAS 085853

Study information

Scientific Title
Radiostereometry of glenoid movement following shoulder replacement for osteoarthritis

Study objectives
The aim of this study is to provide standard RSA migration data for glenoid component of shoulder replacement and increase knowledge of migration in shoulder replacement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/09/2016, North of Scotland Research Ethics Service (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, UK; +44 (0)1224 558458; nosres@nhs.net), ref: 11/NS/0032

Study design
Single centre observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Osteoarthritis of the shoulder

Interventions
Following enrolment patient will have routine shoulder radiographs carried out and complete patient related outcome measures (PROMS) prior to attending for shoulder replacement. The replacement is carried out using a standard surgical protocol with the exception of the addition

of the insertion of tantalum beads in the bone. Prior to discharge patients will have further routine radiographs and their index RSA radiographs performed. Patients are then reviewed at 6 weeks, 3 months, 6 months, one year and two years. At all time points further RSA radiographs are taken, with further PROMS completed at one and two years. Additional standard radiographs are taken at 1 year. Patients will complete 2 years of post-surgery follow up.

Intervention Type
Procedure/Surgery

Primary outcome measure
Migration of glenoid component over 3 years measured with radiosteremetry at 6 weeks, 3 months, 6 months, 1, 2, and 3 years

Secondary outcome measures
1. Quality of life measured using the EQ5D, Constant Score at 1, 2, 3 years
2. Radiolucent lines measured using standard x-ray at 2 years

Overall study start date
01/06/2010

Completion date
02/02/2021

Eligibility

Key inclusion criteria
1. Primary shoulder replacement
2. Primary diagnosis of osteoarthritis
3. Aged between 50 and 75 years old

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
15

Total final enrolment
15

Key exclusion criteria
1. Inflammatory arthritis of the shoulder
2. Previous surgery of the operative shoulder
3. Renal transplant
4. Any metabolic bone disorder

5. The contra-lateral shoulder already included in the study
6. History of active joint sepsis
7. Recent high dose systemic corticosteroids
8. Primary or secondary carcinoma in last 5 years
9. Neurological disease (e.g. Parkinson's disease)
10. Psycho-social disorders that would limit rehabilitation
11. Use of bone graft, disorders of other joints in either arm that could impair rehabilitation or function

Date of first enrolment
17/11/2015

Date of final enrolment
04/04/2019

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Aberdeen Royal Infirmary
Aberdeen
United Kingdom
AB25 2ZN

Sponsor information

Organisation
University of Aberdeen

Sponsor details
Clinical Research Governance
Research and Development Office
Foresterhill House Annexe
Foresterhill
Aberdeen
Scotland
United Kingdom
AB25 2ZB
+44 (0)1224 551123
researchgovernance@abdn.ac.uk

Sponsor type

University/education

Website
http://www.abdn.ac.uk/

ROR
https://ror.org/016476m91

Funder(s)

Funder type
Industry

Funder Name
Mathys Orthopaedics Ltd

Results and Publications

Publication and dissemination plan
Early data will be presented at national and international conferences. We intend publishing the final results of the different elements trial in a number of high-impact peer-reviewed journals.

Intention to publish date
30/06/2021

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?
Protocol file	version v1.6	01/03/2015	07/08/2020	No	No