Proposal: RSA Trial of migration of glenoid components of "Affinis" total shoulder replacements

Company: Mathys

Department: Dept of Orthopaedics, Aberdeen University, Woodend Hospital

Proposed Prostheses
Stem: Affinis (uncemented metal + ceramic)
Glenoid: Affinis (cemented polyethylene)

Primary aim of trial:
- Measure 3D migrations of glenoid component

Secondary aims of trial
- Assessment of clinical outcomes
- Measure 3D inducible migrations of glenoid component

Clinical Study Total
Prospective Start Date: May 2105
Number of Patients: 15
Recruitment Period: 1 year
Initial Trial Period: 2 yr follow up

Existing Clinical Facilities
Grampian University Hospitals is one of the largest single site university hospitals in Europe with over 1400 beds, serving a core population of 600,000. The elective orthopaedic centre sees approximately 7000 new patients per year with over 2000 suffering from osteoarthritis. The Orthopaedic Department is one of the largest in the UK undertaking an average of 1200 total joint replacements including approximately 40 shoulder replacements annually. There is therefore a stable, large population base accessible for research. This research group now has extensive experience of the RSA technique and the orthopaedic surgeons who specialise in arthroplasty are enthusiastic supporters of this research and are committed to developing RSA and DXA.
The current team of consultants, research registrars, audit nurse and research physicist are fully trained in RSA and DXA. Aberdeen has fully staffed theatres, outpatient and x-ray facilities enabling the completion of such projects.

Research Facilities
The University of Aberdeen's new Clinical Research Facility is on the University's Foresterhill site. The building houses clinic rooms and a new custom built digital RSA unit part funded by the CSO and fully installed in November 2009. This is one of the most advanced RSA radiology facilities in

the world and has been built in conjunction with the specialist Danish imaging group Nordik Rontgen Teknik and detector manufacturer Canon.

Study Design: Single cohort study
Patients will be selected for inclusion in the study according to the normal criteria for total shoulder replacement currently applied within the NHS Grampian Orthopaedic Department. Eligible patients will be identified and approached, and if appropriate, be given a patient information leaflet and have the project explained to them, and signed consent to participate in the study obtained, as agreed with the local ethics committee.

In addition the following criteria will apply:

Inclusion criteria: Primary shoulder replacement primary diagnosis of osteoarthritis, aged between 50 and 75 years old, signed patient consent form.

Exclusion criteria: Inflammatory arthritis of the shoulder, previous surgery to that shoulder, renal transplantation, any metabolic bone disorder, the contra-lateral shoulder already included in the study, history of active joint sepsis, recent high dose systemic corticosteroids, primary or secondary malignant disease in last 5 years, neurological disease (e.g. Parkinson's disease), psycho-social disorders that would limit rehabilitation, use of bone graft, disorders of other joints in either arm that could impair rehabilitation or function.

Patient groups*:*
Patients will receive a Mathys “Affinis” total shoulder replacement:

- Humeral component – uncemented metal + ceramic
- Glenoid component – cemented polyethylene

Allocation
Insertion will be carried out in a consecutive group of 15 Patients.

Operative Procedure
All prostheses will be implanted using the same operative technique. The only difference will be in fixation technique for the glenoid component which will be carried out as per manufacturers in struction. Surgery will also include insertion of at least 6 tantalum marker beads of 0.8 mm diameter in the scapula and 6 in the proximal humerus**.**

Clinical Evaluation and Data Collection

Patient Information
Patients will be assessed in the outpatient clinics at Woodend Hospital pre-operatively and the clinical research centre at Forresterhill postoperatively. Each patient will be evaluated using the Shoulder Scores, SF36 quality of life (Garratt 1993) and EQ-5D questionnaires prior to surgery and at 12 and 24

months postoperatively. Operative data and data on early complications will be collected during their hospital stay. Late complications will be monitored at outpatient attendance.

Outcome parameters	**Methods**
Patient details	- Demographic data form
Operation	- Operative form
Patient satisfaction, function	- Shoulder Score, SF 36, EQ-5D
Implant fixation (glenoid)	- Radiostereometry (RSA)
Radiographic evaluation	- Conventional radiography
Complications	- Post-operative clinician
Questionnaire	- nurse

Timing of Follow up
See appendix 1

Data Storage
Data storage will be carried out using a relational database. A regular and secure backup protocol will be adhered to.

RSA Evaluation

- RSA Evaluation will take place at Clinical Research centre, Foresterhill: All images will be taken using the new NRT system with two Canon CXDI-50C (high detection efficiency) DR detectors exposed simultaneously with a suitable reference cage. Images will be imported directly into the measurement software via DICOM. Every patient will receive one same day repeat RSA examination during the study. These double measurements allow the true in vivo precision (repeatability) of both migration and induced movement to be assessed.
- Each patient will be evaluated using RSA post operatively and at 6 weeks, 3 months, 6 months, 12 months and 24 months. RSA radiographs will be taken as per Aberdeen shoulder protocols :
    - Films will be taken supine, on side, arm inclined at 30 degrees by resting on foam wedge between arm and body, arm relaxed, at all time points except postoperatively when it will be supine only.
    - From three months patients will have, in addition, loaded films: supine, on side, arm inclined at 30 degrees by resting on foam wedge between arm and body, arm lifting just off wedge (or as close as possible)

RSA Analysis: UmRSA software (RSA Biomedical AB, Sweden) will be used to measure marker positions on the digital images. This software is used to measure the marker points, both in the patient and calibration cage. Our locally developed software will then be used to measure the position of the glenoid and stem. Locally developed software will also be used to fine tune the marker positions based on improved measurement models. We have also developed software, which we have validated against UMRSA, to investigate marker movement. The stability of the reference scapula markers will be assessed using rigid body analysis. Marker stability will be assessed using

customised point analysis software. This will be applied to all segment markers. With this method each marker's movement is calculated relative to the stable markers within its segment for all examinations with respect to the first post-op examination. If a progressive movement reaching greater than 0.5 mm is identified, the marker will be excluded. Migrations will be calculated relative to the first postoperative examination.

Analysis: Data will be entered into SPSS.

- The following measurements will be made
  - Migrations and rotations of the glenoid in x,y and z directions
  - Migrations of humeral head in x,y and z directions

Technique

A calibration cage containing tantalum beads and two radiograph cassettes will be placed underneath/behind the patient. Two different projections will be produced by using simultaneous exposure by two x-ray tubes using the new direct digital system. These images will be stored on hard drive and primarily on the University secure redundant network server. All images are anonomised, with a patient study id. All scans will then be measured using the Digital UMRSA system. Adaptations unique to Aberdeen will then be utilised in analysis.

At three months, each patient will receive a full double (repeat) examination protocol of both the unloaded and loaded RSA examinations. With this the patient and system is fully repositioned to ensure reliable assessment of (short term) clinical precision as per guidelines.

Standard X-Ray Evaluation

Routine radiographs will be taken initially in the Radiology department at Woodend Hospital and then at the ARI clinical research centre. Each patient will be evaluated by standard X-ray technique prior to surgery, immediately after surgery and at 12 months. Standard views will include an AP and axillary view of the shoulder joint. These radiographs will be assessed by two clinicians who will evaluate and measure bone resorption, cement fracture, and radiolucent lines.

Reports

a) Yearly reports will be provided indicating

- Enrolment numbers
- Clinical results
- RSA results
- Abstract submission data
- Paper submission data

Research Output

Presentations
Presentations will be when sufficient data has been gathered.

Papers will be submitted as appropriate on

- Completion of first year follow up for all patients
- Completion of second year follow up for all patients

Safety
The problems of shoulder replacement for the patients in this study will be the same in the study as for standard shoulder replacement. Ie
After surgery, the shoulder and arm may be sore or uncomfortable for several weeks. There may also be some swelling in the upper part of the arm.

A number of potential complications may occur

1. General complications of any operation: include an unexpected reaction to the anaesthetic, infection, excessive bleeding or developing a deep vein thrombosis, DVT.
2. Complications specific to shoulder replacement
    a. The shoulder may not be as stable as it was before operation and treatment may be required for the instability.
    b. Infection of the wound or joint. Antibiotics are usually given during surgery to help prevent this.
    c. Intra-operative or post-operative fracture
    d. Damage to the nerves or blood vessels controlling the arm and hand. This is rare, and if it does occur, is usually mild and temporary.
    e. Loosening of prosthesis

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Timetable: Glenoid study

	Plain X-ray	Consent	Demographic Data	SF36	EQ-5D	Shoulder score	VAS	Operative Data	Complications	RSA UL*	RSA L*
Preoperative	X	X	X	X	X	X	X				
Operative								X			
Predischarge	X (AP)								X	1	0
6 weeks									X	1	0
3 months										2	2
6 Months							X		X	1	1
1Year	X			X	X	X	X			1	1
2 Year				X	X	X	X			1	1
total	**3**	**1**	**1**	**3**	**3**	**3**	**4**	**1**	**3**	**7**	**5**

* One repeat per patient